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Submitted electronically via Regulations.gov

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–5528-ANPRM
P.O. Box 8013
Baltimore, MD 21244–8013

Re: CMS–5528-ANPRM; Medicare Program; International Pricing Index Model for Medicare Part B Drugs

Dear Administrator Verma:

The Pew Charitable Trusts (Pew) is pleased to offer comments on the Advance Notice of Proposed Rulemaking regarding the International Pricing Index (IPI) Model for Medicare Part B Drugs ("the proposal"). Pew is an independent, nonpartisan research and public policy organization dedicated to serving the American public. Our drug spending research initiative is focused on identifying policies that would allow public programs to better manage spending on pharmaceuticals while ensuring that patients have access to the drugs that they need.

Pew commends the Department of Health and Human Services (HHS) Centers for Medicare & Medicaid Services (CMS) for its commitment to addressing drug spending in the Medicare Part B program. In our comments, we express support for the CMS goal of reducing Part B spending through innovative payment models, and we offer targeted suggestions for how CMS' could implement the proposal.

* * *

Testing Alternatives to the Competitive Acquisition Program Model

This proposal aims to reduce spending on drugs in the Part B program, one of the fastest growing cost centers in Medicare. In Pew's response to the Administration's Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs,[1] we highlighted how the Secretary may be able to use existing Competitive Acquisition Program (CAP) authority to encourage competition in the Part B program without requiring the CAP vendor to take possession or title to individual drugs. The proposal notes many of the

[1] The Pew Charitable Trusts. "Pew Responds to White House's Drug Pricing Blueprint Information Request," July 16, 2018, http://www.pewtrusts.org/en/research-and-analysis/speeches-and-testimony/2018/07/16/pew-responds-to-white-houses-drug-pricing-blueprint-information-request.

challenges that hindered the CAP's ability to generate savings as well many logistical concerns under the CAP. We agree that any IPI model demonstration should address these challenges under the CAP.

Potential Drug Add-on Payment

The proposal calls attention to the perverse incentives present under the current ASP plus 6% reimbursement system under Part B, which can encourage both providers and manufacturers to prefer higher-priced drugs. In contrast, the current proposal would create a set add-on payment not tied to the cost of the drug and to encourage providers to select lower-cost treatment options. In addition to developing incentives for providers to select lower-priced treatments, CMS could consider incentives for manufacturers to lower their prices and to introduce new drugs at lower initial prices. For example, providers could receive a greater add-on payment when selecting an existing drug among therapeutic substitutes that has the greatest price decrease under the IPI model. For new drugs, providers could receive a greater add-on payment for selecting a new drug with a launch price below any discounted prices available on existing therapeutic substitutes. This would encourage manufacturers to compete for the lowest cost while discouraging the introduction of new drugs at artificially high prices to generate the appearance of significant discounts.

Model Payment Methodology for Vendor Supplied Drugs

In the current proposal, CMS aims to reduce spending on Medicare Part B drugs by indexing its reimbursement to prices for drugs that are available at lower prices in other countries. However, while the proposed International Pricing Index (IPI) adjustment would reduce overall Medicare Part B drug spending, it may also fail to generate sufficient revenue for vendors to encourage participation. Because vendors will receive fixed payments, irrespective of their cost of acquisition, they will likely be discouraged from participating if they do not have a reasonable guarantee of their revenue and profits under the program. As the proposal notes, one of the challenges with the CAP was that "[t]here was no guarantee for the CAP vendors that the CAP payments would cover their drug acquisition and operating costs." As proposed, however, the IPI model has the same flaw. Moreover, IPI vendors may be unable to negotiate lower prices with manufacturers, as the proposal does not expressly authorize IPI vendors to operate a formulary or engage in utilization management techniques that may be necessary to extract manufacturer price concessions.

As an alternative, CMS could consider whether vendors should receive a defined profit and administrative expense margin, a successful model that has led to robust participation in the Medicare Part D program.[2] Any additional savings achieved by negotiating prices below the IPI target price could be distributed between the vendor and Medicare in a shared-savings model, encouraging vendors to achieve the lowest price possible while guaranteeing a minimum revenue for participating in the program.

