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July 20, 2020

Mr. Alex M. Azar, II
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
P.O. Box 8013
Baltimore, MD 21244-8013

Attention: CMS–2482–P

Re: 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 Secretary Azar and Administrator Verma:

The Academy of Managed Care Pharmacy (AMCP) thanks the Centers for Medicare & Medicaid Services (CMS) for the opportunity to provide comments in response to its 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"* published on June 19, 2020. We appreciate the opportunity to leverage our members' expertise in providing feedback on this proposed rule.

AMCP is the nation's leading professional association dedicated to increasing patient access to affordable medicines, improving health outcomes and ensuring the wise use of healthcare dollars. Through evidence and value-based strategies and practices, the Academy's 8,000 pharmacists, physicians, nurses, and other practitioners manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models and government.

AMCP offers comments on the following sections of the notice:

A. Current Medicaid Drug Rebate Program and Value-Based Purchasing Arrangements (VBP)

B. Exclusion of Certain Manufacturer Sponsored Patient Assistance Programs ("PBM Accumulator Programs") from Determination of Best Price (§ 447.505) and Average Manufacturer Price (AMP) (§ 447.504)

A. Current Medicaid Drug Rebate Program and Value-Based Purchasing Arrangements (VBP)

CMS Proposal
CMS proposes to define VBP arrangements as "an arrangement or agreement intended to align pricing or payment to an observed or expected therapeutic or clinical value in a population and includes, but is not limited to, evidence-based and outcomes-based measures."

AMCP Response
In June 2017, AMCP hosted a Partnership Forum on "Advancing Value Based Contracting" with participating thought leaders representing a diverse set of health care stakeholders including health plans, integrated delivery systems, pharmacy benefits managers, clinical practice representatives, and biopharmaceutical and laboratory companies. Finding that varying definitions of VBCs exist in the marketplace and pose a challenge to increased adoption of VBCs, this group agreed upon a standard definition of VBC as "a written contractual agreement in which the payment terms for medication(s) or other health care technologies are tied to agreed-upon clinical circumstances, patient outcomes, or measures."[1] AMCP finds that the VBP definition CMS proposes to implement is similar to the consensus definition that emerged from our Partnership Forum and is encouraged by the agency's efforts to develop a standard VBP definition for the Medicaid Drug Rebate Program (MDRP). CMS's definition importantly does not prescribe a one-size-fits-all approach that could stifle the development of innovative contracting types and encourages flexibility so that different factors can be considered, including patient population size, payer size and ability, or whether a treatment is curative or must be taken for longer periods of time to address a chronic condition. Given this, AMCP supports this proposed definition.

AMCP does encourage CMS to recognize that there are evidence-based and outcomes-based measures that may be included in VBP arrangements between manufacturers and payers that are not included in the examples provided in the proposed rule. The examples CMS provides in the proposed rule, such as observing or recording the absence of disease over a period of time, reducing a patient's medical spending, or improving a patient's activities of daily living, are some of the measures that may be included in VBP arrangements but are not nearly encompassing of all potential evidence- and outcomes-based measures that can be incorporated into VBP arrangements. At AMCP's abovementioned Partnership Forum, the stakeholders discussed and agreed upon outcomes measures that could be included in VBPs such as:

- Health care utilization rates.
- Hard clinical endpoints.
- Cancer-free survival, progression-free survival.
- Cure rates.
- Adverse event rates.
- Laboratory values.
- Quality of life (patient-reported outcomes).

[1] See: https://www.jmcp.org/doi/full/10.18553/jmcp.2017.17342

- Medication adherence.
- Medication persistence.[2]

Any definition of evidence- or outcomes-based measures in VBP arrangements should recognize the broad spectrum of drugs for which manufacturers and payers will develop VBPs as well as the varied patient populations who will utilize the medications. AMCP urges CMS to ensure that the definition of evidence- or outcomes-based measures is adaptable to include clinical endpoints as well as direct or indirect surrogate endpoints.

CMS Proposal
CMS proposes to expand its interpretation of "lowest price available" in the MDRP regulations to permit, in the context of a VBP arrangement, to include a set of prices at which a manufacturer makes a product available based on that pricing structure for a single drug (dosage form and strength).

AMCP Response
Manufacturers have consistently held that the requirements of the MDRP, in particular the reporting of best price, are a barrier to their participation in VBP arrangements. As CMS notes in the proposed rule, manufacturers have been reluctant to agree to VBP arrangements, as it is possible that the results of those arrangements could lead to manufacturers owing rebates in the Medicaid program that in some cases could equal 100 percent of a drug's average manufacturer price. VBP arrangements have the potential to help control drug costs and the importance of implementing them will only continue to grow as more innovative, high-investment treatment options come to market. The removal of barriers to the development of VBP arrangements is essential to increasing their use and efficiency and CMS's proposal to allow for the reporting of multiple price points for a single drug under the MDRP for the purpose of determining best price is an important step.

