Medicare Payment Advisory Commission

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Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington DC, 20201

RE: CMS-5528-ANPRM

Dear Ms.Verma:

The Medicare Payment Advisory Commission (MedPAC) welcomes the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) advance notice of proposed rulemaking entitled "**Medicare Program; International Pricing Index Model for Medicare Part B Drugs**," published in the *Federal Register*, vol. 83, no. 210, pages 54546 to 54561. We appreciate your staff's work on the notice, particularly considering the competing demands on the agency.

In the advance notice, CMS describes a potential model the agency is considering testing through the Center for Medicare & Medicaid Innovation. CMS indicates the potential model, referred to as the international pricing index (IPI) model, would shift from paying physician and outpatient hospitals for Part B drugs to paying private vendors for these products. The prices Medicare pays these vendors for Part B drugs would be reduced over a 5-year period to levels closer to international prices.

The Commission commends the agency for its efforts to reduce the prices Medicare pays for Part B–covered drugs. Obtaining good value for Medicare's program expenditures is a central tenet of the Commission's work on Medicare payment policy. The Commission is concerned about the prices Medicare pays for drugs and supports CMS's objective of reducing prices and expenditures for Part B drugs. The Commission's recommendations in the last several years to make improvements to Medicare payment policy for provider-administered drugs within Medicare Part B (2017) and for outpatient drugs delivered by private plans in Part D (2016) reflect that shared goal.[1] We believe both sets of recommendations would improve Medicare payment incentives while using market competition to reduce or constrain growth in drug prices.

[1] Medicare Payment Advisory Commission. 2017. *Report to the Congress: Medicare and the health care delivery system.* Washington, DC: MedPAC. Medicare Payment Advisory Commission. 2016. *Report to the Congress: Medicare and the health care delivery system Medicare.* Washington, DC: MedPAC.

The Commission's 2017 recommendation to create a Part B drug value program (DVP) has some relevance to the IPI model. Both approaches would seek to build on the experience with Medicare's competitive acquisition program (CAP) for Part B drugs.[2] Each model would give private vendors a role in procuring Part B drugs and seek to minimize financial incentives providers may face when prescribing these drugs. However, the two approaches differ in certain fundamental ways. The IPI approach seeks to more closely align Medicare payment with international prices, while the DVP approach seeks to use market forces within the United States to increase competition and put downward pressure on the prices Medicare pays for Part B drugs. Under the IPI model, Medicare would establish a payment rate for Part B drugs based on an international "target price." Medicare would pay that IPI-based rate to vendors, regardless of the price the vendor negotiates with the manufacturer to acquire the drugs. In contrast, the DVP model would permit vendors to use management tools—such as a formulary, step therapy, prior authorization, and in certain circumstances binding arbitration—to negotiate lower prices on Part B drugs and set Medicare payment rates based on these lower vendor-negotiated prices.

Overall, the Commission believes that the IPI model, while laudable in its goal of reducing prices, has several structural features that hamper its feasibility. In contrast, the Commission believes the DVP approach has potential to promote market competition by involving private vendors in the negotiation of Part B drug prices, creating greater incentives for efficient, high quality care and sharing the resulting savings with providers, beneficiaries, vendors, and the government. An attachment to this letter includes a table comparing features of the IPI and DVP models. The remainder of this letter offers comments on certain aspects of the IPI model. We focus on:

- the approach to establishing Medicare payment rates in a vendor model, including model feasibility and stakeholders' concerns about international reference pricing;
- the vendors' role and providers' process of obtaining drugs;
- the new flat payment amount to replace the current 6 percent add-on; and
- the bonus pool or shared savings.

