July 20, 2020

Electronically submitted to: http://www.regulations.gov

The Honorable Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-2482-P
P.O. Box 8013
Baltimore, MD 21244-8013

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 (CMS-2482-P)

Dear Administrator Verma:

On behalf of the Board of Directors of the Community Oncology Alliance (“COA”), I am submitting this comment letter to the Centers for Medicare & Medicaid Services (“CMS”) in response to 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 (“Proposed Rule”).

COA is an organization that is dedicated to advocating for the complex care and access needs of patients with cancer and the community oncology practices that serve them. COA is the only nonprofit organization in the United States dedicated solely to independent community oncology practices, which serve the majority of Americans receiving treatment for cancer. COA’s mission is to ensure that patients with cancer receive quality, affordable, and accessible cancer care in their own communities where they live and work. For 17 years, COA has built a national grassroots network of community oncology practices to advocate for public policies to support patients with cancer.

COA is providing comments on the following provisions of the Proposed Rule:

- Proposals to encourage value-based purchasing (“VBP”)
- Limitations on Best Price (“BP”)/Average Manufacturer Price (“AMP”) Protection for Manufacturer Cost-Sharing Assistance Programs

**COA Strongly Supports Increasing Flexibility to Implement VBP Arrangements**

COA appreciates CMS’ efforts to advance policy changes to lower the cost of prescription drugs and promote payment innovation in state Medicaid programs. Specifically, COA is encouraged by CMS’ efforts to broaden the ability of manufacturers to offer VBP arrangements for drugs covered under Medicaid. The use of VBP arrangements can help to increase competition and lower prices, improving access to the best therapies for cancer patients who...
require complex, often high priced treatments. CMS proposes to define a VBP as an “agreement intended to align pricing and/or payments to an observed or expected therapeutic or clinical value in a population,” including evidence and outcomes-based measures, and proposes that VBPs must “substantially” link the cost of a drug to these measures. COA supports CMS’ intent to tie pricing and payment to therapeutic or clinical value, as we agree VBPs should be designed with the main goal of providing patients with high-quality care. However, we urge CMS to not be overly prescriptive in defining “substantially” in this context as outcomes vary greatly by patient and drug; a highly specific threshold could be burdensome to participants and providers, and ultimately unintentionally inhibit the use of VBPs.

Additionally, while the rule’s discussion of VBPs focuses heavily on manufacturers and insurers, we strongly urge CMS to consider that providers are also key participants in value-based arrangements and should always be consulted in the clinical design of VBPs, especially for vulnerable cancer patients. Boundaries in VBPs are needed so that providers are included in decision making. COA is actively involved in the commercial market, especially with self-funded employers, in developing oncology payment reform models utilizing VBP arrangements. Providers need to be a primary participant in the design, development, and implementation of VBP models.

COA understands and strongly agrees with CMS that “best price” reporting in Medicaid currently inhibits VBPs. The Proposed Rule seeks to clarify that there may be multiple “best prices” under these VBPs. COA has long advocated for the removal of obstacles to value-based contracting and thus agrees that multiple BPs may help foster VBP contracts between payers, providers, and drug manufacturers to ultimately lower the costs of cancer treatment drugs. As Administrator Verma noted in her Health Affairs blog, some drugs in the pipeline, notably gene therapies to treat certain blood cancers, hold the potential to transform the practice of medicine but their costs are often profound.\(^1\)

However, COA seeks further clarification from CMS on how multiple BPs under VBPs may impact pricing outside of VBPs. COA is concerned that the proposed longer time for manufacturers to revise BP and AMP may impact average sales price (“ASP”) reporting and thus negatively affect ASP in the long-term. Because Medicare Part B and other payers reimburse providers based on ASP, a reduction in this measure could result in provider payment below acquisition cost for drugs, not just for Medicare but substantially all commercial plans. COA seeks clarification from CMS that VBP arrangements made by Medicaid programs will not be included in ASP calculations to ensure ASP is not inappropriately negatively impacted, which would hinder administration of the best treatments for their patients. COA underscores that it is essential to exclude drugs purchased through VBPs from ASP determinations.

**While Supportive of the Intent to Ensure Patients Receive Full Value of Copay Assistance, COA Seeks Clarification on How the Proposed Requirement Would Be Operationalized**

COA has always strongly opposed copay accumulator programs. As yet another tool used by pharmacy benefit managers (“PBMs”) to maximize their profits at the expense of patients, these programs prevent cancer patients from meeting their insurance deductibles, thereby keeping their out-of-pocket costs artificially high. As COA notes in our copay accumulator position statement, these programs can make the cost of cancer care prohibitive and force the most vulnerable patients relying on these therapies to limit or stop treatment.\(^2\) For this reason, COA supports CMS’ efforts in the Proposed Rule to limit copay

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accumulators by stipulating that the value of manufacturer cost-sharing assistance must be deducted from AMP and BP if the manufacturer cannot “ensure” the entirety of the assistance is passed on to the patient. COA believes that this proposal could help prevent PBMs’ copay accumulator programs from interfering with patients’ care. **Need-based assistance from manufacturers is critical to making cancer treatments affordable for patients. These need-based programs are not marketing “gimmicks” but legitimate patient assistance that helps limit patients’ out-of-pocket costs.** This is especially true during the current COVID-19 pandemic, as many patients have faced increased financial burdens due to job and insurance loss. **The benefit of manufacturer discounts should not accrue to PBMs but should instead wholly benefit patients.**

However, COA cautions that CMS’ proposal may be challenging, if not impossible, to implement and **CMS must ensure it does not create harmful unintended consequences for patients and providers.** Many manufacturers have told us that they are unaware of whether or not an insurer or PBM is using an accumulator program to prevent this assistance from applying to patients’ deductibles and maximum out-of-pocket costs. In investigating this, we believe that it will be difficult, if not impossible, for manufacturers to do this. COA asks CMS to clarify how manufacturers can ensure that the full value of copay assistance is passed on to patients as there is risk that manufacturers could limit or stop offering copay assistance if they are unable to meet this onerous requirement. **The loss of copay assistance would have severe detrimental effects on cancer patients’ access to their treatments.**

Further, COA seeks clarification that the value of manufacturer copay assistance will not have downstream effects on ASP calculation. As COA has argued in response to the Grassley-Wyden Prescription Drug Pricing Reduction Act of 2019,\(^3\) which would include the value of manufacturer copay assistance in ASP calculation, inclusion of copay assistance programs could have negative consequences for providers by reimbursing below costs for care. As such, manufacturers will not allow drugs’ reimbursement rates to fall below their costs and will simply not offer these assistance programs. That would be devastating to patients in need, especially during the current pandemic.

COA also seeks clarification on how CMS’ proposal that manufacturers establish their own “coverage criteria,” ensuring the full amount of copay assistance goes to the patient, could factor into AMP, BP, and ASP calculations.

COA thanks CMS for its efforts on payment innovation in the Medicaid program, especially during the COVID-19 pandemic when treatment affordability is of even more critical concern for patients with cancer. We look forward to assurance that the multiple BP and copay assistance proposals will not negatively impact ASP, as well as to hearing and understanding details on how CMS intends to direct manufacturers to comply with the requirement to ensure patients receive the full value of copay assistance. We would be happy to discuss any of our comments/concerns further and to assist CMS in any way possible.

Sincerely,

\[Signature\]

Michael Diaz, MD
President

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