While the proposed IPI model will include a consideration of prices paid in other countries, the model would adjust the calculated average of prices in other countries to achieve a "30 percent reduction in

[2] 42 CFR 423.265(c)(1)

Medicare spending for included Part B drugs over time." By adjusting the IPI to achieve a defined savings threshold, the proposal may artificially limit savings; as the proposal notes, HHS has found that acquisition cost for selected Part B drugs was 1.8 times higher in the U.S. than in comparator countries. If CMS intends to better align U.S. prices with international prices, it is unclear why the IPI should be limited to a 30 percent reduction in spending if international prices offer a greater discount.

Other program models may achieve greater cost reductions and more predictable vendor revenues, strengthening the program. For example, combining multi-source products into one reimbursement code encourages manufacturers to compete against each other to be the lowest-cost option within the reimbursement code and has lowered Medicare Part B spending.[3] CMS could expand this model to combine therapeutically-similar products into a single reimbursement code, such as combining biologics and biosimilars or combining multiple single-source products that have been demonstrated to be non-inferior in clinical trials; this market-driven option may yield similar price reductions as those achieved by other countries that encourage manufacturers to compete against each other. Utilization management techniques, such as prior authorization and step therapy, are well-understood by private insurers and pharmacy benefit managers and have been responsible for generating significant savings in the Medicare Part D program; allowing vendors to use those techniques in Medicare Part B may yield similar savings, as CMS has allowed within the Medicare Advantage program.[4] To achieve the greatest savings, vendors should have access to the widest set of tools to encourage price concessions from manufacturers, including applying utilization management techniques to products within a multi-source billing code to discourage tacit price fixing.

The number of vendors selected may also affect the level of discounts vendors are able to achieve, affecting vendor willingness to participate in the program. In designing the vendor system, CMS should consider how the level of vendor competition may encourage or discourage manufacturers from negotiating discounts or developing products that may be candidates for negotiation. If numerous vendors participate in the program, each vendor's negotiating power with manufacturers will be diluted, reducing the ability of each vendor to extract price concessions. Similarly, CMS should also assess the size of the non-Medicare market for drugs included in the IPI model. For example, a single national vendor could exercise significant market power to prioritize the use of one drug relative to competitors in the therapeutic area and obtain a large discount on that drug; however, if the majority of care in that therapeutic area is within the Medicare Part B program and utilization shifts to one drug, manufacturers may be discouraged from developing products to compete in the space. Consider biosimilars – if a nationwide sole vendor in the IPI model selects only one biosimilar product as the preferred treatment for an age-related condition that primarily affects Medicare beneficiaries, other manufacturers may be unwilling to develop a competing biosimilar if only one product will see significant utilization. However,

[3] Office of the Assistant Secretary for Planning and Evaluation. Savings Available Under Full Generic Substitution of Multiple Source Brand Drugs in Medicare Part D. July 23, 2018. Available at: https://aspe.hhs.gov/system/files/pdf/259326/DP-Multisource-Brands-in-Part-D.pdf. (Discussing how ASP declines over time because of competition within the multi-product billing code, reducing costs for Medicare Part B).
[4] Centers for Medicare & Medicaid Services. Medicare Advantage Prior Authorization and Step Therapy for Part B Drugs. Aug. 7, 2018. Available at: https://www.cms.gov/newsroom/fact-sheets/medicare-advantage-prior-authorization-and-step-therapy-part-b-drugs.

if there are multiple vendors in the IPI model, there would be more opportunities for a manufacturer's product to be selected as the preferred treatment, which may foster a more robust and competitive marketplace.

Data Sources on International Drug Sales

To ensure that the IPI is calculated using the most accurate data, the proposal would require manufacturers to provide international pricing and sales information under the same framework manufacturers already use to report prices for the Medicare and Medicaid programs. As part of this reporting, CMS could require manufacturers to report net prices sold in other countries (including any post-sale rebates or discount) and total units sold at each price to ensure that the IPI is not based on artificially-inflated list prices or skewed by any low-volume, high-priced sales. Manufacturers are already familiar with regular price reporting to CMS under the Medicare Part B program,[5] and existing penalties under the False Claims Act will help ensure accurate manufacturer reporting.[6]

