SUMMARY

Medicaid Program; Proposed Rule
Establishing Minimum Standards in Medicaid State Drug Utilization Review and Supporting Value-Based Purchasing for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability Requirements

RIN 0938-AT82
Comments are due 07/20/2020

Overview:
This proposed rule would advance CMS' efforts to support state flexibility to enter into innovative value-based purchasing arrangements (VBPs) with manufacturers, and to provide manufacturers with regulatory support to enter into VBPs with payers, including Medicaid. This proposed rule also proposes revisions to regulations regarding: authorized generic sales when manufacturers calculate average manufacturer price (AMP); pharmacy benefit managers (PBM) accumulator programs and their impact on AMP and best price; state and manufacturer reporting requirements to the MDRP; new Medicaid Drug Utilization Review (DUR) provisions designed to reduce opioid related fraud, misuse and abuse; the definitions of CMS-authorized supplemental rebate agreement, line extension, new formulation, oral solid dosage form, single source drug, multiple source drug, 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).

A. Third Party Liability (TPL): Payment of Claims
CMS proposes to revise current regulations to require states to cost avoid (reject) claims for prenatal care for pregnant women including labor and delivery and postpartum care when the state Medicaid agency has determined there is a legally liable third party responsible for paying the claim. Additionally, CMS proposes to allow the state Medicaid agency 90 days instead of 30 days to pay claims related to medical support enforcement services, as well as requiring states to collect information on TPL before making payments.

B. Changes to Address Medicaid Access to Drugs Using Value-Based Purchasing arrangements
CMS proposes to define value-based purchasing (VBPs) arrangements as 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 such as

- Observing and recording the absence of disease over a period of time,
- Reducing a patient's medical spending, or
- Improving a patient's activities of daily living thus resulting in reduced non-medical spending.

CMS asks for additional measures or rationales that may be used to measure outcomes and interpretations of "substantially" in the measures above, as a percentage of discounts/rebates tied to performance.

Bundled sale: CMS also proposes to add language that allows states' VBP arrangements to qualify as a bundled sale if the arrangement contains a performance requirement such as an outcome(s) measurement metric. The manufacturer may assume that the discount that resulted from a performance requirement of a single unit is distributed proportionally to the total dollar value of the units of all the drugs sold in the bundled arrangement. This smooths out the discount over all the units sold under the arrangement in the rebate period and does not reset the manufacturer's best price based upon the ultimate price of one unit of a drug.

Best Price: Multiple Best Prices, Adjustments: VBP sometimes result in various price points for a dosage form and strength of a single drug or a single drug available at multiple price points. Each arrangement may establish a "best price" based on the relevant or applicable VBP arrangement and patient evidence-based or outcome-based measures. Therefore, CMS proposes that:

- The price realized in a VBP arrangement by the manufacturer when a measure is not met for a single patient would not reset the best price for the drug in the quarter.
- Multiple prices could be realized by the manufacturer and when a price is realized as a result of a VBP pricing structure. Multiple price points (price points as a result of a VBP) and price points absent a VBP may be reported for one dosage form and strength.

CMS says the agency has the authority to do this because CMS previously interpreted the statutory definition of best price to reference the best price "in any pricing structure," contemplating the possibility of various pricing structures, such as capitated payments.

The manufacturer would report a single best price for the drug for the quarter for sales of the drug in that quarter. In addition, the manufacturer would also report a distinct set of "best prices" that would be available based on the range of evidence-based or outcomes measures for that drug that are possible under the VBP arrangement. CMS proposes that the calculated Medicaid Drug Rebate Program (MDRP) rebate due to the state using the VBP best price would be a function of

whether or not the Medicaid rebate is being paid on a unit of a drug dispensed to a Medicaid patient that participated in a VBP and the level of rebate associated with that patient's outcome.

CMS does understand the operational challenges tying the price paid for a unit of a drug a particular patient's outcome will bring to states' MDRP systems and acknowledges that it will take time to make such system changes. CMS welcomes comments on this proposal, its impact on the MDRP, the commercial market, and its operational implications. CMS also seeks comments on steps which would be needed by manufacturers and states to implement these best price changes, including how states would track health outcomes for Medicaid beneficiaries to align with the outcomes developed in a private market VBP.

