NATIONAL HEALTH COUNCIL
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July 20, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-2482-P
P.O. Box 8016
Baltimore, MD 21244-8016

Re: Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third-Party Liability (TPL) Requirements

Dear Administrator Verma,

The National Health Council (NHC) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule to facilitate the adoption of value-based purchasing (VBP) arrangements, update definitions affecting Medicaid drug rebates, and amend reporting requirements for Medicaid best price.

Created by and for patient organizations 100 years ago, the NHC brings diverse organizations together to forge consensus and drive patient-centered health policy. We promote increased access to affordable, high-value, sustainable health care for the more than 160 million people with chronic diseases and disabilities, and family caregivers that we represent. Made up of more than 140 national health-related organizations and businesses, the NHC's core membership includes the nation's leading patient organizations. Other members include health-related associations and nonprofit organizations including the provider, research, and family caregiver communities; and businesses representing biopharmaceutical, device, diagnostic, generic drug, and payer organizations.

The emergence of new, innovative therapies, the rising cost of prescription drugs, and heightened concern about patient access to potentially lifesaving treatments have driven interest in pursuing alternative health care financing structures that drive value and better promote patient interests. The NHC supports[1] policies that ensure adequate access to affordable, high-value, sustainable health care and recognizes VBP arrangements between manufacturers and payers as an important tool to support this patient-focused objective. Specifically, the NHC supports VBP arrangements that not only improve access to expensive treatments and aid in the sustainability of health care systems, but also mitigate the high up-front cost of emerging treatments that patients bear. Thus, the NHC offers support for the overall aim of CMS' proposal to create flexibilities that can facilitate VBP adoption in the commercial and public-payer markets, but strongly advises the Agency take a deeper look at the complex implications of other provisions of the proposed rule given the limited comment period for stakeholder analysis and response. Our organization strives to ensure patient interests are thoroughly considered in system-changing proposals like those included in this proposed rule and ask CMS to better incorporate patient interests throughout the rule. As such, **the NHC would greatly appreciate a 30-day extension of the comment period to ensure we, our member organizations, and other patient groups can adequately respond to the many implications of this proposed rule.**

The NHC appreciates this long-anticipated proposal from CMS to remove barriers to payer and manufacturer adoption of VBPs. Specifically, the NHC commends the proposed rule's intent to allow manufacturers to report separate best prices under VBP agreements without impact to best price for sales outside of VBPs. In addition, the NHC is supportive of CMS' clarification around the use of bundled sales methodologies in conjunction with VBPs. The NHC knows that CMS is still working to add detail and clarify provisions related to VBPs. Below, please find recommendations to help add some clarity to some provisions.

Medicaid best price requirements have consistently been recognized by stakeholders as a deterrent to market adoption of innovative contracting. CMS' proposed changes will mitigate this longstanding barrier to VBP adoption and help to facilitate adoption of these arrangements, which could improve patient access to life-saving treatments. There are additional barriers to effective VBAs, and the NHC looks forward to working with CMS to continue to remove these barriers while ensuring patients remain protected.

Importantly, the proposed rule's provisions to support and advance VBPs should help promote health care system sustainability, as more high-cost but high-value therapies come to market that do not appropriately fit within the current payment paradigm. These new therapies may include cell and gene therapies, which are often one-time treatments for rare diseases that come with a high price tag for both payers and patients, high upfront costs with potential downstream savings that cannot be realized by the payer in

[1] https://nationalhealthcouncil.org/issue/reducing-health-costs/

a traditional payment model, and limited long-term outcome data to affirm their prolonged value. VBPs have the potential to mitigate payers' financial risk and encourage broader coverage and patient access to high-value/high-cost treatments. The NHC consequently recognizes VBPs as a mechanism for improving patient access to high-value health care. The broader adoption of VBPs could also lead to the more widespread collection of real-world data about patient outcomes, driving long-term benefits for patients related to medical innovation and clinical effectiveness.

In the final rule, we ask the Agency to ensure that the needs and priorities of patients are incorporated into the rules designed to facilitate VBPs. As CMS considers the operational aspects of its proposed rule, CMS should ensure that the adoption of VBPs helps to align the broader health care system around value and improved access, particularly from the patient's point of view. Specifically, we recommend that CMS:

1. Require substantive input from patients when establishing criteria for "evidence-based measures" or "outcomes-based measures" and defining "substantial" to ensure that VBPs demonstrate desired outcomes for patients;
2. Engage with a broad set of stakeholders to assess the potential impact of VPBs on Medicaid patients;
3. Withdraw the proposal to require manufacturers to deduct the value of any cost-sharing assistance from best price and Average Manufacturer Price (AMP); and
4. Delay and assess the impact that the proposal to redefine "line extensions" may have on incremental treatment improvements that can benefit patients.

