



CMS Regional Office

Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value Based Purchasing for Drugs Covered in Medicaid - FACT SHEET

Overview

Today, the Centers for Medicare & Medicaid Services (CMS) released the *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 for new expensive therapies, and to provide manufacturers with regulatory flexibility to enter into VBPs with commercial payers, which will benefit Medicaid programs. It also creates 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 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; how 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 in relation to Medicaid Managed Care Organizations (MCOs) and when those sales are exempt from AMP and "best price"; the definition of 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 notice of proposed rulemaking (NPRM), we are proposing policies and revisions to the MDRP which will modify and relax 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 the law which was enacted 30 years ago, and will help implement the President's drug pricing initiatives.

CMS believes state 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 a 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 will for the first time allow manufacturers to report multiple "best prices" for a therapy under the MDRP if the prices are tied to a VBP arrangement. It will also clarify that VBP arrangements can be defined as "performance requirements" under the definition of "bundled sale" which will also facilitate VBP arrangements, especially for small population drugs; and, it will permit revisions to AMP and BP 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

CMS regulations at 42 CFR 456.703(d) require that the state 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 amends this section of the regulation to implement new opioid-related DUR standards that are required of states under section 1004 of the SUPPORT for Patients and Communities Act, as well as additional opioid-related DUR standards that CMS would propose under the authority of section 1927 of the 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

The Continuing Appropriations Act, 2020 and Health Extenders Act of 2019 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 included 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 statute is self-implementing, this 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.

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 providing clarity around 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 clarifies that rebates paid on Medicaid managed care claims are only excluded under a CMS authorized supplemental rebate agreement. The NPRM proposes a definition of line extension and oral solid dosage form, which would be used by the manufacturer as part of their determination of whether they should calculate an alternative inflation penalty on their oral brand name drugs. The NPRM creates 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 codifies the inflation penalty for non-innovator multiple source drugs (generics), as well as modifications to the definitions of single source drug and innovator multiple source drug.

Third party liability (TPL)

States are currently collecting information on liable third parties for all Medicaid beneficiaries and 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.