JUNE 2022

Report to the Congress

Medicare and the Health Care Delivery System

MEDPAC

MEDPAC | *Medicare Payment Advisory Commission*

The Medicare Payment Advisory Commission (MedPAC) is an independent congressional agency established by the Balanced Budget Act of 1997 (P.L. 105–33) to advise the U.S. Congress on issues affecting the Medicare program. In addition to advising the Congress on payments to health plans participating in the Medicare Advantage program and providers in Medicare's traditional fee-for-service program, MedPAC is also tasked with analyzing access to care, quality of care, and other issues affecting Medicare.

The Commission's 17 members bring diverse expertise in the financing and delivery of health care services. Commissioners are appointed to three-year terms (subject to renewal) by the Comptroller General and serve part time. Appointments are staggered; the terms of five or six Commissioners expire each year. The Commission is supported by an executive director and a staff of analysts, who typically have backgrounds in economics, health policy, and public health.

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Two reports—issued in March and June each year—are the primary outlets for Commission recommendations. In addition to annual reports and occasional reports on subjects requested by the Congress, MedPAC advises the Congress through other avenues, including comments on reports and proposed regulations issued by the Secretary of the Department of Health and Human Services, testimony, and briefings for congressional staff.

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REPORT TO THE CONGRESS

Medicare and the Health Care Delivery System

MEDPAC | Medicare Payment Advisory Commission

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Michael E. Chernew, Ph.D., Chair
Paul B. Ginsburg, Ph.D., Vice Chair
James E. Mathews, Ph.D., Executive Director

June 15, 2022

The Honorable Kamala D. Harris
President of the Senate
U.S. Capitol
Washington, DC 20510

The Honorable Nancy Pelosi
Speaker of the House
U.S. House of Representatives
U.S. Capitol
Room H-232
Washington, DC 20515

Dear Madam President and Madam Speaker:

I am pleased to submit the Medicare Payment Advisory Commission's June 2022 *Report to the Congress: Medicare and the Health Care Delivery System*. This report fulfills the Commission's legislative mandate to evaluate Medicare payment issues and make recommendations to the Congress.

In the seven chapters in this report, we consider:

- ways to streamline and harmonize Medicare's portfolio of alternative payment models;
- vulnerable Medicare beneficiaries' access to care (pursuant to a formal congressional request);
- a framework for identifying safety-net providers and evaluating whether new Medicare safety-net funding might be warranted in a given health care sector;
- approaches for addressing high prices of drugs covered under Medicare Part B;
- an option to improve the accuracy of Medicare Advantage payments by limiting the influence of outliers in CMS's risk-adjustment model;
- an approach to align fee-for-service payment rates across ambulatory settings; and
- segmentation in the stand-alone Part D prescription drug plan market.

This report primarily focuses on Medicare's payment policies, which I hope you find useful. At the same time, I and the rest of the Commission remain cognizant of the ongoing challenges posed by the

COVID-19 pandemic. We remain ready to assist the Congress and CMS as part of our mission to preserve beneficiaries' access to high-quality care, control Medicare spending growth, and provide sufficient payment for efficient providers.

Sincerely,

Michael E. Chernew, Ph.D.
Chair

Enclosure

Acknowledgments

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Executive summary

Executive summary

As part of its mandate from the Congress, each June the Commission reports on refinements to Medicare payment systems and issues affecting the Medicare program, including changes to health care delivery and the market for health care services. The seven chapters of the June 2022 report cover the following topics:

- ***An approach to streamline and harmonize Medicare's portfolio of alternative payment models.*** The Commission provides specific suggestions to operationalize our June 2021 recommendation that CMS reduce the number of Medicare alternative payment models (APMs) and design models to work better together.
- ***Vulnerable Medicare beneficiaries' access to care.*** In response to a congressional request, the Commission presents an analysis of the service utilization of beneficiaries who reside in a medically underserved area (MUA), are dually eligible for Medicare and Medicaid, or have multiple chronic conditions.
- ***Supporting safety-net providers.*** The Commission provides a general framework to identify safety-net providers and evaluate whether new Medicare safety-net funding might be warranted in a health care sector. We apply our framework to identify safety-net hospitals, evaluate the financial performance of safety-net hospitals, and model the redistribution of current disproportionate share hospital (DSH) and uncompensated care payments using our safety-net hospital metric.
- ***Addressing high prices of drugs covered under Medicare Part B.*** The Commission discusses approaches for Medicare Part B to address high launch prices for new "first-in-class" drugs with limited clinical evidence, high and growing prices among products with therapeutic alternatives, and financial incentives associated with the percentage add-on to Medicare Part B's payment rate.
- ***Improving the accuracy of Medicare Advantage payments by limiting the influence of outliers in CMS's risk-adjustment model.*** *Post-publication review of the analyses underlying this chapter revealed possible errors. We have withdrawn the chapter while we reevaluate the analyses and our conclusions.*
- ***Aligning fee-for-service payment rates across ambulatory settings.*** The Commission presents an analysis of an approach to align the payment rates across ambulatory settings—hospital outpatient departments (HOPDs), ambulatory surgical centers (ASCs), and freestanding physician offices—that currently have different Medicare payment rates for the same services.
- ***Segmentation in the stand-alone Part D plan market.*** The Commission discusses segmentation in the market for stand-alone prescription drug plans (PDPs) based on beneficiaries' eligibility for Part D's low-income subsidy (LIS) and drug spending, its effects on Medicare spending, and potential policies to address segmentation and its effects.

This report focuses on Medicare's payment policies and ways to improve those policies where appropriate. The Commission is fully aware that the health care system, Medicare beneficiaries, and policymakers have faced extraordinary challenges during the coronavirus public health emergency, and we continue to consider the effects of the COVID-19 pandemic in our work. We remain ready to assist the Congress and CMS as part of our mission to preserve beneficiaries' access to high-quality care, control Medicare spending growth, and provide sufficient payment for efficient providers.

An approach to streamline and harmonize Medicare's portfolio of alternative payment models

In Chapter 1, we present specific suggestions to operationalize our June 2021 recommendation that CMS reduce the number of Medicare APMs and design models to work better together:

- Implement a foundational population-based payment approach that reduces the number of accountable care organization (ACO) model tracks from seven down to a smaller number of tracks that could each be geared toward provider organizations of different sizes and involve different degrees of financial risk.

- Move away from "rebasing" ACOs' spending benchmarks every few years based on actual spending, and instead rely on periodic administrative updates to benchmarks using a growth factor that is unrelated to ACOs' own spending performance and is known to ACOs in advance.
- Implement a national episode-based payment model for certain types of proven clinical episodes (e.g., hip and knee replacements) that will enhance savings and/or improve outcomes.
- Require certain providers to participate in the national episode-based payment model for all their fee-for-service (FFS) Medicare patients, including beneficiaries already attributed to an ACO.
- For beneficiaries concurrently attributed to the episode-based payment model and an ACO, allocate episode bonus payments so that (1) episode-based providers have an incentive to furnish efficient, high-quality care; (2) providers in ACOs have an incentive to refer their attributed patients to low-cost, high-quality episode-based providers; and (3) when combined, these incentives are not so large that they increase total Medicare spending.

The Commission believes implementing these suggestions would reduce the complexity and uncertainty that providers face when deciding to participate in an APM, increase provider participation in these models, and improve incentives for providers to furnish care more efficiently and improve quality.

Congressional request: Vulnerable Medicare beneficiaries' access to care (final report)

In Chapter 2, we present our final report in response to a July 2020 bipartisan request from the House Committee on Ways and Means for an update of our June 2012 report on rural beneficiaries' access to care and for information on access to care for beneficiaries who reside in an MUA, are dually eligible for Medicare and Medicaid, or have multiple chronic conditions.

In our June 2021 interim report to the Congress, we found that rural and urban beneficiaries had similar utilization of care, although some minor differences existed. In this final report, we present descriptive statistics using data from before the COVID-19 pandemic on the service utilization of beneficiaries who reside in an MUA, are dually eligible for Medicare and Medicaid, or have multiple chronic conditions. We found:

- Beneficiaries who reside in MUAs generally received the same volume of services as those who did not across the services we examined—evaluation and management (E&M) encounters with clinicians, hospital inpatient and outpatient visits, skilled nursing facility days, and home health episodes.
- Medicare beneficiaries who were eligible for full Medicaid benefits had substantially higher service use, including about twice the number of hospital inpatient admissions and about five times the number of skilled nursing facility days per beneficiary, compared with other Medicare beneficiaries. However, we cannot rule out the possibility that dual-eligible beneficiaries needed more care than they received or faced difficulties in accessing the care they did receive.
- Beneficiaries with more reported chronic conditions had substantially higher service use compared with those with fewer reported chronic conditions. As with the service use patterns of dual-eligible beneficiaries, we are unable to make any judgment regarding whether the higher levels of service use we observe for beneficiaries with multiple chronic conditions are sufficient to meet their clinical needs.

Because further research is needed to better understand the sufficiency of dual-eligible and other vulnerable beneficiaries' access to care, the Commission is examining how to better identify vulnerable Medicare populations and to evaluate Medicare's policies to support safety-net providers.

Supporting safety-net providers

In Chapter 3, we present a framework, applicable across provider sectors, to identify safety-net providers and evaluate whether new Medicare safety-net funding might be warranted in a health care sector. We apply our framework to identify safety-net hospitals using alternative metrics to those used in Medicare's current DSH program. We then model a redistribution of current DSH and uncompensated care payments using our alternative safety-net metrics. This chapter is the

first in an ongoing body of work on supporting safety-net providers.

A framework for identifying safety-net providers. Our framework first identifies safety-net providers as those that disproportionately serve (1) low-income Medicare beneficiaries who are less profitable to care for than the average beneficiary or (2) uninsured patients or patients with public insurance that is not materially profitable. In our analysis, low-income Medicare beneficiaries are defined as those who receive the Part D LIS. This group includes beneficiaries with limited assets and an income below 150 percent of the federal poverty level, as well as those who receive full or partial Medicaid benefits who automatically qualify for the LIS. Compared to the full Medicare population, LIS beneficiaries are three times as likely to be disabled and are twice as likely to be Black or Hispanic. These beneficiaries often have the greatest health care needs but the fewest personal resources to address those needs, making it critical to ensure that they have access to a safety net of health care providers.

A framework for determining the need for new Medicare safety-net funding. Once safety-net providers are identified, the second part of our framework defines criteria to determine whether the Medicare program should allocate new funding to support safety-net providers. Medicare should spend additional funds to support safety-net providers only if:

- low-income beneficiaries are at risk of negative outcomes (e.g., access problems due to provider closures) without additional funding;
- Medicare is not a materially profitable payer in the sector; and
- current payment adjustments cannot be redesigned to adequately support safety-net providers.

Applying our framework to safety-net hospitals. In acute care hospitals, Medicare patients, and in particular, low-income Medicare patients, would generate lower levels of profitability than commercial patients without additional safety-net payments. Therefore, hospitals with high shares of Medicare patients, low-income Medicare patients, and uninsured patients may have insufficient resources to compete for labor and technology with hospitals that treat a higher share of commercial patients.

The Commission's analyses have shown that, on average, Medicare beneficiaries have good access to hospital care. However, in this analysis of safety-net hospitals, we found that hospitals with high shares of LIS Medicare beneficiaries tend to have lower levels of profitability. The quarter of hospitals with the lowest shares of total Medicare volume associated with LIS beneficiaries had a median non-Medicare margin of 15 percent, compared with 2 percent among the quarter of hospitals with the highest shares of such beneficiaries. Hospitals with high shares of LIS beneficiaries also had a higher risk of closure.

We compared the existing DSH policies with a measure based on LIS beneficiary share and a measure we developed called the Safety-Net Index (SNI), which is the sum of (1) the share of the hospital's Medicare volume associated with LIS beneficiaries, (2) the share of its revenue spent on uncompensated care, and (3) an indicator of how dependent the hospital is on Medicare. Our results suggest that the measures based on LIS beneficiaries and the SNI are better predictors of financial strain than the current DSH measure. In addition, the current DSH measure leads to Medicare subsidizing Medicaid and is negatively correlated with the share of hospitals' patients who are enrolled in Medicare. The results of our analysis suggest that the new SNI metric could do a better job of targeting Medicare funds to safety-net hospitals than simply expanding the funds allocated to the existing DSH program would.

In addition to analyzing how well the three safety-net metrics predicted non-Medicare margins and risk of closure, we also modeled a redistribution of current DSH and uncompensated care payments using the SNI metric. By shifting from the current DSH system of payments to an SNI system of payments, a slightly larger share of safety-net payments would go to hospitals with high Medicare shares and a greater risk of closure. While these results should be considered illustrative, they provide a sense of how distributing safety-net dollars using a metric that considers hospitals' Medicare shares would alter the distribution of Medicare funds.

Addressing high prices of drugs covered under Medicare Part B

In Chapter 4, the Commission examines alternative approaches for Medicare Part B to address high launch prices for new "first-in-class" drugs that have limited clinical evidence, high and growing prices among products with therapeutic alternatives, and financial incentives associated with the percentage add-on to Medicare Part B's payment rate.

Medicare spending on prescription drugs covered under Part B is substantial (about $40.7 billion in 2020) and growing rapidly (increasing nearly 10 percent per year, on average, between 2009 and 2019). The prices Medicare pays for drugs are an important driver of this growth. Manufacturers have historically set high prices for many new treatments whether or not evidence exists that the product is more effective than existing standards of care. As a result, drug launch prices have been increasing, and are not necessarily commensurate with new products' efficacy relative to existing therapies. Prices for existing products are also a concern because of high launch prices and/or postlaunch price growth among some products, even for those with therapeutic alternatives. Cost sharing for high-priced products can deter appropriate uptake, and Medicare program spending on high-priced products can crowd out valuable alternative uses of taxpayer resources.

Medicare has had only an indirect influence on how new Part B–covered drugs are priced. Medicare pays for most Part B drugs and biologics at a rate of 106 percent of the average sales price (ASP + 6 percent). Medicare lacks the authority to use tools to pay for Part B drugs in a way that balances a drug's net clinical benefit with an appropriate reward for innovation and affordability for beneficiaries and taxpayers. Medicare also lacks tools to promote price competition among Part B drugs with therapeutic alternatives.

We discuss three approaches to improve price competition and payment for Part B drugs by the Medicare program. Some of the strategies could also apply to Part D drugs as well as other categories of services, including medical devices.

Addressing uncertain clinical benefit and high launch prices of first-in-class drugs. To address high launch prices of select "first-in-class" Part B drugs that the Food and Drug Administration (FDA) approves with uncertain clinical evidence (i.e., based only on surrogate or intermediate clinical endpoints under its accelerated approval pathway), the Congress could give the Secretary discretion to:

- First, use coverage with evidence development (CED) to collect clinical evidence relevant to Medicare beneficiaries about the new drug while providing patients access to the product. Ensuring that the CED process is clear, transparent, and predictable with a process for public input would be key and might include criteria for evaluating whether the product is a candidate for CED.
- Second, set a cap on the drug's payment rate based on information about the new product's estimated net clinical benefit (based on evidence from, for example, FDA clinical trials) and cost compared with the standard of care, to prevent manufacturers from setting a high price for a new product with little or no evidence that it is more effective than existing standards of care. Medicare would need to develop a clear and predictable decision-making framework that ensures transparency and opportunities for public input, including how comparator treatments would be selected, how costs would be defined, and what time horizon would be used.

This dual approach would likely lead to development of better evidence after FDA approval and better alignment of payment to the known clinical benefit of the drug. We envision that the Secretary would apply such a dual approach when needed for selected drugs approved under the FDA's accelerated pathway, based on factors such as a drug's clinical benefit compared with its alternatives at the time of FDA approval and fiscal impact. We also envision that, over time, Medicare would reevaluate the application of CED and the drug's payment rate based on, for example, information from postapproval clinical trials. Since 2006, under existing statutory authority, the Secretary has applied CED to roughly 25 services, and the dual approach is not intended to affect the Secretary's current use of CED. The Congress would need to provide the Secretary statutory authority to use methods other than ASP to set the payment for select first-in-class Part B drugs.

Promoting price competition among drugs with therapeutic alternatives. To spur manufacturer competition among drugs with similar health effects, the Congress could give CMS the authority to use internal reference pricing, under which Part B drugs would remain in their own billing code but Medicare would establish a single reference price for those with similar health effects. Under reference pricing, manufacturers would have incentive to lower their prices relative to competitors to make their products more attractive to providers and garner market share, which would result in savings for beneficiaries and taxpayers. CMS would need a method for determining groups of products that are clinically similar, the payment rate for a reference group, medical exceptions to reference pricing policies, and payment for products that have multiple indications. CMS would also need to determine how frequently reference prices would be updated.

Improving provider incentives under the ASP payment system. To address concerns about possible financial incentives associated with Medicare Part B's current 6 percent drug add-on to ASP, the add-on could be modified by placing a fixed dollar limit on the add-on payment, converting a portion of the percentage add-on to a fixed fee, or a combination of these approaches. The impact on payments for Part B drugs would vary, with a fixed dollar limit on the add-on payment reducing payment for very expensive drugs, and the application of a fixed fee raising payments for relatively inexpensive drugs while decreasing payments for more expensive ones.

Improving the accuracy of Medicare Advantage payments by limiting the influence of outliers in CMS's risk-adjustment model

Post-publication review of the analyses underlying this chapter revealed possible errors. We have withdrawn the chapter while we reevaluate the analyses and our conclusions.

Aligning fee-for-service payment rates across ambulatory settings

In Chapter 6, the Commission discusses aligning the payment rates across ambulatory settings. Medicare payment differences for the same service across ambulatory settings—HOPDs, ASCs, and freestanding physician offices—encourage arrangements among providers that result in care being provided in the settings with the highest payment rates, thereby increasing total Medicare spending and beneficiary cost sharing without significant improvements in patient outcomes.

To evaluate whether an ambulatory service should continue to have different payment rates in the three settings or whether it would be appropriate to align the payment rates more closely across the three settings, we analyzed the ambulatory payment classifications (APCs) used in the outpatient prospective payment system (OPPS) to pay for services provided in HOPDs. Each APC includes a set of services that are similar in terms of clinical attributes and cost; all services in the same APC have the same OPPS payment rate. Of the OPPS's 169 APCs for services, we identified 57 APCs for which it would be reasonable and appropriate to align the OPPS and ASC payment rates with those set in the physician fee schedule (PFS). We also identified 11 APCs for which it would be appropriate to align the OPPS payment rates with the ASC payment rates and continue to use the PFS payment rate when the service is provided in a freestanding office. In the 68 APCs for which it is reasonable to align payment rates across ambulatory settings, we found that patient severity has little effect on the costs incurred by HOPDs when furnishing the services, so adjustments to payments for patient severity do not appear to be necessary. For 101 APCs, such as emergency department (ED) visits, the HOPD is the most frequent setting, or the services cannot be provided in settings other than HOPDs. For these APCs, each setting should continue to have a different payment rate, with generally higher payments for HOPDs.

As policymakers consider how to align payment rates across ambulatory settings, we suggest that the APCs for ED visits, critical care visits, and trauma care visits be reclassified from standard APCs to comprehensive APCs, which package all services—with a few exceptions—into a single payment unit. As a result, higher payment rates for the provision of services during these visits would be maintained, appropriately reflecting the hospital-level costs of items and services provided.

In aggregate, if changes in payments resulting from aligning payment rates were taken as program savings,

Medicare program spending in 2019 would have declined by $6.6 billion and beneficiary cost-sharing obligations by $1.7 billion. Across all hospitals, a site-neutral policy would have reduced overall Medicare revenue by 4.1 percent and beneficiary OPPS cost sharing by 13.2 percent.

Under current law, CMS would be required to fully offset the lower Medicare spending and beneficiary cost sharing from aligning ambulatory payment rates by increasing the OPPS payment rates for all other (nonaligned) APCs to produce a budget-neutral result. Combining alignment of payment rates with a budget-neutrality adjustment within the OPPS would lower incentives to shift services to higher-cost settings but would reduce savings for Medicare and beneficiaries. However, if the budget-neutrality adjustment were not applied, some hospitals that are the primary source of access to physicians' services for these low-income patients would experience reductions in Medicare revenue under the payment alignment policy, which could adversely affect access for these beneficiaries. Policymakers could consider an alternative to the budget-neutrality policy that would explicitly target hospitals that serve a high share of low-income beneficiaries to limit the loss of Medicare revenue for these hospitals. Over time, the payment rate alignment policy would produce savings for the Medicare program and lower cost sharing for beneficiaries under either the budget-neutrality or the stop-loss policy because incentives to shift services from the lower-cost physician office and ASC settings to the higher-cost HOPD setting would be mitigated.

Segmentation in the stand-alone Part D plan market

In Chapter 7, the Commission discusses segmentation in the market for stand-alone Part D PDPs, including insurers' rationale and strategies for segmenting the market, the effects of segmentation on program spending, and potential reforms to reduce segmentation or limit its negative consequences.

The Part D program uses stand-alone PDPs to provide drug coverage to beneficiaries in the FFS Medicare program. Insurers that participate in the PDP market can offer up to three plans, and they tailor those plans to appeal to different types of beneficiaries. Most major insurers generally offer one plan to target LIS beneficiaries and two plans to target beneficiaries without the LIS—one for those with low drug costs and one for those with high drug costs. Insurers differentiate their plans through a mix of program rules and changes in plan features such as premiums, beneficiary cost sharing, the specific drugs covered by the plan, and pharmacy networks. Two distinctive features of this strategy are keeping the premium for the plan that targets LIS beneficiaries just below the LIS subsidy amount and offering plans with "enhanced" coverage (which combines standard Part D coverage with supplemental benefits) that turn out to have lower premiums than plans with "basic" coverage (which is limited to standard coverage only).

Segmenting the market makes PDPs more profitable for insurers. For LIS beneficiaries, insurers want to maximize the revenue they receive for each enrollee, which is easier to do when LIS enrollees are segmented into separate plans. For other beneficiaries, insurers want to capitalize on the fact that beneficiaries are sensitive to premiums when they first select a PDP but rarely switch plans after that, which insurers can do more easily by pairing a newer, low-premium plan that attracts new Part D enrollees with an older, more established plan with premiums they can increase more easily.

But for beneficiaries, the implications of a segmented market are more complicated. Segmentation benefits many enrollees who do not receive the LIS by giving them greater access to low-premium plans. At the same time, segmentation may make it harder for beneficiaries to understand their plan options, despite requirements that insurers offer plans with meaningful differences. The common-sense distinction between "basic" and "enhanced" plans has been lost, and it can be difficult to determine what extra benefits are provided by enhanced PDPs with low premiums. In addition, beneficiaries in enhanced PDPs with high premiums likely pay more for their coverage than they otherwise would. For the Medicare program, segmentation likely increases Part D spending because it allows sponsors to charge higher premiums for plans that serve LIS beneficiaries and older plans that serve beneficiaries who do not receive the LIS.

Policymakers could consider reforms that would either reduce the level of segmentation in the market or

address undesirable consequences of segmentation. These reforms include:

- Modifying the auto-enrollment process for LIS beneficiaries. Policymakers could give insurers a stronger incentive to bid more competitively by auto-enrolling a larger share of new LIS beneficiaries in plans with lower premiums and reassigning LIS beneficiaries to new plans when premiums rise above the benchmark.
- Changing how the requirement for plans to have "meaningful differences" is administered. For example, policymakers could require enhanced PDPs to cover a minimum percentage of the out-of-pocket costs that their enrollees would otherwise pay for basic coverage. This approach would prevent insurers from offering enhanced PDPs with very little additional coverage.
- Requiring PDP insurers to treat their enrollees as a single risk pool for the purpose of providing basic coverage. Under this reform, every enrollee in an insurer's PDPs would pay the same premium for basic coverage and have the same formulary, cost-sharing rules, and pharmacy network. Insurers would still be allowed to offer enhanced coverage, but only by providing extra benefits on top of the uniform basic coverage, somewhat akin to an insurance rider. As under the current system, enrollees would pay for the full cost of any extra benefits through a supplemental premium.

Overall, segmenting the market based on beneficiaries' LIS eligibility is a greater concern because it reduces the incentives for plans that serve the LIS population to bid competitively. The consequences of segmenting other beneficiaries based on their drug spending are more mixed because segmentation reduces premiums for some beneficiaries while increasing premiums for other beneficiaries. Policymakers could therefore focus any reforms on measures that address the consequences of segmentation based on beneficiaries' LIS eligibility. ■

CHAPTER 1

An approach to streamline and harmonize Medicare's portfolio of alternative payment models

CHAPTER 1

An approach to streamline and harmonize Medicare's portfolio of alternative payment models

Chapter summary

CMS operates numerous alternative payment models (APMs) that providers in the fee-for-service (FFS) Medicare program can participate in. CMS's largest APM is the Medicare Shared Savings Program (MSSP), which is a population-based payment model. Providers who voluntarily form accountable care organizations (ACOs) to participate in this model agree to receive bonuses or owe penalties based on whether total annual per capita spending for a group of attributed Medicare FFS beneficiaries is below or above a specified spending benchmark. MSSP includes five tracks, each with slightly different features. Alongside MSSP, CMS's Center for Medicare and Medicaid Innovation (the Innovation Center) operates another population-based payment model, called the ACO Realizing Equity, Access, and Community Health (REACH) Model (formerly the Global and Professional Direct Contracting Model), which has two tracks. In addition to these population-based payment models, CMS's Innovation Center also operates episode-based payment models, including the Comprehensive Care for Joint Replacement Model and the Bundled Payments for Care Improvement Advanced Model, which hold specialists or hospitals accountable for spending during shorter periods of time (90 days).

In this chapter

By holding them accountable for cost and quality, APMs typically give health care provider organizations a financial incentive to furnish a more efficient mix of services and improve the care they deliver. Yet the presence of multiple APMs operating concurrently can create unnecessary complexity and may dilute incentives when Medicare beneficiaries are attributed to more than one model simultaneously and/or when providers participate in more than one APM at the same time. In our June 2021 report to the Congress, the Commission recommended that CMS reduce the number of Medicare APMs it operates and design models to work better together when combined. In this chapter, we articulate suggestions that are aimed at operationalizing that recommendation.

In particular, to reduce the complexity of CMS's offerings, the Commission supports reducing the number of population-based payment model tracks available to providers. With a smaller number of tracks, each could be geared toward provider organizations of different sizes and involve different degrees of financial risk. For example, a track geared toward groups of small provider organizations (e.g., independent primary care practices) that come together to form an ACO could include the opportunity to earn modest shared savings but not hold these providers accountable for repaying any shared losses. A second track could be geared toward midsize organizations and could give them the opportunity to earn a higher percent of shared savings and be at risk for shared losses. A third track could be geared toward large provider organizations (e.g., health systems with multiple campuses) and could put them at full risk for all Part A and Part B spending generated by their attributed beneficiaries. Alternatively, a population-based payment model could have a single track, with shared savings and loss rates varying based on ACO characteristics, such as an ACO's ability to take on financial risk. Regardless of which approach is used, the Commission envisions allowing provider organizations of any size to move to a more advanced track involving more financial risk if they so choose.

To strengthen incentives for providers to participate in this simplified population-based payment model and to slow the growth in their spending, ACOs' spending targets ("benchmarks") should not be rebased every few years based on actual spending; instead, benchmarks should be updated using exogenous administrative growth factors that would be known to ACOs in advance. Moving away from rebasing would ensure that ACOs that succeed in lowering their spending are not penalized in subsequent years by having their benchmark "ratcheted" down based on their recent actual spending. Ideally, a growth factor would be chosen to produce benchmarks that increase fast

enough to give participating providers a reasonable chance to earn shared savings, but slow enough to give the Medicare program a high probability of realizing net savings (relative to what Medicare would have spent in the absence of this model), while avoiding significant forecasting errors.

It is important to ensure that providers have strong incentives to participate in APMs. Acknowledging that not all providers are capable of bearing financial risk under population-based payment models, the Commission does not see a rapid transition to mandatory participation in ACOs as practical. We do, however, encourage CMS to explore ways to strengthen incentives to participate in population-based payment models, particularly for larger provider organizations.

In addition to a streamlined population-based model, the Commission also supports a national Medicare-run episode-based payment model, in which participation could be mandatory for certain providers and certain proven clinical episodes (e.g., hip and knee replacements), even if a beneficiary were concurrently attributed to an ACO. (CMS already has experience operating a mandatory episode-based payment model in selected geographic areas and has identified several types of episodes that have generated meaningful gross savings for the Medicare program and would be likely to generate net savings if implemented with accurate target prices.) CMS's Innovation Center should continue testing episode-based payment for a variety of types of clinical episodes, with the goal of identifying additional types of clinical episodes that could be added to a national episode-based payment model in the future. Since only a few types of clinical episodes would likely be included in a national Medicare-run episode-based payment model, providers in a population-based payment model would retain the freedom to enter into their own episode-based payment arrangements for many other types of clinical episodes—and they could even layer financial arrangements on top of Medicare's episode-based payment model, if they wished.

To ensure the population-based payment model and the episode-based payment model envisioned here work well together, the Commission asserts that any bonus payments resulting from reducing episode costs should be allocated in such a way that (1) episode-based providers have an incentive to furnish efficient, high-quality care; (2) providers in ACOs have an incentive to refer their attributed patients to low-cost, high-quality episode-based providers; and (3) when combined, these incentives should not be so large that they increase total Medicare spending.

Promoting equity and reducing health disparities should also be a priority for all of Medicare's APMs. When designing and implementing its payment models, CMS should ensure that access to high-quality care is equitable for all populations, and every model should include features that work to address disparities in health outcomes and care experiences.

These strategies would represent a shift for CMS—moving away from temporarily testing a large number of model tracks on a small scale to permanently operating a smaller number of model tracks on a large scale. The Commission asserts that, designed correctly, APMs offer a promising avenue for lowering FFS spending while preserving or improving care quality. The proposed changes to CMS's APM portfolio are intended to help reach this potential by reducing the complexity and uncertainty that providers face when picking an APM, increasing provider participation in these models, and improving provider performance in these models. ■

CMS operates numerous alternative payment models (APMs) that providers in the fee-for-service (FFS) Medicare program can participate in. By holding them accountable for cost and quality, these APMs typically give health care provider organizations a financial incentive to furnish a more efficient mix of services and improve the care they deliver. Yet the presence of so many APMs operating concurrently can create unnecessary complexity and dilute incentives when Medicare beneficiaries are attributed to multiple models simultaneously and/or when providers participate in more than one APM at the same time. In the Commission's June 2021 report to the Congress, we recommended that CMS reduce the number of Medicare APMs it operates and design models to work better together when combined.

In this chapter, we articulate suggestions that are aimed at operationalizing the recommendation from our June 2021 report. We put forward a structure for streamlining Medicare's population-based payment model offerings into a smaller number of tracks geared toward provider organizations of different sizes and involving different degrees of financial risk (including a permanently upside-only track for groups of small provider organizations). To avoid the potentially unsustainable financial incentives associated with periodically "ratcheting down" accountable care organizations' (ACOs') spending targets, a foundational population-based payment model would, instead of periodically rebasing spending targets, rely on annual administrative updates to gradually grow spending targets at a modest rate that yields net savings for the Medicare program. This model would be supplemented by a national Medicare-run episode-based payment model that would be used to pay for certain types of proven clinical episodes (e.g., hip and knee replacements) for all FFS Medicare beneficiaries, even if they were concurrently attributed to an ACO. The Center for Medicare and Medicaid Innovation (the Innovation Center) would be encouraged to continue testing episode-based payment for other types of clinical episodes, with the goal of adding to the national episode-based payment model in the future. The Commission also asserts that all future APMs should have features that promote health equity and reduce disparities in care experiences and health outcomes among different patient populations, especially among underserved beneficiaries.

The changes described in this chapter would represent a shift for CMS—moving away from temporarily testing a large number of model tracks on a small scale, to permanently operating a small number of model tracks on a large scale. The Commission asserts that, designed correctly, APMs offer a promising avenue for lowering FFS spending while preserving or improving care quality. The proposed changes to CMS's APM portfolio are intended to help reach this potential by reducing the complexity and uncertainty that providers face when deciding whether to participate in an APM, increasing provider participation in APMs, and improving provider performance in APMs.

Background

Many observers of the U.S. health care system believe that its reliance on an FFS approach for paying for medical care creates problematic financial incentives because it rewards health care providers who maximize the number and complexity of billable medical services they provide while financially penalizing health care providers who furnish care more efficiently or who furnish services that are not billable (e.g., addressing social determinants of health). FFS payment systems do not incentivize providers to actively manage patients to keep them healthy and out of the hospital. Paradoxically, a patient with well-managed conditions may result in less revenue for providers than a patient with poorly managed conditions.

CMS has been experimenting with alternatives to FFS payment since the 1970s, but these efforts were expanded and accelerated when the Congress created the Innovation Center in the Affordable Care Act of 2010 (ACA). The Congress appropriated the equivalent of $1 billion per year to CMS's Innovation Center to test new payment and service delivery models and authorized the Department of Health and Human Services to expand any Innovation Center model into a permanent, nationwide program if testing found that it reduced spending without harming care quality or improved care quality without increasing spending. In the last 11 years, the Innovation Center has tested more than 50 payment models, including several population-based payment models (otherwise known as ACO models), several episode-based payment models, and several advanced primary care models—often operating

multiple models within each of these categories at once (Medicare Payment Advisory Commission 2021, Smith 2021).[1] In addition to the models tested by the Innovation Center, the ACA also established the nationwide, permanent Medicare Shared Savings Program for ACOs.

The three categories of alternative payment models just mentioned have generally qualified as "advanced alternative payment models" (A–APMs) under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), since CMS has determined that they require participating providers to bear more than nominal financial risk. Since 2019, clinicians who participate in A–APMs have been eligible to receive annual 5 percent bonuses under MACRA, in addition to payments they receive through Medicare's FFS payment systems and the A–APMs in which they participate. In 2025, the MACRA 5 percent A–APM bonus will end, and starting in 2026, clinicians in A–APMs will begin to qualify for higher payment rates through Medicare's physician fee schedule: Payment rates for clinicians in A–APMs will grow by 0.75 percent per year, while payment rates for clinicians not in these models will grow by 0.25 percent per year.[2]

In the Commission's June 2021 report to the Congress, we summarized findings from evaluations of key A–APMs that Medicare has implemented and tested over the last decade. Most population-based and episode-based payment models have generated modest gross savings for the Medicare program, through changes in the quantity and mix of services delivered (e.g., through reductions in institutional post-acute care use). Once performance bonuses are factored in, however, some of these models have generated net losses for the Medicare program.

Certain factors cited in our 2021 report could be limiting the success of A–APMs, including the fact that most models have relied on voluntary participation from provider organizations, thus allowing providers that expect to earn bonuses to opt into models and providers that expect to owe penalties to opt out (either by never enrolling, or by exiting midway through a model's testing period). In subsequent presentations, the Commission has discussed how one feature of CMS's population-based models—spending targets that are "rebased" every few years based on recent actual spending, leading to "ratcheting down" of spending targets for successful ACOs—creates a disincentive for participating provider organizations to deeply reduce their spending because doing so generates bonus payments only in the short run and makes future years' spending targets lower and harder to beat.[3] If bonuses in the initial years are believed to be too small to justify a long-run investment in the ACO program, providers may choose not to participate in ACO models. Another reason A–APMs may not have generated large savings to date is that participating provider organizations often continue to tie their individual clinicians' incomes to the quantity of services they furnish (Ryan et al. 2015).

Our June 2021 report also noted that allowing multiple APMs to operate concurrently can create unintended consequences—increasing complexity for providers and diluting APMs' incentives. The Commission was particularly concerned about this last issue and formally recommended that the Secretary of the Department of Health and Human Services implement a more harmonized portfolio of fewer alternative payment models. Instead of operating a series of models that are largely developed independent of one another, the Commission contended that the Innovation Center should deploy a smaller set of models that are designed to work together (Medicare Payment Advisory Commission 2021).

Streamlining and improving population-based payment models

The Commission asserts that population-based payment models, designed correctly, hold great promise. Population-based payment models hold participating health care providers accountable for the total Part A and Part B spending of the FFS beneficiaries attributed to them and hold these providers accountable for ensuring that care quality standards are met for these beneficiaries. In so doing, these payment models give providers an incentive to engage in active care management to keep patients healthy and out of the hospital, and they financially reward providers who furnish a more efficient mix of services to their patients. One of the reasons that population-based payment models are appealing is

that, theoretically, they should let many parties in the health care system benefit—by slowing Medicare's spending growth while increasing providers' revenues and by improving FFS Medicare beneficiaries' health while slowing the growth in their cost-sharing liabilities.

So far, studies suggest that population-based payment models have produced modest but promising results. In a review of the literature, our June 2021 report found that these models consistently generated gross savings (by slowing the growth in spending on certain services for Medicare beneficiaries) and in some cases generated modest net savings for the Medicare program (after shared savings bonuses and shared loss penalties were factored in). These savings were generally achieved without harming care quality, and in some cases, care quality actually improved (Medicare Payment Advisory Commission 2021).

How population-based payment models work

In population-based payment models, groups of health care providers form an ACO and enter into an agreement with a payer to take accountability for spending and quality for a group of the payer's enrollees. The patients attributed to an ACO are typically those who receive their primary care from the ACO's providers. In Medicare ACO models, an ACO's spending target is often set by calculating the average total Medicare Part A and Part B spending generated by an ACO's attributed patients during some historical baseline period and blending it with regional spending in an ACO's area. The regional component of the spending target has the effect of raising targets for low-spending ACOs and lowering targets for higher-spending ACOs. CMS then trends forward an ACO's blended historical spending level from a baseline period to the current year using a defined growth rate (which can include regional and/or national growth factors), and makes various adjustments to the spending level, depending on whether the population of patients currently attributed to the ACO is sicker (or healthier) than the patients attributed to the ACO in its historical baseline period. The final spending target for an ACO is referred to as an ACO's spending benchmark.

During a performance year, Medicare pays the ACO's participating health care providers using customary FFS payment systems; at the end of the year, CMS reconciles the ACO's spending benchmark with the actual average spending on the ACO's attributed beneficiaries. If the ACO's actual average spending per patient is lower than its spending benchmark, CMS pays the ACO a percentage of the savings it generated. In two-sided risk models, if an ACO's actual spending is higher than its benchmark, CMS recoups a percentage of the losses generated by the ACO. The share of the savings or losses paid to or recouped from the ACO depends on the specific model track an ACO has enrolled in. To ensure that ACOs do not try to withhold needed care to stay below their spending benchmark, ACOs' performance on quality measures is always incorporated into population-based payment models—either in the form of a pass/fail minimum quality standard that must be met to receive shared savings payments or an approach that adjusts the size of an ACO's shared savings bonus or shared loss penalty based on the ACO's performance on quality measures.

To guard against small random variations in year-to-year spending causing shared savings bonuses or shared loss penalties, population-based payment models either use minimum savings and loss rates or benchmark discounts (Table 1-1, pp. 10–11).

Under the minimum savings and loss rate approach, an ACO's spending must be at least a certain percent below its spending benchmark to receive a shared savings bonus (or be at least a certain percent above its benchmark before a penalty is assessed). For example, in MSSP's Basic track, a Level A ACO with 5,000 attributed Medicare beneficiaries must generate average spending per beneficiary that is at least 3.9 percent below its spending benchmark before Medicare will pay out a shared savings bonus to this ACO.

An alternative to a minimum savings rate is to discount an ACO's spending benchmark by some percentage, as in the ACO Realizing Equity, Access, and Community Health (REACH) model (formerly known as Global and Professional Direct Contracting). For example, the benchmark of an ACO that selects this model's Global option is discounted by 2 percent, but if an ACO's average spending is below this discounted benchmark—even by only a small percent—the ACO will qualify to receive these savings on a first-dollar basis.

TABLE 1–1

Key features of Medicare's seven population-based payment model tracks in 2022 *(cont. next page)*

Track	Mechanism to guard against unwarranted shared savings or loss payments	Shared savings rate[a]	Shared loss rate[b]	Limit	
				Gain	Loss
Medicare Shared Savings Program					
Basic track's Levels A & B[c]	Minimum savings rate coupled with a minimum quality standard[d,e]	40%	N/A	10% of benchmark	N/A
Basic track's Level C	Minimum savings rate coupled with a minimum quality standard[d]; minimum loss rate[f]	50%	30%	10% of benchmark	Lower of 2% of revenue or 1% of benchmark
Basic track's Level D	Minimum savings rate coupled with a minimum quality standard[d]; minimum loss rate[f]	50%	30%	10% of benchmark	Lower of 4% of revenue or 2% of benchmark
Basic track's Level E	Minimum savings rate coupled with a minimum quality standard[d]; minimum loss rate[f]	50%	30%	10% of benchmark	Lower of 8% of revenue or 4% of benchmark
Enhanced track	Minimum savings rate coupled with a minimum quality standard[d]; minimum loss rate[f]	75%	40–75% depending on ACO's quality[g]	20% of benchmark	15% of benchmark

Population-based payment models typically employ either a minimum savings rate and minimum loss rate or a benchmark discount, but not both of these mechanisms since either of these approaches can be used to achieve the same general effect.

To prevent an ACO from experiencing catastrophic financial losses, its potential financial losses are capped in Medicare's population-based payment models; an ACO's potential financial gains are also capped, to prevent the Medicare program from experiencing large financial losses.

Specific financial parameters of the tracks currently available in FFS Medicare's flagship population-based payment models are summarized in Table 1-1. (In recent years, CMS's Innovation Center has typically also operated an ACO-style model tailored to beneficiaries with kidney disease; the current iteration is called Comprehensive Kidney Care Contracting and is beyond the scope of this chapter.)

The number of population-based payment model tracks could be reduced

Health care providers seeking to enroll in a population-based payment model for their FFS Medicare beneficiaries currently have seven options to choose from, as shown in Table 1-1—requiring providers to invest significant resources (either in the form of their own time or a paid consultant) to help them choose the most suitable model track. The complexity and resources involved can present a barrier to provider participation in these models, particularly for small independent physician practices (Friedberg et al. 2020). Moreover, with no standard

TABLE 1–1

Key features of Medicare's seven population-based payment model tracks in 2022 *(cont.)*

Track	Mechanism to guard against unwarranted shared savings or loss payments	Shared savings rate[a]	Shared loss rate[b]	Limit	
				Gain	Loss
ACO REACH Model (formerly Global and Professional Direct Contracting)					
Professional Option	5% quality withhold[h]	50%	50%	For ACO gains/losses that are >5% of the benchmark, savings/loss rates are 35% for amounts 5–10% of benchmark, 15% for amounts 10–15% of benchmark, and 5% for amounts >15% of benchmark	
Global Option	2% benchmark discount[i]; 5% quality withhold[h]	100%	100%	For ACO gains/losses that are >25% of the benchmark, savings/loss rates are 50% for amounts 25–35% of benchmark, 25% for amounts 35–50% of benchmark, and 10% for amounts >50% of benchmark	

Note: N/A (not applicable), ACO (accountable care organization), REACH (Realizing Equity, Access, and Community Health).
[a] When an ACO's average spending per beneficiary is lower than its spending benchmark, the difference between those two spending amounts is considered "savings" relative to the benchmark. A "shared savings rate" refers to the percent of those savings that is paid to the ACO by the Medicare program (e.g., in the form of a retrospective payment from CMS).
[b] When an ACO's average spending per beneficiary is higher than its spending benchmark, the difference between those two spending amounts is considered "losses" relative to the benchmark. A "shared loss rate" refers to the percent of those losses that is recouped from an ACO by the Medicare program (e.g., in the form of a retrospective payment to CMS).
[c] "Level A" and "Level B" ACOs face the same model features but progress through Medicare Shared Savings Program's (MSSP's) levels and tracks at a different pace.
[d] A "minimum savings rate" means that an ACO's average spending per beneficiary must be below its spending benchmark by a certain percentage before the ACO can qualify for a shared savings payment; once this threshold is exceeded, and if the ACO meets a quality performance standard, the ACO receives shared savings payments on a first-dollar basis.
[e] In MSSP, the minimum savings rate for an ACO in an upside-only track is based on the number of beneficiaries assigned to the ACO (e.g., an ACO with 5,000 beneficiaries faces a minimum savings rate of 3.9 percent, while an ACO with at least 60,000 beneficiaries faces a minimum savings rate of 2 percent).
[f] A "minimum loss rate" means that an ACO's average spending per beneficiary must exceed its spending benchmark by a certain percentage before the ACO owes any shared loss penalty to CMS; once spending exceeds this level, shared loss penalties are calculated on a first-dollar basis. MSSP ACOs in two-sided risk tracks can choose among several options: (1) a 0 percent minimum savings rate/minimum loss rate; (2) a minimum savings rate/minimum loss rate of 0.5 percent, 1.0 percent, 1.5 percent, or 2.0 percent; or (3) a minimum savings rate/minimum loss rate that varies based on the number of beneficiaries assigned to the ACO.
[g] In the MSSP Enhanced track, an ACO's shared loss rate is determined by its quality score.
[h] A "quality withhold" means a percent of the ACO's benchmark is withheld and available to be earned back based on the ACO's performance on quality measures. In the ACO REACH Model, this quality withhold is set at 5 percent of an ACO's benchmark in 2022 but will be reduced to 2 percent starting in 2023 due to recent model changes.
[i] A "benchmark discount" means the ACO's spending benchmark is reduced by some percentage. In the ACO REACH Global Option, spending benchmarks are discounted by 2 percent in 2021 and 2022, 3 percent in 2023 and 2024, and 3.5 percent in 2025 and 2026.

Source: Centers for Medicare & Medicaid Services' Medicare Shared Savings Program: Shared savings and losses and assignment methodology specifications (https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-and-losses-and-assignment-methodology-specifications.pdf-1), Comparing GPDC to the ACO REACH Model (https://innovation.cms.gov/media/document/gpdc-aco-reach-comparison), Shared Savings Program participation options for performance year 2022 (https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/ssp-aco-participation-options.pdf), and Global and Professional Direct Contracting Model PY2022 financial operating guide: Overview (https://innovation.cms.gov/media/document/gpdc-py2022-fin-op-guide-ovw).

FFS Medicare population-based payment model, payers other than Medicare have no single default model that they can adopt in their own population-based payment arrangements, increasing the complexity and different incentives faced by health care providers from different payers.

A simpler approach favored by the Commission would be to reduce the number of tracks available to health care providers interested in entering into a population-based payment model for their FFS Medicare beneficiaries.[4] The Commission also favors using more consistent parameters in these tracks so that potential participants would have fewer differences between tracks to consider.

One approach to reducing model tracks would be to condense CMS's current offerings into three tracks geared toward provider organizations of different sizes. The first track could offer groups of small provider organizations (including groups of independent primary care practices) the chance to earn 50 percent of the savings they generate relative to their spending benchmark. This upside-only track could be available to these provider organizations indefinitely, with no time limit on how long they could participate in the track. A second track, for medium-size organizations (such as multispecialty physician practices with multiple locations or small community hospitals with a modest number of primary care providers), could hold providers accountable for 75 percent of the savings and losses they generate. A third track, for large provider organizations (such as health systems with multiple campuses), could hold providers accountable for 100 percent of the savings and losses they generate. Provider organizations of any size could have the freedom to move to a more advanced track, involving more financial risk, if they so chose. Although smaller provider organizations might have fewer financial resources compared with larger organizations, their smaller size might facilitate their ability to rapidly adopt the types of care processes that some observers believe are necessary to succeed in APMs.

Another way to reduce the number of population-based payment model tracks would be to offer a single track with shared savings and loss rates that varied based on ACO characteristics, such as their ability to take on financial risk.

Eliminating the periodic "rebasing" of ACO spending benchmarks could increase ACOs' incentives to lower spending

To give ACOs stronger incentives to lower their spending, ACO benchmarks should be based on historical spending that would be trended forward to the current year using a growth factor that is exogenous—that is, unrelated to ACOs' spending performance—and known to ACOs in advance.[5] ACOs' spending benchmarks would be prospectively set one year at a time, before the start of a performance year, using this growth factor. This approach would be in contrast to the current practice in many model tracks of recalculating ACOs' spending benchmarks every few years, based on recent actual spending. Rebasing benchmarks to reflect changes in actual spending has the effect of "ratcheting down" the benchmarks of ACOs that have succeeded in lowering their spending—thus penalizing these ACOs by giving them harder-to-beat benchmarks. Eliminating the "ratchet" effect would give ACOs a stronger incentive to lower their spending.

Under this proposed approach, the growth factor could be set using a single exogenous factor or be based on two components: (1) a price component and (2) a volume and intensity component. The price component could reflect annual updates to Medicare's various FFS payment systems and fee schedules, including customary adjustments to reflect different Medicare payment rates in different geographic areas of the country. Annual increases to the price component of the growth factor could be weighted based on the relative mix of services used by an ACO's beneficiaries in their historical baseline period since Medicare's various payment systems' and fee schedules' payment rates (e.g., for inpatient prospective payment system hospitals, rural health clinics, FFS clinicians) increase at different speeds. The objective of such an adjustment would be to hold providers accountable for limiting growth in the volume and intensity of services while not penalizing or rewarding them for changes in Medicare's prices.

The volume and intensity component could be set in several ways, such as by using CMS actuaries' projected growth rate for the volume and intensity of services in FFS Medicare (which includes the use of new technologies) or the projected growth in real national gross domestic product (GDP) (which is GDP adjusted to remove price inflation) and then discounting this factor by some percentage to generate savings for the Medicare program. To the extent that volume and intensity growth is driven by technological change, ACOs—and not the Medicare program—would be responsible for managing that technological change or reducing spending elsewhere to accommodate it. If technological change is more rapid or costly than

assumed in the benchmark updates, ACOs will find it harder to earn bonuses, and policymakers may be pressured to adjust benchmarks. Conversely, if technology-induced spending growth is lower than what is assumed in the benchmark growth rate, it will be easier for the ACO to keep spending below the benchmark, there may be less pressure for ACOs to control overall spending growth, and ACOs may earn inordinately large bonuses.

Taken together, the growth factor(s) used to trend forward historical spending to the current year should grow at a fast enough rate to ensure that ACOs have a chance to earn shared savings without compromising beneficiaries' care quality, yet slow enough that this model generates net savings for the Medicare program (relative to the FFS Medicare spending that would have occurred in the absence of this model), while avoiding significant forecast errors. Spending benchmarks would need to increase at a slower rate than current FFS spending, especially in the model track that would allow providers to keep 100 percent of the savings they generate relative to their benchmark. If ACOs in this track had benchmarks that rose at the same rate at which CMS actuaries expected FFS spending to grow, then ACOs in this track (large health systems) would not generate any savings for the Medicare program.

The growth factor used to trend benchmarks forward could be adjusted periodically if it underpredicted or overpredicted health care spending levels in a given year (for example, if the growth rate did not predict a recession that led to reduced health care utilization across all payers). It could also be adjusted if policymakers wished to increase or decrease the amount of savings generated from the population-based model. For example, if the model were implemented on a voluntary basis and suffered from weak provider enrollment, policymakers could reduce the size of the discount to raise benchmarks and attract more providers to the model. Or, if the model were implemented on a mandatory basis, policymakers could consider slowly increasing the size of the discount to increase the amount of net savings realized by Medicare over time.

Additional adjustments could be made to ACOs' spending benchmarks to achieve various policy objectives. To reduce the geographic variation in risk-adjusted spending per FFS Medicare beneficiary and ensure that high-spending ACOs did not benefit from having maintained high levels of spending, the benchmarks for high-spending ACOs could rise at a slower rate than the benchmarks for low-spending ACOs. This approach would cause ACOs' benchmarks to eventually converge, thus reducing geographic variation in spending per FFS Medicare beneficiary. To account for local secular changes within a market—such as the recent reduction in spending per beneficiary in the Miami area due to audit enforcement—a local market cap could limit the divergence between an ACO's benchmark and the local market's actual spending.

To limit the degree to which providers can manipulate the composition of their patient panels to maximize their financial performance in an ACO, CMS should calculate ACOs' benchmarks each year based on the historical spending of the clinicians currently participating in that ACO. This would prevent ACOs from having one set of clinicians with expensive patients (relative to their risk scores) in their historical baseline period and another set of clinicians with less costly patients in the performance year. In addition, CMS should require that all local clinicians billing under a provider organization's tax identification number be included in that provider organization's ACO. This requirement would contrast with models that allow providers to set up multiple legal organizations and strategically bill for certain patients through an organization participating in an ACO and other patients through an organization not participating in an ACO. Even with these safeguards, CMS would still need to guard against other provider behaviors that can increase Medicare spending without improving quality. For example, ACOs could still drop physician practices with higher-than-expected spending per beneficiary.

Other design issues

Beyond how benchmarks are set, a number of other design issues would also need to be considered if CMS implemented the population-based payment model envisioned here. For example, policymakers would need to consider what shared savings and loss rates to use in a streamlined population-based payment model (e.g., 50 percent, 75 percent, and 100 percent). And as in current models, a mechanism would need to be used to ensure that shared savings payments were not paid due to random spending variation alone (e.g., through

Policymakers may want to reconsider CMS's current practice of including ACO shared savings bonuses in Medicare Advantage benchmarks

As policymakers consider how to incentivize wide provider participation in a population-based payment model, one related consideration that could have a large impact on Medicare spending is whether shared savings and loss payments should be included in Medicare Advantage (MA) benchmarks. Although such payments are not included in accountable care organizations' (ACOs') benchmarks, these payments are included in MA benchmarks—meaning the Medicare program effectively "double pays" for shared savings to both ACOs and MA plans (through higher MA benchmarks). Because most providers currently do not participate in an ACO and because shared savings payments have been relatively small so far, the impact of shared savings payments on MA benchmarks has not been notable to date. However, if large shares of providers end up participating in our proposed population-based payment model, the total amount of shared savings payments included in MA benchmarks could grow substantially—thus pushing up MA benchmarks and Medicare program spending. This problem is compounded by the fact that MA enrollment has grown rapidly in recent years and will likely encompass half of all eligible Medicare beneficiaries within the next few years. Policymakers may therefore want to reconsider the current practice of including shared savings payments in MA benchmarks if a new population-based payment model is implemented. ■

the use of minimum savings rates). Thornier issues include how to improve the accuracy of benchmark risk adjustment and how to curb an ACO's ability to artificially increase its risk score through excessive coding of beneficiary diagnoses. Policymakers may also want to reconsider CMS's current practice of including ACO shared savings payments in Medicare Advantage benchmarks since it results in CMS "double paying" for these bonuses and drives up Medicare spending (see text box).

Another concern is how to incentivize provider participation in a streamlined population-based payment model and whether to use different types of incentives or mandates for different types or sizes of provider organizations. The various approaches available for incentivizing provider participation present different advantages and disadvantages:

- ***Attractive financial terms.*** If excessively attractive financial terms are offered to providers (e.g., asymmetric shared savings and loss rates that result in large bonuses and small penalties for providers), many providers may elect to participate in the model, but the Medicare program may not realize net savings.
- ***Required participation.*** Mandating that providers participate in the model would ensure strong participation. Yet it could also prompt smaller provider organizations to consolidate into larger provider organizations that are better able to absorb financial risk in APMs, exacerbating the problematic trend toward provider consolidation already under way.[6]
- ***Model design changes alone.*** It could be that the model design changes described in this chapter—particularly moving away from periodically "ratcheting down" ACO spending benchmarks—would make participating in the model financially attractive enough that many providers would opt in without the need for any additional incentives or mandates. Without any other financial incentives or mandates, however, providers who end up owing penalties could easily exit the model—resulting in an unrepresentative sample of providers in the

model. Such selection issues could reduce the likelihood of the Medicare program realizing net savings.

- ***Incentives in current law.*** Providers could become increasingly interested in participating in a population-based payment model due to provisions in the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). MACRA created incentives to participate in APMs (including population-based payment models) through two mechanisms: (1) higher physician fee schedule payment rates that clinicians will begin to receive in 2026 if they are in an advanced APM and (2) pay-for-performance payments that are scheduled to grow in the coming years under current law and have been easiest to maximize when a clinician participates in an APM (Centers for Medicare & Medicaid Services 2022).

Operating episode-based payment models concurrently with a population-based payment model

Episodes of care represent a significant portion of total Medicare spending. In 2019, there were roughly 450,000 inpatient stays for hip or knee replacement procedures among FFS Medicare beneficiaries, with an average 90-day episode cost of about $27,000, which amounts to more than $12 billion in spending for those episodes alone (Centers for Medicare & Medicaid Services 2021, Lewin Group 2022).

Episode-based payment models incentivize health care providers to improve care coordination and quality, rationalize service use, and lower adverse events, such as potentially avoidable readmissions, by holding a single provider (or group of providers) accountable for cost and quality during a defined clinical episode of care. Whereas ACOs incentivize year-round care management across a broad array of services for a broad population of beneficiaries, episode-based payment models in Medicare are geared toward a more specific set of providers (usually specialist physician practices and hospitals that perform or manage particular types of clinical episodes) for a narrower group of beneficiaries and service lines. ACOs can find it costly and burdensome to set up their own custom episode-based payment arrangements, so the presence of a national Medicare-administered model for certain types of episodes would give more specialists and hospitals incentives to provide efficient, high-quality episodes of care.

Over the years, Medicare has tested several episode-based payment models to find ways of reducing spending for selected types of episodes while maintaining or improving quality. Evaluations of Medicare's episode-based payment models have generally found that these models generate gross savings without compromising quality, but their record is mixed in terms of generating net savings for Medicare once performance payments are factored in (Medicare Payment Advisory Commission 2021). For instance, the largest track in the original Bundled Payments for Care Improvement (BPCI) initiative reduced gross spending but generated net losses for Medicare once bonus payments were included (Marrufo et al. 2021).[7] Evaluations of the first two model years of the subsequent BPCI Advanced Model found that surgical episodes (e.g., hip and knee replacements) generated statistically significant gross savings as well as statistically significant net savings to Medicare, while medical episodes (e.g., congestive heart failure) generated modest gross savings and net losses for Medicare (Lewin Group 2022). Evaluators reported that a reason for the difference in performance between these two types of episodes was that target prices were initially set too high for most medical episodes but were set more accurately for surgical episodes.

Meanwhile, evaluations of the Comprehensive Care for Joint Replacement (CJR) Model found that, among hospitals that were mandated to participate, the model generated statistically significant gross savings but net savings that were not large enough to be statistically significant. Among hospitals where participation was voluntary, the model generated gross savings but net losses for Medicare once bonuses and penalties were included (Lewin Group 2021). Medicare has also tested an episode-based model for beneficiaries being treated for certain types of cancer, the Oncology Care Model. Evaluation of this model found that it reduced gross Medicare spending, but once bonus payments and the cost of monthly care management fees were factored in, overall Medicare spending increased (Hassol et al. 2021).

There is evidence that combining an episode-based payment model with a population-based accountable care model can have positive impacts. One study found that when beneficiaries were served by providers in both the original BPCI model and an MSSP ACO, the combination yielded larger cost reductions to postdischarge institutional spending than episode-based payment alone for medical episodes but not for surgical episodes (Navathe et al. 2021). The authors speculate that the additive effect of the two models may result from ACOs' investments in improving ambulatory care complementing efforts by episode-based providers to reduce the cost of post-acute care.

How episode-based payment models work

In Medicare's two largest episode-based payment models—CJR and BPCI Advanced—participating providers are given target prices for different types of episodes prior to the start of a performance year. CMS sets target prices each year using the latest available claims data; these target prices are meant to include the cost of all of the care typically furnished to the beneficiary, across care settings and providers, during a defined period of time (e.g., hip replacement surgery plus the 90 days afterward). Expenditures for almost all Part A and Part B services that a beneficiary would receive during an episode period are included in the episode's benchmark price, with only limited exceptions.[8] Benchmarks are then discounted by 3 percent, which is how the Medicare program attempts to generate savings, to arrive at an episode's target price. (In population-based payment models, the term *benchmark* refers to the amount of spending against which actual ACO spending is reconciled and can include discounts or adjustments. By contrast, in episode-based payment models, *benchmark* generally refers to the estimated cost of an episode before any discount is applied, and *target price* refers to the benchmark minus the applicable discount factor.)

In an episode-based payment model, episodes are triggered when a beneficiary receives certain services from a participating provider (usually a specialist physician practice or hospital). During the episode, the providers who furnish care to the beneficiary are paid for services and items using Medicare's customary FFS payment systems. After the episode ends, CMS reconciles the total FFS spending generated during the episode with the episode's risk-adjusted target price (adjusted to reflect the age, number of chronic conditions, and dual-eligibility status of the beneficiary, among other adjustments).

If participating providers keep total actual spending below an episode's risk-adjusted target price, they receive a bonus payment for up to 100 percent of the difference; conversely, if total episode spending exceeds the target price, CMS recoups up to 100 percent of the difference from the providers. In CJR and BPCI Advanced, CMS includes a stop-gain and stop-loss limit on bonuses and penalties, capping them at 20 percent of the episode target price. CMS also factors in providers' performance on quality measures when calculating the size of bonuses and penalties.

How a Medicare-run episode-based payment model could operate concurrently with a population-based payment model

The Commission has considered several options for how the two payment models (episode-based models and population-based models) could continue to coexist in Medicare. Under the option supported by the Commission, Medicare would implement an episode-based payment model nationwide that would be mandatory for certain proven types of episodes and certain providers. In this approach, all FFS beneficiaries would be attributable to this model for the specified covered episodes (e.g., hip and knee replacement episodes)—regardless of whether the beneficiary was already attributed to an ACO under a population-based model and regardless of what type of ACO the beneficiary was in. Concurrent with their existing attribution to an ACO, beneficiaries would be attributed to the episode-based payment model for the duration of their episode. At the same time, for episodes not covered by Medicare's model, ACOs would be free to develop and administer their own payment arrangements involving contracts with specialists and hospitals. The Commission favors this approach to integrating episode-based payment with the population-based model because it would ensure that every beneficiary would benefit from having an accountable entity focused on furnishing efficient, high-quality care during every covered episode.

The Commission supports requiring all relevant providers that furnish a minimum number of covered

episodes to participate in a Medicare-run episode-based payment model. Requiring provider participation would help to avoid the selection issues that have been observed in prior episode-based payment models, which might have prevented these models from generating larger net savings for Medicare. Reports have found that characteristics of participants in voluntary episode-based payment models are appreciably different from those of comparable nonparticipants (Government Accountability Office 2018). For instance, hospitals that elected to participate in BPCI Advanced are larger and more likely to be located in urban areas and more competitive markets than eligible hospitals that elected not to participate (Dummit et al. 2020). Another study found that physician group practices that elected to participate in BPCI Advanced for joint replacement episodes tended to be larger and more likely to be located in urban areas compared with similar practices that did not participate in the model (Joynt Maddox et al. 2021).

Making the episode-based payment model mandatory would not only ensure that all relevant providers were included in the model, it would also ensure that all relevant beneficiaries were included. In a voluntary model, some providers will choose not to participate, thus making it impossible to achieve the goal of having every beneficiary who triggers a covered episode attributed to the model. In a voluntary model, there is also a risk that participating providers may "cherry pick" low-complexity patients (by billing for their services through a provider organization that is participating in an episode-based payment model) and avoid high-complexity patients (by billing for these other patients' services through an organization that is not participating in the model) (Liao et al. 2020). Even though there is little empirical evidence that providers have used these tactics, requiring participation in the episode-based model would make it more difficult for a provider to pursue these strategies.

Carefully selecting which types of episodes to include in Medicare's national episode-based model is important. To date, a limited number of types of episodes have been shown to generate substantial savings or quality improvements when compared with episodes furnished by providers not in an episode-based payment model. CMS could consider the five criteria listed below to assist in identifying additional episodes to include in the national episode-based payment model envisioned in this chapter. We do not intend to prescribe a specific number of episodes to include in the model and do not suggest that episodes need to meet all five criteria to be included in the model, but we assert that CMS should give ample consideration to each of the following criteria when selecting episodes for the model:

1. ***Whether an episode has attributes that facilitate the implementation of episode-based payment arrangements.*** For example, CMS could consider whether an episode has a reasonably well-defined triggering event and whether the costs of that event and subsequent services can be attributed to an accountable entity. Similarly, the agency could consider whether the episode is conducive to accurate benchmark setting and whether it is common enough to justify including in the model, as well as whether the number of eligible providers—those who furnish enough episodes to be included in the model—would be sufficient for effective implementation.

2. ***Whether an episode has been found to generate gross savings and is expected to generate net savings without harming quality, or whether an episode has been found to improve quality without increasing gross spending and is expected to generate quality improvements without increasing net spending.*** Savings and quality improvements for episodes could also be measured relative to what an ACO could achieve in the absence of an episode payment model. This evaluation would help to identify episodes that can be expected to generate incremental savings and quality improvement beyond what an ACO could generate on its own. In order to avoid net losses to Medicare, CMS should consider whether gross savings from including an episode in the model will be larger than the aggregate bonuses paid to the episode provider and the ACO.

3. ***Whether there are concerns that including a particular type of episode in the episode-based payment model will induce more episodes.*** This potential problem does not appear significant in the limited studies that have looked at this issue to date, but it must be monitored as a continued concern (Chen et al. 2020, Navathe et al. 2018).

4. ***Whether inclusion of the episode is anticipated to discourage participation in ACOs or other existing APMs.*** If bonuses associated with efficiencies generated during an episode are paid to episode providers and not ACOs (a phenomenon known as "siphoning"), incentives to participate in ACOs are dampened. This possibility is less likely to be of concern when savings during the episode would not have been generated by the ACO. Because of the interactions between episodes and the potential for episodes to siphon savings from ACOs, the Commission argues that including episodes in the model must be done cautiously.

5. ***How care processes among different types of episodes interact with each other and with ACOs.*** For example, since beneficiaries often have multiple interacting chronic conditions and these conditions are usually better managed through ongoing, rather than episodic, relationships with providers, CMS should be very cautious about including chronic care episodes.

The above criteria are meant to serve as general principles for CMS to consider when identifying which types of episodes to add to the national episode-based payment model. Since the studies produced to date have not examined the impact of episode-based payment on many of the above criteria, more studies will be needed. CMS's Innovation Center should continue testing episode-based payment for various episode types, with the goal of better understanding which ones meet the above criteria and identifying any additional episodes that could eventually be added to the national model.

As alluded to in the fifth criterion, one issue that CMS will need to consider especially carefully is whether episodes designed around the treatment of chronic conditions are appropriate for inclusion in the national episode-based payment model. Many beneficiaries have multiple interacting chronic conditions (e.g., diabetes, hypertension, and chronic obstructive pulmonary disease), so designing episode-based payment arrangements for chronic conditions may create complexity and potentially conflict with how an ACO manages care for such patients. In addition, chronic conditions can be difficult to accurately diagnose and are frequently misdiagnosed (Skinner et al. 2016), a fact that any episode-based payment model that includes a chronic condition should take into account.

However, there may be certain chronic conditions that lend themselves to inclusion in Medicare's episode-based payment model, such as cancer, macular degeneration, or kidney disease. The best candidates for inclusion may be chronic conditions that are typically managed by specialists, rather than primary care providers, and where a short-term, episode-based approach would complement the way in which ACOs manage care for patients with the condition.

Notably, even with a national payment model for certain types of episodes, ACOs would have the flexibility to design and implement their own episode-based payment arrangements for clinical episodes not included in Medicare's model. And since ACOs would be accountable for the total cost of their beneficiaries' care, including expenditures related to episodes, they would have an incentive to recommend the most efficient and high-quality specialists and facilities to their beneficiaries.[9] In theory, this approach is likely to be appealing to ACOs that operate in markets where the environment for specialists and other episode-based providers is relatively competitive and information about such providers' performance on cost and quality measures is made more transparent and accessible. Competition in this marketplace could create incentives for specialists and facilities to drive down costs and increase quality as they seek to either join an ACO or enter into performance-based agreements with ACOs and increase referrals.

Allocating savings and losses between the two models

An important design consideration when integrating a Medicare-run episode-based payment model with a population-based payment model is how savings or losses generated during covered episodes should be allocated when beneficiaries are concurrently attributed to providers in both model types.

The Commission asserts that, in principle, any bonus payments resulting from reducing episode costs should be allocated in such a way that (1) episode-based providers have an incentive to furnish efficient, high-quality care; (2) providers in ACOs have an incentive to refer their attributed patients to low-cost, high-quality episode-based providers; and (3) when combined, these

incentives should not be so large that they increase total Medicare spending.

The optimal approach for allocating bonuses and losses will depend to some degree on the specifics of the episode-based and population-based models (e.g., how spending benchmarks and episode target prices are calculated and whether there is a discount rate applied to them). Below are examples of approaches for allocating savings generated during covered episodes:

- CMS could use discounted target prices in the episode-based payment model and include any episode bonus payment in the ACO's annual spending tally. The ACO would realize shared savings payments based on the difference between the undiscounted episode price implicitly included in the ACO's annual spending benchmark and the discounted episode target price in the Medicare-run model.
- CMS could use undiscounted target prices in the episode-based payment model and divide any savings relative to the episode target price between episode-based providers, ACOs, and the Medicare program according to some predetermined percentages. For example, Medicare could retain 40 percent of the episode savings, episode-based providers could retain 30 percent, and ACOs could retain 30 percent.

