



Sound Policy. Quality Care.

Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

December 4, 2018

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

To Whom It May Concern:

The Alliance of Specialty Medicine (the "Alliance") represents more than 100,000 specialty physicians from thirteen specialty and subspecialty societies. The Alliance is deeply committed to improving access to specialty medical care through the advancement of sound health policy.

On October 25, 2018, the Department of Health and Human Services issued an Advance Notice of Proposed Rulemaking (ANPRM), outlining its plans for a demonstration project entitled "International Pricing Index Model (IPI)," which is intended to change the way Medicare pays for Part B drugs. The demonstration project will be administered by the Innovation Center, with an intended duration of 2020-2025, following a proposed regulation in 2019. Participation will be mandatory for physicians in randomly selected geographic areas. The agency's goal is to capture half of Medicare Part B spending on separately payable drugs.

The Alliance of Specialty Medicine thanks the Administration for its attention to drug pricing. While the Alliance supports the goal of reducing drug prices, *we are concerned about the demo as currently conceptualized because we fear it would lead to increased complexity in Part B drug acquisition and shift costs to physicians in Part B. Further, we are concerned about procedural shortcomings in the form of mandatory physician participation and the proposed scope of the project.* These concerns are explained in more detail below.

There are many components to the demonstration and we will limit our comments to the following aspects: (1) scope and size of the proposed demo; (2) third party vendors; (3) the average sales price (ASP) add-on; and (4) protection of access and quality for patients. We have organized our comment in this order. We hope this feedback is helpful to you and we welcome the opportunity to discuss it further or answer any questions you may have.

I. Scope and Size of the Proposed Demonstration

Physician participation in the demo would be mandatory for physicians located in the randomly selected geographic areas. This is a disappointing departure from this Administration's move to put guardrails around Innovation Center demonstration projects. In its "New Directions" Request for Information (RFI), the Innovation Center noted that it would "focus on voluntary models" and "smaller scale models."¹ A demonstration project covering half of Part B expenditures on

¹ <https://innovation.cms.gov/Files/x/newdirection-rfi.pdf>.

separately payable drugs with mandatory participation for physician and hospitals does not meet those standards. *The Alliance opposes mandatory physician participation and urges the Administration to allow physicians to opt out.*

II. **Third Party Vendors**

The demo would allow private-sector vendors to negotiate prices for and take title to drugs. Medicare would pay the vendor for the included drugs based on a formula that is intended to align Medicare payment more closely with international prices, with the ultimate goal of a 30% reduction in spending for included products.

Physicians and hospitals in the model would select their vendor(s). At a minimum, model participants would engage with one vendor, but the agency encourages participants to engage with multiple vendors as their needs require. While the vendors must take legal title to the products, the agency will allow for innovative distribution channels in terms of physical possession of the medicines. Additionally, the agency will allow participants to change vendors. As the agency acknowledges, being “locked into” a solitary vendor was one of the major failings of the short-lived Competitive Acquisition Program, so we thank the agency for allowing this freedom in vendor choice and quantity. However, we have many remaining questions and concerns related to how these third party vendors would operate that we hope the agency will take into consideration as it promulgates a proposed rule.

First, we are concerned that physicians will be required to pay the vendor(s) a fee to “continue to pay for certain distribution costs.” Under the current buy-and-bill system for Part B drug acquisition, physicians generally do not pay specialty pharmacies for distribution costs. To the extent those fees exist, they are paid by manufacturers. As such, this proposed fee would be a new financial burden for physicians. Additionally, we are concerned about the potential growth in such fees year-over-year, especially given the agency’s goal of drastically shrinking the “pool” based on which the add-on payment for physicians will be calculated. (See below for more detail.) This could lead to a situation where, eventually, the outgoing fees to be paid are larger than the incoming revenue stream intended to cover the fees. *We oppose any policy or program requirement that requires physicians to pay a fee to third-party vendors, or otherwise requires physicians to be financially responsible, for costs associated with distribution of Part B medicines.*

Second, physicians would remain responsible for collecting beneficiary cost-sharing, including billing supplemental insurers. The agency is considering an “administrative approach that deducts the cost-sharing amounts from Medicare payments made for other services to the model participants.” This seems to run counter to the goal of taking financial risk off the physician by introducing third party vendors. It would also punish a physician for a beneficiary’s or supplemental insurer’s failure to pay by reducing the physician’s Medicare payment for potentially unrelated services. This seems misaligned and *we urge CMS to make vendors responsible for cost-sharing collection.*

The ANPRM asks whether physicians should receive bad debt payments in the event that beneficiaries do not pay. *If the demo in its final iteration does keep the burden of cost-sharing collection on the physician, we strongly urge the agency to consider providing bad debt payments to physicians who cannot collect cost-sharing amounts* from beneficiaries or supplemental insurers.

