Press release

CMS Issues Final Rule to Empower States, Manufacturers, and Private Payers to Create New Payment Methods for Innovative New Therapies Based on Patient Outcomes

Dec 21, 2020 Medicaid & CHIP, Prescription drugs

As part of President Trump's longstanding commitment to lowering drug prices, today the Centers for Medicare & Medicaid Services (CMS) finalized regulatory changes to modernize Medicaid prescription drug purchasing and propel payment innovation by providing states, private payers and manufacturers more flexibility to enter into value-based purchasing (VBP) arrangements for prescription drugs.

By law, state Medicaid agencies are entitled to manufacturer rebates for the prescription drugs provided to Medicaid beneficiaries, which is operationalized by drug manufacturers reporting their "best price" to CMS for brand name drugs, and providing rebates to the federal and state governments under the Medicaid Drug Rebate Program (MDRP). Many insurers are experimenting with value-based payment approaches due to the proliferation of new therapies coming to market today that fight disease in an entirely new way, which could not have been imagined at the start of the MDRP 30 years ago. The potentially transformative impact of these new therapies has prompted insurers, including Medicaid, to rethink innovative payment approaches.

"Rules on prescription drug rebates and related reporting requirements have not been

updated in thirty years, and are thwarting innovative payment models in the private sector," said CMS Administrator Seema Verma. "Medicaid's outdated rules have consistently stymied the ability of payers and manufacturers to negotiate drug reimbursement methods based on the actual outcome of the treatment. A new generation of approaches to payment methods is needed to allow the market the room to adapt to these types of curative treatments while ensuring that public programs like Medicaid remain sustainable and continue to receive their statutorily required discounts."

Under current regulations, prescription drug manufacturers face challenges accounting for VBP arrangements in their Medicaid best price reporting to CMS. This has the unintended consequence of hindering providers, insurers and prescription drug manufacturers in their efforts to develop innovative payment models for new drug therapies and other innovative treatments. Current regulations also discourage payers and manufacturers from designing new payment arrangements based on the value their product may provide.

With the new flexibilities under this final rule, manufacturers will be more willing to negotiate with payers, including Medicaid, with drug pricing being driven by the value of their drug to the individual patient. This is significant, especially in the era of new genetic-based treatments which may initially be expensive, yet in the long run offer significant value to the patient and payer. Payers will be able to negotiate prices with manufacturers for these genetic-based treatments based upon outcomes and evidence-based measures such as reduced hospitalizations, lab visits, and physician office visits, ensuring that if such measures fail to support the value of a drug, the payer is not held accountable for the full price.

Today's final rule codifies a broad definition of VBP, which can better align pricing and payment to observed or expected evidence and/or outcomes-based measures in a targeted population. The final rule also allows manufacturers to report multiple best prices instead of a single best price when offering their VBP arrangements to all states. By making these changes, effective in January 2022, CMS hopes to encourage VBP arrangements and negotiations to help make new, innovative therapies more available to all patients. As a

result, it is estimated that these new VBP approaches could save up to $228 million in Federal and state dollars through the year 2025.

Basing payment on the effectiveness of a given therapy can foster innovation in the treatments that are most impactful to patients, while reducing overall healthcare spending and hospital visits. When payers are positioned to be stronger negotiators with drug manufacturers, Medicaid beneficiaries will benefit from better access to prescription medications.

In addition to furthering value-based payment, this final rule also furthers the Trump Administration's efforts to combat the opioid crisis. The changes that we are finalizing implement provisions under the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (Pub. L. 115-127), and under the existing Medicaid drug utilization review program, to promote safe prescribing of opioids and other medications through state Medicaid Drug Utilization Review (DUR) programs, which is essential to prevent and reduce opioid misuse and abuse. For example, we are finalizing minimum standards that will enhance states' ability to help identify inappropriate prescribing of opioids if a beneficiary is already receiving medication-assisted treatment for a substance use disorder (SUD).

