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December 31, 2018

BY ELECTRONIC DELIVERY

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

Dear Administrator Verma:

The National Health Council (NHC) appreciates the opportunity to respond to the Centers for Medicare & Medicaid Services' (CMS') Advance Notice of Proposed Rulemaking entitled, "International Price Index Model for Medicare Part B Drugs" (the IPI Model). The NHC continues to support CMS in testing new models of care that align payment incentives with value and quality; engage patients in defining high-value, high-quality care; focus on outcomes that matter to patients; and facilitate efficient arrangements among stakeholders.

Founded in 1920, the NHC is the only organization that brings together all segments of the health community to provide a united voice for the more than 160 million people with chronic diseases and disabilities and their family caregivers. Made up of more than 125 diverse national health-related organizations and businesses, the NHC's core membership includes the nation's leading patient advocacy organizations, which control its governance and policy-making process. Other members include professional and membership associations; nonprofit organizations with an interest in health; and representatives from the pharmaceutical, generic drug, health insurance, device, and biotechnology industries.

Early last year, we released a set of proposals to reduce the costs of health care, including, but not limited to, the costs of prescription medicines.¹ The Administration's goals of improving competition, promoting better negotiation, lowering list prices, and reducing out-of-pocket costs are well-aligned with the NHC's priorities. We are committed to working with CMS on proposals to reduce costs, including Center for Medicare and Medicaid Innovation (CMMI) model tests, that promote high-value care, stimulate research and competition,

¹ Policy Recommendations for Reducing Health Care Costs. National Health Council. 2017. <https://www.nationalhealthcouncil.org/sites/default/files/NHC%20Policy%20Proposals%20for%20Reducing%20Health%20Care%20Costs%20UpdatedFINAL052217.pdf>.

and curb costs responsibly.² The NHC does not support policies that achieve savings if they negatively impact patient safety, quality, or access to care.

The NHC recognizes that this Advanced Notice of Proposed Rulemaking (ANPRM) is intended to seek information from relevant stakeholders before a proposed rule is released. Thus, many crucial details that could have a tremendous impact on access to treatments are absent. **Our response to the proposed rule will fully depend on how CMS addresses the missing elements and whether the proposal will restrict access to needed therapies for people with chronic diseases and disabilities.**

The NHC 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 at the center. We also support an 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, we have concerns with this proposal and offer three overarching recommendations related to drug pricing initiatives and CMMI demonstrations and two specific concerns with this model.

General Recommendations

- 1. CMS must develop broad patient safeguards for all Medicare policies, including quality measures, and clearly articulate its process for monitoring and addressing access issues.**

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 model tests. 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 notification requirements and the opportunity for patients to opt out of demonstrations. Additionally, the layering of multiple, large Medicare Part B programmatic changes could present unintended consequences, including reduced access.

We urge CMS to implement sufficient quality measures and other patient protections, and to articulate specific plans to monitor care delivery and quickly address patient access issues. For example, CMS should clearly define how it considers the availability of medicines – or lack thereof – in international markets that are used for the IPI to ensure that prices are being compared on an "apples to apples" basis. Additionally, clarity on how CMS considers rare disease populations in its models would be beneficial.

As part of this process, we urge CMS to engage patient organizations and other stakeholders before any proposed rule is drafted to define how to avoid the potential for access impediments, especially as it relates to ensuring patients continue to receive existing treatment in a timely fashion as the model is rolled out. This level of outreach should be conducted before any CMMI model is developed and implemented.

² Domains and Values: Reducing Health Care Costs for Patients. National Health Council. 2017.
<https://www.nationalhealthcouncil.org/sites/default/files/Health%20Care%20Costs%20Domains%20and%20Values%20FINAL.pdf>.

