

December 31, 2018

The Honorable Seema Verma Administrator
Centers for Medicare & Medicaid Services Attn: CMS-1701-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD. 21244-8013

RE: Advance Notice of Proposed Rulemaking: International Price Index Model for Medicare Part B Drugs; CMS-5528-ANPRM

Dear Administrator Verma:

On behalf of Prevent Blindness and the millions of people of all ages whom we represent across the country who live with low vision, vision impairment, and vision-related eye diseases, we appreciate the opportunity to respond to the Centers for Medicare & Medicaid Services' (CMS') Advance Notice of Proposed Rulemaking (ANPRM) titled, "International Price Index Model for Medicare Part B Drugs" (the IPI Model) [RIN 0938-AT91]. We look forward to working with CMS as it continues engaging patients in defining high-value, high-quality care and defining outcomes that matter to patients.

Introduction

Prevent Blindness is the nation's leading nonprofit, voluntary organization committed to preventing blindness and preserving sight. Prevent Blindness is first and foremost a public health organization. We strive to improve our nation's vision and eye health by enhancing state and community capacities through our core competencies of early detection, improved access to eye care, patient support, care coordination, public policy, research, advocacy, public awareness, and health education. As well, protecting and expanding access to sight-saving care is our priority for patients across the age continuum.

As part of the Administration's goal to lower the costs of drugs for Medicare beneficiaries, CMS is soliciting information from the public through this ANPRM on the feasibility of testing a payment scenario that would tie the amount Medicare pays for drugs under Medicare Part B to international price levels. Additionally, CMS is considering allowing private sector vendors to engage in drug pricing negotiations, and making changes to the drug add-on payment that would set a specific payment amount, thus leading to reduced costs to the Medicare program. In general, we share the Administration's goals of improving competition, better negotiation, lowering list prices, and reducing out-of-pocket costs for patients and we are committed to working with CMS in these endeavors. However, Prevent Blindness does not support policies that achieve savings if they negatively impact patient safety, quality of care, or timely access to care.

We recognize that this ANPRM is intended to seek information from relevant stakeholders before a proposed rule is released. However, many crucial details that could have a tremendous impact on access to treatments are absent from the direction provided in this ANPRM. **Therefore, our response to the forthcoming proposed rule will fully depend on how CMS addresses the missing elements and whether the proposal will restrict access to needed therapies for people who face vision loss and eye disease, including those who deal with vision impairment as a co-morbidity to a chronic illness.**

We reiterate that Prevent Blindness shares CMS' goal of curbing the rising cost of health care, including prescription drugs, and urge that any proposal to change aspects of the Medicare program keep the patient's best interests at the center. We support CMS's alternative to "buy and bill" that facilitates patient access and affordability by removing potentially perverse incentives for providers to prescribe more expensive therapies that may not offer additional patient benefit. However, as part of our comments to the key design considerations of this model, Prevent Blindness urges CMS to consider two overarching recommendations from the National Health Council related to drug pricing initiatives and CMMI demonstrations. As well, we cite our specific concerns with this model as they relate to patient access, depending on specific elements of the forthcoming proposed rule.

Prevent Blindness Recommendations

Patient Safeguards: In order to ensure the Administration's goals of increasing quality of care for beneficiaries, CMS must develop broad patient safeguards for all Medicare policies, including defined quality measures, and clearly articulate its process for monitoring and addressing access issues under this model. Most CMMI models to date have been designed to improve patient outcomes while reducing costs, and have incorporated sufficient patient safeguards to mitigate any risks associated with the testing of any model. The creation of the Oncology Care Model, for example, included measures assessing how service utilization, patient experience, and psychosocial assessment affect quality throughout the model. Models have also included beneficiary notification requirements and the opportunity for patients to opt out of demonstrations. Additional models under accountable care organizations tie patient outcomes to provider reimbursement, which enhances the potential for true care coordination, care management for the chronically ill, and patient engagement to occur under structures that are intended to increase quality and reduce costs. Additionally, layering multiple, large Medicare Part B programmatic changes could present unintended consequences of reducing access; thus, underscoring the need for patient safeguards.