Approach to establishing Medicare payment rates in a vendor model

Under the IPI model, the government would determine a payment rate for Medicare fee-for-service (FFS) Part B drugs based on a target price that is linked to international prices. According to estimates by the Assistant Secretary for Planning and Evaluation (ASPE), in the first quarter of 2018, acquisition costs for certain Part B drugs in the U.S. were, on average, about 1.8 times

[2] The Competitive Acquisition Program (CAP), which operated from 2006 to 2008, gave physicians the option of obtaining Part B drugs from a Medicare-paid vendor instead of the physicians themselves buying and billing for the drugs. The CAP was viewed as unsuccessful largely because physician enrollment was low, the vendor had little leverage to negotiate discounts, and Medicare paid the vendor more than its usual rate (i.e., more than the average sales price plus six percent) for vendor-furnished drugs overall.

higher than in other countries.[3] Over a 5-year period, the IPI model would phase in a target price for Part B drugs, which the agency states would result in about a 30 percent reduction in spending. The target price would be calculated by multiplying the IPI—the ratio of Medicare spending under average sales price (ASP) to international prices (holding volume and the mix of drugs constant)—and a factor that would phase in a spending reduction of about 30 percent over time.[4] The percentage reduction between the target price and ASP would vary for each drug. If a product's ASP were lower than the target price, CMS would set the payment amount to the ASP for that drug.

The IPI target prices would apply to certain Part B drugs furnished in selected geographic areas. CMS indicates that it intends to select geographic areas that account for about 50 percent of Part B drug spending. In those areas, the model would be mandatory for physicians and outpatient hospitals; they would be required to acquire Part B drugs that they furnish to Medicare FFS beneficiaries through IPI vendors. CMS indicates it would phase in the group of products included in the model over time, focusing first on single-source drugs and biologics. The agency states that it could begin by including most of the products that appeared in the ASPE report, which accounted for over 50 percent of Part B drug charges in 2017.[5]

Under the IPI model, Medicare would pay the vendor for Part B drugs at the payment rate established based on the international target price. Vendors would negotiate with manufacturers over their own acquisition costs for drugs, but those negotiations would not affect Medicare payment rates. The vendor's negotiated price would determine if the vendor made a profit or loss given the Medicare payment rate established by CMS. The advance notice mentions the potential for IPI model vendors to pursue indication-specific pricing or outcomes-based arrangements but does not mention pharmacy management tools such as a formulary, step therapy, or prior authorization. [6]

Comment: Model feasibility

Certain aspects of the IPI model may hamper its feasibility. For the IPI model to be viable, vendors would need to be able to purchase drugs from manufacturers at prices within the Medicare payment amount. With the Medicare payment amount being lowered to levels closer to international prices, the vendor would need to be able to negotiate substantial discounts. However, the absence of traditional pharmacy management tools such as a formulary, step therapy, and prior authorization would limit vendors' negotiating leverage. Although the advance notice suggests the potential for vendors to pursue indication-specific pricing or outcomes-based contracts, those approaches are relatively new and are unlikely to yield price concessions of the scale contemplated

[3] Assistant Secretary for Planning and Evaluation. 2018. *Comparison of U.S. and international prices for top Medicare Part B drugs by total expenditures.* Washington, DC: ASPE.
[4] Countries that CMS is considering including in the IPI are: Austria, Belgium, Canada, Czech Republic, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Japan, Netherlands, and the United Kingdom.
[5] Assistant Secretary for Planning and Evaluation, op cit.
[6] In remarks at an October 26, 2018 event hosted by the USC-Brookings Schaeffer Initiative for Health Policy, the Secretary of the Department of Health and Human Services stated that the IPI model would not include formularies. https://www.brookings.edu/wp-content/uploads/2018/10/es_20181026_hhs_medicare_transcript.pdf.

in the IPI model. The advance notice does not mention placing any requirements on manufacturers concerning the prices they offer IPI vendors for their products. Absent strong management tools or requirements on manufacturers, it is unclear how vendors would achieve price reductions in line with IPI target prices.

The advance notice does not explicitly discuss whether a vendor would be obligated to supply a drug if it were unable to purchase the drug at the IPI target price. One potential interpretation of the advance notice is that IPI vendors would not have to furnish a product if it is not financially viable (i.e., the vendor's purchase price is greater than the IPI target price), which would mean that manufacturers would have to reduce their prices if they wanted their products to be available to beneficiaries in model areas. If this were the policy, it would give vendors strong negotiating leverage with manufacturers, but it could result in some products being unavailable in model areas and lead to concerns about differences in access to care between model areas and the rest of the country. An alternative interpretation of the advance notice is that vendors must offer all drugs included in the IPI model even if the vendor could not purchase the product for Medicare's payment rate. Under such a policy, vendors would face substantial financial risk but would have limited negotiating leverage with manufacturers, which could make it difficult to attract vendors to the model. Vendor participation was a challenge CMS faced under the prior CAP program. CMS should clarify the agency's intention on this point in any subsequent proposals or rulemaking concerning the IPI model.

