July 20, 2020

Ms. Seema Verma, MPH
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–2482-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244–1850

Submitted electronically via http://www.regulations.gov

Re: Comments to CMS-2482-P- Proposed Rule: Medicaid Program; 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

Dear Administrator Verma:

We are writing in response to the request for comment for the proposed rule, *Medicaid Program; 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*.

Founded in 1995, the Medicaid Health Plans of America (MHPA) works on behalf of over 100 member health plans, which serve approximately 25 million Medicaid enrollees in 38 states, or about one-third of all Medicaid beneficiaries in states with managed care delivery systems. MHPA's members include both for-profit and non-profit, national and regional, as well as single-state health plans that compete in the Medicaid market. The proposed rule addresses several policy areas that impact the Medicaid program; we will be focusing our comments on proposals related to value-based purchasing, "best price" reporting requirements, the clarification related to supplemental rebate agreements, and the implementation of the SUPPORT Act.

Changes to Address Medicaid Access to Drugs Using Value-Based Purchasing Arrangements

We applaud the efforts of the Centers for Medicare & Medicaid Services (CMS) to support the use of value-based purchasing arrangements (VBPs) as an option for better managing and predicting drug spending and to support access to innovative medicines. Today, innovative products approved for the U.S. market are increasingly expensive. In addition, more one-time cures are appearing as game-changers for the treatment of certain diseases, but often come with a significantly high price tag. For example, in 2019, Zolgensma came to the U.S. market as a groundbreaking treatment for children with spinal muscular atrophy and with a price tag over $2 million.

In 2017, the Food and Drug Administration approved the first use of cell and gene therapy in the United States. As of March 2020, there are 362 cell and gene therapies in clinical development by biopharmaceutical companies in the United States.[1] By 2025, the FDA expects it will be reviewing and approving between 10 and 20 cell and gene therapies each year.[2] These are important breakthroughs, but pharmaceutical manufacturer pricing strategies have created significant access challenges, particularly for programs such as Medicaid that serve vulnerable populations and have limitations based on state budgets.

VBPs are an important option for addressing high cost drug treatments, particularly for state Medicaid programs. Pharmaceutical manufacturers have long pointed to the Medicaid program's "best price" requirements as a major regulatory barrier to VBPs. Despite this, several state Medicaid programs—including Oklahoma, Michigan, Colorado, Louisiana, and Massachusetts—have entered into VBPs with pharmaceutical manufacturers in recent years. MHPA is hopeful that encouraging VBPs as an option for certain drug therapies will support access to innovative medicines for Medicaid beneficiaries as well as for all patients in need of these treatments.

MHPA supports the effort to address "best price" requirements as a barrier to VBPs. We would also encourage CMS to assess and consider addressing other barriers that may continue to hamper implementation of VBPs such as implications for 340B ceiling price; setting average sales price; the applicability of the anti-kickback statute and Stark law; and concerns about potential beneficiary inducements.

Operationalizing VBPs

We believe this proposed rule is an important step forward that lays the foundation for increased use of VBPs between pharmaceutical manufacturers and payors in the near future. However, there are several operational issues that relate to the implementation of VBPs as proposed.

First, we believe that data collection procedures for assessing clinical outcomes of VBP arrangements are currently unclear. The lack of a framework or a process for data collection

[1] https://www.phrma.org/en/Report/Medicines-in-Development-for-Cell-and-Gene-Therapy-2020
[2] https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-and-peter-marks-md-phd-director-center-biologics

leaves considerable room for interpretation and sets up the potential for high variability in the quality of reporting and the value of the data. Given the relationship between clinical outcomes and payment, there should be consideration given to the implementation of quality controls in the reporting process as well as to compensation for the associated burden and costs for health care providers. Further, CMS may wish to consider the development of safe harbors to account for circumstances when data is incorrect but is reported in good faith.

Second, there are a number of issues related to patient portability that should be addressed as part of VBP development. For example, in the context of the Medicaid program, there are questions related to how a VBP would be managed when a patient moves from a Medicaid health plan to the Exchange or a commercial plan. Also, how is a VBP handled when a patient moves from a state's Medicaid program with a VBP for a particular medicine to another state that does not have one in place for that drug in its Medicaid program? Clinical outcomes reporting and rebate tracking are two critical elements of a VBP that would likely be impacted by patient portability. We encourage CMS to support the development of systems and processes that minimize the potential for any disruption of care, promote administrative efficiencies, and that provide clarity and transparency for all parties.

Definitions – VBP; Best Price and Reporting of Multiple Best Prices, Adjustments to Best Price

The proposed rule's definition of VBP is intended to clarify for pharmaceutical manufacturers how discounts, rebates, or pricing in such an agreement should be accounted for when a manufacturer is determining average manufacturer price (AMP) and best price for the purposes of price reporting as required by the Medicaid Drug Rebate Program. The definition also explicitly references arrangements intended to align pricing or payments to therapeutic or clinical value, including evidence-based or outcomes-based measures.

