DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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CENTER FOR MEDICARE

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TO: All Prescription Drug Plans, Medicare Advantage-Prescription Drug Plans, Section 1876 Cost Plans, Medicare-Medicaid Plans, and PACE Organizations

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SUBJECT: Medicare Part D Opioid Safety Edit Reminders and Recommendations and Frequently Asked Questions (FAQs)

This memorandum provides helpful reminders and recommendations related to Medicare Part D opioid point-of-sale (POS) safety edit(s). Updated educational materials are available on the CMS Part D Overutilization website at https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html, including tip sheets for prescribers, pharmacists, and beneficiaries, and a Medicare Learning Network (MLN) Fact Sheet, which sponsors may use to supplement their outreach efforts. We are also releasing updated opioid safety edit Frequently Asked Questions (FAQs).

Background

Medicare Part D sponsors must have concurrent drug utilization review (DUR) systems, policies, and procedures designed to ensure that a review of the prescribed drug therapy is performed before each prescription is dispensed to an enrollee in a sponsor's Part D plan, typically at the point-of-sale (POS) or point of distribution as described in 42 CFR § 423.153(c)(2). To help prevent and address prescription opioid overuse through improved concurrent DUR, sponsors can fulfill 42 CFR § 423.153(c)(2) by implementing opioid safety edits at the POS,[1] including:

- Care coordination edit at 90 morphine milligram equivalents (MME) per day,
- Hard edit at 200 MME per day or more (optional),
- Hard edit for 7 day supply limit for initial opioid fills (opioid naïve),
- Soft edit for concurrent opioid and benzodiazepine use, and
- Soft edit for duplicative long-acting (LA) opioid therapy.

[1] Refer to the 2019 Final Call Letter and 2020 Final Call Letter, as well as the October 23, 2018 HPMS memorandum: *Additional Guidance on Contract Year 2019 Formulary-Level Opioid Point-of-Sale Safety Edits,* Frequently Asked Questions (FAQs) about Formulary-Level Opioid Point-of-Sale (POS) Safety Edits document, and the May 22, 2020 memorandum: *Information Related to Coronavirus Disease 2019 – COVID-19* available on the CMS Part D Overutilization website: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html.

Important Reminders

- The purpose of the opioid safety edits is to prompt prescribers and pharmacists to conduct additional safety review to determine if the enrollee's opioid use is appropriate and medically necessary. Plan sponsors are expected to implement the edits in a manner that minimizes any additional burden on prescribers, pharmacists, and beneficiaries.

- The opioid safety edits should not be implemented as prescribing limits or as a substitute for clinical judgment. Rather, the opioid safety edits aim to strike a better balance between identifying potential opioid overuse without a negative impact on the patient-doctor relationship, preserving access to medically necessary drug regimens, and reducing the potential for unintended consequences.

- Decisions by clinicians to taper opioid dosages should be carefully considered and individualized, if appropriate. Opioids should not be tapered rapidly or discontinued suddenly due to the significant risks of opioid withdrawal, unless there is a life-threatening issue confronting the individual patient. Tapering is most likely to be effective when there is patient buy-in and collaboration, tapering is gradual, and clinicians provide support.[2,3]

- Part D sponsors are expected to develop opioid safety edit specifications that exempt beneficiaries who are residents of a long-term care facility, are in hospice care or receiving palliative or end-of-life care, have sickle cell disease, or are being treated for active cancer-related pain. Sponsors are encouraged to work with their P&T committees to identify other vulnerable patient populations for exemption from the opioid safety edits.

- CMS expects all Part D plan sponsors to have a mechanism in place which allows **all** opioid safety alerts, including hard edits, to be overridden at point of sale based on information from the prescriber or otherwise known to the pharmacist that an enrollee is exempt.

- The care coordination and hard MME edits may also include prescriber counts, pharmacy counts, or both. We recommend including a minimum threshold ("count") of 2 or more opioid prescribers in these edit specifications.

- Coordinated, repetitive, and well-timed outreach to prescribers, pharmacies, and enrollees is strongly recommended ahead of the new contract year to reinforce the opioid safety edit policies. As noted above, educational resources are available on the CMS Part D Overutilization website. Throughout the year, Part D sponsors should repeat their education and outreach efforts to ensure that clinicians are aware of the policies, pharmacists are aware of the options to resolve rejected claims at POS if appropriate, and beneficiaries are aware of their right to request a coverage determination when a prescription cannot be filled at the pharmacy as written.

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[2] More information on the risks of rapid tapering and guidance for gradual, individualized tapering can be found with the HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics.

[3] CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022; https://www.cdc.gov/mmwr/volumes/71/rr/rr7103a1.htm

Recommendations for Part D Sponsors

Based on program experience and feedback from stakeholders, CMS recommends that Part D sponsors do the following:

- Monitor the override rates for soft edits by pharmacy to identify outliers or educational opportunities.

- Review the volume of claims that are rejected at POS and override rates for the care coordination edit. If the vast majority of rejections are being overridden, consider adding a prescriber and/or pharmacy count.

- Assess coverage determination request volume and approval rates (e.g., attestation from the prescriber) for the hard MME edit. For example, sponsors that implemented edit specifications with a minimum of one prescriber may experience a higher number of rejections and/or approvals. The single prescriber will likely attest that the opioid dosage was medically necessary, potentially delaying beneficiary access.

- Conversely, identify low rejection rates based on contract enrollment which may be indicative of ineffective opioid safety controls at POS and reassess the edit specifications as needed.

- Reinforce to pharmacists and customer service representatives that the plan may not have opioid claims history for new enrollees, especially at the start of a new contract year, and they may experience a claim rejection due to the opioid naïve edit with their first opioid prescription over 7 days supply. Pharmacists often have existing knowledge or information that a beneficiary is not opioid naïve and may submit an override code to the plan to avoid an interruption in treatment.

- Instruct pharmacists on how to communicate to the plan when an enrollee should be exempt from any of the opioid safety edits.

Summary

CMS will continue to monitor current literature, clinical guidelines, and the impact of these strategies on Medicare Part D prescription opioid overuse to evaluate the need for potential modifications or development of alternative or additional approaches in the future.

For questions related to Medicare Part D opioid safety edits, please email PartD_OM@cms.hhs.gov.