To provide consistency between AMP and best price, CMS proposes to add a 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.

C. Changes to Update Definitions To Reflect Recent Statutory Changes

CMS proposes to make a number of definitional changes enacted by Medicaid Services Investment and Accountability Act of 2019, BBA 2018 and the Affordable Care Act.

Innovator Multiple Source Drug: CMS proposes to make technical changes to the definition "innovator multiple source drug" as a multiple source drug, including an authorized generic drug, that is marketed under a new drug application (NDA) approved by FDA, unless the Secretary determines that a narrow exception applies. It also includes a drug product marketed by any cross licensed producers, labelers, or distributors operating under the NDA and a covered outpatient drug approved under a biologics license application (BLA), product license application (PLA), establishment license application (ELA) or antibiotic drug application (ADA).

Line Extension and New Formulation: CMS proposes to define to interpret the definition of "line extension" more broadly by proposing that when determining whether a drug is a line extension, only the initial single source drug or innovator multiple source drug must be an oral solid dosage form.

Therefore, "line extension" means new formulation of the drug, including but not limited to:

- extended release formulations;
- changes in dosage form, strength, route of administration, ingredients, pharmacodynamics, or pharmacokinetic properties;
- changes in indication accompanied by marketing as a separately identifiable

drug (for example, a different National Drug Code); and
- combination drugs, such as a drug that is a combination of two or more drugs or a drug that is a combination of a drug and a device.

Line extension does not include an abuse deterrent formulation of the drug.

CMS seeks comments that may provide a way to define and identify those combination drugs that should be identified as line extensions while excluding those combination drugs that should not be so identified. CMS also seeks comments about whether a drug approved with a new indication that is not separately identifiable should be considered a new formulation and, if so, how such a drug could be identified in Drug Data Reporting for Medicaid (DDR) system for purposes of calculating the alternative unit rebate amounts (URA).

Oral Solid Dosage Form: "Oral solid dosage" form is currently defined to mean capsules, tablets, or similar drugs products intended for oral use as defined in accordance with FDA regulation. CMS is proposing to interpret that an oral form of a drug is one that enters the oral cavity, that is neither a gas nor a liquid at the time the drug enters the oral cavity.

Multiple Source Drug: CMS is proposing to revise the definition of "multiple source drug" to mean, for a rebate period, a covered outpatient drug, including a drug product approved for marketing as a non-prescription drug that is regarded as a covered outpatient drug for which there is at least one other drug product which meets all the following criteria:
- Is rated as therapeutically equivalent (under the FDA's most recent publication of "Approved Drug Products with Therapeutic Equivalence Evaluations" (http://www.accessdata.fda.gov/scripts/cder/ob/);
- Is pharmaceutically equivalent and bioequivalent;
- Is sold or marketed in the United States during the period.

Single Source Drug: CMS proposes to define a "single source drug" to mean a covered outpatient drug, including a drug product approved for marketing as a non-prescription drug, that is regarded as a covered outpatient drug which is produced or distributed under a new drug application approved by the FDA, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application unless the Secretary determines that a narrow exception applies and includes a covered outpatient drug that is a biological product licensed, produced, or distributed under a biologics license application approved by the FDA.

CMS-Authorized Supplemental Rebate Agreements: CMS has found that manufacturers made assumptions that all supplemental rebates paid by manufacturers for prescriptions dispensed to Medicaid managed care enrollees should be excluded from the manufacturer's determination of AMP and best price. However, some of those rebates were not a result of a CMS authorized supplemental

rebate agreement, and therefore, not shared with the state or eventually used to offset state drug expenditures prior to claiming Federal financial participation (FFP) from the federal government.

Therefore, in order to clarify that such rebates paid by manufacturers are not part of a state's CMS-authorized supplemental rebate agreement, CMS proposes to define CMS-authorized supplemental rebate agreement to mean an agreement that is approved through a state plan amendment (SPA) by CMS, which allows a state to enter into single and/or multi-state supplemental drug rebate arrangements that generate rebates that are at least as large as the rebates set forth in the Secretary's national rebate agreement with drug manufacturers. Rebates must be paid directly to the state and be used by the state to offset a state's drug expenditures resulting in shared savings with the Federal government.

