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) Fact Sheet

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Overview

Today, the Centers for Medicare & Medicaid Services (CMS) released the proposed rule *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).*

This notice of proposed rulemaking (NPRM) advances CMS' efforts to support state flexibility to enter innovative value-based purchasing arrangements (VBPs) with drug manufacturers, and to provide manufacturers with regulatory flexibility that will encourage VBP arrangements with payers, including Medicaid. It also proposes minimum standards in state Medicaid Drug Utilization Review (DUR) programs designed to reduce opioid-related fraud, misuse, and abuse.

This proposed rule also proposes revisions to current regulations regarding: how manufacturers should calculate the average manufacturer price (AMP) of the brand name drug when there is also a sale of an authorized generic[1]; whether manufacturers should include the value of their patient assistance programs in the calculation of "best price," including when they are impacted by pharmacy benefit managers (PBM) accumulator programs; state and manufacturer reporting requirements to the Medicaid Drug Rebate Program (MDRP); the definitions of CMS-authorized supplemental rebate agreement; line extension, new formulation, oral solid dosage form, single source drug, multiple source drug, and innovator multiple source drug for purposes of the MDRP; payments for prescription drugs under the Medicaid program; and coordination of benefits (COB) and third party liability (TPL) rules related to the special treatment of certain types of care and payment in Medicaid and Children's Health Insurance Program (CHIP).

Increases beneficiary access to medications by promoting value-based purchasing (VBP)

In this NPRM, we are proposing policies and revisions to the MDRP which will modify and provide greater flexibility to some of the manufacturer reporting obligations around AMP and

best price in order to encourage manufacturers and states to enter into VBP arrangements. Consistent with current statute and regulation, this will help modernize our interpretation of how manufacturers adapt the interpretation of the "best price" law - which was enacted 30 years ago, and has only allowed one single best price for each drug to be available to state Medicaid agencies – to contemporary arrangements where more than one price could be available for a drug based on its outcomes in a patient. This change will also help implement the President's drug pricing initiatives.

CMS believes providing states with flexibility to enter into VBP arrangements with drug manufacturers is an important strategy to manage drug costs and promote beneficiary access to needed medications. By addressing the regulatory hurdles in this proposed regulation, CMS will encourage states to enter into VBP arrangements for drug therapies, especially in cases when the therapy will safeguard against unnecessary utilization of other, more expensive medical services.

To accomplish this, the NPRM proposes to allow manufacturers to report multiple "best prices" for a therapy under the MDRP if the prices are tied to a VBP arrangement. To further facilitate VBP arrangements, the NPRM also proposes to define a VBP arrangement in regards to evidence-based and outcomes-based measures, and also include certain VBP arrangements under the definition of "bundled sale"; and, it proposes to permit revisions to AMP and best price reporting beyond the current thirty-six month time limit to allow for revisions to pricing metrics as a result of VBP arrangements.

Encourages the appropriate use of opioids and reduces prescription-related fraud, abuse and misuse

Current CMS regulations at 42 CFR 456.703(d) require states to assess drug use information against predetermined standards developed directly by the state or obtained from another source as provided under 42 CFR 456.703(e). In administering their DUR programs, states have flexibility to develop or select standards that may best fit their programs and patient populations. This proposed rule would amend this section of the regulation to implement new opioid-related DUR standards that are required of states under section 1004 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (Pub. L. 115-271), as well as additional opioid-related DUR standards that CMS is proposing under the authority of section 1927 of the Social Security Act. These changes reflect CMS' continued efforts to reduce prescription-related fraud, abuse and misuse and assure that opioid prescriptions are appropriate, medically necessary, and not likely to result in adverse medical results. Additionally, we are soliciting comments on other opioid-related DUR standards that CMS could propose to adopt through rulemaking in the future.

Clarifies the application of the new authorized generic law to the calculation of a manufacturer's brand name AMP

Section 1603 of the Continuing Appropriations Act, 2020 and Health Extenders Act of 2019 (Pub. L. 116-59) made changes to the calculation of AMP for brand drugs to exclude the sales of authorized generic drugs when brand manufacturers have approved, allowed, or otherwise

permitted an authorized generic to be sold under the brand name drug's new drug application (NDA). Prior to this statutory change, manufacturers were permitted to include the sales of the authorized generic in the AMP of the brand name drug, which resulted in lowered AMPs and reduced rebates paid for the brand name drug. While the changes made to the statute by the Continuing Appropriations Act, 2020, and Health Extenders Act of 2019 are self-implementing, this proposed regulation provides additional clarity to these statutory changes so that manufacturers will understand that they can no longer include the sales of the authorized generic in the calculation of the brand name AMP regardless of the type of relationship between the brand name manufacturer and the authorized generic manufacturer. The proposed regulation will also revise the definition of wholesaler.

Aligns regulation with statute and changes in marketplace which enhance manufacturer and state understanding of the Medicaid Drug Rebate Program

As the pharmaceutical marketplace evolves and new laws are passed, CMS is issuing this proposed rule to define and clarify regulations that will assist manufacturers and states in ensuring compliance with the Medicaid drug rebate statute. We are proposing regulations to clarify how manufacturers calculate their AMP and best price when considering the value of patient assistance programs, especially when a health plan uses a PBM accumulator program. The proposed regulation also proposes a definition of a CMS authorized supplemental rebate agreement in order to clarify that rebates paid are only excluded under a CMS authorized supplemental rebate agreement. The NPRM also proposes a definition of line extension and oral solid dosage form, which would be used by the manufacturer as part of its determination of whether they should calculate an alternative inflation penalty on their oral brand name drugs. The NPRM also proposes new requirements around state reporting and certification of state drug utilization data, which are used by CMS and others for multiple program integrity purposes. Finally, the regulation proposes the inflation penalty for non-innovator multiple source drugs (generics), as well as modifications to the definitions of single source drug, innovator multiple source drug, and multiple source drug.

Third party liability (TPL)

States are currently collecting information on liable third parties for all Medicaid beneficiaries. This rule proposes to change the regulation to instruct states when to cost avoid claims and when to pay and chase claims. In instances when cost avoiding a claim might create an access to care issue for a beneficiary, a state is permitted to pay the claim first and then collect the applicable portion of the payment from the liable third party.

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[1] Section 1603 of the Continuing Appropriations Act, 2020 and Health Extenders Act of 2019 (Pub. L. 116-59)