July 20, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

RE: 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

Dear Administrator Verma:

The Medicaid and CHIP Payment and Access Commission (MACPAC) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) 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, 85 Fed. Reg. 37286 (June 19, 2020). In recent years, MACPAC has devoted considerable attention to addressing the growing cost of prescription drugs in Medicaid, and to analyzing federal and state policies that ensure appropriate opioid prescribing and that may affect access to evidence-based treatment for opioid use disorder (OUD).

The proposed rule includes multiple changes to the Medicaid pharmacy program. In addition to implementing several statutory changes, the proposed rule establishes how best price would be calculated for drugs under VBP contracts. MACPAC is concerned that the proposed rule puts state Medicaid programs at risk of receiving lower prescription drug rebates, which could result in increased state spending on prescription drugs, without receiving any added flexibilities to implement new payment or rebate models.

The proposed rule also creates minimum DUR standards related to medications for opioid use disorder (MOUD) and identification of beneficiaries who could be at high risk of opioid overdose and should be considered for co-prescription or co-dispensing of naloxone. The Commission generally supports using state DUR programs to identify instances when beneficiaries are

prescribed opioid medications during the course of MOUD treatment, and encouraging co-prescribing or co-dispensing of naloxone to beneficiaries at risk for an opioid overdose. However, such DUR interventions should be inclusive of all forms of MOUD, and extend to all settings in which they are provided. In addition, MACPAC encourages CMS to consider how DUR policies may affect access to MOUD.

Value-based purchasing and Medicaid best price

The proposed rule seeks to address concerns that Medicaid best price impedes the adoption of VBP arrangements for prescription drugs by other payers. Under the Medicaid Drug Rebate Program (MDRP), Medicaid receives mandatory rebates for all outpatient drugs. For brand drugs, the rebate may be determined by the lowest or best price available to any wholesaler, retailer, provider, or paying entity, excluding certain governmental payers. In exchange for these rebates, states must cover essentially all drugs, under conditions that the drug is medically necessary and the manufacturer enters into a national rebate agreement with the Secretary of the U.S. Department of Health and Human Services. Under current regulations, best price is calculated as the lowest price offered on any single unit of the drug to eligible payers. Manufacturers have commented that best price limits their ability to offer a large discount through a VBP arrangement if a product did not achieve its stated outcome, since that one-time discount could establish the drug's best price for the entire Medicaid program.

The proposed definition of VBP and changes to Medicaid best price could lead to decreased rebates, and thus increased Medicaid spending, while also increasing administrative burden on states. Specifically, the Commission is concerned that while these changes could incentivize the use of VBP in the commercial market, they would also negatively affect the Medicaid program and do little to address concerns about the impact of high-cost specialty drugs on Medicaid program spending. In addition, the changes would limit how broadly these discounts and rebates would apply to the Medicaid program.

Questionable benefit to Medicaid. The Commission understands that VBP arrangements have potential to better align prices with the benefit a drug provides, and generally supports efforts to align incentives in the delivery system. We appreciate the importance of the goals CMS is pursuing to encourage these innovations in the commercial sector.

Nevertheless, the Commission questions the value of these changes to the Medicaid program for several reasons. First, the proposed changes to the calculation of best price could have detrimental effects on the amount of rebates Medicaid receives (thus increasing costs for the federal government and the states) without substantially increasing the availability of meaningful VBP arrangements.

Second, the Commission is aware of manufacturers' arguments that Medicaid best price is a barrier to VBP arrangements in the commercial market. However, manufacturers can already enter into VBP arrangements with state Medicaid agencies and Medicare Part D plans without triggering best price and adoption of VBP arrangements remains limited in these markets.

Third, best price is not a major barrier to development of VBP in Medicaid and these changes will not necessarily increase the availability of such arrangements. While states could ultimately gain access to some commercial VBP arrangements under the proposed changes, it is not clear whether the quality measures designed for the commercial market are the most appropriate and beneficial for Medicaid beneficiaries and whether those contract terms would deliver the best value to the Medicaid program.

We elaborate on these concerns below.

Lower rebates for Medicaid. The proposed rule establishes a definition for VBP and changes the way best price would be calculated for these arrangements. Together, these two proposals could allow manufacturers to design arrangements with a primary purpose of raising best price and lowering rebate obligations.

The proposed rule defines VBP as an arrangement or agreement that substantially links the price or payment for a drug product to existing evidence of the drug's effectiveness or to the drug's actual performance in a patient or population. The Commission is wary about how the term "substantially" will be interpreted. A broad interpretation of "substantially" in the definition of VBP could allow manufacturers to reclassify existing contracts as VBP arrangements without linking the discounts or rebates to measures that are tied to meaningful outcomes or evidence of value.

