



July 20, 2020

Seema Verma, Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Submitted online via <http://www.regulations.gov>

Re: Comments on Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review and Supporting Value-Based Purchasing for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability Requirements, RIN 0938-AT82 [Docket ID CMS-2482-P]

Dear Administrator Verma:

Arnold Ventures welcomes the opportunity to provide comments to the Centers for Medicare and Medicaid Services (CMS) on the “Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review and Supporting Value-Based Purchasing for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability Requirements” proposed rule (CMS-2482-P) published in the Federal Register on June 19, 2020 (85 FR 37286).

Arnold Ventures is a philanthropy dedicated to investing in evidence-based policy solutions that maximize opportunity and minimize injustice. Our work in prescription drug pricing is driven by the evidence that our current system costs too much and that those costs are unsustainable. Drug spending in the U.S. grew by 32% over the 2012-2018 period, which was more than 3 times inflation during that same period.¹ The problem is not getting better; drug spending growth is projected to increase by 62% between 2019 and 2028.² Even though Medicaid receives generous statutory rebates, high prices for brand-name drugs are still of great concern. Brand-name specialty drugs accounted for just 1% of prescriptions and about 30% of net drug spending in Medicaid in 2015.³ The average net price per prescription of a brand-name specialty drug grew at an average annual rate 12% in Medicaid between 2010 and 2015.⁴

High prescription drug prices, particularly for brand-name products, pose significant affordability problems for patients, employers, and taxpayers. Arnold Ventures’ goal is to promote evidence-based policy solutions that comprehensively lower drug prices while maintaining incentives for meaningful drug innovation. Policy solutions we support address the following underlying drivers of high prescription drug prices: (1) patent abuses and anticompetitive behaviors; (2) market distortions driven by pharmaceutical supply chain actors; and (3) high prescription drug launch prices and unjustified price increases.

Generally, we are concerned that Value Based Purchasing (VBP) arrangements such as pay-over-time (drug mortgage) models create payment mechanisms for states, plans, and patients that facilitate very high launch prices. However, we acknowledge that VBP arrangements may be useful in limited circumstances with appropriate data sharing and oversight. Therefore, we encourage CMS to develop a narrow regulatory framework around best price reporting for pharmaceutical manufacturers that use VBP arrangements with commercial payers.



As drafted, we are concerned that the sections of the proposed rule that address VBP arrangements are too broad in scope and, relatedly, lack clarity in the definitions necessary to implement successfully the intent of the policy. We think the proposed policy will lead to unintended consequences that ultimately make best price discounts less generous to Medicaid and increase drug prices and spending. At a time when states are dealing with significant revenue shortfalls and rapidly increasing Medicaid enrollment related to the economic crisis and pandemic, CMS should be promoting drug-pricing policies that will decisively lower drug prices.⁵

The Medicaid Drug Rebate Program (MDRP) is critical to ensuring that publicly funded Medicaid programs that serve the poor pay some of the lowest prices for prescription drugs in the U.S. The best price component of the MDRP produced federal and state Medicaid savings of up to \$5 billion on brand-name drugs in 2015 alone.⁶ Any approach to facilitate VBP arrangements in the commercial sector must maintain the integrity of the current definition of best price to ensure that it continues to generate billions in savings for state Medicaid programs.

We appreciate the efforts of CMS's staff to administer the Medicaid program at this trying time. Arnold Ventures respectfully submits the following comments on the proposed changes to the MDRP related to VBP Arrangements, Best Price Reporting, and the Line Extension Definition. We hope you find our comments helpful.

B. Subpart I—Payment for Drugs Definitions (§ 447.502) a. Value-Based Purchasing Arrangement (page 37291)

Arnold Ventures is concerned that the proposed definitions of what constitutes a VBP arrangement are too vague and could lead to higher Medicaid spending on prescription drugs. We urge CMS to refine the definitions to ensure that they only apply to a small subset of drugs and contract types.

