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Proposed reforms to Part B Rx for the Medicare Fee-for-Service program

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Several proposed reforms to the Part B Rx Medicare fee-for-service (FFS) program are discussed in President Trump's Fiscal Year 2019 Budget[1] and the Trump Administration "Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs."[2] This paper outlines proposals to shift certain drugs from Part B to Part D and to change Medicare's system for administering Part B drugs.

Background

Medicare Part B covers drugs that are typically not self-administered. Medicare Part B drugs can be furnished in a physician's office as part of a professional service or given by infusion or injection in a hospital outpatient department. Self-administered drugs, such as those typically purchased through a retail pharmacy or mail-order, are covered through Medicare Part D.

Under the current Medicare rules, the purchase of Part B covered drugs is reimbursed based on average sales price (ASP) + 6%.[3] The ASP is the average quarterly price charged by manufacturers in all non-excluded[4] sales in the U.S. market. Rates are updated quarterly based on sales data from two quarters prior. ASP is net of price concessions such as volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates (other than rebates obtained by the Medicaid drug rebate program).[5]

Traditional Medicare reimbursement does not vary with the actual purchase price an individual provider or supplier pays and it is the same across the United States. The 6% fee is added on to cover storage, handling, and other administrative costs at the site of service.

Part B billing and payment occurs at the level of a Healthcare Common Procedure Coding System (HCPCS) code, typically a J-code. Because several different brands or manufacturers' generic products can be assigned to one HCPCS code, reimbursement for each unit of a HCPCS code is based on the weighted average ASPs within the HCPCS code.

Total Medicare spending on Part B covered drugs has increased 9.8% annually from 2011 to 2016, reaching $28 billion in 2016. Most of the growth is due to higher prices, including increased costs for existing products, shifts in the mix of drugs, and the adoption of new drugs.[6] This spending growth has brought criticism to the current system and attention to proposals to reform the way Medicare pays for Part B drugs. Some have expressed the view that providers have an incentive to choose higher priced drugs to increase the 6% ASP add-on.[7] Additionally, in contrast to Medicare's physician fee schedule and other Medicare fees, which are set prospectively, there is no regulatory restraint on increases in ASP.

Beginning in 2019, the Centers for Medicare and Medicaid Services (CMS) is introducing some competition and negotiation into the market by allowing Medicare Advantage plans the option to implement step therapy for Part B drugs.[8]

[1] Office of Management and Budget (February 2018). An American Budget: Budget of the U.S. Government. Retrieved November 14, 2018, from https://www.whitehouse.gov/wp-content/uploads/2018/02/budget-fy2019.pdf.

[2] HHS (May 2018). American Patients First: The Trump Administration to Lower Drug Prices and Reduce Out-of-Pocket Costs. Retrieved November 14, 2018, from https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf.

[3] Reimbursement is reduced to ASP + 4.3% after the impact of sequestration.

[4] Sales excluded from the ASP determination are sales exempt from best price and sales at nominal charge. Per Section 1847A(c)(2) of the Social Security Act, available at https://www.ssa.gov/OP_Home/ssact/title18/1847A.htm.

[5] Section 1847A(c)(2) of the Social Security Act, ibid.

[6] Federal Register Vol. 83, No. 147 (July 31 2018). Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Requests for Information on Promoting Interoperability and Electronic Health Care Information, Price Transparency, and Leveraging Authority for the Competitive Acquisition Program for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model. Retrieved November 14, 2018, from https://www.gpo.gov/fdsys/pkg/FR-2018-07-31/pdf/2018-15958.pdf.

[7] MedPAC (June 2017). Report to the Congress: Medicare and the Health Care Delivery System. Retrieved November 14, 2018, from http://www.medpac.gov/docs/default-source/reports/jun17_reporttocongress_sec.pdf.

[8] Under the new policy, plans can apply step therapy only to new prescriptions or administrations of Part B drugs for beneficiaries who are not actively receiving the affected medication. See CMS (August 2018), Medicare Advantage Prior Authorization and Step Therapy for Part B Drugs, available at https://www.cms.gov/newsroom/fact-sheets/medicare-advantage-prior-authorization-and-step-therapy-part-b-drugs.