2. **Any projected or realized cost savings should be shared with Medicare beneficiaries to reduce their out-of-pocket costs.**

We appreciate the administration's repeated commitment to reducing out-of-pocket costs for Medicare beneficiaries. The NHC has conducted numerous listening sessions with our member patient advocacy organizations to determine what aspects of our health care system currently impede access to appropriate health care for the patients they serve. We found that one common barrier across all people with chronic conditions is a rise in out-of-pocket spending such as copayments, coinsurance, and high deductibles. These challenges are pervasive throughout our health care system, impacting people with both public and private health insurance coverage. In the ANPRM for this proposal, CMS requested feedback on whether any savings from the proposed model should be passed on to beneficiaries. One particular challenge is 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 bulk of any cost savings without proactive attempts to create a mechanism to share savings with patients. **We strongly urge that CMS 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.**

3. **Medicare demonstrations should be small and targeted so that evaluation of access challenges and cost savings can be done successfully.**

Because this model layers three major changes into one mandatory-participation model³, we are concerned that this type of model design injects risk to Medicare beneficiaries and is not amenable to reliable evaluation. The NHC views the proposed model as particularly high risk to patients given that providers and patients randomized to the IPI Model intervention would be required to participate in the study without an opportunity to opt-out. The NHC is also concerned that it may yield a research design that could put CMS in the unfortunate position of encountering access issues and/or compromised patient outcomes, but being unable to clearly identify the cause, much less address it. Additionally, to the extent that this demonstration saves costs for the Medicare program and beneficiaries, it will be difficult to determine which element resulted in the most savings. These challenges are likely to be heightened in instances where these changes are layered on top of other demonstration projects or alternative payment models. **CMS should consider smaller demonstrations that allow for easier assessment of the alignment between the policy change and subsequent outcomes.**

³ Medicare's use of an international pricing index, or otherwise benchmarking Part B drug payments to prices in international markets has not been tested or modeled to assess what, if any, impact it may have on patient access. CMS' previous attempt to encourage provider acquisition of Part B drugs through a competitive acquisition program (CAP) vendor increased costs, frustrated both providers and vendors, and proved unreliable in getting Part B drugs to patients who needed them.

Specific Concerns

1. **CMS must serve an active role in overseeing relationships between those providing and facilitating care to Medicare beneficiaries and create guardrails to ensure access.**

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.⁴ The NHC 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. **Thus, we strongly urge CMS to take an active regulatory and oversight role in the agreements, specifying obligations to ensure access and safety, managing conflicts of interest, and developing appropriate guardrails.** 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 timely delivery to providers, and their incentives and disincentives must be aligned with that role. The NHC strongly opposes any intermediary vendors introducing formularies, utilization management tools, or any other mechanism that constricts access into this already-complex proposal.

Additionally, the NHC has 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.

2. **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.**

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, the NHC supports de-linking 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**

⁴ 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."

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-value to the patients who receive them.

Additionally, the NHC 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.

An Alternative Approach – Personalized Care Management

The NHC fundamentally supports efforts to reduce health care costs by focusing on outcomes that matter to patients and their family caregivers and on value to the broader health care system.⁵ We support proposals that will reduce spending on low-value care while incentivizing high-value care. Thus, we supported many of the proposals of President Trump’s Blueprint to Lower Drug Prices such as value-based care and outcome-based contracts. This proposed model, however, does not consider the value of specific treatments. Rather, it attempts to equally lower the cost of both low-value and high value-care, potentially jeopardizing value-based payment arrangements and other innovative models that may reduce costs while improving care.

The cost of treating and managing chronic conditions is significant and increasing. Five percent of the nation’s population drives nearly half of all health spending.⁶ Two people with the same clinical diagnosis may respond entirely differently depending on the social and behavioral determinants of health. The NHC is keenly interested in working with CMS on demonstration projects that use data to segment populations and behavioral science to drive better outcomes at lower costs. We would be happy to discuss this concept in further detail.

Conclusion

The NHC appreciates the opportunity to submit comments on the proposed model. We urge CMS to consider the potential impact on patient access caused by this model or any proposal to reduce costs prior to moving forward.

Please do not hesitate to contact Eric Gascho, Vice President of Policy and Government Affairs, if you or your staff would like to discuss these issues in greater detail. He is reachable by phone at 202-973-0545 or via e-mail at egascho@nhcouncil.org.

Thank you,



Marc Boutin, JD
Chief Executive Officer

⁵ Please see the NHC’s Value Model Rubric, which helps patient organizations evaluate value frameworks for their patient centricity, and other tools related to value assessment at <http://www.nationalhealthcouncil.org/value-initiative>

⁶ <https://www.cdc.gov/chronicdisease/about/costs/index.htm#ref1>