While developing these new reporting requirements, CMS could ensure that Medicare does not pay significantly higher prices than commercial payers, both within the IPI demonstration and for payments outside of the demonstration, by revising existing price reporting requirements. Specifically, CMS could ensure that the calculations used to set Part B reimbursement are net of all discounts available to commercial payers. Under current practice, the Average Sales Price (ASP) calculation used to set Part B reimbursement is replaced with the Medicaid Average Manufacturer Price (AMP) calculation when ASP exceeds AMP by more than 5 percent in the two previous quarters or three of the previous four quarters.[7] Because Part B drugs are inhaled, infused, instilled, implanted, or injected ("5i drugs"), AMP for these drugs generally includes discounts and rebates to insurers and Pharmacy Benefit Managers (PBMs),[8] which are excluded from ASP.[9] These discounts are reflected in lower AMPs for Part B drugs, which can in some cases trigger AMP substitution of ASP for Medicare reimbursement. However, the AMP calculation also includes all sales under the Medicare Part B program, as the manufacturer performing the calculation does not know whether a unit sold to a physician will ultimately be used for a Medicare or non-Medicare patient. If Medicare Part B sales comprise a significant portion of total sales, then any PBM rebates that are included in the AMP calculation will only moderately reduce AMP, leaving Medicare Part B to pay higher prices than commercial payers. To ensure that AMP truly reflects commercial market sales and discounts for Part B drugs, CMS could instruct manufacturers to remove all units billed under the Medicare Part B program from AMP; CMS billing records could be used to identify sales to be excluded from the AMP calculation. This would also harmonize treatment of Medicare Part B sales with Medicare Part D sales, as all discounts provided under the Medicare Part D program for 5i drugs are exempted from the AMP calculation.[10] Medicare Part B sales under the IPI demonstration

[5] 42 U.S.C. § 1395w–3a
[6] 31 U.S.C. § 3729
[7] 42 CFR § 414.904(d)(3)
[8] 42 U.S.C. § 1396r–8(k)(1)(B)(i)(IV)
[9] 42 U.S.C. § 1395w–3a(c)(2)(A); 42 U.S.C. § 1396r–8(c)(1)(C)(i)
[10] 42 CFR 447.504(e)(8)

would still be included in ASP, ensuring that ASP reflects IPI discounts; AMP would only be substituted for ASP if private payers achieve greater discounts than those realized under the IPI demonstration.

Under this revision, Part B standard reimbursement would reflect the lower of the average price under the IPI demonstration or the average net price achieved by commercial payers in the U.S. If net commercial prices are lower than those calculated under the IPI target price model, CMS would default to these prices, adopting a market-based solution to reduce Medicare Part B spending.

Potential Included Countries

The proposal's IPI calculation differs from existing price reporting mechanisms used by CMS, such as Average Manufacturer Price (AMP) and Average Sales Price (ASP), because it does not volume-weight the prices considered. We encourage CMS to consider how prices included in the IPI could be volume-weighted to better estimate the average price paid in reference countries. For example, if there are multiple therapeutically-similar drugs to treat a particular condition, any given country in the IPI reference group may engage in utilization management to favor one particular therapy (treatment A) over others, presumably for a lower price. In this situation, the disfavored therapy (treatment B) may be nominally available but rarely used in the country, and the manufacturer may not offer any discounts for this infrequent use. However, another country may prefer treatment B over treatment A, extracting significant discounts. An unweighted average of these prices would not fully reflect the discounts achieved from utilization management of these drugs, limiting the benefit of the IPI model. Pew encourages CMS to consider how the IPI calculation could adjust for the volume of utilization for each included price, particularly for treatment categories with multiple therapeutically-similar drugs.

Similarly, the report from the Office of the Assistant Secretary for Planning and Evaluation[11] that accompanied the proposal discusses how many of the countries proposed for the IPI calculation reference other included countries to set their own prices. Pew encourages CMS to analyze how this averaging of prices that are based on each other will affect the IPI calculation.

Impact on Beneficiary Cost-Sharing

Pew commends CMS for reducing beneficiary cost-sharing in line with the discounts achieved under the IPI model. We encourage CMS to consider further reducing or waiving beneficiary cost-sharing when a provider selects the least-costly clinically-suitable therapy. Under this model, manufacturers would compete to have the lowest-cost product, and providers could be required to tell beneficiaries that there is a clinically-appropriate treatment with minimal or zero-dollar cost-sharing. This model would use a market-based mechanism to encourage lower prices without using utilization management techniques, reducing both beneficiary and Medicare spending.

