601 E Street, NW | Washington, DC 20049
202-434-2277 | 1-888-OUR-AARP | 1-888-687-2277 | TTY: 1-877-434-7598
www.aarp.org | twitter: @aarp | facebook.com/aarp | youtube.com/aarp

July 20, 2020

The Honorable Seema Verma
Administrator
Centers for Medicaid & Medicare Services
U.S. Department of Health and Human Services
200 Independence Ave., SW
Washington, DC 20201
Attn: CMS-2482-P

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. Submitted electronically via regulations.gov.

Dear Administrator Verma:

AARP, on behalf of our 38 million members and all older Americans nationwide, is pleased to submit the following comments on a proposed rule that would amend Medicaid drug rebate rules to promote value-based purchasing (VBP) arrangements, among other changes (85 Federal Register (FR) 37286).

Prescription drugs are critical to curing or managing disease, maintaining health, and improving quality of life. Older Americans use prescription drugs more than any other segment of the U.S. population but many struggle to afford them. The Medicaid program is critical for ensuring that millions of older adults have affordable access to their prescription drugs. Keeping Medicaid's prescription drug costs low also helps state Medicaid programs, as well as federal and state budgets. One important source of savings is Medicaid's best price requirement, which ensures that the program obtains prescription drug discounts at least as large as the discounts that are available in the commercial sector.

Some drug manufacturers and other critics have argued that the best price requirement hinders the use of VBP arrangements.[1] AARP broadly supports the concept behind VBP arrangements,

[1] Daniel S. Mytelka, William M. Cassidy, Donald B. Kohn and Mark R. Trusheim, "Managing Uncertainty in Drug Value: Outcomes-Based Contracting Supports Value-Based Pricing,"Health Affairs Blog, January 30, 2020. https://www.healthaffairs.org/do/10.1377/hblog20200128.542919/full/

which would align the price of a drug with its value rather than what the market will bear. However, we continue to believe that concerns about the best price requirement are largely unfounded, particularly given HHS' willingness to assist drug manufacturers in developing value-based designs that do not violate best price requirements.[2]

Consequently, AARP appreciates CMS' efforts to clarify how drug manufacturers can report best price under VBP arrangements while still protecting best price, which is clearly preferable to efforts to eliminate or seriously undermine the requirement. AARP strongly believes that any efforts to reform the Medicaid best price requirement must retain access to prescription drug prices that are equal to or better than what they receive under current policy. Unfortunately, we are concerned that some aspects of the proposed rule do not meet this threshold and could lead to higher costs for the Medicaid program.

AARP Supports Value-Based Purchasing That Does Not Erode Medicaid's Best Price Policy

AARP shares CMS's goal of reducing prescription drug costs while ensuring consumer access to necessary medications. Older Americans' health and financial well-being are affected by high and growing drug prices, and we appreciate CMS's ongoing efforts to find ways to address this challenge. While AARP broadly supports the concepts behind value-based purchasing arrangements, significant challenges confront their implementation. We are concerned that the proposed rules reflected in 85 FR 37286 do not address many of these important challenges and could have major unintended financial consequences for state Medicaid programs.

Unintended Consequences of Eroding Best Price: Medicaid's best price policy ensures that Medicaid programs have access to the lowest prescription drug price available to other payers in the market. Drug manufacturers reduce Medicaid's cost to the "best price," or lowest price offered to private payers, by extending rebates to the state. We know that the "best price" for a drug product is the fairest one on the market because the drug manufacturer has agreed to sell the product at that price to other payers. The policy is an assurance that taxpayers are receiving the lowest price on the market and helps maximize states' ability to use limited public funds to cover prescription drugs and other important health care services.

CMS' proposed modifications to Medicaid best price would permit drug manufacturers using VBP arrangements to report best price in two new ways: bundled sales and variable best price. The first option would give drug manufacturers the option to report a "bundled sale" where they provide a weighted average price based on sales of a product that is available through a VBP arrangement. The second option would allow drug manufacturers to report multiple best prices per drug: a single best price for the drug plus a distinct set of 'best prices' that would be available for the drug under VBP arrangements.