The proposed rule states that any contract where the cost of the product is “substantially” linked to evidence-based or outcomes-based measures qualifies as a VBP arrangement. However, there is no proposed definition of “substantially.” The proposed rule casts a wide net as the definition of a VBP arrangement includes “*but is not limited to*” evidence-based or outcomes-based contracts.

It is conceivable that almost any contract between a manufacturer and a PBM or health plan could be structured to meet the proposed definition of a VBP arrangement. For example, most pricing contracts could meet the “evidenced-based” standard simply by linking the price in some manner to the currently available clinical evidence on the efficacy of the drug. The definitions of what constitute a VBP arrangement should be narrowed to include only specific types of contracts, such as outcome-based contracts, that meet a high and better-defined threshold of “substantially.” Because standard contracts between manufacturers and PBMs or health plans can be highly complex even without value-based components, manufacturers could leverage the very broad proposed definition to make their best price less generous to the Medicaid program.

Arnold Ventures is concerned that the broad definition of a VBP arrangement in the proposed rule coupled with the proposed changes to the best price calculation discussed in *Subpart I—Payment for Drugs.1. Definitions (Section 447.502)* would create significant loopholes that would result in a less generous best price, on average, than under current regulation. We suggest a framework below to help mitigate some of these concerns.



Additionally, we request that CMS clarify whether license-based contracts, such as those to set up subscription or “Netflix” style payments, would be considered a VBP arrangement and how best price would be defined under such contracts.

B. Subpart I—Payment for Drugs Definitions (§ 447.502) b. Bundled Sale (page 37292)

Arnold Ventures recommends that CMS require manufacturers to perform the bundled sale calculation of best price at the individual purchaser (such as a single health plan or managed care organization) and VBP contract level. CMS should also require all manufacturers engaging in VBP arrangements to report best price using a bundled sale methodology as modified by our comments below.

The proposed bundled sale methodology would allow manufacturers to calculate the best price by proportionally allocating discounts (or payments) required for each outcome across the total sales of the product under a VBP arrangement, thus creating a bundled best price. This in effect makes the best price equal to the average price paid per unit, inclusive of all discounts, rebates, or any other payments under the VBP arrangement.

However, the proposed calculation would not result in the true “best price” given to commercial payers largely because it does not address whether, how, or under what conditions the best price under a VBP arrangement could be calculated across multiple VBP contracts or multiple purchasers. We are concerned that this lack of clarity would encourage manufacturers to aggregate best price calculations across commercial payers or commercial contracts in a way that would make best price significantly less generous to Medicaid.

Arnold Ventures recommends that the bundled calculation occur at the individual purchaser and individual VBP contract level. We also recommend that CMS provide clearer language to ensure that, when averaging discounts within a single contract, manufacturers include all discounts provided either with the VBP arrangement or outside of the VBP arrangement, such as discounts for volume of use or formulary placement. The best price for an individual purchaser should equal the average price paid per unit after including (or stacking) all discounts that a purchaser received whether the discounts were within or outside of a VBP arrangement. This is consistent with the best price statute, which is the lowest price paid by any individual purchaser inclusive of all discounts and rebates.

If a manufacturer enters into or creates a model VBP contract that several, smaller purchasers agree to, the bundled best price could be calculated across these multiple small purchasers as long as all of the contract terms are the same for each. Within this structure, manufacturers should still be required to report a price that includes all discounts provided to these small purchasers under common contract terms. For this reason, we believe that aggregation of sales and discounts across purchasers to arrive at a bundled best price should only be allowed for very small purchasers (such as when that the number of patients expected to take the drug is extremely low). If manufacturers were allowed to bundle across a broader range of VBP contracts and purchasers, they will be incentivized to design contracts and aggregate in a manner that would lead to a less generous best price.

CMS should establish a threshold related to covered lives or anticipated treatments to allow for such aggregation and bundling of best price. We believe aggregation within small purchasers is



feasible. Entities that work with manufacturers to design and maintain these contracts, like PBMs, could facilitate bundling under our recommended approach.

