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July 20, 2020

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-2482-P
P.O. Box 8016
Baltimore, MD 21244-8016

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, Proposed Rule (CMS-2482-P)

Dear Administrator Verma:

The Association of American Medical Colleges (AAMC or the Association) welcomes the opportunity to comment on the proposed rule entitled "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), issued by the Centers for Medicare & Medicaid Services (CMS or the Agency).

The AAMC is a not-for-profit association dedicated to transforming health care through innovative medical education, cutting-edge patient care, and groundbreaking medical research. Its members comprise all 155 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems, including 51 Department of Veterans Affairs medical centers; and more than 80 academic societies. Through these institutions and organizations, the AAMC serves the leaders of America's medical schools and teaching hospitals and their 173,000 faculty members, 89,000 medical students, 129,000 resident physicians, and more than 60,000 graduate students and postdoctoral researchers in the biomedical sciences.

PRESCRIPTION DRUG VALUE-BASED PURCHASING ARRANGEMENTS IN MEDICAID

Teaching hospitals are the institutions where patients receive cutting-edge treatment. These institutions are committed to advancing medical knowledge of new therapies and technologies to prevent and treat disease. New innovations offer great promise in the treatment of what were once incurable diseases but often come with high price tags. We agree that well-designed value-based purchasing (VBP) arrangements are one way to address high drug costs and potentially ensure access for patients. However, we are concerned that the proposed rule offers few details on how these VBP arrangements would be structured without imposing financial and reporting

burdens on states and providers. It is unclear if savings would be shared with providers through higher reimbursement for items and services furnished to Medicaid beneficiaries. Furthermore, the proposed rule does not specifically address provider engagement in these VBP arrangements. True value-based innovation occurs when all parties involved in providing high-quality care are included in the development of high-performing VBP arrangements.

As CMS notes, many states already engage in VBP arrangements for drugs through State Plan Amendments thereby bringing into question whether this proposed rule is necessary to encourage states to enter into such agreements. Coupled with the vagueness of the proposed rule, we are worried that state funding may be at risk if states feel obligated to enter into VBP arrangements that are not carefully structured.

Finally, CMS notes that the proposal will present "operational challenges" to the Medicaid Drug Rebate Program (MDRP) systems and that "it will take us time to make such system changes." (p. 37293). CMS should not finalize this proposed rule without fully vetting what the operational challenges are and the impact on states. **We urge CMS to not finalize this proposed rule until the full impact of the proposals on MDRP is understood. We would be happy to meet with CMS to discuss how to structure VBP arrangements that will not only benefit Medicaid but the entire health care system.**

Furthermore, we do not feel that CMS should introduce new policies that could potentially reduce rebates to states as they struggle with the COVID-19 public health emergency. Medicaid enrollment is increasing while state budgets are shrinking. States do not have the additional funds available to cover the shortfall that would occur if rebates are reduced. **CMS provided only a 30-day comment period during a time when hospitals and states are stretched thin due to the COVID-19 public health emergency and therefore we recommend a delay as we further discuss this important policy change.**

Changes to the MDRP Should Not Negatively Impact Best Price

CMS is proposing changes to the MDRP in order to provide increased flexibilities for manufacturers and states to enter into VBP arrangements. However, the proposed rule is silent on how these changes will impact the MDRP and the calculation of best price. In fact, CMS acknowledges in the proposed rule that it "has not addressed the possible impact of offering VBP arrangements on manufacturer compliance with applicable MDRP price reporting obligations, including best price." (p. 37291). Given the lack of understanding about the potential impact it is premature to finalize this rule.

Changes to the best price calculation would considerably reduce the total rebates manufacturers pay to states under current requirements, likely resulting in a significant increase in Medicaid drug costs at a time when state budgets are constrained by the COVID-19 crisis and the increasing number of individuals who are eligible for Medicaid. The result may be to significantly limit patients' access to needed drugs. CMS must ensure that changes to the best price calculation do not result in increased drug costs for states. We urge CMS to evaluate the changes to the calculation of best price on states' ability to provide drug coverage to their

Medicaid beneficiaries. CMS should consider the impact of multiple best prices on safety net programs and ensure that actions intended to encourage the use of VBP arrangements allows safety net hospitals to access the benefits of these arrangements.

Additionally, Medicaid reimbursement to providers that care for Medicaid beneficiaries is inadequate. According to the Medicaid and CHIP Payment and Access Commission, Medicaid fee-for-service (FFS) payment rates for physician services are often much lower than those paid by other payers, raising concerns that low fees affect physician participation in Medicaid, and thus access to care. On average, Medicaid FFS physician payment rates are two-thirds of the rates Medicare pays, although this varies greatly by state and service.[1] The proposed rule does not address how, if at all, providers will benefit from these new VBP arrangements nor how savings from these VBP arrangements benefit hospitals and providers in the form of lower drug costs. Many hospitals that care for a disproportionate share of low-income patients also participate in the 340B Drug Pricing Program (340B Program). Changes to the calculation of best price directly impacts the 340B Program. It is unclear from the proposed rule how 340B covered entities will benefit from the new best prices set under the VBP arrangements. CMS should consider how the scope of the discounts that could be included as part of the VBP arrangements will impact not only Medicaid but also the 340B Program.

