COUNCIL FOR AFFORDABLE
HEALTH COVERAGE

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Summary of 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

Comments Due: July 20, 2020

Top-Line Summary: The CMS Proposed Rule (RIN: 0938-AT82) revises:

- The Medicaid Drug Rebate Program (MDRP) to encourage ***Value-based payment (VBP) arrangements*** for prescription drugs by revising reporting requirements to allow manufacturers to report multiple best prices for therapies tied to a VBP and allow AMP and best price reporting to extend beyond the current thirty-six month time limit;
- ***PBM accumulator programs*** and how they impact AMP and best price;
- Coordination of benefits and ***third party liability*** (TPL) rules related to special treatments of certain types of care and payment in Medicaid and CHIP;
- The calculation of ***Average Manufacturers Price (AMP)*** by excluding the sales of authorized generic drugs when brand manufacturers permit an authorized generic to be sold under the brand name drug's new drug application (NDA);
- New Medicaid ***Drug Utilization Review*** (DUR) provisions designed to reduce opioid-related fraud and abuse; and
- Definitions: supplemental rebate agreement, line extension, new formulation, oral solid dosage form, single source drug, multiple source drug, and innovator multiple source drug.

Value-Based Payment Arrangement Provisions

Key Takeaways: The proposed rule applies to any Medicaid prescription drug. Manufacturers would be allowed to enter into value-based payment arrangements with any payer (both commercial and Medicaid) and reporting requirements would be updated to allow multiple best prices tied to patient-specific outcomes. CMS also proposes to allow VBPs to qualify as bundled sales, which would smooth out discounts that could result from one (or a few) instance(s) of missed performance outcomes.

Detailed Summary:

- **Proposed VBP definition:** An arrangement or agreement intended to align pricing and/or payments to an observed or expected therapeutic or clinical value in a population (that is, outcomes relative to costs) and includes (but is not limited to):
    - Evidence-based measures, which substantially link the cost of a drug product to existing evidence of effectiveness and potential value for specific uses of that product;
    - Outcomes-based measures, which substantially link payment for the drug to that of the drug's actual performance in a patient or a population, or a reduction in other medical expenses.
    - **Requested comments on VBP definition:** what other measures should be used to reflect value from a drug therapy? How to interpret "substantially" with regards to a percent of a drug's costs (i.e how much of the drug's final cost should be associated with the evidence/outcomes measured in order to be considered a VBP)

- **Bundled Sale:** In the Covered Outpatient Drug final rule, CMS defined "bundled sale" as any arrangement regardless of physical packaging under which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug, drugs of different types (NCD) or another product or some other performance requirement (i.e. achievement of market share, inclusion or tier placement on a formulary, or where the resulting discounts or other price concessions are greater than those which would have been available had the bundled drugs been purchased separately or outside the bundled arrangement.
    - Some manufacturers have recognized that the discounts that account from a VBP that has a performance requirement when a measure is not met, as bundled sales.
        - Meaning that the significant discount that could result from one instance of missed outcomes, would be smoothed out over all the units sold under the arrangement in the rebate period and would not reset the best price based upon the ultimate price of one unit of drug.

    - **Proposed revision to "bundled sale":** Add a paragraph that states VBP arrangements may qualify as a bundled sale, if the arrangement contains a performance requirement such as an outcome(s) measurement metric.

- **Best Price**: CMS currently recognizes "best price" as the one lowest price that is available per dosage of a drug.
    - **Proposed change**: A single drug may be available at *multiple price points*, each of which may establish a "best price" based on the relevant or applicable VBP arrangement and patient evidence-based or outcome-based measures.
        - **Requested Comments:** Because the Medicaid rebate would be patient-specific, CMS recognizes the operational challenges. They request comments on this proposal, its impact on the Medicaid Drug Rebate Program, the commercial market, and its operational implications. Request comments on how states would track health outcomes for Medicaid beneficiaries to align with outcomes developed in the private market VBP.
    - **Proposed Change to AMP Definition:** CMS proposes to add a similar qualifying phrase to state that the manufacturer must adjust the best price for a rebate period if cumulative discounts, rebates or other arrangements subsequently adjust the prices available, to the extent that such cumulative discounts, rebates or other arrangements are not excluded from the determination of best price by statute or regulation.
    - **Proposed Reporting Requirement changes:** CMS proposed that a manufacture may make changes outside of the 12-quarter rule as a result of a VBP arrangement when the outcome must be evaluated outside of the 12-quarter period.

- **State Reports on VBPs:** CMS wants to create a mechanism to exchange information about state VBPs.
    - **Proposed Change:** States must provide CMS specific data elements associated with their VBP Supplemental Rebate Agreements (SRAs) to ensure that payments associated with Medicaid patients receiving a drug under a VBP structure are consistent with efficiency, economy and quality of care. The data must be provided on a yearly basis, within 60 days of the end of each year