While these changes could encourage more VBP arrangements in the commercial market, shifting the definition of Medicaid best price from a single, best price to multiple best prices will only exacerbate known best price reporting challenges and make it even more difficult for states

[2] Edwin Park and Andrea Noda, "Alternative Drug Purchasing Arrangements Do Not Justify Raising the Prices Medicaid Pays for Brand Drugs," Health Affairs Blog, April 3, 2020. https://www.healthaffairs.org/do/10.1377/hblog20200325.649781/full/

to ensure drug manufacturer compliance with best price requirements. The inherent inconsistency will also increase opportunities for drug companies to game the system and lower their rebate obligations. As a result, Medicaid prescription drug spending could increase and programs could be forced to cover fewer people, trim benefits, or even raise beneficiaries' copayments.

AARP is also concerned by a number of outstanding methodological questions. For example, the rule does not fully explain how multiple best prices, potentially across multiple purchasers, will be used to calculate Medicaid payments. It is also unclear what states and drug manufacturers in a long-term outcome-based contract should use as their initial price for rebate purposes, as well as how rebates will be shared given that results will likely not be known for years. Similarly, there is no guidance on what should be used as a best price when a drug is exclusively provided through VBP arrangements.

AARP recommends that CMS clarify how a drug manufacturer should structure rebates in a manner that accounts for a delay in outcome measures and put in place a review mechanism to ensure that drug manufacturers are not gaming agreements that have multiple best prices. In addition, AARP recommends that CMS establish a standard that ensures that Medicaid programs retain access to prescription drug prices that are equal to or below what they would have experienced under the existing single best price requirement to ensure the proposed rule does no harm.

Key Definitions Unclear, Raising Opportunities for Exploitation: AARP is also concerned that the proposed definitions included in 85 FR 37286 are not clear and could encourage exploitation and potential waste, fraud or abuse. Incomplete definitions could lead to VBP contracts that are intended to escape Medicaid rebate obligations without providing the expected benefits of reducing cost and increasing value for the commercially insured. For example, with respect to the proposed definition of value-based purchasing (VBP) arrangement:

- The proposed definition is overly broad. We believe that it could present an opportunity for nearly all drug acquisition contracts to be considered a VBP arrangement and that drug manufacturers would be motivated to claim that label to reduce their Medicaid rebate obligations. This outcome would raise revenues for drug manufacturers at the cost of Medicaid programs. If exploited in this way, the proposed definition could dramatically cut into those savings and increase costs to Medicaid.

    - For example, the proposed definition would permit value-based purchases that link prices to "existing evidence of effectiveness" of a drug product to be exempt from Medicaid's single best price. We believe that this language is too broad, potentially opening up the entire universe of prescription drugs to a potential VBP arrangement, since all drug manufacturers have evidence of their drugs' effectiveness. CMS should consider limiting VBP arrangements to only those linking payment to outcomes and not simply to existing evidence.

- The proposed definition does not include any guardrails or features to ensure that VBP arrangements meet reasonable thresholds for providing value. AARP understands that

there is currently no universal definition of value, and that there is very little consensus on what standards and data should be used when evaluating the value of prescription drugs. Nonetheless, we recommend that certain important features of VBP contracts be present before exceptions to Medicaid's best price rule be permitted. For example, CMS might consider only excluding certain outcome-based prices under VBP arrangements from Medicaid's single best price, such as VBP arrangements covering certain very high cost specialty treatments.

- The proposed definition is unclear in that it includes contracts where prices or payments are "substantially" linked to evidence or outcome-based measures. The term "substantially" is not defined. This lack of clarity could contribute to incentives for drug manufacturers to exploit the rules in order to avoid paying Medicaid rebates.

In addition, the definition of "best price" would be modified to eliminate a 3-year time period for drug manufacturers to adjust their best price reporting based on after-the-fact rebates or discounts. We are concerned that the proposed unlimited time period for drug manufacturers to report their best price - an essential component for calculating rebates - could be misused to delay payments of rebates to states. CMS should strongly consider maintaining a reasonable time limit to ensure that such timelines do not stretch on indefinitely.