In contrast, in the DVP model, Medicare's drug payment rates would be based on the prices DVP vendors negotiate with manufacturers. To give DVP vendors negotiating leverage, vendors would be permitted to use management tools such as a formulary (with an exceptions process), step therapy, and prior authorization. Given that negotiating leverage is particularly challenging for drugs with limited competition (e.g., the first drug in a therapeutic class or drugs that offer clinical advantages over existing drugs), the Commission's recommendation for a DVP model also included binding arbitration as a tool that could be used for high-cost drugs with limited competition. In such cases, binding arbitration could be used to encourage drug manufacturers to negotiate with DVP vendors (to avoid going to arbitration) or serve as a means to arrive at an agreed upon price if negotiations fail. In addition, because manufacturers may not necessarily want to participate in a vendor model that would lead to lower prices for their products, the DVP model included a requirement that manufacturers must offer drugs to the DVP vendor for a price no greater than ASP in order for the manufacturer's drugs to be covered by Medicare. We would encourage CMS to consider incorporating these types of approaches to give vendors greater negotiating leverage.

Comment: Stakeholders' concerns about international reference pricing

If designed effectively, a model that benchmarks a drug's payment rate to international prices that are lower (on average) may initially result in lower drug spending.[7] However, over the years, numerous stakeholders—health economists, drug and device manufacturers, and other organizations—have raised issues and concerns about the use of international reference pricing (IRP).

[7] Persson, U. and B. Jonsson. 2016. The end of the international reference pricing system? *Applied Health Economics and Health Policy* 14, vol. 1: 1–8.

- *Transparency of a drug's transaction price across countries.* Accurate measurement of transaction (net) prices is increasingly problematic due to the growing use of confidential rebates and other risk- and cost-sharing measures between manufacturers and payers/countries. Indeed, such confidential (off-invoice) rebates may be preferred by manufacturers to reductions in list prices, which would spill over to countries through IRP.[8] Manufacturers may design and implement pricing and marketing strategies to counteract the effects of IRP.[9] For example, manufacturers can list high prices in reference countries while providing those countries with confidential rebates or discounts. Because off-invoice rebates and other confidential agreements are not reflected in (publicly) available drug prices, payers may ultimately reference inaccurate higher prices.[10] Docteur argues that IRP may inflate manufacturers' list prices.[11] In the study that accompanies the advance notice, ASPE acknowledges that using list prices in its analysis may not accurately reflect the actual amount paid in the U.S. and in other countries, which may bias its results due to differences across countries in the use of after-sale discounts (and other policies) that are not reflected in the manufacturers' list price.[12]
- *Prices from existing data sources are not measured consistently.* Toumi and colleagues state that comparing prices across countries is difficult because available pricing data are varied. For example, pricing data could vary depending on whether they reflect the pharmacy's purchasing price, pharmacy's retail price, or the manufacturer's list price. Adjusting heterogeneous prices can be problematic.[13] In its report, ASPE states that some countries' data are collected at the hospital level, while other countries' data are collected at a higher level such as the wholesale level.[14]
- *Difficulty in identifying the same product across countries.* Manufacturers sometimes launch the same products in different countries using different commercial names, pharmaceutical formulations, dosages, and vial and pack sizes.[10] Indeed, marketing non-identical products may be a technique used by manufacturers to counteract the use of IRP.[15] Thus, IRP may promote minor product differentiation (with no therapeutic advances)