In the forthcoming proposed rule, we urge CMS to consider and implement sufficient quality measures and other patient protections, and to articulate specific plans to monitor care delivery and quickly address patient access issues in a manner that does not create undue burden(s) to the patient, including lengthy appeals processes, facing a shortage of needed treatments, or increased cost-sharing mechanisms that are passed on to patients as a result of changes. For example, CMS should clearly define how it considers the availability of medicines – or lack thereof – or other access hurdles in international markets that are used for the IPI to ensure that prices are being compared on an "apples to apples" basis. As part of this process, we urge CMS to engage stakeholders **before** any proposed rule is released with a focus on defining how to avoid the potential for access impediments, particularly as it relates to ensuring patients are able to continue receiving existing treatment in a timely fashion as the model is rolled out.

Sharing Cost Savings with Patients: In the ANPRM for this proposal, CMS requested feedback on whether any savings from the proposed model should be passed on to beneficiaries. We appreciate the administration's repeated commitment to reducing out-of-pocket costs for Medicare beneficiaries. As such, Prevent Blindness recommends that any projected or realized cost savings should be shared with Medicare beneficiaries to reduce their out-of-pocket costs.

A major, common barrier for patients who face chronic conditions is a rise in out-of-pocket spending such as copayments, coinsurance, and high deductibles. Faced with exorbitant out-of-pocket costs to manage

serious conditions, patients who face vision impairment as a complication of chronic disease or as a comorbidity may often forgo critical sight-saving care at a point when it is needed most. We believe patients should be able to prioritize their vision and eye health, not as a complimentary or secondary component to overall health, but as a primary, holistic component of their own well-being. Ignoring serious complications to vision and eye health could lead to higher spending and increased utilization in the long-term. Sharing cost savings from this proposed model will ensure that patients not only see their out-of-pocket costs reduced, but will be empowered to manage their vision and eye health.

We strongly urge CMS to apply any projected and realized cost savings from proposals to reduce health care costs to beneficiary cost-sharing requirements to reduce out-of-pocket costs for our nation's seniors. However, we note one particular challenge with respect to differentiating those with supplemental insurance and those without. For those without supplemental insurance, cost-sharing presents a major barrier to access. For those with supplemental insurance, we are concerned those plans would receive the majority of cost savings without proactive attempts to create a mechanism to share savings with patients. **We reiterate our recommendation that cost savings be passed directly to the beneficiary's cost-sharing to reduce their out-of-pocket costs, and not circumvented through mechanisms that direct the savings to plans instead.** We ask that CMS address this challenge in drafting a proposed rule.

Prevent Blindness Concerns

Patient Guardrails: Under the proposed model, operational details would be determined through negotiated contractual arrangements between vendors and providers, and these contracts are required to include patient guardrails. CMS is seeking input on the agency's role in overseeing these contracts.¹ Prevent Blindness strongly objects to any CMMI model test for which patient protection guardrails are subject to negotiation between vendors and providers.

CMS, as steward of the Medicare program, has the responsibility to ensure that its model tests do not jeopardize patient health, safety, or access to needed medications. **CMS must serve an active role in overseeing relationships between those providing and facilitating care to Medicare beneficiaries and create guardrails to ensure and protect access. Furthermore, we urge CMS ensure uniformity of patient guardrails across any negotiated contract.** It is imperative that CMS take an active leadership role in regulating agreements in an ongoing and transparent fashion, specifying obligations to ensure access and safety, managing conflicts of interest, and developing appropriate and uniform guardrails in a manner that is transparent and allows for public input prior to the agreement taking effect.