Shifting coverage of certain Part B drugs to Part D

The Fiscal Year 2019 Budget proposes to give the Secretary of the U.S. Department of Health and Human Services (HHS) authority to move certain drugs currently covered under Part B to the Part D benefit in order to leverage the negotiating power of Medicare Part D plans. Unlike in Part B, Part D drug prices are negotiated between manufacturers and private Part D plan sponsors. The objective of shifting drugs to Part D is that private insurers could potentially lower the net price of drugs through cost and utilization control mechanisms already in place for Part D drugs but not currently used for Part B.[9]

Part D sponsors typically negotiate rebates for brand drugs in return for favorable formulary placement. Formularies are used as a tool to either encourage or discourage certain drugs based on net cost to the Part D plan. The sponsor can incentivize manufacturers to increase rebates for their brand drugs and then steer patients to those drugs. Part D sponsors can also use differential cost sharing to encourage beneficiaries to choose certain brands over others or to choose generics over brands.

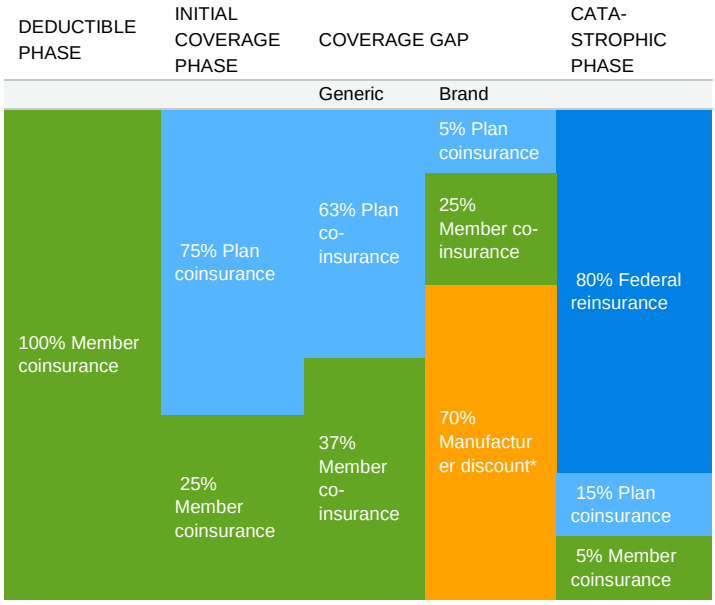
In some cases, Part D plans are restricted from imposing formulary management tools. Cancer drugs, for example, are in a "protected" class and Part D plans are required to cover all or substantially all of these treatment options. In these situations, the Part D plan may not be able to negotiate better pricing than the ASP. According to the "Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs," HHS may send President Trump a report to identify particular Medicare Part B drugs or classes where lower prices could be obtained by Part D.[10]

A benefit to Medicare from shifting drugs to Part D is the introduction of another payer, the pharmaceutical manufacturer, to share in the cost of the drug. Pharmaceutical manufacturers will pay 70% of the cost for brand drugs in the Part D coverage gap in 2019 for applicable beneficiaries.[11] As a result, some drug spending liable to Medicare in traditional Part B would be shifted to the manufacturer.

An important concern in the shift is whether subjecting Part B drugs to Part D rebates will increase prices. Under Part D, plans have an incentive to favor higher priced drugs with higher rebates. This is because in the coverage gap and the catastrophic zone, the portion of the rebate kept by the plan can be a larger dollar amount than the plan's share of the claim cost.

Another key concern in the shift is a potential change in beneficiary out-of-pocket (OOP) spending. For covered Part B drugs, beneficiaries in the traditional fee-for-service Medicare program pay 20% cost sharing of the Medicare-approved amount after the Part B deductible, although some or all of this coinsurance may be covered through supplemental insurance such as a MediGap policy. Under the defined standard Part D benefit design, beneficiary cost sharing for Part D drugs varies throughout the year based on accumulated spending. See the table in Figure 1.

FIGURE 1: 2019 PART D STANDARD BENEFIT FOR APPLICABLE BENEFICIARIES



DRUG COST	$415	$3,820	APPROX. $8,140**
TROOP	$415	$1,266	$5,100

Notes

*Both member and manufacturer liability accumulate toward True Out-of-Pocket (TrOOP), which is the out-of-pocket spending threshold at which members enter the catastrophic phase of the benefit.