In each case, incentives for the ACO to save and participate must be considered if maximizing participation in a population-based payment model is a priority.

Other design issues

According to a former CMS Innovation Center director, the method for determining benchmarks or episode target prices is one of the most important tasks in designing value-based payment models (Smith 2021). Benchmarks and episode target prices determine whether participating providers will receive shared savings or losses and what size these payments will be, which in turn influences whether the Medicare program will see net savings or net losses from a payment model. Medicare's experience with the CJR and the BPCI models shows that episode costs can be quite variable and are sensitive to changes in practice patterns, changes in how hospitals are directed to bill for certain admissions, and other factors. Setting episode target prices prospectively, based on historical spending, offers model participants certainty about their spending targets, but it can be difficult to accurately project episode prices because episode costs can change quickly over time and vary across geographic regions (Smith 2021). Medicare has moved toward using retrospectively determined target prices in its episode-based payment models in order to improve their accuracy.

When episode target prices end up being higher than expected spending, several problems can ensue. First, unduly high target prices can reduce financial incentives for providers to reduce episode spending because their discounted target price may already be close to their expected costs—requiring little change in their clinical behavior to earn a bonus. Second, an episode with unduly high target prices is more likely to generate bonus payments that are larger than gross savings (as measured relative to actual episode spending in a comparison group), resulting in net financial losses for the Medicare program. Net losses in the BPCI Advanced Model for medical episodes have been traced, at least in part, to the fact that benchmarks turned out to be above actual costs for these types of episodes (Lewin Group 2022). Conversely, setting episode target prices below actual costs could make it difficult for providers to generate savings and realize bonus payments.

Consideration should also be given to how episode target prices align and interact with ACOs' spending benchmarks in the national population-based payment model envisioned for Medicare. If target prices in the episode-based model exceed the amount of episode spending implicitly included in an ACO's benchmark, reductions in actual episode spending may result in bonus payments for episode providers but could still be higher than episode costs in an ACO's benchmark—leading the ACO to owe shared losses to CMS despite the reduced spending. Conversely, if episode target prices are set below the amount of episode spending implicitly included in an ACO's benchmark, the ACO may find itself collecting shared savings payments related to episodes even if episode-based providers do not reduce actual spending.

Yet another issue to consider is the degree to which a provider's own spending is used to set episode

target prices. Basing target prices predominantly on the historical spending of each participating provider benefits higher-spending episode providers, since they may find it easy to reduce costs, and could be seen as penalizing providers that already have relatively low spending. Alternatively, basing target prices on regional spending, or a blend of regional and provider spending, benefits low-spending providers, since they would have an easier time staying within such a target price, given their track record of low spending. High-spending providers would have to generate more substantial reductions in spending in order to receive a bonus.

A final issue is how target prices in the episode-based model should be updated over time. Administratively set benchmarks are problematic, given the secular and episode-specific changes in spending on some types of episodes. Currently, episode target prices are updated each year based on a rolling baseline period of recent actual spending. In this approach, episode target prices are essentially "rebased" each year.

A benefit of this approach is that it produces relatively accurate episode target prices, which can be especially important when spending on episodes exhibits a secular decline, unrelated to episode-based payment models. For example, spending on lower-extremity joint replacement episodes has been declining since 2014, both for providers participating in and providers not participating in episode-based payment models (Lewin Group 2021). By rebasing episode target prices each year, CMS has been able to guard against overpayment for these episodes.

A drawback of annually rebasing episode target prices, however, is that it has the effect of "ratcheting down" episode target prices in future years when providers collectively succeed in slowing the growth in their current-year episode spending—thus making it harder for episode providers to keep episode spending below their new, lowered target price in future years. Such ratcheting can make participating in an episode-based payment model unappealing for providers and could theoretically result in providers exiting a voluntary episode-based payment model or seeking to reduce the number of Medicare beneficiaries they treat.[10] (Rebasing is less of a concern in mandatory models since providers cannot opt out.) ■

Endnotes

1 In this chapter, we use "population-based payment" models to refer to ACO-style models in which provider organizations are eligible to receive shared savings payments (and in some tracks, have shared losses recouped) based on the total annual spending and care quality delivered to patients served by their primary care providers. This definition varies from the definition of "population-based payment" in the widely used APM framework developed by CMS's Health Care Payment Learning & Action Network (LAN); the LAN's definition of "population-based payment" includes certain types of episode-based payment models (Health Care Payment Learning & Action Network 2017).

2 These higher payment rates will apply to professional services provided to all of a clinician's FFS Medicare patients—not just the subset of their FFS Medicare patients in A–APMs. To qualify for the higher payment rates, clinicians only have to exceed minimum participation thresholds, not any minimum performance thresholds (i.e., on cost, utilization, or quality measures).

3 In this chapter, the term *providers* refers to provider organizations, as opposed to the individual clinicians who work for provider organizations. Provider organizations face incentives from payers but do not necessarily pass along these incentives to their clinicians; for example, provider organizations can choose to pay clinicians a flat salary, unrelated to clinicians' performance on the cost and quality measures tied to payments in APMs.

4 The Medicare program could, for example, offer one model with a limited number of tracks or offer a few models that each have only one or two tracks.

5 As with current practice, ACOs' spending benchmarks would continue to be adjusted each year to reflect the historical spending and the risk scores of the beneficiaries currently attributed to them.

6 Provider organizations that consolidate into larger organizations have more leverage when negotiating payment rates with private payers, which, in turn, can drive up prices and spending for the privately insured. In our March 2022 report, we noted that private insurers generally pay rates about twice as high as Medicare for hospital services and about one and a half times Medicare rates for physician services. Between 2014 and 2019, health care spending per person grew twice as fast for the privately insured as compared to FFS Medicare beneficiaries. To date, the rise in commercial prices for the privately insured has had little direct impact on the Medicare program because of Medicare's ability to unilaterally set prices for most health care services. However, there is a risk of private sector trends influencing Medicare trends. Over time, if the private sector is unable to constrain price growth, the profitability of caring for privately insured patients will increase relative to the profitability of caring for Medicare beneficiaries, which could create pressure to increase Medicare payment rates. Higher private prices enabled by consolidation could also prompt providers to raise their costs, which could threaten Medicare beneficiaries' access to care if Medicare payment rates do not keep pace (Medicare Payment Advisory Commission 2022).

7 Because of problems with the way benchmark prices were set in the original BPCI model, Track 2 was changed from two-sided risk to one-sided risk for some types of episodes. If the model had retained two-sided risk, it would have generated no net savings or losses for Medicare.

8 Episode target prices typically exclude spending related to organ transplants, major trauma, cancer-related care, and new technology add-on payments.

9 ACOs can recommend particular hospitals or specialists to their beneficiaries for episode care, but beneficiaries in FFS Medicare are free to see whichever providers they choose, so they may not end up receiving care from the providers that their ACO recommends to them.

10 CMS has observed strong provider participation in the BPCI Advanced Model despite its annual resetting of episode target prices, according to discussions with CMS staff.

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CHAPTER 2

Congressional request: Vulnerable Medicare beneficiaries' access to care (final report)

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Congressional request: Vulnerable Medicare beneficiaries' access to care (final report)

Chapter summary

In July 2020, the House Committee on Ways and Means submitted a bipartisan request for the Commission to update its June 2012 report on rural beneficiaries' access to care and examine trends that may have affected rural communities since the 2012 report. The Committee also requested information on beneficiaries who reside in a medically underserved area (MUA), are dually eligible for Medicare and Medicaid, or have multiple chronic conditions. The Committee requested an interim report by June 2021 and a final report by June 2022.

In our June 2021 report to the Congress, the Commission issued an interim report that focused on rural beneficiaries' access to care. We found that rural and urban beneficiaries had similar utilization of care, although some minor differences existed. Beneficiaries in rural areas used more hospital outpatient services but had fewer encounters with specialists, whom they often travel substantial distances to visit. (By contrast, rural beneficiaries had similar use of primary care services, which they more commonly access locally.) Although utilization data are only a proxy for access to care (since they can tell us only what services were used, not what services might have been forgone), most surveys of Medicare beneficiaries find that rural beneficiaries' satisfaction with access to care is similar to that of urban beneficiaries. Our June 2021

In this chapter

- Similar service use in full, partial, and non-MUAs suggests that using MUAs to direct additional Medicare funding is inefficient
- Dual-eligible beneficiaries had higher service use compared with other Medicare beneficiaries, reflecting greater health needs
- Beneficiaries with more reported chronic conditions used more services than those with fewer conditions, reflecting greater health needs

report also discussed trends in rural hospital closures before the coronavirus pandemic and the establishment of a new type of rural hospital designation—rural emergency hospital—designed to maintain access to emergency and other outpatient services in rural areas.

In this report, as a proxy for access to care, we use descriptive statistics on the service utilization of beneficiaries who reside in an MUA, are dually eligible for Medicare and Medicaid, or have multiple chronic conditions. As in our June 2021 report, the utilization data we present here date from before the coronavirus pandemic, to avoid any idiosyncratic effects of the pandemic, and are not risk adjusted due to our concerns about differential diagnosis coding practices in rural and urban areas. Overall, we found that beneficiaries residing in full and partial MUAs had average utilization rates that were similar to those living in non-MUAs. In addition, we found that beneficiaries who were dually eligible for Medicare and Medicaid used more services than non-dual-eligible beneficiaries, and beneficiaries with multiple chronic conditions used more services than beneficiaries without multiple chronic conditions.

The results of our analysis suggest that some definitions of *vulnerable beneficiaries*—such as those living in an MUA—are imprecise, and employing those definitions to identify providers who merit additional support likely leads to poor targeting of Medicare's financial resources. Further, though we found that dual-eligible beneficiaries and those with multiple chronic conditions used substantially more services on average, given their higher health care needs, we cannot rule out the possibility that these beneficiaries needed more care than they received or that they faced difficulties in accessing care they did receive. Further research is needed to better understand the sufficiency of vulnerable beneficiaries' access to care. Thus, the Committee's inquiry has prompted the Commission to undertake a broader examination of how to identify vulnerable Medicare populations and to evaluate Medicare's policies to support safety-net providers who care for them. The first installment of that work focuses on safety-net hospitals (see Chapter 3).

Utilization by beneficiaries who reside in MUAs

MUAs were designed in the 1970s to identify areas with a shortage of personal health services. State Primary Care Offices conduct needs assessments in their states, determine what areas are eligible for MUA designation, and submit applications to the Health Resources and Services Administration (HRSA). HRSA reviews the MUA applications submitted by states and—if they meet the eligibility criteria—designates areas as MUAs. The criteria used to designate

areas as MUAs are the number of primary care physicians per 1,000 people, share of the population with incomes at or below 100 percent of the federal poverty level, share of the population age 65 and over, and infant mortality rate. Entire counties and subdivisions within counties (e.g., towns, census tracts) can be designated as MUAs. We analyzed MUAs at the county level to align with our rural-urban classifications. "Full MUAs" are entire-county MUAs. "Partial MUAs" are counties within which at least one area has been designated as an MUA, and "non-MUAs" are counties without any areas designated as an MUA.

Across the types of services we examined—evaluation and management (E&M) encounters with clinicians, hospital inpatient and outpatient visits, skilled nursing facility days, and home health episodes—beneficiaries generally received a similar volume of care regardless of whether they lived in full, partial, or non-MUAs. For example, in 2018, urban beneficiaries who lived in full, partial, or non-MUA counties averaged 13.4, 13.4, and 13.3 E&M encounters, respectively.

Our finding aligns with previous research on this topic, as researchers have consistently found that MUAs are not accurate predictors of service use. While there are several reasons why MUAs might not predict service use (e.g., beneficiaries travel to access care and MUAs are not statutorily required to be updated), we explore one increasingly important reason why residence in an MUA may not be correlated with less service use: the fact that neither advanced practice registered nurses (APRNs) nor physician assistants (PAs) are incorporated in the measure of primary care supply.

In 2018, we found that about 41 percent of nurse practitioners (the most common type of APRN) and 27 percent of PAs practiced in primary care. We found that APRNs and PAs, despite predominantly practicing in specialty care, still represented about a third of all primary care clinicians who billed Medicare in 2018 and almost half of such clinicians in rural areas. This finding suggests that the measure of primary care supply incorporated into the calculation of MUAs—primary care physicians per capita—is unlikely to reflect the current mix of primary care clinicians.

Utilization by dual-eligible beneficiaries

Medicare beneficiaries who were eligible for full Medicaid benefits had substantially higher service use compared with other Medicare beneficiaries. For example, dual-eligible beneficiaries had about twice the number of hospital inpatient admissions compared with other Medicare beneficiaries and about

five times the number of skilled nursing facility days per beneficiary. The differences in use between dual-eligible beneficiaries and other Medicare beneficiaries were relatively consistent across our rural and urban categories. Experiences accessing care may differ for other Medicare beneficiaries, such as partial-benefit dual-eligible beneficiaries or other low-income beneficiaries.

Higher use rates among full-benefit dual-eligible beneficiaries are likely attributable to their greater health care needs. The Commission has found that, compared with other Medicare beneficiaries, dual-eligible beneficiaries are substantially more likely to be in poor health, live in an institution, and have limitations in activities of daily living. We are unable to make any judgment regarding whether the higher level of service use we observed for full-benefit dual-eligible beneficiaries was sufficient to meet their clinical needs.

Utilization by beneficiaries with multiple chronic conditions

In our analysis of beneficiaries with multiple chronic conditions, we found that beneficiaries with more reported chronic conditions had substantially higher service use compared with those with fewer reported chronic conditions. For example, among one group of rural beneficiaries, those with six or more reported chronic conditions averaged 0.87 hospital inpatient admissions in 2018 compared with an average of 0.03 for those with zero or one reported chronic condition. Our results were generally consistent across our rural and urban categories. As with the service use patterns of dual-eligible beneficiaries, we are unable to make any judgment regarding whether the higher level of service use we observed for beneficiaries with multiple chronic conditions was sufficient to meet their clinical needs. ■

In July 2020, the House Committee on Ways and Means submitted a bipartisan request for the Commission to update its June 2012 report on rural beneficiaries' access to care and to examine trends that may have affected rural communities since the 2012 report. The Committee also requested information on beneficiaries who reside in a medically underserved area (MUA), are dually eligible for Medicare and Medicaid, or have multiple chronic conditions. The Committee requested an interim report by June 2021 and a final report by June 2022.

In its June 2021 report to the Congress, the Commission issued an interim report that focused on rural beneficiaries' access to care. The report found that rural and urban beneficiaries had similar access to care, although some minor differences existed (see text box, pp. 30–31, for a summary of our June 2021 report findings). The report also discussed pre–coronavirus pandemic trends in rural hospital closures and the establishment of a new type of rural hospital designation—rural emergency hospital—that is designed to maintain access to emergency and other outpatient services in rural areas.[1]

In this final report, in response to the congressional request, we present descriptive statistics on the service utilization (a proxy for access to care) of beneficiaries who reside in an MUA, are dually eligible for Medicare and Medicaid, or have multiple reported chronic conditions. As part of the Commission's ongoing work related to safety-net providers, we also discuss the drawbacks of using MUA designations to direct additional Medicare funding to providers. As a complement to this chapter, we discuss alternative ways to define and pay safety-net providers in Chapter 3 of this report.

Background

As in our 2012 and 2021 reports, we classify counties as rural or urban based on Office of Management and Budget metropolitan statistical area designations and further stratify rural counties to examine the effects of increasing rurality. MUAs were designed to identify areas with a shortage of personal health services. The Health Resources and Services Administration (HRSA) designates areas as MUAs based on four metrics: the number of primary care physicians per 1,000 people, share of the population with incomes at or below 100 percent of the federal poverty level, share of the population age 65 and over, and infant mortality rate.[2]

Rural and urban classifications

In this report, we primarily rely on county-level designations established by the Office of Management and Budget to determine whether a beneficiary or provider is located in a rural or urban area. We consider all metropolitan counties to be urban and all other counties rural. We stratify rural counties by whether they are micropolitan or not; we describe rural counties that are not micropolitan as either adjacent to a metropolitan area (i.e., rural adjacent) or not adjacent to a metropolitan area (i.e., rural nonadjacent) (Table 2-1, p. 32).

To supplement our main rural and urban classifications, we also separately analyze frontier counties. A county is classified as frontier if the population density within that county is six or fewer people per square mile.[3] These areas are more sparsely populated than most counties and therefore merit careful consideration.

Medically underserved areas

MUAs were first established by the Health Maintenance Organization Act of 1973, which provided grants and loans to entities to create or expand HMOs. The legislation gave priority access to federal funding to applicants that planned to draw at least 30 percent of their members from MUAs. The law directed the Secretary to identify MUAs based on criteria that included the available health resources in an area, population-based health indices, economic factors affecting access to care, and demographic factors that affect the demand for health services (Health Resources Administration 1975). (Currently, Medicare uses MUAs as one criterion to qualify as a Federally Qualified Health Center and Rural Health Clinic.)

In 1975, the Secretary established the Index of Medical Underservice to identify MUAs. For each area, the index was calculated using four measures:

- number of primary care physicians per 1,000 people,

Summary of the Commission's June 2021 report on rural beneficiaries' access to care

In its June 2021 report, the Commission examined rural beneficiaries' access to care primarily using Medicare claims data, supplemented with survey data and interviews with rural stakeholders. Overall, we found that rural and urban beneficiaries had similar utilization of care, although some minor differences existed. Further, although utilization data are a proxy for access to care (since they can tell us only what services were used, not what services might have been forgone), most surveys of Medicare beneficiaries find that rural beneficiaries' satisfaction with access to care is similar to that of urban beneficiaries. Our June 2021 report also examined rural hospital closures, a trend that had become more prominent since the Commission's 2012 report and could affect access to care. Our analysis of 40 recently closed hospitals found large declines in all-payer inpatient admissions in the years before closure—mostly due to patients bypassing their local hospital in favor of other, more distant hospitals. The overall effects of these hospital closures on beneficiaries' service use were difficult to discern, but rural hospital closures could require beneficiaries to travel farther to access care, which is especially concerning for emergency care. However, beginning in 2023, a new "rural emergency hospital" designation will allow certain rural hospitals to maintain access to emergency and outpatient care without the need to support a low-volume inpatient department.

Comparing rural and urban beneficiaries' access to care

The Commission's annual survey of Medicare beneficiaries and CMS's Medicare Current Beneficiary Survey suggest that rural and urban beneficiaries have similar access to care, although some minor differences exist and those differences may increase as rurality increases.[4]

Likewise, the Commission's analysis of Medicare claims data from 2018 indicates that rural and urban beneficiaries generally had comparable utilization rates among the types of services examined—clinician visits, hospital inpatient admissions, hospital outpatient visits, home health episodes, and skilled nursing facility days. Similar to what was found in the Commission's 2012 report on rural access to care, the variation across geographic regions of the country was substantial, and regional differences often were far larger than differences between rural and urban beneficiaries within a given region. The findings by type of service included the following:

- For clinician services, rural beneficiaries had fewer evaluation and management (E&M) encounters in 2018 than urban beneficiaries after accounting for substantial amounts of regional variation. Rural beneficiaries' lower E&M use was mainly attributable to fewer visits with specialist physicians, which may in turn be related to the longer distances that rural beneficiaries travel to access specialists.
- For hospital inpatient services, utilization rates in 2018 were very similar between rural and urban beneficiaries. Hospital inpatient use varied substantially across geographic regions of the country, but differences between rural and urban beneficiaries within regions were relatively small.
- For hospital outpatient services, rural beneficiaries had greater use in 2018 than urban beneficiaries, and regional variation was very large. Variation in the use of hospital outpatient department services between rural and urban beneficiaries likely reflected differences in where patients received their care, as opposed to how much care they received. For example, rural beneficiaries might have received more of their imaging services at hospitals (which were included in the analysis) rather than freestanding imaging centers (which were not).
- For home health and skilled nursing facility services, rural beneficiaries had similar or higher utilization rates in 2018 than urban beneficiaries. However, service use varied substantially across the nation's geographic regions. Variation in home health use was particularly notable, with utilization rates varying by sixfold to eightfold across regions.

(continued next page)

Summary of the Commission's June 2021 report on rural beneficiaries' access to care (cont.)

Across our claims-based analyses, beneficiaries living in the most remote areas—frontier counties—tended to use fewer services compared with urban and (oftentimes) other rural beneficiaries. Beneficiaries residing in frontier areas represent about 1 percent of the Medicare population, are concentrated in a small number of states that generally have lower use of services (e.g., Montana and Wyoming), and appear to be somewhat healthier than other rural beneficiaries. These factors make it difficult to discern the extent to which lower utilization rates among frontier beneficiaries are attributable to access issues, regional provider practice patterns, beneficiary preferences, differences in health status, or some combination of those factors.

Examining the causes and effects of recent rural hospital closures

The Commission found that rural hospital closures increased since 2013. To study the causes and effects of those closures, the Commission conducted interviews with stakeholders (including community members, hospital executives, and clinician leaders) from three communities that experienced a recent hospital closure and analyzed a cohort of 40 rural hospitals that closed between 2015 and 2019.

Among the cohort of 40 recently closed hospitals, the Commission found large declines in all-payer inpatient admissions in the years before closure. From 2005 to 2014 (a period that began at least a decade before closure), the cohort averaged a 54 percent decline in all-payer inpatient admissions. By 2014, the median number of annual all-payer admissions at the 40 hospitals had fallen to 488—about 1.3 admissions per day. Most of this decline was attributable to patients bypassing their local hospital in favor of other, more distant hospitals. In contrast, up to the date of closure, Medicare beneficiaries continued to use these 40 hospitals regularly to access emergency department (ED) and outpatient care.

The effects of these hospital closures on beneficiaries' service use were difficult to discern. Beneficiaries residing in the market areas of the 40 closed hospitals experienced faster declines in the number of hospital inpatient admissions and hospital outpatient visits per beneficiary after the closure occurred relative to beneficiaries living in rural areas without a hospital closure. However, even before the closures occurred, hospital inpatient and outpatient service use had been declining faster in the 40 market areas of the closed hospitals compared with markets in other rural areas. Therefore, factors other than hospital closure (such as changes in physician practice patterns before and after closure) may have affected service use for beneficiaries in those communities. In addition, some of the decline in hospital outpatient visits in areas with a closure could have represented shifts to other settings, such as freestanding clinician offices and Federally Qualified Health Centers, rather than beneficiaries forgoing needed care. In that vein, the Commission found that areas with a closure experienced faster growth after the closure occurred in the number of E&M visits across all settings compared with areas without a closure. Regardless of the effect on service use, rural hospital closures could require beneficiaries to travel farther to access care, which is especially concerning for emergency care.

To maintain access to ED and outpatient care (without the need to support a low-volume inpatient department), the Congress enacted a program that will allow certain rural hospitals to convert to "rural emergency hospitals" beginning in 2023. These new hospitals will not provide inpatient care but will provide round-the-clock ED care and will be able to furnish other services, such as outpatient services, nursing facility services, and ambulance services. Medicare will pay these new providers a monthly fixed subsidy, enhanced outpatient rates, and standard rates for other types of care. The new rural emergency hospital designation is consistent with the Commission's 2018 recommendation that Medicare allow isolated freestanding EDs to bill Medicare and provide such EDs with annual payments to assist with fixed costs. ■

TABLE 2–1

Definitions of rural and urban counties used in this report

Category		Definition of category
Urban		Urban (i.e., metropolitan) counties contain an urban cluster of 50,000 or more people.
Rural	Rural micropolitan	Rural micropolitan counties contain a cluster of 10,000 to 50,000 people.
	Rural adjacent	Rural adjacent counties are adjacent to urban areas and do not have a city with at least 10,000 people.
	Rural nonadjacent	Rural nonadjacent counties are not adjacent to an urban area and do not have a city with at least 10,000 people.

Note: A rural county is defined as adjacent to an urban area if it physically adjoins one or more metropolitan areas and has at least 2 percent of its employed labor force commuting to central metropolitan counties.

Source: Office of Management and Budget and USDA's Urban Influence Codes.

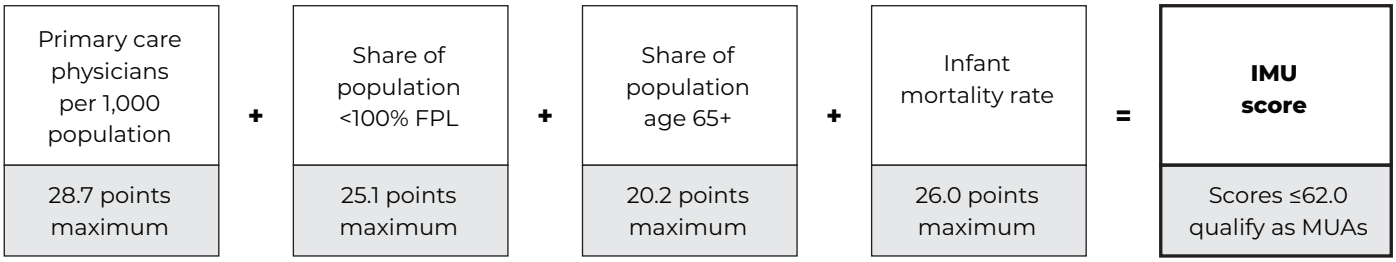
- share of the population with incomes below 100 percent of the federal poverty level,
- share of the population age 65 and over, and
- infant mortality rate.

Once these metrics were calculated for each area, they were combined into a single score that ranged from 0 to 100 based on experts' opinions about how much each of the measures mattered in terms of accessing medical care. Certain measures had a greater weight in the index and (within a measure) points were not awarded on a linear scale (e.g., a 1 percentage point difference in the share of an area's population that was at least 65 years old could mean a change ranging from 0 to 1.7 points). The Secretary established a cutoff point that designated areas as MUAs versus non-MUAs as the median index score among all counties in the United States. The median value was 62.0, meaning that all areas with a score at or below 62.0 were considered MUAs and all areas above 62.0 were considered non-MUAs.

Since the development of the Index of Medical Underservice, the Secretary has issued two proposed rules with the intention of substantially reforming

FIGURE 2–1

Medically underserved area criteria, 2021



Note: FPL (federal poverty level), IMU (Index of Medical Underservice), MUA (medically underserved area).

Source: Health Resources and Services Administration.

TABLE 2–2

Three-fourths of Medicare FFS beneficiaries lived in a full or partial MUA county in 2018

	Share of Medicare FFS beneficiaries		
Type of county	**Full MUA**	**Partial MUA**	**Non-MUA**
Total (all counties)	18%	60%	21%
Urban	11	70	19
Rural micropolitan	35	32	33
Rural adjacent	62	23	16
Rural nonadjacent	60	21	18
Frontier	46	25	28

Note: FFS (fee-for-service), MUA (medically underserved area). Percentages are calculated using a different denominator for each row. Percentages may not sum to 100 percent due to rounding. Table includes all FFS beneficiaries.

Source: MedPAC analysis of Medicare enrollment data and Health Resources and Services Administration data.

the process used to designate MUAs. In addition, the Affordable Care Act of 2010 required the Secretary to use the negotiated rule-making process to reform MUAs. However, both proposed rules were withdrawn due to negative reactions from stakeholders, and the negotiated rule-making committee failed to come to a consensus on a reform proposal (and therefore no reforms were undertaken). As a result, the basic metrics used to designate areas as MUAs are the same in 2021 as they were in 1975 (Figure 2-1) (Health Resources and Services Administration 2021).

Different types of areas can be designated as MUAs, including counties, county subdivisions (e.g., towns or townships), and census tracts. As a result, MUAs and non-MUAs are often located directly adjacent to one another and served by the same providers. In this chapter, we analyze MUAs at the county level to align with our rural-urban classifications. We have three county-level MUA categories:

- ***Full* MUA:** The entire county is designated as an MUA.
- ***Partial* MUA:** The entire county has not been designated as an MUA, but at least one area within the county has been designated as an MUA.
- ***Non*-MUA:** Neither the entire county nor any area within the county has been designated as an MUA.

In 2018, about three-fourths of Medicare fee-for-service (FFS) beneficiaries lived in full or partial MUAs—18 percent in full MUAs and 60 percent in partial MUAs (Table 2-2). The share of beneficiaries living in an MUA varied based on rurality. Beneficiaries who lived in rural counties (especially nonmicropolitan rural counties) were more likely to live in full MUAs, whereas urban beneficiaries were more likely to live in partial MUAs.

MUA designations have been criticized by some stakeholders as imprecise measures of areas in which substantial access issues exist. Criticisms have included that MUA designations:

- are too broad (i.e., too many areas are considered MUAs);
- are not routinely updated to reflect changes in the demographics or supply of clinicians in an area;
- do not incorporate advanced practice registered nurses (APRNs) and physician assistants (PAs) in the supply of primary care clinicians; and

TABLE 2–3

Beneficiaries who lived in full, partial, or non-MUA counties had a similar number of total and primary care physician E&M encounters, 2018

Beneficiary residence, by type of county	Total E&M encounters per beneficiary			E&M primary care physician encounters per beneficiary		
	Full MUA	Partial MUA	Non-MUA	Full MUA	Partial MUA	Non-MUA
Urban	13.4	13.4	13.3	3.7	3.5	3.4
Rural micropolitan	11.9	11.1	11.5	3.4	3.1	3.3
Rural adjacent	11.7	10.4	11.3	3.3	2.8	3.1
Rural nonadjacent	11.0	10.0	9.9	3.0	2.7	2.7
Frontier	9.2	9.0	8.8	2.1	2.3	2.3

Note: MUA (medically underserved area), E&M (evaluation and management). Metropolitan (urban) counties contain an urban cluster of 50,000 or more people, rural micropolitan counties contain a cluster of 10,000 to 50,000 people, rural adjacent counties are adjacent to urban areas and without a city of at least 10,000 people, rural nonadjacent counties are not adjacent to urban areas and do not have a city with at least 10,000 people, and frontier counties have 6 or fewer people per square mile. Only beneficiaries with 12 months of Part B fee-for-service coverage in 2018 are included in the table. E&M encounters include E&M visits billed under the physician fee schedule or critical access hospital method II billing; the category also includes all visits to Federally Qualified Health Centers and Rural Health Clinics. "Total E&M encounters" includes all clinician types, including all physician specialties, advanced practice registered nurses, physician assistants, and other clinicians.

Source: MedPAC analysis of carrier file, outpatient file, and enrollment data from CMS.

- do not incorporate a measure of proximity to health care resources (e.g., a census tract that is considered an MUA may be located directly adjacent to a wealthy area with substantial health care resources).

Similar service use in full, partial, and non-MUAs suggests that using MUAs to direct additional Medicare funding is inefficient

Across most types of services we examined, beneficiaries received a similar volume of care regardless of whether they lived in full, partial, or non-MUAs. For the few service types that varied based on residence in an MUA, we did not find consistent patterns that suggest access issues: Beneficiaries in MUAs had higher average utilization in some cases and lower rates in others. Instead, these differences were likely driven by other factors, such as differences in where beneficiaries received care (e.g., hospital outpatient departments vs. clinician offices) and regional variation in service use.

Our findings align with previous research on this topic. Since MUAs were developed, researchers have consistently found that MUAs are not accurate predictors of service use (Kleinman and Wilson 1977, Kviz and Flaskerud 1984). While there are several reasons why MUA designations do not reliably predict service use (e.g., beneficiaries travel out of their area to access care), we explore one increasingly important reason—the fact that APRNs and PAs are not incorporated in the measure of primary care supply. While most APRNs and PAs practice in specialty care, these clinicians still represented about a third of all primary care clinicians who billed Medicare in 2018, and almost half of such clinicians in rural areas.

Beneficiaries in full and partial MUAs had similar average utilization rates compared with those in non-MUAs

Urban Medicare FFS beneficiaries had a similar average number of evaluation and management (E&M) encounters, regardless of whether they lived in a full, partial, or non-MUA county. In 2018, urban beneficiaries who lived in full, partial, or non-MUA counties averaged 13.4, 13.4, and 13.3 E&M encounters, respectively (Table 2-3). Among rural beneficiaries,

TABLE 2–4

Beneficiaries in MUAs had a similar number of inpatient admissions but generally had fewer hospital outpatient claims compared with those in other areas, 2018

Beneficiary residence, by type of county	Hospital inpatient admissions per beneficiary			Hospital outpatient claims per beneficiary		
	Full MUA	Partial MUA	Non-MUA	Full MUA	Partial MUA	Non-MUA
Urban	0.20	0.20	0.19	3.0	3.2	3.3
Rural micropolitan	0.21	0.20	0.20	3.8	5.2	4.7
Rural adjacent	0.21	0.19	0.20	4.1	5.8	4.7
Rural nonadjacent	0.21	0.19	0.19	4.6	6.0	5.3
Frontier	0.19	0.17	0.17	4.9	4.5	4.5

Note: MUA (medically underserved area). Metropolitan (urban) counties contain an urban cluster of 50,000 or more people, rural micropolitan counties contain a cluster of 10,000 to 50,000 people, rural adjacent counties are adjacent to urban areas and without a city of at least 10,000 people, rural nonadjacent counties are not adjacent to urban areas and do not have a city with at least 10,000 people, and frontier counties have 6 or fewer people per square mile. Only beneficiaries with 12 months of Part A fee-for-service coverage in 2018 are included in the table.

Source: MedPAC analysis of Medicare Provider and Analysis Review file and outpatient file from CMS.

those who lived in MUAs had a similar or slightly higher number of E&M encounters compared with beneficiaries who lived in partial or non-MUAs. These encounters include E&M visits billed under the physician fee schedule or critical access hospital method II billing; the category also includes all Federally Qualified Health Center (FQHC) and Rural Health Clinic (RHC) visits.

Because MUAs are partly based on a deficit of primary care physicians in an area, we also examined the extent to which the rate of E&M encounters furnished by primary care physicians varied based on the MUA status of the county in which beneficiaries lived. We again found few differences in utilization rates across MUA categories. For example, among rural adjacent beneficiaries, those who lived in full MUA counties had a slightly higher number of E&M encounters compared with those who lived in non-MUA counties (3.3 and 3.1 encounters per beneficiary, respectively) (Table 2-3).[5] These results suggest that relying on MUA designations does not accurately predict clinician underservice, even for the services most directly related to the identification of MUAs—visits with primary care physicians.

As we found in our June 2021 report to the Congress, rural beneficiaries had fewer E&M encounters compared with urban beneficiaries, with the most pronounced differences observed in frontier areas (Medicare Payment Advisory Commission 2021a). Rural beneficiaries' lower E&M utilization was mainly attributable to fewer encounters with specialist physicians. In contrast, rural and urban beneficiaries had a similar number of E&M encounters with primary care physicians after controlling for state-level variation (data not shown). Rural beneficiaries also averaged more visits with APRNs and PAs. Rural beneficiaries' E&M visits with APRNs and PAs are more likely to be related to primary care compared with urban beneficiaries' visits because APRNs and PAs who furnish care in rural areas are more likely to practice in primary care.

In line with our findings for E&M encounters, we found that beneficiaries had a similar number of hospital inpatient admissions regardless of whether they lived in a full, partial, or non-MUA county. For example, in 2018, rural micropolitan beneficiaries who lived in full, partial, or non-MUA counties averaged 0.21, 0.20, and 0.20 admissions, respectively (Table 2-4).

TABLE 2–5

Beneficiaries in MUAs had a similar number of SNF days but more home health episodes compared with those in other areas, 2018

Beneficiary residence, by type of county	Skilled nursing facility days per beneficiary			Home health episodes per beneficiary		
	Full MUA	Partial MUA	Non-MUA	Full MUA	Partial MUA	Non-MUA
Urban	1.3	1.4	1.4	0.18	0.18	0.16
Rural micropolitan	1.5	1.5	1.6	0.18	0.12	0.16
Rural adjacent	1.6	1.5	1.7	0.19	0.10	0.13
Rural nonadjacent	1.6	1.3	1.4	0.17	0.08	0.10
Frontier	1.3	1.0	0.9	0.09	0.08	0.05

Note: MUA (medically underserved area), SNF (skilled nursing facility). Metropolitan (urban) counties contain an urban cluster of 50,000 or more people, rural micropolitan counties contain a cluster of 10,000 to 50,000 people, rural adjacent counties are adjacent to urban areas and without a city of at least 10,000 people, rural nonadjacent counties are not adjacent to urban areas and do not have a city with at least 10,000 people, and frontier counties have 6 or fewer people per square mile. SNF figures include only beneficiaries with 12 months of Part A fee-for-service (FFS) coverage; home health figures include only beneficiaries with 12 months of Part B FFS coverage.

Source: MedPAC analysis of the home health standard analytic file and Medicare Provider and Analysis Review file.

In contrast, the number of hospital outpatient claims per beneficiary varied based on MUA status. Beneficiaries who lived in full MUA counties generally averaged fewer outpatient claims than those who lived in partial or non-MUA counties, with the differences being more pronounced among rural beneficiaries (Table 2-4, p. 35). These differences are unlikely to represent inadequate access to hospital outpatient services in MUAs. Instead, they likely reflect differences in the sites where beneficiaries receive care in areas with and without a local hospital and the impact hospitals have on recruiting primary care physicians (especially in rural areas). Specifically, beneficiaries who live in counties with access to a local hospital are more likely to access care in the hospital outpatient setting rather than other settings, such as FQHCs, clinician offices, or imaging centers.[6] In addition, areas with a local hospital (and greater use of hospital outpatient departments) are more likely to be non-MUAs because rural hospitals are often instrumental in recruiting primary care physicians, and the presence of more primary care physicians in an area makes it less likely that the area is designated as an MUA.

For skilled nursing facility (SNF) services, we found that beneficiary utilization was similar across full, partial, and non-MUA counties. For example, in 2018, rural adjacent beneficiaries who lived in full, partial, or non-MUA counties averaged 1.6, 1.5, and 1.7 SNF days, respectively (Table 2-5).

For home health episodes, we found that utilization rates were similar across full, partial, and non-MUA counties for urban beneficiaries. In contrast, among rural beneficiaries, the average number of home health episodes per beneficiary was substantially higher in full MUAs compared with partial and non-MUAs. For example, in 2018, rural nonadjacent beneficiaries who lived in full MUA counties averaged 0.17 home health episodes per beneficiary, which is substantially above the rates in partial and non-MUAs (0.08 episodes and 0.10 episodes per beneficiary, respectively). These differences were likely driven by large regional variations in the use of home health services rather than access issues in partial and non-MUAs. For example, four states—Alabama, Florida, Louisiana, and Mississippi—whose per beneficiary utilization rates of home health services range from about double to triple the national average make up about 16 percent of all rural adjacent beneficiaries who live in full MUA counties but only about 1 percent of rural adjacent beneficiaries who live in partial and non-MUA counties.

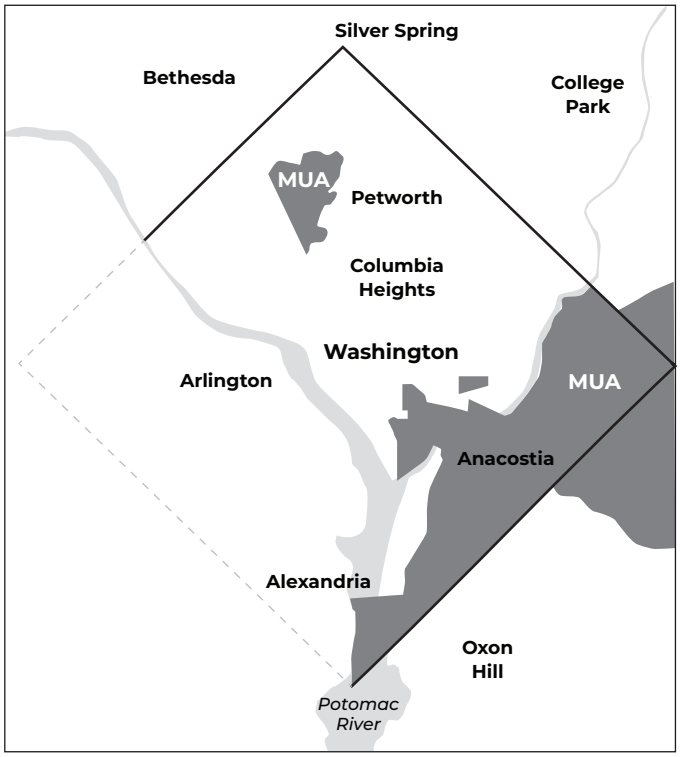
Researchers consistently have found that the MUA designation is a poor predictor of service use

Our finding that service use among Medicare FFS beneficiaries who lived in MUAs was similar to those who lived in non-MUAs is consistent with previous research on this topic. Since MUAs were originally developed, researchers have concluded that the measure is not well suited to identifying areas where services are underprovided. Only a few years after MUAs were created, academic researchers found no difference between MUA and non-MUA residents in terms of the number of physician visits per year or the proportion with at least one visit in the past year (Kleinman and Wilson 1977). Nearly two decades later, the Government Accountability Office concluded that MUAs did not effectively identify areas with primary care shortages or help target federal resources to benefit those who are underserved (Government Accountability Office 1995).[7] Even if MUAs were useful for identifying underserved areas, they are not routinely updated to reflect changes in the demographics or supply of clinicians in an area. Currently, neither statute nor regulation allows HRSA to require recurring updates of MUAs. In practice, the lack of regular updates means that many MUAs were designated a decade or more ago and have not been reevaluated since.

Researchers have cited several reasons why MUAs do not always predict service use accurately. One simple explanation is that beneficiaries often travel to access care. In 2018, the Commission found that beneficiaries traveled a median of 7.1 miles (among urban beneficiaries) to 15.6 miles (among rural adjacent beneficiaries) for visits with primary care physicians (Medicare Payment Advisory Commission 2021a). The granular nature of MUAs (which are often designated at the census tract level) means that beneficiaries residing in MUAs often do not have to travel far to access care. For example, much of Southeast Washington, DC, is considered an MUA despite being located within a few miles of providers in other parts of the city. In addition, two census tracts in a relatively affluent area of Northwest Washington, DC, are also designated as MUAs and have even more proximate access to health care providers (Figure 2-2). Thus, living in an MUA might mean that beneficiaries need to travel farther to access care, but the increase in travel distance is often modest and might not affect utilization rates.

FIGURE 2–2

Map of medically underserved areas in Washington, DC



Note: MUA (medically underserved area).

Source: Health Resources and Services Administration, 2022.

APRNs and PAs are not counted in the supply of primary care clinicians when MUA determinations are made, likely making the designations increasingly inaccurate

Another increasingly important reason why MUAs do not reliably predict service use (especially of clinician services) is that the measure of the supply of primary care clinicians in an area—which has the largest effect on whether an area is considered an MUA (see Figure 2-1, p. 32)—does not include APRNs and PAs.

The supply of APRNs and PAs has been increasing rapidly. From 2010 to 2017, the number of nurse practitioners (NPs) (the most common type of APRN) and PAs billing under the physician fee schedule grew

Methodology used to classify APRNs and PAs as practicing in primary care or specialty care

When advanced practice registered nurses (APRNs) and physician assistants (PAs) enroll in Medicare, they do not have to indicate the specialty in which they practice. We therefore used claims data to classify these clinicians as practicing in primary care or specialty care. We started with a list of all APRNs and PAs who billed fee-for-service (FFS) Medicare in 2018 under the physician fee schedule or through Federally Qualified Health Centers, Rural Health Clinics, or critical access hospital method II billing. If an APRN or PA met any of our three criteria based on the types of services they billed for or the type of groups in which they practiced, we considered them to practice in specialty care (Table 2-6). If an APRN or PA met none of these criteria, we considered them to practice in primary care.[8] ■

(continued next page)

by average annual rates of 14 percent and 10 percent, respectively (Medicare Payment Advisory Commission 2019). To determine APRNs' and PAs' potential impact on MUA determinations, we estimated the share of NPs and PAs that practice in primary care and, subsequently, the share of all primary care clinicians that are APRNs or PAs (see text box for methodology).[9]

In 2018, we found that about 62,000 NPs who practiced in primary care and 89,000 who practiced in specialty care billed the Medicare program, meaning that about 41 percent of NPs who billed Medicare were practicing in primary care. In the same year, we found that about 24,000 PAs who practiced in primary care and 66,000 who practiced in specialty care billed the Medicare program, meaning that about 27 percent of PAs who billed Medicare were practicing in primary care (Table 2-7, p. 40).

While less than half of NPs and PAs who billed Medicare practiced in primary care, NPs and PAs who billed in certain settings were more likely to practice in primary care. In 2018, more than 80 percent of the NPs and PAs who billed under FQHCs and about two-thirds who billed under RHCs practiced in primary care (Table 2-7, p. 40).

While most APRNs and PAs do not practice in primary care, they made up 34 percent of primary care clinicians who billed Medicare in 2018 (Table 2-8, p. 40).[10] In rural areas, they represented an even higher share of primary care clinicians. In 2018, APRNs and PAs accounted for 44 percent of primary care clinicians who billed Medicare in rural micropolitan areas and about half of primary care clinicians in rural adjacent, rural nonadjacent, and frontier areas.[11] These findings suggest that the measure of primary care supply used in the identification of MUAs likely fails to account for a third to a half of all primary care clinicians. In addition, the underestimate will continue to grow in magnitude if the supply of APRNs and PAs continues to expand and the supply of primary care physicians continues to remain flat, as it has over the last several years (Medicare Payment Advisory Commission 2021b).

Dual-eligible beneficiaries had higher service use compared with other Medicare beneficiaries, reflecting greater health needs

In 2018, dual-eligible beneficiaries had a substantially higher number of E&M encounters compared with other Medicare beneficiaries.[12] For example, among rural nonadjacent beneficiaries, dual-eligible beneficiaries had 57 percent more E&M encounters

Methodology used to classify APRNs and PAs as practicing in primary care or specialty care (cont.)

TABLE 2–6

Methodology used to classify APRNs and PAs as practicing in primary care or specialty care in 2018

Sorting order	Criteria	Rationale
1	If 75 percent or more of an APRN's/PA's total payments were billed in the hospital inpatient setting, emergency department, or ambulatory surgical center OR were associated with anesthesia, imaging, procedures, treatments, tests, or certain types of E&M services, **then consider the APRN/PA to practice specialty care.**	Primary care is largely performed in outpatient settings (e.g., clinician offices and hospital outpatient departments) and predominantly involves E&M services.
2	Else if 75 percent or more of total payments associated with an APRN's/PA's practice (i.e., tax ID or provider number) were billed by clinicians other than primary care clinicians (after excluding services billed by APRNs/PAs), **then consider the APRN/PA to practice specialty care.**	This criterion is designed to sort into the specialty care category APRNs/PAs who largely bill E&M visits in the outpatient setting for specialist physicians.
3	Else if an APRN/PA billed for more than 15 beneficiaries AND 75 percent or more of their total payments fell into any of the following high-level diagnosis categories: a. Infectious and parasitic diseases b. Neoplasms c. Diseases of the blood, blood-forming organs, and certain disorders involving the immune mechanisms d. Endocrine, nutritional, and metabolic diseases e. Mental, behavioral, and neurodevelopmental disorders f. Diseases of the nervous system g. Diseases of the eye and adnexa h. Diseases of the ear and mastoid process i. Diseases of the circulatory system j. Disease of the respiratory system k. Diseases of the digestive system l. Diseases of the skin and subcutaneous tissue m. Diseases of the musculoskeletal system and connective tissue n. Diseases of the genitourinary system o. Pregnancy, childbirth, and the puerperium; certain conditions originating in the perinatal period p. Congenital malformations, deformations, and chromosomal abnormalities* **then consider the APRN/PA to practice specialty care.**	Primary care is characterized as being an entry point into the health care system, so primary care APRNs/PAs are likely to see a variety of conditions. If nearly all of their payments are for one type of condition, they are likely practicing specialty care. For example, an NP whose payments are 95 percent related to skin is likely practicing in a dermatologist's office.
4	**Else consider the APRN/PA to practice in primary care.**	

Note: APRN (advanced practice registered nurse), PA (physician assistant), E&M (evaluation and management), ID (identification). Because this methodology relies on national provider identifiers reported on claims, it does not account for "incident to" billing. "Certain types of E&M services" includes critical care services, emergency department services, hospital inpatient services, observation services, and ophthalmological services.
* We do not use all the high-level International Classification of Diseases 10th Revision disease categories to classify APRNs and PAs as practicing in specialty care because not all the categories directly correlate to a specialty.

Source: MedPAC.

TABLE 2–7

Most nurse practitioners and physician assistants who billed Medicare practiced in specialty care, 2018

Clinician specialty	Number of APRNs or PAs who billed Medicare, by billing pathway (in thousands): Physician fee schedule	Federally Qualified Health Center	Rural Health Clinic	Critical access hospital (method II billing)	Total unique APRNs or PAs (in thousands)
NPs (primary care)	56	9	5	3	62
NPs (specialty care)	88	2	2	4	89
Other APRNs (primary care)	2	1	<1	<1	2
Other APRNs (specialty care)	52	<1	<1	<1	52
PAs (primary care)	22	3	2	1	24
PAs (specialty care)	66	<1	1	3	66

Note: APRN (advanced practice registered nurse), PA (physician assistant), NP (nurse practitioner). These numbers do not account for "incident to" billing. The rows do not sum to "total unique APRNs or PAs" because of rounding and the fact that clinicians can bill under multiple billing pathways (e.g., physician fee schedule and Rural Health Clinics). The "Other APRNs" categories include certified registered nurse anesthetists, certified nurse midwives, and clinical nurse specialists.

Source: MedPAC analysis of carrier and outpatient standard analytic files.

than did other Medicare beneficiaries (Table 2-9).[13] The differences in use between dual-eligible beneficiaries and other Medicare beneficiaries were relatively consistent across our rural and urban categories, with dual-eligible beneficiaries using 51 percent to 57 percent more services.

TABLE 2–8

One-third of all primary care clinicians who billed Medicare were APRNs or PAs, 2018

Location where clinician performed services	Number (in thousands): Primary care physicians	APRNs (primary care)	PAs (primary care)	Total primary care clinicians	Share of total primary care clinicians made up of APRNs and PAs
Urban	148	52	19	219	32%
Rural micropolitan	12	7	3	22	44
Rural adjacent	5	3	1	9	49
Rural nonadjacent	3	2	1	7	51
Frontier	1	1	1	3	52
Total	168	64	24	257	34

Note: APRN (advanced practice registered nurse), PA (physician assistant), NP (nurse practitioner). These numbers do not account for "incident to" billing. "Total primary care clinicians" comprises primary care physicians and APRNs and PAs who practiced in primary care. Numbers do not sum to the totals because of rounding, because the frontier designation is not mutually exclusive from the other categories, and because a small number of primary care clinicians could not be sorted into rural or urban locations; they are excluded from the rural and urban categories but are included in the totals.

Source: MedPAC analysis of carrier and outpatient standard analytic files.

TABLE 2–9

Dual-eligible beneficiaries had a higher number of E&M clinician encounters per beneficiary compared with non-dual-eligible beneficiaries, 2018

	E&M clinician encounters per beneficiary		
Beneficiary residence, by type of county	**Dual-eligible beneficiaries**	**Other Medicare beneficiaries**	**Percent higher utilization among dual-eligible beneficiaries**
Urban	18.8	12.4	51%
Rural micropolitan	16.6	10.6	56
Rural adjacent	16.2	10.4	55
Rural nonadjacent	15.3	9.8	57
Frontier	13.2	8.5	56

Note: E&M (evaluation and management). Metropolitan (urban) counties contain an urban cluster of 50,000 or more people, rural micropolitan counties contain a cluster of 10,000 to 50,000 people, rural adjacent counties are adjacent to urban areas and without a city of at least 10,000 people, rural nonadjacent counties are not adjacent to urban areas and do not have a city with at least 10,000 people, and frontier counties have 6 or fewer people per square mile. Only beneficiaries with 12 months of Part B fee-for-service coverage in 2018 are included in the table. E&M encounters include E&M visits billed under the physician fee schedule or critical access hospital method II billing; the category also includes all visits to Federally Qualified Health Centers and Rural Health Clinics. E&M encounters include all clinician types, including all physician specialties, advanced practice registered nurses, physician assistants, and other clinicians.

Source: MedPAC analysis of carrier and outpatient standard analytic files.

Dual-eligible beneficiaries also had substantially higher utilization of all the other types of services we examined compared with other Medicare beneficiaries. For example, dual-eligible beneficiaries averaged about twice the number of hospital inpatient admissions compared with other Medicare beneficiaries and about five times the number of SNF days (Table 2-10, p. 42).[14]

Dual-eligible beneficiaries' higher utilization rates are likely attributable to their greater health care needs. The Commission has found that, compared with other Medicare beneficiaries, dual-eligible beneficiaries are more likely to:

- report being in poor health (14 percent vs. 4 percent),
- have limitations in activities of daily living (54 percent vs. 20 percent), and
- live in an institution (18 percent vs. 3 percent) (Medicare Payment Advisory Commission and the Medicaid and CHIP Payment and Access Commission 2022).

Our finding that dual-eligible beneficiaries used substantially more services than other Medicare beneficiaries is positive in terms of access to care: Providers accepted them as patients and furnished a higher volume of care. However, given their higher health care needs, we cannot rule out the possibility that dual-eligible beneficiaries needed more care than they received or faced difficulties in accessing the care they did receive. In addition, this chapter examines Medicare beneficiaries who are eligible for full Medicaid benefits. Experiences accessing care may differ for other Medicare beneficiaries, such as partial-benefit dual-eligible beneficiaries or other low-income beneficiaries.[15] We explore these issues further in our work on safety-net providers, the first installment of which focuses on safety-net hospitals (see Chapter 3).

TABLE 2–10

Dual-eligible beneficiaries had higher use of hospital inpatient, SNF, and home health services compared with other Medicare beneficiaries, 2018

	Hospital inpatient admissions per beneficiary		Skilled nursing facility days per beneficiary		Home health episodes per beneficiary	
Beneficiary residence, by type of county	Dual-eligible beneficiaries	Other Medicare beneficiaries	Dual-eligible beneficiaries	Other Medicare beneficiaries	Dual-eligible beneficiaries	Other Medicare beneficiaries
Urban	0.35	0.17	4.4	0.9	0.31	0.15
Rural micropolitan	0.36	0.18	5.2	0.9	0.27	0.13
Rural adjacent	0.36	0.18	5.8	1.0	0.28	0.14
Rural nonadjacent	0.35	0.18	5.0	0.9	0.27	0.12
Frontier	0.31	0.16	3.7	0.8	0.16	0.07

Note: SNF (skilled nursing facility). Metropolitan (urban) counties contain an urban cluster of 50,000 or more people, rural micropolitan counties contain a cluster of 10,000 to 50,000 people, rural adjacent counties are adjacent to urban areas and without a city of at least 10,000 people, rural nonadjacent counties are not adjacent to urban areas and do not have a city with at least 10,000 people, and frontier counties have 6 or fewer people per square mile. Hospital inpatient and SNF figures include only beneficiaries with 12 months of Part A fee-for-service (FFS) coverage; home health figures include only beneficiaries with 12 months of Part B FFS coverage.

Source: MedPAC analysis of the Medicare Provider and Analysis Review file, outpatient file, and home health standard analytic file from CMS.

Beneficiaries with more reported chronic conditions used more services than those with fewer conditions, reflecting greater health needs

To examine service use among beneficiaries with multiple chronic conditions, we identified beneficiaries as having any one of 21 reported chronic conditions using Medicare claims data. These conditions ranged from very common, such as high blood pressure and diabetes, to less common, such as HIV/AIDS.[16] We grouped beneficiaries into categories based on how many of these 21 reported chronic conditions they had: 0–1, 2–3, 4–5, or 6 or more. One limitation of our analysis of reported chronic conditions is that we used conditions recorded in claims data. Rural beneficiaries have lower life expectancy and lower self-reported health status but have fewer chronic conditions coded in claims data. This disparity makes comparing risk-adjusted rural and urban service use problematic (see text box, pp. 44–45).

We found that Medicare FFS beneficiaries with more reported chronic conditions compared with those with fewer reported chronic conditions had substantially more E&M encounters. For example, among rural micropolitan beneficiaries, those with 6 or more reported chronic conditions had about 6 times the number of E&M encounters than did those with 0 or 1 reported chronic condition (25.7 E&M encounters vs. 4.4 E&M encounters per beneficiary, respectively) (Table 2-11). Similar to our findings among dual-eligible beneficiaries, our results were generally consistent across our rural and urban categories.

Beneficiaries with more reported chronic conditions also had substantially higher utilization of all the other types of services we examined compared with those with fewer reported chronic conditions. The magnitude of the difference between the sickest and the healthiest beneficiaries was even greater for hospital inpatient, SNF, and home health utilization than for E&M encounters.[17] For example, among beneficiaries in rural nonadjacent counties, those

TABLE 2–11

Beneficiaries with more reported chronic conditions had a higher average number of E&M encounters compared with those with fewer reported chronic conditions, 2018

Beneficiary residence, by type of county	E&M encounters per beneficiary by count of chronic conditions			
	0–1	2–3	4–5	6+
Urban	4.8	10.8	16.0	30.7
Rural micropolitan	4.4	9.6	14.1	25.7
Rural adjacent	4.3	9.5	14.0	25.5
Rural nonadjacent	4.2	9.3	13.6	24.2
Frontier	4.0	9.0	13.5	23.3

Note: E&M (evaluation and management). Metropolitan (urban) counties contain an urban cluster of 50,000 or more people, rural micropolitan counties contain a cluster of 10,000 to 50,000 people, rural adjacent counties are adjacent to urban areas and without a city of at least 10,000 people, rural nonadjacent counties are not adjacent to urban areas and do not have a city with at least 10,000 people, and frontier counties have 6 or fewer people per square mile. Only beneficiaries with 12 months of Part B fee-for-service coverage and who met the CMS-established chronic condition coverage criteria are included in the table. E&M encounters include E&M visits billed under the physician fee schedule or critical access hospital method II billing; the category also includes all visits to Federally Qualified Health Centers and Rural Health Clinics. E&M encounters include all clinician types, including all physician specialties, advanced practice registered nurses, physician assistants, and other clinicians.

Source: MedPAC analysis of the carrier standard analytic file, outpatient standard analytic file, and Master Beneficiary Summary File (chronic conditions segment).

with 0 or 1 reported chronic condition averaged 0.03 hospital inpatient admissions compared with 0.87 admissions among those with 6 or more reported chronic conditions (Table 2-12).

Within each reported chronic condition category, the average number of inpatient admissions generally increased with rurality. For example, among beneficiaries with 4–5 reported chronic conditions, the

TABLE 2–12

Beneficiaries with more reported chronic conditions had a higher average number of inpatient admissions, SNF days, and home health episodes, 2018

Beneficiary residence, by type of county	Hospital inpatient admissions per beneficiary, by number of chronic conditions				Skilled nursing facility days per beneficiary, by number of chronic conditions				Home health episodes per beneficiary, by number of chronic conditions			
	0–1	2–3	4–5	6+	0–1	2–3	4–5	6+	0–1	2–3	4–5	6+
Urban	0.02	0.10	0.24	0.85	0.1	0.4	1.3	7.7	0.02	0.07	0.18	0.65
Rural micropolitan	0.03	0.11	0.25	0.84	0.1	0.4	1.5	8.2	0.01	0.06	0.17	0.59
Rural adjacent	0.02	0.11	0.26	0.85	0.1	0.5	1.6	8.6	0.01	0.07	0.18	0.62
Rural nonadjacent	0.03	0.12	0.27	0.87	0.1	0.5	1.6	8.3	0.01	0.06	0.17	0.57
Frontier	0.03	0.14	0.32	0.91	0.1	0.5	1.8	7.6	0.01	0.05	0.13	0.42

Note: SNF (skilled nursing facility). Metropolitan (urban) counties contain an urban cluster of 50,000 or more people, rural micropolitan counties contain a cluster of 10,000 to 50,000 people, rural adjacent counties are adjacent to urban areas and without a city of at least 10,000 people, rural nonadjacent counties are not adjacent to urban areas and do not have a city with at least 10,000 people, and frontier counties have 6 or fewer people per square mile. Only beneficiaries with 12 months of Part A fee-for-service (FFS) coverage (for hospital inpatient admissions and SNF days), 12 months of Part B FFS coverage (for home health episodes), and who met the CMS-established chronic condition coverage criteria are included in the table.

Source: MedPAC analysis of the Medicare Provider and Analysis Review file, outpatient file, home health standard analytic file, and Master Beneficiary Summary File (chronic conditions segment).

Difficulty in comparing risk-adjusted rural and urban service use

In this report, we compare rural and urban service use by whether beneficiaries reside in a medically underserved area (MUA), are dually eligible for Medicare and Medicaid, or have multiple chronic conditions. One possible next step would be to use the reported chronic conditions as risk adjusters and evaluate, on a risk-adjusted basis, how many services rural and urban beneficiaries who are dually eligible or who live in MUAs use relative to expectations, given their mix of reported chronic conditions. However, as discussed in our June 2021 report, we are reluctant to compare risk-adjusted service use among rural and urban beneficiaries due to apparent differences in diagnosis coding.

We and others have found that rural beneficiaries tend to have lower risk scores compared with urban beneficiaries, but that they also tend to have lower life expectancy and lower self-reported health status. The most plausible explanation for this paradox is that rural beneficiaries' chronic conditions are underreported (Malone et al. 2020). This discrepancy may in part be due to having fewer physician visits (likely attributable to a greater travel distance to specialists), but in part it could also represent differences in coding practices. Rural patients often receive care in critical access hospitals, where fully recording diagnosis codes does not yield additional revenue for the provider. In contrast, urban patients tend to receive care in hospitals paid under the inpatient prospective payment system (under which fully documenting diagnosis codes translates into more revenue from Medicare) and are more likely to be seen by physicians participating in managed care plans (which have an incentive to get physicians to fully document diagnosis codes).

We can see a likely manifestation of this problem in our descriptive data. On average, rural beneficiaries have slightly fewer reported chronic conditions, based on Medicare claims data. For example, compared with urban beneficiaries, beneficiaries in rural nonadjacent counties had, on average, about 7 percent fewer reported chronic conditions: 3.17 conditions and 2.94 conditions, respectively (Table 2-13).[18] At the same time, we found that in a given reported chronic condition category, rural beneficiaries averaged more hospital inpatient admissions (see Table 2-12, p. 43). One explanation

(continued next page)

average number of inpatient admissions increased from 0.24 among urban beneficiaries to 0.32 among frontier beneficiaries (Table 2-12, p. 43). However, we suggest caution when interpreting these data because systematic coding differences between hospitals paid under the inpatient prospective payment system (which predominantly serve urban beneficiaries) and critical access hospitals (which predominantly serve rural beneficiaries) likely mean that rural beneficiaries within each reported chronic condition category are somewhat sicker than urban beneficiaries in the same category (e.g., rural beneficiaries in the 2–3 reported chronic conditions category are slightly sicker than urban beneficiaries in the same category). As a result, higher inpatient use among rural beneficiaries in a given chronic condition category is likely at least in part attributable to less complete diagnosis coding of rural beneficiaries' chronic conditions rather than actual greater use of inpatient care than urban

Difficulty in comparing risk-adjusted rural and urban service use (cont.)

TABLE 2–13

Rural beneficiaries had fewer reported chronic conditions compared with urban beneficiaries, 2018

Beneficiary residence, by type of county	Average number of reported chronic conditions per beneficiary
Urban	3.17
Rural micropolitan	3.10
Rural adjacent	3.09
Rural nonadjacent	2.94
Frontier	2.44

Note: Metropolitan (urban) counties contain an urban cluster of 50,000 or more people, rural micropolitan counties contain a cluster of 10,000 to 50,000 people, rural adjacent counties are adjacent to urban areas and without a city of at least 10,000 people, rural nonadjacent counties are not adjacent to urban areas and do not have a city with at least 10,000 people, and frontier counties have 6 or fewer people per square mile. Only beneficiaries who met the CMS-established chronic condition coverage criteria are included in the table.

Source: MedPAC analysis of the Master Beneficiary Summary File (chronic conditions segment).

for these two sets of facts is that rural beneficiaries are indeed healthier than urban beneficiaries and that, given their number of reported chronic conditions, they use more hospital care. However, we contend that this explanation is improbable and that, more likely, rural beneficiaries are as sick as (or sicker than) urban beneficiaries but have somewhat fewer encounters with the health care system (e.g., specialist physicians), and their encounters are more likely to be with providers that lack incentives to document diagnosis codes fully. ■

beneficiaries. (See the text box for more information on how coding affects the results presented in this chapter.) As with the service use patterns of dual-eligible beneficiaries, we are unable to make any judgment regarding whether the higher levels of service use we observe for beneficiaries with multiple chronic conditions are sufficient to meet their clinical needs. ■

Endnotes

1 The coronavirus pandemic and the Congress's subsequent fiscal support of rural hospitals substantially reduced the number of rural hospital closures in 2021.

2 As part of HRSA's cooperative agreement with state Primary Care Offices (PCOs), state PCOs conduct needs assessments in their states, determine what areas are eligible for MUA designation, and submit designation applications to HRSA.

3 Our frontier designation is not exclusive from our primary rural and urban categories. We classify counties as urban or as one of our three primary rural categories (micropolitan, rural adjacent, or rural nonadjacent). In addition, we categorize all counties as frontier or not frontier. In our primary classification scheme, frontier counties are in all three rural categories, and a small number of frontier counties are considered urban. A county can be urban due to having one large city but still be considered "frontier" if the county is large enough so that the population per square mile in the county is below 6.

4 The Commission annually surveys 4,000 Medicare beneficiaries and 4,000 privately insured individuals to assess the extent to which they had difficulty accessing care. Survey respondents are drawn from across the country, from both urban and rural areas. For more information on the survey, see the Commission's March 2022 report to the Congress.

5 Some may argue that E&M use rates would be lower in MUAs compared with non-MUAs if the federal government did not provide enhanced funding for FQHCs and RHCs, which are predominantly located in MUAs. However, the magnitude of this effect is likely too small to substantially affect our results; in 2018, only 2 percent of E&M encounters among urban beneficiaries were billed by FQHCs or RHCs. Among rural beneficiaries, 10 percent of E&M encounters were billed by FQHCs or RHCs.

6 For example, in the Commission's June 2021 report, we found that the per beneficiary number of FQHC visits grew substantially faster in rural markets with a hospital closure compared with rural markets without a hospital closure (11.4 percent per year vs. 6.7 percent per year), suggesting that beneficiaries sought care in alternative settings when hospital outpatient departments were not available.

7 The Government Accountability Office's report said that Health Professional Shortage Area (HPSA) designations were similarly deficient. We do not analyze HPSAs in this chapter.

8 We used Medicare claims data on the type and location of the services billed by APRNs and PAs to categorize them as predominantly practicing in primary care or specialty care. See the text box (pp. 38–39) for the methodology. We defined *primary care clinicians* as primary care physicians plus APRNs and PAs who practiced in primary care.

9 In 2018, we found that 27 percent of PAs who billed Medicare practiced in primary care. Similarly, the National Commission on Certification of Physician Assistants found that 26 percent of PAs practiced in primary care in 2018 (National Commission on Certification of Physician Assistants 2019). Estimates of the share of NPs who practice in primary care are more dated and vary more widely. Industry representatives suggest that 70 percent of NPs provide primary care, while government researchers in 2010 and 2012 found that 52 percent and 48 percent of NPs practiced in primary care, respectively (Agency for Healthcare Research and Quality 2011, American Association of Nurse Practitioners 2022, Health Resources and Services Administration 2014). Our estimate of the share of NPs who practiced in primary care in 2018 (41 percent) more closely aligns with the previous governmental research, although it suggests that the share of NPs practicing in primary care has declined since 2010.

10 Further, because our analysis does not account for "incident to" billing, the 34 percent figure likely represents a lower bound. For example, if an NP exclusively bills under a physician's national provider identifier (i.e., bills "incident to" the physician), our data do not include that NP. For more information on the potential magnitude of this effect, see the Commission's June 2019 report to the Congress.

11 We sorted clinicians into urban and rural categories based on the ZIP code in which they performed services. If a clinician billed for services in multiple ZIP codes, we distributed that clinician to ZIP codes on a full-time equivalent (FTE) basis. For example, if an NP billed half their services in urban ZIP codes and half in rural micropolitan ZIP codes, we counted 0.5 FTE in each of the urban and micropolitan categories.

12 Our measure of dual-eligible beneficiaries includes Medicare beneficiaries who are eligible for full Medicaid coverage (i.e., full-benefit dual-eligible beneficiaries). In 2018, about 14 percent of Medicare FFS beneficiaries were dually eligible for Medicaid and Medicare. Dual-eligible beneficiaries were relatively evenly distributed across rural and urban areas.

13 Our analysis of clinician services is limited to E&M services. Patterns may differ for other types of clinician services, such as procedures and tests.