VBP Arrangements Should Not Increase Reporting Requirements or Limit Patient Access to Drugs

CMS is proposing to "align pricing and/or payment to an observed or expected therapeutic or clinical value in a population" but does not describe how it will evaluate these outcomes or what information will be used to determine whether the drug meets "an observed or expected therapeutic or clinical outcome." (p. 37292). Evaluating clinical effectiveness may be difficult for some new drugs, such as immunotherapies, because there is limited data on effectiveness due to the newness of these therapies. For some breakthrough therapies, comprehensive data collection on outcomes could take years because of the limited number of treatments currently on the market and the small patient populations these drugs target. Clarity on how clinical effectiveness will be determined is important in optimizing this proposal. The proposed rule is silent on who is responsible to achieve and report the desired health outcomes. If the hope is that these VBP arrangements will provide long-term information on outcomes of new therapies, investments should be made in broader outcomes-based research rather than changing how Medicaid reimburses for prescription drugs. If there is another plan for measuring clinical effectiveness it would be important to discuss and align.

CMS seeks feedback on how states would "track health outcomes for Medicaid beneficiaries to align with the outcomes developed in the private market VBP." (p. 37293). States and providers should not be burdened with additional reporting requirements under a Medicaid VBP arrangement. Hospitals engaged in VBP arrangements with commercial payers have agreed upon measurement evaluation and reporting requirements and hospitals share in the savings

[1] Medicaid and CHIP Payment and Access Commission. Medicaid 101. Provider Payment and Delivery Systems. Available at: https://www.macpac.gov/medicaid-101/provider-payment-and-delivery-systems/

based on their performance. The savings associated with the Medicaid VBP proposals do not extend to hospitals and providers and this should be considered.

Data collection and reporting outcomes would require states and providers to redirect scarce resources in order to participate in expanded VBP programs. We question whether states have the resources or systems in place to perform the necessary data collection. States that wish to participate in these VBP programs should not impose additional data collection and reporting requirements on hospitals and providers as a condition of coverage. Additionally, the outcome metrics agreed to by the drug manufacturer and the state should not impact patient access to medically necessary drugs.

PATIENT ASSISTANCE PROGRAMS

Many pharmaceutical manufacturers offer financial assistance programs to help patients pay for out-of-pocket drug costs. Patient advocacy groups support these programs out of the belief that they improve access and adherence to prescription drugs. Opponents of the programs, including health plans, feel that financial assistance programs incentivize patients to utilize more expensive drugs, particularly when lower-cost alternatives are available. Through the use of "accumulator" and "maximizer" programs, some commercial health plans have chosen not to apply the value of the assistance to a patient's out-of-pocket maximums, and instead receive much of the benefit of the manufacturer's financial assistance. Although financial assistance programs are more commonly used in the commercial market, eliminating these programs could negatively impact patients' access to medically necessary drugs.

Currently, amounts paid by manufacturers under the assistance programs are ignored when determining a drug's best price or average manufacturer price (AMP). In other words, if a manufacturer sells a drug at a given price but then provides financial assistance to a patient who received that drug, the manufacturer does not take into account the value of the financial assistance when reporting the best price or AMP of that drug. CMS is proposing that best price exclusions that reflect this principle will only apply if the manufacture ensures that the full value of the assistance is passed on to the consumers. **We support the proposal that financial assistance programs benefit the patient and not the health plan.**

DEFINITION OF LINE EXTENSION

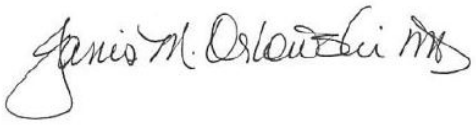
CMS is proposing a new definition for line extension drugs under the MDRP. A line extension drug is a new formulation of an existing drugs such as an extended release formula. (p. 37288). If finalized, for drugs covered under Medicaid, line extension means "a new formulation of the drug, but does not include an abuse-deterrent formulation of the drug." (p. 37295). CMS is proposing this change because it has "found that some manufacturers are unclear about their line extension reporting obligations" and CMS has "noted inconsistencies among manufacturers in their identification of drugs as line extensions." (p. 37289, 37294). CMS goes on to state that it is "concerned that manufacturers may have a financial incentive to be underinclusive in their

identification of drugs as line extensions because a drug identified as a line extension may be subject to a higher rebate." (p. 37294). By excluding some drugs from the definition of line extension allows manufacturers to avoid paying the higher rebate. **The AAMC appreciates CMS' acknowledgement of the issue and supports finalizing this proposal.**

CONCLUSION

Thank you for the opportunity to comment on this proposed rule. We would be happy to work with CMS on any of the issues discussed above or other topics that involve the academic medical community. If you have questions regarding our comments, please feel free to contact Mary Mullaney at 202.909.2084 or mmullaney@aamc.org.

Sincerely,



Janis M. Orlowski, M.D., M.A.C.P.
Chief Health Care Officer

cc: Ivy Baer