D. Exclusion of Certain Manufacturer Sponsored Patient Assistance Programs ("PBM Accumulator Programs") From Determination of Best Price and AMP

CMS has found that certain PBMs have instructed health plans to not allow a manufacturer copay assistance to be applied towards a patient's plan deductible for a brand name drug not on a plan's formulary. As a result, the health plan is benefiting from the manufacturer sponsored copay assistance program instead of the patient. However, manufacturers, claim they are not aware of when these practices by the health plans take place.

CMS is proposing to revise the applicable regulations to provide expressly that the copayment exclusions discussed above apply only to the extent the manufacturer ensures the full value of the assistance or benefit is passed on to the consumer or patient.

E. Authorized Generic Drugs

The Continuing Appropriations Act of 2020 and Health Extenders Act of 2019 revised how manufacturers calculate the AMP for a covered outpatient drug for which the manufacturer permits an authorized generic to be sold. Manufacturers that approve, allow, or otherwise permit any drug to be sold under the manufacturer's own new drug application shall no longer include those sales of these authorized generics in the calculation of AMP. To implement this, CMS proposes to:

- Remove references to manufacturers from the definition of wholesaler.
- Remove "sales to other manufacturers who act as wholesalers for drugs distributed to retail community pharmacies" from the list of sales, nominal price sales, and associated discounts, rebates, payments or other financial transactions included in AMP
- Require a primary manufacturer to exclude from its calculation of AMP any sales of authorized generic drugs to wholesalers for drugs distributed to retail community pharmacies when reporting the AMP of the brand name drug.

- Require a separate AMP to be determined for the brand drug, which shall be exclusive of any authorized generic sale, and a separate AMP to be generated for the authorized generic.

F. Medicaid Drug Rebates (MDR)

CMS proposes to codify the requirement that manufacturers pay additional rebates on their covered outpatient drugs non-innovator multiple source (N) drugs when the AMP of the N drug increases at a rate that exceeds the rate of inflation as required by the Bipartisan Budget Act (BBA) of 2015.

CMS proposes that, in addition to the basic rebate for each dosage form and strength of a N drug, the rebate amount will increase by an amount equal to the product of the following:

- The total number of units of such dosage form and strength paid for under the State plan in the rebate period, and
- The amount, if any, by which the AMP for the dosage form and strength of the drug for the period exceeds the base date AMP for such dosage form and strength, increased by the percentage by which the consumer price index for all urban consumers.

CMS also proposes regulatory changes to specify that in no case will the total rebate amount exceed 100 percent of the AMP of the single source drug, innovator multiple source drug or noninnovator multiple source drug.

G. Requirements for Manufacturers

The current regulation requires that the revision to pricing data be made within the 12 quarters from which the data were due, unless it meets one of several exceptions. To allow for VBP arrangements and pay over time models, CMS proposes that the manufacturer may make changes outside of the 12-quarter rule as a result of a VBP arrangement when the outcome must be evaluated outside of this 12-quarter period.

H. Requirements for States, Findings, Assurances

CMS has found that some states do not have sufficient edits in place to detect, reject and investigate state drug utilization data (SDUD) outliers, which may distort the rebate amounts due by manufacturers. This results in states overbilling manufacturers and generating disputes on rebate invoices, imposing resource burdens on manufacturers, states, CMS, and other MDRP partners, as well as interrupting the payment of rebates to states and CMS. Additionally, CMS has found many states do not send the same SDUD to CMS as they transmit to manufacturers; for instance, submitting ''pre-edited'' SDUD to CMS, while the manufacturer's rebate invoice contains edited data.

Therefore, CMS is proposing to specify that states must submit drug utilization data to CMS, which has information as submitted on manufacturers' invoices, including

any subsequent updates or changes. Additionally, CMS is proposing to add in regulation that the state data submission will be due no later than 60 days after the end of each rebate period. CMS also proposes that the data must be certified by an authorized state official.

State Plan Requirements, Findings and Assurances

CMS wants to create a mechanism to exchange information about state VBP programs generated through supplement rebate arrangements (SRA). Therefore, CMS proposes that states provide specific data elements associated with VBP 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. CMS proposed that a state participating in a VBP arrangement report the following data elements on a yearly basis, and within 60 days of the end of each year:

- State;
- NDC(s) (for the drugs covered under the VBP);
- Product FDA list name;
- Number of prescriptions;
- Cost to the state to administer VBP (for example, systems changes, tracking outcomes, etc.); and
- Total savings generated by the supplemental rebate due to VBP.

