



VIA ELECTRONIC SUBMISSION

July 25, 2023

Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Administrator Brooks-LaSure:

Arnold Ventures welcomes the opportunity to provide comments to the Centers for Medicare and Medicaid Services (CMS) on the following guidance issued on May 26, 2023:

- *Medicaid Program; Misclassification of Drugs, Program Administration and Program Integrity Updates under the Medicaid Drug Rebate Program (CMS-2434-P)*

Arnold Ventures (AV) is a philanthropy dedicated to investing in evidence-based policy solutions that maximize opportunity and minimize injustice. Our work within the health care sector is driven by the recognition that the system costs too much and fails to adequately care for the people it serves. Our work spans a range of issues including commercial-sector prices, provider payment incentives, prescription drug prices, clinical trials, Medicare sustainability, and complex care.

We appreciate the opportunity to provide comments to CMS on this proposed rule that will enhance transparency and strengthen the Medicaid Drug Rebate Program (MDRP). We support efforts to ensure that Medicaid does not overpay for covered outpatient drugs (CODs). This letter provides CMS with comments on the following sections of the rule:

1. *Drug Cost Transparency in Medicaid Managed Care Contracts (B.2)*
2. *Proposal to Revise Definition of Manufacturer for NDRA Compliance (C.1(d))*
3. *Proposal to Define Market Date (C.1(e))*
4. *Proposal to Define Vaccine for Purposes of the Medicaid Drug Rebate Program (MDRP) (C.1(g))*
5. *Proposal to Account for Stacking When Determining Best Price (D)*
6. *Drug Classification: Oversight and Enforcement of Manufacturer's Drug Product Data Reporting Requirements – Proposals Related to the Calculation of Medicaid Drug Rebates and Requirements for Manufacturers (F)(1) and (F)(2)*
7. *Proposals Related to Amendments Made by the American Rescue Act of 2021 — Removal of Manufacturer Rebate Cap (G)*
8. *Proposal to Establish a Drug Price Verification Survey Process of Certain Reported CODs (J)*
9. *Request for Information on Requiring a Diagnosis on Medicaid Prescriptions (M)*



1. Drug Cost Transparency in Medicaid Managed Care Contracts (B.2)

AV supports CMS' proposal to require that a subcontractor that delivers or administers CODs on behalf of a Medicaid managed care plan (such as a pharmacy benefit manager (PBM)) separately report reimbursement for the COD, payment for other patient services, dispensing or provider drug administration fees, and subcontractor fees. Bundling administrative costs with the payment of a prescription occurs more frequently when PBMs charge Medicaid MCOs more for a prescription than the amount paid to the provider/pharmacy (commonly referred to as spread pricing). The proposed approach will bring transparency to the amounts earned by PBMs through spread pricing and conserve Medicaid funding by appropriately classifying administrative costs when calculating MCO medical loss ratios.

In states where spread pricing is still permitted, contracts will likely need to be adjusted so that any amounts earned through spread pricing are accurately reported to the MCO. Relatedly, the National Academy of State Health Policy (NASHP) analyzed PBM contracts in a subset of states and developed [model contract language](#) to address the lack of transparency and promote cost-saving incentives in typical PBM contracts.

2. Proposal to Revise Definition of Manufacturer for NDRA Compliance (C1d)

AV strongly supports this proposal to refine the definition of a manufacturer, which strengthens the ability of CMS to collect Medicaid statutory rebates across a manufacturer's entire product line and ensures these rebates are collected across all relevant national drug codes.

3. Proposal to Define Market Date (C1e)

AV supports CMS' revised definition of first market date that is used to calculate Medicaid's inflation rebate as the date when a drug is first sold rather than the date it is first available for sale.

While this would be a later date in some instances, it allows the manufacturer to calculate the base Average Manufacturer Price (AMP) using actual data rather than relying on "reasonable assumptions." The rebate amount would be calculated more accurately because it would be based on actual sales, defined as the earliest date on which the drug was first sold. "Sold" means the drug is transferred to a purchasing entity. Relatedly, Part D inflation rebates will be linked to this revised definition of first market date, standardizing the calculation of the inflation penalty in both programs.

4. Proposal to Define Vaccine for Purposes of the Medicaid Drug Rebate Program (C.1g)

AV supports CMS' definition of a vaccine in the proposed rule which is "a product that is administered prophylactically to induce active, antigen-specific immunity for the prevention of one or more specific infectious diseases and is included in a current or previous FDA published list of vaccines licensed for use in the United States."

We appreciate CMS acknowledging the growing pipeline of immunological products that work similarly to vaccines by producing antigen specific immune responses for certain types of diseases, such as cancer (we draw a distinction for cancer caused by the human papilloma virus (HPV), which is a sexually transmitted disease and preventable by FDA-approved vaccines). "Therapeutic vaccines" are currently furthest in development for certain types of cancer. These



immunotherapies are not administered prophylactically and are biological products intended to treat an individual with a known disease; importantly, to prevent the disease from recurring.

If this section is finalized, states will be permitted to collect rebates on this new class of products, which are expected to command high prices. For this reason, we encourage CMS to further develop policies to assist states addressing the financial pressures of these and other high-priced therapies.

5. Proposal to Account for Stacking when Determining Best Price (D)

AV supports CMS' proposal requiring that price concessions across multiple entities in the supply chain be combined ("stacked") when calculating the best price.