14 Results for hospital outpatient claims per beneficiary are not included in the table, but the results were substantially similar to results for the other categories of services.

15 Partial-benefit dual-eligible beneficiaries do not receive full Medicaid benefits but qualify for assistance with Medicare cost sharing through one of four Medicare Savings Programs: the Qualified Medicare Beneficiary Program, Specified Low-Income Medicare Beneficiary Program, Qualifying Individual Program, and Qualified Disabled and Working Individuals Program.

16 The 21 conditions include alcohol abuse, Alzheimer's disease/dementia, arthritis (including rheumatoid and osteoarthritis), asthma, atrial fibrillation, autism spectrum disorders, cancer (breast, colorectal, lung, and prostate), chronic kidney disease, chronic obstructive pulmonary disease, depression, diabetes, drug abuse/substance abuse, heart failure, hepatitis (chronic viral B and C), HIV/AIDS, high cholesterol, high blood pressure, ischemic heart disease, osteoporosis, schizophrenia/other psychotic disorders, and stroke/transient ischemic attack.

17 Results for hospital outpatient claims per beneficiary are not included in the table, but the results were substantially similar to results for the other categories of services.

18 The difference between urban and frontier beneficiaries is even larger. Part of this difference is likely due to coding differences between critical access hospitals and prospective payment system hospitals. However, part of the difference may also reflect the fact that frontier beneficiaries may actually be heathier, in certain regards, compared with urban beneficiaries.

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CHAPTER 3

Supporting safety-net providers

CHAPTER 3

Supporting safety-net providers

Chapter summary

The Medicare program strives to ensure access to care for all beneficiaries and to adequately compensate providers for providing that access. The beneficiaries with the greatest health care needs are often low-income Medicare beneficiaries with the fewest personal resources to address those needs, making it critical to ensure that these beneficiaries have access to a safety net of health care providers. However, treating low-income beneficiaries might entail extra costs that are not sufficiently reflected in Medicare's standard payment systems and can generate lower revenues for providers. In addition, public payers (including Medicare and Medicaid) in certain sectors have lower payment rates than commercial insurance, making it more difficult for providers who are substantially dependent on public payers to compete with other providers for labor. The Commission is concerned that the concentration of low-income beneficiaries or patients with public insurance among certain providers may create an undue financial strain on these providers and could result in diminished access to or quality of care for beneficiaries. But implementing large, across-the-board payment rate increases to support this subset of providers would be an inefficient use of scarce Medicare resources. For these reasons, the Commission has begun a body of work examining safety-net providers, including exploring how they should

In this chapter

be defined and how the Medicare program can best support their critical missions.

To identify safety-net providers and evaluate whether new Medicare safety-net funding might be warranted in a health care sector, we developed a conceptual framework intended to be applicable across multiple sectors. We identify safety-net providers as those that disproportionately serve (1) low-income Medicare beneficiaries who are less profitable to care for than the average beneficiary or (2) uninsured patients or patients with public insurance who are not materially profitable. A provider that serves a disproportionate share of patients with above-average profitability (even if those patients are low-income Medicare patients) would not meet our criteria for being a safety-net provider.

We also developed a conceptual framework for determining whether the Medicare program should allocate new funding to support identified safety-net providers. Medicare should spend additional funds to support safety-net providers only if:

- low-income beneficiaries are at risk of negative outcomes (e.g., access problems due to provider closures) without additional funding;
- Medicare is not a materially profitable payer in the sector; and
- current payment adjustments cannot be redesigned to adequately support safety-net providers.

By separating the identification of safety-net providers and the determination of whether new Medicare funds should be allocated to support them, these frameworks allow the Commission to broadly identify safety-net providers while recognizing that new Medicare funding is not warranted in all instances.

Our definition of low-income beneficiaries includes all those who are eligible for full or partial Medicaid benefits and those who do not qualify for Medicaid benefits in their states but who receive the Part D low-income subsidy (LIS) because they have limited assets and an income below 150 percent of the federal poverty level. Collectively, we refer to this population as "LIS beneficiaries" because those who receive full or partial Medicaid benefits are automatically eligible to receive the LIS. To identify hospitals' low-income populations, we use the LIS as the definition of "low income" because it reduces the impact of variation in state Medicaid policies. Our analysis found that, compared with the full Medicare population, LIS beneficiaries are three times as likely to be disabled and are twice as likely to be Black or Hispanic. Given the demographic mix of the LIS population, directing safety-net funds

to LIS patients' providers could promote greater equity in access to care and quality across demographic groups.

Applying our framework to safety-net hospitals

In acute care hospitals, Medicare patients, and in particular low-income Medicare patients, would generate lower levels of profitability than commercial patients without additional safety-net payments. Therefore, hospitals with high shares of Medicare patients, low-income Medicare patients, and uninsured patients may have insufficient resources to compete for labor and technology with hospitals that treat a higher share of commercial patients. This disparity can be problematic if certain hospitals treat a disproportionate share of LIS beneficiaries. In 2019, for the quarter of hospitals that treated the highest share of LIS beneficiaries, these beneficiaries made up 43 percent or more of the hospitals' Medicare inpatient and outpatient volume. In contrast, for the quarter of hospitals that treated the lowest share of LIS beneficiaries, these beneficiaries made up 23 percent or less of the hospitals' total Medicare volume.

The Commission's analyses have shown that, on average, Medicare beneficiaries have good access to hospital care. However, in this analysis of safety-net hospitals, we found that hospitals with high shares of LIS Medicare beneficiaries tend to have lower levels of profitability and a higher risk of closure (that is, the rate of closure increased as the share of total volume associated with LIS beneficiaries increased). For example, the quarter of hospitals with the highest shares of total Medicare volume associated with LIS beneficiaries had a median non-Medicare margin of 2 percent, compared with 15 percent among the quarter of hospitals with the lowest shares of such beneficiaries.

Medicare already provides substantial safety-net funding to hospitals in three ways—via disproportionate share hospital (DSH) payments, uncompensated care payments, and payments through the Medicare-dependent hospital program. Medicare also provides enhanced funding to isolated providers, such as critical access hospitals. These additional payments help maintain access to care in isolated areas. However, in this work, we do not consider them safety-net adjustments because they are targeted solely based on isolation metrics and not based on treating certain types of patients, such as low-income patients.

Because of the continuing association between patient income and hospital profitability, in this chapter we analyze how hospitals' current safety-net payments under the DSH program address the financial difficulties of hospitals treating high shares of Medicare and low-income patients. We compare the existing DSH policies using a metric we developed called the Safety-Net Index (SNI). Each hospital's SNI is computed as the sum of (1) the share of its Medicare volume associated with LIS beneficiaries (including those beneficiaries who are eligible for full or partial Medicaid benefits), (2) the share of its revenue the hospital spends on uncompensated care, and (3) an indicator of how dependent the hospital is on Medicare. Under this computation, hospitals with high SNI scores will have either a high Medicare share of services, low incomes among a high share of its Medicare patients, and/or a high share of its revenue spent on uncompensated care.

Our results suggest that the SNI measure is a better predictor of financial strain (as measured by predicted non-Medicare margins and risk of closure) than the current DSH measure. In addition, the DSH measure is negatively correlated with the share of hospitals' patients who are enrolled in Medicare, and using the measure leads to Medicare indirectly subsidizing Medicaid. The results of our analysis suggest that the new SNI metric could do a better job of targeting Medicare funds to safety-net hospitals than simply expanding the funds allocated to the existing DSH program would.

We also simulated a model that redistributed current DSH and uncompensated care payments using the SNI metric. By shifting from the current DSH system of payments to an SNI system of payments, a slightly larger share of safety-net payments would go to hospitals with high Medicare shares and a greater risk of closure. While these results should be considered illustrative, providing a sense of how distributing safety-net dollars using a metric that considers hospitals' Medicare shares and low-income Medicare beneficiaries would alter the distribution of Medicare funds. The magnitude of the pool of safety-net funds and whether additional safety-net funds are needed will be addressed in future work. ■

The Medicare program strives to ensure access to care for all beneficiaries and to adequately compensate providers for providing that access. The beneficiaries with the greatest health care needs are often low-income Medicare beneficiaries with the fewest personal resources to address those needs, making it critical to ensure that these beneficiaries have access to a safety net of health care providers. However, treating low-income beneficiaries can entail extra costs that are not adequately reflected in Medicare's standard payment systems and can generate lower revenue for providers. In addition, public payers (including Medicare and Medicaid) in certain sectors have lower payment rates than commercial insurance, making it more difficult for providers who are substantially dependent on public payers to compete with other providers for labor and technology. The Commission is concerned that the concentration of low-income beneficiaries or patients with public insurance among certain providers may create an undue financial strain on these providers and could result in diminished access to or quality of care for beneficiaries. But implementing large, across-the-board payment rate increases to all providers to support this subset of safety-net providers would be an inefficient use of scarce Medicare resources.

Medicare's role in preserving safety-net providers has a long history. Over three decades ago, in 1985, the Prospective Payment Assessment Commission (ProPAC) (a predecessor of the current Medicare Payment Advisory Commission) recommended that special payments be given to hospitals with high shares of low-income patients. In line with this recommendation, the Congress enacted the disproportionate share hospital (DSH) program, which began in 1986. The metrics chosen in 1985 to identify hospitals meriting DSH payments have been used in that program for the past 35 years. In addition, the DSH measure has become an off-the-shelf measure used to qualify hospitals for other benefits, including eligibility for the 340B program (starting in 1992) and for uncompensated care payments (starting in 2014).[1] However, the DSH formula omits two categories of patients who can be financially challenging: the uninsured and Medicare beneficiaries. These omissions may result in hospitals that serve high shares of uninsured or Medicare patients being disadvantaged by the current DSH formula.

The Commission has begun a new body of work examining safety-net providers, including how they should be defined and how the Medicare program can best support their critical missions. Our initial examination of safety-net providers focuses on hospitals for a few reasons. First, Medicare's payment rates for hospital services are substantially below average commercial insurer rates. Therefore, having a high share of patients enrolled in Medicare can present financial challenges for hospitals, which is not necessarily the case in other sectors. (For example, Medicare's payment rates for skilled nursing facility services are relatively generous and often subsidize losses generated by patients insured by Medicaid.) Second, hospitals play an important role in preserving access to emergency services, which is a critical part of the safety-net system. While we begin with hospitals, the principles discussed in this chapter have implications for identifying safety-net providers in other sectors.

This chapter begins with conceptual frameworks for identifying safety-net providers and deciding the extent to which new Medicare funding is warranted for all safety-net providers. The intent of developing these frameworks is to be able to apply them across multiple payment sectors to determine whether new safety-net funding is needed. Second, we provide an example of how these frameworks apply to the hospital sector. We start by demonstrating that certain hospitals disproportionately serve low-income beneficiaries and that these hospitals face significant financial challenges. We then examine how different hospital safety-net metrics predict a hospital's profitability and risk of closure, presenting an illustrative example of how hospital payments would change if one of these alternative safety-net metrics were used to reallocate current safety-net funding (i.e., DSH and uncompensated care payments).

In future work, we will consider whether the current level of funding for safety-net hospitals is sufficient or whether the pool of safety-net dollars for hospitals should be expanded. We will also investigate the application of these safety-net principles to other sectors, along with methods for distributing safety-net dollars in those sectors and the appropriate magnitude of those distributions.

A conceptual framework for identifying safety-net providers

Researchers, policymakers, and other stakeholders have defined the term *safety-net provider* in a multitude of ways. Some definitions employ area-based classifications (e.g., clinicians located in medically underserved areas) or facility-type designations (e.g., 340B hospitals). Still others use the term to mean providers situated in isolated locations (see the text box, p. 60, regarding isolation metrics). We did not use any of these criteria to define safety-net providers; instead, we based this designation on a provider's shares of certain patients who are typically less profitable. Defining safety-net providers based on their shares of patients who are typically less profitable is rooted in the premise that providers with comparatively high shares of unprofitable patients are financially disadvantaged relative to their competitors. This financial disadvantage, in turn, could lead to negative outcomes for Medicare beneficiaries, such as limited access (e.g., if providers close or choose not to treat certain beneficiaries) or lower quality (e.g., if financial stress limits capital investments or puts providers at a disadvantage when competing for labor).

As shown in Figure 3-1, under the Commission's framework, determining a provider's safety-net status depends in part on the availability of information on a provider's non-Medicare patients. Where such data are available, the share of uninsured patients and Medicaid patients can be considered. If such data are not available, safety-net status is determined based only on the characteristics of Medicare patients.

Identifying safety-net providers when information on providers' non-Medicare patients is available

When information on providers' non-Medicare patients is available, the relevant question in determining safety-net status is: Are low-income beneficiaries less profitable to care for than the average Medicare patient, or are certain public payers less profitable than average? Low-income beneficiaries can be less profitable to care for than other beneficiaries because treating them could generate higher costs (e.g., patients with fewer resources at home or no home at all may require longer lengths of stay) or lower revenues (e.g., lack of cost-sharing payments). Some payers might be less profitable because their payment rates are set lower than those of other payers. For example, Medicare's payment rates for hospital and clinician services are substantially lower than commercial payers' rates for similar services.

If there is no reason to believe that low-income Medicare beneficiaries are less profitable to care for than the average Medicare beneficiary or that certain public payers are less profitable, on average, then we conclude that safety-net providers cannot be identified in the sector.

If there is reason to believe that low-income Medicare beneficiaries are less profitable to care for than the average Medicare patient or certain public payers are less profitable than average, then safety-net status should be based on a provider's share of patients who are less profitable: those without insurance or with public insurance that is not materially profitable or, alternatively, the share of Medicare patients with low incomes. (See pp. 58–61 for a discussion of how we identify Medicare patients with low incomes.) Defining "materially profitable" in some sectors is straightforward if the sector's providers have large negative or positive margins. In other sectors, judgments would need to be made regarding material profitability based on the sector's unique circumstances. One key decision to make when analyzing a provider's payer mix is deciding how to treat Medicare. In many sectors, Medicare is materially profitable; in others, it is not.

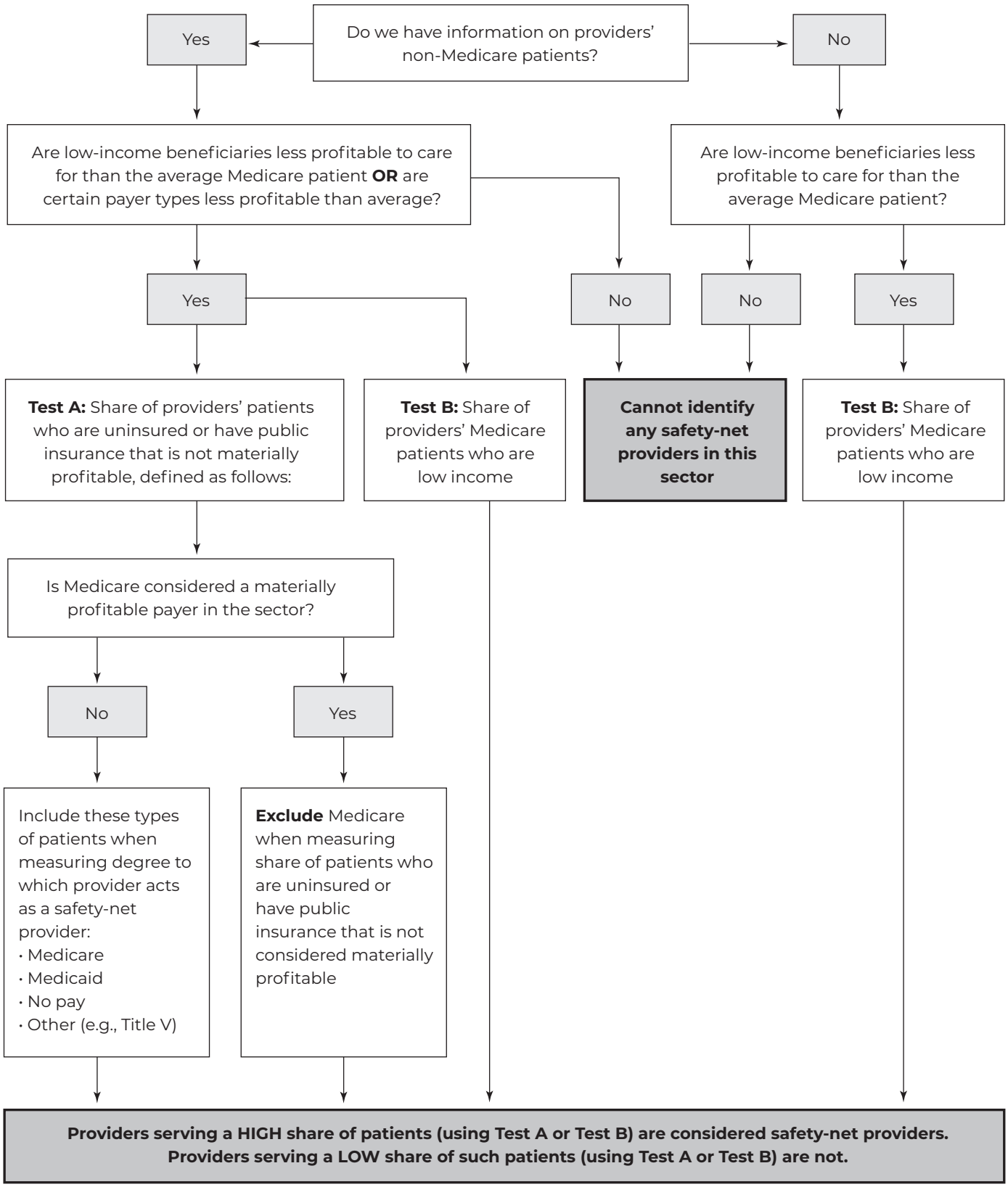
Identifying safety-net providers when no information on providers' non-Medicare patients is available

When information on providers' non-Medicare patients is unavailable, no consideration of providers' uninsured patients or patients with public (non-Medicare) insurance can be made. In this circumstance, the relevant question in determining safety-net status is: Are low-income beneficiaries less profitable to care for than the average Medicare patient?

In sectors where information on providers' non-Medicare patients is not available, if there is no reason to believe that low-income Medicare beneficiaries are less profitable to care for than the average Medicare beneficiary, then we conclude that safety-net providers cannot be identified in the sector. For example, certain

FIGURE 3–1

The Commission's framework to identify safety-net providers



clinical laboratories might disproportionately serve low-income beneficiaries. However, such beneficiaries are likely no less profitable than the average beneficiary because the cost per laboratory test is relatively fixed across beneficiaries (i.e., laboratory tests are relatively commoditized) and laboratories almost always collect full payment for their tests (i.e., the Medicare program pays the full rate with no beneficiary cost sharing, so there is little concern that low-income beneficiaries might be less likely to satisfy their cost-sharing requirements).

In sectors where no information is available on providers' non-Medicare patients, if low-income Medicare beneficiaries are typically less profitable to care for than the average Medicare patient, then safety-net status should be based on a provider's share of Medicare patients who have low incomes.

A conceptual framework for determining the need for new Medicare safety-net funding

After a health care sector's safety-net providers have been identified, the next step is to consider whether the Medicare program should allocate new funding to support these providers (Figure 3-2) based on the following criteria.

- ***Lack of additional funding would place beneficiaries at risk:*** While safety-net providers may be financially disadvantaged relative to other providers, new Medicare funding should be allocated only if failing to do so could lead to negative outcomes for low-income beneficiaries. For example, in the hospital sector, a substantially higher closure rate among safety-net hospitals could compromise beneficiaries' access to care, thereby necessitating new funding.

- ***Medicare is not a materially profitable payer in the sector:*** If Medicare is a materially profitable payer, on average, within a sector, then new Medicare safety-net funding is not warranted. However, a sector's failure to meet this criterion for new safety-net funding does not preclude providers in the sector that serve low-income beneficiaries from being disadvantaged or from experiencing other financial concerns (e.g., difficulties among low-volume, isolated providers). Instead, it means that other solutions, beyond adding new Medicare funding to support safety-net providers, are likely more appropriate. For example, a sector's providers could average 15 percent Medicare margins while a substantial share of providers who serve low-income patients are at risk of closure. Under these circumstances, new Medicare safety-net funding would not be warranted because Medicare already subsidizes the sector's other payers. However, policymakers could explore other solutions, such as redistributing existing Medicare funding within the sector or addressing the problems through the payers that are more directly responsible for poor all-payer financial performance (e.g., Medicaid).

- ***Current payment adjustments cannot be redesigned to address the issue:*** In some sectors, Medicare already makes special payments to help support safety-net providers, some of which may be poorly targeted. Policymakers should reform these adjustments or redirect their funding before considering adding new funding to support safety-net providers.

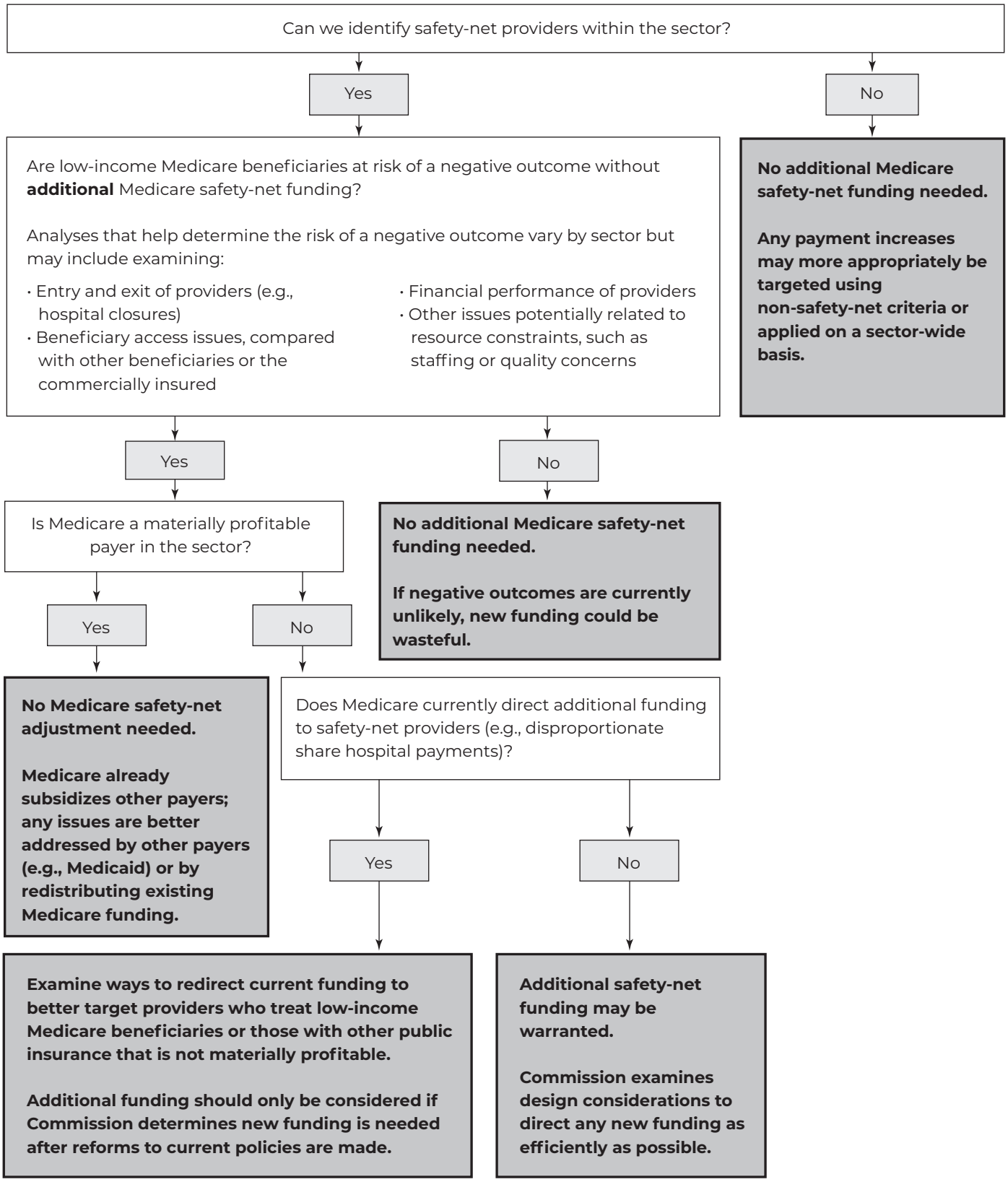
By separating the identification of safety-net providers from the determination of whether new Medicare funds should be allocated to support them, policymakers can broadly identify safety-net providers while recognizing that new Medicare funding is not warranted in all situations. These conceptual frameworks allow for identification of situations in which new funding is critical to maintaining access to care; targeting safety-net providers is the most appropriate way to distribute the funds (e.g., as opposed to across-the-board updates); and Medicare is the most appropriate payer to address the issue (i.e., Medicare does not already cross-subsidize other payers in the sector).

Identifying low-income Medicare beneficiaries

Instead of relying solely on eligibility for full Medicaid benefits as a measure of low-income status, our definition includes (1) those who receive full Medicaid benefits, (2) those who receive partial Medicaid

FIGURE 3–2

The Commission's framework for deciding if new Medicare safety-net funding is needed



Providers' isolation not considered when defining safety-net providers

Proximity to other providers is not incorporated into our framework for identifying safety-net providers. Instead, our definition relies on the extent to which providers treat low-income beneficiaries or patients who are uninsured or have other public insurance with rates that make their covered population not materially profitable to treat.

Under our definition, isolation is not among the criteria for defining a safety-net provider. Requiring a provider to be isolated would result in excluding urban providers that are important sources of access for many low-income patients and beneficiaries enrolled in Medicare or Medicaid. The lack of an isolation criterion means that a hospital serving a largely low-income population in Chicago, for example, could be deemed a safety-net hospital even though there are several other hospitals in the Chicago metro area. Stroger (Cook County) Hospital in Chicago is only a nine-minute walk from the Rush University Medical Center, but that would not preclude the Cook County facility from being categorized as a safety-net hospital if the hospital met the Commission's safety-net criteria.

Isolation is not a sufficient condition for being deemed a safety-net provider for additional reasons. Allowing hospitals to qualify as safety-net providers solely on the basis of isolation could result in providers that predominantly serve a wealthy clientele or that have a relatively large share of patients with materially profitable commercial insurance being considered safety-net providers. For example, the Mayo Clinic Health System is a near monopolist in southeast Minnesota (meaning it is not located near other large hospitals); it would not automatically meet the criteria for a safety-net provider needing special assistance. Similarly, the critical access hospital located in the ski resort community of Snoqualmie, Washington, would likely not qualify for safety-net status due to its high shares of commercially insured patients, even if its rural location qualifies it for a critical access hospital designation.

While we don't consider proximity to other providers in our safety-net definition, Medicare has several programs designed to preserve access to care in isolated rural areas. The Commission has supported many of these programs, and we compare these programs with programs designed to help providers serving low-income patients in Table 3-3 (pp. 66–67). ■

benefits through one of four Medicare Savings Programs, and (3) those who do not qualify for Medicaid benefits in their states of residence but who receive the Part D low-income subsidy (LIS), which provides assistance with Part D premiums and cost sharing.[2] Collectively, we refer to this population as "LIS beneficiaries" because those who receive full or partial Medicaid benefits automatically receive the LIS. In addition, beneficiaries may receive the LIS even if they are not eligible for Medicaid coverage in their states of residence if they have limited assets and incomes below 150 percent of the federal poverty level (about $19,300 for an individual and $26,100 for a couple in 2021).[3] (We refer to LIS beneficiaries who do not receive full or partial Medicaid benefits as "LIS-only beneficiaries.")

The intent of defining low-income beneficiaries in this manner is to reduce the effect of variation in states' Medicaid policies on the share of beneficiaries whom we consider low income, but to allow for appropriate variation across states based on the share of beneficiaries who are at or near the federal poverty level. This definition reduces variation related to state Medicaid policies by allowing all beneficiaries with limited assets and incomes below 150 percent of

the federal poverty level to qualify as a low-income beneficiary in our analyses (Table 3-1, pp. 62–63). Some of the remaining variation is due to differences across states in beneficiary income levels.[4] For example, the poverty rate in New Hampshire (7.3 percent) is much lower than it is in Mississippi (19.6 percent), so even if the two states' Medicaid eligibility criteria were equally generous, we would expect substantial variation in the share of beneficiaries we consider to have low incomes (Census Bureau 2020).

Even using our expanded definition, low-income beneficiaries as a group are markedly distinct from all Medicare beneficiaries. As shown in Table 3-2 (p. 64), in addition to having lower incomes than the full Medicare population, LIS beneficiaries in 2020 were:

- three times as likely to be disabled;
- nearly three times as likely to have end-stage renal disease;
- more than twice as likely to be under age 64, less likely to be 65 to 84, and equally as likely to be 85 or older;
- twice as likely to be Black or Hispanic;
- more likely to be female; and
- slightly more likely to live in a rural area.

Identifying low-income beneficiaries using LIS eligibility has substantial benefits. Compared with other measures (such as those eligible for full Medicaid benefits), the LIS measure is less directly correlated with state Medicaid eligibility policies because all beneficiaries with limited assets and incomes below 150 percent are eligible for the LIS; that is, the LIS creates a national "floor" of 150 percent of the federal poverty level. For our low-income identification purposes, relying on the existing LIS measure would also be less administratively burdensome than creating a new measure. For additional payment purposes, paying an add-on to providers who treat LIS beneficiaries could encourage providers to make their patients aware of and help them enroll in Medicaid, the Medicare Savings Programs, or the LIS. Such a "woodwork effect," whereby previously eligible but unenrolled beneficiaries gain access to these programs' benefits, could improve access to care beyond any positive effects of financially supporting safety-net providers. Increasing enrollment in these programs could be an important second-order effect of a safety-net provider add-on, as researchers have consistently found low participation rates in these programs (Medicaid and CHIP Payment and Access Commission 2020, Shoemaker et al. 2012). For example, the Medicaid and CHIP Payment and Access Commission has found that only 53 percent of individuals eligible for the Qualified Medicare Beneficiary Program were actually enrolled, and the participation rates for other Medicare Savings Programs were even lower (Medicaid and CHIP Payment and Access Commission 2020).

Safety-net hospitals' greater financial challenges and risk of closure suggest need for revisions to Medicare safety-net funding

The concentration of low-income beneficiaries or patients with relatively unprofitable types of insurance in certain hospitals has led policymakers to enact provisions to financially support these hospitals to maintain access to care. For example, in 1985, the Congress enacted safety-net payments in the form of DSH payments to hospitals serving high shares of Medicaid and very low-income Medicare patients. While DSH payments were an improvement to Medicare payment policy when enacted 37 years ago, there have been substantial changes in the delivery of hospital care and in the profitability of different types of payers over the past four decades. Therefore, the Commission is now revisiting the issue of how to identify safety-net hospitals and how Medicare should make supplemental payments to safety-net providers.

Identifying safety-net hospitals

The elements involved in identifying safety-net hospitals include examining a hospital's payer mix (share of Medicare and uninsured patients) and the income of the hospital's Medicare patients. Payer mix is important because public payers tend to pay hospitals far lower rates than commercial payers (Medicare Payment Advisory Commission 2020). The income of Medicare patients is important because costs of care tend to be higher for low-income patients (Nguyen and

TABLE 3–1

Share of state Medicare populations who were full-benefit dual-eligible beneficiaries or LIS beneficiaries, 2020

Beneficiary state	Full-benefit dual-eligible beneficiaries	All LIS beneficiaries
District of Columbia	23.8%	32.9%
Maine	19.2	29.8
California	27.2	29.2
Kentucky	15.3	26.6
Mississippi	12.9	25.7
West Virginia	12.4	25.7
Louisiana	16.1	25.4
Connecticut	13.5	25.3
New York	19.9	23.2
Massachusetts	19.4	22.8
New Mexico	13.1	22.0
Vermont	14.8	21.9
Michigan	15.7	21.5
Alaska	18.2	21.2
Alabama	8.7	19.6
Arkansas	11.1	19.4
North Carolina	13.2	19.0
Oregon	10.2	19.0
Illinois	14.5	18.6
Wisconsin	16.3	18.6
Georgia	9.1	18.3
Oklahoma	13.0	18.1
Indiana	12.9	18.0
Maryland	9.0	17.4
Minnesota	13.6	17.4
Missouri	12.8	17.2
Rhode Island	12.7	17.0
Pennsylvania	12.6	16.6
Colorado	10.7	16.5
Nevada	7.5	16.1
Montana	9.7	16.0
Idaho	8.2	15.5
New Jersey	11.9	15.4
Ohio	9.7	15.4
Texas	7.6	15.3
Washington	10.2	15.3
Delaware	7.3	15.1

TABLE 3-1

Share of state Medicare populations who were full-benefit dual-eligible beneficiaries or LIS beneficiaries, 2020 *(cont.)*

Beneficiary state	Full-benefit dual-eligible beneficiaries	All LIS beneficiaries
Tennessee	7.9	15.0
North Dakota	11.1	14.9
New Hampshire	8.7	14.8
South Dakota	8.6	14.6
Florida	8.2	13.8
Iowa	10.0	13.4
Kansas	7.4	13.3
Virginia	7.3	12.9
Wyoming	7.1	12.9
Nebraska	9.4	12.2
South Carolina	8.3	12.2
Arizona	7.9	11.6
Utah	8.3	11.2
Hawaii	7.7	10.9
Ratio of the highest to the lowest state	3.8	3.0

Note: LIS (low-income subsidy). Beneficiaries are included in the table if they had at least one month of Part A or Part B coverage and no Medicare Advantage coverage.

Source: MedPAC analysis of enrollment data.

Sheingold 2011). Moreover, if low-income patients are less likely to pay cost sharing, revenue may be lower.

Certain hospitals treat disproportionate shares of low-income Medicare beneficiaries or have a relatively unprofitable payer mix. In 2015, we found that, for a quarter of inpatient prospective payment system (IPPS) hospitals, LIS beneficiaries made up over 43 percent of their Medicare volume (averaging inpatient and outpatient claims). In contrast, another quarter of hospitals treated the lowest share of LIS beneficiaries, whose claims made up 23 percent or less of these hospitals' Medicare claims. We found similar distributions in later years of data as well, and previous research has demonstrated that certain hospitals treat more relatively low-margin patients (e.g., uninsured patients and those with public insurance).

Certain hospitals serving higher shares of patients with public insurance and/or higher shares of low-income Medicare patients may have difficulty competing for labor and new technologies against neighboring hospitals with a more profitable payer mix. This disadvantage, in turn, could lead to difficulty maintaining quality of care and even to hospital closure. Therefore, the Medicare program may want to examine whether current Medicare payments are sufficient to preserve access at these facilities.

Current Medicare policies supporting safety-net hospitals

Medicare makes three main types of payments for hospitals commonly considered safety-net providers—DSH payments, uncompensated care payments (which

TABLE 3–2

Compared with all Medicare beneficiaries, those who received the low-income subsidy had substantially different characteristics, 2020

	Type of beneficiary				
	All FFS	Full-benefit dual eligible	Partial-benefit dual eligible	LIS only	All LIS
Total	100.0%	12.9%	3.3%	2.2%	18.4%
Race					
White	77.3	55.3	64.5	64.4	58.0
Black	8.9	17.1	18.9	17.0	17.4
Hispanic	6.4	13.9	10.8	11.5	13.0
Other	7.4	13.7	5.9	7.1	11.5
Geographic location					
Urban	79.9	79.6	69.4	73.6	77.1
Rural micropolitan	11.2	11.3	16.3	13.9	12.5
Rural adjacent	5.4	5.4	8.6	7.4	6.2
Rural nonadjacent	3.5	3.7	5.8	5.1	4.2
Frontier status					
Frontier	1.3	1.1	1.7	1.6	1.2
Not frontier	98.7	98.9	98.3	98.4	98.8
Sex					
Male	47.2	42.6	43.9	45.1	43.2
Female	52.8	57.4	56.1	54.9	56.8
Disability status					
Disabled	12.8	40.1	40.7	36.0	39.8
Not disabled	87.2	59.9	59.3	64.0	60.2
ESRD status					
ESRD	1.2	3.2	3.3	3.2	3.2
No ESRD	98.8	96.8	96.7	96.8	96.8
Age					
64 or younger	16.2	43.7	42.5	38.4	42.9
65 to 74	49.6	27.5	33.8	35.1	29.6
75 to 84	23.6	16.7	16.6	17.6	16.8
85+	10.6	12.0	7.1	8.9	10.8

Note: FFS (fee-for-service), LIS (low-income subsidy), ESRD (end-stage renal disease). Metropolitan (urban) counties contain an urban cluster of 50,000 or more people, rural micropolitan counties contain a cluster of 10,000 to 50,000 people, rural adjacent counties are adjacent to urban areas and without a city of at least 10,000 people, rural nonadjacent counties are not adjacent to urban areas and do not have a city with at least 10,000 people, and frontier counties have 6 or fewer people per square mile. Components may not sum to totals due to rounding.

Source: MedPAC analysis of enrollment data.

are tied to DSH payments), and payments through the Medicare-dependent hospital (MDH) program. (See Table 3-3, pp. 66–67, for a comparison of these and other special hospital payment policies.)

DSH and uncompensated care payments

DSH payments are supplementary inpatient payments that Medicare makes to hospitals that serve high shares of low-income patients. Hospitals are eligible to receive DSH payments if their share of low-income patients, referred to as the DSH patient percentage, meets or exceeds 15 percent. Hospitals' DSH payment adjustments generally increase as their DSH patient percentages increase, with certain limitations.[5] The DSH patient percentage is defined as the sum of two percentages:

- the number of inpatient days for Medicare beneficiaries eligible for Supplemental Security Income (SSI) divided by the total number of Medicare inpatient days,[6] and
- the number of inpatient days for Medicaid beneficiaries (who are not dually eligible for Medicare) divided by the total number of inpatient days for all patients.

Medicare DSH payments were established in the Consolidated Omnibus Budget Reconciliation Act of 1985 and became effective for discharges occurring on or after May 1, 1986. The original rationale for Medicare DSH payments was that low-income Medicare patients were typically more costly to care for in ways that were not accounted for by the original diagnosis related group system. However, subsequent research by the Commission and others concluded that, at most, 25 percent of DSH payments were empirically justified by the higher costs associated with treating low-income Medicare patients (Medicare Payment Advisory Commission 2007, Sheingold et al. 2016).

Despite the limited empirical justification for the established level of DSH payments, some stakeholders argued that full DSH payments should continue to assist hospitals with uncompensated care costs for non-Medicare patients.[7] However, in 2007, the Commission found that DSH payments were not well targeted to hospitals with high uncompensated care costs (Medicare Payment Advisory Commission 2007).

Subsequently, the Congress made several changes to the magnitude and structure of DSH payments as part of Affordable Care Act of 2010. Beginning in 2014, hospitals that qualify for DSH payments may receive two different payment adjustments: a revised DSH payment and an uncompensated care payment.

- First, hospitals receive 25 percent of the DSH payments they would have received under the traditional DSH formula. This lower DSH payment is referred to as the "empirically justified" Medicare DSH payment.
- Second, hospitals that qualify for the empirically justified Medicare DSH payment may also receive a share of a fixed pool of dollars referred to as the "uncompensated care pool." Hospitals each receive uncompensated care payments that are equal to the product of three values—75 percent of all hospitals' aggregate traditional DSH payments, 1 minus the percent change in the national uninsured rate since 2013 for individuals under the age of 65, and the hospital's share of uncompensated care relative to the amount of uncompensated care costs for all DSH hospitals.[8]

In 2022, Medicare expects to pay roughly $3.5 billion in empirically justified DSH payments and $7.2 billion in uncompensated care payments to IPPS hospitals, which together represent 6 percent of all Medicare payments to short-term acute care hospitals (Centers for Medicare & Medicaid Services 2021b).[9] Nearly all hospitals will receive at least some of this funding since the share of hospitals qualifying for DSH payments has expanded over time. (See the text box on maintaining targeting of special payments, pp. 68–69, for more information on this topic.)

The DSH patient percentage has frequently been used to identify safety-net hospitals. However, the DSH formula omits two categories of patients who can be financially challenging for hospitals: the uninsured and Medicare beneficiaries. These omissions may result in hospitals that serve high shares of uninsured or Medicare patients being disadvantaged by the current DSH formula.

The DSH patient percentage does not include a measure of uncompensated care. For example, a hospital stay furnished to an uninsured, low-income

TABLE 3–3

Descriptions of special hospital payment policies *(cont. next page)*

Payment policy	Current primary eligibility requirements	Payment adjustment methods	Annual cost (billions)	Share of urban hospitals	Share of rural hospitals
Disproportionate share hospital	Medicaid share plus SSI share of Medicare beneficiaries generally has to exceed 15%	Inpatient add-on ranging from 0.6% to 19%	$3.5	82%	92% (of IPPS)
Uncompensated care	Must be a DSH hospital	Pays approximately 21% of uncompensated care costs	7.2	82%	92% (of IPPS)
Critical access hospital program	Must have 25 or fewer beds, have been designated as a "necessary provider" by the state prior to 2006, or meet certain criteria for being isolated from other hospitals (e.g., be 35+ miles by primary road from other hospitals)	Pays approximately cost for inpatient, outpatient, post-acute swing services, lab, therapy services, and on-call costs; add-on for physician payments	3–4[a]	Must be rural or classified as rural by the state	64%
Sole community hospital program	Must be 35+ miles from non-CAH hospital or be 15 miles from non-CAH hospitals and meet other criteria	Inpatient operating payments based on the higher of prospective rates or historical costs trended forward from 1982, 1987, 1996, or 2006; outpatient add-on of 7.1%	0.8[b]	4%	48% of IPPS hospitals
Medicare-dependent hospital program	Rural or reclassified as rural, 100 or fewer beds, and 60% of days or discharges were Medicare beneficiaries	Inpatient operating payments equal to the higher of prospective rates or 25% of prospective rate plus 75% of historical costs trended forward; historical costs based on 1982, 1987, or 2002 cost reports	0.1	0	18% of rural IPPS

patient who cannot afford to pay for their care is not counted in the calculation of a hospital's DSH patient percentage.[10] In contrast, the stay would count toward the DSH patient percentage if that same patient were eligible for Medicare and SSI or Medicaid. This difference means that a hospital that treats a high share of patients without insurance could be doubly disadvantaged: It would not receive payment for some of the care it provides (other than through Medicare uncompensated care payments), and it might receive lower Medicare DSH payments because fewer of its patients count toward the DSH patient percentage. Uncompensated care burden may have been excluded from the original DSH patient percentage because data on uncompensated care data were not available at the time it was implemented. However, such data are now available on Medicare hospital cost reports.

The DSH patient percentage also does not account for the share of patients who are Medicare beneficiaries. Instead, it includes only the ratio of Medicare patients who qualify for SSI to all Medicare patients. This metric

TABLE 3–3 **Descriptions of special hospital payment policies** *(cont.)*

Payment policy	Current primary eligibility requirements	Payment adjustment methods	Annual cost (billions)	Share of urban hospitals	Share of rural hospitals
340B program	Must be a nonprofit or government-owned hospital; also must be either a CAH or meet a minimum DSH adjustment percentage (usually 11.75%); approximately half of all hospitals meet this DSH threshold	Receive discount prices on drugs from pharmaceutical companies	Generates slight savings for the Medicare program due to lowering CAH costs[c]	About 55% of IPPS nonprofit/ government hospitals	About 87% of CAHs
Low-volume hospital program	Must have under 3,800 discharges and be more than 15 miles from another IPPS hospital (can be next to a CAH)	Increases payments for inpatient care by up to 25% (linear decline between 500 and 3,799 discharges)	0.4	6%	61% of rural IPPS
Rural emergency hospital program	Rural hospital that ceases inpatient services	Pays a fixed monthly payment plus 105% of PPS rates for outpatient care	Not yet started[d]		

Note: DSH (disproportionate share hospital), SSI (Supplemental Security Income), IPPS (inpatient prospective payment system), CAH (critical access hospital).
[a] This amount represents an estimate of the difference between cost-based payments and what payments (including cost sharing) would have been if CAHs were paid PPS rates. About half of the increase is due to increased program payments (primarily on post-acute swing care) and about half is higher outpatient cost sharing paid by beneficiaries or their supplemental insurers on outpatient care. The last time we formally estimated this amount was for 2011, when the estimate was $2 million per CAH or approximately $2.6 billion dollars in additional payments. Given growth in CAH payments since that time, the net additional payments are estimated to be in the $3 billion to $4 billion range.
[b] The cost of sole community hospital (SCH) special payments is about $250 million from the 7.1% outpatient add-on program payments in addition to $600 million of the combined value of low-volume and SCH hospital–specific payments.
[c] The CAH program makes cost-based payments for Part B drugs and other services. To the extent that the 340B program reduces drug acquisition costs, the cost-to-charge ratio for the CAH's pharmacy will be reduced and cost-based payments will be reduced. There may also be indirect effects of the 340B program on Medicare spending and other payer spending due to increased incentives for 340B hospitals to acquire certain providers, such as oncologists. We have not attempted to quantify those secondary effects.
[d] The rural emergency hospital program is scheduled to begin on January 1, 2023.

Source: MedPAC analysis of IPPS final rules (Centers for Medicare & Medicaid Services 2021a, Health Resources and Services Administration 2021, Medicare Payment Advisory Commission 2005a).

is a measure of the income of Medicare patients served by the hospital rather than a measure of the share of patient days attributed to Medicare patients. Medicare was a relatively profitable payer when the original DSH patient percentage was conceived, so policymakers likely never considered a hospital's share of Medicare patients as an indicator of a provider's need. For example, the average hospital Medicare inpatient margin was about 13 percent in 1985 (Prospective Payment Assessment Commission 1997). However, hospitals' average Medicare margins are now negative, and aggregate hospital payment rates across Medicare and Medicaid are similar (Selden et al. 2015, Stensland et al. 2016). Therefore, including a hospital's Medicare share in the DSH patient percentage may now be warranted.

A third issue with the current DSH formula is that it is based purely on inpatient payments. As the practice of medicine shifts toward outpatient settings, the mix of inpatients may become less reflective of the hospitals' overall patient mix.

Maintaining targeted payment adjustments is often difficult

Many special payments to safety-net or isolated providers are initially targeted narrowly to provide financial support to those providers that are most critical for ensuring beneficiary access to care. However, over time, some of Medicare's special payment programs have been expanded to include a broader array of providers, many of which do not function as safety-net providers or ensure access in isolated areas. For example, in 1988, 35 percent of urban hospitals qualified for payment under the disproportionate share hospital (DSH) program; this figure had increased to 82 percent by 2020 (Table 3-4).

Historically, policymakers face particular pressure to expand programs that have discrete cutoff points in order to qualify. Such programs create a benefit "cliff" whereby providers who qualify receive substantial financial benefits and providers who fall just short of qualifying receive no benefits. Providers who fall just short of qualifying (and their advocates) then often argue that the qualifying criteria should be expanded to maintain equal treatment for similar providers. Over time, this process can lead to broadly expanding what was initially a narrowly targeted program.

Given this history, policymakers may want to design future special payments to allow almost all providers to qualify, with the magnitude of special payments determined on an incremental basis using recent data, so that providers earn higher payments by increasing beneficiary access to care (as opposed to earning higher payments through activities such as reclassifying urban hospitals as rural). As an example, if policymakers wanted to direct additional funding to hospitals or clinicians who treat low-income beneficiaries, instead of requiring providers to treat a certain share of low-income beneficiaries, be located in areas where low-income beneficiaries live, or be a certain type of facility, policymakers could consider:

- determining the magnitude of special payments on an incremental basis using recent data, removing the "cliffs," and allowing most providers who treat some low-income beneficiaries to qualify for special payments; and
- increasing the magnitude of the special payments as the low-income share of safety-net-type patients increases. ■

(continued next page)

Medicare-dependent hospital program

The Medicare-dependent hospital (MDH) program provides small, rural hospitals with enhanced inpatient payments. Specifically, MDH hospitals receive 75 percent of the difference between standard IPPS rates and a hospital-specific rate, which is based on each hospital's historic inpatient operating costs from 1982, 1987, or 2002 (trended forward to account for annual market basket updates and changes in case mix). If IPPS rates are higher than a hospital's updated costs, then the hospital receives standard IPPS rates. To qualify for the MDH program, a hospital must:

- be located in a rural area (with certain exceptions);
- have fewer than 100 beds; and
- have at least 60 percent of its inpatient days or discharges attributable to Medicare beneficiaries using two of the three most recently settled cost reports or using cost reports from 1987 or 1988.

The Government Accountability Office found that, in 2017, 138 hospitals qualified for the MDH program, 78 hospitals received additional payments through the program (the remaining hospitals' updated costs were lower than standard IPPS rates), and the median additional payment per hospital was about $800,000, although additional payments per hospital ranged from $1,000 to $10.4 million (Government Accountability Office 2020).

Maintaining targeted payment adjustments is often difficult (cont.)

TABLE 3–4 **Targeted policies for hospitals have generally expanded over time**

Program	Expanded over time?	Degree of expansion
Medicare disproportionate share hospital program	Yes; criteria were lowered and Medicaid was expanded, which increased the number of providers that qualified[a]	In 1988, 35% of urban hospitals qualified; this rose to 42% in 1991, 52 percent in 1997, and 82% in 2020[a]
Uncompensated care payments for disproportionate share hospitals	All disproportionate share hospitals qualify	The pool of dollars has declined as more hospital patients become insured
340B program (limited to critical access hospitals and nonprofit or government hospitals with moderate or high low-income shares (i.e., Medicaid patients and Medicare patients on SSI))	Special rules for rural hospitals were enacted in 2010, and Medicaid expansion increased the number of eligible hospitals	Hospitals participating in the program increased over 70% from 2011 to 2019, from 1,465 (33% of hospitals) to 2,574 (57% of hospitals)[b]
Medicare-dependent hospital program	Increased the share of payments that can be cost based, but little change in eligibility	Little change
Low-volume and low-provider-density programs		
Sole community hospital program	Expanded due to looser criteria for entering, somewhat offset by critical access hospital expansion[c]	In 1987, 12 percent of rural hospitals were sole community hospitals; this rose to 16 percent of rural hospitals by 2020[c]
Critical access hospitals (formerly medical assistance facilities or rural primary care hospital demonstrations)	Allowed states to waive distance requirements, expanded size to 25 beds, expanded length of stay up to a limit of 4 days, expanded cost-based payments to include post-acute care, and other expansions[d]	Increased from 16 hospitals in 1994 (under demonstrations) to 916 in 2004 to 1,353 in 2021, representing 65% of all rural hospitals[d]
Low-volume hospital program for hospitals more than 15 miles from other providers	Expanded due to legislation changing eligibility criteria from 200 annual discharges to 3,800 annual discharges	Expanded from 3 hospitals in 2010 to 626 hospitals in 2019; by 2019, 61% of rural IPPS hospitals received a low-volume adjustment[e]

Note: SSI (Supplementary Security Income), IPPS (inpatient prospective payment system). Critical access hospitals do not qualify for DSH payments.

Source: [a] Centers for Medicare & Medicaid Services 2021a, Prospective Payment Assessment Commission 1998, Prospective Payment Assessment Commission 1997.
[b] Government Accountability Office 2018, Health Resources and Services Administration 2021.
[c] Centers for Medicare & Medicaid Services 2021a, Freiman and Cromwell 1987, U.S. House of Representatives 1985.
[d] Flex Monitoring Team 2021, Medicare Payment Advisory Commission 2005a, Medicare Payment Advisory Commission 2005b, Wright et al. 1995.
[e] Centers for Medicare & Medicaid Services 2021a, Centers for Medicare & Medicaid Services 2009.

The additional Medicare spending distributed through the MDH program is not well targeted to those hospitals most in need for a few key reasons:

- ***Inpatient services are no longer the dominant service lines for many hospitals:*** When the MDH program was enacted, hospitals' primary source of Medicare revenue was inpatient services. In contrast, outpatient services now represent about half of MDHs' Medicare revenues. Therefore, any measure of "Medicare dependence" should consider outpatient as well as inpatient revenue.
- ***Supplemental payments do not reflect current costs:*** The hospital-specific rate used to calculate extra payments is based on data from 1982, 1987, or 2002. Allowing hospitals to pick their highest-cost year from data that is up to 40 years old results in hospital-specific rates that are unlikely to reflect current costs.
- ***Hospitals with the highest costs may not be those in the most need:*** The Commission's prior work has shown that hospitals under financial pressure tend to have lower costs, while hospitals that are in better shape financially tend to have higher costs (Medicare Payment Advisory Commission 2020). Therefore, cost-based payments that pay more to hospitals with higher costs may not be directing funds to hospitals most in need. In fact, hospitals that are under enough financial pressure to keep their costs below current IPPS rates would not receive any benefit from the MDH program.

The MDH program is premised on the idea that financial viability can be challenging for hospitals when Medicare is their dominant payer. In recent years, the decline in Medicare profit margins has resulted in even greater financial challenges for hospitals dependent on Medicare in both rural and urban areas.

Beneficiaries' access to hospital care is good in the aggregate, but safety-net hospitals are more likely to face financial challenges

Our analyses have shown, on average, that Medicare beneficiaries have good access to hospital care, and hospitals' total (all-payer) margins are near record highs as a result of rapidly increasing rates paid by commercial insurers. However, hospitals' Medicare margins are negative, have decreased over time, and are near zero even for relatively efficient hospitals. These trends suggest a growing disparity between hospitals that predominantly rely on Medicare (and other public payers) and hospitals with a substantial volume of commercially insured patients.

Our analyses confirmed that safety-net hospitals face significant financial challenges, even with the special payments these hospitals already receive from Medicare. We found that hospitals that treated higher shares of low-income beneficiaries had lower total margins and were more likely to close than other hospitals.

The gap between commercial and Medicare payment rates to hospitals has grown, underscoring the importance of payer mix in hospital profitability

Each year the Commission examines trends in the capacity and supply of hospitals, the volume of services per beneficiary, hospitals' financial performance, and other metrics to assess the adequacy of Medicare's hospital payment rates. The Commission has consistently found that hospitals have a financial incentive to treat Medicare beneficiaries (i.e., a positive Medicare marginal profit margin), adequate capacity prior to the coronavirus pandemic (e.g., aggregate occupancy rate of 64 percent in 2019), and strong overall financial performance. For example, from 2005 to 2019, hospitals' average total margin climbed from 4.7 percent to 7.6 percent, a record high.

While hospitals' total (all-payer) margins have reached record highs, their Medicare profit margins have decreased over the last two decades. From 1999 to 2008, the Commission found that hospitals' average Medicare margins fell steadily from 10 percent to −7.6 percent (Medicare Payment Advisory Commission 2020, Medicare Payment Advisory Commission 2017, Medicare Payment Advisory Commission 2008). Since 2008, hospitals' Medicare margins have varied somewhat but have remained substantially negative. In 2019, hospitals' average Medicare margin was −8.7 percent, and it remained below −8 percent in 2020.

Because profit margins on commercial patients continue to diverge from profit margins on Medicare and Medicaid patients, safety-net hospitals may not have sufficient resources to compete for labor and amenities with hospitals that treat a higher share of

commercial patients. The concern is that eventually this disparity could negatively affect access to high-quality care for certain Medicare beneficiaries. In the extreme, hospitals whose patients consist nearly entirely of those on Medicare or Medicaid or patients who are uninsured could have to reduce unprofitable service lines or even be forced to close.

Hospitals with higher shares of low-income patients had lower margins and were more likely to close than other hospitals

Using our proposed definition of low-income beneficiaries (those who receive the Part D LIS), we found that the share of hospitals' Medicare claims associated with low-income beneficiaries was negatively correlated with hospitals' non-Medicare and total margins—that is, both non-Medicare and total margins were lower for hospitals serving higher shares of LIS beneficiaries.[11] For example, the quarter of hospitals with the lowest shares of LIS beneficiaries in 2015 had a median non-Medicare profit margin of 15 percent, suggesting that they did not need to break even on Medicare to remain profitable. In contrast, the quartile of hospitals with the highest LIS shares had a median non-Medicare margin of 2 percent, suggesting that they needed to almost break even on Medicare to remain profitable. Similarly, we found that hospitals with the lowest LIS shares of beneficiaries had a total margin (including investment income) of 8 percent, compared with 2 percent for the hospitals with the highest shares of LIS beneficiaries (Table 3-5, p. 72). These findings are not unique to the years shown in the table. We found similar results when looking at 2019 margins.

It is important to note that the LIS beneficiary variable considers only Medicare beneficiaries. But it is strongly negatively correlated with non-Medicare margins, suggesting that the LIS beneficiary variable is acting as a proxy for other factors at the hospital. For example, hospitals whose Medicare patients tend to have low incomes may be more likely to have a large share of low-income patients among their non-Medicare patients as well, which could result in lower levels of non-Medicare profitability.

In contrast to our findings for total margins, we found that hospitals with higher shares of low-income beneficiaries tended to have higher Medicare margins. The quarter of hospitals with the highest shares of their Medicare volume associated with LIS beneficiaries had a median Medicare profit margin of 0 percent, compared with –13 percent among the quarter of hospitals with the lowest shares (Table 3-5, p. 72). Higher Medicare margins among hospitals with higher shares of LIS beneficiaries in part reflects the fact that these hospitals already receive higher special payments from Medicare in the form of higher DSH and uncompensated care payments.

Hospitals with a high share of volume associated with LIS beneficiaries have a higher risk of closure. Among the quarter of hospitals with the highest shares of LIS beneficiaries in 2015, 3.0 percent closed over the next four years, compared with 0.3 percent among the quarter of hospitals with the lowest shares (Table 3-5, p. 72). This finding suggests that Medicare's current safety-net payments (DSH and uncompensated care) do not fully offset the lower level of profits associated with treating high shares of LIS beneficiaries.

A new safety-net index may be a better way to identify safety-net providers

On average, our relatively simple measure of the share of hospitals' Medicare volume associated with LIS beneficiaries is a strong predictor of total margins and risk of closure, suggesting that the measure might be useful in future analyses of safety-net hospitals. As a comparison, we ran our analyses again using two different measures of hospitals' low-income shares—the DSH patient percentage (which Medicare uses to distribute DSH and uncompensated care funding) and a Safety-Net Index (SNI), which is computed as the sum of (1) the share of a hospital's total patient population associated with LIS beneficiaries, (2) the share of its revenue spent on uncompensated care, and (3) one-half of its Medicare share of total days.[12]

Both the LIS and SNI measures appear to have stronger associations with non-Medicare margins and closures than the current DSH metric. These two safety-net metrics are also closely correlated with each other (correlation coefficient of 0.91). This correlation should not be surprising, given that a key variable in both metrics is the share of Medicare volume associated with LIS beneficiaries.

The SNI was our strongest measure in terms of predicting closures. Among the quarter of hospitals with the lowest SNI, 0.1 percent closed over a four-

TABLE 3–5

High SNI hospitals had lower margins and were more likely to close

	DSH percentage, by hospital quartile				LIS, by hospital quartile				Safety-Net Index, by hospital quartile			
Hospital characteristic	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**
2015 characteristics												
LIS share of Medicare patients	22%	30%	36%	48%	20%	29%	38%	53%	21%	29%	37%	53%
Medicare share	64	62	57	47	57	58	59	54	51	58	61	58
Uncompensated care cost/revenue	2.3	3.2	3.3	3.3	2.1	2.8	3.3	4.2	1.9	2.7	3.3	5.1
Medicaid share	10	19	25	39	14	21	23	31	17	21	23	26
Share teaching hospitals	22	31	37	47	28	41	34	33	35	40	33	30
Share rural hospitals	18	29	30	22	9	20	31	39	10	18	29	42
2016 financial performance (actual 2016 data)												
Non-Medicare margin	13%	9%	7%	5%	15%	9%	6%	2%	14%	10%	6%	2%
Medicare margin	–13	–10	–5	–3	–13	–10	–7	0	–13	–10	–6	–2
Total margin	6	5	5	3	8	6	3	2	8	6	3	1
Share closed 2016–2019	1.7	1.0	1.3	2.1	0.3	0.6	2.3	3.0	0.1	0.4	2.3	3.3

Note: SNI (Safety-Net Index), DSH (disproportionate share hospital), LIS (low-income subsidy), Q (quartile). The unit of analysis is the hospital, with 704 hospitals in each quartile. The full sample of 2,816 hospitals represents all inpatient prospective payment system hospitals with more than 200 Medicare discharges and complete data. The margins presented are the median margin for the quartile. The LIS shares in this table are the average of inpatient and outpatient LIS shares. Medicare shares are presented as a share of adult and pediatric inpatient days, including Medicare Advantage days. Medicare patients tend to have longer lengths of stay and thus a large share of inpatient days. The non-Medicare margin excludes fee-for-service Medicare revenue and costs from the margin computation. "DSH percentage" refers to the disproportionate share patient percentage. The SNI consists of adding the share of Medicare patients who are LIS, the share of revenue spent on uncompensated care, and one-half of the hospital's Medicare share. The half weight of Medicare shares reflects its lower effect on non-Medicare margins as tested in series regression analyses. The redistribution of safety-net dollars (DSH and uncompensated care dollars) was computed as a percentage add-on to each hospital's inpatient and outpatient Medicare payments; it was approximately equal to a 0.3 percent add-on for each 1 percentage point increase in the SNI. The mean add-on is 7 percent in the illustrative example.

Source: MedPAC analysis of claims, cost report, and closure data.

year period compared with 3.3 percent among the quarter of hospitals with the highest SNI (Table 3-5).[13] In addition, the SNI predicted total margins as well as the LIS beneficiary metric did. A potential benefit of the SNI metric over the DSH and LIS measures is that it is positively correlated with the share of hospitals' patients who are enrolled in Medicare (due to Medicare shares being part of the metric). Therefore, the SNI metric combines the positive predictive attributes of the LIS beneficiary metric while avoiding the negative correlation with the share of patients who are enrolled in Medicare observed in both the DSH and LIS metrics. The current DSH metric has a high negative correlation with the Medicare share, and the LIS beneficiary metric has a moderately negative correlation with the Medicare share (data not shown).

We have shown that the SNI is a slightly better predictor of hospitals' non-Medicare margins and closures than the current DSH patient percentage. The SNI can be used to identify safety-net status. Using the SNI metric to determine the distribution of safety-net payments also may be more appropriate than using DSH and uncompensated care payments, given the limitations of the current DSH payments and what appear to be reasonable results if payments were distributed via the SNI.

Limitations of the DSH percentage as an indicator of safety-net status

While the current DSH patient percentage used to qualify for DSH and uncompensated care payments tends to direct more dollars to safety-net hospitals than other hospitals, the DSH patient percentage has three potential shortcomings:

- The DSH measure includes the share of inpatient days that are associated with non-dual-eligible Medicaid beneficiaries. While the original intent of using Medicaid days was as a proxy for a hospital serving low-income patients, incorporating these days into the formula means that Medicare is indirectly subsidizing Medicaid. The Commission has historically asserted that, as a matter of policy, Medicare should not subsidize Medicaid (Medicare Payment Advisory Commission 2020, Medicare Payment Advisory Commission 2016). When Medicare shifted 75 percent of DSH funds to paying for uncompensated care, the magnitude of the subsidy was reduced. However, the Medicaid share remains the primary factor in determining which hospitals receive DSH funds.
- The DSH metric is an inpatient-only metric. As the practice of medicine shifts toward outpatient settings, the mix of inpatients may be less reflective of the hospitals' overall patient mix.
- The DSH patient percentage is negatively correlated with the hospitals' share of Medicare patient days. For example, the typical hospital in the quartile of hospitals with the lowest DSH patient percentages had a patient mix that was 64 percent Medicare, compared with 47 percent Medicare at a typical high-DSH hospital (Table 3-5). The shift of special payments away from hospitals with high shares of Medicare patients may not have been a concern in 1985, when the DSH formula was established, because Medicare was a relatively profitable payer. However, because Medicare margins have declined over time, policymakers may want to consider targeting a larger share of Medicare's special payments to hospitals with higher shares of Medicare beneficiaries in the future. Much of the shift in safety-net payments shown in Table 3-5 stems from bringing Medicare shares into the safety-net formula.

Using the Safety-Net Index to better target Medicare payments for safety-net hospitals

Given the flaws in the current DSH metric, simply adding additional dollars to the DSH program does not appear to be a good way of targeting Medicare dollars. However, reasonable options exist for altering the distribution of Medicare's current safety-net payments.

We illustrate one such approach, which is designed to accomplish three objectives:

- ***Target payments to safety-net hospitals, using the SNI.***[14]
- ***Avoid a "cliff" effect, under which add-on payments increase dramatically if the provider meets a predetermined threshold.*** To avoid the cliff effect, we modeled the adjustment so that it starts at zero for all those below the 5th percentile of the SNI distribution and increases in a linear fashion up to the 99th percentile of the distribution. The 5th and 99th percentiles were used to limit the influence of tails or potential errors in data while still allowing for higher payments to hospitals at the highest SNI level. The result was that the new SNI adjustment would eliminate current DSH and uncompensated care payments and redirect current DSH dollars by increasing inpatient and outpatient payments by approximately 0.3 percent for every 1 percentage point increase in the hospital's SNI.[15] Under this approach, the magnitude of the payment would be targeted, but almost all providers would receive some safety-net payment. For example, hospitals at the 10th percentile of the LIS beneficiary share distribution would receive about a 2 percent add-on to their Medicare rates, while providers at the 95th percentile of the distribution would receive a 17 percent add-on to their inpatient and outpatient rates.
- ***Fully expend the dollars currently being spent on DSH and uncompensated care payments.*** In future work, we can evaluate whether additional funds are needed in the safety-net pool.

In our illustrative example, we model SNI payments as a pure budget-neutral redistribution of existing DSH and uncompensated care payments. Policymakers could decide whether additional funds are needed in the pool of SNI dollars to create a pool of safety-net payments

that is larger than the current DSH/uncompensated care pool of funds. The Congress could set the size of the initial pool of dollars and then have the pool increase annually by some factor, such as the expected percentage increase in IPPS hospital spending. That would keep the SNI pool of dollars proportionate to the Medicare program's overall hospital spending.

The SNI for hospitals in this chapter was created with a combination of data on hospitals' fee-for-service (FFS) and Medicare Advantage (MA) Medicare patients. While we only illustrate the effect of SNI payments on FFS Medicare payments, an equal percentage add-on could be made to MA hospital claims. Because of the encounter data provided by MA plans, CMS will have the data to make payments directly to safety-net providers for MA patients. CMS should make SNI payments directly to providers serving low-income MA patients rather than simply increasing MA plans' capitated payments. Making payments directly to providers would ensure that the SNI payments are received by providers serving low-income Medicare beneficiaries rather than being used by MA plans for other purposes. In addition, beneficiary cost sharing should not increase with SNI payments, as increasing cost sharing for low-income beneficiaries could have a negative effect on access to care. The result would support safety-net providers serving both FFS and MA patients without an increase in cost-sharing burdens on low-income beneficiaries.

Illustrative effect on hospital revenue of redistributing safety-net payments

Under current DSH policies, hospitals with high SNI values tend to have above-average Medicare margins and below-average total margins. The higher Medicare margins reflect the DSH and uncompensated care payments these hospitals receive, and the lower total margins suggest that these hospitals have fewer profitable commercial patients.

In the illustrative model shown in Table 3-6, replacing current DSH payments with a new SNI add-on would raise Medicare payments to high-SNI hospitals and thus slightly increase their Medicare margins and total margins relative to the current DSH model (Table 3-5, p. 72). For example, the hospitals in the quartile with the highest SNI values would see their Medicare payments increase by an average of 1.8 percent and their total revenue increase by 0.4 percent. In contrast, hospitals with the lowest SNI values would see their total revenue decline by 0.4 percent (Table 3-6).

One concern would be the financial impact on hospitals with high DSH shares that currently benefit from the DSH and uncompensated care policies. On average, the quartile of hospitals with the highest DSH patient percentage (primarily due to high Medicaid patient loads) would see a decline of 2.3 percent of their Medicare payments, equivalent to a decline of 0.4 percent of total revenue. But the effects within the high-DSH group would vary. About 21 percent of the high-DSH hospitals would experience a decline of more than 1 percent in revenue, and about 13 percent of high-DSH hospitals would receive more than a 1 percent increase in total revenue. Because Medicare shares are a factor in the SNI metric but not in current DSH or uncompensated care metrics, hospitals that tend to have high Medicare shares would tend to benefit from the change and those with low Medicare shares would tend to lose under the SNI model. While high-DSH hospitals would tend to receive a reduction in Medicare payments under a policy of using the SNI rather than the DSH percentage to measure safety-net status, high-DSH hospitals would still receive an above-average share of safety-net payments (SNI adjustments equal to 8 percent of Medicare revenue, on average, in the top DSH quartile), and high-DSH hospitals would disproportionately benefit from any increase in the pool of safety-net dollars, even if those dollars were distributed through the SNI.