I. Drug Utilization Review (DUR) Program and Electronic Claims Management System for Outpatient Drug Claims Managed Care Standard Contract Requirements and Requirements for MCOs, PIHPs, or PAHPs That Provide Covered Outpatient Drug

The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act requires states to implement certain opioid-specific drug use review (DUR) standards within their fee-for-service (FFS) and managed care programs. Although the SUPPORT Act provides considerable flexibility for states to specify particular parameters of their DUR standards, CMS believes it is necessary in order to assure that prescriptions are appropriate, medically necessary, and not likely to result in adverse medical results, to codify several standards in regulation

To that end, CMS is proposing additional minimum DUR standards that states would be required to use, with the detailed design and implementation specifications left to the state's discretion to meet state-specific needs. CMS is proposing to require states to:

- Implement a days' supply limit when an initial opioid prescription is dispensed to a patient not currently received in ongoing therapy with opioids;
- Implement quantity limits on opioids prescriptions (both initial and subsequent fills) to help identify abuse, misuse, excessive utilization, or inappropriate or medically unnecessary care;
- Implement safety edits for therapeutically duplicative fills for initial and subsequent prescription fills on opioids prescriptions and identify suspected abuse, misuse, excessive utilization, or inappropriate, or medically unnecessary care;

- Implement safety edits that indicates when an individual enrolled under the plan (or waiver) is prescribed the morphine equivalent for such treatment in excess of the morphine milligram equivalents dose limitation identified by the state;
- Conduct retrospective claims review automated processes that indicate prescription fills in excess of the prospective safety edit limitations specified by the state to provide for the ongoing review of opioid claims data to identify patterns of fraud, misuse, abuse, excessive utilization, inappropriate or medically unnecessary care, or prescribing or billing practices that indicate abuse or provision of inappropriate or medically unnecessary care among prescribers, pharmacists and individuals receiving Medicaid benefits above-proposed limitations;
- Implement a claims review automated process that monitors when an individual is concurrently prescribed opioids and benzodiazepines, or opioids and antipsychotics;
- Implement programs to monitor and manage the appropriate use of antipsychotic medications by children enrolled under the State plan, including any Medicaid expansion groups for the Children's Health Insurance Program (CHIP);
- Include a process to identify potential fraud or abuse of controlled substances by individuals enrolled under the State plan, health care providers prescribing drugs, and pharmacies dispensing drugs;
- Establish prospective safety edit alerts, automatic retrospective claims review, or a combination of these approaches as determined by the state, to identify cases where a beneficiary is prescribed an opioid after the beneficiary has been prescribed one or more drugs used for medication assisted treatment or had an opioid use disorder diagnosis within a specified number of days (as determined by the state), without having a new indication to support utilization of opioids (such as a new cancer diagnosis, new palliative care treatment or entry into hospice);
- Establish prospective safety edit alerts, automatic retrospective claims review, or a combination of these approaches as determined by the state, to identify beneficiaries who could be at high risk of opioid overdose and should be considered for co-prescription or co-dispensing of naloxone with the goal of expanding appropriate utilization of naloxone to individuals at risk of opioid overdoses.

CMS proposes that the above DUR requirements do not and would not apply for individuals who are receiving hospice or palliative care or those in treatment for cancer; residents of a long-term care facility, an intermediate care facility for the intellectually disabled, or of another facility for which frequently abused drugs are dispensed for residents through a contact with a single pharmacy; or other individuals the state elects to treat as exempted from such requirements.

States must ensure their contracts with managed care organizations and managed care entities have the safety edits, automated review process, a program to monitor antipsychotic medications in children, and fraud and abuse identification requirements, CMS proposes to also extend these requirements to contracts with prepaid ambulatory health plans (PAHPs) and prepaid inpatient health plans (PIHPs).

Currently, states submit annual reports to CMS on the operation of the DUR programs which have been published on Medicaid.gov since 2010. CMS proposes to publish all information in annual DUR reports from managed care programs as well.