Ensure that Benefits of VBP Accrue to Consumers and Not Just to Drug Manufacturers

While AARP encourages continued exploration of the value of VBP arrangements, we note that there is little available evidence that VBP agreements are meeting their objectives to increase therapeutic value while reducing cost for consumers and insurers.[3] This proposal also does little to ensure that the VBP arrangements incentivized by the proposed changes to best price actually meet those objectives. If VBP arrangements ultimately result in little demonstrable improvement in achieving value for beneficiaries and payers, and Medicaid prescription drug spending subsequently increases, this proposal will have the opposite impact as intended.

In addition, given that beneficiaries' out-of-pocket costs occur at the point of sale, savings from VBP arrangements can be difficult to pass along to beneficiaries because the value-based price often is not determined until after a prescription is filled or administered. If CMS moves forward with policies to incentivize such arrangements, we believe that CMS should consider waiving cost-sharing requirements for beneficiaries participating in those arrangements or develop other approaches for sharing savings achieved after the point-of-sale with beneficiaries.

Consumer Safeguards: AARP strongly believes that robust consumer safeguards must be included in efforts to pursue VBP arrangements for prescription drugs. More specifically, HHS should ensure that consumer access to necessary prescription drugs is not negatively affected under such contracts. As part of these efforts, appeals processes should be evaluated and improved to help ensure that they are not too complicated or cumbersome for enrollees to successfully navigate. Appeals processes must be transparent, easy-to understand, and fair in

[3] E. Seeley and A. S. Kesselheim, Outcomes-Based Pharmaceutical Contracts: An Answer to High U.S. Drug Spending? The Commonwealth Fund, September 2017.

order for them to function as a true recourse. HHS should also be willing to regularly revisit and make changes to these processes as necessary to ensure beneficiary access.

We also strongly recommend CMS include a transparent, comprehensive, and publicly available monitoring process as part of any value-based purchasing arrangement – especially those incentivized by exemptions from best price reporting. As part of the monitoring process, AARP encourages HHS to identify formal processes for regularly engaging and involving consumers and their advocates, including techniques such as consumer experience surveys and focus groups.

More Transparency is Needed: State Medicaid programs may not even be aware of the existence of value-based agreements that would, under the proposed rule, impact their drug prices. Further, as noted above, the proposed rule opens up a strong possibility of encouraging contracts that have less to do with value and more with avoiding Medicaid rebates. AARP recommends that before permitting VBP arrangements to report multiple best prices, CMS establish an approach to understanding the contract provisions for those arrangements and hold drug manufacturers accountable to meeting certain minimum standards. States or CMS should be able to reject multiple best prices tied to VBP arrangements that do not reduce costs, do not improve value, or do not meet minimum standards. Without data transparency, minimum assurances cannot be made.

Similarly, we strongly encourage CMS to move toward a better understanding of whether or not the arrangements that it is promoting actually achieve value. We are aware that it can be difficult to obtain the data needed to ensure value is achieved – for example, claims data often do not include information on desired outcomes and drug manufacturers, providers, and payers may not have the necessary data and infrastructure to track needed data, or be willing to share data with other entities in the supply chain. However, CMS should address these challenges prior to incentivizing value-based purchasing arrangements, especially when they could result in higher Medicaid drug costs.

AARP is encouraged that CMS is proposing data reporting requirements for Medicaid agencies that enter into VBP arrangements. We believe those data elements represent a start but we believe that data reporting transparency should also be required for commercial VBP arrangements that impact Medicaid's best price. In addition, for Medicaid VBP reporting, we recommend several additional data elements be included in the final rule. In addition to identifying the drugs under the VBP arrangement, the number of prescriptions, and the costs and savings attributed to the arrangement, CMS should also require reporting of the number of beneficiaries covered under a VBP arrangement as well as information that indicates how well the VBA is performing overall - whether its financial as well as health outcomes are generally being reached. We also encourage guidance from CMS to ensure that the elements are reported in a consistent manner across states so that the data may be used over time for assessing how well VBP arrangements are working.

CMS Must Analyze Medicaid Program Spending in Response to Proposed Changes

The proposed rule does not include a regulatory impact analysis that indicates whether Medicaid program spending will increase in response to the proposed changes to best price, simply stating that it does not constitute a major rule with economically significant effects. However, the best price requirement produced total Medicaid savings of up to $5 billion in 2015 alone[4] and—as noted previously—the proposed changes could significantly weaken best price and reduce such savings. Meanwhile, evidence indicates that VBP arrangements may actually encourage high launch prices for new drugs, further increasing Medicaid spending.[5] Taken together, it seems evident that there is indeed a strong potential for substantial increases in Medicaid spending over time. AARP strongly urges CMS to conduct a comprehensive analysis of the impact of this proposal on Medicaid program spending before finalizing any changes to best price.

