

Insight

Is an International Price Index the Solution to High Drug Prices?

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Executive Summary

- The Trump Administration just announced its intent to change reimbursement rates for physicianadministered drugs covered by Medicare Part B and test this proposal through a demonstration project accounting for half of Part B spending.
- Currently, Medicare provides reimbursement for physician-administered drugs based on the average sales price of the drug in the private market, inclusive of all discounts and rebates.
- Under this demonstration, Medicare payments for Part B drugs will be based on the average price paid for such drugs by other economically similar countries. In all of these other countries, the government sets the prices for pharmaceutical products, and access to new drugs is severely limited in many of these countries as a result.
- Through this proposal, the administration is hoping both to eliminate a perverse incentive for providers to use the highest-cost drug and to reduce spending through brute force.

Introduction

The Trump Administration just announced its intent to change the payment system for certain drugs under Medicare. These changes would affect reimbursement rates for physician-administered drugs covered by Medicare Part B. The administration plans to test this proposal through a demonstration project run by the Center for Medicare and Medicaid Innovation (CMMI), an office established by the Affordable Care Act for such purposes.

The proposal does address some real problems with how Medicare Part B reimburses doctors, but it raises a host of other possible problems.

The Current State of Medicare Drug Spending

Since 2005, the Medicare payment rate for physician-administered drugs covered by Part B is set by law through a market-based formula: 106 percent of the average sales price (ASP) of a drug, net of all rebates, discounts, and other price concessions.[1] More specifically, single-source drugs and biologics are paid 106 percent of their own ASP. For drugs produced by multiple manufacturers, the average price is weighted by sales volume across all manufacturers of the drug, including both brand-name and generic manufacturers. Payment for biosimilars is set at 100 percent of the volume-weighted ASP for the biosimilar (which may have multiple manufacturers) plus 6 percent of the reference biologic's ASP. The government pays 80 percent of the total payment under Medicare Part B, with the beneficiary covering the remaining 20 percent.

While there are more than 700 drugs covered under Medicare Part B, spending in the program is highly concentrated. The top 10 drugs in terms of total reimbursement amounts accounted for 42 percent of all Part B

drug spending in 2016.[2] Yet these costs are not driven primarily by extremely high cost drugs: Of the 102 drugs covered by Part B in 2016 with a cost per beneficiary of at least \$10,000, only 50 were used by more than 1,000 beneficiaries (or 0.0019 percent of all Part B enrollees) and only 22 were used by more than 10,000 beneficiaries (or 0.019 percent of enrollees).[3]

Problems with the Existing Reimbursement Method

The ASP reimbursement methodology was intended to reduce overpayment for physician-administered drugs and take advantage of the pressures of the free market that were producing significant discounts and rebates for such drugs in the commercial market. In fact, in the first year that this new methodology was implemented, Part B spending for pharmaceuticals declined 8 percent. That reduction didn't last, however. From 2005 to 2009, the average increase in spending was 3.7 percent per year, but spending grew more quickly between 2009 and 2016, increasing at an average annual rate of 9.5 percent, primarily as a result of increases in prices for existing drugs and the adoption of new, higher-priced drugs.[4] (For comparison, Part D drug spending increased 9.1 percent annually, on average, from 2006-2009 and 7.5 percent from 2010-2016.) Hospital outpatient departments (HOPDs) have accounted for much of the spending growth in Part B: The average annual growth rate for Part B drug spending at HOPDs was 16.5 percent from 2009-2016, but only 7.3 percent for physicians. This is likely related to increased hospital acquisition of physician practices which many of the government's payment policies, including the 340B drug discount program, incentivize.