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[8] These include product-specific rebates and broader provisions for price rollbacks or rebates if drug expenditures exceed targets. Danzon, P. M. 2018. Differential pricing of pharmaceuticals: Theory, evidence and emerging issues. *PharmacoEconomics* 36, vol. 12: 1395–1405.
[9] Espin, J., J. Rovira, and A. O. de Labry. 2011. *WHO/HAI project on medicine prices and availability. Working paper 1: External reference pricing.* World Health Organization and Health Action International.
[10] Young, K. E., I. Soussi, and M. Toumi. 2017. The perverse impact of external reference pricing (ERP): A comparison of orphan drugs affordability in 12 European countries. A call for policy change. *Journal of Market Access & Health Policy* 5, vol. 1: 1–11.
[11] Docteur, E. 2008. Value for money and valued innovation: A trade-off or mutually compatible goals? Presented at Organisation for Economic Co-opertion and Development high-level symposium on pharmaceutical pricing policy. October 27. https://www.oecd.org/els/health-systems/41593281.pdf.
[12] Assistant Secretary for Planning and Evaluation, op cit.
[13] Toumi, M., C. Remuzat, A-L. Vataire, et al. 2014. *External reference pricing of medicinal products: Simulation-based considerations for cross-country coordination.* European Union. https://ec.europa.eu/health/sites/health/files/healthcare/docs/erp_reimbursement_medicinal_products_en.pdf.
[14] Assistant Secretary for Planning and Evaluation, op cit.
[15] Docteur, op cit.

across markets. ASPE acknowledges that products available in the U.S. do not always align with products available in other countries.[16]

Vendors' role and providers' process of obtaining drugs

Under the IPI model, the vendor would take title to Part B drugs, but not necessarily hold physical possession of the product. Vendors would be responsible for ensuring those drugs are supplied to providers for treatment of Medicare FFS beneficiaries. CMS states that vendors would have the flexibility to offer innovative delivery mechanisms and distribution arrangements such as electronic ordering, frequent delivery, onsite stock replacement programs, and other technologies. Under the IPI model, vendors would compete to supply drugs to providers. Vendors would charge providers distribution fees for their services. Providers could work with multiple vendors for different drugs and change vendors.

Comment

Experience with the prior CAP model was challenging in part because vendors were required to take title to drugs and ship them to providers. One of the reasons physicians were reluctant to enroll in the CAP was concern about the process and burden of ordering drugs from vendors and the need to keep CAP inventory separate from that of other patients. The IPI model would seek to address those challenges. Although IPI vendors would take title to drugs, unlike the CAP, IPI vendors could facilitate the distribution of drugs to providers through more flexible mechanisms. This is an improvement over the original CAP design. Nevertheless, questions remain about whether such an approach could be nimble enough to respond to changes in treatment plans that occur on the day of an office visit, so as to not disrupt clinical care and to minimize wastage. Also, the IPI approach may complicate program oversight. Medicare would need effective processes in place to ensure that payments to vendors for drugs are appropriate—meaning drugs were administered to FFS beneficiaries for medically reasonable and necessary indications—while also ensuring the processes would not delay Medicare payment to vendors. If post-payment review were used in the IPI model, there would be the question of which entity—the vendor (who was paid by Medicare for the drug) or the provider (who administered the drug)— would be liable for the cost of any drugs later determined to be noncovered, and how that repayment process would work.

The Commission believes the DVP approach would present fewer logistical challenges and risks for providers. Under the DVP model, providers would take title to drugs as they do today. DVP vendors would be responsible for negotiating prices with manufacturers and making those prices available to providers through a network of distributors and wholesalers. DVP vendors would not ship product to beneficiaries. Instead, providers would order drugs from distributors or wholesalers at the vendor-negotiated price for FFS beneficiaries and Medicare would pay those providers for the drugs at the same DVP-negotiated price. Permitting providers to order drugs in the marketplace would give providers control over their inventory and the ability to be sure they are positioned to treat patients with a last-minute change in regimen.

[16] Assistant Secretary for Planning and Evaluation, op cit.

The DVP vendor model also differs from the IPI model in that it would require providers who choose to enroll to select a single vendor, while the IPI model would permit providers to work with multiple vendors. The Commission believes there are several advantages to having each provider select a single vendor. For management tools to be effective, providers must work with a single vendor for all products used to treat the same condition. Otherwise, providers could bypass a vendors' management tools (such as a formulary or step therapy) by seeking product from another vendor. Requiring providers to select one vendor also enhances vendors' negotiating leverage with manufacturers because it gives the vendor certainty about the size of the population for which it is negotiating.