***Estimated* total dollar catastrophic coverage limit corresponding to TrOOP spending of $5,100

The table in Figure 2 shows the approximate change in beneficiary OOP costs from shifting a brand drug from Medicare Part B to Medicare Part D at different drug prices, given the Figure 2 assumptions.

[9] Office of Management and Budget (February 2018), ibid.

[10] HHS (May 2018). American Patients First, ibid.

[11] Applicable beneficiaries are Part D enrollees who do not receive income-related subsidies under section 1860D-14(a) of the Social Security Act.

FIGURE 2: CHANGE IN FEE-FOR-SERVICE BENEFICIARY OOP CCOST

TOTAL ANNUAL COST FOR TARGET DRUG	OOP COST IN PART B*	OOP COST IN PART D**	DOLLAR INCREASE IN OOP COST IN MOVING FROM PART B TO PART D
$500	$100	$440	$340
$5,000	$1,000	$1,560	$560
$10,000	$2,000	$2,380	$380
$15,000	$3,000	$2,630	($370)

*Assuming no supplemental coverage

**Assuming no low – income cost - sharing subsidies and no other Part D claims

FIGURE 2 ASSUMPTIONS

- Traditional fee-for-service Medicare Part B coverage (20% coinsurance). Assumes the $185 Part B deducible has been met by other services.
- Defined Standard Part D Benefit Design with 2019 parameters and no low-income cost-sharing subsidies.
- The Part D price would be the same as the ASP.
- No supplemental coverages or cost-sharing assistance.
- No other Part D spending aside from the target brand drug.
- Does not include potential impact to beneficiary cost of changes to annual beneficiary premiums for either Part B or Part D, which would likely occur with this policy change.

As shown in Figure 2, shifting drugs from Part B to D will increase OOP costs for those with lower annual costs and lower them for those with higher annual costs. OOP cost savings begin when the beneficiary reaches the catastrophic benefit phase and pays only 5% coinsurance. Spending on other Part D drugs will push the beneficiary into the catastrophic phase sooner, resulting in more OOP cost savings.

However, almost 90% of beneficiaries covered by Medicare fee-for-service have some form of supplemental coverage, through MediGap, employer-sponsored retiree plans, or Medicaid, that can cover a large portion of Part B cost sharing.[12]

For this reason, for many beneficiaries, any shift from Part B to Part D could increase OOP costs. The ultimate change in OOP spending will vary depending on the beneficiary's spending on other drugs, Medicaid coverage, low-income subsidies, Part D enhanced plan benefit designs, and supplemental coverages.

Beneficiaries who qualify for Part D low-income cost-sharing subsidies (LIS) pay only a small copay for Part D drugs. Many beneficiaries who qualify for LIS will also qualify for Medicaid, which would cover Part B cost sharing. The change in cost sharing for such beneficiaries would likely be minimal.

Alternative systems for buying Part B drugs

Other proposals to improve negotiation for Part B drugs include the Competitive Acquisition Program (CAP) and the Drug Value Plan.

The CAP would be an alternative system enabling providers to acquire Part B drugs from vendors selected by Medicare through a competitive bidding process. The goal of the competitive process is for vendors, through private-market cost utilization techniques and fixing misaligned incentives, to buy the drugs from manufacturers and supply them to providers at a lower price than under the ASP methodology. This could result in lower Medicare and beneficiary expenditures while giving providers the opportunity to no longer bear the financial burdens and risk associated with drug acquisition. As described in the "Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs," physicians would still have the choice to purchase Part B drugs from manufacturers directly and continue to be reimbursed at the ASP + 6% price.