The 6 percent add-on serves several valid purposes, yet some have raised concerns about its consequences. The additional payment is primarily intended to pay providers for the actual cost of storing and administering the drug, typically referred to as associated overhead costs that are incurred beyond the cost of simply acquiring the drug. This practice is common among private payers for the same reason. Further, the add-on provides a buffer, particularly for smaller practices that may not be able to negotiate as steep a discount as larger hospital systems and thus may have to pay more than the ASP. The add-on can also help to offset potential losses that may be incurred when a beneficiary is unable to pay their co-insurance of 20 percent, which may be quite significant given that the average spending per beneficiary for the top 10 most expensive Part B drugs in 2016 was \$373,440. (That said, it's important to keep these figures in perspective: Those most expensive drugs were used by an average of 249 people. On the other hand, the average price of the top 10 most commonly used Part B drugs was \$23 and were used by an average of more than 2 million individuals. Past analysis shows this has consistently been the case.) The 6 percent add-on may also provide cushion for when a drug's price increases but the payment rate is not yet reflecting the cost increase, given that there's a two-quarter lag in the calculation of the ASP.

Despite the numerous reasons to provide an add-on payment, there have been concerns that because the add-on is paid as a percentage of the ASP, providers are incentivized to use more expensive drugs to increase the amount of their add-on payment. This would only be true for certain categories of drugs, though. For multiple-source drugs, the add-on is calculated as 6 percent of the ASP of all manufacturers of that drug, which would incentivize use of the least expensive drug so as to create the largest spread between the acquisition cost and the reimbursement rate. There would appear to be no option to influence the purchase decisions for single-source drugs given that, as their name implies, there is only one drug for a provider to choose; single-source drugs may face competition from therapeutic alternatives, however. In this instance, it may be more profitable for a provider to prescribe the single-source drug if it has a higher ASP because the 6 percent add-on will be greater, but it is certainly not guaranteed that the higher-priced drug will provide the greatest profit to the provider and there have been few studies done to analyze this concern.[5] Cheaper therapeutic alternatives may similarly exist for biologics, known as biosimilars. In this case, our current payment policy does in fact incentivize use of the higher-priced biologic, as explained here, and a change would be welcome.

The Solution: An International Price Index?

Regardless of whether or not there are real problems with how Medicare currently pays for physicianadministered drugs, there is a growing perceived problem that drug costs are too high. The administration is looking for ways to deal with the perception and has announced through an Advance Notice of Proposed Rulemaking (ANPRM) its intention to propose a demonstration project to test a potential solution that will be run by CMMI.

The most noteworthy aspect of the proposal is to set Medicare reimbursement rates for Part B drugs based on prices paid for those drugs in other countries. Under this proposal, drugs will be procured by private vendors who will distribute them to physicians and hospitals. The Secretary of Health and Human Services (HHS) would develop an International Price Index (IPI) based on the prices paid in 16 economically similar countries—where the governments set the prices in their single-payer health care systems—to develop a Target Price. The IPI will be updated regularly, though how regularly is yet to be determined. A recent report conducted by the Assistant Secretary for Planning and Evaluation (ASPE) found that the average price paid in these countries for 27 of the most commonly administered drugs covered by Medicare Part B was 80 percent lower than the average price for such drugs in the United States, with the most egregious example being seven times lower.

CMS will pay vendors the Target Price established for a drug, which will be equal to 126 percent of the average price paid for the drug in other countries as determined by the IPI. The vendors will then be responsible for negotiating discounts from pharmaceutical manufacturers in order to make the biggest profit.

Providers will be paid an add-on by CMS to compensate for the costs of storing and handling drugs (similar to the 6 percent (or sequestration-imposed 4.3 percent) add-on they currently receive), but that fee will not be tied to the price of the particular drug. The intent is to make providers financially neutral to the drug used. CMS is considering three different possibilities for determining the add-on payment: a 6 percent fee based on the average price of the drugs in the drug's given class (similar to the current add-on payment), an amount based on the physician's specialty, or an amount based on the physician's practice. The administration's comments since the ANPRM was released seem to indicate it is leaning toward the first option of providing a 6 percent add-on, which in some cases could actually be larger than the add-on payment currently provided. CMS intends to ensure that providers will neither no longer be incentivized to prescribe higher-cost drugs nor risk losing money if they do prescribe a needed high-cost drug.