Inclusion of Line Extensions in AMP

AARP supports CMS' proposed definition of line extension drugs that must be included in average drug manufacturer price reporting. We encourage CMS to finalize its definition in order to reduce inconsistency in drug manufacturer reporting of those drugs. In the absence of a consistent definition, drug manufacturers have an incentive to be less inclusive in their identification of such drugs in an effort to minimize rebate payments.

We also support CMS' proposed more expansive interpretation of line extension drugs to include new strengths and drugs not in oral solid dosage form, as these definition clarifications will expand the universe of drugs that can be line extensions.

We believe that a broad definition of line extension drugs will help reduces manufacturers' ability to unfairly reduce their Medicaid rebate obligations. Most importantly, it supports and strengthens States' ability to collect rebates. Ensuring states can collect all of the rebates that they are owed helps states' budgets and promotes their ability to continue to fund necessary medical care for neediest populations.

Conclusion

Thank you for the opportunity to comment on this proposed rule. Medicaid rebates are essential to the financial health of state Medicaid programs. According to the Medicaid and CHIP Payment and Access Commission (MACPAC), in fiscal year 2018, drug manufacturers paid $36.2 billion in rebates, lowering Medicaid prescription drug costs by 59.5 percent.[6] Moreover,

---

[4] E. Park and A. Noda, Alternative Drug Purchasing Arrangements Do Not Justify Raising The Prices Medicaid Pays For Brand Drugs, Health Affairs Blog, April 3, 2020, https://www.healthaffairs.org/do/10.1377/hblog20200325.649781/full/

[5] Peter Bach, "CMS' Proposed Medicaid Best Price Loophole for Value-Based Purchasing of Drugs," Health Affairs Blog, July 6, 2020. https://www.healthaffairs.org/do/10.1377/hblog20200701.841730/full/.

[6] Medicaid and CHIP Payment and Access Commission, "MACStats: Exhibit 28 Medicaid Gross Spending and Rebates for Drugs by Delivery System, FY 2018," December 2019, https://www.macpac.gov/wpcontent/uploads/2015/11/EXHIBIT-28.-Medicaid-Gross-Spending-and-Rebates-for-Drugs-by-DeliverySystem-FY-2018-millions.pdf

states are presently confronting major challenges in financing Medicaid while addressing the COVID-19 crisis and the massive job losses that will likely increase program costs. These challenges are already forcing state Medicaid programs to consider reducing Medicaid benefits, cutting back on Medicaid enrollment, or reducing payments to health care providers, which could have a deleterious impact on access to health care. Without modifications to the current proposed rule, these challenges may be further exacerbated. AARP urges CMS to ensure the proposed changes do undercut the Medicaid best price program, especially without additional action to address the high price of prescriptions drugs set by drug manufacturers.

Finally, while increasing the use of value-based purchasing arrangements remains laudable, AARP is mindful that such agreements remain in their infancy and international experience indicates that meaningful savings could take years or decades to materialize.[7] Further, VBP agreements have thus far only involved a small subset of drugs. As such, this approach should not be expected to provide a meaningful reduction in drug prices in the near future.

AARP remains pleased with the Administration's continued focus on high drug prices. While we appreciate the intentions of this proposed rule, we urge the Administration to continue working with Congress to enact meaningful solutions that will lower drug prices and substantially reduce out-of-pocket costs for older Americans. If you have any additional questions, feel free to contact me or have your staff contact Amy Kelbick on our Government Affairs staff at akelbick@aarp.org or 202-434-2648.

Sincerely,

David Certner
Legislative Counsel and Legislative Policy Director
Government Affairs

[7] Peter Bach, "CMS' Proposed Medicaid Best Price Loophole for Value-Based Purchasing of Drugs," Health Affairs Blog, July 6, 2020. https://www.healthaffairs.org/do/10.1377/hblog20200701.841730/full/.