New flat payment amount to replace current 6 percent add-on

Under the IPI model, Medicare would pay vendors instead of providers for Part B drugs. CMS is considering creating a fixed drug add-on for the purposes of holding providers harmless "to the greatest extent possible" with respect to the 6 percent add-on to ASP currently paid for Part B drugs. CMS indicates the add-on would be a set amount per drug per encounter or per month. CMS states that the add-on amount might vary by class of drug, physician specialty, or physician practice. In constructing this set payment amount, the agency would estimate the aggregate dollars associated with the 6 percent add-on without accounting for the effect of the current law budget sequester, which would represent an increase in drug add-on payments to providers compared to current law.

Comment

The Commission does not support CMS's proposal to create a drug add-on payment within the IPI vendor model for the purposes of holding providers harmless with respect to the 6 percent ASP add-on. While we agree a benefit of a vendor model is that it would move away from paying a 6 percent add-on for Part B drugs, we do not believe there is a need to create a new drug add-on payment as part of a vendor model. As the Commission discussed with respect to the DVP, when moving to a vendor type model where providers no longer earn a percentage add-on for Part B drugs, it will be important to review Medicare's payment rates for drug administration services to ensure that the inputs used to set those rates are accurate and reflect the cost of administering drugs. Creating an add-on payment for the purposes of holding providers harmless would not be consistent with the principle of setting payment rates at a level that reflects actual costs. The ASP plus 6 percent add-on policy was first developed to pay physicians for the cost of drugs that they purchase directly and administer in their offices. While the intent of the 6 percent add-on policy was never articulated, if its purpose was to address drug acquisition price variation across physicians, the rationale for such add-on payments is diminished—if not eliminated entirely—under a vendor model. To the extent that CMS believes there are costs associated with drug administration that are not currently reflected in the drug administration payment rates, CMS should use existing processes to evaluate the adequacy of those payment rates as it does for all physician services.

Bonus pool or shared savings

CMS seeks comment on whether the IPI model should include a bonus pool that would give providers bonus payments for prescribing lower-cost drugs or practicing evidence-based utilization.

Comment

The Commission supports the inclusion of shared savings in a vendor model, a concept similar to a bonus pool, to give providers an incentive for delivery of efficient, high-quality care. An essential part of the DVP model is shared savings for providers. Shared savings have the potential to engage providers in managing the total cost of Part B drugs (i.e., the choice of product, the duration of treatment, and the appropriateness of treatment), thereby creating incentives for more efficient care. Provider eligibility for shared savings could also be contingent on quality performance. For example, one option would be to condition providers' receipt of shared savings on their use of clinical guidelines or pathways.

Conclusion

Reducing the prices Medicare pays for drugs is a crucial priority for the Medicare program. High prices translate into unnecessary added costs borne by beneficiaries and taxpayers, and contribute to concerns about the sustainability of the Medicare program. The IPI model represents an important effort by CMS to bring down the prices Medicare pays for drugs. Although we have concerns that certain aspects of the IPI model's design hamper its feasibility, we commend CMS's efforts and encourage the agency to continue to pursue policies aimed at achieving our shared goal of obtaining the best value possible in Medicare's payment systems for drugs.

The Commission values the ongoing cooperation and collaboration between CMS and our staff on technical policy issues. We look forward to continuing this productive relationship. If you have any questions, or require clarification of our comments, please feel free to contact James E. Mathews, the Commission's Executive Director, at 202-220-3700.

Sincerely,

Francis J. Crosson, M.D.
Chairman

Attachment: Comparison of DVP and IPI models

	MedPAC Drug Value Program (DVP)	CMMI International Pricing Index (IPI) Model

Mandatory or voluntary for providers*	• Voluntary for physicians and outpatient hospitals
	• Enrollment encouraged by:
	  • reducing ASP add-on in buy-and-bill system
	  • offering shared savings for providers
		• Mandatory for physicians and outpatient hospitals located in demonstration areas; may consider other providers (e.g., ASCs). Comment sought on whether there should be criteria for excluding certain providers.
		• Randomized design based on geography by CBSA or aggregation of CBSAs. Demonstration to cover geographic areas that account for 50% of spending.

