



The Honorable Secretary Alexander Azar
Office of the Secretary
Department of Health and Human Services (HHS)
200 Independence Ave, SW
Room 600E
Washington, DC 20201

RE: HHS Blueprint to Lower Drug Price and Reduce Out-of-Pocket Costs

The Medicaid Health Plans of America (MHPA) applauds the Administration's efforts to begin to address the high cost of drugs through the comprehensive blueprint offered by the Department of Health and Human Services (HHS). MHPA is the national trade association representing 90+ private-sector health plans that contract with state Medicaid agencies in 39 states plus DC to provide comprehensive, high-quality health care to more than 24 million Medicaid enrollees in a coordinated and cost-effective way.

MHPA fundamentally believes that the challenge with drug pricing in the United States is a lack of transparency in pricing and the artificial cost shifts that are part of accessing life science medications. While we will touch upon a number of the areas scoped in the Blueprint, most of our commentary focuses on the impact the Medicaid Drug Rebate Program (MDRP) has on drug pricing in Medicaid.

Achieving Better Negotiated Prescription Drug Pricing in Medicaid Through A Medicaid Managed Care Prescription Drug Program

The Blueprint suggests that "HHS may [...] develop proposals related to the Affordable Care Act's Maximum Rebate Amount provision, which limits manufacturer rebates on brand and generic drugs in the Medicaid program to 100% of the Average Manufacturer Price."¹ The Blueprint provision is based on the idea that removing or significantly increasing the rebate cap would be a disincentive for a manufacturer to increase its list price for any drug for which Medicaid collects rebates.

However, the MDRP maintains structural defects that are remnants of an archaic program. First, the MDRP masquerades as a tax disguised as a rebate for the use of life sciences medications in Medicaid that get passed on to other purchasers.

In addition, the current statute requires that life sciences products used by Medicaid are also subject to a "best price" calculation, along with a CPI-U (Consumer Price Index-Urban) adjuster that attempts to regulated prices by giving any rebate above the CPI-U to Medicaid or the best price offered to nearly any purchaser.

When the MDRP was created in 1990, less than 1 in 11 Americans were insured by Medicaid, and only about 8% were in full risk managed care. Twenty-seven years

later, more than 1 in 5 Americans get access to health care via Medicaid, and over 75% are in full risk, managed care programs.ⁱⁱ

Obviously, the most direct remedy is Congressional action through statutory revisions to the MDRP. This effort would be well-informed by the current construct of existing Federal insurance programs including the Medicare Advantage (MA) prescription drug program (MA-PDP). However, Congressional action is not the only avenue for change.

The Blueprint recognizes the need for a new Medicaid demonstration authority whereby a State participating in a pilot would determine their own drug formularies and negotiate drug prices directly with manufacturers. This suggested architecture comports with the restrictions that the Centers for Medicare and Medicaid Services (CMS) articulated in its letter to the Commonwealth of Massachusetts relating to its 1115 waiver. The waiver sought, in part, to give Massachusetts the ability to exclude certain Medicaid covered outpatient drugs from coverage under its Medicaid program, but CMS noted that the Commonwealth would need to forgo the rebates available under the MDRP and have a budget neutral demonstration.

MHPA proposes to make Medicaid MCOs (MMCOs) responsible for actively managing the prescription drug benefit. MMCOs already pay for roughly 70% of all Medicaid prescriptions, a fact that reflects MMCOs are already established as the main delivery system for Medicaid beneficiaries.ⁱⁱⁱ

Medicaid plans, unlike commercial ones, are contractually bound to provide a comprehensive set of services for a specified rate and do not have the latitude to change the conditions of the agreement in mid-contract or to cost shift to the enrollee. This unique accountability creates a compelling incentive for plans to continually strive for the best outcomes. The pharmaceutical benefit is a key component of achieving that goal. Enrollees and plans will be better served if managed care plans are responsible for the full continuum of care including full responsibility for the drug benefit.

MHPA's proposal follows the same basic model as MA-PDPs under Medicare and aims to ensure Medicaid enrollees receive the same or higher level of pharmaceutical benefit provided to other large federal programs such as the VA, TRICARE, etc.

Our proposal duplicates many of the key elements used in the aforementioned programs:

- States using fully capitated risk programs will require Medicaid MCOs to create a formulary for enrollees similar to that used by Medicare Part D plans, including class and category requirements. States that provide Medicaid coverage through managed care will not be permitted to create a separate formulary (FFS programs will continue to abide by the MDRP).