A CAP for Part B drugs was authorized by the Medicare Modernization Act in 2003. The program was not successful and ended in 2008. The Medicare Payment Advisory Commission (MedPAC) outlined some of the key reasons for the failure of the initial program: 1) low physician enrollment, 2) vendors did not have enough leverage to negotiate discounts, and 3) Medicare paid the vendor more than ASP + 6% for the drugs.[13] HHS Secretary Alex Azar expressed optimism that the market has developed sufficiently, with purchasing groups more equipped to secure discounts and work effectively with providers, to now better execute a CAP.[14]

Prices paid in the United States for the drugs with the greatest expenditures are approximately 1.8 times higher than the prices paid in countries with similar economic conditions.[15] CMS recently announced it is considering implementing a new model, with some features similar to the CAP, called the International Pricing Index (IPI) model. The IPI model would use private vendors to supply providers with the drugs. However, instead of

[12] Based on beneficiaries not living in institutions. Excludes those who were not in both Part A and Part B throughout their calendar year enrollment or who had Medicare as a secondary payer. See MedPAC (June 2017). A Data Book: Health Care Spending and the Medicare program, Section 3: Medicare Beneficiary and Other Payer Financial Liability, available at http://www.medpac.gov/docs/default-source/data-book/jun17_databooksec3_sec.pdf?sfvrsn=0.

[13] MedPAC (June 2017). Report to the Congress, ibid

[14] HHS (May 14, 2018). Remarks on Drug Pricing Blueprint, Retrieved November 14, 2018, fromhttps://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-on-drug-pricing-blueprint.html.

[15] HHS (October 25, 2018). Comparison of U.S. and International Prices for Top Medicare Part B Drugs by Total Expenditure. Retrieved November 14, 2018, from https://aspe.hhs.gov/system/files/pdf/259996/ComparisonUSInternationalPricesTopSpendingPartBDrugs.pdf.

reimbursing the vendors based on the competitive bid amounts, under the IPI model, Medicare would pay the vendor based on a target price derived from the international price index. The IPI would apply only when the ASP is higher than the international price index. [16]

In the June 2017 MedPAC report, the Commission supported the development of a Part B Drug Value Program (DVP), an approach that is informed by the CAP, but with design modifications meant to address several of the CAP program's challenges. The DVP, like CAP, would use private vendors to negotiate drug prices with manufacturers and allow voluntary enrollment for providers. But the structure of the DVP would differ from the CAP in the following ways:

- **Use existing distributors:** The DVP vendors would not ship drugs to providers, but instead providers would continue to receive physical delivery through current distributors, pay the DVP price, and be reimbursed by Medicare at the DVP price. The CAP had problems with physical delivery.
- **Encourage provider enrollment:** To discourage providers from remaining in the ASP + 6% system, the ASP add-on would be gradually reduced.
- **Give DVP vendors greater negotiating leverage with manufacturers**: The DVP vendors would be permitted to use greater formulary management tools than CAP vendors were allowed. In certain circumstances, binding arbitration would be used to determine prices for high-priced drugs without close substitutes.
- **Allow DVP vendors to establish medical management**: DVPs would be able to encourage a shift to generics and establish medical management processes.
- **Allow for providers, beneficiaries, vendors, and Medicare to share in the savings achieved by the program**: Providers could share in savings if DVP costs fell below a budget. Savings achieved from lower drug prices would reduce Medicare reimbursement and beneficiary cost sharing.

Several organizations encouraged CMS to consider the DVP proposal or other similar approaches in response to a September 2017 CMS New Direction Request for Information.[17]

In some ways, the DVP resembles a group purchasing organization combined with formulary and medical management capabilities.

Conclusion

The objective of shifting drugs to Part D, the CAP, and the DVP is for Medicare to benefit from private insurers' cost and utilization control mechanisms already in place for Part D drugs and for non-Medicare payers.

A consequence of shifting Part B drugs to Part D is the potential change in beneficiary cost sharing. Medicare beneficiaries with private supplemental health coverage and low Part D spending are particularly at risk for greater out-of-pocket costs due to a Part B to Part D shift. An important challenge will be how to handle the approximately 9 million people with Part B coverage but without Part D coverage. Other questions include: Should the Part B premium be reduced to account for the reduced Part B coverage? Will Part D premiums increase?

Lower prices as a result of the CAP or the DVP could reduce beneficiary cost sharing more uniformly. Policy proposals will need to balance these changes with federal spending changes. The complexity of the programs will require sophisticated modeling to determine likely impacts.

[16] CMS (October 25 2018). ANPRM International Pricing Index Model for Medicare Part B Drugs. Fact Sheet. Retrieved November 14, 2018, from https://www.cms.gov/newsroom/fact-sheets/anprm-international-pricing-index-model-medicare-part-b-drugs.

[17] Federal Register Vol. 83, No. 147 (July 31, 2018), ibid.

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