AMCP urges CMS to consider the potential reporting burden that is likely to be associated with this change in the reporting structure for the MDRP and to require that manufacturers report only the information necessary for determining the "lowest price available" in the context of VBP arrangements. As always, CMS should be sure to balance the need for transparency with the protection of confidential and proprietary information involving the contracted arrangements between payers and drug manufacturers, as well as with the burden on the reporting entities.

Additionally, AMCP continues to have concerns about the MDRP best price requirements in general and about the effect its requirements have on market dynamics. We believe that while the government does have a responsibility to protect consumers from anti-competitive activity, it must not establish rules that have the unintended consequence of undermining competition. The best price requirement of the MDRP represents government interference in the competitive marketplace for prescription drugs that has increased costs for consumers and the health care system through its distortion of market incentives. Prior to the passage of the MDRP, purchasers such as health maintenance organizations (HMOs) and hospitals, were able to negotiate deep discounts with manufacturers but after the implementation of the best price requirements, instead of extending these discounts to Medicaid programs, manufacturers terminated discounts with HMOs and

[2] Ibid.

hospitals, leading to increased costs. While some actions have been taken in the interim to address the market distortions caused by the best price requirements, AMCP urges CMS to consider additional reforms to the MDRP to correct the impact the impact it has had on drug market dynamics.

B. Exclusion of Certain Manufacturer Sponsored Patient Assistance Programs ("PBM Accumulator Programs") from Determination of Best Price (§ 447.505) and Average Manufacturer Price (AMP) (§ 447.504)

CMS Proposal
CMS proposes to revise MDRP regulations to provide expressly that the exclusions from the calculation of best price for manufacturer-sponsored discount and assistance programs apply only to the extent that the manufacturer ensures the full value of the assistance or benefit is passed on to the consumer or patient.

AMCP Response
AMCP supports the use of programs that help plans continue to effectively utilize proven cost management tools. Nearly all employer-sponsored group health plans require employees and their dependents to pay a portion of the costs for most prescriptions out-of-pocket, and these expenses generally come in the form of deductibles, copays, and coinsurance. The intent of these costs is to influence a number of outcomes including: lowering monthly premiums in exchange for the enrollee covering additional costs throughout the plan year if needed; helping direct patients to more cost-effective therapies, including the use of low-cost generic medications; and ensuring that patients understand the financial impact of high cost prescription medications by engaging enrollees as consumers involved in financial decisions around their treatment options. The amount of out-of-pocket costs an individual or family may be subject to pay in a given plan year is also often limited by a defined maximum out-of-pocket (MOOP) amount.

Drug manufacturers regularly offer financial assistance to patients (generally referred to as "copay cards" or "coupons") to offset out-of-pocket expenses for certain high-cost drugs. Although these programs can help offset costs for plan enrollees, they have the overall effect of increasing prescription drug costs for plans, as patients will no longer be incentivized to use lower cost alternatives, including generic drugs, when they reach their MOOP limit.

Manufacturer coupons and other forms of financial assistance programs sponsored by manufacturers distort the economic incentives used by health plans and pharmacy benefit managers (PBMs) to encourage patients to use prescription drugs with lower overall costs and can undermine the formulary development process and utilization management techniques. Perhaps counterintuitively, they also raise the risk of increased overall costs for patients. While the patient has a lower cost-sharing responsibility at the initial point of sale for a high cost drug, the health plans, pharmacy benefit managers, or plan sponsors are responsible for the reimbursement cost to the pharmacy. This raises the costs of administering the prescription drug benefit as a whole, which in turn leads to higher premiums for patients. Additionally, some programs can needlessly encourage the use of more expensive brand-name products over their generic counterparts and can undermine the formulary development process by encouraging the use of products that have lower cost therapeutic alternatives.

CMS has agreed that manufacturer assistance programs can distort the prescription drug market[3] and in its recently published Notice of Benefit and Payment Parameters (NBPP) final rule, the agency granted health plans the flexibility to not apply the value of manufacturer assistance programs toward an enrollee's cost sharing obligations.[4] AMCP is concerned by the language used by CMS in this proposed rule that appears to contradict the intent of the NBPP provisions and which states that PBMs are the only entities that claim manufacturer assistance programs distort the market and economic incentives, when as mentioned above, CMS has made similar claims in a regulation released earlier this year. We are troubled by the use of language that has the effect of making it harder for health plans and their PBM partners to efficiently and effectively manage their drug benefit programs, which will lead to higher costs for consumers and for the Medicare program. AMCP strongly urges CMS to include more accurate language in the final rule that describes the CMS-accepted fact that manufacturer assistance programs create market distortions that lead to higher costs.

Conclusion

AMCP appreciates the opportunity to comment on CMS–2482–P: *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*. We are committed to being a valuable resource to CMS on improving access to prescription drugs at lower costs and reducing costs in the health care system. If you have any questions regarding AMCP's comments or would like further information, please contact me at 703-684-2600 or scantrell@amcp.org.

Sincerely,

Susan A. Cantrell. RPh, CAE
Chief Executive Officer

[3] See: https://www.regulations.gov/document?D=CMS-2019-0006-0016
[4] See: https://www.regulations.gov/document?D=CMS-2020-0009-1086