Number of vendors	Small number of national vendors	At least 3 national vendors
Provider choice of vendor	Provider chooses only 1 vendor	Provider can enroll with multiple vendors
Medicare Part B drug payment rate under model	DVP-negotiated price, not to exceed 100% ASP	• CMS sets drug payment rate based on international target prices**, not to exceed 100% ASP. ASPE estimates U.S. prices are approximately 80% higher than international prices for a group of drugs and countries. CMS intends to reduce Medicare payment rates for drugs included in the model over a 5-year period to reach an international target price that would amount to about a 30 percent decrease in spending. • Vendor negotiates its own acquisition price for drugs, but that does not affect Medicare payment rate
Potential management tools	• Formulary • Step therapy • Prior authorization • Binding arbitration • Indication-based pricing • Outcomes-based contracts	• Indication-based pricing • Outcomes-based contracts

Attachment: Comparison of DVP and IPI models

	MedPAC Drug Value Program (DVP)	CMMI International Pricing Index (IPI) Model
Who takes title to drug	*Provider:* Provider continues to buy drugs in the marketplace but at the DVP-negotiated price	*Vendor:* Vendor takes title to the drug and facilitates providers' access to the drug through more flexible means than prior CAP model
Medicare payment rate to providers	• *Drug:* DVP-negotiated price • *Admin:* PFS/OPPS drug administration payment rate	• *Drug:* No payment • *Admin:* PFS/OPPS drug administration payment rate • *New:* Flat add-on payment (per encounter or per month) aimed at keeping providers whole relative to the prior 6% (without sequester)
Provider shared savings	Yes. Provider would be eligible for shared savings if DVP reduced total cost of Part B drugs and provider met quality metrics.	Uncertain. CMS seeks comment on whether model should include bonus pool.
How vendor is paid	• Administrative fee from CMS not tied to volume of drug spending • Vendor eligible for shared savings if total cost of Part B drugs reduced by DVP and vendor met quality standards	• Vendor keeps any spread between the Medicare payment rate and vendor's drug acquisition cost • Distribution fees paid by providers • Potential manufacturer fees • Comment sought on whether CMS should pay vendor an administrative fee
Beneficiary cost sharing	Beneficiaries pay lower cost sharing based on DVP-negotiated prices	Beneficiaries pay lower cost sharing based on the IPI model target price
Who collects beneficiary cost sharing for drug	Provider collects and retains drug cost sharing	• Provider collects drug cost sharing • Cost sharing collected by providers goes back to Medicare program
Requirements for manufacturers	Manufacturer required to offer DVP vendor drugs at a price no greater than 100% of ASP for manufacturer's drugs to be covered by Medicare	CMS considering requiring manufacturers to report international prices to CMS

Attachment: Comparison of DVP and IPI models

	MedPAC Drug Value Program (DVP)	CMMI International Pricing Index (IPI) Model
Phase-ins	• Phase-in reduction in ASP add-on in buy-and-bill system from 6% to 3% over 3 years • *Phase in drugs:* First focus on subset of drugs with largest savings potential and most straightforward to implement	• Model phases in the price reductions over time to reach a 30 percent spending reduction in 5 years • *Phase in drugs:* First focus on single source drugs and biologics with high spending and available international data and broaden over 5 years

Note: CMMI (Center for Medicare & Medicaid Innovation), ASP (average sales price), ASC (ambulatory surgical center), CBSA (core based statistical area), ASPE (Assistant Secretary for Planning and Evaluation), CAP (competitive acquisition program), IPI (international pricing index), PFS (physician fee schedule), OPPS (outpatient prospective payment system).

*The term "provider" is used to refer to physicians and outpatient hospitals.
**The countries included in determining the international price index are Austria, Belgium, Canada, Czech Republic, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Japan, Netherlands, and the UK. According to CMS, these countries have economies comparable to the U.S. or they are included in Germany's market basket for reference pricing, and their existing data sources contain pricing information.

Source: CMS advance notice of proposed rulemaking 2018. Medicare Payment Advisory Commission. 2017. *Report to the Congress: Medicare and the health care delivery system.* Washington, DC: MedPAC. Assistant Secretary for Planning and Evaluation. 2018. *Comparison of U.S. and international prices for top Medicare Part B drugs by total expenditures.* Washington, DC: ASPE.