CMS should require substantive input from patients when establishing criteria for evidence- or outcomes-based measures and defining "substantial."

The NHC is committed to the promotion of high-value care and works to ensure that the cost of health care products and services align with value to the patient. The proposed rule's definition of a VBP as an "agreement intended to align pricing and/or payments to an observed or expected therapeutic or clinical value in a population" correctly connects product price with the achievement of an outcome, but it leaves significant uncertainty about the permissible measures used to assess "value." Given this lack of specificity, we appreciate CMS' effort to seek specific feedback to clarify the measures that can be used to quantify value in evidence-based and outcomes-based arrangements.

The NHC recognizes patients as the source of authority on defining "value" in the context of the health care system and therefore urges CMS to incorporate the patient-centric perspective in its refinement of the definition of VBP. In CMS' establishment of the criteria for an evidence or outcomes-based measure, the agency must find ways to assure substantive input from patients on factors, such as disease mitigation and management, impact on patient out-of-pocket (OOP) spending, ease of adherence, and

improved aspects of quality of life. The NHC has outlined a set of domains of patient centeredness in value assessment that we recommend CMS adopt when establishing criteria for the above measures:

1. Patient Partnership: Patients should be involved in every step of the process, including planning and dissemination.
2. Transparency: All activities should be conducted in an open way, and assumptions, inputs, processes, and results need to be disclosed to patients in plain language and a timely fashion.
3. Representativeness: Representativeness connotes that a sufficient number and types of people are included in the engagement activity to ensure that those engaged can speak on behalf of the target population. It refers to "who" and "how many" individuals to include in an interaction in order to, as closely as possible, engage with individuals that represent the broader, target patient population.
4. Diversity: The activity should consider differences among patients, including patient subpopulations, trajectory of disease, and stage of a patient's life.
5. Outcomes that Patients Care About: Whether the activity is research, policy, or care delivery oriented, the outcome(s) being measured should include those that patients state are important to them.
6. Patient-Centered Data Sources and Methods: Having a variety of credible sources can facilitate timely incorporation of new information and account for the diversity of patient populations and patient-centered outcomes, especially those from real-world settings and reported by patients directly.

The NHC urges CMS to require a process that meets the six criteria above to support that the outcomes are ones that patients care about and the measures being used to judge success or failure are robust and fit-for-purpose. Evidence can then be used to evaluate the outcomes and align them with patients' needs.

In addition, CMS proposes that VBPs must "substantially" link the cost or payment of a drug to evidence- or outcomes-based measures and asks stakeholders for input on the definition of "substantial." We agree that it is important that CMS provide guidance and guardrails to ensure that manufacturers and payers adopt meaningful VBP arrangements that deliver benefit to patients. At the same time, they must not be overly restrictive, thereby inhibiting the evolution of innovative contracting arrangements in the future.

CMS should engage with a broad set of stakeholders to assess and minimize the impact of VPBs on Medicaid patients.

The NHC supports CMS' goals to facilitate adoption of VBPs in Medicaid that can meaningfully improve patient access and outcomes. While the proposed rule seeks to

alleviate regulatory barriers that have curbed state adoption of VBPs, specifically for manufacturers, the proposed rule does not address state administrative burdens and associated costs with executing these arrangements.

Today, only a few states have implemented innovative contracting agreements with manufacturers. This limited adoption by states is likely related to a host of challenges to state Medicaid programs. Specifically, in recent years states have identified the operational and administrative requirements of a VBP arrangement as one of the key barriers to engagement. State Medicaid programs already operate on a limited budget; moreover, states will likely face budget pressure in the coming years as the COVID-19 pandemic continues and will need to look for ways to control administrative costs to avoid reducing benefits. The NHC asks CMS to consider engaging with a broad set of stakeholders, including patients, payers, and state Medicaid directors, to identify and offer recommendations to alleviate the administrative burden of VBP arrangements and to offer additional guidance to states on VBP implementation to encourage broader adoption.

CMS should withdraw its proposal to require manufacturers to deduct the value of any cost-sharing assistance from best price and AMP.