Finally, the bundled best price approach should cover all types of VBP arrangements. The rule seems to limit this approach primarily to outcomes-based contracts by revising the definition of bundled sale in section 447.502 to include VBP arrangements “if the arrangement contains a performance requirement such as an outcome(s) measurement metric” (page 37292 of the proposed rule). If CMS chooses a more expansive definition of VBP arrangements, then the bundled approach should cover those arrangements as well.

Reporting of Multiple Best Prices, Adjustments to Best Price (§ 447.505(d)(3)) (page 37292)

Arnold Ventures strongly urges CMS not to permit manufacturers to report multiple best prices. As a matter of principal, this approach defeats the purpose of having a single best price discount. We suggest requiring all manufacturers that use VBP arrangements to report a single best price using the bundled sale calculation we suggest in the previous section of our comment letter.

Certain VBP arrangements result in different prices depending on how well the drug works to treat different patients. The proposed rule would permit a manufacturer to establish multiple best prices for a single drug based on patient evidence-based or outcome-based measures specific to a VBP arrangement, instead of reporting one best price that reflects the lowest unit price, which is current policy. States would need to document outcomes or other measures required by the VBP arrangement in order to access any of these multiple best prices.

We are concerned, first and foremost, that reporting multiple best price discounts undercuts the intent of the Medicaid statute, which requires manufacturers to report a single best price discount for purposes of the MDRP.⁷ The authority CMS is using to establish the proposed multiple best price calculation is questionable.

Second, most states’ Medicaid data systems are inadequate to track multiple best price discounts and to link specific patient medical outcomes to prescription drug claims.^{8,9} It is unclear to us how states would use multiple best prices appropriately without: (1) clear line of sight into the commercial contract terms that generated the multiple best price discounts and, relatedly, (2) significant new investments in data systems that track patient outcomes or other measures required to ensure they access the most appropriate best price. We are very concerned that most manufacturers would choose this approach because the complexity of its application to the MDRP would likely result in fewer best price discounts paid, which leads to higher net prices paid by Medicaid for these drugs.

Lastly, state Medicaid programs are permitted to engage in VBP arrangements under current law and several have approved state plan amendments to do so (Oklahoma, Michigan, Colorado, Washington, Louisiana, Massachusetts, and Alabama).¹⁰ Those with the capacity are already adopting these arrangements. This section of the proposed rule would essentially force all other states to implement the infrastructure necessary to engage in VBP arrangements in order to access reasonable best price discounts, which would be incredibly burdensome especially given the economic downturn.



C. Changes To Update Definitions To Reflect Recent Statutory Changes Made by Medicaid Services Investment and Accountability Act of 2019 (Pub. L. 116– 16, Enacted April 18, 2019), Balanced Budget Act of 2018, and the Affordable Care Act (page 37294)

Arnold Ventures supports CMS’s proposed definition and intent to expand the drugs that would be subject to the “line extension” policy. However, we are concerned that without further refinement, the proposed definition will be difficult for CMS to enforce and lead to inconsistent manufacturer rebate calculations that increase the prices charged to Medicaid for drugs that are line extensions.

The inflation rebate component of the MDRP is calculated differently for new formulations of existing brand-name drugs. For new formulations, the inflation rebate is the greater of its inflation rebate or the inflation rebate (calculated as a percentage of average manufacturer price) for the original brand-name drug. In order for manufacturers to calculate that feature of the MDRP, the proposed rule defines the statutory terms “line extension”, “new formulation”, and “oral solid dosage form.”

A 2017 National Bureau of Economic Research paper examined various definitions of drug line extensions.¹¹ It notes that the [Drugs@FDA](#) database includes a classification code for each New Drug Application based on a variety of characteristics, including their relationship to existing products.¹² We suggest that CMS link its proposed definition of line extension to the definitions [created by the Food and Drug Administration \(FDA\)](#) to enable easier compliance and agency oversight. We believe that the following definitions in the FDA document could be incorporated into the final rule: Type 2 - New Active Ingredient; Type 3 - New Dosage Form; Type 4 - New Combination; Type 5 - New Formulation or Other Differences.