The proposed rule changes how best price would be calculated under VBP arrangements. Current regulatory language defines best price as the lowest price available for the manufacturer during the rebate period in any pricing structure. The rule proposes to reinterpret any pricing structure in a way that would allow VBP arrangements to be considered different pricing structures. This would allow a single drug to be available under multiple pricing structures, each of which may establish a best price based on the relevant or applicable VBP arrangement and patient evidence-based or outcome-based measures. Medicaid would only get a rebate based on the VBP best price when a unit of the drug was dispensed to a Medicaid enrollee under a VBP arrangement and the person's outcome met the criteria associated with that level of rebate. There is no requirement that drug manufacturers offer these arrangements to Medicaid. This could allow manufacturers to effectively raise the best price and lower rebate obligations by not offering arrangements that would allow Medicaid to access the VBP best prices.

Administrative burden. The Commission also has concerns about the administrative complexity and the operational challenges of applying multiple best prices to a single drug. The rule does not appear to limit the number of best prices calculated for a single product, potentially leading to hundreds of best prices for a single drug if the manufacturers make slight alterations to the terms of the VBP arrangement for each payer. Moreover, the proposed rule states that the VBP best price would only be available to a Medicaid enrollee participating in a VBP arrangement whose outcome meets the criteria associated with that level of rebate. This suggests that states would be required to know the specific terms of each VBP contract associated with each best price for that quarter, and then collect outcome data based on these contract terms for each person affected. Furthermore, the best price could change quarterly, and thus, the

measures and outcomes used to qualify for VBP best prices could vary quarter to quarter. Finally, Medicaid agencies would need to coordinate the measurements and data collection across multiple managed care plans. The administrative costs and challenges of managing multiple best prices and corresponding outcome measures could outweigh any savings from the VBP arrangement.

High list prices. Lastly, there are no provisions that would limit a manufacturer's ability to set list price. From the Commission's discussions with states, managed care plans, and drug pricing and policy experts, most stakeholders have shared concerns that any increases in rebates could be built into the list price so that manufacturers would ultimately receive a similar amount of net revenue (MACPAC 2019a). There is no guarantee that VBP arrangements will ultimately lead to a lower net price for payers.

More analysis needed. The proposed rule does not include a regulatory impact analysis. Given that the changes to best price would primarily benefit commercial payers and could lead to lower Medicaid rebates and increased administrative burden on states, the Commission suggests that CMS develop an economic analysis to better understand how these changes could affect the Medicaid program before making any changes to best price.

Establishing minimum DUR standards

The proposed rule would implement requirements under Section 1004 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act, P.L. 115-271) which requires states to adopt DUR standards in their Medicaid fee-for-service (FFS) and managed care programs. The proposed rule would also require states to establish DUR policies to monitor ongoing opioid prescriptions to beneficiaries receiving MOUD, and to identify beneficiaries who should be considered for co-prescribing or co-dispensing of naloxone to reduce the risk of opioid overdose.[1,2] States may choose which DUR strategy (e.g., prospective, retrospective, or a combination of the two) to use to fulfill proposed requirements.

MACPAC supports the Administration's efforts to ensure that dangerous drug interactions that result from co-prescribing or administration of MOUD and other opioids are identified through the DUR process. In the proposed rule, CMS notes that using opioid medications during the course of MOUD is dangerous from a clinical perspective. A safety edit designed to notify health care providers of the co-administration of MOUD drugs and opioids would be useful to signal a possible need for increased coordination of care. Acute care providers may be unaware of an individual's history of OUD and could prescribe opioids to someone in recovery, potentially contributing to relapse, poor health outcomes, or sometimes death (MACPAC 2018a).

While the Commission recognizes the value of DUR activities for MOUD, it is important that such policies do not create additional barriers to access by delaying initiation or continuation of medically necessary treatment.

Administration and dispensing of MOUD in outpatient treatment programs and other settings. States are only required to conduct DUR activities on covered outpatient drugs under the MDRP. The Commission is concerned that DUR activities, including those under the proposed regulation, may not account for MOUD dispensed in an opioid treatment program (OTP) or MOUD administered in settings where regulations pertaining to covered outpatient drugs do not apply, such as inpatient settings.[3] Specifically, the proposed rule does not indicate whether states should conduct DUR activities for Medicaid beneficiaries receiving MOUD in OTPs.[4] It also does not discuss whether states should conduct DUR activities for beneficiaries who receive implantable or injectable formulations of MOUD.[5]

MACPAC encourages CMS to clarify how the proposed DUR requirements should be applied when MOUD are not considered covered outpatient drugs, such as when MOUD is provided in OTPs and other office-based settings that are paid as part of a bundled clinic service. This would help ensure that DUR policies are consistent for all beneficiaries receiving MOUD, regardless of the setting in which they receive medications or the type of medication they receive.