In this illustrative redistribution of DSH and uncompensated care funds, both teaching and nonteaching hospitals would see little change in total revenue (shifting by less than 0.3 percent; data not shown). Rural IPPS hospitals would see their Medicare revenue increase by about 3 percent and their total revenue increase by about 0.7 percent.[16] Urban hospitals would see a decline of Medicare revenue of about 0.3 percent, on average, and total revenue would decline by about 0.1 percent, on average. Rural hospitals tend to receive more money under the SNI metric than under the DSH and uncompensated care policies due to having relatively high Medicare shares (which are included in the SNI metric) and receiving lower payments under current DSH regulations. The change would not affect critical access hospitals, which receive cost-based payment and are not eligible for DSH or

TABLE 3–6

Illustrative example: Redistributing existing DSH and uncompensated care dollars based on the SNI would slightly increase margins of hospitals with large shares of low-income Medicare beneficiaries

	DSH percentage, by hospital quartile				LIS, by hospital quartile				Safety-Net Index, by hospital quartile			
Hospital characteristic	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**
Medicare FFS payment change (in millions)	1.0	0.5	0.1	–1.6	–0.3	–0.3	0.5	0.2	–1.4	–0.1	0.8	0.7
Mean DSH payments as a share of total Medicare payments	1.4%	4.9%	5.6%	10.3%	2.7%	5.0%	6.3%	10.9%	3.8%	5.2%	5.8%	10.4%
Mean simulated SNI payments as a share of total Medicare payments	3.4%	4.0%	5.8%	8.0%	2.4%	4.5%	7.0%	11.4%	2.0%	5.0%	7.7%	12.2%
2016 margins given current DSH policy												
Medicare margin	–13%	–10%	–5%	–3%	–13%	–10%	–7%	0%	–13%	–10%	–6%	–2%
Total margin	6	5	5	3	8	6	3	2	8	6	3	1
Simulated changes in margins caused by a shift to using the SNI to distribute safety-net dollars												
Percent change in Medicare payments	2.0%	0.9%	0.2%	–2.3%	–0.4%	–0.5%	0.7%	0.4%	–1.7%	–0.2%	1.5%	1.8%
Percent change in total payments	0.5%	0.2%	0.0%	–0.4%	–0.1%	–0.1%	0.2%	0.1%	–0.4%	0.0%	0.3%	0.4%
Simulated Medicare margin under SNI	–11%	–9%	–5%	–5%	–14%	–10%	–6%	0%	–15%	–10%	–4%	0%
Simulated total margin under SNI	7%	5%	5%	3%	8%	5%	4%	2%	8%	6%	4%	2%

Note: DSH (disproportionate share hospital), SNI (Safety-Net Index), LIS (low-income subsidy), FFS (fee-for-service). The unit of analysis is the hospital, with 704 hospitals in each quartile. The full sample of 2,816 hospitals represents all inpatient prospective payment system hospitals with more than 200 Medicare discharges and complete data. The margins presented are the median margin for the quartile. The LIS shares in this table are the average of inpatient and outpatient LIS shares. Medicare shares are presented as a share of adult and pediatric inpatient days, including Medicare Advantage days. Medicare patients tend to have longer lengths of stay and thus a large share of inpatient days. The non-Medicare margin excludes FFS Medicare revenue and costs from the margin computation. "DSH percentage" refers to the disproportionate share patient percentage. The SNI consists of adding the share of Medicare patients who are LIS, the share of revenue spent on uncompensated care, and one-half of the hospital's Medicare share. The half weight on Medicare shares reflects its lower effect on non-Medicare margins, as tested in series regression analyses. The redistribution of safety-net dollars (DSH and uncompensated care dollars) was computed as a percentage add-on to each hospital's inpatient and outpatient Medicare payments; it was approximately equal to a 0.3 percent add-on for each 1 percentage point increase in the SNI. The mean add-on is 7 percent in the illustrative example.

Source: MedPAC analysis of claims, cost report, and closure data.

uncompensated care dollars. While the ownership of hospitals that gain under the redistribution would vary, hospitals benefiting from the redistribution are more likely to be government-owned hospitals. About 17 percent of the hospitals that would gain 1 percent or more due to the SNI redistribution are government hospitals, while only about 10 percent of the hospitals that would lose 1 percent or more of revenue would be government hospitals. For-profit hospitals would represent 28 percent of the hospitals gaining at least 1 percent and 39 percent of hospitals with revenue declines of 1 percent or more. Nonprofit hospitals

would represent 54 percent of the hospitals gaining at least 1 percent and 51 percent of hospitals with revenue declines of 1 percent or more. These results are based on assumptions included in the model and are used to illustrate how margins could change with a shift from a DSH and uncompensated care framework to an SNI framework. While these figures provide a sense of the magnitude of the changes in a budget-neutral model, actual changes would depend on both the size of the SNI pool of funds and on regulations governing the SNI model. ■

Endnotes

1 The 340B Drug Pricing Program allows certain hospitals to obtain discounted prices from drug manufacturers. The 340B program could continue in its current form, using existing DSH thresholds, even if the Medicare DSH program was reformed and DSH was no longer used as the basis for distributing Medicare payments to hospitals. Because the 340B program does not distribute Medicare dollars to providers, it differs from the Medicare safety-net policies discussed in this chapter.

2 Full-benefit dual-eligible beneficiaries are enrolled in Medicare and also receive the full range of Medicaid benefits offered in a given state. In 2019, about half of full-benefit dual-eligible beneficiaries qualified for Medicaid because they received Supplemental Security Income (SSI) (Medicare Payment Advisory Commission and the Medicaid and CHIP Payment and Access Commission 2022). In 2021, beneficiaries were eligible for SSI if they had limited assets and their income was $794 or less per month for an individual ($1,191 for a couple), which equates to about 74 percent of the federal poverty level. Partial-benefit dual-eligible beneficiaries do not receive full Medicaid benefits but qualify for assistance with Medicare costs through one of four Medicare Savings Programs: the Qualified Medicare Beneficiary Program, which pays for Part A and Part B premiums, coinsurance, and deductibles; the Specified Low-Income Medicare Beneficiary Program, which pays for Part B premiums; the Qualifying Individual Program, which pays for Part B premiums; or the Qualified Disabled and Working Individuals Program, which pays for Part A premiums.

3 The federal poverty level is the same for the 48 contiguous states, meaning it is not adjusted for cost of living. Alaska and Hawaii have separate, higher federal poverty levels.

4 Some variation may also be due to differences in take-up rates of Medicaid, the Medicare Savings Programs, and the LIS across states and because some states set income limits for Medicaid eligibility higher than 150 percent of the federal poverty level. For example, the federal government sets income and asset standards to qualify for the Medicare Savings Programs; states may set their income and asset limits higher than federal standards but may not use more stringent criteria. The federal income limit to qualify for the Qualified Medicare Beneficiary Program is 100 percent of the federal poverty level, but in 2020, Connecticut set the income limit at 211 percent of the federal poverty level (Medicaid and CHIP Payment and Access Commission 2020). In 2020, a total of 14 states and the District of Columbia set more generous income or asset limits for one or more of the Medicare Savings Programs (Medicaid and CHIP Payment and Access Commission 2020). Many of the 14 states increase or eliminate the asset test but keep the income standards at or near the federal standard.

5 Medicare's DSH payments are operationalized as a percentage adjustment to diagnosis related group rates. While the magnitude of the adjustment generally increases as a hospital's DSH patient percentage increases, the amount varies based on formulas that differ depending on hospital characteristics (e.g., urban or rural, number of beds, share of low-income patients). We discuss the primary method for qualifying for DSH payments here. Hospitals may also qualify under an alternate special exception. In this report, "DSH payments" refers to operating DSH payments; Medicare has separate rules for capital DSH payments.

6 In 2021, SSI payments are made to individuals with basic income below $794 per month. Not all income is counted toward the limit (e.g., the first $20 of Social Security income is not counted). About 10 percent of Medicare discharges are for beneficiaries receiving SSI, while over 20 percent of discharges are for dual-eligible beneficiaries. In most states, all Medicare beneficiaries who receive SSI benefits are eligible for full Medicaid benefits.

7 "Non-Medicare" refers to all payments and costs other than for fee-for-service Medicare. Medicare Advantage revenue and costs are still included in the "non-Medicare" margin due to our lack of data on Medicare Advantage payments to hospitals.

8 The Affordable Care Act of 2010 stipulated the formula by which the available DSH funds will decline in proportion to the decline in the share of the uninsured population from the 2013 baseline. The rationale is that as the rate of uninsurance declines, hospitals' uncompensated care burdens should also decline.

9 For 2022, the DSH pool under the original formula would have been approximately $14 billion. Therefore, empirically justified DSH payments are equal to $3.5 billion ($14 billion × 0.25). Because CMS actuaries predict that the uninsured rate will be 68.57 percent as high in 2022 as it was in 2013, uncompensated care payments are $7.2 billion ($14 billion × 0.75 × 0.6857).

10 While the patient would not count in terms of the hospital's DSH patient percentage, a hospital would receive some additional funding through the uncompensated care pool if the hospital qualified as a DSH hospital.

11 For this analysis, the LIS share measure is an average of LIS shares from inpatient and outpatient claims. We divided IPPS hospitals into quartiles based on the share of their total Medicare volume associated with LIS beneficiaries in 2015. We then analyzed how well this measure predicted hospitals' 2016 margins and closures from 2016 until April 2020. We stop the analysis with the onset of the coronavirus pandemic to avoid confounding factors. However, as a robustness check, we also ran the same analysis using more recent data and found similar results. Specifically, we examined how our various safety-net metrics from 2018 predicted 2019 profit margins and closures from 2019 through fiscal year 2021.

12 Using one-half of the Medicare share of total days was determined based on regression models that attempt to explain differences in non-Medicare margins based on the characteristics of hospitals' patients. We found that Medicare shares, uncompensated care shares, and LIS shares were all predictors of hospital margins. Medicaid shares and characteristics of the ZIP codes where the patients lived added little to the explanatory models and were excluded for empirical reasons and to avoid having Medicare directly subsidize Medicaid.

13 We measured closures as counts of hospitals. We also measured closures in terms of closed beds to adjust for size of closures and found similar results. The number of closed beds was 10 times larger among hospitals in the highest SNI quartile compared with hospitals in the lowest SNI quartile.

14 We also tested redistributing the funds using the LIS variable as the safety-net indicator and achieved results similar to the SNI redistribution.

15 This example is oversimplified, and several policy decisions would have to be made in any redistribution. For example, in this model, we allow the new safety-net payments go to all hospitals, including Medicare-dependent hospitals, even if those hospitals receive cost-based payments based on historical costs.

16 Under current regulations, sole community hospitals can choose to receive traditional IPPS rates plus DSH and uncompensated care payments or a hospital-specific rate based on their historical costs. In this model, we assumed hospitals that choose the hospital-specific payment rate would continue to do so. However, a few hospitals could switch to the IPPS rates if they were allowed to obtain SNI payments, which could result in slightly higher increases in rural payments than those indicated in this simulation.

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CHAPTER 4

Addressing high prices of drugs covered under Medicare Part B

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Chapter summary

Medicare spending on prescription drugs is substantial and growing rapidly. Under Part B, Medicare covers drugs administered by physicians and outpatient hospitals and a few types of drugs furnished by pharmacy suppliers. In 2020, the Medicare program and beneficiaries spent about $40.7 billion on Part B–covered drugs. Between 2009 and 2019, Part B drug spending grew at an average rate of nearly 10 percent per year. In 2020, spending grew more slowly (about 4 percent), likely in part a reflection of the more general effect of the coronavirus pandemic on health care service utilization.

Between 2009 and 2019, the largest factor contributing to Part B drug spending growth was the rise in the average price Medicare paid for Part B drugs, which reflected increased prices for existing products; the introduction of new, higher-priced drugs; and shifts in the mix of drugs. Manufacturers set launch prices based on what they believe the U.S. health care market will bear and, historically, have set high prices for many new treatments, whether or not evidence exists that the product is comparatively more effective than existing standards of care. As a result, drug launch prices have been increasing, and increases in prices are not necessarily commensurate with the new products' efficacy relative to existing therapies. Likewise, prices for existing products are a concern.

In this chapter

Some launched at high prices when first introduced to market, and prices have grown rapidly for certain drugs and biologics, even those with therapeutic alternatives, despite a lack of evidence of increased efficacy. Cost sharing for high-priced products can deter appropriate uptake, and Medicare program spending on high-priced products can crowd out valuable alternative uses of taxpayer resources.

Generally, Medicare has had only an indirect influence on how new Part B–covered drugs are priced. Medicare pays for most Part B drugs and biologics at a rate of 106 percent of average sales price (ASP + 6 percent). Medicare lacks the authority to use tools to pay for Part B drugs in a way that balances a drug's net clinical benefit with an appropriate reward for innovation and affordability for beneficiaries and taxpayers. Medicare also lacks tools to promote price competition among Part B drugs with therapeutic alternatives.

In this chapter, we discuss three approaches that Medicare could use to address high launch prices for new "first-in-class" drugs with limited clinical evidence, high and growing prices among products with therapeutic alternatives, and financial incentives associated with the percentage add-on to Medicare Part B's payment rate. Although we focus on strategies to improve price competition and payment for Part B drugs, some of the issues facing Part B drugs are similar to the issues facing Part D drugs. In addition, although we focus here on pharmaceuticals, the discussion may be applicable more broadly to other categories of medical treatments and products, including medical devices.

Addressing uncertain clinical benefit and high launch prices of first-in-class drugs

For costly new drugs that face limited competition, such as first-in-class drugs, manufacturers have significant market power to set prices. Medicare does not have the authority to consider a new Part B drug's net clinical benefit compared with the standard of care to set its payment rate. Consequently, Medicare's Part B payment rate for a drug may exceed the payment justified by its net clinical effectiveness. Under the Part B ASP-based payment system, the program is a price taker, and a drug manufacturer with a new product with limited competition effectively sets its own Medicare payment rate. Linking information about the net clinical benefit of an item or service to fee-for-service (FFS) payment policies has the potential to improve Medicare's payment for products with uncertain clinical benefit. To address high launch prices of select first-in-class Part B drugs that the Food and Drug Administration

(FDA) approves with uncertain clinical evidence—based only on surrogate or intermediate clinical endpoints under its accelerated approval pathway—the Congress could give the Secretary discretion to:

- First, use coverage with evidence development (CED) to collect clinical evidence relevant to Medicare beneficiaries about the new drug. This approach would generate useful clinical evidence (which Medicare could use to refine coverage policies) while providing patients access to the product. CMS would need to develop a well-defined, consistent approach to designing CED studies, determining research methods, and setting a time line to reevaluate its application. Ensuring that the CED process is clear, transparent, and predictable with a process for public input would be key. Such a process might include criteria (e.g., disease prevalence, mortality, morbidity, practice variation, information gaps, estimated benefits and risks over existing therapies, and duplication with existing research efforts) for evaluating whether an item or service is a candidate for CED. In addition, a systematic and dedicated approach to fund CED (primarily focused on the administrative costs of conducting a CED study) might ease implementation. Some observers have suggested that CED applications should build on existing/emerging registries and data collection networks and partner with other organizations, including relevant regulatory bodies and private payers.
- Second, set a cap on the drug's payment rate based on information about the new product's estimated net clinical benefit (based on evidence from, for example, FDA clinical trials) and cost compared with the standard of care. This approach would prevent a manufacturer from setting a high price for a new product with little or no evidence that it is more effective than existing standards of care. This approach would require Medicare to develop a clear and predictable decision-making framework that ensures transparency and opportunities for public input. Medicare would also need to consider the methods for conducting such analyses, including the selection of comparator treatments, the method of defining costs, the prices of comparator drugs, the perspective of the analysis, and the time horizon.

This dual approach would likely lead to development of better evidence after FDA approval and better alignment of payment to the known clinical benefit of the drug. We envision that the Secretary would apply such a dual approach when needed for selected drugs approved under the FDA's accelerated pathway, based on factors such as a drug's clinical benefit compared with its

alternatives at the time of FDA approval and fiscal impact. We also envision that over time, Medicare would reevaluate the application of CED and the drug's payment rate based on, for example, information from postapproval clinical trials.

Since 2006, under existing statutory authority, the Secretary has applied CED to roughly 25 services. We do not envision that this dual approach would affect the Secretary's current use of CED. The Congress would need to provide the Secretary statutory authority to use methods other than ASP to set the payment for select first-in-class Part B drugs.

Promoting price competition among drugs with therapeutic alternatives

The current ASP payment system maximizes price competition among generic drugs and their associated brand products by assigning these products to a single billing code, which we call a consolidated billing code. By contrast, single-source drugs, originator biologics, and biosimilars are assigned their own billing codes and paid according to their ASP, which undermines price competition. Indeed, research suggests that in many therapeutic classes, approval of a new brand-name drug or biologic leads to higher list prices, not just for the new product but also for the existing products.

To spur manufacturer competition among drugs with similar health effects, the Congress could give CMS the authority to use internal reference pricing or consolidated billing, under which Medicare would establish a single reference price for drugs that have similar health effects based on the Part B drug payment rates of the products in the reference group. (This policy is distinct from international reference pricing, in which a reference price for a drug is derived from the prices other countries pay for it.) Under reference pricing, products remain in their own billing code, while under consolidated billing, all clinically similar products are assigned to the same billing code. Because products remain in their own billing codes under reference pricing, the policy might offer more flexibility in defining groups of products that are clinically similar (e.g., to account for potential differences in dosage sizes between therapeutically similar drugs) and addressing medical exceptions. Importantly, because drugs would retain their own billing code under a reference pricing approach, researchers would continue to be able to use Medicare claims data to conduct pharmacoepidemiology studies.

Under reference pricing policies for Part B drugs, manufacturers would have incentive to lower their prices relative to competitors to make their products

more attractive to providers and garner market share, which would result in savings for beneficiaries and taxpayers. To carry out reference pricing for Part B drugs, Medicare would need to develop a clear and predictable decision-making framework that ensures transparency and opportunities for public input. CMS would need to determine a method for establishing the payment rate for a reference group; a process for determining exceptions to reference pricing policies (for example, when a beneficiary's clinical circumstances support the medical necessity for a more costly product); a method for defining groups of products that are clinically similar; and a method for products with similar health effects that have multiple indications. CMS would also need to determine how frequently reference prices would be updated.

Improving provider incentives under the ASP payment system

While clinical factors play a central role in prescribing decisions, at the margins, financial considerations can also play a role in providers' choice of drugs. Medicare's 6 percent add-on to ASP may create incentives for use of higher-priced drugs when less-expensive therapeutic alternatives are available. Since 6 percent of a higher-priced drug generates more revenue for the provider than 6 percent of a lower-priced drug, selection of the higher-priced drug can generate more profit, depending on the provider's acquisition costs for the two drugs. The 6 percent add-on may also affect a provider's decision to initiate or continue drug treatment in some circumstances. To address concerns about these financial incentives, the add-on could be modified by placing a fixed dollar limit on the add-on payment or by converting a portion of the percentage add-on to a fixed fee, or a combination of these approaches could be used. The impact on payments for Part B drugs would vary, with a fixed dollar limit on the add-on payment reducing payment for very expensive drugs and the application of a fixed fee raising payments for relatively inexpensive drugs while decreasing payments for more expensive ones. ■

Under Part B, Medicare covers drugs administered by physicians and outpatient hospitals and a few types of drugs furnished by pharmacy suppliers. Medicare spending on these drugs is substantial and growing rapidly. In 2020, the Medicare program and beneficiaries spent about $40.7 billion on Part B–covered drugs. Between 2009 and 2019, Part B drug spending grew at an average rate of nearly 10 percent per year.

An important driver of Medicare Part B drug spending is the price Medicare pays for drugs. Manufacturers set prices based on what they believe the U.S. health care market will bear and, historically, have set high prices for many new products, whether or not evidence exists that the treatments are comparatively more effective than existing standards of care. Likewise, prices for existing products are a concern. Some launched at high prices when first introduced to market, and prices have grown rapidly for certain drugs and biologics, even those with therapeutic alternatives, despite a lack of evidence of increased efficacy. Cost sharing for high-priced products can deter appropriate uptake, and Medicare program spending on high-priced products can crowd out valuable alternative uses of taxpayer resources.

Generally, Medicare has had only an indirect influence on how new Part B–covered drugs are priced. Under the current Part B payment system based on average sales price (ASP), the program is a price taker. Improvements to Medicare's payment system for Part B drugs would help CMS balance a drug's net clinical benefit with an appropriate reward for innovation and affordability for beneficiaries and taxpayers and would promote price competition among Part B drugs with therapeutic alternatives. However, it is important to recognize that Medicare operates within a context involving other payers as well as federal and state laws, agencies, and policies. Many influences over drug prices are outside Medicare's purview, such as funding for biomedical research and development (R&D), patent policy, tax policy, and the Food and Drug Administration's (FDA's) drug approval process.

This chapter examines alternative approaches for Medicare Part B to address:

- ***High launch prices for first-in-class drugs.*** To address high launch prices of select first-in-class Part B drugs that the FDA approves based only on surrogate or intermediate clinical endpoints under its accelerated approval pathway, one approach is to (1) collect clinical evidence about the new drug through coverage with evidence development (CED) and (2) set a cap on the drug's payment based on its net clinical benefit compared with the standard of care. We consider this approach specifically for use of selected accelerated approval drugs because these products are approved with uncertain clinical benefit.
- ***High-priced therapeutic alternatives to existing and new drugs.*** To spur manufacturer competition among drugs with similar health effects, we consider the use of reference pricing or consolidated billing codes.
- ***Financial incentives under current payment of 106 percent of ASP.*** We explore several policy options to modify Medicare's current 6 percent add-on payment to improve financial incentives, including placing a fixed dollar limit on the add-on payment, converting a portion of the percentage add-on to a fixed fee, or a combination of these approaches.

Although we focus on strategies to improve price competition and payment for Part B drugs, some of the issues facing Part B drugs are similar to the issues facing Part D drugs. For example, certain Part D drugs lack robust clinical outcome data specific to Medicare beneficiaries. In addition, although we focus here on pharmaceuticals, the discussion may be applicable more broadly to other categories of medical treatments and products, including medical devices.

Background

Medicare Part B covers drugs and biologics that are administered by infusion or injection in physician offices and hospital outpatient departments (HOPDs). Medicare Part B also covers certain other drugs provided by pharmacies and suppliers (e.g., inhalation drugs; certain oral anticancer, oral antiemetic, and immunosuppressive drugs; and certain home infusion drugs).

Medicare Part B spending on prescription drugs is substantial and has grown rapidly. In 2020, the Medicare program and beneficiaries spent about $40.7 billion on Part B–covered drugs. Part B drug spending grew at an average rate of nearly 10 percent per year

between 2009 and 2019. In 2020, spending grew more slowly (about 4 percent), likely in part a reflection of the more general effect of the pandemic on health care service utilization.

Prescription medicines play a crucial role in managing or treating many conditions (e.g., cancer, rheumatoid arthritis, macular degeneration, and many others). Important breakthroughs have contributed to an increased life expectancy for patients suffering from several cancers, such as immunotherapy for melanoma, second-generation androgen receptor antagonists for prostate cancer, and new drugs for myeloma (Schnog et al. 2021). Some products—such as hepatitis C treatments and COVID-19 vaccines—are transformative and represent large advancements in the standard of care and health outcomes. At the same time, many new drugs and biologics represent modest improvements over existing treatments or have similar efficacy to products already on the market. For example, six studies that reviewed newly approved cancer drugs over various time periods found that, among the group of new products included in each study, the median or mean gain in overall survival was roughly two to four months (Schnog et al. 2021). In addition, manufacturers sometimes develop new products that are modifications of existing products (e.g., different formulations or routes of administration, modifications of delivery devices like inhalers or injector pens) as ways to potentially improve products' utility, extend patents or market exclusivity, or increase product revenues (Berger et al. 2016, Feldman 2018, Sumarsono et al. 2020).

Drug launch prices have been increasing, and increases in prices are not necessarily commensurate with the new products' efficacy relative to existing therapies. For example, research suggests that launch prices for anticancer drugs have been increasing over time and that the increases are unrelated to increases in efficacy. Howard and colleagues analyzed the launch prices of anticancer drugs from 1995 and 2013 and found that, after controlling for inflation and differences in survival benefits, launch prices have increased about 10 percent per year (i.e., about $8,500 per year) (Howard et al. 2015). The authors did not find a statistically significant relationship between launch prices and survival benefits. Similarly, a study by Vokinger and colleagues of 65 cancer drugs found no significant relationship between a drug's price and the product's level of clinical benefits (as measured by the American Society for Clinical Oncology value framework scores) in the U.S. and in several European countries (England, Switzerland, and Germany) (Vokinger et al. 2020).

Prices of existing drugs have also been increasing, generally without new evidence of increased effectiveness. In a report from the Institute for Clinical and Economic Review (ICER), researchers determined that, among the top drugs with price increases in 2020 contributing to the largest increase in U.S. spending (including all types of drugs, not exclusively Part B drugs), 9 of 12 lacked adequate new evidence to demonstrate a substantial clinical benefit that was not yet previously known.[1] The 2020 price increases of these products, even after rebates and other price concessions, resulted in an additional $1.7 billion beyond what payers would have spent if their net prices had remained flat (Rind et al. 2022).

Drug prices in the U.S. are substantially higher than in other countries. An analysis by the Department of Health and Human Services's Assistant Secretary for Planning and Evaluation found that Medicare Part B's payment rates (106 percent of ASP, or ASP + 6 percent) in 2018 were, on average, about double (2.05 times) the average prices in 19 high-income Organisation of Economic Co-operation and Development countries (Department of Health and Human Services 2020). Similarly, a study by Hwang and colleagues compared ASP for 67 Part B drugs with prices from 4 other high-income countries (Japan, Germany, Switzerland, and the U.K.). Median prices in the comparator countries were roughly 45 percent to 60 percent lower than ASP (Hwang et al. 2019).

Higher prices in the U.S. are the result of both higher launch prices and higher price inflation once products are on the market. According to research by Vokinger and colleagues on 65 new drugs approved between 2009 and 2019 to treat solid tumors and hematologic cancers, launch prices were substantially higher in the U.S. than in England, Germany, and Switzerland (Vokinger et al. 2021). Among the group of cancer drugs included in the study, the U.S. median monthly treatment costs at launch, adjusting for currency and inflation, were 45 percent higher than in Germany, 57 percent higher than in Switzerland, and 63 percent higher than in England. In addition, after launch of these products, prices tended to

increase faster than inflation for most products (74 percent) in the U.S., but not in England, Germany, or Switzerland (Vokinger et al. 2021).

Other countries' payment methods have evolved to address high launch prices and price increases over time. In our June 2019 report, we discussed how Germany refined its payment method to address rising drug spending and, since 2011, uses evidence on a drug's comparative clinical effectiveness in determining payment (Medicare Payment Advisory Commission 2019). In Appendix 4-A of this chapter, we describe Japan's use of multiple approaches to achieve price reductions over time.

Medicare coverage of Part A and Part B drugs

The Social Security Act requires that the Medicare program cover Part A and Part B items and services that are included in a Medicare benefit category, are not statutorily excluded, and are "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." Based on statutory and regulatory text, "traditional," or fee-for-service (FFS), Medicare covers on-label use of a drug that the FDA has approved that is reasonable and necessary for the beneficiary. According to the *Medicare Benefit Policy Manual*:

> Use of the drug or biological must be safe and effective and otherwise reasonable and necessary. . . . Drugs or biologicals approved for marketing by the Food and Drug Administration are considered safe and effective for purposes of this requirement when used for indications specified on the labeling. Therefore, the program may pay for the use of an FDA approved drug or biological, if:
>
> - It was injected [furnished] on or after the date of the FDA's approval;
> - It is reasonable and necessary for the individual patient;[2] and
> - All other applicable coverage requirements are met. (Centers for Medicare & Medicaid Services 2021)

In addition, the statute requires that Medicare cover off-label use of anticancer drug regimens if supported in the cancer compendia or peer-reviewed literature. Medicare may cover off-label use of noncancer drugs if the use is recognized, following Medicare's review of the peer-reviewed literature, as an appropriate treatment. Part B drug coverage is limited to products that are furnished "incident to" a physician's service, provided that the drugs are not usually self-administered by the patients who take them.

Some Part B drugs are covered without the need for an explicit coverage policy. If the product is used for indications that the FDA approved and can be reimbursed on the basis of an existing billing code or a bundled payment system (e.g., the inpatient prospective payment system), Medicare may cover it without an explicit coverage policy. However, even when a drug is used for an FDA-approved indication, there may be uncertainty about its clinical benefits (see text box on the FDA's expedited approval pathways, pp. 92–93).

For other products, either CMS or Medicare administrative contractors (MACs) make explicit coverage determinations under which a formal review of the medical, technical, and scientific evidence is conducted to evaluate the relevance, usefulness, and medical benefits of an item or service to Medicare beneficiaries, with opportunities for public participation. MACs develop the majority of explicit coverage policies through the local coverage determination (LCD) process, which determines coverage of items and services that apply only in the contractor's regional jurisdiction. CMS develops coverage determinations for items and services that apply nationwide through the national coverage determination (NCD) process. Outcomes of the coverage process include (1) Medicare coverage of an item or service with no restrictions, (2) covering a service for beneficiaries with certain clinical conditions or when furnished by certain providers or facilities, (3) leaving the coverage determination to the discretion of the MACs, or (4) Medicare not covering the service. CMS can initiate an NCD internally or can initiate one at a stakeholder's request due to specific circumstances such as the following:

- Practitioners, patients, providers, or other members of the public have raised significant questions about the health outcomes attributable to the use of services by Medicare beneficiaries.

The FDA's expedited approval pathways may shorten time to drug approval but can pose uncertainty for patients, clinicians, and payers

The role of the Food and Drug Administration (FDA) in the drug development process as a regulator is distinct and separate from the role of CMS as a payer. The FDA regulates whether a pharmaceutical product is "safe and effective" for its intended use by consumers. The FDA approval process may or may not include the new pharmaceutical product's safety or effectiveness with regard to the Medicare population, and it typically does not provide clinical evidence about a product's effectiveness relative to existing treatments. By contrast, the Medicare program adjudicates coverage and spending determinations based on the specific needs of the Medicare population.

The FDA approves most new drugs and biologics under two pathways—traditional or expedited. Traditional approval requires that manufacturers demonstrate the clinical benefit of a new drug before FDA approval. The four expedited pathways—fast track, breakthrough, accelerated, and priority—are used to approve drugs that treat serious conditions and address unmet medical needs, thus allowing patients quicker access to therapies compared with drugs approved under traditional pathways (Table 4-1).[3] Expedited pathway approvals are more likely to be based on surrogate outcomes, single-arm trials, phase I or II trials, and studies with smaller sample sizes and shorter duration than drugs approved under traditional pathways (Government Accountability Office 2015, Puthumana et al. 2018, Ribeiro et al. 2020). On average, a drug approved using an expedited pathway reaches market almost a year sooner than drugs approved under traditional pathways (Frakt 2018).

Evidence of a new product's effectiveness relative to existing treatments—comparative clinical effectiveness evidence—is often not collected under either the traditional or expedited approval pathways. Furthermore, because of expedited pathways' use of surrogate outcomes and other design features, clinicians, patients, and payers generally have less data with which to judge the benefits, risks, and value of products approved under expedited pathways compared with drugs approved under traditional pathways.[4,5] ■

(continued next page)

- Rapid diffusion of a service is anticipated, and the evidence may not adequately address questions regarding impact on the Medicare beneficiaries.

Our review of NCDs and LCDs for drugs found that (1) the coverage policies appear to be aligned with the FDA's label indications, and (2) some policies delineate off-label conditions (for noncancer drugs) and the types of facilities or providers that Medicare will cover. For example:

- In 2007, CMS opened an NCD internally in response to the FDA's boxed warning regarding the safety of erythropoiesis-stimulating agents (ESAs) when prescribed to treat cancer (i.e., nonrenal indications). The finalized NCD sets forth the Medicare-covered and noncovered indications of ESAs, which are aligned with the FDA's label and black box warnings (Centers for Medicare & Medicaid Services 2007).
- In 2019, CMS opened an NCD at a stakeholder's (United Healthcare) request to clarify the circumstances under which Medicare would cover chimeric antigen receptor T-cell (CAR–T) therapy. The finalized NCD covers CAR–T therapies when they are (1) administered at health care facilities enrolled in the FDA risk evaluation and mitigation

The FDA's expedited approval pathways may shorten time to drug approval but can pose uncertainty for patients, clinicians, and payers (cont.)

TABLE 4–1 **FDA's expedited drug approval pathways**

Approach	Criteria	Features
Fast track	A drug that: • is intended to treat a serious condition AND nonclinical or clinical data demonstrate the potential to address unmet medical need OR • has been designated as a qualified infectious disease product	• More frequent meetings and communications with FDA • Eligibility for accelerated approval and priority review if relevant criteria are met • Rolling review[a]
Breakthrough therapy[b]	A drug that treats a serious condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint(s)	• Impacts clinical trial design[c] • Eligible for all fast track designation features
Accelerated approval	A drug that treats a serious condition that fills an unmet medical need; approval based on a surrogate or intermediate clinical endpoint followed by confirmatory trials	• Priority review, fast track, and breakthrough drugs can also be eligible for accelerated approval
Priority review	A drug that is a significant improvement in the safety or effectiveness of the treatment, prevention, or diagnosis of a serious condition	• 6-month priority review versus 10-month standard review • Drugs qualifying for fast track, breakthrough therapy, and accelerated approval can also be eligible for priority review

Note: FDA (Food and Drug Administration).
[a] "Rolling review" means that a drug company can submit completed sections of its biologic license application (BLA) or new drug application (NDA) for review by the FDA, rather than waiting until every section of the NDA is completed before the entire application can be reviewed. BLA or NDA review usually does not begin until the drug company has submitted the entire application to the FDA.
[b] Similar to fast track, but breakthrough drugs must show early clinical evidence of substantial improvement over existing therapies.
[c] Because breakthrough drugs have early ability to benefit patients, the FDA aims to collaboratively examine a breakthrough drug's entire development program and, for example, take scientifically appropriate steps to minimize the number of patients receiving placebos or less efficacious treatment as part of the testing process.

Source: Food and Drug Administration 2022.

strategies and (2) used for a medically accepted indication as defined in Social Security Act Section 1861(t)(2)—that is, used for either an FDA-approved indication (according to the FDA-approved label for that product) or for other uses when the product has been FDA-approved and the use is supported in one or more CMS-approved compendia.

A small subset of NCDs links a service's national coverage to participation in an approved clinical study or to the collection of additional clinical data.[6]

This policy is referred to as coverage with evidence development (CED), and its goal is to expedite early beneficiary access to innovative technology while ensuring that patient safeguards are in place. CED allows coverage of certain items or services where additional data gathered in the context of clinical care would further clarify the impact of these items and services on the health of Medicare beneficiaries. Because CED provides Medicare the opportunity to generate clinical evidence that otherwise might not have been collected, it enables the program to ultimately develop better, more evidence-based policies. CED also provides an opportunity to collect clinical evidence for groups that are often underrepresented in clinical trials, including older beneficiaries and minorities. CMS currently applies CED to 21 items and services, and since the program's inception in 2005, 2 CED policies have been applied to drugs.[7]

For Part B drugs, FFS Medicare generally bases payments on manufacturer-reported or provider-reported data

FFS Medicare largely acts as a price taker for Part B–covered drugs and biologics and under current law can do little to affect the amount the program pays for these products. Part B covers drugs that are administered by infusion or injection in physician offices and hospital outpatient departments, as well as certain drugs furnished by suppliers. Under FFS Medicare, these providers purchase drugs in the marketplace to administer to patients for whatever price the provider is able to negotiate. FFS Medicare pays these providers a prospectively determined rate for a Part B–covered drug, regardless of what the provider paid for the product. In many cases, FFS Medicare makes a separate payment for each drug administered, and in other cases Medicare bundles payment for drugs with payment for other services.

Medicare pays physicians and hospital outpatient departments for Part B drugs based on the manufacturer's ASP. ASP reflects the average price realized by the manufacturer for sales to most purchasers net of rebates, discounts, and price concessions, with certain exceptions. ASP is determined by the manufacturer's pricing decisions and is generally unrelated to the clinical value of the product. Medicare pays physicians and outpatient hospitals for separately payable Part B drugs based on 106 percent of the average sales prices, except for 340B hospitals, to which Medicare pays a lower rate (ASP – 22.5 percent) for some products.[8]

In contrast, Medicare FFS pays some providers for Part B drugs as part of a broader payment bundle. For example, under the hospital outpatient prospective payment system (OPPS), hospitals are paid for a subset of Part B–covered drugs—those that are low cost or that function as supplies to a service—as part of the ambulatory payment classification (APC) payment for other services. The APC payment rates are determined based on a relative weight-setting process, in which CMS estimates the average cost of services associated with each APC, including bundled drugs.[9] Under the dialysis prospective payment system (PPS), Part B covers drugs furnished by end-stage renal disease (ESRD) facilities and makes a single case-mix-adjusted payment that bundles together payment for composite rate services and other ESRD-related services, including drugs.[10] The inclusion of drugs in the dialysis payment bundle has spurred price competition and use of the less costly product among some dialysis drug groups.

Medicare Part B currently has limited tools to manage drug prices

Under current policy, Medicare Part B lacks tools to influence launch prices for new products or spur price competition among competing brand alternative products. Medicare exerts no influence on spending for biologics and brand drugs without generic competitors. For these products, Medicare Part B pays each product an ASP-based rate under the product's own billing code. With respect to first-in-class products, this policy means that Medicare will pay whatever launch price the manufacturer establishes for a product without generic competitors. Even for therapeutic classes in which there are multiple brand products, Medicare pays each product under its own billing code based on its own ASP, which permits manufacturers to establish high launch prices for "me-too" products and does little to spur price competition.

In contrast, for brand drugs with generic competitors, Medicare Part B pays for the brand product and its generic equivalents in the same billing code based on

106 percent of a volume-weighted average ASP. This policy creates incentives for providers to select the lower-cost product within a billing code and in turn lowers the weighted average ASP in future calendar quarters, leading to substantial price reductions in payment rates for brand products after generic entry.

Medicare pays for biosimilars differently from its payment for generic drugs. Each biosimilar receives its own billing code and is paid 100 percent of its own ASP, plus 6 percent of the originator's ASP. Medicare payment rates for originator biologics and their biosimilars have declined to some degree, but not to the extent observed with generic drugs.

In 2017, to address the lack of tools that Medicare has to influence Part B drug prices and spending, the Commission recommended several improvements to payment for Part B drugs. Two of the recommended policies included:

- consolidated billing codes for biosimilars and originator biologics that would spur price competition among these products and
- a manufacturer ASP inflation rebate that would address price growth in the years after a product's launch.

The recommendation included additional policies such as improvements to ASP data reporting and to payment for drugs without ASP data (which have been fully or partially adopted) and the development of a voluntary alternative to the ASP payment system based on a private vendor approach (Medicare Payment Advisory Commission 2017).

Recommended policies (e.g., consolidated billing codes for biosimilars and originator biologics and an ASP inflation rebate), if adopted, would be important steps forward to reduce the prices Medicare Part B pays for certain drugs; nonetheless, several additional issues remain that increase spending for the Medicare program and beneficiaries. For new drugs, Medicare lacks tools to arrive at payment rates that balance an appropriate reward for innovation with affordability for beneficiaries and taxpayers. Medicare also has limited tools to promote price competition among Part B drugs with therapeutic alternatives. In addition, the 6 percent add-on to Medicare Part B's ASP payment rates may create incentives for some providers to select higher-priced products in some circumstances.

Price has been the biggest driver of spending growth

Medicare Part B spending on prescription drugs is substantial and has been growing rapidly. Between 2009 and 2019, FFS Medicare Part B drug spending grew nearly 10 percent per year, from $15.4 billion to $39.0 billion (Figure 4-1, p. 96). Growth in the size of the Medicare FFS population accounted for only a small portion of that spending growth: The total number of FFS beneficiaries with Part B grew only 0.4 percent per year on average from 2009 to 2019. In 2020, Medicare Part B drug spending growth slowed, increasing about 4 percent to $40.7 billion. The slower growth in 2020 is likely in part related to the effect of the coronavirus public health emergency.

The largest factor contributing to spending growth between 2009 and 2019 was the change in the average price Medicare paid for Part B drugs, which reflects increased prices for existing products; the introduction of new, higher-priced drugs; and shifts in the mix of drugs. Between 2009 and 2019, spending on separately payable Part B drugs climbed, on average, by nearly 12 percent per year (Table 4-2, p. 96).[11] We found that the average annual payment per drug increased at an average rate of 7.1 percent per year. The number of beneficiaries using Part B drugs also increased, about an average of 4.6 percent per year, while the number of Part B drugs received per user declined slightly during this period (by about 0.2 percent per year).

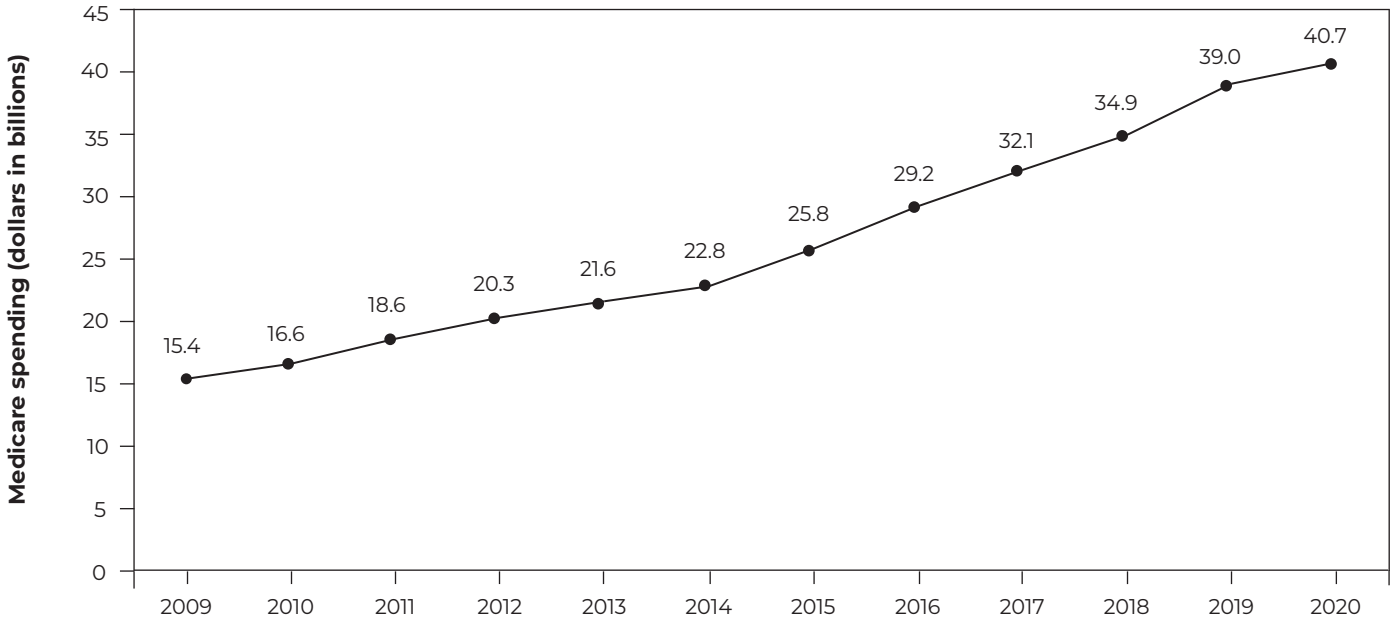
Medicare spending on Part B drugs

In 2020, Medicare and beneficiaries paid about $40.7 billion for Part B–covered drugs and biologics.[12] Although there are roughly 900 billing codes for Part B drugs, spending is concentrated. In 2020, Part B drug spending for the top 10 products, which were all biologics, accounted for $15.6 billion, or 38 percent of total Part B drug spending. Spending on the top 20 products accounted for $21.0 billion, or about 52 percent of total Part B drug spending.

The top 20 Part B drugs tend to be concentrated in certain therapeutic areas (Table 4-3, p. 97). Nine of the top 20 Part B drugs are for the treatment of

FIGURE 4–1

Medicare Part B drug spending has grown rapidly since 2009



Note: Data include Part B–covered drugs furnished by several provider types, including physicians, suppliers, and hospital outpatient departments, and exclude those furnished by critical access hospitals, Maryland hospitals, and dialysis facilities. "Medicare spending" includes program payments and beneficiary cost sharing. Data reflect all Part B drugs whether they were paid based on the average sales price or another payment formula. Data exclude blood and blood products (other than clotting factor).

Source: MedPAC and Acumen LLC analysis of Medicare claims data.

TABLE 4–2

Growth in the average price per Part B drug was the largest factor contributing to spending growth for separately payable Part B drugs, 2009–2019

	2009	2019	Average annual growth, 2009–2019
Total payments: Separately payable* Part B drugs, excluding vaccines (in billions)	**$11.7**	**$35.8**	**11.9%**
Number of beneficiaries using a Part B drug (in millions)	2.6	4.1	4.6
Average total payments per beneficiary who used a Part B drug	$4,420	$8,639	6.9
Average number of Part B drugs per user	1.39	1.36	–0.2
Average annual payment per Part B drug per user	$3,182	$6,343	7.1

Note: This analysis includes Part B drugs paid based on the average sales price as well as the small group of Part B drugs that are paid based on the average wholesale price or reasonable cost or that are contractor priced. "Vaccines" refers to three Part B–covered preventive vaccines: influenza, pneumococcal, and hepatitis B. Data include Part B drugs furnished by physicians, hospitals paid under the outpatient prospective payment system, and suppliers and exclude data for critical access hospitals, Maryland hospitals, and dialysis facilities. Yearly figures presented in the table are rounded; the average annual growth rate was calculated using unrounded data.

*For purposes of this analysis, spending on separately payable Part B drugs excludes any drug that was bundled in 2009 or 2019 (i.e., drugs that were packaged under the outpatient prospective payment system in 2009 or 2019 were excluded from both years of the analysis, regardless of the setting in which the drug was administered), drugs billed under not-otherwise-classified billing codes, and blood and blood products (other than clotting factor).

Source: MedPAC analysis of Medicare claims data for physicians, hospital outpatient departments, and suppliers.

TABLE 4–3

The top 20 highest-expenditure Part B drugs accounted for 52 percent of total Part B drug spending in 2020

		2020				
Part B drug	**Indication**	**Number of beneficiaries who used product**	**Total spending (in billions)**	**Average annual spending per user**	**Average annual ASP growth 2005–2022**	**Earliest year of ASP data if not 2005**
Keytruda	Cancer	58,900	$3.5	$59,400	2.3%*	2016
Eylea	MD	286,900	3.0	10,500	–0.8*	2013
Prolia/Xgeva	OS, cancer SE	587,200	1.6	2,800	3.9*	2012
Opdivo	Cancer	25,500	1.6	62,200	2.4*	2016
Rituxan	Cancer, RA	57,400	1.3	22,700	4.0	
Lucentis	MD	121,600	1.1	9,200	–2.0*	2008
Orencia	RA	30,100	1.0	34,100	6.0*	2007
Neulasta	Cancer SE	67,800	0.9	13,300	–0.2	
Darzalex	Cancer	13,000	0.8	64,600	4.0*	2017
Avastin	Cancer, MD	176,500	0.7	3,900	1.0	
Remicade	RA	45,100	0.7	14,800	–2.0	
Tecentriq	Cancer	12,500	0.6	50,000	1.2*	2018
Ocrevus	MS	12,500	0.6	49,900	0.8*	2018
Soliris	Autoimmune	1,700	0.6	363,800	1.9*	2008
Cimzia	RA	19,700	0.5	25,900	4.4*	2010
Imfinzi	Cancer	9,200	0.5	55,000	0.8*	2020
Alimta	Cancer	18,700	0.5	26,700	3.8	
Fluzone High-Dose	Vaccine	8,046,600	0.5	60	7.6***	2011
Herceptin	Cancer	13,500	0.5	34,400	2.9	
Sandostatin LAR Depot	Cancer SE	10,000	0.4	44,800	5.3	
Top 20 drugs			21.0			
All Part B drugs			40.7			

Note: ASP (average sales price), MD (macular degeneration), OS (osteoporosis), SE (side effects), RA (rheumatoid arthritis), MS (multiple sclerosis). The drugs shown in the chart reflect the 20 Part B drug billing codes with the highest total Medicare spending in 2020. "Total spending" includes Medicare program payments and beneficiary cost sharing. Number of beneficiaries, total spending, and average spending per user displayed in the table are rounded; average spending per user was calculated using unrounded numbers. For originator biologics that have biosimilar competitors, data in the table reflect only the originator biologic. If spending for an originator biologic and its biosimilars is summed, 2020 total spending was $1.6 billion for Rituxan, $1.2 billion for Neulasta, $1.0 billion for Avastin, $0.8 billion for Remicade, and $0.7 billion for Herceptin and their biosimilars.
*Product was not on the market for the full period from 2005 to 2022. The average annual growth rate was calculated using the alternate base year displayed through 2022.
**Fluzone High-Dose is a preventive vaccine paid based on 95 percent of the average wholesale price. Percent change in actual payment rate rather than ASP is displayed in the table.

Source: MedPAC analysis based on claims data, publicly available ASP payment rate files, and outpatient prospective payment system Addendum B from CMS.

cancer, and another three are supportive drugs used to treat cancer side effects. Three of the top 20 are used to treat macular degeneration. Four of the top 20 Part B products are used to treat rheumatoid arthritis. The top 20 also include one product for multiple sclerosis, one extremely high-cost product (spending greater than $300,000 per patient per year) for rare autoimmune conditions, and one influenza

TABLE 4–4

Prices for certain biologics have declined due to biosimilar entry, after substantial price growth for these products during the preceding 10-year period

	First biosimilar entry	Percent change in originator biologic's ASP: In 10 years before biosimilar entry	Percent change in originator biologic's ASP: Since biosimilar entry (through 2022 Q1)	Biosimilars' payment rate as a percentage of originator biologic's payment rate (2022 Q1)	Biosimilar market share (2021 Q1)
Neupogen and biosimilars	2015 Q3	71%	–1%	31–46%	79%
Remicade and biosimilars	2016 Q4	54	–55	105–120%	19
Neulasta and biosimilars	2018 Q3	117	–54	111–148%	31
Procrit/Epogen and biosimilars	2018 Q4	35	–33	99%	54
Avastin and biosimilars	2019 Q3	42	–17	59–75%	56
Herceptin and biosimilars	2019 Q3	69	–19	55–71%	56
Rituxan and biosimilars	2019 Q4	68	–10	66–75%	43

Note: ASP (average sales price), Q (quarter). An originator biologic is a drug product derived from a living organism. A biosimilar product is a follow-on product that is approved by the Food and Drug Administration (FDA) based on the product being highly similar to the originator biologic. The biosimilars included in the analysis are Zarxio, Nivestym, and Granix for originator Neupogen; Inflectra, Renflexis, and Avsola for originator Remicade; Fulphila, Udenyca, Ziextenzo, and Nyvepria for originator Neulasta; Retacrit for originator Procrit/Epogen; Mvasi and Zirabev for originator Avastin; Ontruzant, Herzuma, Ogivri, Trazimera, and Kanjinti for originator Herceptin; and Truxima, Ruxience, and Riabni for originator Rituxan. Although Granix is not a biosimilar in the U.S. (because it was approved under the standard FDA approval process for new biologics), we include it here because it was approved as a biosimilar to Neupogen in Europe and it functions as a competitor to Neupogen in the U.S. market. "First biosimilar entry" date reflects the earliest market date for a product approved by the FDA as a biosimilar to the originator biologic.

Source: MedPAC analysis of Medicare ASP payment rate files publicly available on CMS website and Medicare claims data for physicians and outpatient hospitals.

vaccine product. The top 20 Part B drugs did not change between 2019 and 2020, although the ranking of some products within the top 20 shifted.[13]

The patterns of spending among the top 20 products illustrate the effect of high launch prices on Medicare spending. For example, two products—Keytruda and Opdivo—were approved in late 2014 and belong to a newer class of immune-oncology biologics. Spending on these products in 2020 was $3.5 billion and $1.6 billion, respectively, reflecting these products' substantial launch prices as well as additional price inflation after launch. In 2020, average annual Medicare spending per user for these products was about $59,000 and $62,000, respectively. Other recently launched cancer products in the top 20, such as Darzalex, Imfinzi, and Tecentriq, also had average annual spending per patient of about $50,000 or more.

Price inflation among products that have been on the market for a longer period also contributes to spending growth. For example, Alimta, Cimzia, Darzalex, Orencia, Prolia/Xgeva, Rituxan, and Sandostatin LAR Depot have all experienced average ASP growth of between 3.8 percent and 6.0 percent per year between 2005 and 2022 (or since launch if after 2005) (Table 4-3, p. 97). Fluzone High-Dose, which is paid 95 percent of the average wholesale price, also experienced substantial price growth (7.6 percent per year on average over the analysis period).

Biosimilar entry has led to some price competition. Recently, some biologics, including several in the top 20 (Rituxan, Herceptin, Neulasta, Avastin, and Remicade), have faced biosimilar entry. Biosimilars have resulted in savings because originators have

generally lowered their prices in response to biosimilar competition and because biosimilar prices are in some cases substantially below innovators' prices (Table 4-4).[14] These price reductions, however, have come after many years of price growth for the originator biologics. Medicare's ASP + 6 percent payment rate for the 7 originator biologics that now face biosimilar competition increased substantially in the 10 years before biosimilar entry, with price growth ranging from 35 percent to 117 percent over that period (Table 4-4).

Drug research and development

As we consider changes to Medicare's payment approach for Part B drugs, it is important to consider the implications for drug R&D and innovation.

The price that Medicare and other entities pay for drugs is one of many factors that influence manufacturer R&D investment. According to the Congressional Budget Office (CBO), manufacturer R&D investment is influenced by the expected lifetime global revenues a new drug would generate, the expected cost of developing the new drug, and any policies that affect supply or demand for the drug (Congressional Budget Office 2021b). Expected global revenues from new drug development depend on the prices and volume of sales that companies expect in different markets and the likelihood that drug development efforts will succeed (Congressional Budget Office 2021b). Several studies have found a positive relationship between market size, as measured by expected revenue or other related proxies, and R&D investment, such as the number of products undergoing clinical trials or the number of new products launched (Blume-Kohout and Sood 2013, Cerda 2007, Dubois et al. 2015). Because Medicare's payment rates for drugs contribute to expected global revenues, changes in how Medicare pays for drugs could have some influence on R&D spending, all else being equal.

Not only is the amount of R&D investment of interest, but also the type of products R&D is focused on. In response to the establishment of Medicare Part D, several studies found increased clinical trial activity among drugs intended to treat clinical conditions prevalent among Medicare beneficiaries (Blume-Kohout and Sood 2013, Dravone et al. 2020). However, Dravone and colleagues found the increase in clinical trial activity was most pronounced among "less scientifically novel" products, whereas clinical trials for products that were in the most scientifically novel category (meaning the first use of a targeted base action) increased only modestly (Dravone et al. 2020).

R&D is influenced by many factors beyond Medicare policy, including regulatory policies related to drug approval, patents and intellectual property, and tax policy; payment policies of other payers within the U.S. and internationally; the cost of drug development, including capital availability and costs; and collaboration between pharmaceutical manufacturers and academic institutions (Congressional Budget Office 2021b). In addition, the federal government contributes to innovation both indirectly (through its substantial funding of basic science research) and directly (through its funding of drug development research for some products) (Galkina Cleary et al. 2018, Sampat and Lichtenberg 2011).

Some stakeholders raise concerns that policies aimed at reducing Medicare spending for drugs would reduce drug R&D and innovation. For example, Danzon and Ketcham argue that certain policies to reduce drug prices for on-patent innovator drugs reduce the manufacturer's ability to recoup the costs of R&D, which in turn negates the intent of patents and undermines the incentives for product improvement or innovation (Danzon and Ketcham 2004). CBO released a working paper discussing the agency's simulation model to analyze legislation that may affect drug development (Congressional Budget Office 2021a). CBO's model assumes that policies that reduce earnings for drug manufacturers would lead to some reduction in the number of new drugs developed; however, CBO explicitly makes no assumptions about the types of new drugs affected or the effect on health outcomes.[15]

Even if changes in payment policy influence the number of new drugs, it is possible that payment policy changes focused on a drug's net clinical benefit will drive R&D investment toward products that have potential for larger impacts on patient health and expected profitability. For example, Sachs and Frakt suggest that some drug payment policy changes,

including reference pricing, have the potential to shift the mix of innovation toward drugs that provide more value (Sachs and Frakt 2016). Under the current process, drug development typically focuses on a stand-alone assessment of the safety and efficacy of a product. In an environment that considers a drug's comparative clinical effectiveness, manufacturers would have an incentive to compare the efficacy of their product with other products in the clinical trials they sponsor to demonstrate the clinical benefit that their product offers over existing treatments.

To promote innovation, it could be argued that drug manufacturers should receive a reasonable return on investment for the development of new, innovative products. However, under current Medicare policy, drug manufacturers are largely able to set their own prices even when incremental benefits to Medicare beneficiaries are low or are not well established. Payment policy approaches such as comparative effectiveness analysis and reference pricing could be used to account for a drug's net clinical benefit and spur competition in the system.

Addressing uncertain clinical benefit and high launch prices of first-in-class drugs

For costly new drugs that face limited or no competition, such as the first drug in a class, manufacturers have significant market power to set prices. Medicare lacks authority to consider a drug's net clinical benefit compared with the standard of care to set its payment rate. In essence, the program has no way of ensuring that Medicare's payments for new drugs covered under Part B do not exceed the products' incremental clinical benefits relative to existing treatments. In addition, certain first-in-class drugs are approved with uncertain clinical benefit.

One approach to address the lack of evidence and high launch price of certain "first-in-class" drugs would (1) collect evidence on the product's risks and benefits through CED and (2) set a cap on a drug's payment using information about the new product's clinical benefit compared with the standard of care.[16] We consider this approach specifically for accelerated approval drugs because the FDA approves the products based only on surrogate or intermediate clinical endpoints. Several of the top 20 drugs have been approved through accelerated approval pathways for some indications, including Alimta, Avastin, Darzalex, Imfinzi, Keytruda, Opdivo, and Tecentriq. In some cases, the products have been converted to full approval after securing confirmatory evidence, while trials are still underway for specified indications for some of these products. In several cases, approvals for specified indications were withdrawn after trials failed to confirm clinical benefits for patients with that condition (Food and Drug Administration 2022). Examples of drugs that lost approval for specified indications include Avastin and Tecentriq for breast cancer, Keytruda for previously treated gastric cancer, Opdivo for hepatocellular carcinoma as a single agent, Keytruda and Opdivo for small cell lung cancer, and Imfinzi and Tecentriq for urothelial carcinoma in certain circumstances.

This dual approach would likely lead to:

- development of better clinical evidence after FDA approval and
- better alignment of payment with the known clinical benefit of the drug.

Moreover, this dual approach would "help implement the infrastructure necessary to generate complementary real-world evidence while limiting the financial risk of using products with uncertain benefit" (Lederer and Dusetzina 2021). The use of CED and a payment cap could evolve over time. Based on new clinical evidence that the drug manufacturer and other providers gather after FDA approval, Medicare could reevaluate the level of the application of CED and the payment rate. Doing so might also provide strong incentives for the completion of post-approval trials (Gyawali et al. 2021).

For first-in-class drugs with high launch prices and unclear clinical evidence, we envision that the Secretary would have discretion in applying a dual approach using CED and setting a cap on payment based on the new product's net clinical benefit. CMS already applies CED in the NCD process to services covered under Medicare Part A and Part B.[17] Applying

CED under this dual approach is not intended to affect the program's ongoing application of CED for other items and services.

The Congress would need to provide the Secretary with statutory authority to set a cap on a new drug's payment based on factors such as its net clinical benefit compared with the standard of care. On two occasions, Medicare tried to consider clinical benefit and/or cost in the coverage process when determining whether an item or a service was reasonable and necessary. In 1989, the agency issued a proposed regulation that explicitly considered the cost-effectiveness of services in the coverage process. In 2000, CMS released a notice of intent (NOI) on new criteria that would have considered cost in the coverage process only for services that provided equivalent clinical benefits compared with an existing covered service but were more costly. Neither the 1989 proposed rule nor the new criteria included in the NOI were finalized.

Need for more systematic use of CED in Medicare

More systematic use of CED is an approach that could generate clinical evidence to cover products that lack evidence showing their clinical effectiveness in specific patient populations. Some items and services diffuse quickly into routine medical care with incomplete information about their clinical effectiveness. At the time of FDA approval, evidence on some new medical products may be incomplete, particularly for those drugs in which surrogate and intermediate endpoints were the basis of their approval under the accelerated approval pathway. CED is a policy that CMS has implemented in the NCD process. Using CED more systematically would help generate clinical effectiveness evidence to support coverage and use of products in certain patient populations. Under CED, beneficiaries have access to medical services while clinical evidence is being collected in prospective clinical studies and registries. The Commission supported CMS's use of CED for coverage of CAR-T products, a type of immunotherapy used to treat certain types of cancer, and Aduhelm, a treatment for Alzheimer's disease (Medicare Payment Advisory Commission 2022a, Medicare Payment Advisory Commission 2021).

Since 1995, Medicare has linked coverage to the collection of clinical evidence.[18] In making coverage decisions involving CED, CMS (as part of the NCD process) can decide, after a formal review of the medical literature, to cover a service only in the context of an approved prospective clinical study or when additional clinical data are collected to assess the appropriateness of an item or service for use with a particular beneficiary. In 2006, CMS formally adopted CED (issued in guidance). As of March 2022, 21 NCDs included a CED policy (Table 4-5, pp. 102–103), but few were related to drug therapies. The design of each CED effort has varied, depending on the service and circumstance leading to the CED policy. A CED cycle is considered "completed" when CMS completes a reconsideration of the coverage determination and removes the CED requirement as a condition of coverage. CMS has removed the CED requirement for the following services:

- implantable cardioverter defibrillators (CED released in 2005 and removed in 2018);
- fluorodeoxyglucose–positron emission tomography (FDG–PET) imaging for cancers (CED released in 2005 and removed in 2013);
- artificial hearts (CED released in 2008 and removed in 2020);
- MRI for beneficiaries with implanted cardiac devices (CED applied in 2011 and removed in 2018); and
- home use of oxygen to treat cluster headaches (CED released in 2011 and removed in 2021).

The benefits of applying CED include improving postmarket evidence development and providing important new knowledge for care decisions and clearer understanding for patients, providers, and payers regarding the risks and benefits of a new intervention. CED could help support, and be reinforced by, other efforts to improve the postmarket data infrastructure (McClellan 2012). CED, along with other postmarketing surveillance efforts implemented by the manufacturer, could be used by Medicare to establish a payment rate. For example, Medicare payment could be lowered if the product does not demonstrate that it is better than an existing standard of care (Pearson and Bach 2010).

TABLE 4–5 **Medicare's ongoing coverage with evidence development studies**

CED	Year CED released	Study type and CMS approval year	Sponsor
Allogeneic hematopoietic stem cell transplant for myelodysplastic syndromes	2010	Clinical trials approved by CMS, 2010, 2013	Medical College of Wisconsin, Center for International Blood and Marrow Transplant Research
Allogeneic hematopoietic stem cell transplant for multiple myeloma	2016	Clinical trial approved by CMS, 2017	Center for International Blood and Marrow Transplant Research
Allogeneic hematopoietic stem cell transplant for myelofibrosis	2016	Clinical trial approved by CMS, 2016	Medical College of Wisconsin
Allogeneic hematopoietic stem cell transplant for sickle cell disease	2016	Clinical trials approved by CMS, 2016–2017	Medical College of Wisconsin
Autologous platelet-rich plasma	2012	Clinical trials, Medicare claims analysis approved by CMS, 2013–2019	Reapplix, RegenLab SA, ACR Biologics LLC, and others
Beta amyloid PET in dementia and neurodegenerative disease	2013	Clinical trials approved by CMS, 2014–2020	American College of Radiology, University of Utah, NIA
Cochlear implantation	2005	Clinical trial approved by CMS, 2013–2018	MED-EL Corporation, Washington University School of Medicine, Advanced Bionics, and others
Continuous positive airway pressure for obstructive sleep apnea	2008	No clinical trial is listed on CMS's website	—
Extracorporeal photopheresis for bronchiolitis obliterans syndrome following lung transplant	2012	Clinical trial approved by CMS, 2014	Washington University School of Medicine
FDG–PET and other neuroimaging devices for dementia	2004	Clinical trial approved by CMS, 2006	University of California, Los Angeles
Home oxygen for chronic obstructive pulmonary disease	2006	Clinical trial approved by CMS, 2006	NHLBI

Implementation issues

The Commission contends that CED can generate useful clinical evidence at the same time as patients are provided access to a service and that Medicare can use this evidence to refine its coverage policies (Medicare Payment Advisory Commission 2021, Medicare Payment Advisory Commission 2020, Medicare Payment Advisory Commission 2010). However, CMS lacks a well-defined, consistent approach to (1) designing CED studies, (2) developing methods, and (3) setting a time line to reevaluate Medicare's payment for the service under study (Medicare Payment Advisory Commission 2010).

Ensuring that the CED process is clear, transparent, and predictable and includes a process for public input is

TABLE 4-5 **Medicare's ongoing coverage with evidence development studies** *(cont.)*

CED	Year CED released	Study type and CMS approval year	Sponsor
Leadless pacemakers	2017	Clinical trials approved by CMS, 2017	Abbott Medical Devices, Medtronic
NaF–18 PET for bone metastasis	2010	Registry approved by CMS, 2010	American College of Radiology
Off-label use of colorectal cancer drugs	2005	Clinical trials approved by CMS, 2005–2006	NCI, Alliance for Clinical Trials in Oncology, Eastern Cooperative Oncology Group, and others
Percutaneous image-guided lumbar decompression for lumbar spinal stenosis	2014	Clinical trials, Medicare claims analysis approved by CMS, 2014, 2017	Vertos Medical, VertiFlex Inc.
Percutaneous left atrial appendage closure	2016	Clinical trials, registry approved by CMS, 2016–2022	Boston Scientific, American College of Cardiology
Pharmacogenomic testing for warfarin response	2009	Clinical trials approved by CMS, 2009–2010	Washington University School of Medicine, Iverson Genetic Diagnostics Inc.
Transcutaneous electrical nerve stimulation for chronic low back pain	2012	No clinical study has been approved by CMS	—
Transcatheter aortic valve replacement	2012	Registry, clinical trials approved by CMS, 2012–2022	Society of Thoracic Surgeons, Edwards Lifesciences, Medtronic, and others
Transcatheter edge-to-edge repair	2014	Registry, clinical trials approved by CMS, 2014–2022	American College of Cardiology, Cardiothoracic Surgical Trials Network, Abbott, and others
Vagus nerve stimulation for treatment-resistant depression	2019	Clinical trial approved by CMS, 2019	LivaNova

Note: CED (coverage with evidence development), PET (positron emission tomography), FDG–PET (fluorodeoxyglucose–PET), NIA (National Institute on Aging), NHLBI (National Heart, Lung, and Blood Institute), NaF (sodium fluoride), NCI (National Cancer Institute).

Source: MedPAC analysis of CMS's Medicare coverage database.

key. Currently, when CMS decides to develop a national coverage policy (with or without a CED policy), the agency provides public notice and seeks input from the public and clinical evidence from manufacturers and physicians. For example, after CMS posts proposed NCDs, stakeholders may submit written comments to the agency. CMS responds to these comments in its final NCDs, which are published on the agency's website.

Some researchers argue that clearer statutory authority might enable Medicare to develop a more systematic approach in applying CED (Daniel et al. 2013, Mohr and Tunis 2010). Medicare's statutory justification to apply CED has shifted over time. The agency's early CED decisions were made under the Secretary's authority to cover items and services that

are "reasonable and necessary" (in Section 1862(a)(1)(A) of the statute). NCDs issued since 2006 rely on the Secretary's authority under the statute's Section 1862(a)(1)(E), which allows Medicare payment for services determined by the Agency for Healthcare Research and Quality (AHRQ) to reflect the research needs and priorities of the Medicare program.[19,20] When CED under this section is required, it is because there are outstanding questions about the service's health benefit in the Medicare population. As such, the service is covered only in the context of a study that requires patient monitoring, data collection, and an open presentation of results. When CED under Section 1862(a)(1)(A) is required, it is because additional clinical information is needed to ensure the appropriate use of the service in the Medicare population to facilitate accurate claims processing and payment (Centers for Medicare & Medicaid Services 2014). Mohr and Tunis argue that the agency's lack of clear statutory authority has affected the research questions and study design of the CED effort, the clinical evidence that was collected, and Medicare's ability to develop a proactive mechanism to identify potential CED topics (Mohr and Tunis 2010).[21]

Stakeholders have raised other issues about the implementation of CED, including:

- ***Developing a process to identify potential candidates for CED.*** Currently, Medicare lacks a process to actively identify and determine which medical services—new services or new indications of existing services—would be suitable candidates for CED. CED generally has been applied on a case-by-case basis within the time frame of an NCD (McClellan 2012, Tunis et al. 2011). Some health plans in the U.S. have developed such a capability (Institute of Medicine 2008). Such a process might include criteria (e.g., disease prevalence, mortality, morbidity, practice variation, information gaps, estimated benefits and risks over existing therapies, and duplication with existing research efforts) for evaluating whether a service is a candidate for CED. A more proactive process with predictable priorities and implementation might lead to a more efficient CED process (McClellan 2012).