We also recommend explicitly adding “authorized generics” to the definition of “line extension” for purposes of the inflation rebate. The proposed rule states that CMS believes the *“line extension provision was codified in statute to assure that manufacturers are not circumventing rebate liability by creating a line extension drug and avoiding inflation-based additional rebates.”* Since authorized generics are chemically equivalent to brands already on the market, we are concerned that manufacturers are launching authorized generics (particularly those with large Medicaid market share) to avoid higher inflation rebates. Launching an authorized generic moves Medicaid market share from the brand equivalent with a low net price (driven by a very high inflation rebate), to the authorized generic, which has a lower inflation rebate and typically a higher net price to Medicaid. Some examples of authorized generics that could be affected by this recommended change are those that are chemically equivalent to the brand-name hepatitis C drugs Epclusa and Harvoni.¹³

G. Requirements for Manufacturers (§ 447.510) (page 37301)

Arnold Ventures is concerned that the proposed rule removes the time limit on revisions to best price reporting under a VBP arrangement and suggest, instead, that CMS add back a limit that is not longer than 3 years, which is current practice. We have concerns that manufacturers would initially determine a best price that is not in the best interest of the Medicaid program and defer the full amount of what is actually owed in perpetuity. We view this as a particularly significant issue if the application of the rule is not narrowed. We also concur with comments submitted on this issue by Edwin Park of Georgetown University.¹⁴



H. State Plan Requirements, Findings and Assurances (§ 447.518) (page 37302)

Arnold Ventures recommends that, at a minimum, states report to CMS the average net price paid per unit and per prescription of each drug for which a VBP arrangement was used by the state.

As drafted, the rule proposes that state Medicaid agencies that enter into VBP arrangements with manufacturers report certain data to CMS including estimated savings under any VBP arrangement, the number of prescriptions dispensed, and the cost of administering the VBP arrangement. We are concerned that the proposed rule would lead to inconsistent state reporting. We want to ensure that states perform net drug calculations uniformly so researchers can compare prices between states and different VBP arrangements.

Conclusion

Thank you again for the opportunity to comment and for your review. Arnold Ventures looks forward to working with CMS to implement policies that encourage innovation while also best serving patients, employers, and taxpayers.

Arnold Ventures is prepared to assist with any additional information needed. Comments were drafted with assistance from Anna Anderson-Cook, Kevin Love, Kristi Martin, and Andrea Noda. Please contact Kristi Martin at kmartin@arnoldventures.org with any questions.

Sincerely,

Mark Miller
Executive Vice President

¹ Analysis of Centers for Medicare & Medicaid Services, Office of the Actuary prescription drug spending data from the National health Expenditure Accounts, Table 16 and BLS data on CPI-U 2011-2017.

² Analysis of Centers for Medicare & Medicaid Services, Office of the Actuary prescription drug spending data, Table 11.

³ <https://www.cbo.gov/system/files/2019-03/55041-presentation.pdf>

⁴ Ibid

⁵ <https://www.chcs.org/news/rising-medicaid-rolls-the-impact-of-covid-19-on-medicaid-enrollment-and-state-budgets/>

⁶ <https://www.healthaffairs.org/doi/10.1377/hblog20200325.649781/full/>

⁷ Section 1927(c)(1)(C)(i)

⁸ <https://ccf.georgetown.edu/2020/06/22/cms-proposes-medicaid-drug-rebate-changes-to-facilitate-commercial-adoption-of-value-based-purchasing-arrangements/>

⁹ <https://ccf.georgetown.edu/wp-content/uploads/2020/07/CCF-Comments-to-MDRP-Rule-7-8-20.pdf>

¹⁰ <https://www.healthaffairs.org/doi/10.1377/hblog20200325.649781/full/>

¹¹ <http://www.nber.org/aging/valmed/WhitePaper-Fowler10.2017.pdf>

¹² Ibid.

¹³ <https://www.asegua.com/authorized-generic-therapies>

¹⁴ <https://ccf.georgetown.edu/wp-content/uploads/2020/07/CCF-Comments-to-MDRP-Rule-7-8-20.pdf>