



APhA

AMERICAN PHARMACISTS ASSOCIATION
Improving medication use. Advancing patient care.

December 31, 2018

[Submitted electronically via www.regulations.gov]

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services (CMS)
U.S. Department of Health and Human Services (HHS)
Attention: CMS-5528-ANPRM
P.O. Box 8013
Baltimore, MD 21244-8013

**Re: Medicare Programs: International Pricing Index Model for Medicare Part B Drugs
CMS-5528-ANPRM [ID: CMS-2018-0132-0001]**

Dear Administrator Verma:

APhA is pleased to submit comments to CMS's advance notice of proposed rulemaking (ANPRM) to solicit public comments on potential options for testing changes to payment for certain separately payable Part B drugs and biologicals. APhA, founded in 1852 as the American Pharmaceutical Association, represents 62,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, hospitals, long-term care facilities, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and the uniformed services.

APhA strongly supports patient access to affordable and cost-effective medications and appreciates HHS's continued efforts to look at ways to improve efficiencies and reduce patients' rising prescription drug costs by reforming current Medicare reimbursement models. As CMS notes in the ANPRM, many Part B medications are expensive, making it difficult for providers, including pharmacies, particularly those which are small, to float the inventory expense of these products for an extended period. In addition, it is administratively burdensome for pharmacists and pharmacies to obtain reimbursement for the Part B drugs they are able to provide, and reimbursements often fail to cover the actual cost of the product. As a result, patient access to many of these needed Part B medications is hindered because pharmacies cannot provide many of these products due to inadequate reimbursement and often undergo a complicated and time-consuming audit process requiring dozens of pages of documentation. APhA appreciates CMS testing any new model before implementing this policy more broadly but has some concerns with the proposed IPI model and offers the following comments.

General Concerns

The proposed IPI model uses vendors to negotiate drug prices, which resembles the role that pharmaceutical benefit managers (PBMs) play in Medicare Part D, Medicaid and commercial plans. In multiple recent proposals CMS has pointed out certain PBM practices negatively impact Medicare beneficiary costs, care and access.¹ Additionally, the Administration has recently highlighted the negative consequences of adding an extra negotiating layer in drug coverage/ pricing, stating "...hidden negotiation and wealth transfer between drug manufacturers and PBMs is now a direct increase on consumer out-of-pocket spending that likely decreases drug adherence and health outcomes."² Therefore, we caution against creating another system to negotiate drug prices on behalf of the Medicare program, particularly as Congress, HHS and CMS are trying to solve existing problems with this policy.

While APhA is pleased CMS plans to "...monitor drug utilization carefully throughout the model to ensure beneficiary access to drugs is not compromised," we foresee some providers needing to increase their patient volume to make up for any lower reimbursement. This could result in additional access issues as providers consolidate or relocate to more populated geographical areas. In addition, the proposed IPI model may further incentivize the creation of narrow distribution networks, whereby manufacturers contract with select providers and limit patient access and choice.

Model Concept Design and Vendor Selection Pg. 54550 - 54552

The ANPRM asks for feedback on "what limitations would be in place on the entities that could participate as vendors (e.g. pharmacies, manufacturers, providers themselves)?" CMS specifically asks for feedback to the question "[s]hould any vendor be required to provide services on a national basis?" As CMS likely understands, not all potential vendor participants have the resources necessary to fulfill the vendor role on a national basis. If required to operate nationally and/ or if the number of vendors are restricted, the pool of entities who could participate will be smaller, limiting competition and the potential for innovation. APhA recommends CMS leverage competition by not restricting the number and type of entity that can qualify as a vendor or limiting to those who can operate on a national basis.

Model Geographic Areas Pg. 54553

As mentioned in the ANPRM, CMS is "...considering using CBSAs (Core Based Statistical Areas) as the primary unit of analysis in the model." CMS also states one of the "...main factors that need to be considered when selecting geographies for the model: (1) The most appropriate geographic unit (ZIP code, county, core based statistical area, state, etc.) that reflects how care is delivered in markets." As CMS works to redefine the selected model

¹ CMS. Medicare Program; Contract Year (CY) 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program. Proposed Rule. November 27, 2017. Available at: <https://www.regulations.gov/document?D=CMS-2017-0156-0046>. Also, See CMS. Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out of Pocket Expenses. Proposed Rule. November 30, 2018. Available at: <https://www.regulations.gov/document?D=CMS-2018-0149-0002>.

² HHS. American Patients First - The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs. May 2018. Available at: <https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf>

geographic areas, we suggest the agency consider state-wide competitive areas. Because most potential vendor participants are licensed on a state level; it makes sense to include state-wide acquisition areas in any model test. A state-based system would not prevent bidders who wish to provide drugs in multiple regions or nationwide from submitting multiple bids to do so.

Potential Alternative to the ASP Add-On Pg. 54553

APhA appreciates CMS's sensitivity regarding adding administrative burden to model participants and the financial burdens associated with furnishing Part B drugs. However, as noted in the ANPRM, current ASP reimbursement does not cover provider costs for certain Part B medications. APhA cautions against efforts to simply lower reimbursement payments as this will only exacerbate many of the problems in the current system. APhA urges CMS, when addressing drug pricing, to make certain the reimbursement of the product is separate from the reimbursement of any related service. In addition, as treatments become increasingly complex and expensive, the Medicare program needs to invest in better medication management services, to ensure these costly medications are appropriate and taken/ used correctly.

Requests for Feedback and Information Pg. 54555

If CMS moves forward with the IPI model, APhA recommends CMS first thoroughly test the model before determining whether to expand it, including to "...multiple source drugs and drugs provided in other settings." In the ANPRM, CMS also states the agency "...seek[s] comment as to whether aspects of mandatory participation would require physicians and hospitals to have an agreement with a single vendor or would require physicians and hospitals to obtain all drugs included in the model via a single vendor." As previously mentioned, APhA recommends CMS leverage competition by not restricting the number and type of entity that can qualify as a vendor or limiting to those who can operate on a national basis. Basic economic theory suggests if mandatory participation would require model participants to use/ obtain all drugs in the model via a single vendor such anti-competitive action would remove the ability to utilize competition to reduce costs and potentially impact patient access to necessary Part B medications.

Finally, APhA wants to underscore the need for CMS to look comprehensively at Medicare expenditures when evaluating the cost effectiveness of any new payment or delivery model. Because of the fragmentation of the Medicare program (i.e., Part A, Part B, Part C, Part D), in order to truly assess the effect of any new Part B drug payment model on cost, CMS needs to include the impact these models will have on hospitalizations and/ or Part D drug expenditures. Unless the cost and outcomes of all parts of the Medicare program are included in the evaluation of these new pricing models, CMS will have an incomplete valuation and may falsely attribute savings.

We appreciate CMS's continued work to spend health care dollars more cost-effectively for the benefit of the Medicare Program and its beneficiaries. As CMS moves forward, we hope you will use APhA as a resource. Thank you again for the opportunity to provide information on this important issue. If you have any questions or require additional information, please contact

Michael Baxter, Director of Regulatory Affairs, at mbaxter@aphanet.org or by phone at (202) 429-7538.

Sincerely,

A handwritten signature in black ink that reads "Thomas E. Menighan". The signature is written in a cursive, flowing style.

Thomas E. Menighan, BSPHarm, MBA, ScD (Hon), FAPhA
Executive Vice President and CEO

cc: Stacie S. Maass, RPh, JD, Senior Vice President, Pharmacy Practice and Government
Affairs
The Honorable Alex Azar, Secretary, HHS
John O'Brian, PharmD, Senior Advisor to the Secretary for Drug Pricing Reform