Moreover, the Commission wishes to emphasize that beneficiaries receiving treatment in OTPs are vulnerable to adverse reactions that result from concurrent prescribing, particularly for beneficiaries receiving methadone, which has a greater potential for drug interactions than buprenorphine. (SAMHSA 2018).

Ensuring access to MOUD. Given the considerable flexibility granted to states to comply with the proposed DUR requirements, the Commission is concerned that some DUR interventions, combined with other utilization management policies (e.g., prior authorization or preferred drug lists), may limit access to MOUD. As such, MACPAC encourages CMS, in its review of state DUR polices, to consider how proposed interventions complement other utilization management strategies to ensure that states are not restricting access to MOUD. Access to MOUD is already limited due to a variety of factors, including stigma associated with OUD, a limited pool of providers offering MOUD, and provider unwillingness to participate in Medicaid. In addition, while Medicaid prescriptions for MOUD have increased in recent years, a large treatment gap remains (Clemans-Cope 2019).

Again, we appreciate the opportunity to provide comments on this proposed regulation.

Sincerely,

Melanie Bella, MBA
Chair

cc: The Honorable Chuck Grassley, Chair, Senate Finance Committee
The Honorable Ron Wyden, Ranking Member, Senate Finance Committee
The Honorable Frank Pallone, Chair, House Energy and Commerce Committee
The Honorable Greg Walden, Ranking Member, House Energy and Commerce Committee

Endnotes

[1] There are three FDA-approved medications for opioid use disorder treatment: methadone, buprenorphine, and naltrexone.

[2] Specifically, the proposed rule would require states to establish prospective safety edit alerts, automatic retrospective claims review, or a combination of these approaches, in order to identify cases where a beneficiary is prescribed an opioid after the beneficiary has been prescribed one or more drugs used for MOUD or had an opioid use disorder diagnosis within a specified number of days, without having a new indication to support utilization of opioids (e.g., a new cancer diagnosis or entry into hospice care).

[3] Federal DUR requirements apply to covered outpatient drugs, which include drugs that are generally dispensed by pharmacies, but do not apply to drugs that are provided and billed as part of a bundled service.

[4] Methadone, and sometimes buprenorphine, is dispensed only in OTPs as a bundled clinic service; as such, it is not considered a covered outpatient drug (SAMHSA 2018).

[5] Injectable formulations of naltrexone and the injectable and implantable formulations of buprenorphine, which are administered in a clinician's office, are only considered covered outpatient drugs if the payment is calculated separately from the clinician fee (MACPAC 2018b).

References

Clemans-Cope, L. 2019. *Tracking Medicaid covered prescriptions to treat opioid use disorder*. Washington, DC: Urban Institute. https://www.urban.org/policy-centers/health-policy-center/projects/tracking-medicaid-covered-prescriptions-treat-opioid-use-disorder

Medicaid and CHIP Payment and Access Commission (MACPAC). 2019a. Themes from expert roundtable on Medicaid policy on high-cost drugs. Presentation, December 2019. Washington, DC: MACPAC. https://www.macpac.gov/publication/themes-from-expert-roundtable-on-medicaid-policy-on-high-cost-drugs/.

Medicaid and CHIP Payment and Access Commission (MACPAC). 2019b. *Report to Congress: Utilization management of medication-assisted treatment in Medicaid*. Washington, DC: MACPAC. https://www.macpac.gov/wp-content/uploads/2019/10/Report-to-Congress-Utilization-Management-of-Medication-Assisted-Treatment-in-Medicaid.pdf.

Medicaid and CHIP Payment and Access Commission (MACPAC). 2018a. Chapter 2: Substance use disorder confidentiality regulations and care integration. In *Report to Congress on Medicaid and CHIP*. June 2018. Washington, DC: MACPAC.

https://www.macpac.gov/wp-content/uploads/2018/06/Substance-Use-Disorder-Confidentiality-Regulations-and-Care-Integration-in-Medicaid-and-CHIP.pdf

Medicaid and CHIP Payment and Access Commission (MACPAC). 2018b. Chapter 4: Access to substance use disorder treatment in Medicaid. In *Report to Congress on Medicaid and CHIP.* June 2018. Washington, DC: MACPAC. https://macpac.gov/wp-content/uploads/2018/06/Accessto-Substance-Use-Disorder-Treatment-in-Medicaid.pdf.

Substance Abuse and Mental Health Services Administration (SAMHSA), U.S. Department of Health and Human Services. 2018. *Medicaid coverage of medication-assisted treatment for alcohol and opioid use disorders and of medication for the reversal of opioid overdose.* Rockville, MD: SAMHSA. https://store.samhsa.gov/sites/default/files/d7/priv/medicaidfinancingmatreport_0.pdf