COUNCIL FOR AFFORDABLE
HEALTH COVERAGE

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July 20, 2020

Submitted electronically

The Honorable Seema Verma, Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attn: CMS-2842-P
7500 Security Boulevard
Baltimore, MD 21244-8016

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

Dear Administrator Verma:

Thank you for the opportunity to provide comments on the *Medicaid Program; 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* Proposed Rule.[1]

The Council for Affordable Health Coverage (CAHC) is a broad-based alliance with a singular focus: bringing down the cost of health care for all Americans. CAHC promotes policies that lower health costs through increased competition, informed consumers and more choices. Our members include providers, patient groups, insurers, pharmaceutical manufacturers, pharmacy benefit managers (PBMs), and employers. To that end, because of our diverse membership and the wide implications of the proposed rule, our comments apply only to the proposed rule's effects on value-based purchasing arrangements (VBPs) for pharmaceuticals.

CAHC is supportive of CMS' efforts to provide a path for VBPs, which are an important step forward in innovative contracting that bases reimbursement on whether or not a therapy works. They hold the promise of precision medicine by enabling patients, prescribers and payers to coordinate collecting outcomes data to match the right therapy to the right patient.

CAHC will continue to lead on both legislative and regulatory solutions that drive VBP as a critical piece of the debate to lower the cost of prescription drugs while improving outcomes. Our specific comments on the proposed rule are outlined below:

[1] 85 Fed. Reg. 37286 (June 19, 2020)

DEFINITIONS

Value-Based Purchasing Arrangement (VBP)[2]

CMS defines a VBP arrangement as, "an agreement intended to align pricing and/or payments to an observed or expected therapeutics or clinical value in a population and includes (but is not limited to): evidence-based measures, which substantially link the cost of a drug product to existing evidence of effectiveness and potential value for specific uses of that product; [and] outcomes-based measures, which substantially link payment for the drug to that of the drug's actual performance in a patient or a population, or a reduction in other medical expenses."[3]

Comments: CAHC supports this definition and believes that it appropriately encompasses a variety of measures- like clinical measures such as biomarkers (i.e. tumor size or blood pressure) and process measures like adherence or hospital stays. This variety is key because not all VBPs will be structured the same.

Additionally, CAHC believes the term "substantially" should be kept without naming specific threshold numbers. The parties to the VBP must maintain autonomy to negotiate the terms of the contract necessary to appropriately address the specific therapy and unique patient population. It is not the place of the Federal government to arbitrarily set parameters that could have the unintended consequence of impeding access to some therapies through VBPs.

Bundled Sale[4]

CMS proposes to revise the definition of "bundled sale" to incorporate VBPs as long as the arrangement(s) contain performance requirements such as outcomes measures.

As CMS recognized, "gene therapies and potentially curative orphan drug treatments"[5] are key targets for VBPs. It is, however, important to note that in most cases covered outpatient drugs indicated for a rare disease will not have enough volume with individual payers to use the bundled sale pathway. Indeed, with respect to the Agency's two proposed options to prevent refunds or reimbursements for patients who do not respond to covered outpatient drugs sold under a VBP from potentially skewing the quarterly reported best price, rare disease therapies are better suited to using the multiple best price option.

Comment: CAHC supports this definition. We would like to note that most- if not all- VBPs that involve a therapy targeted at rare diseases will not be able to utilize the pathway established by this revised definition because there is not enough volume of rare disease therapies to justify a bundled sale. Because of this lack of applicability to rare disease therapies, it is critical that the Agency finalize the multiple best price option[6] to ensure a path forward so those living with a rare disease can also access and benefit from therapies utilizing VBPs.

