

CMS ANNOUNCES NEW OPIOID SAFETY MEASURES FOR PART D PLAN SPONSORS: WHAT IS REALLY GOING ON?

The Centers for Medicare & Medicaid Services ("CMS") recently finalized several new policies aimed at preventing and combating prescription opioid misuse by Medicare Part D beneficiaries. The policies, detailed in CMS's 2019 Final Call Letter ("Call Letter")^[1] and outlined below, require Part D plan sponsors to implement various safety measures to reduce opioid overuse among Medicare beneficiaries.

The new safety measures are structured according to recommendations made in the U.S. Centers for Disease Control and Prevention ("CDC") Guideline for Prescribing Opioids for Chronic Pain ("Guideline")^[2] and parallel efforts in a majority of states, such as [Indiana](#), to prevent opioid overuse by placing certain prescribing limitations on providers. Additionally, the new safety measures work in tandem with CMS's newly released opioid policies in the Contract Year 2019 Final Rules for Medicare Advantage and Part D.

Notably, like the recent related CVS Caremark announcement regarding that pharmacy benefit manager's payment for opioid prescriptions, these limitations speak to payment for opioids. As such, they would not alone preclude a patient from requesting a self-pay transaction, although such requests implicate a variety of other state and federal legal considerations beyond the scope of this article.

With these combined efforts, CMS, state legislatures and even the DEA have made it clear that addressing the opioid epidemic is a top priority. As a result, Part D plan sponsors, pharmacies and prescribers should ensure that they are up to date on new state and federal regulatory requirements as well as CMS and state Medicaid agency guidance related to the prescribing, dispensing and payment of and for opioids dispensed to Medicare Part D beneficiaries, specifically, and to all patients irrespective of payor, generally. Given the complexity of these issues, however, this article focuses on the impact on Part D participating pharmacies.

2019 CMS OPIOID OVERUTILIZATION POLICIES

While CMS's overall strategy seeks to reduce opioid overuse and overdoses, CMS tailored its approach to target distinct populations of Medicare Part D prescription opioid users (e.g., new opioid users, chronic users, beneficiaries with uncoordinated care, beneficiaries currently using opioids with benzodiazepines, etc.). In the Call Letter, CMS provided several key safety edits for Part D sponsors to use to curb the overutilization of opioids while maintaining beneficiary access to necessary medications. Specifically, CMS expects Part D sponsors to implement the following safety edits for targeted groups of Part D beneficiaries.

Opioid Naïve Patients

- Implement a hard safety edit limiting initial opioid prescription fills for the treatment of acute pain to no more than a 7-day supply. This safety edit will prevent pharmacies from processing a claim for an initial opioid prescription exceeding a 7-day supply without authorization from the plan sponsor. In defining an "opioid naïve patient," CMS recommends that plan sponsors use a look back period of at least 60 days.

Chronic Opioid Users

- Implement real-time safety edits for chronic opioid users at the time of dispensing as a proactive step to engage both patients and prescribers about overdose risk and prevention.

Opioid Care Coordination

- Implement an opioid care coordination edit at 90 morphine milligram equivalent ("MME") per day, which would trigger when a beneficiary's cumulative MME per day across all opioid prescriptions reaches or exceeds 90 MME. When this limit is reached or exceeded, sponsors should instruct the dispensing pharmacist to consult with the prescribing physician to confirm their intent to prescribe a dosage higher than 90 MME per day and use an explicit override code noting that the prescriber has been consulted.
- Plan sponsors will also have flexibility to implement a hard safety edit at a threshold of 200 MME or more, which may include prescriber or pharmacy counts.

High-Risk Opioid Users

- Through integration with the drug management program provisions required by the Comprehensive Addiction and Recovery Act of 2016 ("CARA"), plan sponsors will have the ability to "lock-in" or limit beneficiaries' coverage for frequently abused drugs by requiring a beneficiary to obtain frequently abused drugs from selected pharmacy(ies) and/or prescriber(s) after case management and notice to the beneficiary. CMS also plans to revise the Overutilization Monitoring System ("OMS") metrics to provide additional information to sponsors about high-risk beneficiaries, especially those receiving opioid prescriptions from multiple providers or pharmacies.

Opioid Users also Taking Duplicative or Key Potential Drugs

- Implement additional soft safety edits to alert the pharmacist about duplicative opioid therapy and concurrent use of opioids and benzodiazepines.

To drive performance improvement among Part D plan sponsors, CMS will also use quality measures to track trends in opioid overuse across the Part D program. Specifically, CMS plans to implement technical revisions to the Pharmacy Quality Alliance ("PQA") opioid overuse measures and add a new PQA measure, Concurrent Use of Opioids and Benzodiazepines.

Notably, CMS recommends that beneficiaries who are long-term care residents, hospice care, palliative care or end-of-life care recipients, or patients being treated for active cancer-related pain, be excluded from its new strategies to prevent opioid overuse. Finally, CMS emphasized the importance of not impacting or disrupting beneficiaries' access to medication-assisted treatment, such as buprenorphine.

PRACTICAL TAKEAWAYS

Although the strategies announced in the Call Letter apply directly to Part D sponsors, health care providers (including prescribers, pharmacists and pharmacies) who serve Medicare patients should prepare for the impact of these new safety measures on their treatment of Part D beneficiaries.

At the prescriber level, prescribers should plan for the possibility of increased consultations with payors and pharmacies when prescribing high doses of opioid medications. At the pharmacy level, CMS stated in the Call Letter that it expects Part D sponsors to train their network pharmacies to comply with the new safety measures. As a result, pharmacies serving Part D beneficiaries should be prepared to implement these safety edits. Process considerations include increased communication from and to pharmacy benefit managers ("PBMs") and plan sponsors, including new PBM and payor policies for participating pharmacies related to opioid dispensing. Processes and policies will also need to be established to operationalize prescriber communications, prescription changes and treatment of drug remainders in compliance with applicable state laws. In sum, providers and pharmacies should work to develop strategies and procedures to address coverage limitations for certain opioid treatments in accordance with recommendations in the Call Letter and other applicable state and federal requirements.

If you have any questions or if you would like additional information on this or related topics, please contact:

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[1] See Centers for Medicare and Medicaid Services, "CY 2019 Final Call Letter," available at <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf>.

[2] See Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. MMWR Recomm Rep. 2016;65:1-49, available at <http://dx.doi.org/10.15585/mmwr.rr6501e1>.