The regulation also finalizes a regulatory definition of a line extension, which will become effective on January 1, 2022 for the purposes of the alternative rebate calculation under the Medicaid Drug Rebate Program. Manufacturers of line extension drugs are required to make such a calculation on these drugs under section 1927(c)(2)(C) of the Social Security Act. The final definition will create incentives for manufacturers to continue to bring new innovative therapies to market, but protect the Medicaid program from excessive manufacturer inflation on some older drugs. It is estimated that these new final policies clarifying the definition of line extension drugs could produce savings of $2.3 billion through the year 2025 in the form of additional manufacturer rebates to states.

In addition, the final rule protects patients by clarifying requirements that help to ensure that cost sharing assistance, including copayment assistance cards, has the effect of lowering the out of pocket costs for patients as intended. The new rules make clear that if the discounts are not benefiting the patient and instead lower the costs for health insurance companies and their pharmacy benefit managers (PBMs), they must be counted in drug manufacturers' reporting to CMS for Medicaid rebate purposes, as required by law. Drug manufacturers are generally required to report an Average Manufacturer Price (AMP) as well as their "best price," accounting for any discounts or rebates provided to such entities as health plans and PBMs. This change will help ensure that when patients use a copayment assistance card provided by a drug manufacturer, the value is passed through to the patient's deductible or cost sharing obligations in full, as opposed to offsetting what the health insurance company would have to normally reimburse the pharmacy. CMS is delaying the effective date of this policy until January 1, 2023 to give manufacturers and payers time to make any necessary changes to their patient assistance programs and reporting mechanisms to help ensure that these discounts are accounted for appropriately. Further instructions regarding those provisions whose effective dates will be delayed are described in the final regulation.

Finally, this final rule also builds on the steps that the Trump Administration has already taken to lower drug prices, including the following actions:

- In Medicare Part D, which covers prescription drugs that beneficiaries pick up at the pharmacy, the average basic premium for Medicare Part D prescription drug plans was projected to decline to the lowest level in seven years, saving beneficiaries about $1.9 billion in premium costs over that time.
- Announced the Senior Savings Model where, starting in 2021, participating enhanced Part D prescription drug plans across the country will provide Medicare beneficiaries access to a broad set of insulins at a maximum $35 copay for a month's supply, saving beneficiaries on average $446 for their insulins.
- Allowing Part D plans to substitute certain generic drugs onto plan formularies more

- Allowing Part D plans to substitute certain generic drugs onto plan formularies more quickly during the year, so beneficiaries immediately have lower cost sharing for these drugs.
- Increasing competition among plans by removing the requirement that certain Part D plans have to "meaningfully differ" from each other, making more plan options available for beneficiaries.
- Providing more information on out-of-pocket costs for prescription drugs to beneficiaries by requiring Part D plans to adopt, starting no later than January 2021, tools that provide clinicians with information that they can discuss with beneficiaries on out-of-pocket drug costs at the time a prescription is written.
- Implementing Part D legislation signed by President Trump to prohibit "gag clauses," which keep pharmacists from telling beneficiaries about lower-cost ways to obtain prescription drugs.
- Approved Medicaid state plan amendments from nine states to negotiate supplemental rebate agreements involving innovative value-based payment arrangements with drug manufacturers, so states can demand results from manufacturers in exchange for payment.
- Issued guidance intended to help states monitor and audit Medicaid and Children's Health Insurance Program (CHIP) managed care plans to address spread pricing and appropriately incorporate administrative costs of the PBM when calculating their medical loss ratio (MLR).

A Fact Sheet on the Final Rule can be viewed at: https://www.cms.gov/newsroom/fact-sheets/establishing-minimum-standards-medicaid-state-drug-utilization-review-dur-and-supporting-value-based-0

The Final Rule can be viewed at:https://www.federalregister.gov/public-inspection/2020-28567/medicaid-program-establishing-minimum-standards-in-medicaid-state-drug-utilization-review-and

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