[2] 85 Fed. Reg at 37291
[3] 85 Fed. Reg at 37292
[4] 85 Fed. Reg at 37292
[5] 85 Fed. Reg at 37291
[6] 85 Fed. Reg at 37292

Multiple Best Prices[7]

CMS introduced a novel concept by proposing to allow multiple best prices for a single drug as long as that drug is part of a VBP. CMS proposes that a "single drug may be available at multiple price points, each of which may establish a 'best price' based on the relevant or applicable VBP arrangement and patient evidence-based or outcome-based measures."[8]

Comment: While the proposal is promising, we have questions that we believe must be resolved as they relate to both implementation and operational issues:

- How will managed Medicaid programs collect and report VBP outcomes data vs. non-managed Medicaid states?
- How will multiple best prices impact other government pricing policies (i.e. Medicare Part B Average Sales Price, and 340B ceiling price)?
- Does CMS intend for pay-over-time VBPs to also report multiple best prices?
- How is CMS planning to update its data collection and reporting systems?

We agree with CMS that this proposal could pose implementation difficulties. Additionally, there is a lack of clarity surrounding the multiple best price reporting and how various VBP scenarios would apply.

CAHC recommends CMS finalize the multiple best price proposal with additional clarifications. We do recognize the promise that allowing for multiple best prices will enable VBPs to flourish in both the public and private marketplaces. As such, we look forward to continue working with CMS to ensure that all stakeholders can take full advantage of this proposal in executing meaningful VBPs.

Clarifications to AMP Definition

CAHC recommends that CMS encourage the adoption of value-based payment-over-time arrangements by clarifying the average manufacturer price (AMP) definition such that the total price of a product may be reflected in AMP at the time of sale -- as opposed to just the initial installment payment, with subsequent installment payments reflected in AMP when they occur. We ask that CMS should offer the following clarifications in the Final Rule:

- First, manufacturers can reasonably interpret the AMP definition to permit reporting in the AMP at the time of sale the full price of the unit, inclusive of all installment payments subsequently due to be paid. In other words, the manufacturer may report AMP at the time of sale based on the total amount that the customer is obligated to pay for the unit, even though payment will be made over time.
- Second, with respect to value-based payment-over-time arrangements, if remaining installment payments do not come due because of the failure of the unit, manufacturers may treat these forgiven installment payments as a lagged price concession under the AMP smoothing methodology.

By making these clarifications, CMS would achieve its stated goal of enabling value-based payment-over-time arrangements. CMS would do so by addressing the ways in which the contrary interpretation of the

[7] 85 Fed. Reg at 37292
[8] 85 Fed. Reg at 37293

AMP definition—i.e., that only the initial payment may be reflected in AMP at the time of sale, with subsequent payments reflected in AMP when they occur—disincentivizes such arrangements. This contrary interpretation could result in great volatility in AMP on a quarterly basis, and also lead to AMP increasing greatly over time (even if the price of the therapy had not changed), thus triggering the inflation penalty.

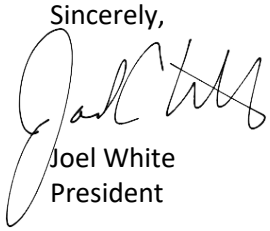
Additional Comments

While the proposed rule takes an important first step showcasing VBPs as a priority area for the administration, CAHC believes additional rulemaking is necessary to truly operationalize VBPs and recognize their potential in improving outcomes and lowering total cost of care. Specifically, this proposed rule does not address the Anti-Kickback Statute (AKS) and its barriers against VBPs. The AKS is a significant hurdle for payors and manufacturers to enter VBPs. ***CMS should work with the Office of the Inspector General (OIG) to promulgate rulemaking that follows-up on its work with value-based care[9] to address value-based payment arrangements for prescription drugs. Additionally, the proposed section on multiple best prices[10] will require further clarity from CMS to operationalize.***

CONCLUSION

Thank you again for the opportunity to comment on the proposed rule. If you have any questions, please do not hesitate to contact me at joel.white@cahc.net. CAHC looks forward to our continued work with the administration as you move forward encouraging value-based reimbursement models that will improve prescription drug affordability and access.

Sincerely,



Joel White
President

[9] 84 Fed. Reg. 55694 (October 17, 2019)
[10] 85 Fed. Reg at 37292