For example, discounts given to a specialty pharmacy would be combined with rebates received by a health plan. If the regulation is finalized, manufacturers can adjust their contracts with actors in the supply chain (such as wholesalers, specialty pharmacies, pharmacy benefit managers and providers) to obtain the necessary information to aggregate these price concessions and accurately estimate the best price in compliance with this proposed rule.

6. Drug Classification – Oversight and Enforcement of Manufacturer's Drug Product Data Reporting Requirements -- Proposals Related to the Calculation of Medicaid Drug Rebates and Requirements for Manufacturers (F)

AV supports CMS on the proposed drug product data reporting requirements because they will ensure that drugs are correctly classified as brand-name or generic so that the appropriate rebate amounts are collected from manufacturers.

The Medicaid Services Investment and Accountability Act of 2019 addressed the issue of misclassification of drugs by manufacturers which has in some instances caused statutory rebates to be underpaid. The proposed rule implements this Act through regulatory changes that will help ensure that manufacturers have appropriate incentives to correctly classify their drugs (as brand-name or generic) for the purposes of the MDRP. Epipen is a well-known example of a drug that was misclassified by its manufacturer as a generic drug and as a result, rebate revenues were underpaid for several years.

7. Proposals Related to Amendments Made by the American Rescue Act of 2021— Removal of Manufacturer Rebate Cap (G)

AV supports CMS' efforts to align the statute lifting the manufacturer rebate cap and regulations governing the MDRP. This will mitigate confusion prior to the removal of the manufacturer rebate cap early next year.

AV is supportive of Congress giving the Secretary flexibilities to reduce Medicaid inflation rebate amounts owed for drugs in shortage as it did for inflation rebates recently established in the Medicare program by the Inflation Reduction Act.

- The Part B inflation rebate statute does not apply to generic drugs covered by Part B (older, generic sterile injectables are often covered by Part B and are susceptible to shortages), and
- The Part D inflation rebate gives the Secretary the authority to reduce the inflation rebate amount owed by manufacturers with drugs in shortage.



Drug shortage issues are complex and result from a variety of different factors. We view giving the Secretary additional flexibility to reduce inflation rebates owed by manufacturers with drugs in shortage as one tool to help manufacturers ramp up production in certain instances.

8. Proposal to Establish a Drug Price Verification Survey Process of Certain Reported CODs (J)

AV supports CMS' proposal to establish a drug price verification survey of up to 10 drugs each year. We believe the drug pricing verification survey would help state Medicaid programs and CMS to better understand manufacturer pricing and assure that prices are accurately reported to CMS by manufacturers.

The survey will be particularly helpful for high-cost drugs dispensed through specialty pharmacies because prices and distribution costs for these drugs are opaque.

CMS requested comments on how best to refine the list of drugs selected for the survey. This includes whether accelerated approval drugs should also be included (especially when they have high prices and have not completed their confirmatory trials). To that end, we recommend the following considerations when refining the list of drugs selected for the survey:

- **Drugs Subject to Limited Distribution Networks.** Limited distribution networks restrict the distribution channel for a pharmaceutical drug to a very small number of distributors and specialty pharmacies. The limited number of actors in the supply chain can contribute to a lack of transparency around how AMP and best price are calculated. Furthermore, and without being overly restrictive, we recommend CMS initially focus on physician-administered and 5i drugs. These drugs are typically provided in nonretail settings – often through limited distribution networks – which may impact the standard calculation of AMP and the ability for states to claim significant rebate dollars.
- **Accelerated Approval Drugs.** Several accelerated approval drugs remain on the market for years without confirming a clinical benefit, often commanding high prices regardless of the underlying clinical uncertainties. We recommend CMS prioritize accelerated approval drugs using a combination of the following criteria: (a) high net spending and (b) unconfirmed clinical benefit after a set number of years on the market.¹

9. Request for Information on Requiring a Diagnosis on Medicaid Prescriptions (M)

AV supports CMS collecting diagnosis codes in Medicaid drug claims data. AV believes that adding the diagnosis code would give states an additional tool to determine whether a drug is medically appropriate. Off label uses that appear in certain medical compendia are considered CODs under current law. As such, we do not think this requirement would have a big impact on the ability of a Medicaid patient to obtain coverage for medically appropriate off-label use of a drug.

Additionally, requiring diagnosis codes would help researchers study important questions such as which drugs are most effective for a given condition.

¹ MACPAC has focused its attention on drugs approved under the accelerated approval pathway where confirmatory clinical trials have not been completed after a set number of years recommending that their statutory rebates be increased. [June 2021 Report to Congress on Medicaid and CHIP: MACPAC](#)



Conclusion

AV is prepared to assist with any additional information needed. Comments were prepared by Kirk Williamson, MPH, Health Care Manager- Drug Pricing at Arnold Ventures and Anna Anderson-Cook Ph.D., with assistance from Andrea Noda, MPP, Vice President of Health Care at Arnold Ventures and Mark E. Miller, Ph.D. Executive Vice President of Health Care at Arnold Ventures.

Please contact Andrea Noda, MPP at anoda@arnoldventures.org or Mark E. Miller, Ph.D. at mmiller@arnoldventures.org with any questions. Again, thank you for the opportunity to comment and your work to ensure that Medicaid does not overpay for outpatient prescription drugs.

Sincerely,

Andrea Noda
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