- ***Designing CED studies.*** Some observers have raised concerns about whether CMS has sufficient time to consider applying CEDs. The agency deliberates on CEDs in the NCD process under the following deadlines the Congress established: (1) six months to issue an initial draft of an NCD that does not require a technology assessment or deliberation from the Medicare Evidence Development and Coverage Advisory Committee and (2) nine months for an NCD that requires such an assessment or deliberation. At issue is whether CMS is able to develop well-considered methods for CED implementation within this time frame. Researchers have also suggested that CMS should provide periodic evaluation and updates of ongoing CED studies.

- ***Establishing a time frame to reconsider CED.*** CMS lacks a specific time frame as to when it will reevaluate Medicare's coverage for a service studied under CED. There have been five instances to date in which CMS removed a service's CED. The concern is that without time lines, the goal of CED—to evaluate the clinical effectiveness of a service—may not be achieved. That is, a service whose clinical effectiveness is not well established could be covered under a CED indefinitely.

- ***Funding CED efforts.*** In some, but not all, instances, the lack of a designated funding source to pay for the research costs of CED studies has delayed the start of the data collection effort. Medicare pays for the cost of services being studied under CED. However, Medicare generally does not fund clinical research and data collection activities. The lack of Medicare funding means that other public sources, such as the National Institutes of Health, or private sources, such as medical societies, providers, and product developers, are needed to cover a CED's research costs (Tunis et al. 2011). Some analysts have called for a more systematic and dedicated approach to fund CED (primarily focused on the administrative costs of conducting a CED study) that would ease its implementation, while some observers have suggested that CED applications should build on existing/emerging registries and data collection networks and partner with other organizations, including relevant regulatory bodies and private payers.

Finally, a key challenge is that CED is likely to face pushback from multiple stakeholders, including clinical and patient communities as well as product manufacturers. Recent proposed CED policies for

CAR–T products exemplify concerns from stakeholders related to patient access, higher administrative burden, and duplication of or competition with FDA review and approval.

In 2019, CMS proposed to apply CED in its NCD for CAR–T products, which, based on publicly available payment rate information under the OPPS in effect as of January 2022, are paid roughly $400,000 to $450,000 per treatment. The proposed CED policy would have covered the products when they were furnished in a CMS-approved registry or clinical study, in which patients would be monitored for at least two years post-treatment. CMS anticipated that the clinical evidence obtained from the CED would help the program identify the types of patients who benefit from CAR–T therapy (Centers for Medicare & Medicaid Services 2019a). However, stakeholders raised concerns about the additional administrative burden of CED and potential patient access issues (American Society of Gene + Cell Therapies 2019, Twachtman 2019).[22] When CMS finalized its NCD for CAR–T therapies, the agency did not implement the CED policy (Centers for Medicare & Medicaid Services 2019b).

Since CMS issued the final NCD for CAR–T products (without invoking CED), some clinicians have noted that limited clinical information exists regarding the products' adverse effects. For example, according to Gupta and colleagues, "extremely limited information exists regarding adverse kidney manifestations or electrolyte disorders in patients receiving CAR–T therapy, with existing data derived from clinical trials rather than real-world practice and mostly limited to the pediatric population with acute lymphoblastic leukemia" (Gupta et al. 2020b). The completion date of the final reports of the postapproval trials that the FDA is requiring of each manufacturer of a CAR–T product is more than 15 years in the future (in 2037 and beyond).

Setting a cap on the payment for Part B drugs

For costly new drugs that face limited competition, such as the first drug in a class, manufacturers have significant market power to set prices, and payers—including Medicare—currently have very limited ability to influence those prices. Under Section 1847A of the Social Security Act (which established the ASP-based system for Part B drugs), FFS Medicare lacks the authority to use tools to pay for Part B drugs in a way that balances a drug's net clinical benefit with both an appropriate reward for innovation and affordability for beneficiaries and taxpayers. Consequently, Medicare's Part B payment rate for a drug may have little relationship to a drug's clinical effectiveness compared with other available treatments. Under the Part B ASP-based payment system, the program is a price taker, and a drug manufacturer with a new product with limited competition effectively sets its own Medicare payment rate. Linking information about the net clinical benefit of health care services to FFS payment policies has the potential to improve Medicare payment policies (Medicare Payment Advisory Commission 2007). Medicare rarely uses such information to set payment rates.[23]

There are different policy options to address high launch prices of first-in-class drugs with unclear clinical benefit. In the Commission's 2019 report to the Congress, we discussed a policy that would permit the Secretary to enter into binding arbitration with drug manufacturers for costly new Part B drugs that have limited competition, such as the first drug in a class or a product that offers added clinical benefit over existing treatments (Medicare Payment Advisory Commission 2019). In this chapter, we discuss an approach to set a cap on the payment rate of select first-in-class drugs that have unproven clinical benefit using information about products' net clinical benefit and cost-effectiveness. Such an approach would address instances in which the manufacturer sets a high price for a new product with little or no evidence that it is more effective than existing standards of care.

Comparative clinical effectiveness of two or more treatment options for the same condition serves as the foundation for cost-effectiveness analysis (CEA). For most items and services, including most pharmaceuticals, Medicare lacks statutory authority to consider evidence on cost-effectiveness in either the coverage or payment processes.[24] CEA compares the incremental cost in dollars of one intervention with another in creating one unit of health outcome. It has been used to assess a wide range of interventions, including vaccination against pneumococcal pneumonia, bypass surgery for coronary artery disease, and diabetes prevention programs. The results of CEAs are typically summarized in a series

of incremental cost-effectiveness ratios that show, for one intervention compared with another, the cost of achieving an additional unit of health (outcome). To estimate expected health effects and costs, CEAs require data on each treatment's clinical effectiveness (including comparative clinical effectiveness evidence, if available), health outcomes, and health care resource use and costs.

CEAs measure the effect (outcome) of a medical intervention in terms of the quantity of health gained. Some CEAs express health benefits in terms of outcomes specific to the treatment and disease under investigation, such as the number of cancer cases prevented or the number of cancer-related hospital admissions prevented. Alternatively, other CEAs express health benefits in terms of the number of years of life gained. Under this approach, an added month of life with disability or pain is valued the same as an added month without disability or pain.

A related outcome measure—quality-adjusted life years (QALYs)—accounts for gains in both the quantity and quality of health gained, is widely used in economic evaluations, and has been endorsed by several CEA research panels (Gold et al. 1996, Neumann et al. 2017). However, there is debate among researchers and stakeholders about their use, centering on the methods used to develop QALYs as well as concerns that QALYs may be biased against certain populations, including the elderly and the disabled (Drummond et al. 2015, Gold et al. 1996). The Affordable Care Act of 2010 prohibits the Secretary from using QALYs (or similar measures) as a threshold to determine Medicare coverage or reimbursement.[25]

Pharmaceutical manufacturers are common sponsors of cost-effectiveness studies (published in peer-reviewed literature). For example, in a review of CEAs published between 1991 and 2012 that examined breast cancer drugs, 62 percent (65 of 105 studies) were sponsored by pharmaceutical manufacturers (Lane et al. 2016). An earlier analysis found that nearly half of the cost-effectiveness studies published between 1988 and 1998 on cancer drugs (20 of 44 studies) were sponsored by pharmaceutical manufacturers (Friedberg et al. 1999).

Reports in the lay press suggest an increasing interest in examining information on the comparative clinical effectiveness and cost-effectiveness of medical interventions (Cohen 2019). In particular, pharmacy benefit managers, insurers, and government agencies show increasing interest in using reports by ICER on products' comparative clinical and cost-effectiveness in negotiating pricing and preferred formulary placements with manufacturers (Berkrot 2017).[26] Medicare organizations that take on financial risk, including Medicare Advantage (MA) plans and accountable care organizations, have flexibility in using cost-effectiveness in the design of their medical and pharmacy management programs.

Implementation issues

There are several implementation issues to consider in setting a cap on a new drug's Part B payment rate based on its net clinical benefit. Medicare would need to develop a clear and predictable decision-making framework that ensures transparency and opportunities for public input. A key issue is which entity should sponsor CEAs—manufacturers, Medicare, or both, or Medicare with other public payers and private groups (e.g., academia).

Medicare would also need to consider the methods for conducting cost-effectiveness analyses and the procedures for evaluating evidence on cost-effectiveness.[27] Methodological issues that the program would need to consider when designing such a process include:

- ***The selection of comparator treatments.*** Omission of relevant comparators can produce misleading results. For example, researchers may overestimate the cost-effectiveness of an intervention (and underestimate its incremental cost-effectiveness ratio) because an intervention has not been compared with more cost-effective alternatives that are available (Drummond et al. 2015). According to Bach, "Highly expensive but poorly effective treatments look good when they are marginally superior on either dimension (i.e., slightly less expensive or slightly more effective) to the treatment they are replacing. The picture can be quite different when you compare new treatments with a lower-cost alternative" (Bach 2015). For example, the absence of active surveillance for treating localized prostate cancer would alter the comparative clinical effectiveness

and cost-effectiveness of the other treatment options (e.g., radiation therapy, surgery, hormone therapy).

- ***The method of defining costs.*** Costs include direct medical (e.g., cost of medical services to payers and patients), direct nonmedical (e.g., transportation costs), and non–health care costs (also referred to as indirect costs). For example, lost productivity (an indirect cost) measures monetary effects associated with impaired ability to work or engage in leisure activities and lost economic productivity due to death.
- ***The prices of comparator drugs.*** The assignment of prices or costs to pharmaceuticals (as well as other medical services) to which the product being evaluated is compared will affect the results and conclusions that are derived from CEAs. For example, under a payer (health system) perspective, some researchers use as price estimates for comparator products, when available, ASP or other price estimates that are net of discounts, rebates, and other price concessions as the base-case input for prices.[28] However, if comparator products are priced high relative to their net clinical benefit, those high prices will carry through into the price determination of the new product.
- ***The perspective of the analysis.*** A cost-effectiveness analysis from a societal perspective includes everyone who is affected by the service, all health outcomes and costs borne by insurers and patients, other medical costs, and nonmedical costs. By contrast, a cost-effectiveness analysis from a health care purchaser's viewpoint would include only those outcomes and costs that affect the purchaser.
- ***The time horizon.*** Researchers must choose the period of time to measure a service's costs and outcomes. The time horizon of the analysis should extend far enough into the future to capture important health effects, and the choice of a time horizon should not bias the analysis in favor of one intervention over another (Drummond et al. 2015). Analyses with a societal perspective often follow patients over their lifetime, while analyses with a health care purchaser's perspective typically use a shorter time period (e.g., five years).
- ***The discounting of costs and outcomes.*** When the time horizon of the analysis extends into the future, researchers often convert future costs and future health outcomes to present value. In doing so, researchers adjust the cost-effectiveness ratios for the different timing of cost and outcomes.

An illustrative example of applying CED and setting a cap to cover and pay for a new drug: Aduhelm

The newly approved Alzheimer's biologic Aduhelm exemplifies the challenges the Medicare program faces with coverage and payment for new drugs.

First, the first-in-class product was approved by the FDA under the accelerated approval pathway with limited, conflicting data on its clinical effectiveness, using surrogate endpoints. Available evidence has not yet tied reductions in brain plaque to improved cognitive outcomes. The FDA is requiring the manufacturer (Biogen) to conduct a new randomized, controlled clinical trial to verify the drug's clinical benefit within a nine-year time frame (Food and Drug Administration 2021). If the trial does not confirm the product's benefit, the FDA can withdraw approval.

Second, the spending implications of the product could be very large if there is significant uptake of Aduhelm. Biogen initially set the price for a one-year supply at $56,000 but later reduced the price to $28,200 to increase uptake (Biogen 2021b). An estimated 6.2 million adults ages 65 and older have Alzheimer's dementia, but it is unclear what share is likely to receive the product (Alzheimer's Association 2021). When launching the product, Biogen stated that although the product is appropriate for up to 2 million individuals, the company expected uptake to be gradual and not all patients will receive the product (Biogen 2021a). In December 2021, Biogen projected that 50,000 patients would begin treatment in 2022 (Biogen 2021b). At the current price of $28,200 for a year of maintenance therapy, Medicare Part B spending and beneficiary cost sharing could total $1.5 billion if 50,000 FFS beneficiaries receive the product and $15 billion if 500,000 receive it. Thus, with substantial uptake, spending for Aduhelm has the potential to swamp current Part B drug spending, which totaled $40.7 billion in 2020.

In addition, use of Aduhelm would likely increase use of and Medicare spending for magnetic resonance

imaging (which the FDA has stated should be done at certain intervals to monitor for brain swelling) and potentially positron emission tomography (PET) scans (which Medicare currently covers under an NCD to diagnose Alzheimer's disease in limited circumstances). Higher spending on Aduhelm and related services has implications for Medicare Part B premiums and deductibles and Medigap premiums for beneficiaries with supplemental coverage and could have substantial spending implications for MA plans, which generally must cover Part A and Part B services covered by traditional FFS Medicare (including following NCDs and, in some cases, LCDs). One of the factors contributing to the increase in the Part B monthly premium for 2022 was the need to create contingency reserves due to uncertainty over the potential use of Aduhelm.[29]

Thus, Aduhelm is an example of a first-in-class drug approved with limited and conflicting clinical evidence, under which the dual approach could be beneficial: (1) Issue a national coverage determination to implement CED, enabling the Medicare program to collect evidence about the product's use among Medicare beneficiaries, and (2) set a cap on the drug's payment rate based on an analysis of its net clinical benefit in relation to the standard of care.

In January 2022, CMS proposed an NCD to apply CED for monoclonal antibodies that target amyloid (antiamyloid mAb), including Aduhelm, for the treatment of Alzheimer's disease. In its proposal, the agency noted that although there was insufficient evidence that this therapeutic class is reasonable and necessary for the treatment of Alzheimer's disease, the condition is a particularly important disease that affects many beneficiaries, and "the CED paradigm provides the most appropriate pathway to provide Medicare coverage while additional evidence is developed" (Centers for Medicare & Medicaid Services 2022a).[30] In April 2022, CMS finalized its NCD policy that applies CED to the use of antiamyloid mAb products. For Aduhelm and other drugs in this therapeutic class that the FDA approves under its accelerated approval pathway (based on a surrogate outcome), coverage is linked to participation in FDA-approved randomized controlled clinical trials (RCTs) or trials supported by the National Institutes of Health (Centers for Medicare & Medicaid Services 2022b).[31]

By contrast, for antiamyloid mAb products that the FDA approves under its traditional pathway (based on a direct measure of clinical benefit), coverage is linked to participation in CMS-approved prospective comparative studies.[32]

The agency lacks statutory authority to set a cap on a Part B drug's payment rate based on its net clinical benefit. With respect to Aduhelm, ICER used comparative clinical effectiveness and cost-effectiveness analysis to estimate that, for the product to reflect its clinical benefit, a fair annual price would lie between $2,500 and $8,300. ICER's report also stated, "Even in our most optimistic cost-effectiveness scenario—which ignores the contradictions within the two pivotal trials and presumes that only the positive trial captures the true benefits of treatment—[Aduhelm's] health gains would support an annual price between $11,100 to $23,100" (Institute for Clinical and Economic Review 2021a).

Given these pricing estimates from ICER, if the product's annual payment rate under Part B was capped at $8,300, annual spending for beneficiaries and the Medicare program would decline by roughly 70 percent. If the product's annual payment was capped at $23,100, annual spending would decline by roughly 20 percent.

Promoting price competition among drugs with therapeutic alternatives

One approach to improve the existing ASP payment system for drugs with therapeutic alternatives uses reference pricing or consolidated billing codes to spur price competition among drugs with similar health effects. The current ASP payment system maximizes price competition among generic drugs and their associated brand products by assigning these products to a single billing code, which we call a consolidated billing code. For example, after the launch of generic zoledronic acid, the ASP for the branded product and generics assigned to the same billing code declined by roughly 55 percent within four quarters. By contrast, products that are assigned to their own billing code and paid according to their ASP—single-source drugs, originator biologics, and biosimilars—do not face the same incentives for price competition. In addition, the 6 percent add-on to ASP can create incentives for

some providers to choose higher-priced products over lower-priced products (Dusetzina and Mello 2021).

Thus, the current system does not always spur competition among originator biologics and their biosimilars. Since the availability of biosimilars, the ASP for some originator biologics has declined (Table 4-4, p. 98). Others, however, do not face much price competition. For example, the originator biologic Rituxan has faced biosimilar competition since the fourth quarter of 2019 but has reduced its price, as measured by ASP, by only 10 percent. As of the first quarter of 2022, the payment rates for Rituxan's biosimilars were 25 percent to 34 percent lower than the originator's payment rate. Biosimilars accounted for 43 percent of the market share as of the first quarter of 2021. Addressing the issue of price competition, in 2017 the Commission recommended that the Congress establish consolidated billing codes to pay for an originator biologic and its biosimilars (Medicare Payment Advisory Commission 2017).

In addition, the current system does not spur competition among therapeutically similar single-source drugs and biologics. Table 4-6 (pp. 112–113) presents examples of groups of drugs with similar health effects; each group includes the top three drugs as measured by Medicare spending in 2020. Two or more brand-name products in the same class paid under separate billing codes do not always compete much on price. Several of the top 20 Part B products ranked by expenditures have ASPs that have either remained the same or increased over more than a decade (Table 4-3, p. 97). For example, the ASP for Cimzia has increased on average by 4.4 percent per year since 2010, and the ASP for Orencia has increased by 6.0 percent per year since 2007, despite the availability of other targeted immune modulators for the treatment of rheumatoid arthritis.

Indeed, research suggests that in many therapeutic classes, approval of a new brand-name drug or biologic leads to higher list prices, not just for the new product but also for the existing products. For example:

- Hartung and colleagues reported that, between 1993 and 2013, the cost of first-generation disease-modifying therapies for treating multiple sclerosis increased many times more than overall prescription drug inflation. The authors concluded that the cost growth may have been a response to the introduction of competing treatments with higher prices (Hartung et al. 2015).[33]

- Gordon and colleagues found that, between 2005 and 2017, the mean cumulative price increase of 24 Part B anticancer drugs was 36.5 percent. Using multivariate regression, the authors reported that new supplemental FDA approvals, new off-label indications, and new competitors did not influence rates of changes in each drug's ASP (Gordon et al. 2018).[34]

- A systematic review of 10 original studies on competition among branded drugs found no evidence of a price-lowering effect of new drug entry on intraclass brand-name products (Sarpatwari et al. 2019).

- Hernandez and colleagues reported that the annual mean change in the net prices (measured using data from SSR Health) of drugs (available in January 2007) in six therapeutic classes increased by 4.5 percent between 2007 and 2018.[35] When the authors included drugs that entered the market after 2007, the estimates for net price increases rose (Hernandez et al. 2020).

One reason some new drugs that are not first in class have not experienced price competition could be that lowering prices has not historically resulted in selling more units of a drug. Instead, some manufacturers with lower market share in a given therapeutic class have raised their drug's price to make up for lost market share. Drugs in the class with larger market shares can, in turn, follow with price hikes (Herper 2020). According to San-Juan-Rodriguez and colleagues, the rising prices for existing products could reflect manufacturers' opportunism in response to new, higher-priced agents (San-Juan-Rodriguez et al. 2019).

To address too little competition among FFS Part B products with therapeutic alternatives, policymakers could consider reference pricing or consolidated billing codes, approaches that set a single reference price for products with similar health effects that are currently assigned to their own billing codes. Both approaches are tools that payers outside of Medicare already use. Compared with other drug management strategies (e.g., formularies), reference pricing does not restrict the selection of drugs within a given therapeutic class. By contrast, MA plans have several

mechanisms to promote more efficient prescribing of Part B drugs, through use of prior authorization and contracting arrangements that direct enrollees to more efficient sites of care. Anderson and colleagues noted that in four clinical scenarios where similarly or equally effective Part B drugs exist and are substantially different in terms of cost, older adults receiving treatment for the given condition with MA coverage more often received the low-cost drug alternative compared with older adults with FFS coverage (Anderson et al. 2021).

In the past, Medicare used reference pricing policies to pay for Part B drugs, but it does not do so currently. Between 1995 and 2010, Medicare implemented two reference pricing policies—referred to as the least costly alternative (LCA) and functional equivalence policies—to pay for groups of drugs with similar health effects (prostate cancer drugs and antianemia biologics). Since 2010, because of judicial rulings and statutory changes, Medicare Part B no longer uses either reference pricing policy and pays for each drug according to its own ASP. Because the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) requires that biologics and single-source drugs (without generic competition) be paid based on their ASP and not averaged with other products' ASPs, a change in the statute would be necessary. Consequently, the Secretary would require statutory authority to apply either reference pricing or consolidated billing policies to groups of drugs with similar health effects. (A detailed description of Medicare's prior application of reference pricing approaches can be found online at https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun18_ch10_medpacreport_sec.pdf.)

Some researchers have called for applying reference pricing to Part B drugs. Tunis and colleagues called for the Congress to restore and expand Medicare's authority to apply reference pricing (under an LCA policy) to products that are similar in their biological or physical characteristics and achieve comparable clinical outcomes (Tunis et al. 2011). Pearson and Bach proposed a "dynamic pricing model" to encourage Medicare to pay equally for services that provide comparable patient outcomes (Pearson and Bach 2010). Under their approach, only services with superior effectiveness would be paid based on a drug's own ASP, while the remainder would be paid based on reference pricing.[36] To improve competition, Conti and colleagues called for Medicare not to pay the additional costs associated with a more expensive drug when a clinically similar, lower-priced drug is available (Conti et al. 2021).

Establishing a single reference price for products with similar health effects

Under Part B, reference pricing policies could take the form of assigning products with similar health effects to the same billing code—a consolidated billing code. Alternatively, Medicare could establish a single reference price for products with similar health effects that are assigned to their own billing codes—reference pricing. Under both approaches, the payer sets a single payment rate. The reference price can be based on the average, median, or volume-weighted average of the prices of all the products in the reference group. When the reference price is based on the least costly product of all the products in the group, the reference pricing policy is referred to as the LCA policy. Reference pricing might offer more administrative flexibility in, for example, defining groups of products that are clinically similar and in addressing medical exceptions.

The Commission has held that Medicare should pay similar rates for similar care. As such, this principle might warrant that Medicare Part B use reference pricing when paying for drug products with similar health effects. Table 4-6 (pp. 112–113) presents examples of groups of competing products, with each product paid under a separate billing code based on its separate ASP. We derived these groups from approaches that group therapeutically similar branded drugs implemented by Medicare or commercial payer policies or suggested by CBO, the Office of Inspector General (OIG), and other researchers. The pricing behavior exhibited by some manufacturers—in which ASPs for some of the products did not substantially decline between 2005 and 2022—suggests there is room for greater price competition among these products. In 2020, Medicare spending for all the products in the therapeutic groups included in Table 4-6 totaled roughly $10 billion (data not shown).

Not included in Table 4-6 (pp. 112–113) are other groups of drugs that would be subject to the Commission's 2017 consolidated billing code recommendation, a reference pricing policy that sets a single payment rate

for an originator biologic and its biosimilars, including (1) long-acting leukocyte growth factor Neulasta and its biosimilars Fulphila, Ziextenzo, Nyvepria, and Udenyca; (2) short-acting erythropoietin-stimulating agent Epogen and its biosimilar Retacrit; (3) Herceptin and its biosimilars Kanjinti, Trazimera, Ontruzant, Herzuma, and Ogivri; and (4) Remicade and its biosimilars Inflectra, Renflexis, and Avsola.

Potentially, reference pricing could be applied to other Part B drugs, including:

- Part B drugs approved under the FDA's 505(b)(2) pathway (e.g., the chemotherapy agents Treanda, Bendeka, and Belrapzo/bendamustine). A 505(b)(2) application is a type of new drug application (NDA) that contains full reports of investigations of safety and effectiveness, in which at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. In some cases, drugs approved under Section 505(b)(2) share significant portions of labeling with generic drugs that are paid as multiple-source drugs under Section 1847A of the Social Security Act. The 505(b)(2) pathway is a hybrid between the generic approval process (under 505(b)(j)) and a full NDA under 505(b)(1). According to Freije and colleagues, most 505(b)(2) applications consist of changes to a previously approved drug product (e.g., a new dosage form or new route of administration) (Freije et al. 2020).
- The six CAR–T therapies, as their outpatient use becomes more common over time. When furnished in an inpatient setting (the setting in which most beneficiaries currently receive treatment), these products are paid for under a single diagnosis related group. By contrast, when they are furnished on an outpatient basis, they are paid according to each product's ASP.

Reference pricing would likely reduce Part B spending for drugs

Under reference pricing policies for Part B drugs, manufacturers would have incentive to lower their prices relative to competitors to make their products more attractive to providers and garner market share. Federal government agencies have estimated that applying reference pricing policies to Part B drugs would result in savings for beneficiaries and taxpayers:

- OIG estimated that by using an LCA policy in 2008 and 2009 to pay for drugs that treat wet age-related macular degeneration (Avastin and Lucentis), beneficiaries would have saved $275 million and Medicare would have saved $1.1 billion (Office of Inspector General 2011). Conversely, OIG calculated that if Medicare reimbursement for all beneficiaries treated with Avastin or Lucentis for wet age-related macular degeneration had been paid at the Lucentis rate, Part B spending would have increased by approximately $1.5 billion and beneficiaries would have paid approximately $370 million more in copayments.
- CBO projected that if Medicare had used an LCA policy between 2010 and 2019 for drugs that treat osteoarthritis of the knee, the program would have saved almost $500 million (Congressional Budget Office 2008).
- OIG has twice recommended that the Secretary apply LCA policies to prostate cancer drugs. In 2004, OIG reported that not all carriers included one of the prostate cancer drugs (leuprolide acetate) in their LCA policy and recommended that CMS encourage all Medicare contractors to include this product when applying LCA policies to this drug group. OIG estimated that if implemented, Medicare and beneficiaries would have saved $40 million per year (Office of Inspector General 2004). In 2012, OIG reported that after LCA policies were removed for a group of drugs that treat prostate cancer, utilization patterns shifted dramatically in favor of costlier products, and the agency concluded that spending for these products was higher in the absence of LCA policies (Office of Inspector General 2012).[37] OIG estimated one-year savings of nearly $7 million for beneficiaries and nearly $27 million for Medicare if an LCA policy was used to pay for these prostate cancer drugs (Office of Inspector General 2012). Neither study addressed the effect of the LCA policies on beneficiaries' use of other medical services.

Researchers have also estimated significant savings from reference pricing:

- Dickson and colleagues estimated Medicare savings of $7 billion for setting a "domestic reference

TABLE 4–6

Medicare spending for products with similar health effects varies

	Average annual spending per beneficiary, 2020	Average annual ASP growth 2005–2022	First year of pricing data if not 2005
Anti-vascular endothelial growth factors: Biologics that treat wet age-related macular degeneration and other eye disorders			
Eylea (aflibercept)	$10,241	–0.8%	2013
Lucentis (ranibizumab)	$8,867	–2.0	2008
Beovu (brolucizumab)	$6,132	–0.9	2020
Avastin (bevacizumab)[a]	$306	1.0	
Targeted immune modulators: Biologics that treat rheumatoid arthritis			
Orencia (abatacept)	$33,904	6.0%	2007
Rituxan (rituximab)	$24,769	4.0	
Cimzia (certolizumab pegol)	$24,728	4.4	2010
Short-acting leukocyte growth factors: Biologics that stimulate proliferation and differentiation of normal white blood cells[b]			
Neupogen (filgrastim originator)	$2,356	3.0%	
Zarxio (filgrastim-sndz)	$1,475	–17.5	2016
Granix (tbo-filgrastim)	$1,134	–7.7	2015
Immune globulins: Products that treat primary humoral immunodeficiency and other selected conditions			
Gamunex-c/Gammaked	$26,823	2.5%	2008
Gammagard liquid injection	$22,098	2.8	2008
Privigen	$23,303	2.1	2009
Luteinizing hormone–releasing hormone agonists for prostate cancer: Products that treat prostate cancer			
Lupron/Eligard (leuprolide acetate suspension)[c]	$1,631	–1.4%	
Trelstar (triptorelin pamoate)	$1,805	3.7	
Firmagon (degarelix)	$1,311	2.9	2010

price" for new drugs based on the payment rates of three existing drugs that are clinically comparable (i.e., of similar therapeutic class, mechanism of action, and indication) (Dickson et al. 2021). The domestic reference price would be calculated as the inflation-adjusted launch price of its comparators, weighted by the relative utilization of each comparator, and adjusted by an innovation premium based on the average time since approval for comparators. Under their approach, the domestic reference price of the 66 drugs analyzed was not always lower than the launch price of the new drug. However, across all Part B and Part D drugs, the researchers estimated this approach

TABLE 4-6 **Medicare spending for products with similar health effects varies** *(cont.)*

	Average annual spending per beneficiary, 2020	Average annual ASP growth 2005–2022	First year of pricing data if not 2005
Botulinum toxins: Products that treat cervical dystonia			
Botox (onabotulinumtoxinA)	$3,123	1.6%	
Myobloc (rimabotulinumtoxinB)	$3,132	2.7	2010
Xeomin (incobotulinumtoxin A)	$2,705	–0.9	2012
Viscosupplements using hyaluronate for osteoarthritis of the knee			
GenVisc 850[d]	$2,599	16.2%	2017
Gel-One[d]	$1,709	8.1	2013
Synvisc or Synvisc-One	$764	–1.0	2010
Bone-modifying agents for osteoporosis			
Prolia (denosumab)	$1,689	3.9%	2012
Evenity (romosozumab-aqqg)	$10,068	1.4	2020
Zometa (zoledronic acid)[c]	$55	–18.8	
Iron agents for anemia			
Injectafer (ferric carboxymaltose)	$1,617	0.8%	2015
Feraheme (ferumoxytol)	$1,193	2.4	2010
Infed (iron dextran)	$366	2.1	

Note: ASP (average sales price). For each group (other than the group containing products that treat eye disorders), the table lists only the three leading drugs based on their total 2020 Part B Medicare spending. For the eye disorder group, we also include a fourth product (Avastin) that clinicians extensively prescribe off label. Average annual spending per beneficiary in 2020 is based on Part B claims data for patients with conditions listed in the title for each drug group. Average annual ASP growth is calculated based on first-quarter data for each year.
[a] In February 2004, the Food and Drug Administration (FDA) approved Avastin for colon cancer. According to the American Academy of Ophthalmology, since 2004, ophthalmologists commonly use the drug to treat age-related macular degeneration off label (i.e., use of a drug for indications other than those that the FDA approves) with "great results" (Mukamal 2020). Compared with the on-label alternatives, a greater possibility of infection exists with Avastin due to potential contamination when the drug is being repackaged into smaller doses for the eye. According to Mukamal, when appropriate guidelines are followed for preparing such medicines, this risk is minimized (Mukamal 2020).
[b] Pricing estimates include all furnished indications of the products.
[c] Billing code includes one or more brand or generic drugs.
[d] Payment rates for 2022 were based on data from CMS's 2022 Addendum B of the outpatient hospital prospective payment system (because the first-quarter 2022 ASP payment rate file publicly displayed on CMS's website does not include a payment amount for this product).

Source: MedPAC analysis of data from CMS's publicly available ASP payment rate files, 2005–2022, and CMS carrier and institutional outpatient files, 2020.

would have yielded Medicare savings of $7 billion between 2015 and 2019.

- After adjusting for sociodemographic and clinical characteristics and regional effects, Anderson and colleagues found that, compared to FFS beneficiaries, MA enrollees were more likely to receive the lower-cost drug in four therapeutic drug classes (Anderson et al. 2021). The authors estimated that if FFS use aligned with MA prescribing patterns, FFS spending (in 2016 dollars) would be reduced by:

- $204 million for anti-vascular endothelial growth factor used to treat macular degeneration (representing 8 percent of FFS spending for this drug group);
- $28 million for bone resorption inhibitor treatment of osteoporosis (representing 6 percent of FFS spending for this drug group);
- $101 million for bone resorption inhibitor treatment of malignant neoplasms (representing 20 percent of FFS spending for this drug group); and
- $6 million for intravenous iron treatment of anemia (representing 7 percent of FFS spending for this drug group).

- The Committee for a Responsible Federal Budget proposed "clinically comparable drug pricing," under which Part B payment for physician-administered drugs would be set at a single price for groups of drugs within the same therapeutic class (Committee for a Responsible Federal Budget 2021). That price would be set at the weighted average of prices manufacturers charge for each of the clinically comparable drugs. For any such group, Medicare would set the payment for all drugs at a volume-weighted average price, which would be calculated quarterly using each product's quarterly ASP, weighted by the average annual usage of each product, and amortized based on each drug's standard dosing. The researchers estimated that for drugs that treat macular degeneration, rheumatoid arthritis, and prostate cancer, their policy would reduce Medicare FFS spending between 2021 and 2030 by $81 billion and result in $29 billion in savings for the MA program. Most of these estimated savings come from the macular degeneration and rheumatoid arthritis groups, due to the high price differential for the drugs in these groups and their significant use among FFS beneficiaries.

Implementation issues

To carry out reference pricing for Part B drugs, Medicare would need to develop a clear and predictable decision-making framework that ensures transparency and opportunities for public input. The program would also need a clear legal foundation to apply such a payment approach. Specifically, the Congress would need to restore the Secretary's authority to apply reference pricing approaches that was changed by the MMA, which requires that biologics and single-source drugs (without generic competition) be assigned to their own billing code and be paid based on their own ASP.

A key issue is deciding which reference pricing strategy Medicare would apply—reference pricing, under which products are assigned to their own billing codes, or consolidated billing, under which products are assigned to the same billing code. Both approaches would set one payment rate for each group of therapeutically similar drugs. However, reference pricing might offer more flexibility in defining groups of products that are clinically similar (e.g., to account for potential differences in dosage sizes between therapeutically similar drugs) and in addressing medical exceptions. Importantly, because drugs would retain their own billing code under a reference pricing approach, researchers could continue to use Medicare claims data to conduct pharmacoepidemiology studies.

Another key issue is how CMS would establish the payment rate for a reference group. The agency could determine the payment rate for each drug based on the prevailing payment policy and then set the payment rate for all the clinically similar products in the drug group based on, for example, the weighted average of all products within the group, the 50th percentile of all ASPs of all the products within the group, or the ASP of the LCA. CMS currently uses a volume-weighted approach when determining the payment rate for generic drugs and their associated brand drug assigned to a single billing code. In 2016 and 2017, CMS used a volume-weighted approach to pay for all biosimilar products associated, but not grouped, with a given originator biologic. Another alternative would be to set the reference price based on the lower of (1) the volume-weighted ASP of all drugs within the reference group or (2) the ASP for the individual drug. The statute uses such an approach to pay for certain drugs.[38] Compared with other alternatives, basing payment on the least-costly product in a reference group would likely yield the greatest savings to beneficiaries and taxpayers. On the other hand, an advantage of the volume-weighted ASP compared with the LCA is that the volume-weighted approach might give providers time to adjust to the new payment rates without creating financial disruption, especially for practices

that might have already purchased the higher-priced drug before the policy went into effect.

CMS would need to establish a process for determining exceptions to reference pricing policies when a beneficiary's clinical circumstances support the medical necessity of a more costly product. Our recommendation for establishing consolidated billing codes for the original biologic and its biosimilars discussed the potential for a medical exception process (Medicare Payment Advisory Commission 2017). We said that under such a policy, the clinician would continue to have the choice to prescribe the product most appropriate for the patient, with Medicare's payment based on the reference price. The Congress could consider allowing the Secretary to provide a very limited payment exception process under which Medicare would reimburse the provider based on the ASP of the higher-priced product if the clinician provided justification that the product was medically necessary, such as instances for which there has been documented clinical failure of a particular product (Medicare Payment Advisory Commission 2017). A payment exception process addresses the concern that beneficiary access under a reference pricing policy could be harmed if some providers were unwilling to supply the higher-cost product to a beneficiary for whom the product was a medical necessity. Providers could submit medical justification to the regional Medicare administrative contractors (MACs), and the exception process could be coupled with Medicare's existing appeals process that gives beneficiaries, providers, or their representatives the right to appeal the MACs' coverage and payment decisions.

However, unless carefully designed, a payment exception process could create incentives for the use of higher-priced products when the beneficiary's clinical circumstance does not support an exception. Since the add-on of a higher-priced product generates more revenue for the provider than the add-on of a lower-priced product, selection of the higher-priced product could generate more profit, depending on the provider's acquisition costs for the two products. In 2017, the Commission said that to minimize such unintended effects:

- the clinician's payment from Medicare when an exception is granted could be set at the higher-cost product's ASP without an add-on payment (i.e., 100 percent of ASP); and
- the Medicare program would pay the provider 80 percent of the ASP of the exception (higher-cost) product that was furnished, and the beneficiary would pay the provider 20 percent of the exception (higher-cost) product's ASP (Medicare Payment Advisory Commission 2017).

A related issue concerns situations in which a beneficiary and their provider opt for a more costly product that is not supported by clinical necessity. Under one approach, the provider would absorb any additional costs (i.e., the difference in the ASP between the product prescribed and the reference price). Alternatively, some payers have designed their reference pricing policies for drugs and medical services such that, absent a medical exception, the patient absorbs the additional costs (Robinson 2017).

For a drug newly approved by the FDA, the Secretary would need a clear, transparent, and timely process for evaluating its comparative clinical effectiveness compared with existing drugs that are the standard of care and for determining whether the drug should be included in an existing reference product group.[39] The Secretary already has experience under the prospective payment systems for inpatient, outpatient, and end-stage renal disease services to assess whether new services represent clinical improvements compared with existing treatments. While a new drug's comparative clinical effectiveness is being considered, its payment rate could be based on prevailing Medicare payment policies (i.e., ASP + 6 percent), which would obviate delays in beneficiaries' access. Determining the overall length of time for the Secretary to implement this process would also need to be addressed.

How Medicare would define groups of products that are clinically similar—narrowly or broadly—is another significant design issue. For example, a group could be defined that would broadly apply to both short-acting erythropoiesis-stimulating agent (ESAs) (Epogen and its biosimilar Retacrit) and long-acting ESAs (Aranesp and Mircera). Alternatively, two groups could be defined—one for short-acting agents and another for long-acting agents. Designing groups more broadly would have a greater effect on Medicare spending than groups defined narrowly.

Another issue concerns whether a repackaged drug used for an off-label indication should be included in a given reference group. One example is the off-label

use of Avastin, a cancer treatment that is repackaged by compounding pharmacies into smaller doses for treatment of eye disorders, including wet age-related macular degeneration. Medicare may cover off-label use of FDA-approved drugs and biologics if it determines the use to be medically accepted, which the program has for off-label Avastin use for ophthalmologic indications.[40,41]

Another design issue with reference pricing is how to pay for products with similar health effects that have multiple indications (i.e., on label and covered off label). Approaches include Medicare's payment at the reference price across all indications or only for indications that the reference group covers. These approaches differ in their ease of implementation and predictability for providers. Under a single payment approach, the Secretary would need to consider the payment of products with multiple indications.

Three additional design elements would be involved in establishing reference pricing policies:

- how frequently the reference price would be updated (e.g., quarterly, annually);
- providing pricing information to beneficiaries and clinicians (to make them sensitive to the difference in out-of-pocket spending); and
- whether Medigap policies could cover beneficiary cost sharing that is greater than the reference price.

Improving provider incentives under the ASP payment system

The 6 percent add-on to Medicare Part B's payment rates has garnered attention because of concern that it may create incentives for use of higher-priced drugs when lower-priced alternatives exist. While clinical factors play a central role in prescribing decisions, at the margins, financial considerations can also play a role in providers' choice of drugs. Several studies examining utilization patterns for specific products have found shifts in utilization of higher-priced products that could reflect the effect of the 6 percent add-on. Policy options to modify the add-on could be considered to improve incentives under the ASP payment system.

Context for Medicare's ASP + 6 percent payment rate

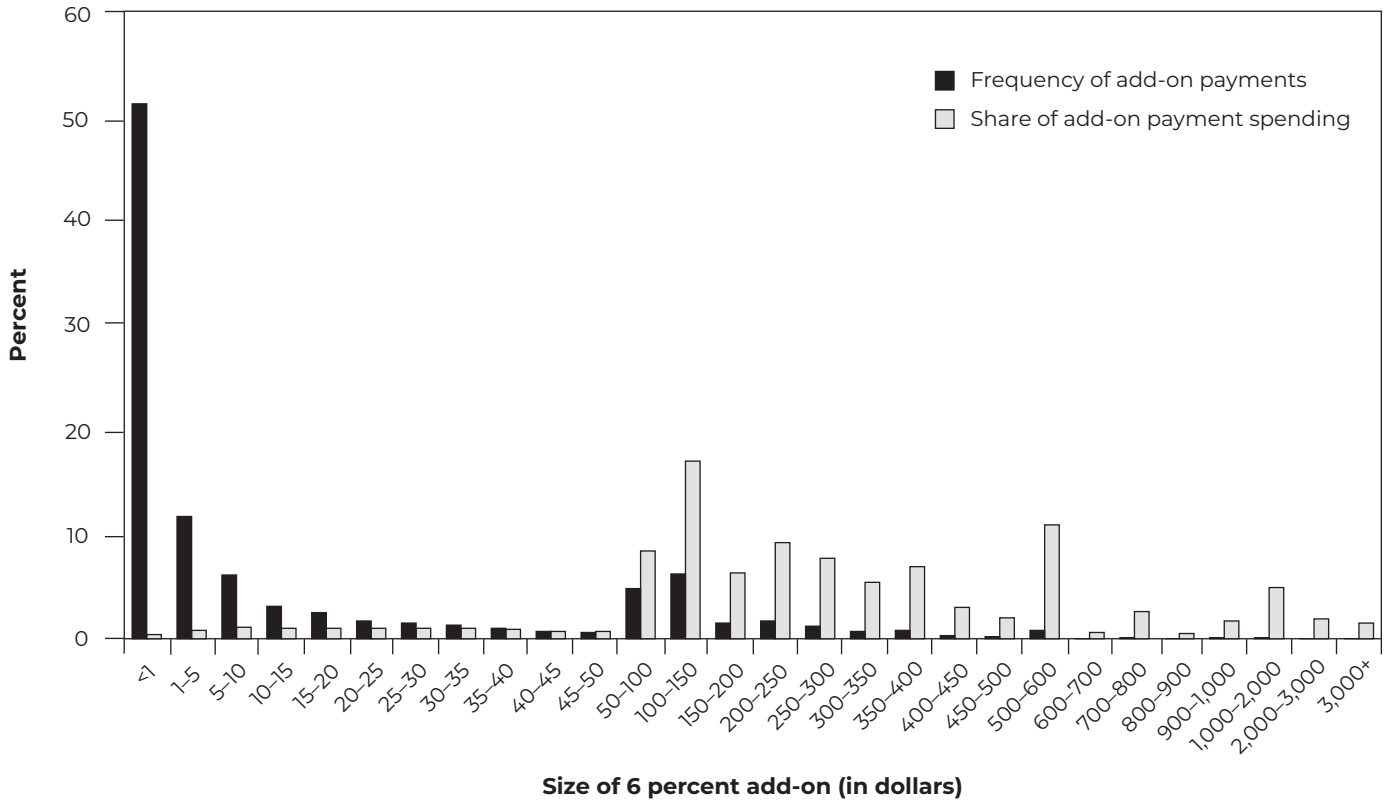
The 6 percent add-on is often thought of as the profit margin providers make on Part B drugs, but the actual profit margin may be greater or less than 6 percent (including possibly negative margins in some circumstances), depending on a variety of factors. If a provider purchases a drug at a price equal to ASP, the profit margin on the drug is 6 percent.[42] A provider may purchase a drug at a price other than ASP for several reasons. Since ASP is an average, some providers will pay more and some will pay less than the average if there is price variation across purchasers (e.g., due to volume discounts). Because there is a lag in the ASP payment rates, the provider's margin is reduced when a drug's price increases (and the margin increases when the drug's price declines) until the ASP payment rates catch up two quarters later. In addition, prompt-pay discounts paid by manufacturers to wholesalers (which are anecdotally reported in the range of 1 percent to 2 percent) can create a gap between ASP and provider's acquisition costs because these discounts are subtracted from ASP but are reportedly not fully passed on to purchasers. Information on providers' acquisition costs for Part B drugs is very limited, but a few older studies examined this issue for certain drugs and found that pharmaceutical manufacturers' pricing patterns responded to past policy changes (see text box on providers' acquisition costs, pp. 118–120).

There is no consensus on the original intent of the 6 percent add-on to ASP. Some analysts have suggested that the 6 percent is intended to cover price variation across purchasers or other factors that can result in a provider's purchase prices being above the ASP. Another view is that the 6 percent is intended to cover drug storage and handling costs, although it seems unlikely that these costs would vary across products based on a percentage of each product's price.[43] Some stakeholders have also suggested that the 6 percent add-on is intended to cover the financing costs associated with maintaining a drug inventory.

Because Medicare Part B covers a diverse set of products ranging in price from very inexpensive to extremely expensive, the size of ASP add-on payments varies widely across Part B drugs. In 2019, about

FIGURE 4–2

Most Part B drug add-on payments are small, but expensive drugs with large add-on payments account for most add-on spending



Note: Analysis includes all Part B–covered drugs paid under the ASP + 6 percent system, excluding drugs billed through not-otherwise-classified Healthcare Common Procedure Coding System codes. Part B drugs furnished by 340B hospitals paid ASP – 22.5 percent are excluded from the analysis. Data for critical access hospitals, Maryland hospitals, and beneficiaries with Medicare as a secondary payer are excluded from the analysis.

Source: MedPAC analysis of Medicare claims data for physicians, hospitals, and suppliers.

40 million Part B drug administrations received a 6 percent add-on, and those add-on payments accounted for about $1.7 billion of the total $29 billion in payments for those drugs.[44] Most Part B drug administrations involve low-cost products with small add-ons. In 2019, about half of Part B drug administrations involved an add-on of less than $1; 69 percent of Part B drug administrations involved an add-on of less than $10 (Figure 4-2). Examples of products with small add-on payments include corticosteroid injections, vitamin B-12, and contrast agents. The bulk of add-on payment spending is concentrated among relatively lower-frequency, high-priced drugs and biologics. For example, less than 15 percent of drug administrations had an add-on payment exceeding $100, and those administrations accounted for more than 80 percent of add-on spending (Figure 4-2). Furthermore, just over 1 percent of drug administrations had an add-on payment exceeding $500, and those administrations accounted for 25 percent of add-on spending. Examples of products with some of the highest add-ons include CAR–T products, certain clotting factors, and certain products for rare conditions.

When a provider furnishes a Part B drug, in addition to receiving a payment of ASP + 6 percent for the

Information on providers' acquisition costs for drugs is limited

Information on providers' acquisition costs for Part B drugs is very limited, but a few older studies examined this issue for certain drugs.

When the average sales price (ASP) payment system was adopted in January 2005, the Commission found evidence suggesting that pharmaceutical manufacturers responded to the new payment system by narrowing the variation in invoice prices across purchasers (Medicare Payment Advisory Commission 2006). Specifically, we found that between December 2004 and June 2005, variation in invoice prices (which included discounts but not retrospective rebates) declined for the basket of 26 drugs overall and for various categories of drugs including chemotherapy drugs, supportive drugs, brand drugs, and generic drugs. This analysis was based on proprietary invoice price data from IMS Health for clinic purchasers for 26 drugs commonly used by oncologists. In addition, two Office of Inspector General studies that collected drug acquisition cost data during the first six months of the ASP payment system found that oncology practices could generally acquire most drugs for prices at or below Medicare's payment rates (Office of Inspector General 2007b, Office of Inspector General 2005).

In the Commission's June 2016 report to the Congress, we analyzed more recent proprietary IMS Health data on invoice prices for a group of high-expenditure Part B drugs to get a sense of how providers' acquisition costs for drugs compared with ASP (Medicare Payment Advisory Commission 2016). The analysis focused on 34 high-expenditure Part B drugs for which we had quarterly invoice price data for the clinic channel of purchasers for the entire period from the first quarter of 2012 to the second quarter of 2015. Data were available only for the clinic channel as a whole, which included physician offices, hospital outpatient departments, dialysis clinics, nonhospital surgical centers, and public health service clinics. Because the IMS data for the clinic channel included discounted sales to 340B entities, we focused on invoice prices for the top half of the price distribution (i.e., the 50th, 75th, and 90th percentiles) to avoid reflecting 340B prices in our analysis. The prices in the IMS data reflected all on-invoice discounts and rebates but not off-invoice rebates, so in some cases the data may have overstated the actual end price paid by the purchaser. Our analysis did not report prices for any individual drugs due to the terms of our contract with IMS. Instead, we divided each drug's invoice

(continued next page)

drug, the provider also receives a separate payment for drug administration services. Medicare Part B pays providers for drug administration services under the physician fee schedule and OPPS. For example, under the physician fee schedule in 2022, payment for an injection is about $75 for a chemotherapy product and $15 for a nonchemotherapy product, and payment for the first hour of infusion of a chemotherapy product is $140 and $69 for a nonchemotherapy product.[45] Additional payments are made if more than one drug is furnished or if an infusion lasts longer than the initial hour. Hospital outpatient departments generally receive higher drug administration payment rates than physician offices.

Does the 6 percent add-on influence use of high-cost drugs?

Prescribing decisions depend on a variety of clinical factors. For example, drugs can vary in terms of their effectiveness in treating patients with certain conditions or comorbidities, and they can differ in terms of side effects. In addition, providers may take into account whether a drug is on label or off label for a patient's condition or whether a drug is compounded.

While clinical factors play a central role in prescribing decisions, at the margins, financial considerations can also play a role in providers' choice of drugs. Some researchers and stakeholders have expressed concern

Information on providers' acquisition costs for drugs is limited (cont.)

price by 100 percent of the ASP that was in effect for payment purposes in each quarter to create a ratio of the invoice price to ASP and summarized the results across the group of 34 drugs.

Analysis of the IMS data offered a sense of the distribution of invoice prices across clinic purchasers. As shown in Table 4-7 (p. 120), 35 percent of the drugs had a 75th percentile invoice price that was less than 100 percent of ASP, and another 29 percent of the drugs had a 75th percentile invoice price that was between 100 percent of ASP and 101.9 percent of ASP. In other words, for about two-thirds of the drugs (22 of 34 drugs), at least 75 percent of the volume was sold at an invoice price that was less than 102 percent of ASP. The remainder of the drugs had a 75th percentile invoice price that for 12 percent of the drugs ranged from 102 percent to 103.9 percent of ASP; for another 12 percent of the drugs, from 104 percent to 105.9 percent of ASP; and for another 12 percent of drugs, 106 percent or more of ASP. In interpreting these results, we note that prices for some purchasers could have been lower than what was observed in these data because the data did not include any off-invoice rebates that may have been given.

The analysis also found evidence suggesting that manufacturers responded to implementation of the sequester (a 2 percent reduction to the Medicare program payment) by changing their pricing to mitigate the effect of the sequester on providers' margins. In the second quarter of 2013, Medicare's net payment rate for Part B drugs was effectively lowered from 106 percent of ASP to 104.3 percent of ASP due to the sequester. Our analysis of IMS Health data found a decline in invoice prices for Part B drugs that coincided with the reduction in Medicare's payment rates. Specifically, the study found that the median across the 34 drugs of the 75th percentile invoice price as a percentage of ASP declined in the second quarter of 2013 when the sequester went into effect (from around 103 percent of ASP in the first quarter of 2012 through the first quarter of 2013 to about 101.5 percent of ASP in the second quarter of 2013 through the second quarter of 2015) (Medicare Payment Advisory Commission 2016).

Another source of information on acquisition costs is a report from the Office of Inspector General (OIG) examining the acquisition costs for two drugs for wet age-related macular degeneration (AMD) and certain other eye conditions (Office of Inspector General 2011). OIG surveyed ophthalmologists to

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that the 6 percent add-on to ASP creates an incentive to use higher-priced drugs when less-expensive therapeutic alternatives are available (Bach and Ohh 2018, Dusetzina and Mello 2021, Hutton et al. 2014, Sanghavi et al. 2014). Since 6 percent of a higher-priced drug generates more revenue for the provider than 6 percent of a lower-priced drug, selection of the higher-priced drug can generate more profit, depending on the provider's acquisition costs for the two drugs. At the same time, other financial considerations might create an incentive to use lower-priced drugs in some situations. For example, when selecting a drug, a provider may take into account the cost sharing associated with each drug and the patient's ability to pay, which might lead to choosing a lower-priced drug for some patients. Also, the financial capital required to acquire and keep an inventory of a high-priced drug can be a disincentive for some providers to furnish expensive drugs. With respect to oncology specifically, some payers and providers use clinical pathways to guide clinicians' choice of a patient's most appropriate drug regimen. It is not clear how often clinicians have the opportunity within oncology pathways to choose among differently priced drugs that are equally appropriate for a given patient.

Information on providers' acquisition costs for drugs is limited (cont.)

TABLE 4–7 **Distribution of invoice prices for 34 Part B drugs, 1st quarter 2015**

	50th percentile invoice price as a percentage of ASP	75th percentile invoice price as a percentage of ASP	90th percentile invoice price as a percentage of ASP
Percentage of 34 drugs with invoice price as percent of ASP:			
Less than 100%	59%	35%	18%
100% to 101.9%	21	29	6
102% to 103.9%	6	12	26
104% to 105.9%	6	12	21
106% or greater	9	12	29
Median across the 34 drugs	99.7% ASP	101.6% ASP	104.0% ASP

Note: ASP (average sales price). The data are for the clinic channel of sales, which includes physician offices, hospital outpatient departments, dialysis centers, nonhospital surgical centers, and public health services clinics. Figures reflect invoice price data for 34 drugs that have high total expenditures. For drugs with multiple national drug codes (NDCs), the data for the highest-volume NDC were used. Data come from a sample of wholesalers and do not include direct sales by manufacturers. The percentile distribution of invoice prices is at the drug unit level. Prices reflect on-invoice discounts and rebates but not off-invoice rebates. Invoice prices are for the first quarter of 2015 and are displayed as a percentage of the ASP that was in effect for payment purposes in the first quarter of 2015. Numbers may not sum to 100 percent due to rounding.

Source: These figures are MedPAC estimates derived from the use of information under license from the following IMS Incorporated information service: Pricetrak for the first quarter of 2015.

obtain data on their acquisition costs in the first quarter of 2010 for Lucentis and Avastin. Lucentis is a biologic with a label indication for wet AMD for which Medicare paid just over $2,000 per dose in 2010. Avastin is a biologic that is used off label for wet AMD at a significantly lower cost; Medicare paid roughly $50 per dose on average in 2010. OIG found that, on average, ophthalmologists reported acquiring Lucentis for 5 percent below Medicare's 106 percent of ASP (ASP + 6 percent) payment amount in the first quarter of 2010. OIG also found that 98 percent of survey respondents acquired Lucentis at a price below Medicare's payment rate in the first quarter of 2010. Since that time, additional biologics (Eylea and Beovu) with indications similar to Lucentis have entered the market, and together these biologics accounted for over $4 billion in Medicare program payments and beneficiary cost sharing in 2020.

Research on providers' drug acquisition costs is limited by lack of available data. Periodically, OIG has done studies collecting drug acquisition cost data directly from providers, including the aforementioned studies of oncology drugs and Lucentis, as well as studies of immune globulin acquired by physicians and hospitals and drugs acquired by dialysis facilities (Office of Inspector General 2010, Office of Inspector General 2007a). To the extent that there is interest in understanding more about providers' acquisition costs for drugs, OIG may be best positioned to obtain this type of data. It is important to note, however, that any data on drug acquisition costs reflect prices at a historical point in time and do not necessarily reflect what acquisition costs might look like if Medicare policy changed and manufacturers altered their pricing behavior in response. ■

Several studies examining utilization patterns for certain products with therapeutic alternatives found some growth in use of higher-priced products that could reflect the effect of the 6 percent add-on. A study by Jacobson and colleagues examining oncologists' prescribing patterns for lung cancer found a modest increase in use of the most expensive cancer drug after January 2005, when Medicare began paying for Part B drugs based on ASP + 6 percent (Jacobson et al. 2010).[46] Another study by Conti and colleagues of drugs used to treat colorectal cancer found that use of the chemotherapy drug irinotecan declined (by just under 20 percent) after it went generic in 2008 relative to use of an alternative higher-priced brand drug, oxaliplatin (Conti et al. 2012). The authors suggested that physician reimbursement incentives may have been a driver of those utilization changes, but they also stated that changes in recommended treatment regimens that occurred over this period could also have contributed to these trends. When the LCA policy for certain prostate cancer drugs was removed in 2010 and Medicare began paying for the drugs based on 106 percent of their own ASPs, OIG found a shift from the lowest-priced prostate cancer drug toward higher-priced competitor products (Office of Inspector General 2012). A study by Hambley and colleagues examined utilization of several iron products among Medicare beneficiaries between 2015 and 2017, a period that included a shortage of the low-priced product iron dextran during the early part of 2016 (Hambley et al. 2020). The study found increasing market share for a high-priced iron product, ferric carboxymaltose, even after the shortage of iron dextran subsided, which the authors suggest may have been related to its higher add-on payment. Gupta and colleagues found that after the FDA approved denosumab (a bone resorption inhibitor drug) in 2018 for skeletal-related events in patients with multiple myeloma, the product rapidly diffused among FFS beneficiaries with multiple myeloma, despite lack of evidence of superiority compared with its lower-cost alternatives, zoledronic acid and pamidronate (Gupta et al. 2020a). The authors questioned the routine use of denosumab except in patients with renal dysfunction or in those unable to tolerate the lower-cost agents. In addition, a study by Anderson and colleagues examining use of Part B drugs for differently priced products for the treatment of four conditions found that MA beneficiaries had a higher likelihood of receiving the lower-cost product (ranging from 5 percentage points to 13 percentage points higher) than FFS beneficiaries (Anderson et al. 2021). The authors stated that a variety of factors could contribute to these differences, such as choice of network providers, MA plans' utilization management efforts, beneficiary cost sharing and lack of supplemental coverage, and how providers are paid, including Part B's payment of ASP + 6 percent.

The 6 percent add-on may also affect a provider's decision to initiate or continue drug treatment rather than opt for nondrug treatment, watchful waiting, or palliative care. Although studies have not evaluated this question directly, some have looked at whether large reimbursement changes—specifically, the payment rate changes that occurred when the MMA changed the Part B drug payment rates from 95 percent of average wholesale price (AWP) to ASP + 6 percent—affect utilization of drugs. A study by Elliott and colleagues found that when reimbursement for androgen suppression therapy (AST) declined by 64 percent between 2003 and 2005, AST use declined among nonindicated, low-risk patients (from 10 percent to 6 percent receiving AST) but remained steady among higher-risk patients with metastatic disease (Elliott et al. 2010). A study by Colla and colleagues found some reduction in patients with a poor prognosis receiving chemotherapy in the last 14 days and and in the last 3 months of life in physician offices, but not in hospital outpatient departments, after the payment rate was reduced from 95 percent of AWP to ASP + 6 percent (Colla et al. 2012). The authors attributed the decrease in chemotherapy provision to physician offices' response to reduced drug profit margins, hypothesizing that physician offices were more responsive to the payment reduction than outpatient hospitals because physicians' income is more directly related to chemotherapy use in the physician office setting than it is in the hospital outpatient setting.

Taken together, the literature suggests that the 6 percent add-on likely has an effect on prescribing in some circumstances. The size of the effect is difficult to quantify because many factors affect prescribing. Identifying what portion of utilization patterns reflects the effect of the 6 percent add-on versus other factors is challenging. In addition, for the percentage add-on to have the potential to affect product selection, differently priced therapeutic alternatives must exist. Researchers have not quantified the amount of total Part B drug spending accounted for by drugs for which differently priced substitutes are available at the

patient level. This calculation in some cases depends on clinical information not available in claims data (e.g., stage of cancer, comorbidities, and laboratory or pathology results).

Considering alternatives to the 6 percent add-on

Over the years, the Commission has explored a number of options to modify the percentage add-on to ASP. Most recently, in 2017, the Commission recommended reducing the percentage add-on as part of its recommendation to develop what we described as the Drug Value Program (DVP). As recommended, the DVP would be a voluntary, market-based alternative to the ASP payment system that would rely on private vendors to negotiate drug prices using tools like a formulary and share savings with providers that chose to enroll. To create pressure for DVP development and implementation and to encourage provider enrollment in the DVP, the Commission recommended that the percentage add-on be reduced beginning no later than 2022, regardless of the status of the DVP. The report suggested that the ASP add-on could be reduced gradually, by 1 percentage point per year (i.e., ASP + 5 percent in 2022, ASP + 4 percent in 2023, and ASP + 3 percent in 2024 and onward).

Before the 2017 report, the Commission explored several models for converting the percentage add-on to a flat fee. Building on that work, we explored additional approaches to modify the ASP add-on. Previously, we observed that policies to modify the ASP add-on would involve trade-offs (Medicare Payment Advisory Commission 2016, Medicare Payment Advisory Commission 2015). Eliminating the percentage add-on would reduce any incentives that exist for providers to use a higher-priced drug when a lower-priced drug with similar health effects is available to treat a particular patient. At the same time, eliminating a percentage add-on might result in Medicare's payment rate being lower than providers' acquisition costs for some products or some providers. An alternative to fully eliminating the percentage add-on is a hybrid approach with a reduced percentage add-on and flat fee, which might reduce the potential for unintended consequences on providers' ability to acquire drugs for the Medicare payment amount. A hybrid approach would reduce, but not eliminate, the difference in add-on payments between high-priced and low-priced drugs. We also explored the use of a flat dollar limit on the percentage add-on. Such an approach would reduce add-on payments for very expensive products that account for most add-on spending while maintaining the current ASP + 6 percent payment for other products.

To explore the implications of modifying the percentage add-on, we developed three illustrative policy options. In developing these options, we sought to balance a number of goals, including (1) improving financial incentives under the ASP payment system, (2) minimizing unintended consequences such as providers having difficulty acquiring drugs at Medicare payment rates, and (3) paying more efficiently and potentially generating savings for beneficiaries and taxpayers.

The first option would place a flat dollar limit on the 6 percent add-on. We chose a $175 limit as an illustration. In 2019, about 25 percent of Part B drugs had an average add-on payment greater than $175, accounting for less than 7 percent of all drug administrations and nearly three-fifths of total add-on payments. Thus, this approach would modify add-on payments for a subset of expensive products that account for a disproportionate share of add-on payment spending while maintaining the existing 6 percent add-on for most Part B drugs. A rationale for this approach is that a percentage add-on is particularly inefficient for high-priced drugs. If one rationale for an ASP add-on is price variation across purchasers, paying a percentage results in a large dollar add-on payment that may not be in line with actual price variation. Even if prices currently vary across purchasers for these products, changes to Medicare add-on payments could spur manufacturers to reduce or eliminate the variation. The existence of a large add-on on top of an already expensive drug also raises concerns from a beneficiary cost-sharing perspective, particularly when the purpose of large add-on payments is unclear. While placing a dollar limit on the ASP add-on would reduce the financial incentives to choose a very expensive drug subject to this limit, it would not affect potential incentives to use more expensive drugs among the group of products that are priced below the limit. Also, the add-on limit might create incentives to furnish drugs in smaller, more frequent doses to lessen the effect of the limit.

The second option reduces the percentage add-on and converts that portion of payments to a flat fee across all drugs. We modeled a policy of ASP + 3 percent + $21 per drug per administration day. We arrived at the $21 flat fee by estimating the budget-neutral equivalent of a 3 percent add-on (i.e., the average of 3 percent of ASP across all drug administrations). By reducing the percentage add-on by half, the differential in add-on payments between high-cost and low-cost products would be reduced by half, reducing the potential incentives to use a higher-cost product. However, a concern with this approach is the relatively large flat add-on for very inexpensive Part B drugs, which account for the majority of Part B drug administrations. In past work, the Commission has noted that if the flat fee is very large relative to low-priced drugs, it might create incentives for use of the product when treatment might not otherwise be initiated (Medicare Payment Advisory Commission 2016, Medicare Payment Advisory Commission 2015). It is also unclear how manufacturers of lower-cost products would respond to the large add-on and whether they would see it as an opportunity to raise prices. The fact that lower-cost products tend to be generics with competition might mitigate concerns about price increases. Finally, from a beneficiary cost-sharing perspective, an issue to be considered is how large an add-on for low-cost drugs is appropriate when the beneficiary is liable for 20 percent cost sharing on the add-on.

The third policy option combines Options 1 and 2 as a way to address some of the issues raised by each option separately. This third option would pay the lesser of (1) 6 percent of ASP or (2) 3 percent of ASP + $21, with a $175 limit on the add-on for very expensive drugs. For lower-cost drugs, this option maintains the 6 percent add-on, which could address potential concerns about a large flat fee for inexpensive drugs. For higher-cost drugs, the 6 percent add-on is reduced to 3 percent and a $21 flat fee would be added, reducing financial incentives for use of these products relative to less-expensive products. This option also includes a $175 flat dollar limit on the ASP add-on to address concerns about a percentage add-on generating large dollar add-ons for very expensive drugs.

To illustrate the effect of the three policy options, Table 4-8 (p. 124) displays the current add-on payments and total payments as a percentage of ASP under current policy (6 percent of ASP) compared with the three policy options for a variety of differently priced drugs (as measured by ASP).

- Under Option 1, the $175 limit on add-on payments reduces add-on payments for drugs with an ASP greater than $2,917 per administration but leaves add-on payments unchanged for drugs with an ASP below that threshold. This means Option 1 affects incentives only for very expensive drugs.
- Under Option 2, add-on payments change across all Part B drugs. Relative to the current 6 percent add-on, add-on payments drop for drugs with an ASP per administration greater than $700 and rise for drugs with an ASP less than $700. Because the percentage add-on is reduced from 6 percent to 3 percent, the differential in add-on payments between higher-cost and lower-cost products is reduced by half compared with current policy. Option 2 also results in very large add-on payments for drugs with small ASPs, which account for a large share of Part B drug administrations. For example, a drug with a $5 ASP would receive a $21.15 (i.e., 3% of $5 + $21) add-on payment under Option 2.
- Option 3 combines Option 1 and Option 2. For drugs with an ASP under $700, add-on payments are unchanged from current policy. For drugs with an ASP greater than $700, add-on payments are reduced to 3 percent + $21. Add-on payments are also capped at $175, which limits the add-on for drugs with an ASP greater than $5,133. Thus, for products with an ASP greater than $700, incentives to use a higher-priced product compared to a lower-priced product are reduced.

Comparing the difference in add-on payments among differently priced drugs further illustrates the effect of the various policy options. Table 4-8 (p. 124) shows the current dollar amounts of add-on payments for drugs at different ASPs, with add-ons for our three options. If two drugs, one with an ASP of $100 and the other with an ASP of $1,000, were therapeutic alternatives, under current policy the difference in add-on payments between the two products would be $54 (i.e., $60 – $6). The add-on differential would remain the same under Option 1 ($54), would be cut in half ($27) under Option 2, and would be reduced by 17 percent ($45) under Option 3. Comparing two drugs with an ASP of $1,000 and $3,000, the difference in add-on payments

TABLE 4–8

ASP add-on amounts for differently priced drugs under current policy and illustrative policy options

	Add-on payment amount				Add-on payment amount as percentage of ASP		
ASP per drug administered	Current: 6%	Option 1: Lesser of: 6% or $175	Option 2: 3% + $21	Option 3 (combine Options 1 & 2): Lesser of: 6%, 3% + $21, or $175	Option 1 Lesser of: 6% or $175	Option 2: 3% + $21	Option 3 (combine Options 1 & 2): Lesser of: 6%, 3% + $21, or $175
$5	$0.30	$0.30	$21.15	$0.30	6.0%	423.0%	6.0%
10	0.60	0.60	21.30	0.60	6.0	213.0	6.0
50	3.00	3.00	22.50	3.00	6.0	45.0	6.0
100	6.00	6.00	24.00	6.00	6.0	24.0	6.0
250	15.00	15.00	28.50	15.00	6.0	11.4	6.0
500	30.00	30.00	36.00	30.00	6.0	7.2	6.0
750	45.00	45.00	43.50	43.50	6.0	5.8	5.8
1,000	60.00	60.00	51.00	51.00	6.0	5.1	5.1
3,000	180.00	175.00	111.00	111.00	5.8	3.7	3.7
5,000	300.00	175.00	171.00	171.00	3.5	3.4	3.4
10,000	600.00	175.00	321.00	175.00	1.8	3.2	1.8
15,000	900.00	175.00	471.00	175.00	1.2	3.1	1.2

Note: ASP (average sales price). "ASP per drug administered" is defined as the ASP unit price times the number of units of the drug administered to the patient on a particular day. For drugs furnished by suppliers (e.g., nebulizer drugs and certain oral drugs), the data reflect ASP per prescription rather than ASP per administration. Add-on payment amounts include Medicare program payments and beneficiary cost sharing and are calculated before application of the sequester.