MHPA believes the definition of VBP establishes an important foundation for encouraging the development and implementation of VBPs. Accordingly, we believe the definition should be sufficiently inclusive of varying types of VBPs, such as subscription model contracts and complex multi-product arrangements, and flexible enough to accommodate new, innovative value-based approaches. We also believe it is important that the proposed definition of VBP encourages arrangements based on clinical outcomes, rather than measurements such as adherence. The language should clearly preclude arrangements that are not actually value based, such as modified rebate agreements, from meeting the definition.

In light of the proposed changes to the definition of a VBP, and the revisions to best price reporting, we would also request that CMS clarify the impact of these changes on the process for states to pursue VBPs. For example, would the finalization of this rule impact existing arrangements approved through state plan amendments (SPAs)? Would existing arrangements that required SPAs still follow the same process to pursue similar arrangements in the future?

CMS proposes two different methodologies by which manufacturers can accommodate VBPs in the best price determination: as a bundled sale and using multiple best prices. The proposed rule lacks any detail on the operationalization of these methodologies and CMS acknowledges the "operational challenges" presented by the reporting requirements under these arrangements.

MHPA believes that additional detail on how to operationalize the changes to best-price reporting would be helpful and provide clarity. Additionally, further clarification around how VBP best price(s) are developed is needed. For example, will there only be two "best prices" – one for non-VBP contracts and one for VBP contracts? If so, how will the VBP contract best price be chosen from what could be multiple VBP arrangements that all differ in their financial and outcome metrics? Alternatively, will there be multiple VBP "best prices" – one for each VBP contract? We also recommend that CMS consider adding language that ensures the overall best price is not significantly lowered in cases where there is a negative outcome in a VBP for a limited subset of participants.

Changes to Update Definitions to Reflect Recent Statutory Changes Made by Medicaid Services Investment and Accountability Act of 2019, BBA 2018 and the Affordable Care Act.

CMS proposes several new definitions intended to reflect recent statutory changes. The proposals include a new definition of "line extension" intended to address some inconsistencies among manufacturers in their identification of line extension drugs. Specifically, CMS proposes to define "line extension" as: "for a drug, a new formulation of the drug, but does not include an abuse-deterrent formulation of the drug (as determined by the Secretary)."

We believe this definition could be broadened to further discourage pharmaceutical manufacturers from interpreting this definition in a way that reduces their Medicaid rebate liability.

Exclusion of Certain Manufacturer Sponsored Patient Assistance Programs from Determination of Best Price and Average Manufacturer Price

CMS proposes to revise certain AMP and best price exclusion provisions that relate to manufacturer-sponsored patient assistance programs. Specifically, CMS proposes to revise the regulatory language so that each exclusion would apply "only to the extent the manufacturer ensures the full value of the assistance or benefit is passed on to the consumer or patient." The proposed rule does not provide requirements or details on how this would be operationalized. To provide some additional guidance and to prevent gaming of best price determinations, we would recommend that the exemption from best price apply only when a pharmaceutical manufacturer pays for the entire cost of a drug during the entire length of the prescription.

State Plan Requirements, Findings, and Assurances

Under current policy, "CMS-authorized supplemental rebate agreements" (SRAs) are excluded from both AMP and best price. The proposed rule establishes a new definition for a SRA that would require such agreements to be approved by CMS through a state plan amendment and that supplemental rebates must be paid directly to a state in order to be excluded from Medicaid best price and AMP calculations.

We believe this provision promotes clarity and greater transparency that would support pharmaceutical manufacturer compliance with best price reporting. However, we have concerns

that this approach could have the unintended effect of excluding Medicaid managed care organizations from negotiations between states and pharmaceutical manufacturers.

In addition, supplemental rebate agreements reported by Medicaid managed care organizations should be exempt from AMP and best price calculations because they are already factored into state rate setting which serves to return the rebates to the state through lowered capitation rates paid to MCOs. We would recommend that CMS add language to clarify that rebates paid to MCOs can be excluded from AMP and best price as long as the state's rate setting process includes actuarially sound adjustments for manufacturer rebates received by MCOs in which case the rebate is considered exempt. It is important to note that the rate setting process requires MCOs to report rebates received for members, but that these rebates are usually an allocation of a larger contract that the MCO has with the manufacturer. The regulation should be flexible enough to account for the fact that rebates are not paid on a member level basis, and that data reported by using common allocation methods suffices to meet this requirement.

Managed Care Standard Contract Requirements and Requirements for MCOs, PIHPs, or PAHPS that Provide Covered Outpatient Drugs.

The proposed rule implements several provisions of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act, an important contribution to the national response to the ongoing opioid epidemic signed into law in 2018. Specifically, among other things, the proposed rule establishes standard managed care contract requirements related to the operation of drug utilization review (DUR) programs. We believe DUR programs are critical safeguards for the health of Medicaid beneficiaries that can assess the appropriateness of drug therapy and help reduce fraud and abuse; we support this important step forward in the implementation of the SUPPORT Act.

Thank you for your consideration of our comments on this proposed rule. We are encouraged by the promising pipeline of innovative medicines that bring hope to patients with current unmet needs; however, we remain concerned that high drug prices will persist as a significant barrier for patient access. These proposals are an important step forward for developing a pathway for patient access that will benefit patients in need and help support the financial sustainability of the Medicaid program. 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

Shannon Attanasio
Vice President, Government Relations and Advocacy