- Plans will be responsible for negotiating any rebates for products provided in the outpatient setting.
 - The negotiated rebates will flow directly to the plans
 - The rebates will reduce the overall actuarial cost of the population covered, reduce per member per month (PMPM) rates, and reduce up front states and federal outlays.
 - Rebates will be reported to the states for an accurate rate calculation in the next contract cycle.
 - The rebate is proprietary and will not be subject to public reporting.
 - The states will be able to use the reported rebates to reduce the overall cost of the program and provide targets for the total drug spend of a specific population covered under a capitated risk program.
- Plans will be permitted to combine their populations for the purposes of negotiating a discount from manufacturers. This model allows plans to combine their Medicaid populations in several states to obtain the best discounts. They may also combine commercial and Medicaid populations to obtain higher discounts.
- Negotiated drug price discounts to Medicaid MCOs will be excluded from the “best price” calculation.
- Pharmaceutical manufacturers will be permitted to enter into risk bearing contracts that include services that would otherwise be excluded under “anti-kickback” statutes. Manufacturers will be able to provide value added services, including, but not limited to, population management or treatment designs that are risk-based for Medicaid MCOs and that have been proven to affect total cost of care.
- Pharmaceutical manufacturers will be exempt from pre-approval marketing requirements pertaining to labeled indications and price prior to FDA approval. To ensure that plans accurately account for the price of new medications likely to be approved in a given contract year, pharmaceutical manufacturers will be permitted to communicate certain information such as likely labeled indication and possible pricing of products with appropriate Medicaid MCO staff (likely CMOs).
- State arbitration for the provision of outpatient drugs will be limited to whether the plans provided access to pharmaceuticals in accordance with the contract signed between the state and the MCO.

- Plans will be required to have an exceptions process to address those rare situations where a patient needs a product not included on the plan formulary.

Under the MHPA proposal, the existing MDRP program would remain in effect along with all existing mandated rebating, “best price,” etc., in two situations. First, states may continue to administer the Medicaid program or some portion of their Medicaid program using the FFS model. Second, there may be instances in which Medicaid MCOs and pharmaceutical companies are not able to reach an agreement on a discounted price.

A recent presentation before the Medicaid and CHIP Payment and Access Commission (MACPAC) indicated that the use of Medicaid drug benefit administrators captures 3-6% incremental rebate over the MDRP.^{iv} Unpublished analyses indicate that our proposal would reap additional savings beyond those captured by existing Medicaid drug benefit administrators who negotiate for the States including for supplemental rebates. We estimate that the policy would save the Federal government \$11.8B over 10 years. In addition, we believe such a policy would enable MMCOs to achieve an additional 56 basis points of rebates from manufacturers of brand drugs.

Adding Needed Clarity in The Administration of the Medicaid Prescription Drug Benefit

Another proposal in the Blueprint is noteworthy: removing ambiguity over how drugs are reported in Medicaid. MHPA supports efforts to close inappropriate interpretations of the definition of Medicaid brand drugs which leads some manufacturers to classify certain brand and over-the-counter drugs as generics for Medicaid rebate purposes.

In addition, MHPA suggests that HHS consider recent recommendations from the Medicaid and CHIP Payment and Access Commission (MACPAC) including closing a loophole in current law that allows a manufacturer to sell its authorized generic at a low price to a corporate subsidiary, reducing the rebate obligation for its brand drug; and to give the Secretary of HHS clear authority to impose intermediate financial sanctions on manufacturers that misclassify a brand drug as a generic to lower their rebate payments.^v

Creating Definition Around Specialty Drugs in Medicaid Would Help to Align Formularies Across Federal Programs

High-cost specialty drugs have underscored the limits of the MDRP as a tool for controlling Medicaid prescription drug costs. This is an especially acute problem in the specialty pharmacy space where recent advancements in pharmacotherapeutics for certain conditions (e.g. hepatitis C) have confounded State payor arrangements.

In general, specialty drugs share a common number of common characteristics, including but not limited to, treatment of serious conditions for which there are few or no alternative treatments, requiring special storage, handling, or administration, and high costs. During 2016, over 1,700 National Drug Codes (NDCs) had an average nationwide cost of \$1,000+ per Medicaid prescription.^{vi}

In light of the State experiences with drugs like Sovaldi and Harvoni, a common definition of specialty drugs under Medicaid would create a common lexicon to assist in designing payment models for high-cost drugs. Our suggestion for a broad definition is broad enough in scope that it could conceivably sweep in most of the existing definitions (i.e. Medicare +\$600).

Our tentative definition centers on three-prongs: access, targeting towards the treatment of complex conditions, and cost. Under our definition for State Medicaid programs, specialty drugs are defined as those drugs for which (i) access is limited by the distribution of the manufacturer (e.g. certain sites of care such as a clinical trial hospital) or by the State (e.g. through a specialty pharmacy network); (ii) are prescribed for complex conditions (e.g. HIV, Hepatitis C, etc.) and that may require specific disease management/care coordination services; (iii) exceeds the threshold cost of the definition of specialty drugs as found in the Medicare Part D program; (iv) or is a combination thereof.

MHPA thanks HHS for the opportunity to provide feedback on the prescription drug RFI. We appreciate the Administration's commitment to lowering prescription drug costs and are grateful to be able to offer our contributions to this effort. Please feel free to contact our organization for any additional detail regarding our comments.

Sincerely,



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ⁱ 83 FR 22692 (May 16, 2018).

ⁱⁱ The Complicated State of Medicaid in the United States: Stability Amidst Considerable Future Uncertainty, Ari Gottlieb, PWC, October 2017.

ⁱⁱⁱ Key Trends in Medicaid Prescription Drug Usage and Cost, Menges Group presentation, September 2017.

^{iv} State Levers for Managing Medicaid Prescription Drug Utilization and Cost: Connecting the Dots between Supplemental Rebates, Preferred Drug Lists, and Other Utilization Tools. Magellen Rx Management Presentation before the Medicaid and CHIP Payment and Access Commission (MACPAC), December 14, 2017.

^v June 2018 Report to Congress on Medicaid and CHIP (MACPAC).

^{vi} Menges Group presentation.