Source: MedPAC calculation of Medicare payment rates under alternative payment formulas.

between the products would be smallest under Options 2 and 3 ($60) compared with current policy ($120) and Option 1 ($115). For two more-expensive products with ASPs of $5,000 and $10,000, the add-on differential between the products is $300 under current policy. Option 1 would eliminate and Option 3 would nearly eliminate the add-on differential between the two products, while Option 2 would reduce the add-on differential by half. These examples show that Option 1 has the most effect on reducing the add-on differential among very expensive products; Option 2 has the most effect on mid- and low-priced products; and Option 3 has the most effect on mid- and high-priced products.

Table 4-9 shows the effect of the add-on policy options on overall Part B drug spending. These estimates are based on 2019 utilization data without any assumptions about how the policies might affect prescribing behavior. Overall, Options 1 and 3 would reduce aggregate Part B drug payments by 1.9 percent and 2.6 percent, respectively, while Option 2 results in no change in aggregate Part B drug spending. Options 1 and 3 generate savings due to the $175 cap on add-on payments for very expensive drugs. Option 3 generates additional savings by paying the lower of ASP + 6 percent or ASP + 3 percent + $21. Option 2 generates no overall savings and instead redistributes add-on revenue across drugs and specialties because the reduction in the ASP add-on by 3 percentage points

TABLE 4–9

Simulated impact of the policy options on total Part B drug payments by type of provider

		Percentage change in total Part B drug payments		
	2019 Total payments for Part B drugs paid ASP + 6% (in billions)	Option 1 Lesser of: 6% or $175	Option 2: 3% + $21	Option 3: Lesser of: 6%, 3% + $21, or $175
All	$28.7	–1.9%	0.0%	–2.6%
Physician	18.7	–1.6	0.6	–2.4
Oncology	7.5	–2.4	–1.1	–2.8
Ophthalmology	3.9	–0.2	–1.3	–1.8
Other	2.3	–1.8	6.7	–2.3
Rheumatology	2.3	–1.4	–1.6	–2.4
Primary care	1.8	–1.7	7.0	–2.3
Neurology	0.5	–2.3	–1.2	–2.9
Urology	0.4	–1.2	0.8	–1.9
Hospital outpatient departments	8.2	–2.5	–2.1	–3.0
Suppliers	1.8	–1.4	3.9	–1.8

Note: ASP (average sales price). Total payments include Medicare program payments and beneficiary cost sharing and include the effect of the sequester. Analysis includes all Part B–covered drugs paid under the ASP + 6 percent system, excluding drugs billed through not-otherwise-classified Healthcare Common Procedure Coding System codes. Part B drugs furnished by 340B hospitals paid ASP – 22.5 percent are excluded from the analysis. Data for critical access hospitals, Maryland hospitals, and beneficiaries with Medicare as a secondary payer are excluded from the analysis. Components may not sum to totals due to rounding.

Source: MedPAC analysis of Medicare claims data for physicians, hospitals, and suppliers.

was converted into a budget-neutral flat fee of $21 paid on each Part B drug administered. To the extent that the policy options result in substitution of lower-cost drugs for higher-cost drugs, the Medicare program and beneficiaries could realize additional savings beyond those estimated. At the same time, if a flat add-on or dollar limit on the 6 percent add-on resulted in some drugs being furnished in smaller, more frequent doses, those dynamics could to some extent reduce the savings generated by the policy options.

The effects of the policy options vary across clinical specialties under each option (Table 4-9). With Option 1, Part B drug revenues decrease across different provider types and specialties by 0.2 percent to 2.5 percent. This variation is driven entirely by the extent to which these provider groups utilize drugs that currently receive add-on payments greater than $175 per drug administered. Under Option 2, some provider types (oncologists, ophthalmologists, rheumatologists, neurologists, and outpatient hospitals) would experience a decline in Part B drug payments of 1.1 percent to 2.1 percent, and some would experience an increase in Part B drug payments (primary care physicians, suppliers, urologists, and other physician specialties) ranging from 0.8 percent to 7.0 percent. The redistribution in payments across specialties is driven by the mix of drugs used by each specialty, with those specialties that tend to use very low-cost drugs

seeing a substantial payment increase due to the $21 flat add-on. For example, under Option 2, drugs with an ASP per administration of less than $100 would experience a 141 percent increase in their Part B drug payments, from roughly $365 million under current policy to $880 million (data not shown). Under Option 3, all provider categories would experience a decline in Part B drug payments, ranging from 1.8 percent to 3.0 percent.

In considering a change to the ASP add-on, it is important to consider the effect on providers' ability to purchase drugs within the Medicare payment amount. Table 4-8 (p. 124) displays what the add-on under each policy option equates to in terms of a percentage of ASP. These models all reflect payment rates before the sequester. The 2 percent sequester, which the Congress suspended from May 2020 through March 2022 and reduced to 1 percent from April to June 2022, will be reinstated July 2022. A 2 percent sequester generally lowers the total payments a provider receives for Part B drugs by 1.6 percent. Under Options 1 and 3, the flat $175 add-on equates to a smaller percentage add-on the higher the ASP for the drug. With a 2 percent sequester, net payments for some very expensive drugs would fall below 100 percent of ASP unless the $175 add-on limit policy was explicitly designed to avoid that outcome. For example, for a drug with an ASP of $15,000 per administration, a $175 add-on equates to a payment of about ASP + 1.2 percent before the sequester (Table 4-8) and a payment of 99.5 percent of ASP after the sequester. For a drug with a $100,000 ASP per administration, the net payment rate with a $175 add-on would equal about 98.6 percent ASP after the 2 percent sequester. However, the add-on cap under Options 1 or 3 could be structured to ensure that net payments do not fall below ASP. For example, the add-on cap could be set at a level equal to the greater of $175 or, only if the 2 percent sequester is in effect, 1.6 percent of ASP.[47] This formula would ensure that with the $175 add-on limit, net payment for expensive drugs would not fall below 100 percent of ASP.

Over the years, some stakeholders have expressed concern about small purchasers' ability to acquire drugs for the Medicare payment amount if the ASP add-on is changed. Under Options 2 and 3, Medicare's payment for drugs with an ASP per administration over $700 would be reduced based on a formula of ASP + 3 percent + $21 (with Option 3 also having a $175 cap on add-on payments). Before the sequester, this payment formula equates to a payment of ASP + 5.1 percent for a drug with an ASP per administration of $1,000 and a payment rate of ASP + 3.4 percent for a drug with an ASP of $5,000 before the sequester (Table 4-8, p. 124); net payment rates would be about ASP + 3.4 percent and ASP + 1.8 percent, respectively, after application of a 2 percent sequester. In addition, under Options 1 and 3, as previously discussed, the $175 add-on cap could bring the net payment rates for very expensive drugs close to or equal to 100 percent of ASP (assuming the adjustment to the add-on cap just discussed). As the payment rate gets close to ASP, it is possible that smaller purchasers could have difficulty purchasing the product for the Medicare payment amount if volume discounts exist for a product that the small purchaser does not receive. However, it is unknown whether prices vary substantially across purchasers for expensive drugs with generally smaller patient populations. In addition, it is in manufacturers' interest to ensure that providers are able to acquire drugs at a price in line with the Medicare payment amount.

In addition, some stakeholders have raised concerns that changing the ASP add-on could accelerate a trend toward hospitals buying community oncology practices. Several reasons have been cited for hospitals' acquisition of these practices (e.g., availability of 340B discounts at some hospitals, general reimbursement pressures, a movement toward integrated care models, and interest among some physicians in employment rather than running a practice). If a change to the ASP add-on resulted in some practices having difficulty purchasing drugs at the Medicare payment rate, this circumstance might contribute to the trend toward more hospital-based oncology care. However, it is in drug manufacturers' interest to support community oncology practices since acquisition of practices by hospitals, some of which participate in the 340B program, would potentially subject more manufacturer sales to 340B discounts. ■

APPENDIX 4–A

Japan's approach to lowering drug prices

Under the Japanese health care system, medicines and medical devices approved by the Pharmaceutical and Medical Devices Agency (PMDA) are generally covered by the National Health Insurance (NHI) program and are reimbursed by payers (e.g., insurers, labor unions) based on prices set by the Ministry of Health, Labour, and Welfare (MHLW).[48] The MHLW maintains a price list called the Drug Price Standard (DPS) for all medicines covered by the NHI. DPS prices are approved by the Central Social Insurance Medical Council ("Chuikyo"), which is an advisory board consisting of individuals representing payers, health care providers, and individuals intended to represent the public interest (Shiroiwa et al. 2017). Chuikyo plays a central role in setting prices for medicines and medical devices covered by the NHI.

Price of a new medicine reflects incremental value when a therapeutic alternative is available

When a new brand-name drug (or biologic product) is approved by the PMDA, the price is determined using one of two methods: "similar efficacy comparison method" or "cost calculation method." Under the former, the price of a new drug is based on the price of an existing medicine that is similar in terms of efficacy and pharmacological properties (a comparator drug) (Yamate 2016). If the new drug is determined to be superior to the comparator drug (e.g., higher efficacy and safety), it qualifies for premium pricing that would be set at a level ranging from 5 percent to 120 percent above the comparator drug's price (Yamate 2016).

The second method, the cost calculation method, is used when there is no comparator drug on the DPS list. The price calculated under this method would account for cost of manufacturing (or importing) and other costs such as marketing, distribution, research and development, and consumption taxes. The method also has an allowance for operating profit, in which the base rate is the average profit rate across all industries. However, the rate may be adjusted upward based on factors such as novelty, efficacy, and safety compared with an existing therapy (Yamate 2016).

Elements of external and internal reference pricing may help constrain high prices at launch

The final step in setting a price for a new drug is to compare the price determined using one of the two methods described above with an average price from four countries—the U.S., the U.K., France, and Germany. The price is adjusted downward if it exceeds 125 percent of the average foreign price and adjusted upward if it is lower than 75 percent of the average foreign price (Mamiya 2018). The adjustment formula applies a proportionately greater adjustment as the differential between the price in Japan and the average foreign price increases.

A new generic or biosimilar product is priced at a discount relative to the price of the brand counterpart listed on the DPS (typically a 50 percent discount for generics and a 30 percent discount for biosimilars). For drugs and biologics in competitive classes (defined as more than 10 competitors), larger discount rates are applied, while lower discount rates may apply for biosimilars that meet certain conditions (Mamiya 2018).

Routine and "special" price adjustments are used to lower prices over time

After the initial price is set, DPS prices tend to decline because the prices are reviewed every two years to ensure that the reimbursement amounts are not excessive relative to prevailing market prices (Mamiya 2018).[49] If the DPS price is higher than the prevailing market price, the DPS price is adjusted downward (Mamiya 2018). Among drugs that were subject to price revisions, adjustments have averaged between −5 percent and −7 percent in most years since 2000 (Fukuda 2018). Prevailing market prices are typically lower than DPS prices because purchasers, such as medical institutions, may require that the manufacturer or the wholesaler provide discounts as a condition for their purchase or in exchange for a guarantee of a certain market share (Shiroiwa et al. 2017).

To promote generic use, an "exceptional reduction" is also applied in some circumstances. For an off-patent,

brand-name drug with at least one generic drug that has been on the market for at least five years, an additional price reduction of between 1.5 percent and 2 percent applies unless the generic drug(s) accounted for is at least 70 percent of the product's market (Mamiya 2018).

Special repricing for market expansion ("huge-seller" repricing)

This repricing policy allows the MHLW to revise the price for high-priced, high-sales drugs more frequently than the standard two-year increment when the sale of a product is expected to far exceed the manufacturer's forecast submitted at the time the price was set (Yamate 2016). Depending on the magnitude of expected sales relative to the original projection and the amount of the expected sale, the price could be reduced by up to 50 percent. This repricing policy was implemented in response to concerns raised by academics and policymakers about the cost of Opdivo (nivolumab) after it gained additional indications in 2016 (Niki 2020). The policy has subsequently been applied to at least four other drugs and biologics, including Harvoni (ledipasvir/sofosbuvir) and Avastin (bevacizumab) (Branch et al. 2017).

Cost-effectiveness evaluation system

Beginning in April 2019, Chuikyo implemented a new cost-effectiveness (CE) evaluation system for repricing medicines and medical devices.[50] Products are selected for CE evaluation based on the magnitude of the premium add-on and market size (Shiroiwa et al. 2017).[51] CE data submitted by the manufacturer are then reviewed by the Center for Outcomes Research and Economic Evaluation for Health.[52] As of December 2019, six medicines, including Kymriah (Novartis), had undergone a CE evaluation (Shiroiwa 2020). During the 2016 to 2017 period, Chuikyo conducted trial evaluations of seven medicines and six medical devices. The evaluations resulted in price reductions for two products—Opdivo (nivolumab) and Kadcyla (trastuzumab emtansine)—and a price increase for one medical device (Shiroiwa 2020). The lack of price adjustments for the other medicines and medical devices examined may reflect difficulty in reaching agreement among the parties involved in the evaluation. According to one researcher, CE evaluations did not result in more price adjustments "due to large gaps between results of appraisals undertaken by drug companies and those by independent researchers" (Niki 2020). ■

Endnotes

1 On the basis of SSR Health data, the authors identified a list of prescription drugs that met each of the following criteria: (1) were among the top 250 drugs by 2020 U.S. sales revenue; (2) had list price increases that were more than 2 percentage points higher than the rate of medical inflation between the end of 2019 and the end of 2020; (3) had net price increases after accounting for rebates and other concessions; and (4) after net price increases were vetted with manufacturers, were found to be the top 10 drugs whose price increases—as opposed to volume increases—contributed to the largest increase in U.S. spending. Based on public input, an additional two drugs were included in the analysis.

2 CMS considers a service "reasonable and necessary" if the service is safe and effective, not experimental or investigational, and appropriate for beneficiaries (Centers for Medicare & Medicaid Services 2019c).

3 Depending on the specific expedited program, sponsors of new drugs may receive a variety of benefits, such as additional opportunities to meet with and obtain advice from FDA officials during drug development; a rolling review (the FDA reviews portions of the application as they come in instead of waiting for the complete application); the ability to use certain surrogate endpoints or an intermediate clinical endpoint that is reasonably likely to predict clinical benefit; and a shorter goal for review time for the drug application.

4 FDA guidance states that there is a risk under accelerated approval that patients may be exposed to a drug that ultimately will not be shown to provide an actual clinical benefit and that with fewer, smaller, or shorter clinical trials, there may be less information about rare or delayed adverse events (Food and Drug Administration 2014).

5 The Government Accountability Office and others have found weaknesses in the FDA's oversight of postmarket safety for drugs approved under the expedited pathways. The agency lacks reliable information to determine the progress of postmarket studies and manufacturers have delayed confirmatory studies of drugs approved under the accelerated approval pathway (Government Accountability Office 2015, Institute for Clinical and Economic Review 2021b).

6 According to CMS, although the definition of an LCD in the Social Security Act does not support the use of coverage with evidence development (under Section 1862(a)(1)(E)), MACs may use LCDs to determine coverage of items and services to the extent that they do not conflict with national Medicare policy (Centers for Medicare & Medicaid Services 2014).

7 In 2005, CMS applied CED to cover off-label use of colorectal cancer drugs (oxaliplatin, irinotecan, cetuximab, or bevacizumab), linking coverage to participation in nine clinical trials sponsored by the National Cancer Institute. As of September 2021, this CED is ongoing. In 2009, Medicare applied CED for pharmacogenomic testing for warfarin response.

8 The 340B Drug Pricing Program allows certain hospitals to obtain discounted prices from drug manufacturers on drugs and biologics other than vaccines. Under the hospital outpatient prospective payment system (OPPS), 340B hospitals are paid ASP + 6 percent for drugs with pass-through status. New drugs, biologics, and biosimilars typically receive pass-through status for the first two to three years on the market.

9 CMS takes the charges for items and services, including bundled drugs, and multiplies them by department-level cost-to-charge ratios to estimate the average cost associated with each APC. In this way, an estimate of hospitals' average drug costs flows into the bundled payment rates under the OPPS.

10 Drug costs are incorporated into the dialysis payment bundle based on CMS's estimate of historical utilization and the manufacturer's ASP for the drugs.

11 This analysis of separately payable Part B drugs between 2009 and 2019 excludes any drug that was bundled in 2009 or 2019. That is, drugs that were packaged in 2009 or 2019 were excluded from both years of the analysis, regardless of the setting in which the drug was administered.

12 In addition to payment for a drug, Medicare makes a separate payment for administration of the drug under the physician fee schedule or OPPS. Medicare pays a dispensing or supplying fee to pharmacies that dispense inhalation drugs and oral anticancer, oral antiemetic, and immunosuppressive drugs to beneficiaries; Medicare also pays a furnishing fee to providers of clotting factors.

13 This is the first year we have included preventive vaccines paid 95 percent of average wholesale price in our top 20 Part B drug analysis. Previously, we focused only on drugs paid under the ASP payment system. If the 2019 version of Table 4-2 (p. 96) had included preventive vaccines, Fluzone High-Dose would have been the 20th highest expenditure drug, with spending over $400 million that year. With that adjustment to our 2019 analysis, the same drugs were in the top 20 in both 2019 and 2020.

Among the top 20 highest-expenditure products, relative rankings shifted somewhat between 2019 and 2020. Spending on several originator biologics with biosimilar competition declined between 2019 and 2020, reflecting greater biosimilar uptake and price decreases among originator biologics with biosimilar competitors. However, it is important to note that spending on biosimilar competitors is not reflected in the data in the table for the originator biologic. If biosimilar spending is summed with each originator biologic's spending, total 2020 spending was $1.6 billion for Rituxan, $1.2 billion for Neulasta, $1.0 billion for Avastin, $0.8 billion for Remicade, and $0.7 billion for Herceptin and their respective biosimilars.

14 The extent to which originator biologics have lowered their prices in response to biosimilar entry and the extent to which market share has shifted to biosimilars vary by product. For example, the originator Remicade has lowered its price substantially and retained most of its market share. In contrast, the originator Neupogen has lowered its price slightly and most market share has shifted to biosimilars.

15 In describing the assumptions of its simulation mode, CBO stated that "a 15 percent to 25 percent reduction in expected returns for drugs in the top quintile of expected returns is associated with a 0.5 percent average annual reduction in the number of new drugs entering the market in the first decade under the policy, increasing to an 8 percent annual average reduction in the third decade" (Congressional Budget Office 2021a).

16 Policymakers could consider setting a cap on a drug's payment based on its net clinical benefit separately from applying CED. However, this chapter has not considered such an approach.

17 Medicare Advantage (MA) plans are generally required to provide the same set of benefits that are available to beneficiaries under FFS Medicare. In addition, MA plans must adhere to NCDs and LCDs applicable in their service areas (with two exceptions related to regional preferred provider organizations and MA plans that include multiple MAC areas). In NCDs requiring CED, Medicare covers items and services in CMS-approved CED studies. MA plans are responsible for payment of items and services in CMS-approved CED studies unless CMS determines that the significant cost threshold is exceeded for that item or service.

18 In addition, although the framework to implement "coverage with evidence development" had yet to be developed, in 1995 Medicare linked coverage of lung volume reduction surgery to the collection of clinical evidence (Mohr and Tunis 2010). The publicly funded study was completed and main findings published in 2003. Medicare revised its NCD to cover all patients who matched the characteristics of patients in the trial who experienced a survival or quality-of-life benefit. In addition, in 2001, Medicare linked coverage of angioplasty of the carotid artery with stenting (Mohr and Tunis 2010).

19 Section 1142 of the statute describes the authority of AHRQ to conduct and support research on outcomes, effectiveness, and appropriateness of services and procedures to identify the most effective and appropriate means to prevent, diagnose, treat, and manage diseases, disorders, and other health conditions.

20 Under Section 1862(a)(1)(E) of the statute, the Secretary has the authority to "conduct and support research through the AHRQ administrator with respect to the outcomes, effectiveness, and appropriateness of health care services and procedures in order to identify the manner in which diseases, disorders, and other health conditions can most effectively and appropriately be prevented, diagnosed, treated, and managed clinically."

21 See the Commission's June 2010 report to the Congress, Chapter 1 and appendixes, for a more detailed discussion of Medicare's statutory foundation to implement CED and other implementation issues.

22 Some stakeholders argue that CED can be burdensome. However, researchers have noted that modernizing data collection by, for example, designing registries that can be used for multiple purposes (e.g., CED, FDA surveillance, and quality benchmarking) and enhancing data linkages across other databases can minimize operational challenges of CED (Duke Margolis Center for Health Policy 2020).

23 Medicare uses clinical information to determine when new technologies qualify for add-on payments under the inpatient, outpatient, and end-stage renal disease prospective payment systems.

24 Only for preventive services (including vaccinations and colorectal screening tests), and based on legislative requests and statutory directives, has Medicare explicitly considered the cost-effectiveness of a service when making a national coverage decision.

25 According to the statute: (1) "The Secretary shall not utilize such an adjusted life year (or such a similar measure) as a threshold to determine coverage, reimbursement, or incentive programs under title XVIII," and (2) "The Secretary shall not use evidence or findings from clinical comparative effectiveness research . . . in determining coverage, reimbursement, or incentive programs . . . in a manner that treats extending the life of an elderly, disabled, or terminally ill person as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill."

26 ICER is an independent nonprofit organization that, since 2005, conducts independent analyses of the comparative clinical effectiveness and cost-effectiveness of medical interventions, including drugs, medical devices, tests, and delivery system innovations.

27 For example, should studies limit the population to Medicare beneficiaries or patients of all ages? Should costs be limited to Medicare payments? Should the model include all costs—taking the societal perspective? Should the analysis measure outcomes that use QALYs or another method, such as life years gained?

28 Researchers use sensitivity analysis to test the effect of varying parameters of interest (e.g., drug prices) on the conclusions of CEAs.

29 See Chapter 1 of the Commission's March 2022 report for a more detailed discussion of Aduhelm's implications for the Part B premium (Medicare Payment Advisory Commission 2022b).

30 The Commission's comment letter that supports the agency's CED proposal can be found at https://www.medpac.gov/wp-content/uploads/2022/02/Feb22_NCD_Monoclonal_Alzheimers_MedPAC_comment_v2_SEC.pdf.

31 CMS is not requiring a separate RCT that duplicates an RCT conducted for FDA approval. According to the final NCD, because each antiamyloid mAb product (approved based on a surrogate outcome) may have a distinct mechanism of action resulting in a distinct benefit/risk profile, CMS will evaluate each on its own merit in its own studies (Centers for Medicare & Medicaid Services 2022b).

32 Prospective comparative studies may include a variety of study designs, ranging from observational comparative studies to pragmatic randomized trials, and study data may be collected in a registry. These studies must address the following questions: (1) Does the drug meaningfully improve health outcomes (i.e., slow the decline of cognition and function) for patients in community practice? (2) Do benefits and harms associated with use of the drug, such as brain hemorrhage and edema, depend on characteristics of patients, treating clinicians, and settings? (3) How do the benefits and harms change over time (Centers for Medicare & Medicaid Services 2022b)?

33 According to the authors, net costs to a Medicaid program were estimated by adjusting the acquisition cost (as measured by average wholesale price, the prevailing payment during most of the study period) for average rebates.

34 The 24 Part B anticancer drugs were approved by the FDA between 1996 and 2012 and did not go off patent during the follow-up period (between 2005 and 2017). Adjusting for annual general and health-related inflation rates, the mean cumulative increases were 19.1 percent and 8.4 percent, respectively. Using multivariate regression techniques, the researchers reported that the number of years after a drug's launch may have influenced price change rates. For every additional year after a drug's launch, there was an additional increase of 0.3 percent in inflation-adjusted price change and a 0.2 percent increase in health-related inflation-adjusted price change rates.

35 The authors included the following six classes: antineoplastic agents, insulins, lipid-lowering agents, multiple sclerosis therapies, noninsulin antidiabetic agents, and tumor necrosis factor inhibitors.

36 Services that lack comparative clinical effectiveness information would be paid according to current Medicare policies for a period of three years. At the end of this period, Medicare would decide whether evidence was currently available to determine whether the service was superior, comparable, or inferior to alternatives.

37 The prostate cancer drugs were triptorelin pamoate, goserelin acetate implant, and leuprolide acetate suspension.

38 Under the Medicare, Medicaid, and SCHIP Extension Act of 2007, CMS calculates the payment rate for albuterol and levalbuterol based on the lower of (1) the volume-weighted average of 106 percent of the ASP for both drugs or (2) the payment rate based on 106 percent of the ASP for the individual drug.

39 The statute constrains Medicare's use of comparative clinical effectiveness evidence to pay for drugs. Medicare cannot withhold coverage of prescription drugs using comparative clinical effectiveness evidence that AHRQ produces. The Affordable Care Act of 2010 constrains Medicare's use of comparative clinical effectiveness research conducted by the Patient-Centered Outcomes Research Institute when making coverage decisions and setting payment rates.

40 The statute requires that Medicare cover off-label indications of cancer drugs if the drug's off-label use is supported by selected third-party drug compendia.

41 The National Eye Institute funded a study that found that off-label Avastin and on-label Lucentis had equivalent effects on visual acuity when administered according to the same schedule (Catt Research Group et al. 2011).

42 When the 2 percent sequester is in effect, it reduces payments providers receive for Part B–covered drugs by 1.6 percent, which results in a net payment equivalent to ASP + 4.3 percent. Legislation suspended the sequester through

March 31, 2022. For April to June 2022, the sequester was reduced to 1 percent, and in July 2022 the 2 percent sequester will be reinstated.

43 For drugs provided by outpatient hospitals, some portion of the drug payment amount is intended to cover pharmacy overhead. With respect to payment for separately paid drugs under the OPPS, CMS has stated that the drug payment rate (currently ASP + 6 percent; in prior years, as low as ASP + 4 percent) includes payment for drug acquisition costs and pharmacy overhead (Centers for Medicare & Medicaid Services 2012).

44 This analysis of add-on payments excludes drugs furnished by 340B hospitals that are paid ASP – 22.5 percent. Specifically, we exclude those drugs billed by OPPS hospitals using the JG modifier.

45 The payment amount for drug administration varies by type of drug and mode of administration. For example, under the physician fee schedule, the payment rates for some common drug administration services in 2022 are $14.54 for a therapeutic, prophylactic, or diagnostic injection, subcutaneous or intramuscular, and $69.21 for a therapeutic, prophylactic, or diagnostic intravenous infusion, first hour, excluding chemotherapy and other highly complex drugs or highly complex biologic agents. In contrast, the payment rate for a chemotherapy antineoplastic injection, subcutaneous or intramuscular, is $77.86, and for a chemotherapy intravenous infusion, first hour, is $140.16. Additional payments are made if the infusion lasts longer than the initial hour or if more than one drug is furnished. In addition, drug administration payment rates may vary based on the location of the injection (e.g., injections in the eye and in the knee).

46 Whereas 9.2 percent of beneficiaries used the most expensive drug in the 10 months before the payment change, 11.0 percent of beneficiaries used that drug in the 10 months after.

47 The 2 percent sequester reduces the total payment a provider receives for Part B drugs by 1.6 percent because the sequester applies to the Medicare program payment (80 percent of the payment) but not beneficiary cost sharing (20 percent of the payment). A $175 add-on cap policy could be designed to ensure that payments do not fall below 100 percent of ASP after application of the sequester. That could be accomplished using the following formula: Cap equals the greater of $175, or if the 2 percent sequester is in effect, 1.626 percent of ASP. The percentage of ASP in this formula is slightly higher than 1.6 percent because it accounts for the effect of the sequester on both the ASP portion and add-on portion of the payment.

48 Japan's multipayer social insurance–based system is similar to the systems in France and Germany (Shiroiwa et al. 2017).

49 Prevailing market prices are obtained through a survey of wholesalers and purchasers such as medical institutions and pharmacies (Mamiya 2018).

50 The results of the cost-effectiveness evaluation are not used by the NHI to make coverage decisions (Shiroiwa 2020).

51 Under the CE evaluation system, highly innovative drugs associated with high spending are subject to a CE evaluation and, if warranted, price adjustments. This policy applies to (1) newly listed products with projected peak sales of over ¥10 billion (about US$92 million) or annual sales of between ¥5 billion and ¥10 billion; and (2) existing products with projected peak sales of over ¥100 billion, or significantly high prices. CE is measured using an incremental cost-effectiveness ratio (ICER) and estimates of costs per quality-adjusted life years gained. The price adjustment, if warranted, applies to the premium add-on (if applicable) and the operating profit portion of the NHI price. Cancer drugs and other specialty drugs are assessed against "relaxed" ICER thresholds. Therapies targeting designated intractable diseases, HIV, hemophilia, and some cancer indications can be excluded from CE evaluation (Sharma 2020).

52 The Center for Outcomes Research and Economic Evaluation for Health is a department within the National Institute of Public Health that was founded in 2018 to conduct independent CE analysis to be used during the CE evaluation process (Hasegawa et al. 2020).

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CHAPTER 5

Improving the accuracy of Medicare Advantage payments by limiting the influence of outliers in CMS's risk-adjustment model

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Improving the accuracy of Medicare Advantage payments by limiting the influence of outliers in CMS's risk-adjustment model

Post-publication review of the analyses underlying this chapter revealed possible errors. We have withdrawn the chapter while we reevaluate the analyses and our conclusions.

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CHAPTER 6

Aligning fee-for-service payment rates across ambulatory settings

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Chapter summary

Medicare payment rates often differ for the same service among ambulatory settings (hospital outpatient departments (HOPDs), ambulatory surgical centers (ASCs), and freestanding physician offices). These payment differences across settings encourage arrangements among providers—such as consolidation of physician practices with hospitals—that result in care being provided in the settings with the highest payment rates, which increases total Medicare spending and beneficiary cost sharing without significant improvements in patient outcomes. From 2015 to 2019, for example, the volume of chemotherapy administration in freestanding clinician offices, the setting for which payment rates are generally lowest, fell 5.4 percent, while the volume in HOPDs, the setting for which payment rates are generally highest, climbed 27.8 percent.

In general, the Commission maintains that Medicare should base payment rates on the resources needed to treat patients in the most efficient setting. If the same service can be safely provided in different settings, a prudent purchaser should not pay more for that service in one setting than in another. Payment rate differences across the three ambulatory settings could be addressed simply by setting payment rates for a given service equal to that of the setting that has the lowest payment, which

In this chapter

is usually—but not always—freestanding offices. However, HOPDs have important differences from freestanding offices and from ASCs that can lead to higher costs in HOPDs for certain services. For example, hospitals incur costs to maintain standby capacity for handling emergencies and to comply with additional regulatory requirements that ASCs and freestanding offices do not have. Also, some services can be safely provided only in HOPDs for most beneficiaries, so it is vital that HOPDs are adequately reimbursed to remain a viable setting for the provision of those services. In addition, identifying payment rate differences among the three payment systems requires careful analysis because the outpatient prospective payment system (OPPS) and the ASC payment system generally package payment for ancillary items provided with a service, while the fee schedule for physicians and other health professionals, also known as the physician fee schedule (PFS), does not. This difference in the packaging of services must be considered when comparing payment rates among settings.

To evaluate whether an ambulatory service should continue to have different payment rates in the three settings or whether it would be appropriate to align the payment rates more closely across the three settings, we analyzed the ambulatory payment classifications (APCs) used in the OPPS to pay for services provided in HOPDs. Each APC includes a set of services that are similar in terms of clinical attributes and cost; all services included in a single APC have the same payment rate. Of the OPPS's 169 APCs for services (as opposed to drugs and devices), we identified 57 APCs for which it would be reasonable to align payment rates across the three ambulatory care settings with those of the PFS. The physician office is the most frequent site of service for these 57 APCs, indicating that freestanding offices are a safe and appropriate setting for these services and that PFS payment rates are adequate to ensure beneficiaries' access to care. We also identified 11 APCs for which ASCs have the largest volume among the three ambulatory settings. For these APCs, it would be appropriate to align the OPPS payment rates with those paid in the ASC setting, while continuing to use the PFS payment rate when the service is provided in a freestanding office. Finally, for 101 APCs, including emergency department (ED) visits, the HOPD is the most frequent setting, or the services cannot be provided in settings other than HOPDs. For these APCs, each setting should continue to have a different payment rate, with generally higher payments for HOPDs.

As policymakers consider how to align payment rates across ambulatory settings, they must ensure that hospitals continue to receive adequate financial

support to maintain standby emergency capacity. To maintain this support, the APCs for ED visits, critical care visits, and trauma care visits could be reclassified from standard APCs to comprehensive APCs (C–APCs). C–APCs are an advanced form of APC in which all services—with a few exceptions—that appear on the same claim are packaged together into a single payment unit. By transforming payment for these services from standard APCs to C–APCs, higher payment rates for the provision of services during these visits would be maintained, appropriately reflecting the hospital-level costs of items and services provided.

Some stakeholders contend that payment rates should be higher for services provided in HOPDs relative to other ambulatory settings because HOPD patients are sicker and more complex on average relative to patients in other ambulatory settings. However, we have found that patient severity has little effect on the costs incurred by HOPDs when furnishing the services in the APCs for which payment rate alignment across settings would be reasonable. Therefore, we concluded that, if payment rates were aligned, adjustments for patient severity would not be needed.

In aggregate, if changes in payments resulting from aligning payment rates were taken as program savings, Medicare program spending in 2019 would have declined by $6.6 billion and beneficiary cost-sharing obligations by $1.7 billion. Across all hospitals, a site-neutral policy would have reduced overall Medicare revenue by 4.1 percent and beneficiary OPPS cost sharing by 13.2 percent.

Under current law, CMS would be required to fully offset the lower Medicare spending and beneficiary cost sharing from aligning ambulatory payment rates by increasing the OPPS payment rates for all other (nonaligned) APCs to produce a budget-neutral result. Combining alignment of payment rates with a budget-neutrality adjustment within the OPPS would lower incentives to shift services to higher-cost settings but would reduce savings for Medicare and beneficiaries. However, if the budget-neutrality adjustment were not applied, some hospitals that are the primary source of access to physician services for low-income patients would experience reductions in Medicare revenue under the payment alignment policy, which could adversely affect access for these beneficiaries. In response to these concerns, policymakers could consider an alternative to the budget-neutrality policy that would explicitly target hospitals that serve a high share of low-income beneficiaries to limit the loss of Medicare revenue for these hospitals. Over time, the payment rate alignment

policy would produce savings for the Medicare program and lower cost sharing for beneficiaries under either the budget-neutrality policy or the stop-loss policy because incentives to shift services from the lower-cost physician office and ASC settings to the higher-cost HOPD setting would be mitigated. ■

Medicare's payment rates often vary for the same ambulatory services provided to similar patients in different settings, including freestanding physicians' offices, hospital outpatient departments (HOPDs), and ambulatory surgical centers (ASCs). These payment differences across settings encourage arrangements among providers—such as the consolidation of physician practices with hospitals—that result in care being billed at the payment rates of the provider with the highest rates, increasing program and beneficiary spending without meaningful changes in patient care.

This chapter discusses a method to more closely align payment rates across the three ambulatory care settings—HOPDs, ASCs, and freestanding offices—that is broader than Medicare's current policies. This method would move beyond the policies recently implemented by CMS and the Commission's previous recommendations in 2012 and 2014 by aligning payment rates across a greater number of services. We examine the impact of potential payment changes on Medicare spending, beneficiary cost sharing, and hospital revenue. We also discuss accompanying budget-neutrality or stop-loss policies that would mitigate the impact on hospital revenue and whether an adjustment to payments for differences in patient severity would be needed.

Background

CMS sets payment rates for clinician services in the fee schedule for physicians and other health professionals, also known as the physician fee schedule (PFS); payment rates for most HOPD services in the outpatient prospective payment system (OPPS); and payment rates for ASC services in the ASC payment system. For services provided in freestanding clinician offices, Medicare makes a single payment to the practitioner under the PFS. For services provided in HOPDs or ASCs, Medicare makes two payments: one for the clinician's professional fee under the PFS and one for the HOPD or ASC facility fee under the OPPS or ASC payment system.

Medicare payment rates for ambulatory services often differ among the three ambulatory settings and are usually highest in HOPDs. For example, in 2022, Medicare pays 141 percent more in an HOPD than in a freestanding office for the first hour of chemotherapy infusion (counting both the professional fee and facility fee). In addition, in 2022, Medicare pays 105 percent more in on-campus HOPDs than in freestanding offices for a midlevel office visit. These types of variations raise questions about how Medicare should pay for the same service when it is delivered in different settings.

Generally, the Commission has maintained that Medicare should strive to base payment rates on the resources needed to treat patients in the most efficient (meaning the highest quality, lowest cost) setting, which would mitigate incentives to shift the provision of services to higher-cost settings. In the absence of comparable data on providers' costs and quality across settings that justify payment differences, Medicare should set payment rates such that the cost to the program and beneficiaries is not higher than necessary to ensure beneficiaries' access to high-quality care. On the basis of these principles, the Commission recommended in 2012 that Medicare reduce payment rates and cost sharing for office visits provided in HOPDs and, in 2014, for services meeting certain criteria so that total payment rates and cost sharing would be equal whether these visits were provided in an HOPD or in a freestanding physician's office (Medicare Payment Advisory Commission 2014, Medicare Payment Advisory Commission 2012).

In the Bipartisan Budget Act (BBA) of 2015, the Congress directed CMS to develop a limited system that more closely aligns payment rates between HOPDs and freestanding offices. CMS satisfied this mandate in 2017 by implementing payment rates that approximate PFS rates for certain services provided in off-campus provider-based departments (PBDs) of hospitals that were not providing services when the Congress enacted the BBA of 2015 on November 2, 2015 (Centers for Medicare & Medicaid Services 2016). In 2019, CMS moved beyond the BBA of 2015 requirements by reducing the OPPS payment rate to more closely align with the PFS rate for office visits that occur in any off-campus PBD, not just those specified in the BBA of 2015 (Centers for Medicare & Medicaid Services 2019).

While CMS's policies more closely align OPPS payment rates with PFS payment rates for some services, the effects of these policies are somewhat limited. Only 0.8 percent of total OPPS spending is for services provided in off-campus PBDs covered by the BBA of

TABLE 6–1

Provision of important ambulatory services has shifted from physician offices to hospital outpatient departments

	Share in HOPDs	
Service	**2012**	**2019**
Office visits	9.6%	13.1%
Chemotherapy administration	35.2	50.9

Note: HOPD (hospital outpatient department).

Source: MedPAC analysis of 100 percent standard analytic claims files, 2012 and 2019.

2015 requirements. In addition, only one-third of the office visits provided in HOPDs occur in off-campus PBDs. Also, the off-campus PBDs not subject to the BBA of 2015 site-neutral payments have no restrictions on expanding the range of services they provide. Therefore, if a hospital acquires a physician practice and adds it to an existing off-campus PBD that is excepted from the BBA of 2015, the services furnished by that practice would be paid at full OPPS rates (with the exception of office visits covered by CMS's policy mentioned above that aligns OPPS payment rates for all office visits provided in off-campus PBDs with the PFS payment rates).

Payment rate differences across ambulatory settings cause services to shift to the highest-paid setting

Some stakeholders have argued that Medicare should pay higher rates for all services provided in HOPDs because hospitals incur costs that other settings do not to maintain 24/7 emergency care, standby capacity, access to care for low-income patients, efforts to improve care coordination, and community outreach. However, the costs for maintaining standby capacity and other hospital programs are spread across all HOPD services, including those that are unrelated to the additional hospital activities. The spreading of the costs for standby capacity across all HOPD services is part of the reason that OPPS payment rates are generally higher than PFS and ASC payment rates.

The resulting payment rate differences among the ambulatory settings provide incentives for hospitals to work out arrangements that shift the site of care from lower-paid freestanding offices and ASCs to the higher-paid HOPD setting—or that reclassify a site of care so that bills can be submitted and paid under the OPPS. Partly in response to these incentives, in recent years hospitals have acquired more physician practices, and hospital employment of physicians has increased. Analysis of data from the American Medical Association's Physician Practice Benchmark Surveys indicates that the share of physicians who were either in practices that had at least some hospital ownership or were employees of hospitals increased from 29.0 percent in 2012 to 39.8 percent in 2020 (Kane 2021).

As hospitals acquire more physician practices and more physicians become employed by hospitals, large shifts in billing from the PFS to the OPPS have occurred for four service categories: chemotherapy administration, echocardiography, cardiac imaging, and office visits. For example, the HOPD share of office visits provided to fee-for-service (FFS) beneficiaries grew from 9.6 percent in 2012 to 13.1 percent in 2019, and the HOPD share of chemotherapy administration services rose from 35.2 percent to 50.9 percent (Table 6-1). Because most services receive higher payment rates when provided in HOPDs than in freestanding

offices, migration of services from freestanding offices to HOPDs results in higher program spending and beneficiary cost sharing without meaningful changes in patient care. For example, the Commission estimates that the shift of office visits from the office setting to the HOPD setting from 2015 through 2019 increased Medicare program spending by $615 million and beneficiary cost sharing by $150 million. Program spending and beneficiary cost sharing could be reduced by more closely aligning OPPS payment rates with PFS payment rates for services that are clearly safe to provide in freestanding offices for most Medicare beneficiaries.

We are also concerned about pricing differences between the OPPS and the ASC payment system for similar services. For the OPPS, CMS creates a relative weight for each service, which indicates the resources needed to provide the service relative to a benchmark service (the office visit). CMS multiplies the relative weights by a conversion factor to create payment rates in the OPPS. For the ASC payment system, CMS bases the relative weights for most procedures on the OPPS relative weights, but the ASC system uses a lower conversion factor. Therefore, payment rates for all procedures are much higher in the OPPS. For 2022, the Medicare rates for most services are 97 percent higher in the OPPS than in the ASC system. Beneficiary cost sharing is also much higher in HOPDs than in ASCs, as coinsurance is 20 percent of the payment rate for most services in both settings. Moreover, the gap in payment rates between the two settings has widened over time.

Program spending and beneficiary cost sharing could be reduced by more closely aligning OPPS payment rates with ASC payment rates for services that are clearly safe to provide in ASCs for most Medicare beneficiaries.

HOPDs incur costs that are unique to that setting

Payment rate differences between the OPPS, the PFS, and the ASC payment system could be addressed simply by setting payment rates equal across the three settings. There are precedents for this approach: Medicare pays the same amount for outpatient therapy services, mammography tests, dialysis services, and clinical lab tests regardless of setting. In addition, CMS sets the payment rate for some services provided in ASCs at the nonfacility practice expense rate from the PFS.

However, HOPDs have important differences from freestanding offices and ASCs that can lead to higher costs in HOPDs for certain services:

- Hospitals incur costs to maintain standby capacity for handling emergency care. They are subject to the Emergency Medical Treatment and Active Labor Act of 1986 (EMTALA), which requires them to screen and stabilize (or transfer) patients who believe they are experiencing a medical emergency, regardless of their ability to pay.
- Hospitals face a unique set of licensing and accreditation requirements that increase their cost structure. Hospitals must meet conditions of participation in the Medicare program, which adds to their costs; these conditions do not apply to ASCs or freestanding offices.
- Hospitals must comply with more stringent building codes and life-safety codes. Also, an outpatient facility that is considered part of a hospital must meet CMS's rules for provider-based status, such as maintaining financial integration with the parent hospital.[1] These rules could result in higher costs for providers, Medicare, and beneficiaries, without evidence that patient care has improved.

A final issue to consider when aligning payment rates across ambulatory settings is whether patients in some settings are sicker than others, as it can be more costly to provide the same service to sicker patients than to healthier patients. The American Hospital Association (AHA) has argued that patients in HOPDs tend to be more medically complex than patients who receive the same type of service in an ASC or freestanding office (American Hospital Association 2021). This finding from the AHA suggests that treating these patients may require more time and resources. As discussed later in this chapter, however, Commission analysis has found only a weak relationship between beneficiaries' health status and HOPD charges.

Some may argue that the requirements that apply to hospitals but do not apply to ASCs or freestanding offices are a reason for maintaining higher OPPS

payment rates for all services provided in HOPDs. However, the additional requirements faced by HOPDs are a reason to encourage less provision in HOPDs of services that are clearly safe to provide in freestanding offices or ASCs. The additional requirements faced by HOPDs help to ensure safe provision of services that can be provided only in HOPDs, such as emergency department (ED) visits, or that are too complex to reasonably provide in the other settings, such as many joint replacement procedures. These additional requirements faced by hospitals are not needed to ensure safe provision of less complex services that can be safely provided in lower-cost settings, such as office visits or the administration of most drugs. A prudent purchaser of care would encourage provision of the less complex services in the lowest-cost setting where it is reasonable to do so. More closely aligning OPPS payment rates with PFS rates or ASC rates for services that are reasonable to provide in the other ambulatory settings is an efficient way to do so. Aligning OPPS payment rates with the payment rates in the lower-cost settings for the less complex services would reduce spending by the Medicare program and beneficiary cost-sharing liabilities.

Identifying services for which payments can be more closely aligned across settings

While more closely aligning the payment rates across ambulatory settings is beneficial, ensuring beneficiaries' access to the services they need is vital. To ensure beneficiaries' access to care, several issues need to be addressed:

- As discussed above, hospitals incur costs to maintain standby capacity and licensing and accreditation.
- The services subject to payment alignment must be safe to provide to most beneficiaries in the lower-cost setting.
- The differences between payment systems in the packaging of ancillary items must be accounted for. Specific differences in packaging ancillary items between payment systems include the following:
  - In general, the OPPS and ASC payment system use the same method of combining the cost of primary services with ancillary items into a single payment bundle. In contrast, the PFS has less packaging of ancillary items, and Medicare tends to pay separately for each item. Therefore, for many services, some portion of the higher payment rates under the OPPS and the ASC system relative to PFS rates reflects a greater level of packaging.
  - The PFS uses 90-day global codes for some surgical procedures, while the OPPS and the ASC payment system do not. The PFS payments for 90-day global surgical codes include the surgical procedure itself and office visits that occur within a 90-day period after the procedure. The PFS payment rates for these services also include the cost of staff time spent scheduling the procedure and coordinating presurgical services when the procedure is performed in a facility (rather than an office).

To identify services for which it is reasonable to more closely align payment rates across ambulatory settings, we took the following steps:

- We sorted services into ambulatory payment classifications (APCs), which are the payment classifications used in the OPPS. APCs are made up of services represented by Healthcare Common Procedure Coding System (HCPCS) codes. CMS classifies HCPCS codes that are similar in terms of cost and clinical attributes in the same APC. All HCPCS codes in the same APC have the same OPPS payment rate.
- Some APCs include services that can be reasonably provided only in HOPDs, such as emergency care, critical care, and trauma care. We removed these APCs from consideration.
- For the remaining APCs, we compared the volume of services provided in HOPDs, ASCs, and freestanding offices over a four-year period (2016 through 2019).
  - If freestanding offices had the highest volume for an APC, we determined that the services in that APC could be safely provided in freestanding offices for most beneficiaries and

that beneficiaries would be able to access the services in that APC. Therefore, it would be reasonable to align the OPPS and ASC payment rates more closely with the PFS payment rates for those services.

- If ASCs had the highest volume for an APC, we determined that the services in that APC could be safely provided in ASCs for most beneficiaries. Therefore, the OPPS payment rates could be aligned more closely with the ASC payment rates for those services. Freestanding offices would still be paid PFS rates for those services.
- If HOPDs had the highest volume for an APC, it might not be safe to provide those services outside the HOPD setting for most Medicare beneficiaries. In addition, we would be concerned about beneficiaries' access to those services if HOPD payments were aligned with either PFS or ASC payment rates. We therefore determined that, for these APCs, HOPDs should continue to be paid OPPS payment rates, ASCs should continue to be paid ASC payment rates, and freestanding offices should continue to be paid PFS rates.

Services for which differential payment rates should continue

The OPPS has 169 APCs for services provided in HOPDs.[2] Some of these service APCs represent emergency care, critical care, trauma care, and observation care, which can be provided only in HOPDs. For some additional APCs, volume is higher in HOPDs than in the other two ambulatory settings. Because these services are predominantly provided in HOPDs and tend to represent complex services, the current OPPS payment rates should continue to be paid when they are provided in HOPDs. Overall, we identified 101 APCs for which payment rates should not be aligned across ambulatory settings. For these APCs, services provided in HOPDs should continue to be paid at OPPS rates, services provided in ASCs should continue to be paid at ASC rates, and services provided in freestanding offices should continue to be paid at PFS rates. Combined Medicare spending and beneficiary cost sharing under the OPPS for these APCs was $34 billion in 2019.

Services for which alignment of OPPS and ASC payment rates with PFS payment rates is reasonable

Of the 169 APCs examined, we identified 63 APCs for which the volume of services provided in each year from 2016 through 2019 was highest in freestanding offices. However, six of these APCs have a substantial amount of packaging under the OPPS, and in these six APCs, some of the HCPCS codes have low volume in freestanding offices and high volume in HOPDs. We have reservations about aligning OPPS and ASC payments rates with PFS payment rates for these APCs. Therefore, we determined that it would be appropriate to maintain differential payment rates for these six APCs.

For the remaining 57 APCs, it would be reasonable to more closely align OPPS and ASC payment rates to PFS payment rates. These APCs constitute 71 percent of Medicare volume and 22 percent of Medicare revenue for services covered under the OPPS and constitute 28 percent of Medicare volume and 11 percent of Medicare revenue for services covered under the ASC system. In Table 6-2 (pp. 170–171), we list the OPPS volume, OPPS Medicare spending, and beneficiary cost sharing from 2019 for these 57 APCs. In general, the services in these 57 APCs are of lower complexity than the average APC—that is, they require comparatively fewer resources. The average OPPS payment rate for these 57 APCs is $149, much lower than the average OPPS payment rate of $381 for all service APCs.

Aligning payment rates across three ambulatory settings

When a physician provides a service in a freestanding office, ASC, or HOPD, the physician's payment under the PFS has three components: physician work, practice expense (PE), and professional liability insurance (PLI). The work and PLI payments are the same in all settings. However, the PE payment for a service provided in a freestanding office (the "nonfacility" PE) is usually higher than the PE payment for a service provided in an ASC or HOPD (the "facility" PE). The higher nonfacility PE payment reflects the cost of clinical staff, medical equipment, medical supplies, and additional overhead incurred by the physician. Therefore, for most services, the total payment received by clinicians under the PFS is higher in a freestanding office than in the other two settings.

TABLE 6–2

Program spending, beneficiary cost sharing, and volume for 57 APCs for which alignment of OPPS payment rates with PFS payment rates is reasonable, 2019

APC	APC description	Program spending (in millions)	Beneficiary cost sharing (in millions)	Volume (in thousands)
5012	Clinic visits	$3,029	$757	32,685
5693	Level 3 drug administration	976	244	6,521
5522	Level 2 imaging w/o contrast	765	191	8,501
5524	Level 4 imaging w/o contrast	738	185	1,855
5593	Level 3 nuclear medicine	685	171	696
5523	Level 3 imaging w/o contrast	643	161	3,486
5694	Level 4 drug administration	580	145	2,516
5521	Level 1 imaging w/o contrast	441	110	8,852
5691	Level 1 drug administration	330	82	10,879
5724	Level 4 diagnostic tests and related services	296	74	406
5373	Level 3 urology and related services	278	70	200
5443	Level 3 nerve injections	249	62	423
5052	Level 2 skin procedures	243	61	1,106
5442	Level 2 nerve injections	234	58	506
5054	Level 4 skin procedures	226	56	202
5692	Level 2 drug administration	200	50	4,178
5441	Level 1 nerve injections	180	45	959
5822	Level 2 health and behavior services	161	40	2,643
5611	Level 1 therapeutic radiation treatment preparation	146	51	1,592
5722	Level 2 diagnostic tests and related services	152	38	754
5051	Level 1 skin procedures	112	28	890
5734	Level 4 minor procedures	82	20	963
5071	Level 1 excision/biopsy/incision and drainage	76	19	170
5733	Level 3 minor procedures	75	19	1,672
5723	Level 3 diagnostic tests and related services	73	18	199
5823	Level 3 health and behavior services	71	18	698
5372	Level 2 urology and related services	69	17	155
5053	Level 3 skin procedures	66	17	208
5721	Level 1 diagnostic tests and related services	62	15	568
5153	Level 3 airway endoscopy	56	14	51
5101	Level 1 strapping and cast application	47	12	538
5671	Level 1 pathology	35	9	857
5371	Level 1 urology and related services	29	7	163
5164	Level 4 ENT procedures	28	7	15
5741	Level 1 electronic analysis of devices	26	7	886
5055	Level 5 skin procedures	26	6	12
5481	Laser eye procedures	24	6	62

TABLE 6-2

Program spending, beneficiary cost sharing, and volume for 57 APCs for which alignment of OPPS payment rates with PFS payment rates is reasonable, 2019 *(cont.)*

APC	APC description	Program spending (in millions)	Beneficiary cost sharing (in millions)	Volume (in thousands)
5151	Level 1 airway endoscopy	19	5	147
5732	Level 2 minor procedures	16	4	634
5111	Level 1 musculoskeletal procedures	12	3	67
5743	Level 3 electronic analysis of devices	9	2	39
5163	Level 3 ENT procedures	9	2	9
5102	Level 2 strapping and cast application	8	2	47
5161	Level 1 ENT procedures	8	2	51
5152	Level 2 airway endoscopy	7	2	22
5411	Level 1 gynecologic procedures	4	1	34
5162	Level 2 ENT procedures	4	1	10
5413	Level 3 gynecologic procedures	4	1	9
5412	Level 2 gynecologic procedures	4	1	18
5821	Level 1 health and behavior services	3	1	127
5501	Level 1 extraocular, repair, and plastic eye procedures	3	1	13
5742	Level 2 electronic analysis of devices	3	1	29
5502	Level 2 extraocular, repair, and plastic eye procedures	3	1	4
5621	Level 1 radiation therapy	1.7	0.4	19
5731	Level 1 minor procedures	0.8	0.2	56
5735	Level 5 minor procedures	0.6	0.1	2
5811	Manipulation therapy	0.5	0.1	26

Note: APC (ambulatory payment classification), OPPS (outpatient prospective payment system), PFS (physician fee schedule), ENT (ear, nose, and throat). Program spending indicates outlays by the Medicare program under the OPPS and excludes beneficiary cost sharing. For all APCs listed, "beneficiary cost sharing" is 25 percent of "program spending" except for APC 5194, for which the beneficiary copayment is capped at the deductible amount under the inpatient prospective payment system, and APC 5611, for which the beneficiary copayment is 35 percent of the payment to the provider.

Source: MedPAC analysis of 100 percent standard analytic claims files from 2019 and MedPAC analysis of payment rates in the 2019 OPPS.

However, for services provided in an ASC or HOPD, Medicare makes an additional payment to the ASC under the ASC system or to the hospital under the OPPS to cover the costs of the clinical staff, medical equipment, medical supplies, and overhead incurred by the facility. In most cases, the PFS payment for a service provided in a freestanding office is lower than the combined PFS and ASC payments or combined PFS and OPPS payments for a service delivered in an ASC or HOPD. For example, when a service from APC 5442 (level 2 nerve injections) was provided in a freestanding office in 2019, the payment to the physician equaled the sum of the physician work, PLI, and nonfacility PE payments, which totaled $256.28 (Table 6-3, p. 172). If the service was provided in an HOPD, the payment equaled the sum of the work, PLI, and facility PE payments, plus the OPPS payment, for a total of $701.16.

TABLE 6–3

Differences in Medicare payment rates for level 2 nerve injection provided in physician's office or HOPD, 2019

Actual 2019 payment rates		Policy that would align rates across settings	
Service in physician's office		***Service in physician's office***	
Physician work	$64.87	Physician work	$64.87
Nonfacility PE	$185.64	Nonfacility PE	$185.64
Professional liability insurance	+ $5.77	Professional liability insurance	+ $5.77
Total payment	**$256.28**	**Total payment**	**$256.28**
Service in HOPD		***Service in HOPD***	
Physician work	$64.87	Physician work	$64.87
Facility PE	$31.71	Facility PE	$31.71
Professional liability insurance	+ $5.77	Professional liability insurance	+ $5.77
Payment to physician	$102.35	Payment to physician	$102.35
Payment to HOPD (OPPS rate)	+ $598.81	Payment to HOPD (nonfacility PE – facility PE)	+ $153.93
Total payment	**$701.16**	**Total payment**	**$256.28**

Note: HOPD (hospital outpatient department), PE (practice expense), OPPS (outpatient prospective payment system). Payments include both program spending and beneficiary cost sharing.

Source: MedPAC analysis of physician fee schedule and OPPS payment rates for 2019.

However, the payment rates for this service could be more closely aligned across settings if CMS replaced the existing OPPS and ASC payment rates with rates based on the differences between the nonfacility PE rate and the facility PE rates in the PFS.[3] Making this adjustment would drop the HOPD payment to $153.93, and the total payment would fall to $256.28, the same rate paid in a freestanding office. (The difference between the payment rates for freestanding offices and ASCs would be smaller: Total payment when this service was provided in ASCs in 2019 was $402.82.)

Note that all of the 57 APCs where payment rates could be more closely aligned have more than one HCPCS code, and all HCPCS codes within an APC have the same payment rate under the OPPS and the ASC system. In contrast, the PFS has separate payment rates for each HCPCS code. When we aligned the OPPS and ASC payment rates with the PFS rates for an APC, we used a weighted average of the payment rates from the PFS for the HCPCS codes in that APC, using the volume for the HCPCS codes as the weights. We multiplied the weighted average of the differences in the nonfacility PE and facility PE payment by the PFS conversion factor to obtain a base rate for the APC.

However, because the policies for packaging ancillary items differ among the PFS, OPPS, and ASC system, we could not rely strictly on the average differences between nonfacility and facility PEs to accurately align payment rates for all 57 APCs. To adjust for the greater packaging of ancillary items in the OPPS and ASC system relative to the PFS, for each of the 57 APCs, we used data from OPPS hospitals to estimate the share of the cost of the services in the APCs that was attributable to packaged ancillary items.[4] To determine the payment rate for services provided in HOPDs and ASCs, we multiplied the base rate for the APC by the share of costs that was attributable to ancillary items.

For example, APC 5012 (the APC for clinic visits) had an average difference between the nonfacility PE and facility PE of $29.37 (the base rate). We found that, when the services in this APC were provided in HOPDs, the average cost of these services was $120.55 and the average cost of the ancillary items packaged with them was $18.49, for an average total cost of $139.04 ($120.55 + $18.49). The cost of the packaged items added 26.4 percent to the total cost of the service, and we applied this percentage to the base rate of $29.37. Therefore, the payment rate for aligning OPPS rates with PFS rates for APC 5012 would be $29.37 × 1.264 = $37.12.

A second adjustment that must be addressed for packaging differences across payment systems relates to the 90-day global bundles used in the PFS but not in the ASC system or OPPS. The 90-day global bundles include the surgical procedure itself and office visits that occur within a 90-day period after the procedure. In addition, CMS assumes that the physician's staff spends time scheduling the procedure and coordinating presurgical services when the procedure is performed in a hospital or ASC. This scheduling and coordination is not necessary when the services are provided in a physician's office. Therefore, these services are assumed to have a higher cost when delivered in an HOPD or ASC. For the instances in which a HCPCS code has a 90-day global bundle under the PFS, we chose to use the PFS nonfacility PE alone rather than the difference between the nonfacility PE and the facility PE in the calculation of APC base rates. Use of the nonfacility PE rates alone for this purpose is not unprecedented. CMS used the nonfacility PE rates for some HCPCS codes in its method to align OPPS payment rates for services provided in off-campus PBDs with PFS rates to satisfy requirements in Section 603 of the BBA of 2015 (Centers for Medicare & Medicaid Services 2019).

An example of our process for aligning OPPS and ASC payment rates with PFS payment rates is APC 5151 (level 1 airway endoscopy). From 2016 through 2019, about 90 percent of the volume for APC 5151 was provided in freestanding offices, so this service is a clear candidate for payment rate alignment. The average weighted sum of the difference between the nonfacility PEs and facility PEs for the HCPCS codes in APC 5151 is 2.59.[5] We multiplied that weighted average by the PFS conversion factor ($36.04) to obtain a base rate of $93.19. We have also found that packaged items add 4.3 percent to the HOPD costs for the services in APC 5151. We multiplied that percentage by the base rate to obtain a payment rate for APC 5151 of $97.17.

Considering the need for a patient-severity adjustment

After identifying the APCs that we deemed appropriate for payment rate alignment, we considered whether aligned payments should be adjusted for differences in patient severity. Analysis sponsored by the American Hospital Association suggests that patients receiving care in HOPDs are more medically complex than those receiving care in freestanding offices (American Hospital Association 2021). Subsequently, we evaluated risk scores from the CMS–hierarchical condition category (HCC) risk-adjustment model to compare the medical complexity of HOPD patients with patients in freestanding offices. The results indicate that HOPD patients have higher average risk scores. Greater patient complexity in HOPDs relative to physician offices suggests that adjusting for patient severity could be warranted.

However, we also found substantial overlap in the CMS–HCC risk scores of patients in these two settings. In most APCs, the median CMS–HCC risk score among HOPD patients falls between the median and 75th percentile of CMS–HCC risk scores among patients in freestanding offices. Moreover, most of the APCs for which it is reasonable to align OPPS payment rates with PFS payment rates represent low-complexity services, so patient acuity might have little effect on the resources needed to provide these services. Indeed, before 2014, the OPPS had five APCs for office visits, which represented 10 HCPCS codes. To some extent, these five APCs distinguished patients by complexity. In 2014, however, CMS combined the five APCs into a single APC for all office visits. One of CMS's arguments for combining the five APCs into one APC was that variation in resources needed to provide office visits was not large enough to warrant five different APCs and payment rates. Notably, researchers at RAND found that differences in patient clinical characteristics did not support payment differences across ambulatory settings (Wynn et al. 2011).

The uncertainty over whether it would be necessary to adjust aligned payment rates for differences in patient severity led us to evaluate the extent to which hospital

Analyzing the effect of patient severity on charges for services provided in hospital outpatient departments

The Commission used regression analysis to estimate the relationship between patient severity and the hospital charges for services provided in hospital outpatient departments (HOPDs). We used the beneficiary's Charlson comorbidity index (CCI) as a measure of patient severity, which is an index that represents a patient's health. The CCI is based on the patient's age and whether the patient has any of these 19 conditions: myocardial infarction, congestive heart failure, peripheral vascular disease, cerebrovascular disease, dementia, chronic pulmonary disease, rheumatic disease, peptic ulcer disease, mild liver disease, diabetes without chronic complication, diabetes with chronic complication, hemiplegia or paraplegia, renal disease (mild to moderate), renal disease (moderate to severe), any malignancy (except malignant neoplasm of skin), moderate to severe liver disease, metastatic solid tumor, HIV infection (no AIDS), and AIDS. Each age category and each condition has a weight. A patient's CCI is the sum of the weight from their age category and the weights from the applicable conditions. A beneficiary's CCI can range from 0 to 36.

Our analysis examined the 57 ambulatory payment classifications (APCs) for which it is reasonable to align Medicare payment rates across the 3 ambulatory settings for patient care. To ensure that we had enough observations to produce reliable

(continued next page)

charges are affected by patient severity in the APCs for which it is reasonable to align payment rates. To measure the relationship between charges and patient severity, we performed a regression for each of the 22 APCs that have enough records to provide statistically reliable results. In these analyses, we used hospital charges for providing a service to a beneficiary as the dependent variable and used the following explanatory variables:

- sex of the beneficiary who received the service,
- a dichotomous indicator (0 or 1) for whether the beneficiary had full dual-eligibility status,[6]
- an indicator for the hospital that provided the service, and
- the beneficiary's Charlson comorbidity index (CCI) to account for the beneficiary's health status (Charlson et al. 1987, Glasheen et al. 2019, Quan et al. 2005).

We included an indicator for the hospital providing the service because charging practices vary by hospital, especially in the extent to which hospitals mark up charges above costs (for more details, see the text box on patient severity and charges for services).

For each of the 22 APCs that we evaluated, we used the results from the regressions to estimate the percentage change in charges corresponding to a 10 percent increase in the average CCI score. We found that for the APC for which charges were most responsive to a change in the CCI, a 10 percent increase in the CCI was associated with a 0.9 percent increase in charges. In summary, the results from these regressions indicate that the level of a beneficiary's CCI typically has a small effect on the claim charges.

In addition to our finding of a weak relationship between a beneficiary's health status (as measured by the CCI) and hospital charges, we identified four additional arguments that call into question the need for a patient-severity adjustment under a payment rate alignment policy:

Analyzing the effect of patient severity on charges for services provided in hospital outpatient departments (cont.)

results, we limited our analysis to the 22 APCs that had the most claims suitable for this analysis. These APCs constitute about $13 billion in Medicare spending under the outpatient prospective payment system (OPPS). For each APC, we identified the claims covered under the OPPS that had services that matched to the APC. For each of these claims, we determined the hospital charges for the service and the charges for the ancillary items packaged with the service under the OPPS packaging rules to create the total charges for the service and the packaged ancillary items that form the unit of payment under the OPPS. For example, if during an HOPD visit for chemotherapy administration the patient also has a complete metabolic panel and a complete blood count (CBC), the chemotherapy is the service and the metabolic panel and CBC are ancillary items, and these three items are packaged into a single unit for payment under the OPPS. For this analysis, we summed the charges for the three items to create a total charge for the service.

We collected the charges for the services and their bundled ancillary items into the APCs of the services. For each APC, we performed the regressions using the dependent variable (the charges for the service and the packaged ancillary items) and four explanatory variables, which include an identifier for the hospital that provided the service, whether the beneficiary had full Medicaid benefits, the beneficiary's sex, and the beneficiary's CCI. ■

- During a patient visit to an HOPD, the provider can furnish more than one service for which they can bill under the OPPS. The structure of the OPPS contrasts with payment systems that have adjustments for patient severity—such as the inpatient prospective payment system (IPPS)—or for which adjustments for patient severity would be beneficial, such as the skilled nursing facility payment system. In these payment systems, the unit of payment is much broader relative to the OPPS. For example, the unit of payment for the IPPS is the inpatient stay. All services provided during an inpatient stay are covered under a single payment unit, with allowances for higher payments based on patient severity. Under the OPPS, if a relatively complex patient requires more intensive care or a more costly drug than a less complex patient for the same type of visit, the hospital is often able to bill for the additional care or more costly drug as covered under the OPPS.
- Most of the 57 APCs suitable for payment rate alignment represent low-complexity services—office visits, X-rays, minor procedures, and drug injections are common. For these services, patient complexity may have little effect on the resources needed to provide the service.
- CMS has grouped the 169 service APCs into hierarchies; each level within a hierarchy represents a different level of resources needed to provide a service. For example, the OPPS has four APCs for imaging without contrast—level 1 through level 4. Under this construct, providers may be able to code more complex patients to higher-level APCs, for which the providers receive a higher payment.
- The services in many of the 57 APCs suitable for payment rate alignment are overwhelmingly provided in physician offices. For example, for 13 of the APCs, more than 90 percent of the volume occurs in offices, suggesting that, for these APCs,

the PFS payment rates are adequate for patients of any complexity. In these situations, adjustments for patient complexity are not needed.

Based on our finding of a weak relationship between beneficiaries' health status and HOPD charges and the arguments discussed in this section, we concluded that adjustments for patient severity are not needed in aligning payment rates across ambulatory settings.

Supporting HOPDs' standby capacity A final concern about payment rate alignment for these 57 APCs is that these services are sometimes provided during ED visits. When these services are provided as part of an ED visit, the payments hospitals receive for them support the hospitals' standby and emergency capacity. Aligning the payment rates for these APCs with the typically lower PFS rates would reduce the revenue supporting the standby and emergency capacity. In the Commission's previous work on site-neutral payments, we addressed this issue by excluding from the site-neutral payments any APC for which the services within the APC were billed more than 10 percent of the time with an ED visit (Medicare Payment Advisory Commission 2013). However, the 10 percent threshold was not based on any empirical result, and we could have used a different cut point. Also, this approach eliminated from our site-neutral assessment APCs that were otherwise reasonable to include.