Vendor Roles: One specific concern with this model is the role vendors might play in day-to-day treatment decisions. Vendor roles should be related to purchasing drugs from manufacturers and ensuring

¹ CMS notes that: "Agreements between the vendors and physicians/hospitals would establish the terms of their arrangements and would include appropriate guardrails to protect all parties, including beneficiaries and the Medicare program. CMS seeks feedback on whether CMS should be a party to and/or regulate these agreements, and whether the agreements should specify obligations to ensure the physical safety and integrity of the included drugs until they are administered to an included beneficiary, how drug disposition would be handled, and data sharing methods, confidentiality requirements, and potentially other requirements."

timely delivery to providers; their incentives and disincentives must be aligned with that role rather than with cost savings derived from decreased utilization or treatment selection. Prevent Blindness strongly opposes any intermediary vendors introducing formularies, utilization management tools, or any other mechanism that constricts access into this already-complex proposal.

Additionally, we have serious concerns that these agreements could be subject to a great deal of variability, both among vendors and between providers and provider types. This may create a greater level of complexity for patients who are seeing multiple providers, making it more difficult for them to navigate the system to seek appropriate care. We also expect that the highest-volume providers would have the greatest leverage to negotiate favorable terms, which could lead to further consolidation of medical practices. This consolidation could reduce competition, which may result in higher costs and fewer providers serving certain geographic regions.

Finally, we reiterate that the role of vendors should the proposal proceed further be related **only** to purchasing drugs from manufacturers and ensure timely, adequate access to patients. As written, this ANPRM seems to place vendors in the middle of clinical decisions that should only be made by providers with their patients as a result of potential formularies. Prevent Blindness believes that beneficiaries who face serious ophthalmic conditions that require complex treatments should have unburdened access to the Part B-covered drugs prescribed by their eye care provider and not determined by a vendor to which the patient had no approved role in his or her course of treatment. We urge CMS to protect the provider-patient relationship over the role of vendors should this proposed model move forward.

Provider Payments: CMS proposes to pay a fixed, add-on fee to providers that will be calculated to approximate the average add-on fee before sequestration [6% of average sales price (ASP)]. As previously stated, Prevent Blindness supports disassociating the price of medicines from provider payment, thus removing any potential influence on provider decision-making. Ideally, an add-on fee would be sufficient to enable physicians to administer the most medically appropriate Part B drugs without influencing the decision on which one.

Without detail on how add-on fees will be calculated, we are concerned that this attempt to remove incentives to prescribe high-cost/low-value care may create the opposite impact by incentivizing low-value care if it is less expensive for providers to administer. An ideal payment methodology would reward providers for administering care that is of highest treatment value to the patients who receive them. **CMS must carefully consider its methodology for determining provider payments to ensure any new proposal does not have the unintended consequence of incentivizing selection of low-value treatments.**

Cost-Sharing to Beneficiaries: Additionally, Prevent Blindness is concerned that the fixed add-on fee will actually increase beneficiary copayments for some patients receiving some Part B drugs. Without built-in protections for beneficiaries, the proposed model, and its use of averages, would leave some patients paying less and some paying more than they would pay absent the model. Further, the proposal does not specify whether vendor fees created by this model would be considered in the provider add-on payment and could potentially be passed on to patients through increased copayment. As previously stated, beneficiaries should share in savings projected or accrued in CMMI models and should not have an increased out-of-pocket cost. One way of moving toward achieving this would be to omit the provider add-on fee from beneficiary copayment calculations. Ultimately, we urge CMS to consider carefully the

potential ramifications of these proposals and ensure that vulnerable patients who face progressive vision loss are not capriciously subjected to increased costs as an unintended consequence of its proposals.

Conclusion

Once again, Prevent Blindness appreciates the opportunity to submit comments on the ANPRM. We stand ready to work with CMS and the Administration to develop a model that truly lessens the cost burden for patients and creates true access for those facing vision loss and eye disease. Please do not hesitate to contact Sara D. Brown, Director of Government Affairs, at (312) 363-6031 or email at sbrown@preventblindness.org if you or your staff would like to discuss these issues in greater detail.

Sincerely,



Jeff Todd
President and Chief Executive Officer
Prevent Blindness