Third, the agency notes that it wants to allow for flexibility, both in terms of distribution approaches and in terms of who can be a vendor. The ANPRM states that a group of physicians could be a vendor, and we support that concept. However, we are concerned that CMS is considering requiring national participation of any vendor in the demo. We urge CMS to allow the flexibility of physicians and physician groups to become vendors, even if they only wish to serve their own practice or their own geographic region. Most physician groups will not have the capacity to act as a nationwide vendor and a requirement to do so may effectively freeze out physicians from participating as vendors. We urge CMS to allow physician groups to act as vendors without a requirement to serve nationwide.

Finally, it is our understanding that vendors would not be engaging in any type of utilization management. We strongly support such a prohibition, as prescribers and patients have had negative experiences with utilization management imposed by third parties in Part D. We should not replicate this system in Part B. We urge CMS to clearly and unequivocally state in any proposed and final rule that vendors will be prohibited from imposing any utilization management. We further urge CMS to devise an enforcement mechanism for vendors who violate this prohibition.

III. Average Sales Price Add-on

HHS proposes to phase down the Medicare payment amount for selected Part B drugs to more closely align with prices paid by other developed nations. CMS will phase in a “Target Price” over the five years of the demonstration as a blend of ASP and the Target Price. Over time, the goal is to achieve a 30% reduction in Medicare spending for included drugs.

Currently, physicians are reimbursed at ASP plus 6%, which was made 4.3% by sequestration. HHS plans to move away from a percentage-based add-on, toward a set payment amount structure. For demo participants, CMS would calculate what it would have paid in the absence of the model, before sequestration, and redistribute this amount to model participants based on a set payment amount. This “pool” of money to be distributed would be based on the most recent year of ASP data available. Thus, if the demo is successful, over the five years, the pool would shrink significantly. This is concerning as the cost of administration, which is one of the things intended to be covered by the add-on payment, will not shrink. The Alliance opposes the agency’s proposed add-on payment policy because it will eventually leave physicians underwater with regard to administration costs, especially if physicians will be expected to cover distribution costs as well.

The agency is considering creating a bonus pool, where model participants would achieve bonus payments for prescribing lower-cost drugs or practicing evidence-based utilization. We have consistently objected to the assumption that physicians prescribe more costly medicines due to the ASP percentage add-on. The agency is suggesting that physicians will allow their clinical judgment and treatment decisions to be influenced by the potential to receive a bonus payment. Again, the Alliance finds this highly objectionable. As for evidence-based utilization, that must be defined by the relevant specialty itself through clinical guidelines, which many societies already have in place.

IV. Quality and Access

CMS is interested in establishing several categories of quality measures to ensure quality and access for beneficiaries, specifically related to: patient experience measures, medication management measures, medication adherence, and measures related to access and utilization. We strongly support the inclusion of quality measures developed by the relevant specialty societies

in any demonstration project involving Part B medicines. Furthermore, we urge the agency to ensure there is a robust, real-time access monitoring program to ensure that beneficiary access is not compromised.

In sum, the Alliance has significant concerns about the proposed demonstration moving forward as described in the ANPRM. We urge the Administration not to move forward with a proposed rule until these concerns are addressed. At a minimum, we urge the Administration to follow the Innovation Center guardrails described in its “New Directions” document, and make the demonstration voluntary and smaller scale.

Thank you for your consideration of these comments. Please do not hesitate to contact any of the undersigned organizations, should you have questions or require follow-up information.

Sincerely,

American Association of Neurological Surgeons
American College of Mohs Surgery
American College of Osteopathic Surgeons
American Gastroenterological Association
American Society of Cataract and Refractive Surgery
American Society for Dermatologic Surgery Association
American Society of Plastic Surgeons
American Society of Retina Specialists
American Urological Association
Coalition of State Rheumatology Organizations
Congress of Neurological Surgeons
Society for Cardiovascular Angiography and Interventions