An alternative approach to maintain support for hospitals' standby capacity is to change the APCs for ED visits, critical care visits, and trauma care visits from standard APCs to comprehensive APCs (C–APCs). C–APCs are an advanced form of APC in which all services—with a few exceptions—that appear on the same claim are packaged together into a single payment unit. Before CMS included C–APCs in the OPPS in 2015, the OPPS provided separate payments for all separately payable services that appeared on the same claim. Under C–APCs, a claim has one separately payable service, and other services that would otherwise be separately paid under the OPPS are packaged items. Designating the APCs for ED visits as C–APCs would combine all the services provided during an emergency visit into a single payment unit. The costs of all of the services and supplies provided during ED visits would be reflected in the OPPS payment rates for ED visits. This includes the services that would otherwise be paid at the site-neutral rates. Under this approach, when a service from one of the 57 APCs for which it is reasonable to align payment rates across the three ambulatory settings is provided with an ED visit, the cost of that service would be packaged into the payment for the ED visit. When the service is provided separately from an ED visit, it would be paid at the aligned payment rate. Also, the flow of revenue supporting the hospitals' standby and emergency capacity would not be diminished by aligning payments across ambulatory settings.

Effects of aligning payment rates across three ambulatory settings

We modeled the effects of aligning payment rates for the 57 APCs for which OPPS and ASC payment rates could be based on PFS payment rates. We modeled the effects for a single year, 2019, and did not model a transition or any behavioral changes on the part of providers. To estimate the magnitude of the impact of these changes, we also ignored the current statutory requirements, discussed below, that adjustments to the OPPS relative weights must be budget neutral relative to current OPPS expenditures.

For some APCs, the reduction in beneficiary cost sharing and savings to the Medicare program would be substantial. We recognize that most beneficiaries in FFS Medicare have some form of supplemental coverage, so most of the reduced cost sharing would not result in smaller direct outlays from beneficiaries to providers. However, lower cost-sharing liabilities would result in lower beneficiary premiums for both supplemental insurance and Part B coverage.

Effects of aligning payment rates on spending and cost sharing within the OPPS In aggregate, payment rate alignment for the 57 APCs, in the absence of a budget-neutrality adjustment, would reduce beneficiary cost sharing under the OPPS by $1.4 billion and Medicare outlays by $5.5 billion.[7] Clinic visits (APC 5012) would have the largest reduction in beneficiary cost sharing and program spending (Table 6-4); beneficiary cost sharing would decline by more than $300 million, and program spending would decrease by $1.4 billion. Two APCs would have small increases in cost sharing and program spending under the OPPS (level 1 musculoskeletal procedures and level 1 minor

TABLE 6–4

Impact of aligning payment rates across three ambulatory settings: APCs with the largest and smallest reductions in beneficiary cost sharing and program outlays, 2019

		Change (in millions)	
APC	APC description	Program spending	Beneficiary cost sharing
5 APCs with largest reduction			
5012	Clinic visits	–$1,379	–$339
5524	Level 4 imaging without contrast	–508	–129
5694	Level 4 drug administration	–375	–97
5724	Level 4 diagnostic tests and related services	–281	–71
5522	Level 2 imaging without contrast	–232	–61
5 APCs with smallest (or no) reduction			
5742	Level 2 electronic analysis of devices	–0.4	–0.1
5811	Manipulation therapy	–0.4	–0.1
5502	Level 2 extraocular, repair, and plastic eye procedures	0.0	0.0
5731	Level 1 minor procedures	1.0	0.3
5111	Level 1 musculoskeletal procedures	2.1	0.5

Note: APC (ambulatory payment classification). "Program spending" indicates outlays by the Medicare program and excludes beneficiary cost sharing. Positive values indicate increases in program spending and beneficiary cost sharing.

Source: MedPAC analysis of 100 percent standard analytic claims files from 2019 and MedPAC analysis of payment rates in the 2019 physician fee schedule and outpatient prospective payment system.

procedures), as aligning OPPS payment rates with PFS payment rates would increase the OPPS rates for these APCs.

For all OPPS hospitals (the OPPS excludes critical access hospitals (CAHs) and Maryland hospitals), changing the payment rates for the 57 APCs would reduce overall Medicare revenue—which includes hospitals' Medicare revenue for all service lines (inpatient, outpatient, post-acute care)—by 3.4 percent and Medicare OPPS revenue by 10.4 percent. In addition, beneficiary OPPS cost-sharing liabilities would decrease by 11.0 percent.

Effects of aligning payment rates on spending and cost sharing within the ASC payment system Aligning the ASC payment rates with the PFS payment rates for the 57 APCs would reduce beneficiary cost sharing under the ASC payment system by $60 million and Medicare outlays by $230 million. This reduction in spending and cost sharing under the ASC system would reduce aggregate ASC Medicare revenue by 5.5 percent. While this policy would lower ASCs' total Medicare revenue by a larger percentage compared with the percentage for hospitals' total Medicare revenue (5.5 percent for ASCs vs. 3.4 percent for hospitals), the effect on ASCs' Medicare revenue would be much smaller than on the hospitals' OPPS revenue (5.5 percent in ASCs vs. 10.4 percent in HOPDs). This discrepancy between ASCs and HOPDs would occur because services provided in HOPDs and freestanding offices overlap more than services provided in ASCs and freestanding offices. In particular, office visits are frequently provided in both freestanding offices and HOPDs, but office visits are not covered under the ASC system. In addition, HOPDs

TABLE 6–5

Program spending, cost sharing, and volume for 11 APCs for which we aligned OPPS payment rates with ASC payment rates, 2019

APC	APC description	Program spending (in millions)	Beneficiary cost sharing (in millions)	Volume (in thousands)
5312	Level 2 lower GI procedures	$787	$204	1,012
5491	Level 1 intraocular procedures	651	169	428
5311	Level 1 lower GI procedures	274	27	405
5492	Level 2 intraocular procedures	222	57	77
5431	Level 1 nerve procedures	204	53	158
5112	Level 2 musculoskeletal procedures	100	26	96
5116	Level 6 musculoskeletal procedures	83	8	6
5503	Level 3 extraocular, repair, and plastic eye procedures	51	13	36
5504	Level 4 extraocular, repair, and plastic eye procedures	14	4	6
5494	Level 4 intraocular procedures	1	0	0.1
5493	Level 3 intraocular procedures	1	0	0.1

Note: APC (ambulatory payment classification), OPPS (outpatient prospective payment system), ASC (ambulatory surgical center), GI (gastrointestinal). Program spending indicates outlays by the Medicare program under the OPPS and excludes beneficiary cost sharing.

Source: MedPAC analysis of 100 percent standard analytic claims files from 2019 and MedPAC analysis of payment rates in the 2019 OPPS.

provided services in each of the 57 APCs included in our analysis, but ASCs provided services in only 39 of these APCs.

Services for which OPPS payment rates should be aligned with ASC payment rates

We identified 11 APCs for which the ASC setting has the highest volume among the ambulatory settings. Because ASCs focus on ambulatory surgical procedures, these 11 APCs represent surgical procedures including musculoskeletal, lower gastrointestinal, nerve, and ophthalmologic procedures. For these APCs, an alignment of OPPS payment rates with the ASC payment rates would be appropriate. When these services are provided in freestanding offices, the PFS payment rates would continue to apply.

Because ASC payment rates on average are nearly 50 percent lower than OPPS payment rates, aligning the OPPS payment rates with the ASC payment rates for these services would reduce OPPS spending for these services by nearly 50 percent. For example, the service provided to Medicare FFS beneficiaries most frequently in ASCs is cataract removal with intraocular lens insertion. The ASC payment rate for this service is $977, while the OPPS payment rate is $1,917.

Access to care is an issue when considering a payment rate alignment. Although the number of Medicare-certified ASCs (more than 5,900) is greater than the number of hospitals that provide outpatient services (about 4,900, including CAHs), ASCs are more geographically concentrated, so beneficiaries in some areas who have access to hospital outpatient services could have difficulty accessing ASC services. If hospitals reduce the provision of the services in these 11 APCs in response to payment rate alignment, access to these services could become difficult in areas that lack ASC presence. Most rural areas and some states (especially Vermont) could be particularly vulnerable. For example, two ASCs are located in Vermont, and

TABLE 6–6

Aligning OPPS payment rates with ASC payment rates would reduce program spending and cost sharing for 11 APCs, 2019

		Change (in millions)	
APC	APC description	Program spending	Beneficiary cost sharing
5312	Level 2 lower GI procedures	–$384.6	–$96.2
5491	Level 1 intraocular procedures	–318.3	–80.0
5311	Level 1 lower GI procedures	–132.9	–13.5
5492	Level 2 intraocular procedures	–105.5	–26.3
5431	Level 1 nerve procedures	99.9	–25.0
5112	Level 2 musculoskeletal procedures	–46.8	–11.7
5503	Level 3 extraocular, repair, and plastic eye procedures	–25.3	–6.3
5116	Level 6 musculoskeletal procedures	–16.8	–1.7
5504	Level 4 extraocular, repair, and plastic eye procedures	–6.9	–1.7
5494	Level 4 intraocular procedures	–0.7	–0.2
5493	Level 3 intraocular procedures	–0.2	0.0
	Total	–1,138	–263

Note: OPPS (outpatient prospective payment system), ASC (ambulatory surgical center), APC (ambulatory payment classification), GI (gastrointestinal). "Program spending" indicates outlays by the Medicare program and excludes beneficiary cost sharing. This table reflects the effects of aligning OPPS payment rates with ASC payment rates for 11 APCs, assuming no budget-neutrality adjustment within the OPPS.

Source: MedPAC analysis of 100 percent standard analytic claims files from 2019 and MedPAC analysis of payment rates in the 2019 ASC payment system and OPPS.

both are in the Burlington area. In contrast, Vermont has seven OPPS hospitals and nine CAHs, located throughout the state. However, it is not clear whether hospitals would respond to the ASC-aligned payment rates by substantially reducing the provision of these services.

Effects of aligning OPPS payment rates with ASC payment rates

Aligning OPPS payment rates with ASC payment rates would be less complicated than aligning OPPS payment rates with PFS payment rates because the ASC system and the OPPS have largely the same packaging policies and payment units. Our method for aligning HOPD and ASC payment rates for the 11 APCs involved calculating a weighted average of the ASC payment rates across the HCPCS codes in each APC. We used the volume for the HCPCS codes as the weights. For example, the weighted average of the ASC payment rates for APC 5491 (level 1 intraocular procedures) is $977.16.

In Table 6-5, we list the OPPS volume, OPPS Medicare spending, and beneficiary cost sharing from 2019 for these 11 APCs. In 2019, OPPS spending (program outlays and cost sharing) for the services included in the 11 APCs totaled $2.9 billion. We estimated that combined Medicare program spending and beneficiary cost sharing would decrease by $1.4 billion if the OPPS payment rates were aligned with the ASC payment rates for these 11 APCs, assuming no budget-neutrality adjustment, and beneficiaries would continue to have the same access to these services (Table 6-6). We estimated that program spending

would decrease by $1.1 billion and beneficiary cost sharing by $0.3 billion.

Under an alignment, the revised payment rates for the 11 APCs would reduce OPPS hospitals' overall Medicare revenue by 0.7 percent, Medicare outpatient revenue by 2.1 percent, and beneficiary cost sharing on OPPS services by 2.3 percent.

Combined effects of aligning payment rates on hospitals' Medicare revenue and beneficiary cost sharing

We evaluated the combined effects of a payment rate alignment between OPPS and PFS rates and between OPPS rates and ASC rates.

In aggregate, if changes in payments resulting from aligning payment rates were taken as program savings, Medicare program spending in 2019 would have declined by $6.6 billion and beneficiary cost-sharing obligations by $1.7 billion. Across all hospitals, a site-neutral policy would have reduced overall Medicare revenue by 4.1 percent and beneficiary OPPS cost sharing by 13.2 percent (Table 6-7). However, some hospital categories would have been affected more than others:

- Overall Medicare revenue for rural hospitals would have declined by 6.9 percent compared with a 3.8 percent decline for urban hospitals.
- Nonprofit and government-owned hospitals would have had larger decreases in overall Medicare revenue than for-profit hospitals.
- Major teaching hospitals and nonteaching hospitals would have had larger decreases in overall Medicare revenue than other teaching hospitals.
- Hospitals that had disproportionate share hospital (DSH) patient percentages of less than the median (28.1 percent) would have had larger declines in overall Medicare revenue compared with hospitals that had DSH patient percentages above the median.
- Hospitals that had 100 or fewer beds would have had larger decreases in overall Medicare revenue than hospitals that had more beds.

Limiting the effects of aligning payment rates on hospitals that serve low-income patients

This impact assessment ignores an element of the current OPPS: Sections 1833(t)(9)(A) and 1833(t)(9)(B) of the Social Security Act (SSA) require that when CMS adjusts the relative weights in the OPPS, the agency must make budget-neutral adjustments to fully offset the effects on Medicare expenditures resulting from the adjustment to the relative weights. The payment alignment policy we have presented would affect the relative weights in the OPPS. Therefore, Sections 1833(t)(9)(A) and 1833(t)(9)(B) of the SSA would require CMS to use a budget-neutrality adjustment to offset the reduced Medicare spending under the OPPS that would occur from aligning payment rates across ambulatory settings. CMS would apply a uniform percentage increase to the OPPS payment rates of the 101 APCs not included in the payment alignment policy.

The primary effect of the budget-neutrality adjustment is that it would fully offset the aggregate decrease in Medicare spending and beneficiary cost sharing that would result from the payment alignment policy. That is, the net change in aggregate Medicare spending and beneficiary cost sharing would be zero, with no savings for the program or for beneficiaries unless provider behavior changed.

However, the budget-neutrality policy would not explicitly target any specific group of hospitals. Some hospitals that are the primary source of access to physician services for low-income patients would experience reductions in Medicare revenue under the payment alignment policy, which could adversely affect access for these beneficiaries. In response to these concerns, policymakers could consider an alternative to the budget-neutrality policy that would generate savings for the Medicare program and its beneficiaries while limiting reductions in revenue for hospitals that serve a high share of low-income beneficiaries.

Over time, the payment rate alignment policy would produce savings for the Medicare program and lower cost sharing for beneficiaries under either the budget-neutrality or the stop-loss policy because incentives to shift services from the lower-cost physician office and ASC settings to the higher-cost HOPD setting would be

TABLE 6–7

Change in overall Medicare revenue from aligning OPPS payment rates with PFS and ASC rates for select ambulatory services, assuming no budget-neutrality adjustment, 2019

	Percent change	
Category	**Overall Medicare revenue**	**Outpatient cost sharing**
All hospitals	–4.1%	–13.2%
Urban	–3.8	–12.7
Rural	–6.9	–16.9
Nonprofit	–4.1	–13.0
For profit	–3.3	–12.5
Government	–4.6	–14.8
Major teaching	–4.0	–14.2
Other teaching	–3.7	–12.3
Nonteaching	–4.5	–13.3
DSH patient percentage		
Below median	–4.3	–13.3
Above median	–3.8	–13.1
Number of beds		
Less than 50	–8.1	–18.6
50–100	–6.6	–16.5
101–250	–4.4	–13.5
251–500	–3.5	–12.0
More than 500	–3.5	–12.5

Note: OPPS (outpatient prospective payment system), PFS (physician fee schedule), ASC (ambulatory surgical center), DSH (disproportionate share hospital). "Overall Medicare revenue" is the sum of Medicare revenue across multiple hospital service lines, including inpatient, outpatient, swing bed, skilled nursing facility, rehabilitation, psychiatric, and home health services. "DSH patient percentage" is the sum of the percentage of inpatient days for Medicare beneficiaries that are attributed to patients who are eligible for both Medicare Part A and Supplemental Security Income and the percentage of inpatient days for all patients that are attributable to patients eligible for Medicaid but not eligible for Medicare Part A. Inpatient days are the number of days of inpatient care. This table reflects the effects of aligning OPPS payment rates with PFS payment rates for 57 ambulatory payment classifications (APCs) combined with the effects of aligning OPPS payment rates with ASC payment rates for 11 APCs, assuming no budget-neutrality adjustment within the OPPS.

Source: MedPAC analysis of data from hospital cost reports and standard analytic claims files, 2019.

mitigated. Reducing the shift of services from physician offices and ASCs to HOPDs would produce savings for Medicare and lower cost sharing for beneficiaries in the future.

It is not clear what effect the payment alignment policy would have on hospitals' overall Medicare margin. The impact on the margin would be affected by what is done with the savings from the aligned payment rates and how hospitals respond to the change in policy. If the payment alignment policy were coupled with a budget-neutral adjustment to the OPPS payment rates of the nonaligned APCs, there would be no effect on the overall Medicare margin. In contrast, if the savings from the payment alignment policy were used strictly

TABLE 6–8

Change in overall Medicare revenue from aligning OPPS payment rates with PFS and ASC rates for select ambulatory services, coupled with budget-neutrality policy

Category	Percent change in overall Medicare revenue from payment alignment policies combined with budget-neutral adjustment
All hospitals	0.0%
Urban	0.2
Rural	–2.3
Nonprofit	0.0
For profit	1.0
Government	–0.9
Major teaching	–0.9
Other teaching	0.5
Nonteaching	0.2
DSH patient percentage	
Below median	0.2
Above median	–0.2
Number of beds	
Less than 50	–2.9
50–100	–1.7
101–250	0.0
251–500	0.6
More than 500	0.0

Note: OPPS (outpatient prospective payment system), PFS (physician fee schedule), ASC (ambulatory surgical center), DSH (disproportionate share hospital). "Overall Medicare revenue" is the sum of Medicare revenue across multiple hospital service lines, including inpatient, outpatient, swing bed, skilled nursing facility, rehabilitation, psychiatric, and home health services. "DSH patient percentage" is the sum of the percentage of inpatient days for Medicare beneficiaries that are attributed to patients who are eligible for both Medicare Part A and Supplemental Security Income and the percentage of inpatient days for all patients that are attributable to patients eligible for Medicaid but not eligible for Medicare Part A. Inpatient days are the number of days of inpatient care. Under current law, CMS would be required to use a budget-neutrality adjustment to offset the reduced Medicare spending under the OPPS that would occur from aligning payment rates across ambulatory settings. This table reflects the effects of aligning OPPS payment rates with PFS payment rates for 57 ambulatory payment classifications (APCs) combined with the effects of aligning OPPS payment rates with ASC payment rates for 11 APCs on hospitals' overall Medicare revenue, assuming a budget-neutrality adjustment within the OPPS. Positive values indicate that the hospital category would have higher overall Medicare revenue under a policy that combines payment alignment with the budget-neutral adjustment relative to standard OPPS payment policies.

Source: MedPAC analysis of data from hospital cost reports and standard analytic claims files, 2019.

to reduce Medicare spending and beneficiary cost sharing, the effect on the overall Medicare margin would be large. In addition, if hospitals responded to the payment alignment policy by reducing their provision of the services for which payments were aligned across settings, the effect on the overall Medicare margin would be mitigated.

Effects of a budget-neutral adjustment of nonaligned APCs

To assess the impact of aligning payment rates under the current budget-neutrality requirements, we increased the OPPS payment rates by a uniform percentage for the 101 service APCs for which payment rates should not be aligned across ambulatory care

settings. We increased the OPPS payment rates for these APCs by 24.4 percent, which would fully offset the decrease in hospitals' overall Medicare revenue under the payment rate alignment.

Because the provision of services differs across hospitals (with some providing comparatively more of certain types of services), the financial effect of reducing payments for the 68 APCs would differ across hospitals, even with a budget-neutrality adjustment. Overall Medicare revenue would fall by 2.3 percent for rural hospitals and rise by 0.2 percent for urban hospitals (Table 6-8). In addition, for-profit hospitals would see a net gain in overall Medicare revenue of 1.0 percent, whereas nonprofit hospitals would have no change in overall revenue and government-owned hospitals would have a decrease of 0.9 percent (Table 6-8).

Relative to the change in overall Medicare revenue under the payment rate alignment without the budget-neutrality adjustment (see Table 6-7, p. 181), the hospital categories that would benefit most from the budget-neutrality adjustment—measured by the difference between the percentage change in overall Medicare revenue with the budget-neutral adjustment versus without the adjustment—included rural hospitals, hospitals with DSH patient percentages below the median, hospitals with 100 or fewer beds, and nonteaching hospitals. Government hospitals and hospitals with DSH patient percentages above the median would benefit less than the average hospital, which is a concern because these hospitals often serve a high share of low-income beneficiaries. Some hospital categories, however, would have higher overall Medicare revenue with the payment alignment policies coupled with the budget-neutrality adjustment than they would under standard OPPS payment rates. These hospital categories have positive values for the percentage change in Table 6-8.

Design of illustrative stop-loss policy

Combining alignment of payment rates with a budget-neutrality adjustment within the OPPS would lower incentives for hospitals to consolidate with physician practices but would reduce savings for Medicare and beneficiaries. However, if the budget-neutrality adjustment were not applied, some hospitals that are the primary source of access to physician services for low-income patients would experience reductions in Medicare revenue under the payment alignment policy, which could adversely affect access for these beneficiaries. In response to these concerns, policymakers could consider an alternative to the budget-neutrality policy that would explicitly target hospitals that serve a high share of low-income beneficiaries to limit the loss of Medicare revenue for these hospitals.

In considering an alternative to an across-the-board budget-neutrality adjustment, we evaluated a stop-loss policy that would be a temporary, narrowly focused approach to ensure access to care among low-income beneficiaries who rely on safety-net hospitals. Such a policy would require congressional action because current law requires CMS to make payment policy changes budget neutral. (If policymakers consider a stop-loss policy, they should also consider that some of these hospitals receive additional payments as rural emergency hospitals, which is a type of rural hospital that the Congress created in 2020.)

In previous analyses, the Commission addressed access to care for low-income beneficiaries by evaluating the effects of combining a phase-in of aligned payment rates over a three-year period with a stop-loss policy that would limit the payment reductions to 2 percent of overall Medicare revenue during the phase-in for hospitals that have DSH patient percentages above the median (Medicare Payment Advisory Commission 2013, Medicare Payment Advisory Commission 2012). The Commission found that this policy would have a modest effect on mitigating the declines in hospitals' overall Medicare revenue and would affect only 7 percent of hospitals. However, applying a stop loss to the payment alignment policy analyzed in this chapter should have a larger loss limit than 2 percent because the effects of this policy are larger than those evaluated in our previous studies.

Historically, the Commission has used DSH patient percentages to determine the extent to which hospitals serve low-income or vulnerable populations. However, the Commission is currently evaluating alternative measures to the DSH patient percentage to identify these hospitals more accurately. Because the Commission has not made a final determination of the best measure for identifying hospitals that serve a high

TABLE 6–9

Change in overall Medicare revenue for hospitals under a payment alignment policy across ambulatory care settings with and without a stop-loss provision

	Percent change, overall Medicare revenue under payment alignment policies	
Category	**Without stop loss**	**With stop loss**
All hospitals	–4.1%	–3.6%
Urban	–3.8	–3.4
Rural	–6.9	–5.5
Nonprofit	–4.1	–3.7
For profit	–3.3	–3.1
Government	–4.6	–3.8
Major teaching	–4.0	–3.5
Other teaching	–3.7	–3.3
Nonteaching	–4.5	–4.0
DSH patient percentage		
Below median	–4.3	–4.3
Above median	–3.8	–3.0
Number of beds		
Less than 50	–8.1	–7.3
50–100	–6.6	–5.5
101–250	–4.4	–3.8
251–500	–3.5	–3.1
More than 500	–3.5	–3.1

Note: DSH (disproportionate share hospital). "Overall Medicare revenue" is the sum of Medicare revenue across multiple hospital service lines, including inpatient, outpatient, swing bed, skilled nursing facility, rehabilitation, psychiatric, and home health services. "DSH patient percentage" is the sum of the percentage of inpatient days for Medicare beneficiaries that are attributed to patients who are eligible for both Medicare Part A and Supplemental Security Income and the percentage of inpatient days for all patients that are attributable to patients eligible for Medicaid but not eligible for Medicare Part A. Inpatient days are the number of days of inpatient care. This table reflects the effects of aligning OPPS payment rates with physician fee schedule payment rates for 57 ambulatory payment classifications (APCs) combined with the effects of aligning OPPS payment rates with ambulatory surgical center payment rates for 11 APCs, assuming no budget-neutrality adjustment within the OPPS, with and without a stop-loss provision for hospitals that (1) have a DSH patient percentage greater than 28.1 percent and (2) otherwise would have a decrease in overall Medicare revenue of greater than 4.1 percent due to the payment rate alignment policy.

Source: MedPAC analysis of data from hospital cost reports and standard analytic claims files, 2019.

share of low-income beneficiaries, we chose to use the DSH patient percentage in this illustrative example of a stop-loss policy.

For illustrative purposes, we evaluated the effects of a stop-loss limit for hospitals with a DSH patient percentage above the median of 28.1 percent that would have a decrease in overall Medicare revenue of greater than 4.1 percent from the payment rate alignment policy. No other hospitals would receive stop-loss benefits. We chose a stop-loss limit of 4.1 percent because that is the median percentage loss in overall Medicare revenue among OPPS hospitals.

Under this stop-loss policy, about 23 percent of hospitals would have reductions in overall Medicare revenue capped at 4.1 percent, and the other 77 percent of hospitals would receive no benefits from the stop-loss policy. Under this stop-loss policy, the decrease in overall Medicare revenue for all hospitals would be 3.6 percent (versus 4.1 percent without the loss limit) (Table 6-9). The types of hospitals that would benefit the most from the stop-loss policy include rural hospitals, government-owned hospitals, and hospitals that have 100 beds or fewer. Rural hospitals would benefit the most among all hospital categories; the percentage decrease in overall Medicare revenue for rural hospitals would fall from 6.9 percent without the stop-loss policy to 5.5 percent with the stop-loss policy. ■

Endnotes

1 When a hospital purchases a physician practice or ASC and converts it to an HOPD to obtain higher payment rates, the hospital may need to make changes to the office or ASC to comply with regulatory requirements applicable to HOPDs.

2 The OPPS also has 512 APCs for drugs and devices. The number of service APCs is fairly stable from year to year, but the number of drug and device APCs varies as new drugs and devices are brought to market and as all older devices and some older drugs become packaged into the payment rates of the related services.

3 For diagnostic tests, the PFS payment rates are the sum of a professional component and technical component. The technical component is equivalent to the difference between the nonfacility and facility PEs.

4 The hospital cost data are charges adjusted to costs using hospital cost-to-charge ratios from hospital cost reports. CMS uses these cost data to create the OPPS payment rates.

5 The weights are the volume in the three ambulatory settings for the HCPCS codes in APC 5151.

6 Beneficiaries who have full dual-eligibility status have both Medicare benefits and full Medicaid benefits. In contrast, beneficiaries who have partial dual-eligibility status have Medicare benefits and only partial Medicaid benefits, such as having their Medicare cost sharing or Medicare premiums covered by Medicaid.

7 The change in beneficiary cost sharing could be smaller than our estimates because some state Medicaid programs do not pay Medicare cost sharing if the difference between the Medicare payment rate for the service and the cost sharing for the service is greater than the Medicaid payment rate. In these situations, the effect of the payment alignment policies on beneficiaries' cost-sharing liabilities would be zero, and the aggregate effect of the payment alignment policies would be smaller than the amounts we report in this chapter.

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CHAPTER 7

Segmentation in the stand-alone Part D plan market

CHAPTER 7

Segmentation in the stand-alone Part D plan market

Chapter summary

The Part D program uses stand-alone prescription drug plans (PDPs) to provide drug coverage to beneficiaries in the fee-for-service (FFS) Medicare program. The insurers that participate in the PDP market, known as plan sponsors, can offer up to three plans, and they tailor those plans to appeal to different types of beneficiaries.

Most large sponsors follow the same general approach of dividing, or segmenting, the market based on beneficiaries' eligibility for Part D's low-income subsidy (LIS) and drug spending. Under this approach, sponsors use one plan to target LIS beneficiaries and two plans to target beneficiaries without the LIS—one for beneficiaries with low drug costs and one for beneficiaries with high drug costs. Sponsors differentiate their plans through a mix of program rules and changes in plan features such as premiums, beneficiary cost-sharing rules, formularies (the specific drugs covered by the plan), and pharmacy networks. Two distinctive features of this strategy are keeping the premium for the plan that targets LIS beneficiaries just below the LIS subsidy amount and offering plans with "enhanced" coverage (which combines standard Part D coverage with supplemental benefits) that turn out to have lower premiums than plans with "basic" coverage (which is limited to standard coverage only).

In this chapter

Segmenting the market makes PDPs more profitable for plan sponsors. For LIS beneficiaries, sponsors want to maximize the revenue they receive for each enrollee, which is easier to do when LIS enrollees are segmented into separate plans. For other beneficiaries, sponsors want to capitalize on the fact that beneficiaries are sensitive to premiums when they first select a PDP but rarely switch plans after that, which sponsors can do more easily by pairing a newer, low-premium plan that attracts new Part D enrollees with an older, more established plan with premiums they can increase more easily.

But for beneficiaries, the implications of a segmented market are more complicated. Segmentation benefits many enrollees who do not receive the LIS by giving them greater access to low-premium plans. At the same time, segmentation may make it harder for beneficiaries to understand their plan options, despite requirements that sponsors offer plans with meaningful differences. The common-sense distinction between "basic" and "enhanced" plans has been lost, and it can be difficult to determine what extra benefits are provided by enhanced PDPs with low premiums. In addition, beneficiaries in enhanced PDPs with high premiums likely pay more for their coverage than they otherwise would. For the Medicare program, segmentation likely increases Part D spending because it allows sponsors to charge higher premiums for plans that serve LIS beneficiaries and older plans that serve beneficiaries who do not receive the LIS.

Policymakers could consider several reforms that would either reduce the level of segmentation in the market or address some of the undesirable consequences of segmentation. These reforms include:

- Modifying the auto-enrollment process for LIS beneficiaries. Policymakers could give plan sponsors a stronger incentive to bid more competitively by auto-enrolling a larger share of new LIS beneficiaries in plans with lower premiums and reassigning LIS beneficiaries to new plans when premiums rise above the benchmark.
- Changing how the requirement for plans to have "meaningful differences" is administered. For example, policymakers could require enhanced PDPs to cover a minimum percentage of the out-of-pocket costs that their enrollees would otherwise pay for basic coverage. This approach would prevent sponsors from offering enhanced PDPs with very little additional coverage.
- Requiring PDP sponsors to treat their enrollees as a single risk pool for the purpose of providing basic coverage. Under this reform, every enrollee in a

sponsor's PDPs would pay the same premium for basic coverage and have the same formulary, cost-sharing rules, and pharmacy network. Sponsors would still be allowed to offer enhanced coverage, but they would do so by providing extra benefits on top of the uniform basic coverage, somewhat akin to an insurance rider. As under the current system, enrollees would pay for the full cost of any extra benefits through a supplemental premium.

Overall, segmenting the market based on beneficiaries' LIS eligibility is a greater concern than segmenting other beneficiaries based on their drug spending because it reduces the incentives for plans that serve the LIS population to bid competitively. The consequences of segmenting other beneficiaries based on their drug spending are more mixed, because segmentation reduces premiums for some beneficiaries while increasing premiums for other beneficiaries. Policymakers could therefore focus any reforms on measures that address the consequences of segmentation based on beneficiaries' LIS eligibility. ■

The Part D program relies on private plans to deliver prescription drug benefits to Medicare beneficiaries. These plans are either stand-alone prescription drug plans (PDPs) that provide coverage to beneficiaries in the fee-for-service (FFS) Medicare program or Medicare Advantage–Prescription Drug plans (MA–PDs) that provide both medical and drug coverage to beneficiaries in the MA program.

Every insurance company that participates in the PDP market (known as a plan sponsor) offers multiple plans. Plan sponsors tailor their plans to appeal to different parts of the Medicare population, and most large sponsors seek to divide, or segment, the market based on two factors: (1) whether a beneficiary receives Part D's low-income subsidy (LIS) and (2) whether a beneficiary has low or high drug spending. Under this approach, sponsors offer three PDPs: one plan to target LIS beneficiaries and two plans to target beneficiaries without the LIS—one for beneficiaries with low drug costs and one for beneficiaries with high drug costs. Two distinctive features of this strategy are keeping the premium for the plan that targets LIS beneficiaries just below the LIS subsidy amount and offering plans with "enhanced" coverage that turn out to have lower premiums than plans with "basic" coverage.

This chapter reviews the policies governing the number of PDPs that sponsors can offer and examines the strategies that sponsors use to differentiate their plans. As part of this work, we analyzed relevant Part D administrative data and interviewed several actuaries with Part D expertise to get their perspectives. We assessed how segmentation in the PDP market affects beneficiaries and program spending, and we explored reforms that would either reduce the level of segmentation in the market or address some of the undesirable consequences of segmentation. Overall, segmenting the market based on beneficiaries' LIS eligibility is a greater concern because it reduces the incentives for plans that serve the LIS population to bid competitively. The consequences of segmenting other beneficiaries based on their drug spending are more mixed, because segmentation reduces premiums for some beneficiaries while increasing premiums for other beneficiaries.

Background

Under the Part D program, all plans provide either *basic coverage*, which consists of a standard benefit defined in law or its actuarial equivalent, or *enhanced coverage*, which is basic coverage plus some type of additional benefits, such as a lower deductible or lower cost sharing. Medicare subsidizes the cost of basic coverage, while enrollees pay for the full cost of any additional benefits through a supplemental premium. All Part D sponsors are required by law to offer a basic plan; enhanced plans are optional.

Plan sponsors can offer up to three PDPs but must demonstrate that these plans have "meaningful differences"

At the start of the Part D benefit in 2006, CMS did not specify the number or type of PDPs that sponsors could offer, except for the statutory requirement that all participating sponsors had to offer a basic plan. In the years that followed, the agency expressed concern about the similarity among PDPs and the potential for similar plans to confuse beneficiaries and make it harder for them to select a plan. CMS encouraged sponsors to offer plans that provided beneficiaries with meaningful choices, but it could not require sponsors to make their PDPs more distinctive.

In 2010, CMS changed its approach by issuing a regulation that established the "meaningful difference" requirement for PDPs. Under this rule, CMS will not approve a PDP's bid unless it is sufficiently different from the other bids submitted by the same sponsor. CMS prohibited sponsors from offering more than one basic plan (which had been a common practice at the time) because those plans have the same actuarial value and thus cannot be shown to be meaningfully different from each other. CMS also said sponsors could not offer more than two enhanced plans and that the second plan must cover some drugs in the "coverage gap" that then existed in the basic Part D benefit. When CMS began enforcing these limits in 2011, the number of PDPs dropped sharply.

When two sponsors are involved in a merger or acquisition, CMS gives the combined entity a two-year grace period before it must comply with the meaningful difference requirement. At that point,

the sponsor has to consolidate or close some of its PDPs. For example, in 2022, Cigna and Centene both consolidated plans following their respective acquisitions of Express Scripts and Aetna's PDP business. Before these mergers, all 4 companies offered 3 PDPs in each region, so these consolidations resulted in the elimination of 204 PDPs (2 former sponsors × 3 plans per region × 34 Part D regions).

CMS enforces the meaningful difference requirement by comparing the average out-of-pocket cost (OOPC) for a sponsor's PDPs. The agency estimates that cost by calculating what a nationally representative sample of Part D enrollees would spend on deductibles, copayments, and coinsurance under each plan. This approach accounts for plan-to-plan differences in both formularies (the specific drugs covered by each plan) and benefit structures (the specific cost-sharing rules for each plan). CMS has traditionally required the OOPC estimates for a sponsor's PDPs to differ by a specific dollar amount; bids for plans that have smaller differences were rejected. From 2011 to 2018, CMS used two separate OOPC thresholds: one for measuring differences between the basic plan and the first enhanced plan, and another for measuring differences between the first enhanced plan and the second enhanced plan. Those thresholds changed from year to year; the first ranged from $18 to $24 per month while the second ranged from $12 to $37 per month.

The gradual closure of the Part D coverage gap between 2011 and 2019 made it increasingly difficult for plan sponsors to have meaningful differences between their enhanced PDPs because the coverage of some drugs in the gap was the main feature that distinguished them. In 2014, CMS proposed limiting sponsors to offering just two PDPs—one basic plan and one enhanced plan—but did not finalize its proposal. In 2018, the agency instead eliminated the meaningful difference threshold between enhanced plans, effective in 2019. (Plan sponsors must still show that their enhanced PDPs are meaningfully different from their basic PDP, but they no longer have to show that their enhanced PDPs are meaningfully different from each other.) Sponsors are still limited to offering one basic plan and up to two enhanced plans.

CMS's approach for measuring meaningful differences lets it compare PDPs in a consistent manner but also has its limitations. The OOPC model has traditionally used prescription drug claims that are four to five years old and do not reflect current utilization patterns, and it overstates the impact of adding or removing drugs from a plan's formulary by assuming that beneficiaries who take nonformulary drugs keep paying for them out of pocket instead of switching to another medication (Kranovich 2016). Drug manufacturers have argued that this assumption gives plan sponsors an incentive to cover fewer drugs in basic PDPs because they get credit toward the meaningful difference threshold by covering more drugs in enhanced PDPs (Pharmaceutical Research and Manufacturers of America 2017). One actuary we interviewed said the OOPC model also does not account for the effects of preferred pharmacy networks, which are a common PDP feature and increase out-of-pocket costs for enrollees who use nonpreferred pharmacies. Finally, the model's estimate of how much an enhanced PDP lowers out-of-pocket costs can differ substantially from the supplemental premium the plan actually charges for its extra coverage because the model uses a nationally representative sample of enrollees while the plan's premium is based on its specific mix of enrollees.

CMS has developed a revised OOPC model and will use it to review plan bids for 2023. Due to the switch to the new model, CMS will use another method to measure meaningful differences. CMS still expects a sponsor's enhanced plans to have lower OOPC estimates than its basic plan, but instead of using a specific dollar threshold, the agency will examine bids where the differences in the OOPC estimates are unusually small. It is unclear whether CMS will resume using a specific dollar threshold in the future. The revised model uses a different source for its claims data (a 0.1 percent sample of Part D claims instead of data collected in the Medicare Current Beneficiary Survey) and will have more recent data (two years old). The agency is also considering changes to the model that would make more realistic assumptions about how beneficiaries respond when they take a drug that is not covered on a plan's formulary. The actuaries we interviewed thought the revised model was an improvement and would make the meaningful difference requirement more rigorous.

Throughout this chapter, we divide PDPs into three groups: *basic*, *first enhanced*, and *second enhanced*.[1] The basic category is straightforward; these plans

TABLE 7–1

More plan sponsors are offering enhanced PDPs, and more beneficiaries are enrolling in them

	2017	2018	2019	2020	2021	2022
Number of PDPs						
Basic PDP	359	361	348	382	378	302
First enhanced PDP	270	270	308	342	359	285
Second enhanced PDP	117	151	245	224	259	179
Total	746	782	901	948	996	766
Offer rates for enhanced PDPs						
First enhanced PDP	75%	75%	89%	90%	95%	94%
Second enhanced PDP	33	42	70	59	69	59
Enrollment (millions)						
Basic PDP	12.2	12.3	11.9	11.1	9.5	8.9
First enhanced PDP	4.5	4.6	5.0	4.4	5.5	6.4
Second enhanced PDP	3.9	3.9	3.8	5.0	4.5	3.9
Total	20.6	20.8	20.7	20.5	19.6	19.1
Enrollment (share)						
Basic PDP	59%	59%	58%	54%	48%	46%
First enhanced PDP	22	22	24	21	28	33
Second enhanced PDP	19	19	18	24	23	20

Note: PDP (prescription drug plan). We counted plans based on unique combinations of contract and plan numbers. When plan sponsors offered one enhanced PDP in a region, we included it in the "first enhanced" category; when sponsors offered two enhanced PDPs, we included the plan with the lower overall premium in the "first enhanced" category and the plan with the higher overall premium in the "second enhanced" category. Table does not include employer-sponsored plans or plans in the U.S. territories. Enrollment figures for 2017–2021 are for July of each year; enrollment figures for 2022 are for January. The number of PDPs dropped in 2022 largely because Centene and Cigna consolidated their PDPs to comply with the meaningful difference requirement. Components may not sum to totals due to rounding.

Source: MedPAC analysis of 2022 Part D landscape file and enrollment data.

provide the standard Part D benefit without any supplemental benefits. When sponsors offer just one enhanced PDP, we assigned it to the first enhanced category. When sponsors offer two enhanced PDPs, we assigned the plan with the lower overall premium (i.e., the premium for basic coverage plus the supplemental premium) to the first enhanced category and the plan with the higher overall premium to the second enhanced category.

Plan sponsors have become more likely to offer enhanced PDPs in recent years (Table 7-1). Five years ago, sponsors offered a first enhanced plan in 75 percent of the regions they served and a second enhanced plan in 33 percent of the regions they served. Those figures have since risen to 94 percent and 59 percent, respectively. The growth largely occurred in 2019, after CMS relaxed its meaningful difference requirement and made it easier for sponsors to offer two enhanced plans. In 2022, the PDP market has 28

TABLE 7–2

In 2020, spending and utilization patterns differed substantially across the three PDP types

	Basic PDPs	First enhanced PDPs	Second enhanced PDPs
Share of enrollees receiving the LIS	55%	3%	7%
Average annual spending			
Total drug costs	$5,122	$2,253	$3,831
Basic benefit costs	$3,436	$1,426	$2,478
Average number of 30-day prescriptions	55	44	56
Average cost for a 30-day prescription	$93	$51	$69
Share of enrollees reaching the catastrophic phase	12%	3%	6%
Share of enrollees with no prescriptions	10%	8%	4%

Note: PDP (prescription drug plan), LIS (low-income subsidy). When plan sponsors offered one enhanced PDP in a region, we included it in the "first enhanced" category; when sponsors offered two enhanced PDPs, we included the plan with the lower overall premium in the "first enhanced" category and the plan with the higher overall premium in the "second enhanced" category. Spending figures do not include any postsale rebates or discounts. Prescription figures are based on standardized, 30-day counts. Figures do not include PDPs in the U.S. territories.

Source: MedPAC analysis of 2020 Part D landscape, enrollment, and prescription drug event data.

distinct plan sponsors. The 5 largest sponsors—CVS Health, Centene, Humana, UnitedHealth, and Cigna—offer the maximum 3 PDPs in all 34 Part D regions. They account for a majority of the first enhanced plans and almost all of the second enhanced plans. The other sponsors typically offer a basic plan and one enhanced plan.

Enhanced plans have also grown as a share of overall PDP enrollment, rising between 2017 and 2022 from 41 percent to 54 percent. Given how we define the "first enhanced" and "second enhanced" categories, the share of beneficiaries in those categories can fluctuate from year to year as plan sponsors modify their offerings. (For example, if a sponsor has one enhanced plan and introduces a second enhanced plan with a lower premium, the enrollment in the older plan shifts from the "first enhanced" category to the "second enhanced" category.) Currently, about a third of all PDP enrollees are in first enhanced plans and a fifth are in second enhanced plans.

Most major sponsors use the same general approach to segment the PDP market

When plan sponsors offer multiple PDPs, they try to tailor them to appeal to different parts of the Medicare population. Most major sponsors currently use the same basic approach to divide, or segment, the PDP market based on a beneficiary's LIS eligibility and whether a beneficiary has low or high drug spending. Under this approach, sponsors offer three PDPs, and each plays a distinct role:

- The basic PDP targets LIS beneficiaries;
- The first enhanced PDP targets beneficiaries who do not receive the LIS and have low drug costs; and
- The second enhanced PDP targets beneficiaries who do not receive the LIS and have high drug costs.

There are clear differences in the mix of enrollees for each PDP type, which indicates that sponsors have

been able to segment the market to some degree (Table 7-2). LIS beneficiaries are heavily concentrated in basic PDPs. Compared with basic PDPs, enrollees in first enhanced PDPs have fewer prescriptions, use less expensive medications, and have much lower total drug costs. Total spending for enrollees in second enhanced PDPs is roughly halfway between the averages for the other two PDP types; they have about the same number of prescriptions as basic PDP enrollees but use less expensive drugs. The share of enrollees who reach the catastrophic phase of the Part D benefit follows a similar pattern. However, the share of enrollees with no prescriptions follows a different pattern—highest for basic PDPs (10 percent) and lowest for second enhanced PDPs (4 percent). The fact that basic PDPs have both the highest share of enrollees reaching the catastrophic phase and the highest share of enrollees with no prescriptions suggests that the spending distribution for LIS beneficiaries is somewhat bimodal.[2]

Although the mix of enrollees varies across the three PDP types, efforts by plan sponsors to segment the market do not work perfectly. For example, in 2021, 7 percent of LIS beneficiaries were enrolled in enhanced PDPs and 30 percent of beneficiaries without the LIS were in basic PDPs (data not shown). Similarly, some enrollees in first enhanced PDPs have high drug costs and some enrollees in second enhanced PDPs have low drug costs. Since Medicare beneficiaries can enroll in any PDP, can weigh different considerations when selecting a plan, and may not always select the plan that best meets their needs, there will always be limits on how effectively sponsors can segment the market.

Nonetheless, the relaxation of the meaningful difference requirement in 2019 has increased the level of segmentation in the PDP market in some respects. For example, before 2019, the share of beneficiaries without the LIS who were enrolled in basic PDPs had been slowly rising, from 37 percent in 2016 to 41 percent in 2018. Following the change, that figure has fallen to 30 percent. Similarly, the share of basic PDP enrollees who are LIS beneficiaries had been gradually declining in the years before 2019 but has since increased.

Segmentation is common in many health insurance markets—for example, Medicare Advantage has distinct plans (special needs plans) that serve beneficiaries who receive both Medicare and Medicaid, live in a nursing home, or have certain chronic conditions. By itself, segmentation is not problematic; policymakers may decide to segment a market to achieve certain policy goals, such as the development of specialized plans that better serve populations with unusual care needs. However, segmentation in the PDP market may be more of a concern, because Part D has features (such as the auto-enrollment process for LIS beneficiaries) that encourage plan sponsors to charge higher premiums for certain types of plans.

The actuaries we interviewed emphasized that the major plan sponsors have many different lines of business and that PDPs are just one element of their overall business strategy. PDP enrollment is thus attractive partly because it supports those other lines of business. For sponsors that own a pharmacy benefit manager, specialty pharmacy, mail-order pharmacy, or retail pharmacy, PDPs can provide volume, administrative fees, and greater leverage with drug manufacturers. Sponsors that offer MA plans try to cultivate "brand loyalty" in their PDP enrollees and encourage them to switch to one of the company's MA plans, which the actuaries said are much more profitable.

The LIS has features that limit the incentives for plan sponsors to bid competitively with their basic PDPs

Part D's low-income subsidy covers most premiums and cost sharing for eligible beneficiaries and was designed by the Congress to use basic PDPs as the default form of drug coverage. The LIS's premium subsidy has a dollar limit, known as the benchmark, that represents the maximum amount the LIS will pay for basic coverage. LIS beneficiaries who enroll in basic plans with premiums that are less than the benchmark do not pay a premium; those who enroll in basic plans with higher premiums pay the difference. In addition, LIS beneficiaries who enroll in enhanced PDPs must pay the plan's supplemental premium, even if the plan's overall premium is lower than the benchmark. The LIS thus gives beneficiaries a clear incentive to enroll in the subset of basic PDPs known as **benchmark plans** where they do not have to pay a premium.

The Part D program also ensures that LIS beneficiaries have coverage by automatically enrolling them in

benchmark PDPs if they do not select a drug plan. This approach gives plan sponsors an incentive to offer benchmark PDPs because auto-enrollment enables them to generate enrollment without incurring expenses such as marketing costs. In addition, if plans lose their benchmark status when CMS calculates Part D premiums and benchmarks for a new plan year, the agency will reassign LIS beneficiaries in the "losing" plans to other benchmark plans to ensure that they do not have to start paying a premium. (The auto-enrollment process does not apply to LIS beneficiaries who have selected a Part D plan on their own.) When there is more than one benchmark PDP in a region, CMS auto-enrolls LIS beneficiaries by randomly assigning them to one of the eligible plans. Each benchmark plan in a region typically receives an equal number of auto-enrollees.

Together, these two features—the lack of coverage for supplemental premiums and the use of auto-enrollment—have been very effective at channeling LIS beneficiaries into basic PDPs. In 2021, 92 percent of LIS beneficiaries with FFS coverage were enrolled in basic plans, and they represented a majority of the enrollees in basic PDPs. This approach provides LIS beneficiaries with a stable source of drug coverage, but it also reduces the incentives for benchmark plans to bid competitively. A plan that wants to serve LIS beneficiaries has an incentive to keep its premium below the benchmark to ensure that LIS beneficiaries can enroll without paying a premium and the plan can receive auto-enrollments. However, once a plan has qualified as a benchmark plan, it does not have an incentive to reduce its premium any further (Congressional Budget Office 2014). If the plan does lower its premium further below the benchmark, it cannot expect to receive any more LIS enrollees in return, for two reasons. First, every benchmark plan in a region typically receives the same number of auto-enrollments. Second, LIS beneficiaries do not have an incentive to switch to the plan because they will not benefit from the lower premium. (Medicare saves money if they enroll in the lower-premium plan instead of another benchmark plan that is more expensive, but the beneficiaries themselves pay no premium in either case.) At the margin, a benchmark plan that lowers its premium thus receives less Medicare revenue for the same number of LIS enrollees.

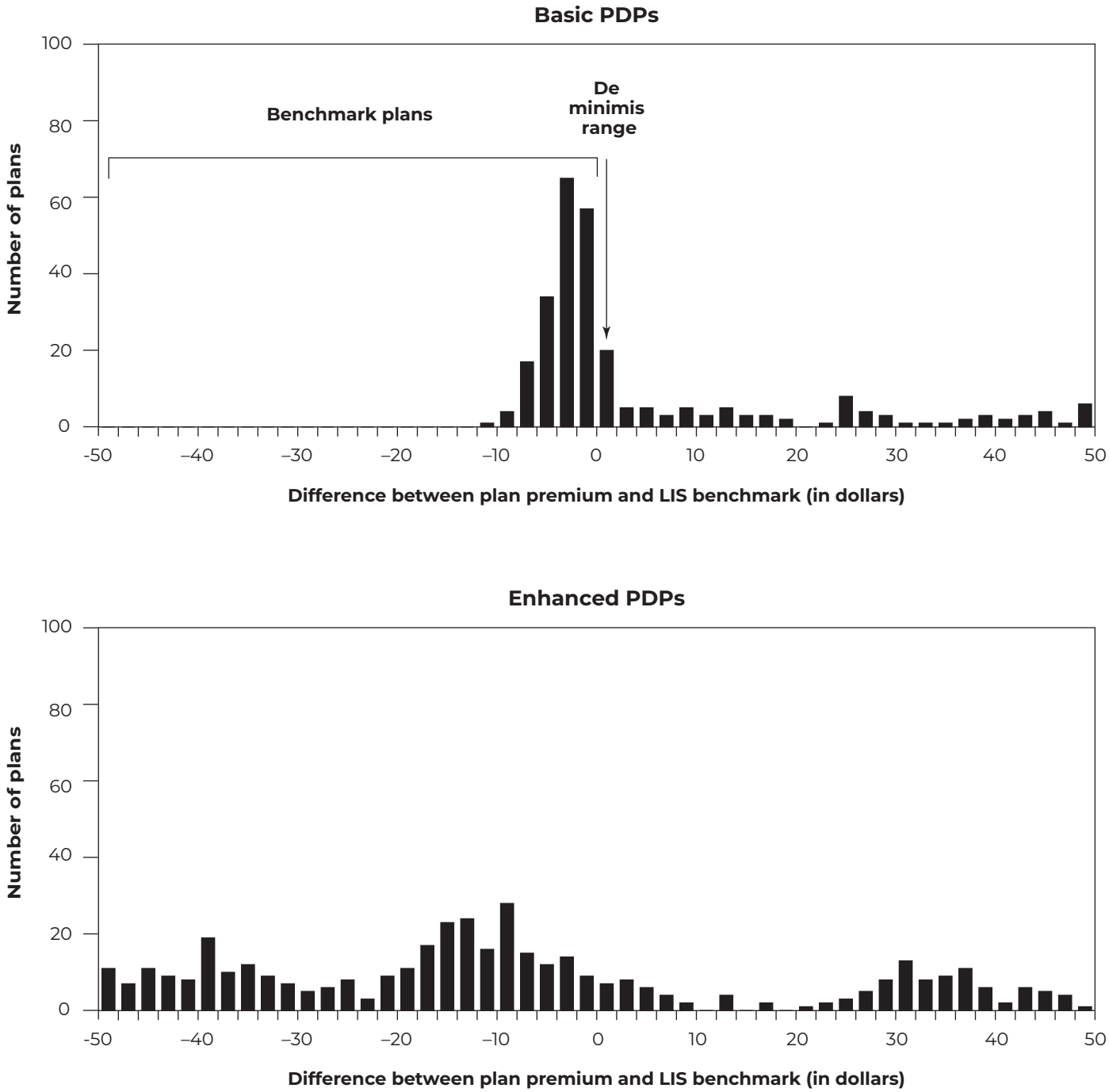
As a result, benchmark plans try to keep their premiums just below the LIS benchmark (Figure 7-1). The top half of Figure 7-1 shows the distribution of the 2022 premiums for basic PDPs, based on the difference between the plan's premium and the benchmark. Almost 90 percent of the benchmark plans have premiums that are within $6 of the benchmark, and only one has a premium that is more than $10 below the benchmark. Another cluster of PDPs have premiums that are slightly higher than the benchmark; CMS allows plans with premiums that exceed the benchmark by a "de minimis" amount, which has always been $2, the option of waiving the remaining premium to avoid having their LIS enrollees reassigned to new plans. For comparison, the bottom half of the figure shows the distribution of the basic portion of the premiums for enhanced PDPs. These plans cannot qualify as benchmark plans, and their premiums do not show the same clustering pattern as basic plans.

The Congressional Budget Office (CBO) released a working paper in 2014 that examined how benchmark plans respond to these incentives (Congressional Budget Office 2014). CBO found that benchmark plans were less responsive than other basic plans to greater competition (in the form of another plan sponsor entering the market). Consistent with economic theory, CBO found that the entry of a new sponsor prompted both types of plans to reduce their bids, but the changes for benchmark plans were much smaller and not statistically significant. CBO also found that plans with premiums that were farther below the benchmark were more likely than plans with premiums that were closer to the benchmark to significantly increase their bids the following year. Both findings support the conclusion that the LIS limits the incentives for benchmark plans to bid competitively.

Further evidence that benchmark plans do not bid as competitively as they could comes from the behavior of plans that qualify for the de minimis option. Participation is voluntary, but the vast majority of eligible PDPs participate: Over the last five years (2018 to 2022), we found that 95 percent of the PDPs that qualified for the de minimis option (127 out of 134 plans) agreed to waive the additional premium. The high participation suggests that most of these PDPs were willing to serve LIS beneficiaries for less revenue than they stated in their bid. In addition, de minimis plans

FIGURE 7–1

The premiums for most benchmark PDPs are clustered around the LIS benchmark



Note: PDP (prescription drug plan), LIS (low-income subsidy). This figure is based on plan premiums and benchmarks for 2022 and does not include plans in the U.S. territories. Basic PDPs with premiums that exceeded the LIS benchmark by a "de minimis" amount ($2 or less) could waive the difference and avoid having their LIS enrollees reassigned to other plans. For enhanced PDPs, we used the portion of the premium that reflects the cost of basic Part D coverage only; we did not include the supplemental premium that those plans charge to finance the cost of their enhanced benefits. This figure does not include plans with premiums that are more than $50 below the benchmark (33 enhanced PDPs) or more than $50 above the benchmark (30 basic PDPs and 11 enhanced PDPs).

Source: MedPAC analysis of CMS Part D premium and benchmark data.

know they are in danger of not qualifying as a zero-premium plan for LIS beneficiaries and tend to bid more conservatively the next year: 82 percent of the plans that took the de minimis option between 2017 and 2021 qualified as a benchmark plan the next year, and only 5 percent lost zero-premium eligibility altogether.

Plan sponsors use a variety of strategies to differentiate their enhanced PDPs

This section takes a closer look at how plan sponsors tailor their PDPs to appeal to different parts of the Medicare population. We examine four areas: premiums, cost sharing, formularies, and pharmacy networks.

Premiums for enhanced PDPs are often lower than premiums for basic PDPs and have declined in recent years

Under Part D, plan premiums are determined through competitive bidding. Plans submit bids reflecting the monthly cost of providing the standard Part D benefit or alternative coverage with the same actuarial value. CMS calculates the national average bid and a standard premium known as the base beneficiary premium.[3] For 2022, the national average bid is $38.18 and the base beneficiary premium is $33.37. The premium for each plan equals the base beneficiary premium plus the difference between the plan's bid and the national average bid. As a result, plans with above-average bids have higher premiums and those with below-average bids have lower premiums. Plans that provide enhanced coverage also charge a supplemental premium that reflects the full cost of the additional coverage.[4]

The Part D actuaries we interviewed emphasized the key role that premiums play in the PDP market. They said premiums are the most important factor that many beneficiaries consider when choosing a plan and that premiums are particularly important to beneficiaries with low drug costs—the population many sponsors try to attract with their first enhanced PDP. Plan sponsors thus want to offer a PDP with a very low premium to attract these beneficiaries. This view is consistent with studies that have found many beneficiaries do not pick the Part D plan that best meets their needs because they put too much emphasis on premiums over other factors like cost sharing (Abaluck and Gruber 2011).

In theory, plan sponsors should use their basic PDP as their low-premium option because it does not have any added costs for supplemental benefits. However, for sponsors that also want to attract LIS beneficiaries, this approach poses difficult trade-offs because lowering the basic PDP's premium to attract non-LIS beneficiaries worsens the financial picture for the plan's LIS beneficiaries. Plan sponsors also find it more difficult to manage LIS beneficiaries' drug spending because their cost sharing is limited to modest copayments, which makes it harder to keep premiums low.

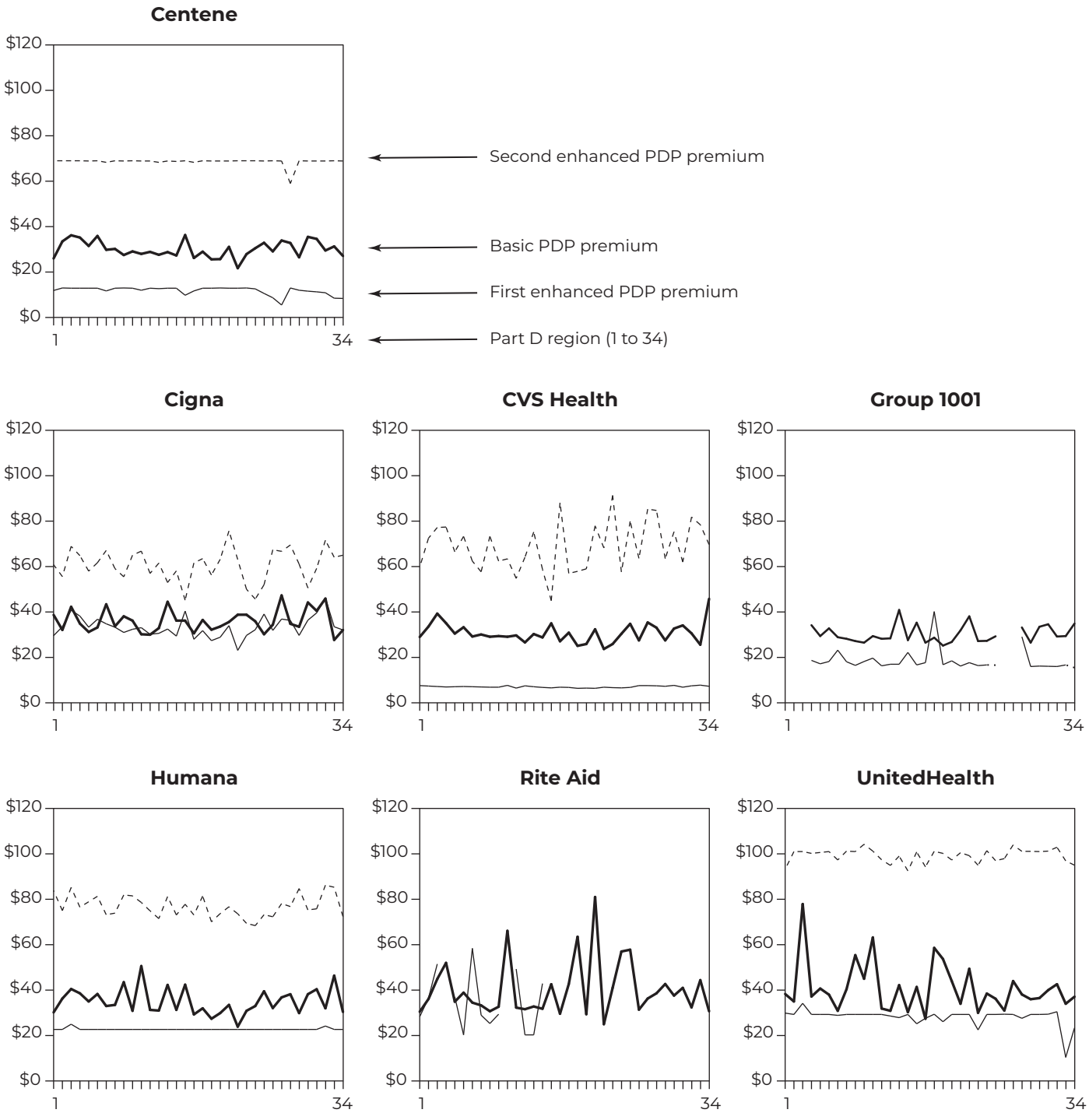
Given these challenges, many plan sponsors use an enhanced PDP as their low-premium option, despite its supposedly richer benefits. Segmenting the market in this manner lets sponsors offer a low-premium plan without reducing the revenue they receive for the LIS beneficiaries enrolled in their basic PDPs. Figure 7-2 shows the 2022 premiums for the PDPs offered by the seven largest plan sponsors. Five sponsors (Centene, CVS Health, Group 1001, Humana, and UnitedHealth) offer an enhanced PDP with a lower premium than their basic PDP in all or nearly all Part D regions. The only exceptions to this pattern are Cigna and Rite Aid, where the enhanced PDP premium is higher than the basic PDP premium in some regions and lower in others. When sponsors offer a second enhanced plan (Group 1001 and Rite Aid do not), their premiums are significantly higher than the premiums for the other two PDPs.

The practice of offering an enhanced PDP with a premium that is lower than the basic PDP's premium has been used since the early years of the program. In 2010, about half of the enrollees in first enhanced PDPs were in plans that had a lower overall premium than the sponsor's basic PDP. That figure fell to almost zero in 2011, likely due to the adoption of the meaningful difference requirement, but has risen steadily since then. This year, about 90 percent of the enrollees in first enhanced PDPs are in plans that have a lower premium than the sponsor's basic PDP.

Over the past five years, the relationship between the monthly premiums for basic PDPs and for enhanced PDPs has fundamentally changed (Table 7-3, p. 204).

FIGURE 7–2

In 2022, most major PDP sponsors offer an enhanced plan that has a lower premium than their basic plan



Note: PDP (prescription drug plan). Figures for enhanced plans include supplemental premiums.

Source: MedPAC analysis of 2022 Part D premium data.

TABLE 7–3

Premiums for basic Part D coverage have increased for basic PDPs but decreased sharply for enhanced PDPs

Average monthly premiums	2017	2018	2019	2020	2021	2022
All PDPs (basic coverage)	$36	$35	$33	$31	$30	$29
Basic PDPs	31	30	32	30	32	35
Enhanced PDPs						
Basic coverage	42	41	34	31	28	24
Supplemental coverage	11	15	15	15	16	21
Total premium	53	56	49	46	43	46

Note: PDP (prescription drug plan). Figures are enrollment-weighted averages for July of each year (2017–2021) or January (2022). Table does not include employer-sponsored plans or plans in the U.S. territories. Components may not sum to totals due to rounding.

Source: MedPAC analysis of Part D premium and enrollment data.

In 2017, the premium that enhanced PDPs charged for basic coverage was $11 higher, on average, than the premium for basic PDPs ($42 vs. $31). Since then, the average premium for enhanced PDPs has dropped sharply while the average premium for basic PDPs has risen somewhat. The premium that enhanced PDPs charge for basic coverage is now $11 lower, on average, than the premium for basic PDPs ($24 vs. $35). At the same time, much of the decline in the basic portion of the premium has been offset by growth in supplemental premiums, which have almost doubled (from $11 to $21).

The actuaries we interviewed attributed the decline in the average premiums for enhanced PDPs to two factors. The first was higher enrollment growth in low-premium enhanced PDPs relative to other PDPs. The second was growth in direct and indirect remuneration (DIR), the postsale rebates and discounts that plans receive from drug manufacturers and pharmacies. Total DIR payments to Part D plans have grown rapidly over time, rising between 2007 and 2019 from less than 10 percent of total drug spending to 26.5 percent (Boards of Trustees 2021, Boards of Trustees 2015). One actuary said that plan sponsors have made particular efforts to generate more DIR, especially pharmacy DIR, in their low-premium enhanced plans—for example, by giving enrollees stronger incentives to use preferred pharmacies (see the discussion of cost sharing later in the chapter). The overall growth in DIR has thus benefited those plans more than other PDPs, and their premiums have declined as a result. Plans use DIR to lower their bids, and when plans submit their bids, they include an estimate of the DIR payments they expect to receive. We analyzed plan bids for 2022 and found that, on a percentage basis, DIR has a larger impact on the bids for first enhanced PDPs than on the bids for basic PDPs and second enhanced PDPs.

The average premiums for enhanced PDPs obscure a great deal of underlying variation, as shown by the 2022 premiums for plans offered by the largest sponsors (Table 7-4). The premiums for first enhanced PDPs range from $7 to $35, but even when plans have relatively similar overall premiums, the basic and supplemental components may be very different. Three plans (offered by Centene, CVS Health, and Group 1001) have basic premiums that are actually negative, which occurs when the plan's bid is so far below the national average bid that the difference is larger than the base beneficiary premium. In these situations, plans must provide supplemental benefits that are at least equal in value to the difference between the plan's bid and the national average bid.

TABLE 7–4

In 2022, the premiums that enhanced PDPs charge for basic and supplemental coverage both vary widely

			Average premium		
Plan sponsor	**Plan name**	**Type**	**Basic**	**Supplemental**	**Total**
Centene	Wellcare Value Script	E1	–$19	$31	$12
	Wellcare Medicare Rx Value Plus	E2	32	36	68
Cigna	Cigna Essential Rx	E1	21	14	35
	Cigna Extra Rx	E2	17	43	60
CVS Health	SilverScript SmartRx	E1	–5	13	7
	SilverScript Plus	E2	20	47	67
Group 1001	Clear Spring Health Premier Rx	E1	–12	30	18
Humana	Humana Walmart Value Rx Plan	E1	22	1	23
	Humana Premier Rx Plan	E2	66	11	77
Rite Aid	Elixir RxPlus	E1	10	18	28
UnitedHealth	AARP MedicareRx Walgreens	E1	23	6	29
	AARP MedicareRx Preferred	E2	72	28	100

Note: PDP (prescription drug plan), E1 (first enhanced PDP), E2 (second enhanced PDP). When plan sponsors offer one enhanced PDP in a region, we included it in the "first enhanced" category; when sponsors offer two enhanced PDPs, we included the plan with the lower overall premium in the "first enhanced" category and the plan with the higher overall premium in the "second enhanced" category. Figures are weighted using January enrollment and do not include plans in the U.S. territories. Components may not sum to totals due to rounding.

Source: MedPAC analysis of 2022 Part D premium and enrollment data.

Other first enhanced PDPs, such as those offered by Humana and UnitedHealth, have higher premiums for basic coverage but lower supplemental premiums. Humana is an extreme case; the average supplemental premium for its Humana Walmart Value Rx Plan is less than $1. (The lowest amount, in Maine and New Hampshire, is just $0.40.) Except for Wellcare Value Script, every first enhanced PDP has a supplemental premium that is lower than the $22 meaningful difference threshold that all enhanced plans were required to meet in their 2022 bids, which indicates that the meaningful difference standard is not very effective at forcing sponsors to differentiate their plans.

For a given sponsor, the basic and supplemental premiums for its second enhanced PDP are almost always higher than for its first enhanced PDP. But both components still vary widely across sponsors (from $17 to $72 for basic coverage and from $11 to $47 for supplemental coverage).

We asked actuaries why the composition of the premiums for enhanced PDPs, particularly those with low premiums, varies so much across sponsors. Some actuaries said the age of the plan was a factor: Newer plans have more latitude to make assumptions in their bids about the expected costliness of their enrollees, which can lead plans that hope to serve relatively healthy enrollees to have low bids and potentially negative premiums for basic coverage. Older plans must base their bids on historical experience; if their enrollees turn out to be more expensive than expected,

they will have higher bids and higher premiums for basic coverage. The actuaries we interviewed said it was very unlikely that an older plan would have a negative premium. One added that some plan sponsors may find the combination of a low or even negative premium for basic coverage and a relatively high supplemental premium attractive because Part D's risk corridors provide some protection against unexpected losses and the higher supplemental premium will do more to discourage LIS beneficiaries from enrolling.

