
# CMS NEWS

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**CMS Issues Proposed Rule to Empower Commercial Plans and States to Negotiate Payment for Innovative New Therapies Based on Patient Outcomes**

*Proposed rule updates provisions to promote value-based payment for prescription drugs*

As part of President Trump's longstanding commitment to lowering drug prices, today the Centers for Medicare & Medicaid Services (CMS) issued a proposed rule that would start to remove barriers to the development of payment models based on value for innovative new therapies. Therapies are coming to market today that fight disease in an entirely new way, including at the genetic level. While the impact of these therapies can be transformative, their costs are unprecedented. New approaches to payment are needed to allow the market room to adapt to these types of curative treatments while ensuring that public programs like Medicaid remain sustainable. Several proposals will also enhance CMS's efforts to combat the opioid epidemic and make sure that opioid outpatient drug coverage is appropriate, medically necessary, and avoids adverse medical events.

"CMS's rules for ensuring that Medicaid receives the lowest price available for prescription drugs have not been updated in thirty years and are blocking the opportunity for markets to create innovative payment models," said CMS Administrator Seema Verma. "By modernizing our rules, we are creating opportunities for drug manufacturers to have skin in the game through payment arrangement that challenge them to put their money where their mouth is."

Under current regulations, prescription drug manufacturers face challenges reporting payments under value-based arrangements to CMS. Current regulations hinder payers and manufacturers from designing new payment arrangements based on the value provided to a patient, which leads to price negotiations based on quantity of drugs sold instead of the quality of a drug product, as well as efforts by payers to limit access to emerging treatments through utilization management practices like prior authorization and step therapy. Today's proposals seek to modernize these regulations, encouraging innovation and empowering states, private payers, and manufacturers to pay for prescription drugs based on clinical outcomes. 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.

These proposals would support the healthcare system's move to paying on the basis of value instead of volume and increasing accountability for outcomes, as insurers would be able to better negotiate discounts based on a drug's effectiveness. In addition, more widespread adoption of payment arrangements based on value could lead to the collection of more evidence on clinical outcomes for a given therapy. This type of real-world, real-time evidence could help providers use new medications and treatments in a more targeted fashion. Increasing the link between reimbursement and drug effectiveness will also encourage payers to facilitate patients' access to new therapies by easing more traditional utilization management practices.

By offering more flexibility for payers and manufacturers to enter into value-based agreements while still ensuring that Medicaid always gets the best deal, CMS is continuing our efforts to foster innovation, increase access to the latest technologies, and ensure that the Medicaid program is sustainable and can continue to serve our most vulnerable populations.

These proposals build 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 13.5 percent since 2017 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 to 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 tools that provide clinicians with information that they can discuss with patients 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 patients about lower-cost ways to obtain prescription drugs.

- Approved state plan amendments from eight 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 CHIP managed care plans to identify spread pricing when calculating their medical loss ratio (MLR).

The changes CMS is proposing also furthers the Trump Administration's efforts to combat the opioid crisis. The proposed rule would implement provisions under the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act to promote safe prescribing of opioids and other medications, which is essential to prevent and reduce opioid misuse and abuse. These proposals include standards that would enhance a states' ability to identify or limit inappropriate prescribing of opioids if a beneficiary is already receiving medication assisted treatment for substance use disorder (SUD).

CMS is also seeking input on proposals for future rulemaking that would require additional review of opioid prescribing, medication assisted treatment, and naloxone prescribing. CMS is requesting comments on potential new standards that would enhance states' ability to identify or limit inappropriate prescribing of opioids if a beneficiary is already receiving medications that can be unsafe when taken with opioids. These proposals are key to addressing the misuse and overuse of opioids in order to help reduce hospitalizations, emergency department visits, and family crises associated with the epidemic.

A Fact Sheet on the Proposed 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

The Proposed Rule can be viewed at: https://www.federalregister.gov/documents/2020/06/19/2020-12970/medicare-program-establishing-minimum-standards-in-medicaid-state-drug-utilization-review-and

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