



Advancing Health in America

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July 20, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

RE: Proposed Rule: CMS–2482–P, Medicaid Program: Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid (Vol. 85, No. 119), June 19, 2020

Dear Administrator Verma:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed regulation related to supporting Medicaid drug value-based purchasing (VBP) arrangements and other changes to the Medicaid drug rebate program.

If finalized, the proposed rule would grant states greater flexibility in developing VBP arrangements with drug manufacturers and health plans within the context of the Medicaid drug rebate program. In addition, the rule proposes to clarify certain issues related to how patient assistance programs should be accounted for in determining a drug manufacturers' "best price" and how line extension drugs are defined within the context of Medicaid rebates.

Lastly, the rule codifies several provisions required by legislation regarding the average manufacturer price of brand name drugs and safer prescribing of opioids. AHA's comments will focus on the new VBP flexibility, patient assistance program clarification and line extension drug definition.



The AHA strongly supports efforts to rein in the high cost of drugs. High and rising drug prices have created significant financial barriers for patients and the providers who care for them. The AHA supports innovations in drug purchasing arrangements, so long as these arrangements preserve or enhance patient access to critical medications and result in lower drug costs. However, we do not support financing arrangements that masquerade as innovation or increases in access but do nothing to reduce the underlying cost of drugs and, in fact, may increase drug spending over time.

We appreciate CMS's efforts to promote and encourage VBP arrangements to better align care and patient experience with reimbursement. Ideally, the core value of these arrangements focus on alignment, including eliminating waste; coordinating and streamlining care; and establishing risk/reward mechanisms to incentivize and encourage improvements in quality, patient experience and efficiency.

While we remain supportive of actions that would encourage VBP utilization generally, we must emphasize that the appropriate balance of risk and responsibility is critical.

The proposed rule provides a framework for state Medicaid programs, drug manufacturers, health plans and other stakeholders to consider appropriate models to achieve these objectives while not resulting in unintended negative consequences. These arrangements, while aspirational in ensuring best value for price, only will be effective in the long-term if they successfully provide increased value for patients. However, in this instance, it is unclear that the models discussed in the rule would achieve this value. In fact, they could enable drug manufacturers to rush drugs to market and increase — instead of reduce — costs without taking on any meaningful risk or committing to efforts that rein in unsustainable drug prices.

In addition, these models place considerable burden on providers to track and report on outcomes, as well as to hold manufacturers accountable for returning any revenue in the event that a drug does not perform as promised.

It is unclear how states will account for this burden, and we are deeply concerned that states would not be required to coordinate with providers before adopting such models. Should these data collection provisions be finalized, we expect the agency will ensure adequate mechanisms are in place to compensate providers in instances where drug manufacturers seek to access this data.

Through the proposed rule, CMS seeks to encourage drug manufacturers to enter into VBP arrangements. Specifically, the proposed rule would define a VBP arrangement as one that aligns pricing and clinical outcome using evidence-based and outcomes-based measures. It would allow drug manufacturers to report multiple “best prices” for a therapy if the prices are tied to patient outcomes through VBP arrangements. In addition, the proposed rule would allow drug manufacturers to include VBP arrangements as part of a bundled sale. The agency determined that these two

changes could remove existing barriers to VBP arrangements and therefore help facilitate broader adoption of VBP for pharmaceuticals.

While we generally support VBP, we believe the specific proposals put forth in this rule **require further consideration from the agency prior to finalization.**

Specifically, we are concerned that the rebate provisions as drafted place intensive data collection and tracking requirements on providers. If finalized, providers would bear a significant portion of the burden of tracking patient outcomes, including those individuals who transition into and out of the Medicaid system, to determine if a rebate from the drug manufacturer is appropriate. In this instance, drug manufacturers may be encouraged to bring a drug to market with a “possible outcome,” but rely on providers to track whether or not that outcome is met. In addition to increasing provider burden, this model raises significant patient safety concerns by basing payment on prospective drug outcomes, not proven ones, with the potential for drug manufacturers to short-circuit the full review process.¹

We recommend the agency reexamine this approach. In its place, CMS should consider requiring drug manufacturers to demonstrate the outcome effectiveness of a drug prior to entrance into the market and receive payment based on that proven outcome. In instances where a drug proves to be more effective than initially demonstrated, the manufacturer should have the opportunity to demonstrate the increased benefit and reapply for payment that reflects the new outcome effectiveness.

The agency should also consider the fact that state Medicaid agencies and providers are at many different points along the transition to value, meaning that implementation of these provisions likely would result in the need to make significant changes to the care processes and policies currently in place to comply with existing regulatory structures.