[11] Office of the Assistant Secretary for Planning and Evaluation. Comparison of U.S. and International Prices for Top Medicare Part B Drugs by Total Expenditures. October 25, 2018. Available at: https://aspe.hhs.gov/pdf-report/comparison-us-and-international-prices-top-medicare-part-b-drugs-total-expenditures.

Interaction With Other Federal Programs

The proposal expresses concern that sales under the IPI model would trigger the Medicaid Best Price provision, which may have unintended consequences. Several mechanisms exist, however, which would allow the IPI model to avoid triggering Best Price.

First, Best Price is only triggered when a discount exceeds the standard Medicaid discount of 23.1% of AMP. As the proposal notes, AMP will likely decrease as a result of the IPI proposal.[12] As AMP decreases to reflect the discounts under the IPI, discounts that may have triggered Best Price under the prior AMP would be less likely to trigger Best Price under the new, lower AMP, attenuating the possibility that discounts to vendors under the IPI proposal will trigger Best Price. For example, if the IPI achieves a $25 discount from a current price (and AMP) of $100, these $75 sales will not trigger Best Price unless AMP remains above $97.50.

Second, sales and transactions to a variety of entities are already excluded from Best Price;[13] if these entities serve as vendors under the program, sales to these vendors would not trigger Best Price even if the discounts exceed 23.1% of AMP. All sales to entities that participate in the 340B Drug Discount Program are exempt from Best Price, even if those sales are not themselves under the 340B Program; this would allow 340B entities to act as vendors without triggering Best Price. Similarly, rebates and discounts to PBMs are exempted from Best Price, which has allowed PBMs to negotiate significant discounts in the commercial insurance market without Best Price consequences. If a PBM acts as the vendor, these rebates would be exempt from Best Price so long as the PBM is not simultaneously considered a wholesaler or pharmacy. This caveat may require that PBMs do not take title to the drugs supplied under the demonstration, which differs from the model in the proposal. However, changing this element of the proposal may avoid Best Price concerns entirely, facilitating manufacturer participation in the IPI model.

The proposal notes that AMP may fall as a result of manufacturer price reductions under the IPI model, which could reduce the rebates paid to Medicaid programs. Indeed, this challenge already exists, as PBM rebates may lower AMP for these drugs but Medicaid continues to reimburse for drugs at acquisition cost,[14] which does not reflect PBM rebates. To avoid exacerbating these lower rebates and to insulate Medicaid programs from other discounts that reduce rebates but do not reduce acquisition costs, manufacturer rebates to Medicaid programs could be calculated as the difference between the Medicaid program's reimbursement and the AMP net of the Unit Rebate Amount. For example, consider a drug with a $100 list price and an AMP of $80. Currently, Medicaid programs reimburse for the acquisition cost of the drug $100 and receive a rebate of 23.1% of the AMP (.231 * $80, or $18.50), for a net cost of $81.50 – more than the average commercial price realized after PBM rebates ($80). Instead, CMS could revise the rebate to allow the Medicaid program to achieve a net price of a 23.1% discount

[12] Pew's proposal to exclude IPI sales from AMP to better reflect commercial discounts means that AMP would not fall to reflect the IPI sales, which may cause IPI sales to trigger Best Price if commercial discounts do not reduce AMP.
[13] 42 CFR 447.505(c)
[14] 42 CFR 447.512

off $80, or $61.50; the rebate would be calculated as $100 – ($80 – (.231 * $80)) = $38.50. Not only would this ensure that Medicaid programs realize lower prices than commercial payers, it would encourage manufacturers to discount list prices rather than offer large PBM rebates, which may reduce out-of-pocket costs for consumers.

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We appreciate the opportunity to respond to this proposal and commend the Administration for its attention to drug spending. Should you have any further questions, please contact me by phone at 202-540-6939 or via email at sdickson@pewtrusts.org.

Sincerely,

Sean Dickson, JD MPH
Officer, Drug Spending Research Initiative
The Pew Charitable Trusts