This reimbursement model will only apply to select drugs, at least at the outset. Most drugs are multi-source

drugs, which typically have enough competition that the market has already produced significant price reductions and thus payment reforms for these drugs are typically needed least. The drugs targeted in this demonstration—single-source drugs, biologics, biosimilars, and drugs that are technically multiple source but have only one existing manufacturer—are those for which a perverse incentive does exist under the current reimbursement system to prescribe higher-cost drugs (provided there is a cheaper therapeutic alternative available). Providing an add-on payment equal to 6 percent of the ASP of all the drugs in a given class—as opposed to a drug's own ASP—would eliminate this incentive.

Critiques of the Proposal

The use of vendors to acquire drugs for distribution to providers has been done previously through a program known as the Competitive Acquisition Program (CAP). CAP was developed under the Medicare Modernization Act of 2003 (best known for creating the Medicare Part D program), but it was not particularly successful. First put into effect in 2006, the program was suspended at the end of 2008 following low participation from providers and only one vendor; the low participation and other program constraints stymied the vendor's ability to achieve significant discounts as intended and as a result, the average price paid for drugs under CAP was actually 3 percent more than would have been paid under the 106 percent of ASP formula.[6] Also, similar to CAP, the vendors will be responsible for negotiating the lower prices for pharmaceuticals on which this new system will depend, much like pharmacy benefit managers.

The one potential change that may undermine the effort to remove providers' incentive to prescribe higher-cost drugs is that the providers will still receive the beneficiaries' 20 percent coinsurance without having to pay to acquire the drug. Because of this, providers may now net a larger reimbursement for higher-priced drugs based on the coinsurance received rather than the add-on payment. As such, it will be necessary for vendors to align providers' incentive with theirs to use lower-cost drugs. This must be done, though, without inadvertently recreating the same bad incentives to use higher-priced drugs that have been found to exist with PBMs.

Also of interest is the administration's insistence that this new payment system would be *more* market-based than the current system. Given that the current system provides reimbursement based on the average price paid in the private market, inclusive of all discounts and rebates provided, the winning argument for the current system's adoption at the time was that it would indeed provide a market-based payment, allowing Medicare to benefit from the low prices gleaned by the pressures of competition in the private market. The new payment method would fix Medicare's payment rate at a set percentage of the average price set by other governments where there is no private health care market. That hardly seems like a market-based approach—certainly not more market-based than the current system.

Of final note, this proposal leans on the systems in other countries that are much worse along one particular metric: One significant trade-off to the lower prices received in other countries is the reduced access patients there have to newly approved drugs. Patients in the United States obtain access to 88 percent of new drugs within three months of their launch; patients in the 16 other countries referenced in the ASPE report had access to an average of 48 percent of new drugs, and it took an average of 17 months to gain access to those drugs. If this policy change results in similar access restrictions for U.S. patients as currently exist in other countries, many Americans could suffer unnecessarily from the delay of new treatment options.

Looking Ahead

The administration is aiming to issue its proposed rule in the Spring of 2019, with a goal of implementing the

pilot program a year later, running until the Spring of 2025. Based on the ASPE report, CMS expects the Medicare program and its beneficiaries could save \$17.2 billion over five years under this proposal. Any reimbursement change that reduces the amount the Medicare program pays for a drug in turn reduces the amount Medicare beneficiaries enrolled in fee-for-service pay, since their co-insurance is based on Medicare's payment rate. This demonstration will be implemented for half of the country based on Medicare Part B spending on separately payable drugs.

[1] Since the Budget Control Act of 2011, the actual payment rate has been 104.3 percent of ASP due to sequestration; however, policy experts still consistently refer to the payment rate as being 106 percent of ASP, and thus this paper will do the same. This fact is relevant, though, to the administration's proposed changes discussed here and that point will be discussed in more detail later.

[2] http://www.medpac.gov/docs/default-source/data-book/jun18_databooksec10_sec.pdf?sfvrsn=0

[3] https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartB.html

[4] http://www.medpac.gov/docs/default-source/data-book/jun18_databooksec10_sec.pdf?sfvrsn=0

[5] http://www.medpac.gov/docs/default-source/reports/chapter-3-part-b-drug-payment-policy-issues-june-2015-report-.pdf?sfvrsn=0

[6] https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/downloads/CAPPartB_Final_2010.pdf