In addition, while states can choose to enter into VBP arrangements with drug manufacturers, CMS should carefully review the implications of these VBP arrangements on state Medicaid budgets as well as eligibility and enrollment policies. States are facing significant budget pressures resulting from the COVID-19-related economic recession. Considerable investment of Medicaid agency resources such as information technology systems and staff time will be required to effectively establish and manage these VBP arrangements yet state Medicaid programs currently are facing deep budget cuts.

¹ Bach, Peter B. (July 6, 2020), *CMS’s Proposed Medicaid Best Price Loophole for Value-Based Purchasing of Drugs*. Health Affairs Blog.
https://www.google.com/search?q=citing+a+blog+apa&rlz=1C1GCEJ_enUS845US845&oq=citing+a+blo&ags=chrome.1.0l2j69i57j0l5.4479j1j4&sourceid=chrome&ie=UTF-8

The adjustments made to the Medicaid rebate program to permit more flexibility for VBP arrangements could have the unintended effect of reducing state revenue by reducing the number of drugs for which state Medicaid agencies can claim rebates from drug manufacturers. CMS needs to better assess how these VBP arrangements may affect the state revenue derived from the Medicaid rebate program.

Lastly, CMS needs to assess more fully how an individual's participation in a VBP arrangement would be affected by that individual's Medicaid eligibility status. Because Medicaid eligibility is largely based on income, an individual could lose their eligibility and access to covered treatment with a change in their income. This potential for enrollment churn could affect the proposed VBP arrangement that permits multiple "best prices," since the manufacturer's drug rebate to the state is individualized for each enrollee.

As CMS continues to pursue an increase in VBP opportunity, we urge the agency to consider the appropriate balance that must be struck to make these arrangements work effectively for the Medicaid program as well as throughout the health care delivery system.

The proposed rule also includes other important changes to the Medicaid drug rebate program. Specifically, the proposed rule addresses how patient assistance programs are to be counted in the manufacturers' "best price" determination as well as propose a definition for line extension drugs for purposes of the Medicaid rebate formula.

With regard to patient assistance programs, current regulations permit that the full value of patient assistance for non-Medicaid commercial plans be excluded from a manufacturers' reported Medicaid "best price" as long as the full value of the assistance is passed on to the patient.

Examples of patient assistance programs include drug discount cards, drug manufacturer coupons, copayment assistance, or patient rebate or refund programs. Concern has been raised regarding the role health plans and pharmacy benefit managers (PBMs) have played in managing patient assistance programs. In some cases, the health plans and PBMs have not passed on the full value of the assistance to the patient or consumer. CMS proposes to address these concerns by explicitly stating that a drug manufacturer's patient assistance programs may only be excluded from the Medicaid "best price" reporting to the extent that the full value of the assistance is passed on to the patient.

The AHA supports CMS's recommendation regarding how patient assistance programs should be accounted for in the Medicaid "best price" reporting.

In addition, CMS proposes a definition for line extension drugs for purposes of the Medicaid rebate program. The Affordable Care Act established an alternative rebate formula requiring that drug manufacturers pay a high rebate for line extension drugs by

linking the line extension to the original drug. (A line extension drug is a new formulation of an existing drug such as an extended release formulation.) The agency, however, has never put forward a regulatory definition for line extension drugs. CMS has raised concerns that drug manufacturers were excluding some drugs from the definition of line extension drugs to avoid paying the higher rebate. To address this concern, CMS proposes to define a “new formulation” of a line extension drug as any change to the drug that contains at least one active ingredient in common with the original drug.

The AHA commends CMS’s efforts to improve the Medicaid drug rebate program through its proposed definition of line extension drugs.

Lastly, we recommend that CMS extend the comment period beyond the current 30-day period. While the AHA supports CMS’s interest in promoting VBP arrangements to better align patient care with cost, stakeholders should have longer than 30 days to assess the implications of applying VBP arrangements for Medicaid drug coverage and purchasing.

These are new and complicated proposals that warrant more time for careful and thoughtful consideration.

The AHA shares CMS’s goal to improve access to drug treatment for Medicaid beneficiaries that ensures safe and effective care. We look forward to working with CMS on these and other initiatives.

Please contact me if you have questions, or feel free to have a member of your team contact Molly Collins, AHA’s director of policy, at (202) 626-2326 or mcollins@aha.org or Mark Howell, AHA’s senior associate director of policy, at (202) 626-2317 or mhowell@aha.org.

Sincerely,

/s/

Ashley B. Thompson
Senior Vice President of Public Policy Analysis & Development.