As the NHC has consistently noted, the current health care system subjects patients to high OOP costs, particularly for drugs used to treat complex and chronic conditions. Patients requiring branded medications without an available generic substitute often rely on copay coupons, discount cards, charitable assistance, and other assistance as the only means to afford the medication they need. The NHC has long recognized that there are various types of assistance programs that should be addressed by nuanced policy to eliminate gaming of manufacturer assistance in instances where generic competition exists for conditions with little heterogeneity, while allowing for charitable assistance or manufacturer assistance for products without competition.

Accordingly, the NHC supports[2] limitations on copay accumulator and maximizer programs and appreciates CMS recognizing how these programs can limit the benefit of cost-sharing assistance to patients. Specifically, NHC agrees with CMS that there are current arrangements involving accumulators that can result "in the health plan delaying the application of its plan benefit to the patient **to the detriment of the patient or consumer,** thus generating savings for the plan."

The presence of a copay accumulator means that it will take longer for an individual to reach their deductible and out-of-pocket maximum, resulting in treatments becoming unaffordable for many patients.

[2] https://nationalhealthcouncil.org/wp-content/uploads/2020/03/NBPP-2021-Comment-Final.pdf

While the NHC supports CMS' stated intent to ensure cost-sharing assistance fully benefits the patient, we are concerned that the growing prevalence of copay accumulators means that a portion of the value actually accrues to payers if the patient receiving the assistance is subject to an accumulator. Because of the lack of transparency into the application of copay accumulators, the proposal to require manufacturers to guarantee the full value of the assistance accrues to patients is likely to be unworkable. We are concerned that manufacturers' most likely response will be to stop offering assistance to help patients afford their medications.

If this proposal should proceed as part of this rule or in future rulemaking, the NHC would strongly urge significant modifications, including specific patient guardrails to ensure the provision on cost-sharing assistance has the intended effect of eliminating inappropriate use of manufacturer assistance while protecting people who rely on assistance to afford their medications. At a bare minimum, needed patient guardrails would include requiring greater transparency from plans about accumulators, withdrawing the expansion of CMS' copay accumulator proposal in the 2021 Notice of Benefit and Payment Parameters (NBPP) to allow copay accumulators for products without generic competition, and more narrowly targeting this proposal to focus on products without generic competition. As currently proposed, this provision and the expansion of CMS' policy in the 2021 NBPP take an overly-broad approach that will result in increased OOP spending by patients.

The NHC urges CMS to carefully reevaluate the complex nature of this proposal and constrained ability of manufacturers to ensure the benefits of their patient assistance programs fully accrue to patients. We strongly urge CMS to consider potential incremental approaches as opposed to this sweeping proposal, and to consider potential implications on patient access.

CMS should delay and assess the impact that definition of "line extension" may have on incremental treatment improvements that can benefit patients.

CMS is proposing to modify the term "line extension" to include any new formulation of the drug. This will mean that companies will be required to pay greater rebates to Medicaid if they reformulate their products, regardless of whether or not such a reformulation improves patient outcomes. The NHC understands and appreciate CMS' overall intent to prevent manufacturers' misuse of the distinctions surrounding reformulation of products. However, while some of the expansions of the definition may indeed eliminate misuse, others are likely to disincentivize reformulations that improve patient adherence and/or outcomes. For example, the most transformative advancement in the treatment of HIV/AIDS came when individual treatments were combined. Without appropriate guardrails such as more nuanced definition, this proposal may discourage these types of improvements.

We caution the agency against advancing this broad definition without appropriately assessing the impact it may have on incremental treatment improvements that can greatly benefit patients. Given the inadequate comment period, it is difficult for patient community to fully respond to which aspects of the redefinition will have negative or positive impacts on patient access. We request that CMS narrow the redefinition of line extension in future rulemaking with adequate time for stakeholder to consider the impact and comment.

Conclusion

The NHC believes in the adoption of policies that promote adequate access to affordable, sustainable, high value health care. We generally support CMS' proposal to facilitate VBP and ask CMS to consider our recommendations to improve the proposal. We also ask CMS to consider the issues raised above regarding manufacturer assistance and reformulations, which have the potential to negatively impact patients.

Finally, given the short comment period, if CMS decides to finalize this rule, we ask that CMS take all steps necessary to ensure that comments from a full spectrum of stakeholders, particularly patients and their family caregivers, are thoroughly considered to promote VBP adoption and system-wide change in a way that is most beneficial to patients.

Please do not hesitate to contact Eric Gascho, our 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.

Sincerely,

Marc Boutin, JD
Chief Executive Officer