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2005 Market Street, Suite 2800
Philadelphia, PA 19103-7077
215.575.9050 Phone

901 E Street NW
Washington, DC 20004
202.552.2000 Phone

www.pewtrusts.org

November 20, 2017

Submitted electronically via https://innovation.cms.gov/initiatives/direction/

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: Innovation Center New Direction
PO Box 8016
Baltimore, MD 21244-8016

Re: Request for Information; Innovation Center New Direction

To Whom It May Concern:

The Pew Charitable Trusts is pleased to respond to the Centers for Medicare and Medicaid Services (CMS) request for information (RFI) regarding the development of Innovation Center models to promote patient-centered care and test market-driven reforms, provide price transparency, increase choices and competition to drive quality, reduce costs, and improve outcomes. Pew is an independent, nonpartisan research and public policy organization dedicated to serving the public.

Pew's efforts on drug spending are focused on identifying policies that would allow public programs, such as Medicare and Medicaid, to better manage the cost of pharmaceuticals while ensuring that patients maintain access to the drugs that they need. The Innovation Center can play an essential role in advancing effective practices and policies through its unique ability to test and evaluate new models to improve care and lower costs in public programs.

The Innovation Center has requested feedback on potential models for prescription drugs. Below, we discuss two potential areas where the Innovation Center could test prescription drug models that align with the guiding principles articulated in the RFI, including 1) choice and competition in the market, 2) provider choice and incentives, and 3) benefit design and price transparency.

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Misaligned incentives and lack of drug price competition in Medicare Part B

Drug spending in Medicare Part B reached $22 billion in 2015, and Part B drug costs have increased by an average of 8.6 percent annually since 2007.[1] The drugs reimbursed under Part B include infusible and injectable products administered in physician offices and hospital outpatient departments. Under current Part B reimbursement policy Medicare pays providers the Average Sales Price (ASP) of the drug plus a 6 percent add-on payment. This has been reduced to ASP plus 4.3 percent by the budget sequester. Medicare also makes a separate payment to providers for the administration of Part B drugs. Limitations of the current reimbursement policy include:

- ASP, calculated quarterly, is based on manufacturer pricing strategies and national sales inclusive of some, but not all, discounts and rebates.[2] Therefore, there is no statutory limit on how much ASP, and in turn Medicare payment, can increase.

- Except in cases where brand drugs share billing codes with their generic equivalents, Part B reimbursement policy does not include any financial incentive for providers to choose lower-cost therapies. This is true even when multiple drugs would be equally effective. In fact, the current methodology may provide an incentive for providers to select higher-cost drugs over cheaper alternatives of equal effectiveness. If a provider administers a higher cost product, Medicare pays not only a higher ASP, intended to cover the cost of the drug itself, but also a higher add-on payment based on the ASP of that drug. While little research has evaluated how the Part B drug add-on payments influence provider drug selection, one study found an increase in oncologists' use of the most expensive therapy for lung cancer after the introduction of the ASP+6 percent payment policy.[3] Similarly, the Office of the Inspector General found that utilization for lower cost prostate cancer drugs decreased after the implementation of the ASP+6 percent payment for those products in 2010.[4]

- The Part B program does not take advantage of any of the tools widely employed in commercial insurance plans to ensure appropriate utilization and manage costs.

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[1] Medicare Program; Part B Drug Payment Model; Proposed Rule, 81 Fed. Reg. 13230 (Mar. 11, 2016).
[2] ASP calculations excludes sales that are exempt from the determination of "best price" in the Medicaid drug rebate program, such as discounts and rebates offered to pharmacy benefits managers. 42 U.S. Code § 1395w-3a(c)(2)(A)
[3] Jacobson, Mireille, Craig C. Earle, Mary Price, and Joseph P. Newhouse. "How Medicare's payment cuts for cancer chemotherapy drugs changed patterns of treatment." *Health Affairs* 29, no. 7 (2010): 1391-1399, http://www.healthaffairs.org/doi/full/10.1377/hlthaff.2009.0563
[4] Department of Health and Human Services, "Least Costly Alternative Policies: Impact on Prostate Cancer Drugs Covered Under Medicare Part B" (2012), http://oig.hhs.gov/oei/reports/oei-12-12-00210.pdf.