Separately, the low supplemental premiums for many enhanced PDPs reflect limitations in how CMS enforces the meaningful difference requirement. The model that CMS uses to measure whether enhanced PDPs meet the requirement is based on a nationally representative sample of beneficiaries, while the actual premium that plans charge is based on the expected costs for their own mix of enrollees. Plans that have healthier enrollees will have lower supplemental premiums. The actuaries we interviewed also highlighted some strategies that plans can use to satisfy the requirement while keeping their actual premiums low, such as charging higher cost sharing when enrollees use nonpreferred pharmacies (this feature increases out-of-pocket costs for some enrollees, but CMS's model does not account for those costs) or adding certain drugs to their formulary (an issue we discuss in more detail in the formulary section). The actuaries said that it is very difficult to determine exactly what additional benefits a plan with low supplemental premiums provides relative to the standard Part D benefit.

Part D's risk-adjustment system has limitations that allow PDP sponsors to segment the market

Medicare pays Part D plans using a combination of capitated payments, which finance benefits covered by the competitive bidding process, and cost-based reinsurance, which finances 80 percent of spending in the benefit's catastrophic phase. CMS adjusts the capitated payments to account for differences in beneficiaries' health status: Plans with sicker enrollees receive higher payments and vice versa. The risk-adjustment system aims to limit the incentives for plans to avoid or underserve enrollees with above-average costs.

CMS makes these adjustments by using demographic information and diagnostic information from claims to calculate a risk score that shows how the expected costs for a beneficiary compare with the overall average. For example, a risk score of 1.0 indicates that a beneficiary's expected costs equal the overall average, while a score of 1.3 indicates that a beneficiary's expected costs are 30 percent higher than the overall average.

CMS risk adjusts plan bids when it calculates the national average bid and each plan's premium for basic Part D coverage. In theory, risk adjustment should make it more difficult to segment the PDP market. Plans that want to attract healthier enrollees would like to submit low bids so they can have low premiums. Without risk adjustment, the low bids translate directly into low premiums. With risk adjustment, CMS divides each plan's bid by its average risk score, which increases the bids for plans with healthier enrollees because their average risk scores are less than 1.0, resulting in premiums that are higher and less attractive to healthy enrollees.

However, plan sponsors have still been able to segment the PDP market to some degree—as shown in Table 7-2 (p. 198) by the differences in the enrollees served by the three PDP types—which suggests that the risk-adjustment system is somewhat inaccurate. The actuaries we interviewed highlighted two particular limitations. First, the system predicts a beneficiary's gross drug costs (which are essentially payments at the pharmacy counter) and does not account for postsale rebates and discounts. Since the low-premium enhanced PDPs collect proportionally more rebates and discounts than other PDPs, their risk scores are too high relative to other plans, which puts downward pressure on their risk-adjusted bids and their premiums. Second, the system tends to overestimate spending for beneficiaries with very low drug costs and underestimate spending for beneficiaries with very high drug costs. These errors tend to offset each other when plans have a broad mix of enrollees, but the low-premium enhanced PDPs tend to have a disproportionate number of enrollees with low drug costs. One actuary said those plans are particularly interested in beneficiaries who do not use any medications; plans must compete to enroll those beneficiaries because they are so sensitive to plan premiums, but they are still profitable because the risk-adjustment system expects them to have some drug spending.

Beneficiary cost sharing

Under the standard Part D benefit for 2022, beneficiaries have a complicated cost-sharing structure with four distinct phases:

- a deductible of $480;
- coinsurance of 25 percent on spending between $480 and $4,430, which is known as the initial coverage limit;
- coinsurance of 25 percent on spending between $4,430 and the start of the catastrophic phase, which is typically around $10,690; and
- coinsurance of 5 percent on any spending above $10,690.

Beneficiaries once paid all costs in the third phase of the benefit, which is still referred to as the coverage gap and is treated as a distinct phase because the other 75 percent of spending is largely financed by manufacturer discounts on brand drugs.

However, Part D plans can offer alternative benefits that have the same actuarial value as the standard benefit, and all PDPs use this option. Plan sponsors prefer to offer alternative benefits because they can use formularies that favor certain drugs (and require enrollees to pay cost sharing that is effectively higher than 25 percent for some drugs and lower than 25 percent for other drugs). These changes in cost sharing are limited to the first two phases—the deductible and spending below the initial coverage limit—because plans have financial incentives that lead them to use uniform coinsurance in the coverage gap and catastrophic phases.

Nearly all enhanced PDPs partially or completely eliminate the Part D deductible

The Part D actuaries we interviewed said that, after the premium, the deductible is the most important feature for many beneficiaries when choosing a PDP. Plan sponsors respond to these preferences by trying to offer plans that reduce or eliminate the deductible, and there are clear differences among the three PDP types (Table 7-5, p. 208).

All basic PDPs have a deductible, with almost all (93 percent) using the standard deductible. The actuaries we interviewed said that it is difficult to design a basic plan that eliminates the deductible and passes the tests for actuarial equivalence. Plan sponsors may also feel less need to eliminate or reduce the deductible because many basic PDP enrollees receive the LIS, which covers any deductible. About a quarter of basic PDPs exempt certain drugs from the deductible, usually generic medications on the two lowest formulary tiers.

In contrast, virtually all enhanced PDPs exempt some drugs from their deductible or eliminate the deductible entirely. Almost all first enhanced PDPs (91 percent) have a deductible but exempt certain drugs, while a majority of second enhanced plans (61 percent) eliminate the deductible entirely. Only one enhanced PDP, offered by a national plan sponsor in all 34 Part D regions, exempts some brand drugs (those on tier 3) from its deductible.

Copayment and coinsurance amounts differ in several ways

Under a PDP's alternative benefit package, the cost sharing for each medication depends on its formulary placement. All PDPs use tiered formularies that assign the drugs they cover to distinct groups, or tiers. Each tier has its own cost-sharing requirements, with enrollees paying more for drugs on higher tiers. The goal is to encourage enrollees to use lower-cost medications by placing them on "preferred" tiers with more favorable cost sharing. Plans can also charge lower cost sharing when enrollees fill prescriptions at a preferred pharmacy.

For several years now, all PDPs have used formularies that have five tiers:

- tier 1: preferred generic
- tier 2: generic
- tier 3: preferred drug
- tier 4: nonpreferred drug
- tier 5: specialty tier

As their names suggest, tiers 1 and 2 are limited to generic drugs. However, it is worth noting that those tiers do not include every generic on the formulary. Plans can include generics on any tier, and by some measures PDPs now cover more generic drugs on the higher tiers, which are usually associated with brand

TABLE 7–5

In 2022, enhanced PDPs are much more likely than basic PDPs to partially or completely eliminate the Part D deductible

	Basic PDPs		First enhanced PDPs		Second enhanced PDPs	
	Number	Share	Number	Share	Number	Share
Number of plans	302	100%	285	100%	179	100%
Standard deductible ($480)	282	93	222	78	36	20
Reduced deductible ($1 to $479)	20	7	36	13	34	19
No deductible	0	0	27	9	109	61
Among plans with deductibles:						
Deductible applies to all formulary tiers	224	74	1	<1	0	0
Deductible does not apply to all formulary tiers	78	26	257	100	70	100
Among plans where deductible does not apply to all tiers:						
Tier 1 drugs exempt	3	4	68	26	0	0
Tier 1 and 2 drugs exempt	75	96	189	74	36	51
Tier 1, 2, and 3 drugs exempt	0	0	0	0	34	49

Note: PDP (prescription drug plan). When plan sponsors offer one enhanced PDP in a region, we included it in the "first enhanced" category; when sponsors offer two enhanced PDPs, we included the plan with the lower overall premium in the "first enhanced" category and the plan with the higher overall premium in the "second enhanced" category. Figures do not include plans in the U.S. territories.

Source: MedPAC analysis of 2022 Part D landscape and beneficiary cost files.

drugs (Avalere 2022). Brand-name drugs are covered on tiers 3, 4, and 5. The specialty tier is used for expensive drugs that cost more than a specific dollar threshold—in 2022, $830 for a one-month supply.

The median cost-sharing amounts for the three PDP types are shown in Table 7-6. (These figures are for a 30-day supply from a retail pharmacy.) Nearly all plans use copayments for tiers 1 and 2 and coinsurance for tiers 4 and 5. Tier 3 is a mixed case, with some plans using copayments and others using coinsurance. There are some noteworthy differences among the PDP types:

- Each PDP type has very low copayments for drugs on tier 1 ($0 or $1) or tier 2 ($4 or $6) when enrollees use preferred pharmacies. However, the median copayments differ noticeably when enrollees use nonpreferred pharmacies: for tier 1, $6 in basic PDPs versus $15 in first enhanced PDPs and $10 in second enhanced PDPs. The larger differential may help the first enhanced plans, in particular, keep their premiums low and attract a more favorable mix of enrollees.
- For preferred drugs (tier 3), basic PDPs and first enhanced PDPs have similar cost-sharing amounts (preferred copayments of $40 or $42; preferred coinsurance of 17 percent or 18 percent). Second enhanced PDPs have much higher cost sharing, with preferred coinsurance of 45 percent.
- For brand drugs, a key consideration is the difference in cost sharing between tier 3 and tier 4—larger differences give enrollees stronger

TABLE 7–6

Median 2022 cost-sharing amounts, by PDP type and formulary tier

	Tier 1	Tier 2	Tier 3	Tier 4	Tier 5
	Preferred generic	Other generic	Preferred drug	Nonpreferred drug	Specialty drug
Basic PDPs (*n* = 295)					
Preferred pharmacy	$1	$4	$40 / 17%	39%	25%
Nonpreferred pharmacy	6	11	$47 / 20%	40	25
First enhanced PDPs (*n* = 279)					
Preferred pharmacy	0	6	$42 / 18%	45	25
Nonpreferred pharmacy	15	20	$47 / 20%	50	25
Second enhanced PDPs (*n* = 176)					
Preferred pharmacy	1	4	45%	50	33
Nonpreferred pharmacy	10	20	47%	50	33

Note: PDP (prescription drug plan). All figures are for a 30-day supply dispensed by a retail pharmacy. When plan sponsors offer one enhanced PDP in a region, we included it in the "first enhanced" category; when sponsors offer two enhanced PDPs, we included the plan with the lower overall premium in the "first enhanced" category and the plan with the higher overall premium in the "second enhanced" category. For tier 3 drugs, 53 percent of basic PDPs use copayments and 47 percent use coinsurance, 63 percent of first enhanced PDPs use copayments and 37 percent use coinsurance, and 100 percent of second enhanced PDPs use coinsurance. The figures for tier 1 and tier 2 do not include three basic PDPs that use coinsurance; the figures for tier 4 do not include two enhanced PDPs that use copayments. This table does not include 16 PDPs that do not use preferred pharmacies (their enrollees pay the same cost sharing at all participating pharmacies) or PDPs in the U.S. territories.

Source: MedPAC analysis of 2022 Part D landscape and beneficiary cost files.

incentives to use the preferred drugs on tier 3. Compared with basic PDPs, first enhanced PDPs have higher coinsurance for their nonpreferred drugs (45 percent vs. 39 percent in preferred pharmacies) and thus do more to encourage enrollees to use preferred drugs. For second enhanced PDPs, the calculus appears to be different. The coinsurance amounts for tier 3 and tier 4 are fairly similar (45 percent vs. 50 percent) and there is little or no incentive to use a preferred pharmacy. These plans appear to focus on giving enrollees broader access (in terms of both drugs and pharmacies), somewhat akin to the difference between a preferred provider organization and an HMO.

- For the specialty tier, CMS sets limits on cost sharing that are linked to the plan's deductible. Plans that use the standard deductible cannot require enrollees to pay more than 25 percent in coinsurance, while plans with no deductible can charge up to 33 percent in coinsurance. Most basic and first enhanced plans use the standard deductible, so the median coinsurance amount for them is 25 percent. More than half of the second enhanced plans eliminate the deductible, so the median coinsurance amount for them is 33 percent.

Relative to basic PDPs, then, first enhanced PDPs have stronger incentives for enrollees to use drugs on preferred tiers and to obtain their prescriptions from preferred pharmacies. Second enhanced plans provide broader access to brand drugs but also have features that encourage the use of preferred pharmacies, at least for generics on the lowest tiers.

Targeted differences in plan formularies

Under Part D, each plan develops its own formulary, which details the specific drugs that the plan covers, the tier placement for each drug, and the drugs that are subject to some type of utilization management. CMS requires all formularies to meet certain minimum standards to ensure that they provide adequate coverage. For example, plans must cover at least two drugs in each therapeutic class and all drugs in six classes where access is considered especially important (immunosuppressants, antidepressants, antipsychotics, anticonvulsants, antiretrovirals, and antineoplastics).

Plan sponsors typically have a separate formulary for each PDP type.[5] We used 2022 data to see how much these formularies differ. We counted the number of drugs on each formulary based on their active ingredients. Most drugs have multiple dosage strengths, and many have multiple dosage forms, such as tablet versus injection; we gave plans credit for covering a drug if their formulary had at least one dosage strength/form with the drug's active ingredient. When plans cover multiple dosage strengths/forms of a drug, these are usually on the same tier, but there are instances when they appear on multiple tiers (for example, the tablet version could be on the preferred tier while the injectable version is on the nonpreferred tier). We assigned drugs to the lowest tier where they appear on a formulary. Finally, we classified drugs as either brand or generic using CMS's formulary reference file, which lists every drug that Part D plans can potentially cover and indicates which drugs have generic versions available.

Figure 7-3 compares the formularies for the PDPs offered by the five largest plan sponsors. There are six columns for each sponsor: The three columns on the left show the share of brand drugs covered by each PDP, and the three columns on the right show the share of generic drugs covered by each PDP. The denominator for each column is the total number of either brand drugs (n = 572) or generic drugs (n = 784) in the formulary reference file.

We found that these sponsors' basic plans cover roughly the same number of drugs—between 58 percent and 62 percent of brands, and between 76 percent and 78 percent of generics. Relative to the basic plan, a sponsor's enhanced PDPs usually cover more brand drugs, but the differences are often relatively small. For example, the CVS Health plans cover 58 percent, 60 percent, and 61 percent of brand drugs. All five sponsors cover more generic drugs in their enhanced plans than they do in their basic plan.

These figures measure the total number of drugs covered by each PDP, and it is worth keeping in mind that their coverage for specific drugs can vary. For example, while an enhanced plan may cover more drugs than a basic plan, there may still be drugs that are covered by the basic plan but not by the enhanced plan. The number of covered drugs may also change more for some tiers than others. Even when sponsors cover more drugs in an enhanced plan, the change in the number of drugs on a favorable tier may be more limited. For example, CVS Health's second enhanced plan, SilverScript Plus, covers more brand drugs than its basic plan (348 vs. 334), but the change in the number of drugs on the preferred tier is smaller (73 vs. 69) (data not shown). The clearest example of a sponsor offering an enhanced PDP with a more generous formulary is UnitedHealth, which covers 69 percent of brand drugs and 86 percent of generics in its second enhanced plan, compared with 62 percent and 76 percent, respectively, in its basic plan. (As shown in Figure 7-2 (p. 203), this plan's premiums are also much higher than the premiums for the other plans offered by the major sponsors.)

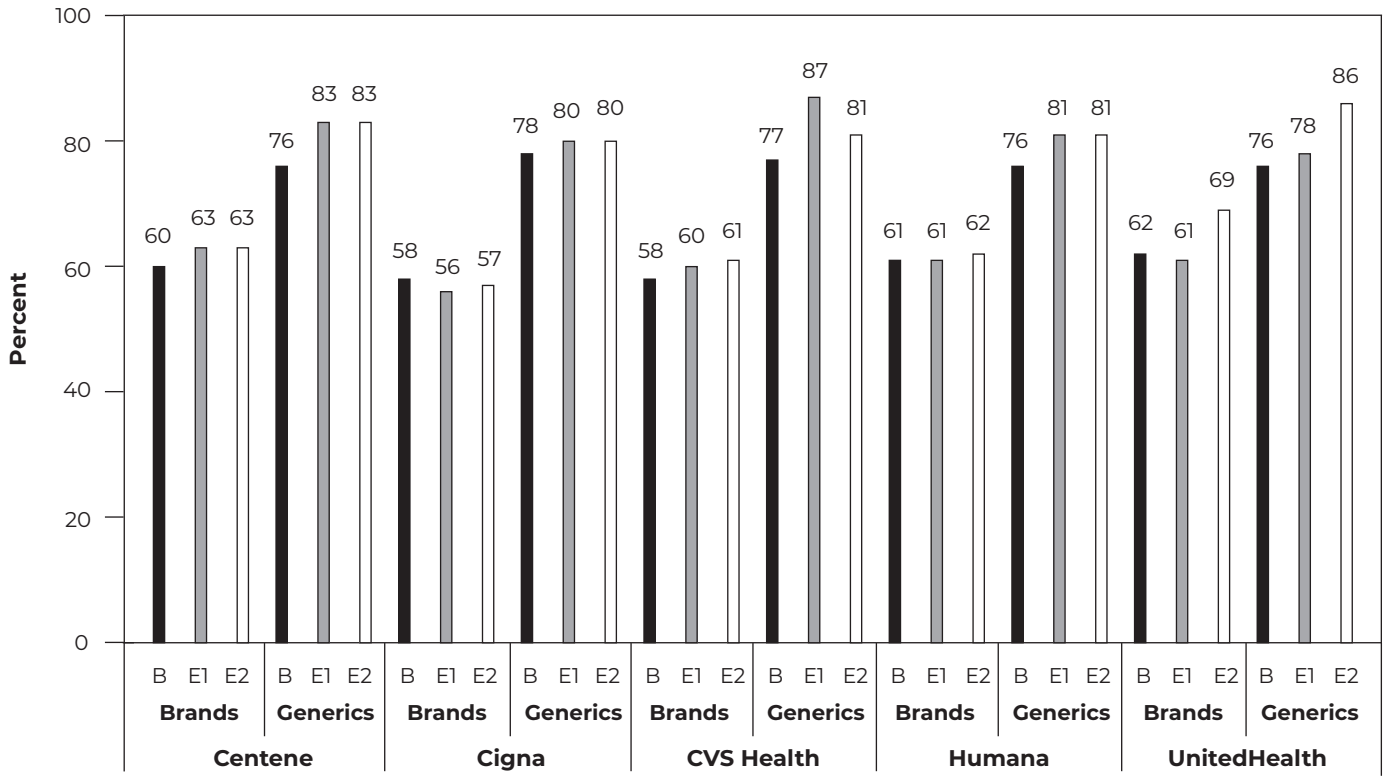
We also looked for differences across a sponsor's PDPs in the share of drugs that are subject to utilization management—quantity limits, prior authorization, or step therapy—but did not find any significant variation. When sponsors employ utilization management, they appear to do so in a reasonably consistent manner across their PDPs.

During our interviews with Part D actuaries, we asked about formulary differences across a sponsor's PDPs, particularly for the basic plan versus first enhanced plan. The actuaries said that there could be systematic differences, but these would involve a limited number of drugs and thus would be difficult to identify using broader metrics like the number of covered drugs. The actuaries pointed out two areas where formularies could differ:

- ***Adding older drugs to an enhanced PDP's formulary to satisfy the meaningful difference requirement.*** The OOPC estimates that CMS uses to measure whether plans have meaningful differences are

FIGURE 7–3

Share of brand and generic drugs covered in 2022 by the PDPs offered by the five largest plan sponsors



Note: PDP (prescription drug plan), B (basic PDP), E1 (first enhanced PDP), E2 (second enhanced PDP). Each plan sponsor shown in this figure offers two enhanced PDPs; we included the plan with the lower overall premium in the "first enhanced" category and the plan with the higher overall premium in the "second enhanced" category. Figures do not include plans in the U.S. territories. The denominator for these figures is the number of either brand drugs (*n* = 572) or generic drugs (*n* = 784) listed in the 2022 formulary reference file.

Source: MedPAC analysis of 2022 Part D formulary files.

based on older claims data; for example, the model used to review 2022 plan bids was based on claims data from 2016 to 2017. This lag lets sponsors get credit toward the meaningful difference requirement by adding older drugs that are no longer widely used to an enhanced plan's formulary. These changes reduce the enhanced plan's OOPC in the CMS model but may have little practical effect. So while enhanced plans tend to cover more drugs than basic plans, those differences may not always be very meaningful.

The hepatitis C treatment Sovaldi provides a good example. The drug was approved by the Food and Drug Administration in 2013 and had a significant impact on Part D spending before being rapidly eclipsed by newer drugs. In 2016 and 2017, the years used to provide claims data for the OOPC model that CMS used to review 2022 plan bids, total spending on Sovaldi—measured at the pharmacy counter, before manufacturer rebates—was $930 million and $210 million, respectively. By 2020, spending on Sovaldi had fallen to $4 million. (Only 50 beneficiaries had claims.) Nevertheless, for 2022, the five largest plan sponsors all cover Sovaldi in their first enhanced PDP but not their basic PDP.

- ***Excluding a few drugs in high-spending therapeutic areas from an enhanced PDP's formulary.*** Another problem with using the number of covered drugs to measure a formulary's generosity is that Part D spending is highly concentrated in a few therapeutic classes. The actuaries we interviewed said that plan sponsors can have a significant impact on a plan's projected costs by narrowing their coverage in a handful of therapeutic classes such as rheumatoid arthritis drugs, diabetes medications, and anticoagulants (blood thinners).

  Anticoagulants are a case in point. Part D spending on these drugs has been very high in recent years, driven largely by two medications—Eliquis (total spending of $9.9 billion in 2020) and Xarelto ($4.7 billion). For 2022, the five largest plan sponsors cover both drugs on the preferred tier in their basic PDPs, but two sponsors do not cover Eliquis in their first enhanced PDP, and a third sponsor places the drug on the plan's nonpreferred tier.

The actuaries we interviewed thought the new OOPC model that will be used to review plan bids for 2023 would make the tactic of covering older drugs less effective because the new model has more current data on drug spending patterns. CMS has also discussed refining the model to account for beneficiaries switching to other drugs if their current medication is not covered; the model now assumes that beneficiaries continue to pay for their current medication on an out-of-pocket basis. This change could make it easier for plan sponsors to cover fewer drugs in their first enhanced PDPs, but it is unclear if it will be implemented. (Right now, sponsors that cover a drug in their basic PDP but not their enhanced PDP effectively pay a penalty because the model assumes that all of the spending on that drug becomes out-of-pocket spending, which makes it harder for the enhanced plan to meet the meaningful difference requirement. Under a model that accounts for drug switching, that penalty would be smaller.)

Some low-premium enhanced PDPs have smaller pharmacy networks

Some commercial health plans try to manage their drug spending by contracting with a limited network of pharmacies that dispense medications at a lower cost. Part D does not allow PDPs to use a similar approach because all plans are required to have pharmacy networks that provide adequate access and plans must contract with any pharmacy that agrees to accept the plan's terms and conditions.

However, plan sponsors can achieve some of the same aims as a limited pharmacy network by designating some network pharmacies as "preferred pharmacies." Enrollees in these plans pay lower cost sharing when they use a preferred pharmacy (Table 7-6, p. 209). When pharmacies participate in a preferred network, they agree to make a variety of postsale payments to plans—known as pharmacy DIR payments—in return for higher prescription volume. This year, nearly all PDPs (98 percent) have a preferred pharmacy network.

We examined whether the major plan sponsors use the same pharmacy network for all of their PDPs (Table 7-7). Broadly speaking, the major sponsors' pharmacy networks are roughly similar in size, with between 60,000 and 65,000 participating pharmacies nationwide. However, the number of preferred pharmacies is more varied. Several sponsors (Centene, Cigna, Group 1001, and Rite Aid) have between 28,000 and 35,000 preferred pharmacies. CVS Health (about 23,000), UnitedHealth (about 19,000), and Humana (about 10,000) have progressively smaller preferred networks.

Although there is substantial variation in the size of pharmacy networks *across* sponsors, there appears to be less variation *within* sponsors. Many large sponsors use the same pharmacy network for all of their PDPs. However, in two notable instances, a sponsor has a smaller pharmacy network for its first enhanced PDP: CVS Health (where the number of preferred pharmacies is the same as for the basic PDP but the total number of network pharmacies is 33 percent lower) and UnitedHealth (where the number of preferred pharmacies is 54 percent lower than for the basic PDP and the total number of network pharmacies is 12 percent lower).

These findings suggest that, when it comes to pharmacy networks, the main differences in a sponsor's PDPs are the cost-sharing amounts that enrollees pay at preferred and nonpreferred pharmacies, rather than the size of the pharmacy network itself.

TABLE 7–7 **In 2022, most large plan sponsors use the same retail pharmacy network for all PDPs**

			Network retail pharmacies		Percent difference from basic plan	
Plan sponsor	**Plan name**	**Type**	**Preferred**	**Total**	**Preferred**	**Total**
Centene	All plans		27,940	59,880		
Cigna	Cigna Secure Rx	B	30,153	64,053		
	Cigna Essential Rx	E1	30,153	64,053	0	0
	Cigna Extra Rx	E2	31,723	65,898	5	3
CVS Health	SilverScript Choice	B	23,351	65,528		
	SilverScript SmartRx	E1	23,351	43,761	0	–33
	SilverScript Plus	E2	23,351	65,528	0	0
Group 1001	All plans		29,301	64,080		
Humana	All plans		9,508	60,847		
Rite Aid	All plans		35,406	52,696		
UnitedHealth	AARP MedicareRx Saver Plus	B	19,398	60,936		
	AARP MedicareRx Walgreens	E1	9,019	53,426	–54	–12
	AARP MedicareRx Preferred	E2	19,398	60,936	0	0

Note: PDP (prescription drug plan), B (basic PDP), E1 (first enhanced PDP), E2 (second enhanced PDP). When plan sponsors offer one enhanced PDP in a region, we included it in the "first enhanced" category; when sponsors offer two enhanced PDPs, we included the plan with the lower overall premium in the "first enhanced" category and the plan with the higher overall premium in the "second enhanced" category. Figures do not include mail-order pharmacies or plans in the U.S. territories.

Source: MedPAC analysis of 2022 Part D landscape and pharmacy files.

Plan sponsors periodically revamp their PDP lineups to introduce new low-premium plans

Up to this point, our analysis of plan sponsors' efforts to segment the PDP market has been mostly cross-sectional, focusing on differences among the three PDP types in a given year, usually 2022. However, the prevailing three-plan strategy also tends to follow a distinctive pattern over time.

As we have seen, the low-premium enhanced PDP plays a key role in the three-plan strategy by targeting beneficiaries who do not receive the LIS and have low drug costs. The low premiums for these plans are their biggest selling points, but their premiums tend to increase over time. The actuaries we interviewed said that it was very difficult for sponsors to keep the premiums in these plans low over time. They noted that when sponsors first introduce low-premium plans, they can make assumptions about the expected costliness of their enrollees that turn out to be optimistic and force the plans to increase their bids and premiums in later years. They also said that even when plans do attract desirable enrollees, such as beneficiaries who do not use any drugs, those enrollees' costs often rise in later years as their health worsens and they use more medications.

These explanations attribute the growth in premiums to external forces that are beyond a plan's control, but the dynamic is also entirely consistent with studies that have found this pricing strategy is profitable for plans (Ho et al. 2017, Marzilli Ericson 2014). Those studies have observed that beneficiaries are very price-sensitive when they first select a Part D plan but rarely switch plans after that. This behavior gives sponsors an incentive to offer plans that initially have low prices and then raise those prices later, once the plan has attracted a sufficient number of enrollees. Sponsors also have an incentive to periodically introduce new low-priced plans so they can continue attracting enrollees (Marzilli Ericson 2014).

Figure 7-4 shows how this dynamic has played out in recent years for CVS Health and Humana, two of the largest PDP sponsors. The top half of the figure shows the average premium for each plan, and the bottom half shows the corresponding enrollment.

CVS Health had stopped offering two enhanced PDPs in 2014 (except following an acquisition), but it resumed offering a second plan in 2019, possibly as a result of the easing of the meaningful difference requirement. The company made two attempts to launch a second plan, and the contrast between them is instructive. In 2019, CVS Health deviated from the strategy that plan sponsors typically use by launching a plan with a substantially higher (instead of lower) premium than its existing enhanced PDP. The plan was not well received—only about 30,000 people enrolled—and it was closed at the end of the year.[6] In 2021, the company switched gears and launched an enhanced PDP with a much lower premium (about $7, on average). This plan has been very popular and now has about 1.2 million enrollees.

Unlike CVS Health, Humana has offered three PDPs for many years. Between 2015 and 2019, the average premium for its second enhanced PDP rose appreciably, from $53 to $76, and the plan's enrollment gradually declined. This behavior is consistent with the theory that sponsors will raise premiums more for established plans because their enrollees are unlikely to switch plans. The company also had a lower-premium enhanced PDP, but its enrollment growth slowed noticeably in 2018, which may have raised concerns about the potential for declining enrollment in both enhanced plans. Sponsors must notify CMS of their intent to offer a new plan about 14 months before the start of a plan year, so the soonest the company would have been able to modify its PDP offerings to address any potential concerns was 2020. In 2020, Humana combined the two plans into a single PDP, with an average premium of $58, and introduced a new enhanced PDP with an average premium of $13.[7]

Note that these competitive dynamics did not apply to the companies' basic PDPs because many of their enrollees are LIS beneficiaries and sponsors cannot offer more than one basic plan.

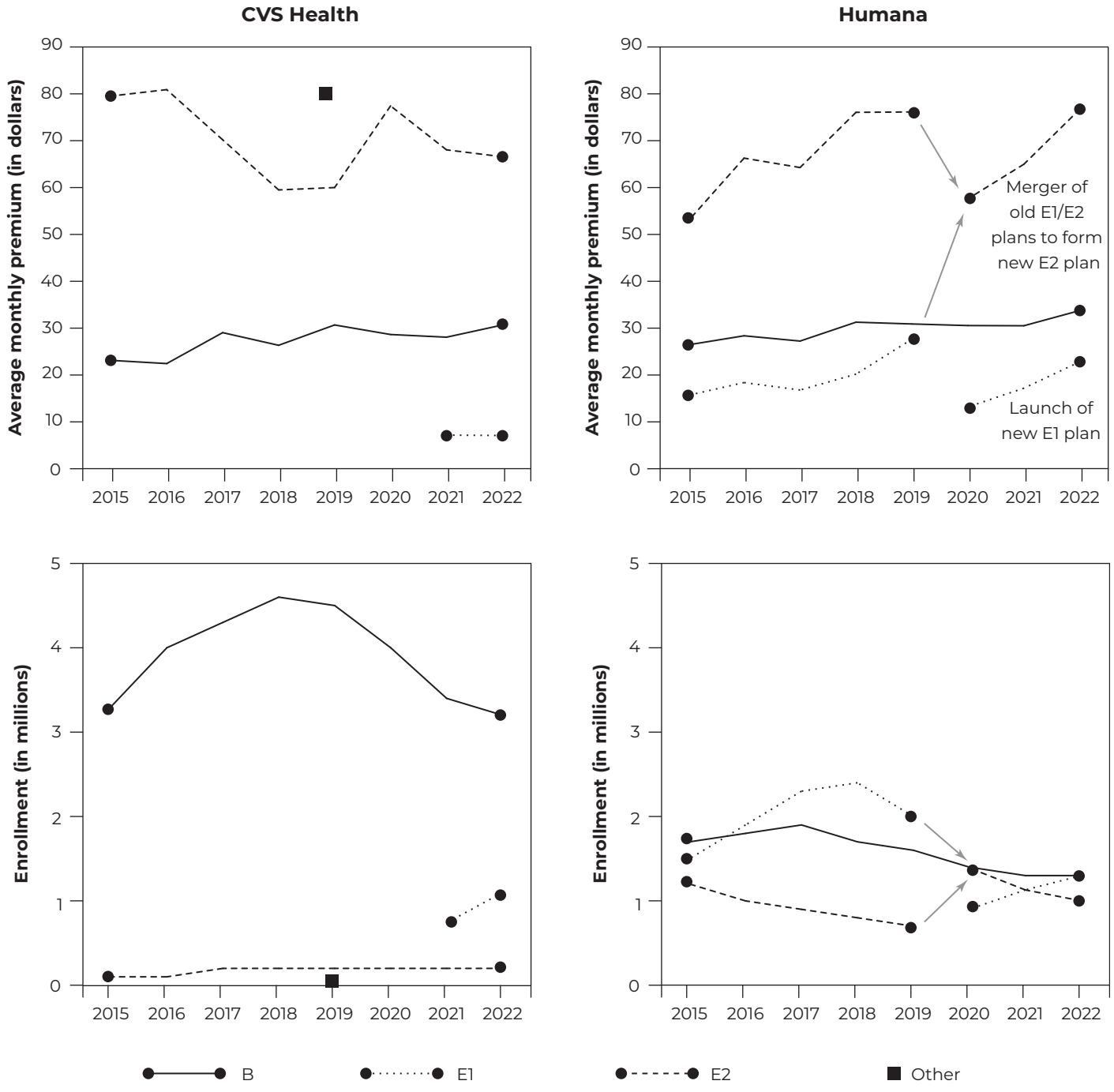
Segmentation makes PDPs more profitable for plan sponsors but has implications for beneficiaries and program spending

Our examination of the PDP market demonstrates how segmentation has been driven by a combination of policy choices and efforts by plan sponsors to differentiate their plans. These factors have led to the development of three distinct types of PDPs that each target a different part of the Medicare population:

- Sponsors use their basic PDP to target LIS beneficiaries because Part D has two features that strongly encourage these beneficiaries to enroll in basic PDPs—the LIS premium subsidy does not cover supplemental premiums and only basic plans can qualify as benchmark plans and receive auto-enrollments. LIS beneficiaries can join an enhanced PDP if they pay the supplemental premium, but only 7 percent do so. The concentration of LIS beneficiaries in basic PDPs lets sponsors use their enhanced PDPs to target beneficiaries who do not receive the LIS.
- Sponsors target beneficiaries who do not receive the LIS and have low drug costs by offering enhanced PDPs that have very low premiums and little or no cost sharing for some generic drugs (for example, by waiving the deductible and having $0 copays for generics on the lowest formulary tiers). These plans are more tightly managed because enrollees have to pay higher cost sharing if they use a nonpreferred drug or a nonpreferred pharmacy; some plans may also cover fewer drugs in certain

FIGURE 7–4

Plan sponsors periodically revamp their PDP lineups so they can keep offering a low-premium enhanced plan



Note: PDP (prescription drug plan), B (basic PDP), E1 (first enhanced PDP), E2 (second enhanced PDP). When plan sponsors offer two enhanced PDPs, we refer to the plan with the lower overall premium as the "first enhanced" PDP and the plan with the higher overall premium as the "second enhanced" PDP. Premium and enrollment figures are for July of each year (2015–2021) or January (2022). Premiums for enhanced PDPs include supplemental premiums. Table does not include plans in the U.S. territories.

Source: MedPAC analysis of Part D premium and enrollment data.

key therapeutic classes or have smaller pharmacy networks. This tighter management makes it easier for these plans to collect DIR payments that lower their premiums. These plans also benefit from limitations in the enforcement of the meaningful difference requirement, the risk-adjustment system, and the bidding process.

- Sponsors target beneficiaries who do not receive the LIS and have high drug costs by offering enhanced PDPs that have high premiums but also reduce or eliminate the Part D deductible and have a somewhat broader formulary. These plans are also less tightly managed because the financial penalties (i.e., the higher cost sharing) for enrollees who use nonpreferred drugs or nonpreferred pharmacies are smaller.

For plan sponsors, this strategy for segmenting the market makes PDPs a more profitable line of business than if they did not segment. Plan sponsors want to maximize the revenue they receive for LIS beneficiaries while also offering a low-premium plan to attract other beneficiaries. There is no clear way to do this with a single PDP; efforts to achieve one goal make it harder to achieve the other goal. Covering beneficiaries with and without the LIS in separate plans lets sponsors avoid this trade-off by charging higher premiums in their basic PDPs and lower premiums in one of their enhanced PDPs. For beneficiaries without the LIS, sponsors also want to capitalize on the fact that many beneficiaries are sensitive to premiums when they first select a Part D plan but are unlikely to switch plans after that. The ability to offer two enhanced PDPs lets sponsors have a newer low-premium plan that is attractive to new Medicare beneficiaries and an older established plan where they can more easily raise premiums.

For beneficiaries, the implications are more complicated. In some ways, segmentation makes it harder for beneficiaries to understand their plan options, even with the meaningful difference requirement. The common-sense distinction between "basic" and "enhanced" plans has been lost, and it can be difficult to determine what extra benefits the low-premium enhanced PDPs provide. Nevertheless, those plans have been popular and allow many beneficiaries to pay lower premiums for their drug coverage than they might under other financing arrangements (for example, if Part D had a standard national premium like Part B). However, beneficiaries in high-premium enhanced PDPs likely pay higher premiums than they otherwise would, and to the extent that segmentation makes PDPs more profitable for plan sponsors, aggregate beneficiary spending on premiums is higher.

For the Medicare program, segmentation (by allowing PDPs to charge higher premiums for some beneficiaries and making PDPs more profitable) increases spending for the basic Part D benefit, although the impact would be very difficult to quantify. Spending on the LIS premium subsidy is likely higher as well. When Part D was created, the expectation was that basic PDPs would have lower premiums than enhanced PDPs. Lawmakers thus tied the premium subsidy to the cost of basic coverage because the LIS covers most out-of-pocket costs and they wanted to limit program spending by enrolling LIS beneficiaries in lower-cost plans for basic coverage. The proliferation of low-premium enhanced PDPs means that the LIS premium subsidy is now essentially tied to a higher-cost plan instead of a low-cost plan.

The actuaries we interviewed did not see segmentation as a significant problem, particularly for enhanced PDPs, and were uncertain about its effect on program spending. One actuary thought that other Part D features were much more problematic—particularly Medicare's use of cost-based payments (reinsurance) to cover 80 percent of spending in the catastrophic phase, which he thought reduced the incentives for plans to manage costs, and plan sponsors' use of DIR payments to lower premiums instead of providing discounts at the point of sale, which he thought provided too little insurance protection to individuals with high drug costs. Another actuary thought the three-plan limit was reasonable and gave beneficiaries a good mix of choices.

Policy changes that could improve competition and limit the negative impacts of segmentation

The segmentation of the PDP market results in higher program spending and makes it difficult for beneficiaries to understand how the coverage offered by some enhanced PDPs differs from basic coverage.

TABLE 7–8

Illustrative examples of how more auto-enrollees could be assigned to benchmark plans with lower premiums

	Plan A	Plan B	Plan C	Plan D	Plan E
Plan premium	$22	$24	$26	$28	$30
Share of auto-enrollees assigned to each plan:					
Current auto-enrollment process	20%	20%	20%	20%	20%
Example 1: Plan with lowest premium gets an extra 20% of auto-enrollments; remaining 80% divided equally	36	16	16	16	16
Example 2: Plans with lower premiums get progressively larger shares of auto-enrollments	30	25	20	15	10
Example 3: Reduce number of benchmark plans from five to four; divide auto-enrollments equally	25	25	25	25	0

Although the market is segmented in two ways (by beneficiaries' LIS eligibility and, for beneficiaries who do not receive the LIS, by drug spending), the segmentation of LIS beneficiaries into distinct plans may be more problematic because the plans that serve those beneficiaries have limited incentives to bid competitively and because the effects of segmenting beneficiaries who do not receive the LIS are mixed (benefiting some enrollees but not others). In this section, we examine some potential reforms that would address these shortcomings and could thus improve competition, but would also require policymakers to consider a variety of trade-offs.

Modify the auto-enrollment process for LIS beneficiaries

Potential reforms to the auto-enrollment process could focus on changing two key features: (1) the practice of assigning the same number of beneficiaries to every benchmark plan in a region and (2) the practice of assigning beneficiaries to basic plans only. These changes would apply to both the initial auto-enrollment of new LIS beneficiaries who have not selected a plan and the reassignment of beneficiaries when plan premiums rise above the benchmark.

Assign more LIS beneficiaries to plans with lower premiums

The practice of assigning the same number of auto-enrollees to each benchmark PDP plays a key role in discouraging those plans from bidding more competitively. At the margin, benchmark plans have no incentive to further lower their premiums because they do not receive any additional LIS enrollment in return.

Policymakers could give benchmark PDPs a stronger incentive to bid more competitively by assigning a larger share of auto-enrollees to plans with lower premiums. This change could be made in one of several ways. Table 7-8 provides three illustrative examples, using a hypothetical region with five benchmark plans. Under the existing process, each plan receives 20 percent of the auto-enrollments. This allocation is close to the current reality: In 2022, there are an average of 5.3 benchmark plans in each region, those plans receive an average of 19 percent of the auto-enrollees in their region, and more than 90 percent of plans receive between 14 percent and 25 percent.

In the first example, CMS would reserve 20 percent of the auto-enrollments for the plan with the lowest

premium and divide the other 80 percent equally among all plans. This approach would increase the share for Plan A, which has the lowest premium, from 20 percent to 36 percent and reduce the shares for the other four plans from 20 percent to 16 percent. In the second example, CMS would rank plans based on their premiums and assign progressively larger shares of the auto-enrollees to plans with lower premiums. This approach would increase the shares for Plans A and B while reducing the shares for Plans D and E. In the third example, the plan with the highest premium (Plan E) would lose its eligibility as a benchmark plan. CMS would reduce the number of benchmark plans from five to four but still divide auto-enrollments equally, which would increase the share assigned to Plans A through D from 20 percent to 25 percent.

One challenge with all three examples is that CMS might need to limit the number of PDPs that qualify as benchmark plans. (Under the current system, the number of plans is determined by the bidding process and the subsequent calculation of the benchmark.) This issue is easiest to see with example 3, which explicitly aims to reduce the number of plans relative to the current system. But it might also apply with examples 1 and 2, given the need to assign more auto-enrollees to low-premium plans to spur greater competition. For example, under example 2, selecting a smaller number of benchmark plans would allow the incremental difference in the share of the auto-enrollees going to each plan to be larger, which would give plans a stronger incentive to bid competitively. If there were four or five benchmark plans, the incremental difference could be 5 percentage points to 10 percentage points. By comparison, if there were seven plans, the incremental difference would have to be much smaller, perhaps 2 percentage points to 3 percentage points, and the shares for the last few benchmark plans (those with the sixth- and seventh-lowest premiums) would be much smaller than they typically are now, which could discourage some plan sponsors from competing to serve LIS enrollees.

If CMS limited the number of benchmark plans, the agency would need to decide whether the number of plans in each Part D region would be the same. Under the current system, the number of plans has varied both across regions and within a given region from year to year. Between 2017 and 2021, the average number of benchmark plans in each region ranged from 2.6 in Florida to 9.4 in Arizona. Within a given region, the average difference between the largest and smallest number of benchmark plans that were offered during that same period was 3.3 plans. Selecting the same number of benchmark plans in each region could thus increase the number of benchmark plans in some regions, decrease the number in some regions, and have little impact in some regions.

Another factor to consider is the number of plan sponsors that might be interested in offering benchmark plans. As a practical matter, only seven companies currently offer these plans. (Those companies are shown in Figure 7-2 on p. 203; together, they account for 98 percent of the benchmark PDPs offered in 2022.) Selecting a small number of benchmark plans in each region, such as two or three plans, would create a stronger incentive for plans to bid competitively because each benchmark plan could receive a large number of auto-enrollees. However, policymakers would also need to consider other factors, such as ensuring that LIS beneficiaries had a reasonable number of benchmark plans available.

Changing the auto-enrollment process to reward lower-bidding plans would likely also require policymakers to develop a new method for calculating the LIS benchmarks. Under the current system, the benchmark equals the average premium for basic coverage in a region, with the premium for each plan weighted by its LIS enrollment. However, changes in the distribution of LIS enrollees across benchmark plans now have relatively little effect on the benchmark because their premiums do not vary significantly. If the reforms to the auto-enrollment process prompted plans to bid more competitively, they would put downward pressure on the benchmarks because the premiums for at least some plans would be lower and the LIS enrollment in those plans would be higher. However, this downward pressure could create an undesirable dynamic that reduces the number of benchmark plans over time.

As an illustration, consider a hypothetical region where the benchmark is $30 and there are five benchmark plans. Given the incentives of the current system, the premiums for the benchmark plans are clustered just below the benchmark and range from $28 to $30. The auto-enrollment process is then modified to assign more beneficiaries to lower-premium plans, but the process for setting the benchmark stays the same. The

new auto-enrollment process spurs plans to lower their premiums to the amounts shown in Table 7-8 (p. 217), which in turn reduces the benchmark to $28 (data not shown). Now that the benchmark is lower, Plan E no longer qualifies as a benchmark plan and its beneficiaries are reassigned to Plans A through D. The following year, this cycle might repeat itself, with the benchmark dropping again because more beneficiaries are enrolled in lower-premium plans and Plan D losing its eligibility. At the extreme, this process might continue until Plan A is the only benchmark plan left in the region, assuming no new plans enter the market.[8]

The possibility that a new auto-enrollment process might lead to this downward spiral raises the same issue we explored earlier: whether policymakers should be more explicit about the number of benchmark plans that would be chosen in each region. Under the current system, the number of plans is determined by the bidding process, although the Part D statute specifies that each region must have at least one benchmark PDP. Policymakers could increase the minimum number of plans (for example, to two or three plans) to ensure that LIS beneficiaries have multiple plans available and to help avoid, or at least limit, any downward spiral in the number of benchmark plans. Policymakers could also give CMS the authority to specify the exact number of benchmark plans that would be chosen in each region.

If the minimum number of plans were higher, CMS could continue setting the LIS benchmark equal to the average premium and then, if needed, raise that amount to ensure that a sufficient number of benchmark plans was available. For example, returning to Table 7-8 (p. 217), if there had to be at least three benchmark plans in each region and the average premium was $25, CMS would set the benchmark at $26, the premium for the third-lowest plan (Plan C). If CMS specified the exact number of plans that would be chosen, it could dispense with the calculation of the average premium and simply set the benchmark at the premium for the last plan that qualified.

Although assigning more auto-enrollees to plans with lower premiums would encourage plans to lower their bids, we do not know how much bids would change in response. This uncertainty makes it difficult to estimate the potential savings from changing the auto-enrollment process—and any related changes to the benchmark-setting process—and to know which approach to rewarding lower-premium plans would generate the largest savings. Of the three illustrative approaches shown in Table 7-8 (p. 217), the concept in example 2—in which plans with lower premiums receive a progressively larger share of the auto-enrollments—is arguably the most promising because every plan would have an incentive to reduce its premium below that of its nearest competitor. Given the uncertainty about how plans would respond, policymakers could consider giving CMS flexibility to develop the specific method for assigning more auto-enrollees to lower-premium plans and to modify it as needed as the agency gains experience with the new auto-enrollment process. Changes to the auto-enrollment process could also increase the number of LIS beneficiaries who are reassigned to the new plans, at least initially, and the agency could use its existing authority to mitigate any disruption (for example, by temporarily increasing the de minimis exception for plans that narrowly miss the benchmark).

Assign LIS beneficiaries to enhanced PDPs when these plans are less expensive than basic PDPs

One way to reduce segmentation would be to change the auto-enrollment process so LIS beneficiaries are no longer assigned exclusively to basic PDPs. For example, the process could auto-enroll beneficiaries in a sponsor's lowest-cost plan, regardless of whether it is a basic PDP or enhanced PDP. This determination could be based only on the plan's premium for basic coverage because LIS beneficiaries do not need any supplemental benefits. Similarly, if LIS beneficiaries were assigned to enhanced PDPs, the plan could provide basic coverage only.

In theory, this reform would reduce segmentation by spreading the LIS population across basic and enhanced PDPs and would reduce program spending by auto-enrolling LIS beneficiaries in PDPs that often have lower premiums than basic PDPs. However, it may not work well in practice. The low-premium enhanced PDPs that are now available have low premiums partly because they manage drug spending more tightly. Features such as higher cost sharing for nonpreferred drugs and nonpreferred pharmacies would not be as effective with LIS beneficiaries because their cost sharing is limited to relatively modest copayments (in 2022, $3.95 for a generic and $9.85 for a brand).

In addition, to the extent that these lower-premium plans charge higher cost sharing for drugs that LIS beneficiaries use, savings from lower LIS spending on premium subsidies could be at least partly offset by higher LIS spending on cost-sharing subsidies.

As a result, the actuaries we interviewed thought the premiums for these enhanced PDPs would increase if they received LIS auto-enrollments. The actuaries thought sponsors might stop offering these plans entirely if they were unable to keep their premiums lower than those of their basic PDPs. CMS now reassigns LIS beneficiaries to new plans when their current plans lose benchmark status. If sponsors did continue offering these enhanced PDPs, their premiums might rise and fall after they gained or lost benchmark status, which could lead to a substantial increase in LIS reassignments. The savings from this reform might therefore end up being smaller than anticipated while generating instability.

Change how the requirement for plans to have "meaningful differences" is administered

The contrast between the meaningful difference threshold that enhanced PDPs must meet during the bid review process and their supplemental premiums—which can be much lower, particularly for low-premium enhanced PDPs—indicates that the current approach for measuring meaningful differences is somewhat ineffective. As discussed, CMS has made some changes to its OOPC model that make the model more accurate and will strengthen the meaningful difference requirement, and it may make further changes of this kind in the future.

Policymakers could consider other reforms as well. For example, the OOPC model estimates the difference in out-of-pocket costs for a sponsor's basic and enhanced PDPs using a nationally representative sample of enrollees. However, the meaningful difference requirement has limited relevance for LIS beneficiaries, because the vast majority of them (more than 90 percent) are in basic PDPs and sponsors cannot offer more than one basic PDP. The requirement is much more relevant for other beneficiaries who are deciding whether to enroll in a basic PDP versus an enhanced PDP. Policymakers could thus consider excluding LIS beneficiaries from the OOPC model to make its estimates more reflective of the population that actually enrolls in enhanced PDPs.

Another option would be to require enhanced PDPs to cover a minimum percentage of the out-of-pocket costs that their enrollees would otherwise pay for basic coverage. This approach would prevent sponsors from offering enhanced PDPs with very little additional coverage. For example, all enhanced PDPs could be required to cover at least 10 percent of beneficiary cost sharing in the deductible and initial coverage phases of the standard benefit (the parts of the benefit where enhanced PDPs now provide most of their supplemental benefits). Policymakers could also consider requiring a sponsor's second enhanced PDP to cover a higher percentage than its first enhanced PDP, such as 20 percent instead of 10 percent. This approach could be more challenging to administer because plan bids would need to be reviewed on more of a case-by-case basis than they are now with the OOPC model, but it should still be feasible since the information that plans submit as part of their bids is highly standardized.

These changes to the meaningful difference requirement would not reduce segmentation directly; sponsors would still be able to offer three PDPs and would seek to tailor them to attract different types of beneficiaries. But these changes would help ensure that all enhanced PDPs provide some minimum additional value to the basic Part D benefit and would likely make it more difficult for sponsors to offer low-premium enhanced PDPs.

Require PDP sponsors to treat their enrollees as a single risk pool

One approach that would use changes to the Part D bidding process to effectively eliminate segmentation is an alternative that CMS discussed in a 2014 proposed rule but did not pursue further (Centers for Medicare & Medicaid Services 2014).[9] Under this alternative, plan sponsors would be required to treat their PDP enrollees as a single bloc (or risk pool) for the purpose of providing the basic Part D benefit. (Right now, each PDP is a separate risk pool, which is why the premiums for many first enhanced PDPs, which have healthier enrollees, are often much lower.) Plan sponsors would submit one bid for their entire PDP population in a given region, which means that every enrollee would pay the same premium for basic coverage and

have the same formulary, cost-sharing rules, and pharmacy network. Sponsors would still be allowed to offer enhanced coverage, but only by providing extra benefits on top of the uniform basic coverage, somewhat akin to an insurance rider. As under the current system, enrollees would pay for the full cost of any extra benefits through a supplemental premium.

Figure 7-5 (p. 222) illustrates how this alternative would work. In this example, a hypothetical sponsor now offers three PDPs: a basic plan, a low-premium enhanced plan, and a high-premium enhanced plan. Each plan is a separate risk pool, with its own bid, formulary, cost-sharing rules, and pharmacy network. As we have seen, the formularies and cost-sharing rules for each PDP typically differ, but the pharmacy network may be the same. The mix of enrollees in each plan differs, and their premiums for basic coverage range from $15 to $45. The first enhanced plan has an overall premium of $20 ($15 for basic coverage and $5 for supplemental benefits) and the second enhanced plan has an overall premium of $65 ($45 for basic coverage and $20 for supplemental benefits).

Under the alternative, the sponsor would still offer three PDPs but treat its entire PDP population as a single risk pool for the purpose of providing basic coverage, and all enrollees would pay the same $30 premium for basic coverage. The enhanced plans would continue to charge supplemental premiums of $5 and $20, respectively, but those costs would be added to the uniform $30 premium for basic coverage, and their overall premiums for those plans would now be $35 and $50.

With a single risk pool, plan sponsors would no longer be able to segment the market to increase profits (or program spending). For example, putting all enrollees in the same risk pool would put downward pressure on LIS benchmarks due to the broader need for sponsors to keep their premiums competitive, and sponsors would no longer be able to raise premiums more rapidly for older enhanced plans. Although plan sponsors would have stronger incentives to manage drug spending for LIS enrollees, their ability to do so would be limited because the LIS covers most cost sharing. The Commission has on several occasions recommended making limited changes to the LIS to encourage beneficiaries to use less expensive drugs. Most recently, our package of recommendations to redesign the Part D benefit included establishing a higher LIS copayment amount for nonpreferred and nonformulary drugs (Medicare Payment Advisory Commission 2020).

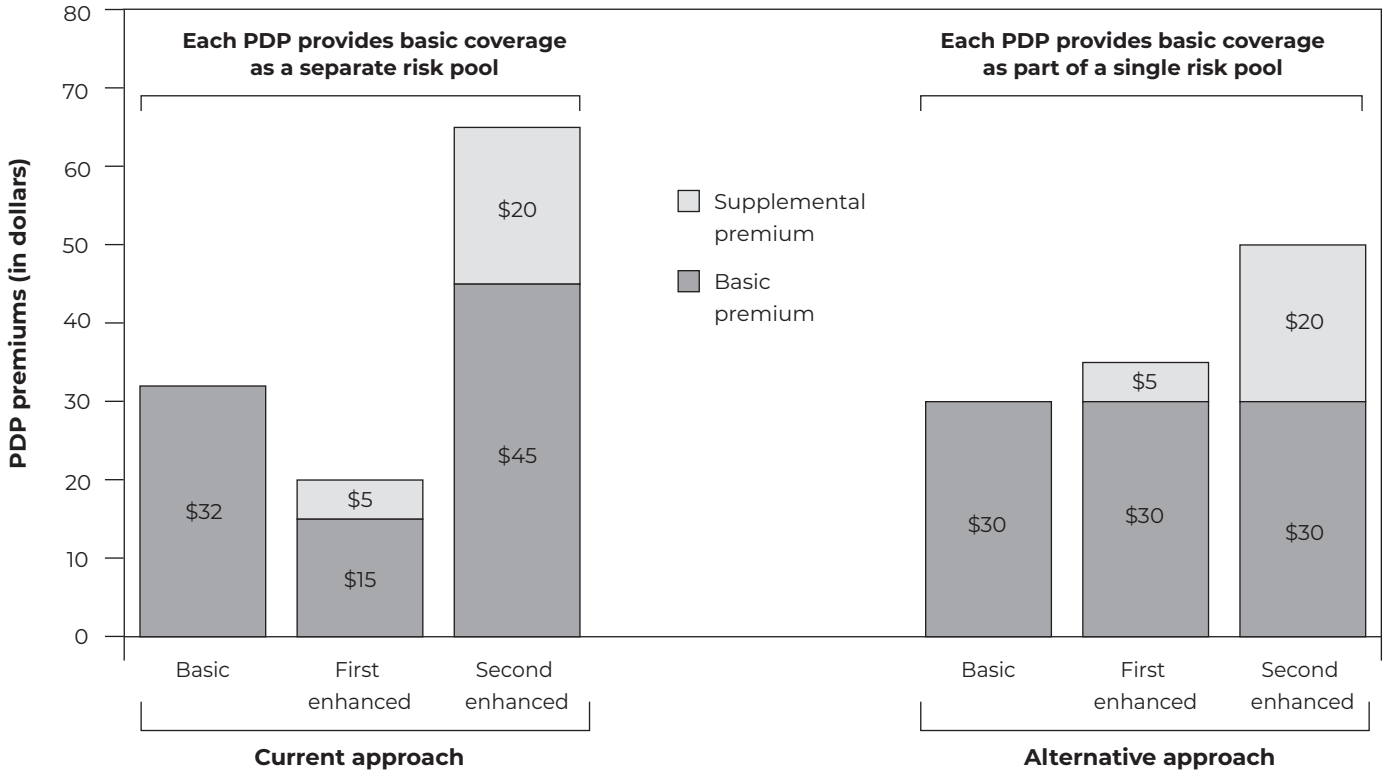
The alternative would also create a clear hierarchy where the basic PDP is always the lowest-cost option and enhanced coverage is always more expensive. This arrangement would likely make it easier for beneficiaries to understand the differences between basic and enhanced coverage and determine which plan meets their needs. Sponsors could also be required to clearly explain how the coverage they offer in their enhanced plans differs from the basic coverage they offer to all PDP enrollees.

The sponsor's premium for basic coverage under the alternative would depend on several factors. First, the share of enrollees who are in basic PDPs versus low-premium enhanced PDPs versus high-premium enhanced PDPs varies, both across sponsors (for example, in Figure 7-4 on p. 215, the share of enrollees in basic PDPs is higher for CVS Health than for Humana) and within an individual sponsor (for example, the share of enrollees in basic PDPs is higher in regions where the basic PDP qualifies as a benchmark plan and receives auto-enrollments). Sponsors would also need to determine what formularies to use for plans that serve the broader Medicare population rather than a particular segment. For some beneficiaries, such as those in high-premium enhanced PDPs, the single formulary might cover fewer drugs than their current plan; for other beneficiaries, such as those in basic PDPs, the single formulary might cover more drugs. Sponsors would need to go through a similar process to develop a single set of cost-sharing rules.

Despite these uncertainties, it seems likely that many enrollees who are now in low-premium enhanced PDPs would pay higher premiums, while many enrollees who are now in high-premium enhanced PDPs would pay lower premiums. The impact on basic PDP enrollees would probably be more variable—lower in many instances but sometimes higher. With all of a sponsor's PDP enrollees in a single risk pool, healthier enrollees would cross-subsidize sicker enrollees more extensively than they do now. However, the increase in premiums might prompt some beneficiaries with very low drug costs to consider dropping their Part D

FIGURE 7–5

Illustrative example of how PDP premiums would change if plan sponsors treated their enrollees as a single risk pool



Note: PDP (prescription drug plan). When plan sponsors offer two enhanced PDPs, we refer to the plan with the lower overall premium as the "first enhanced" PDP and the plan with the higher overall premium as the "second enhanced" PDP.

coverage entirely, although the program's late-enrollment penalty would discourage this behavior.

Another source of uncertainty would be the potential impact on the LIS benchmarks that determine which basic PDPs qualify as benchmark plans. When plans lose their benchmark status, CMS reassigns the LIS enrollees in those plans to other benchmark plans to ensure that they do not have to pay a premium.[10] In recent years, the number of reassignments has been low (usually affecting between 1 percent and 3 percent of the LIS beneficiaries in PDPs), but this number could increase under the alternative, at least during the first few years following the transition to a single risk pool. CMS could reduce the amount of disruption by temporarily increasing the benchmarks or the so-called "de minimis" exception that allows plans that narrowly miss the benchmark to waive the difference and keep their LIS enrollees.

Under the alternative, policymakers could reconsider some issues raised by the existing enhanced PDPs. For example, would sponsors be allowed to offer more than two enhanced plans? Since all of a sponsor's PDP enrollees would have the same basic coverage, policymakers could consider giving sponsors more flexibility. That said, it is unclear whether sponsors would be interested in offering more enhanced plans under the alternative, because they would no longer be able to use those plans to segment the PDP market in their favor. Would enhanced plans still be required to meet a meaningful difference requirement, and if so,

how would it be administered? Under the alternative, there may be less need for the requirement because the differences between the premiums for a sponsor's basic and enhanced PDPs would provide clearer signals about the differences in their coverage and sponsors could be required to explain those differences in their marketing materials.

The actuaries we interviewed thought relatively few beneficiaries would pay for supplemental coverage under the alternative and expressed concern about the potential for adverse selection. One actuary said that MA plans can offer optional supplemental benefits, but few beneficiaries buy them. However, adverse selection is a concern for any type of optional insurance, and it is unclear whether it would be worse under the alternative than in the current market. For example, concerns about adverse selection likely explain why no enhanced PDPs reduce beneficiary cost sharing in the catastrophic phase of the Part D benefit. If sponsors were required to treat their PDP enrollees as a single risk pool, their basic coverage would probably have a deductible (since the actuaries we interviewed said it is difficult for basic PDPs to eliminate the deductible and still meet actuarial equivalence tests). If that happened, the experience with enhanced PDPs suggests that a significant number of beneficiaries could be interested in supplemental coverage that partially or completely eliminates the deductible. ■

Endnotes

1 This chapter focuses only on PDPs that are available to all Medicare beneficiaries and thus excludes employer-sponsored PDPs, which have significant enrollment (about 4.4 million in 2022) but are available only to beneficiaries who worked for the company that sponsors the plan.

2 The relatively high share of LIS beneficiaries without a prescription could be partly due to factors beyond those beneficiaries being in good health, such as obtaining drugs from other programs such as the Veterans Administration or a state pharmacy assistance program, or lack of access to physicians and pharmacies.

3 The base beneficiary premium equals 25.5 percent of the sum of the national average bid and the amount that plans project Medicare will spend on cost-based payments (known as reinsurance) for enrollees with catastrophic drug costs.

4 MA–PDs participate in a separate bidding process to determine their payment rates for providing the Part A and Part B benefit package. As part of this process, most plans receive MA rebates that they use to provide extra benefits for their enrollees. Sponsors can use their MA rebates to finance the cost of any enhanced Part D benefits or to cover some or all of the premium that enrollees would otherwise pay for basic Part D coverage.

5 For 2022, there are 28 PDP sponsors, and only 5 sponsors use the same formulary for more than one PDP type. All five sponsors are regional Blue Cross Blue Shield insurers.

6 The plan, called SilverScript Allure, was also unusual because it used the rebates and discounts it received from drug manufacturers to reduce beneficiary cost sharing at the point of sale. (Part D plans typically use these rebates and discounts to reduce premiums instead of cost sharing.) This difference was one reason why the plan's premiums were high, but the larger point about the challenges of introducing a high-premium plan remains.

7 CMS does not allow sponsors to consolidate a first enhanced PDP into a second enhanced PDP unless the enrollees in the first plan experience no reduction in benefits. This policy gives sponsors another reason to offer richer benefits in their second enhanced PDP.

8 It is worth noting that the benchmark is based on the premiums for both PDPs and MA–PDs, and the presence of MA–PDs in the calculation would probably dampen this dynamic to some extent. The auto-enrollment changes outlined in this chapter would apply to PDPs only and would probably not have much effect on MA–PD premiums. As a result, the MA–PD component of the benchmark might not change much, which would reduce the impact of any changes in the PDP component on the overall benchmark.

9 The 2014 proposed rule contained numerous proposals affecting the MA and Part D programs. The preamble to the rule outlined several options for reducing segmentation as potential topics for future rulemaking.

10 Reassignment applies only to LIS beneficiaries who have been auto-enrolled in a plan. LIS beneficiaries who have selected a plan on their own are not affected.

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APPENDIX A

Commissioners' voting on recommendations

APPENDIX A

Commissioners' voting on recommendations

In the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, the Congress required MedPAC to call for individual Commissioner votes on each recommendation and to document the voting record in its report. The information below satisfies that mandate.

Chapter 1: An approach to streamline and harmonize Medicare's portfolio of alternative payment models

No recommendations

Chapter 2: Congressional request: Vulnerable Medicare beneficiaries' access to care (final report)

No recommendations

Chapter 3: Supporting safety-net providers

No recommendations

Chapter 4: Addressing high prices of drugs covered under Medicare Part B

No recommendations

Chapter 5: Improving the accuracy of Medicare Advantage payments by limiting the influence of outliers in CMS's risk-adjustment model

No recommendations

Chapter 6: Aligning fee-for-service payment rates across ambulatory settings

No recommendations

Chapter 7: Segmentation in the stand-alone Part D plan market

No recommendations

Acronyms

Acronyms

A–APM	advanced alternative payment model
ACA	Affordable Care Act of 2010
ACO	accountable care organization
AHA	American Hospital Association
AHRQ	Agency for Healthcare Research and Quality
AIDS	acquired immunodeficiency syndrome
AMI	acute myocardial infarction
APC	ambulatory payment classification
APM	alternative payment model
APRN	advanced practice registered nurse
ASC	ambulatory surgical center
ASP	average sales price
ASP + 6 percent	106 percent of average sales price
AST	androgen suppression therapy
AWP	average wholesale price
BBA	Bipartisan Budget Act
BLA	Biologic License Application
BPCI	Bundled Payments for Care Improvement
CAH	critical access hospital
C–APC	comprehensive ambulatory payment classification
CAR–T	chimeric antigen receptor T-cell
CBC	complete blood count
CBO	Congressional Budget Office
CCI	Charlson comorbidity index
CE	cost-effectiveness
CEA	cost-effectiveness analysis
CED	coverage with evidence development
CHF	congestive heart failure
CJR	Comprehensive Care for Joint Replacement
CMS	Centers for Medicare & Medicaid Services
CMS–HCC	CMS hierarchical condition category
COPD	chronic obstructive pulmonary disease
CPM	Cumming's prediction measure
DIR	direct and indirect remuneration
DRG	diagnosis related group
DPS	Drug Price Standard
DSH	disproportionate share hospital
DVP	Drug Value Program
E&M	evaluation and management
ED	emergency department
EHR	electronic health record
EMTALA	Emergency Medical Treatment and Labor Act
ENT	ear, nose, and throat
ESA	erythropoiesis-stimulating agent
ESRD	end-stage renal disease
FDA	Food and Drug Administration
FDG–PET	fluorodeoxyglucose–positron emission tomography
FFS	fee-for-service
FPL	federal poverty level
FQHC	Federally Qualified Health Center
FTE	full-time equivalent
GAO	Government Accountability Office
GDP	gross domestic product
GI	gastrointestinal
HCC	hierarchical condition category
HCPCS	Healthcare Common Procedure Coding System
HIV	human immunodeficiency virus
HMO	health maintenance organization
HOPD	hospital outpatient department
HPSA	Health Professional Shortage Area
HRSA	Health Resources and Services Administration
ICD	International Classification of Diseases
ICD–9–CM	International Classification of Diseases, Ninth Revision, Clinical Modification
ICD–10–CM	International Classification of Diseases, Tenth Revision, Clinical Modification
ICER	Institute for Clinical and Economic Review
ICER	incremental cost-effectiveness ratio
IMU	Index of Medical Underservice
IPPS	inpatient prospective payment system
LAN	Health Care Payment Learning & Action Network
LCA	least costly alternative
LCD	local coverage determination
LIS	low-income [drug] subsidy
LVH	low-volume hospital
MA	Medicare Advantage
MAC	Medicare administrative contractor
MACRA	Medicare Access and CHIP Reauthorization Act of 2015
MA–PD	Medicare Advantage–Prescription Drug [plan]
MD	macular degeneration

MDH	Medicare-dependent hospital
MedPAC	Medicare Payment Advisory Commission
MHLW	Ministry of Health, Labour, and Welfare
MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003
MS	multiple sclerosis
MSSP	Medicare Shared Savings Program
MUA	medically underserved area
NaF	sodium fluoride
NCD	national coverage determination
NCI	National Cancer Institute
NDA	new drug application
NDC	national drug code
NHI	National Health Insurance
NHLBI	National Heart, Lung, and Blood Institute
NIA	National Institute on Aging
NOI	notice of intent
NP	nurse practitioner
OIG	Office of Inspector General
OOPC	out-of-pocket cost
OPPS	outpatient prospective payment system
OS	osteoporosis
PA	physician assistant
PBD	provider-based department
PCO	Primary Care Office
PDP	prescription drug plan
PE	practice expense
PFS	physician fee schedule
PLI	professional liability insurance
PMDA	Pharmaceutical and Medical Devices Agency
PPS	prospective payment system
PR	predictive ratio
ProPAC	Prospective Payment Assessment Commission
Q	quarter
Q	quartile
QALY	quality-adjusted life year
R&D	research and development
RA	rheumatoid arthritis
RHC	Rural Health Clinic
RCT	randomized controlled trial
REACH	Realizing Equity, Access, and Community Health
REH	rural emergency hospital
SCH	sole community hospital
SE	side effects
SNF	skilled nursing facility
SNI	Safety-Net Index
SSA	Social Security Act
SSI	Supplemental Security Income
VBP	value-based purchasing

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