Submitted via email: drugshortages@mail.house.gov

August 25, 2023

The Honorable Cathy McMorris Rodgers
Chair of House Energy & Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515

Re: Discussion Draft to Address Drug Shortages

Dear Chair McMorris Rodgers,

Medicaid Health Plans of America (MHPA) appreciates the opportunity to respond to your request for input on the recently released Discussion Draft to address drug shortages. We applaud this important initiative to identify legislative solutions to this problem and look forward to collaborating with you as you craft policy to best serve the millions of Americans who rely on Medicaid for high quality health coverage and care.

MHPA is the only national trade association with a sole focus on Medicaid, representing more than 130 Medicaid Managed Care Organizations (MCOs) serving more than 52 million Medicaid beneficiaries in 40 states, the District of Columbia and Puerto Rico. MHPA's members include both for-profit and non-profit, national, regional, as well as single-state health plans that compete in the Medicaid market. Nearly three-quarters of all Medicaid beneficiaries receive health care through MCOs, and the Association provides research and advocacy services that support policy solutions to enhance the delivery and coordination of comprehensive, cost-effective, and quality health care for Medicaid beneficiaries.

MHPA applauds efforts by Congress to address drug shortages and ensure that Americans have access to affordable generic drugs. Ensuring that generic, sterile injectable drugs are accessible for use in surgery and in emergency departments and for serious diseases such as cancer is an issue of critical importance for Medicaid enrollees especially, who rely on the program to treat chronic and acute health conditions.

We welcome the opportunity to work with your committee to identify solutions to drug shortages in a way that improves access to treatments and does not cause unintended consequences for the sustainability of the Medicaid program. Given our perspective as a trade association focusing on Medicaid, we are limiting our feedback to provisions in Title I and II of the Discussion Draft. Below are our recommendations on ways to address this important issue.

General remarks

As Congress considers approaches to alleviate drug shortages, we encourage members to consider solutions that support access to life-saving medicines and treatments. However, we also

note that ensuring that states are able administer their programs to fit the needs of their populations, including managing costs, is integral to the sustainability of the Medicaid program. As states navigate the resumption of redeterminations and the sunset of enhanced federal assistance under the Families First Coronavirus Response Act, promoting a stable policy and fiscal landscape for the Medicaid program is more important than ever.

Section 101. Exempting Certain Specified Drugs from Certain Increases in Rebates Under the Medicaid Program; Rebate Cap for Certain Drugs.

We applaud the Committee for exploring solutions to shortages of generic, sterile injectable drugs, but raise concerns that this provision, if implemented, could lead to unintended consequences for the Medicaid program.

Specifically, we have concerns with suspending inflationary rebates and limiting total rebates to 100% of the Average Manufacturer Price (AMP) cap for drugs under the Medicaid program. Inflationary rebates are critical to ensuring access to drugs for Medicaid enrollees and to ensuring that the program remains sustainable from a state budgetary perspective. It also remains the primary tool used by the Medicaid program to put downward pressure on drug price increases over the long term. Indeed, prior to Congress taking action with the American Rescue Plan Act, the Congressional Budget Office estimated that lifting the rebate cap under the Medicaid Drug Rebate Program (MDRP) would reduce federal Medicaid spending by $15.9 billion over ten years, which the Georgetown University Center for Children and Families concluded would save states $7.6 billion, for a total savings of $23.5 billion over ten years.[1] The Medicaid and CHIP Payment and Access Commission (MACPAC) recommended that Congress eliminate the rebate cap as well,[2] articulating that it would generate significant savings and that manufacturers would only be impacted by the cap if they increase their prices substantially over time.

Should the Committee move forward with this proposal, we seek clarification on the definition of "generic" in this discussion draft. The Discussion Draft defines "specified generic drug" as a drug that is currently in shortage on the shortage list in effect under section 506E of the Federal Food, Drug, and Cosmetic Act[3], or that the Secretary determines there is a severe supply chain disruption caused by a natural disaster or other unique or unexpected event. It would appear that this definition could apply to brand drugs that are on the shortage list or are identified as being impacted by a severe supply chain disruption during a specified rebate period. We recommend that the Committee clarify the definition of "specified generic drug" in the draft language to specifically reference generic drugs and to exclude brand drugs, to ensure that this provision does not unintentionally increase costs for brand drugs.

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[1] Georgetown University McCourt School of Public Policy. February 21, 2021. https://ccf.georgetown.edu/2021/02/21/cbo-estimates-confirm-lifting-medicaid-drug-rebate-cap-results-in-significant-federal-and-state-savings/

[2] Medicaid and CHIP Payment and Access Commission. Recommendations on Prescription Drug Policy. April 2019. https://www.macpac.gov/publication/review-of-draft-chapter-for-june-report-and-recommendations-on-prescription-drug-policy-grace-period-and-cap-on-rebates/

[3] U.S. Food and Drug Administration: Drug Shortages. Accessed August 21, 2023. https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm

Finally, we wanted to clarify one item in the in the Section-by-Section summary of the Discussion Draft, which states that generic drugs in Medicaid are subject to a statutory rebate of 17.1% plus an inflationary rebate. It's our understanding that under 42 U.S.C. 1396r-8(c), generic drugs are subject to a statutory rebate of 13%, whereas brand drugs approved for pediatric indications and certain clotting factors are subject to a rebate of 17.1%.

Sec. 201 Exempting Generic, Sterile Injectable Drugs from the 340B Drug Discount Program.

While we appreciate efforts to alleviate drug shortages, we are concerned that excluding certain drugs from the 340B drug discount program could have unintended impacts on the ability of states and health plans to meet network adequacy standards under the Medicaid program. Safety net hospitals serving a high number of uninsured and low-income patients typically qualify for 340B rebates for covered outpatient drugs. The 340B program is intended to incentivize hospitals to serve low-income and uninsured patients by giving them additional resources to cover uncompensated costs. This provision could soften incentives for hospitals to serve the Medicaid population, potentially creating long term pressure on the ability of Medicaid MCOs to meet network adequacy standards and hampering access to care for Medicaid enrollees. Further, we are concerned that as with Section 101, this section could be interpreted to apply to brand drugs as well as generic drugs. Should the Committee move forward with this provision, we recommend clarifying that applicability is limited to generic drugs only.

Again, thank you for the opportunity to contribute to this important work. Addressing drug shortages is one of the keys to unlocking more robust access for the millions of Americans who rely on the Medicaid program – a goal shared by MHPA and its member health plans. Please feel free to reach out to me directly at sattanasio@mhpa.org with any questions or should you need any additional information.

Sincerely,

Shannon Attanasio
Vice President, Government Relations and Advocacy