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> Specifically, there is no formulary for Part B drugs. FDA-approved drugs are almost always covered by Medicare, regardless of their effectiveness or cost compared to existing therapies. This contrasts with Medicare Part D and employer-sponsored coverage, where private plans choose which drugs to cover based on their effectiveness and cost. Other common payer tools not utilized in Part B include prior authorization and step therapy.[5]

Each of these challenges can contribute to rising drug costs and in some cases undermine quality of care. This increases Medicare spending, but also results in higher out-of-pocket costs for beneficiaries, who are required to pay 20% of the Medicare-approved cost of Part B services.

Potential approaches to drug price competition in Medicare Part B

Drug Value Program

The Medicare Payment Advisory Commission (MedPAC) has recommended an approach to reimbursement of drugs in Part B fee for service that, with some modifications for the purposes of a Centers for Medicare and Medicaid Innovation (CMMI) demonstration, has the potential to create competition, expand choice and offer savings to the federal government, providers and beneficiaries.

The Drug Value Program (DVP), as proposed, would allow providers, on a voluntary basis, to opt in to a market-based alternative to the ASP payment system that would use private vendors to negotiate prices for Medicare Part B drugs.[6] The key elements of this program and suggested modifications are described below.

Under this approach, Medicare would contract with a small number of private vendors to participate in the DVP. These vendors would be responsible for negotiating prices with manufacturers for Part B drugs and making those prices available to providers through a network of distributors and wholesalers. Vendor-negotiated prices would be known by Medicare, participating providers and distributors, but would not be disclosed to the public. In order to provide DVP vendors leverage in negotiating prices, the program would allow for the use of management tools that are standard in commercial insurance coverage, such as formularies and prior authorization or step therapy for certain products. This would introduce drug price competition in Part B by providing incentives to manufacturers to offer discounts

[5] A form of prior authorization, step therapy is a requirement to try a lower-cost preferred drug before moving up a "step" to a more expensive alternative.
[6] The Medicare Payment Advisory Committee, "Medicare Part B Drug Payment Policy Issues" (2017), http://www.medpac.gov/docs/default-source/reports/jun17_ch2.pdf?sfvrsn=0

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on their products. In addition, the small number of DVP vendors would consolidate the significant purchasing volume of Part B to provide vendors leverage in negotiations with manufacturers. There may be circumstances under which a vendor cannot obtain a favorable price for a particular drug, so the DVP would limit prices to 100 percent of ASP. This would ensure that vendors are able to obtain at least typical market prices for Part B drugs. Vendors would be compensated through an administrative fee paid by Medicare as well as the ability share in program savings.

The DVP would be voluntary. Physicians and hospital outpatient departments could choose whether to participate in the program or stay on the current ASP-based payment system for Part B drugs. Providers who enroll would choose a single DVP vendor for all their Part B drug purchasing. This would introduce competition among the vendors for providers, who may select vendors based on factors such as formulary design and potential for shared savings.

The DVP would not require significant changes in current provider practice. Participating providers would continue to purchase drugs in the marketplace from wholesalers, distributors or, in some cases, manufacturers, but they would do so at the price negotiated by the DVP vendor. Medicare would, in turn, reimburse providers for Part B drugs at the DVP vendor-negotiated price. Medicare would continue to pay providers for drug administration services at the standard rate.

This approach avoids creating additional administrative burdens for providers. Because providers would not know in advance what proportion of the drugs they order would be administered to Medicare fee-for-service beneficiaries, purchases would be completed through a retroactive reconciliation process that ensures they receive the DVP-negotiated price for drugs administered to these beneficiaries.

As an incentive to participate in the DVP, providers would be eligible to share in program savings. Importantly, a demonstration should not be structured in a way that would incentivize providers to generate savings through decreased use of necessary therapies. One approach to ensure clinically appropriate use of drugs is to require that participants adhere to published clinical guidelines or pathways. Alternatively, as a condition of eligibility for sharing in savings, providers could be required to meet certain quality metrics.

Medicare beneficiaries would be partners in a DVP demonstration. First, enrollees receiving Part B drug services from providers participating in the DVP would be eligible to share in cost savings achieved through the program. While Part B cost sharing is generally set at 20 percent of Medicare-approved costs, the negotiated prices for drugs would not be made public

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under this program. To address this challenge, Medicare could estimate aggregate DVP prices across all products and set patient cost sharing at 20 percent of that amount. For example, if a DVP vendor negotiates prices that are an average of 10 percent less than ASP across all drugs, beneficiaries could be required to pay a coinsurance of 20 percent of 90 percent of ASP for each drug.

