Viohl and Associates Highlights: CMS Proposed Rule on Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid

Overview

On June 17, 2020, the Center for Medicare and Medicaid Services (CMS) announced a proposed rule intended to encourage value-based purchasing (VBP) arrangements between drug manufacturers and payers. The proposed rule would make changes in the Medicaid Prescription Drug Rebate Program (MDRP) as well adjustments to how a manufacturer should calculate the Average Manufacturer Price (AMP) calculation of a drug when there is also an authorized generic version. Additionally, the proposed rule updates requirements on third-party liability, commonly referred to as "pay and chase" rules, and implements new qualifications for opioid-related Drug Utilization Review (DUR).

CMS's full proposed rule can be found here. CMS's press release and fact sheet can be found here. CMS is accepting public comment on their proposed rule, and the public comment period ends on July 20, 2020.

Major Topics

Promoting VBP between Manufacturers and Payers

- Proposes a definition of a VBP arrangement as one that aligns drug pricing and/or payments to an observed or expected therapeutic or clinical value with evidence-based and outcomes-based measures.
- Provides a new interpretation of "best price" definition and allows manufacturers to report multiple "best prices" for a single drug therapy under MDRP if the prices are tied to a relevant VBP arrangement.

Adjustments to AMP Calculation

- Implements new requirements under the Continuing Appropriations Act of 2020 and Health Extenders Act of 2019, namely revising the definition of wholesaler and prohibiting manufacturers from including the sales of an authorized generic in the AMP of a brand name drug, regardless of the relationships between the brand name manufacturers and the authorized generic manufacturer.
- Proposes to amend regulations to state that exclusions from best price or AMP for manufacturer patient assistance apply only to the extent a manufacturer ensures the full value of the assistance or benefit is passed on to the consumer or patient.
- Clarifies that supplemental rebates negotiated by MCOs for drugs not part of the CMS-authorized supplemental rebate agreement are not excluded from the manufacturer's determination of AMP and best price if not used by a state to offset its drug expenditures.

Third-Party Liability

- Instructs states on when they may reject claims outright and when to "pay and chase" claims to ensure access to care before properly assigning liability to relevant third parties.
- Removes prenatal care for pregnant women from the list of services for which state Medicaid agencies must pay and chase.

Preventing Fraud, Misuse, and Abuse of Opioids

- Amends regulations to implement new requirements under the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act as well as new minimum state Medicaid DUR standards for opioids.

State Data Requirements

- Proposes new requirements for state reporting and certification of state drug utilization data used by CMS for program integrity purposes.
- Proposes that state Medicaid agencies report certain elements from their VBP supplemental rebate agreement.

Alternative Rebate Formula

- For purposes of applying an alternative rebate formula to drugs that are line extension, proposes more detailed definitions of "line extension" and "new formulation," and modifies definition of "oral solid dosage form."