For the purposes of a CMMI demonstration, we suggest some modifications to the DVP as proposed by MedPAC. The DVP would implement a reduction to the current ASP add-on payment of 6 percent for Part B drugs for providers who elect not to participate in the DVP. This reduction is designed as an incentive for providers to participate in the DVP. However, this reduction would be challenging to implement as part of a demonstration. Furthermore, such a reduction to ASP may not be necessary if Medicare ensures that enough of the DVP savings on aggregate drug costs realized through negotiated prices, management tools and appropriate use are shared with providers. This reduction in ASP add-on payments should not be included as part of an initial DVP demonstration, though it may be a consideration for subsequent demonstrations or policy proposals.

Another important clarification to the DVP as proposed would be full transparency for beneficiaries. In order to inform beneficiary decisions, providers participating in a DVP demonstration should be required to disclose to beneficiaries the formulary their selected vendor has implemented. Beneficiaries should also have access to information on their required cost sharing, which may vary from vendor to vendor depending on the negotiated savings. Medicare could also play a role in making this information available to beneficiaries online, with details available on a per-provider basis, as the specifics would vary depending on which vendor the provider partners with.

Compensation to DVP vendors should be structured in a way that encourages savings and does not allow payments from manufacturers to vendors, to avoid conflicts of interest. Per beneficiary administrative fees coupled with an opportunity to share in the savings would achieve this balance. When estimating savings, it is important to consider not just per unit drug savings, but also overall Part B drug spending, which may be reduced through appropriate clinical management.

Ensuring the correct distribution of savings between Medicare, providers, vendors and beneficiaries is critical to aligning the incentives across these stakeholders. CMMI should consider the breakdown that would achieve the highest aggregate savings while maximizing competition between vendors and ensuring the federal government and taxpayers benefit from reduced costs.

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Adapting effective practices from the private sector to the Medicare Part B program has the potential to introduce competition where none exists, expand choice for providers and patients, and generate savings for the federal government, providers and beneficiaries. We encourage CMMI to thoroughly examine MedPAC's proposal for a DVP and consider how it could be tested under a demonstration.

Value-based purchasing

We encourage CMMI to evaluate the value-based purchasing approaches proposed under phase II of the 2016 Part B Drug Payment Model.[7] The second phase of the model proposed to test value-based purchasing tools similar to those widely utilized by commercial health plans, pharmacy benefit managers, hospitals, and other entities. The Part B Drug Payment Model did not move forward, but there is an opportunity for CMMI to design more targeted, non-mandatory demonstrations to evaluate the impact of value-based purchasing tools on costs and patient outcomes in the Medicare program.

- Indication-based pricing allows payers to align the reimbursement for a drug with the outcomes it produces for a particular condition or indication.
- Reference pricing involves setting equal payments for therapeutically similar drugs that yield similar outcomes.
- Reductions in patient cost-sharing for therapies determined to be high value.

Each of the approaches above has the potential to generate savings by moving toward value in the Part B reimbursement for drugs. However, a critical step in developing any value-based purchasing policy is the assessment of the effectiveness and cost-effectiveness of pharmaceuticals to determine their value. Pew has previously provided comments to CMMI on this topic based on a 2016 public stakeholder convening.[8] One overarching priority articulated in by participants is the need for a transparent process to assess the value of medicines that draws on the knowledge of experts and stakeholders.

While no value-based purchasing approach could be applied to all Part B drugs, we encourage CMMI to consider whether there are particular drug classes for which one or more of the tools outlined above would be appropriate. Other priorities for designing models include

[7] Medicare Program; Part B Drug Payment Model; Proposed Rule, 81 Fed Reg. 13230, pg. 13243 (Proposed Mar. 11, 2016).
[8] The Pew Charitable Trusts, "CMS-1670-P—Medicare Program; Part B Drug Payment Model; Proposed Rule", (2016), http://www.pewtrusts.org/~/media/assets/2016/05/pew-comments-part-b.pdf

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developing rigorous study designs, ensuring sufficient incentives for provider participation and allowing for public input.

Future directions

Thank you for the opportunity to provide input on the future direction of the Innovation Center. We believe these approaches have the potential to test market-driven reforms to reduce costs to Medicare and beneficiaries and improve quality of care. We encourage The Innovation Center to consider these and other models that can address the current lack of drug price competition and additional challenges that drive up spending in the Medicare Part B program. Should you have any questions, or if we can be of assistance with your work, please contact me by phone at 202-540-6512 or via email at ireynolds@pewtrusts.org.

Sincerely,

Ian Reynolds

Associate Manager, Drug Spending Research Initiative

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