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 plans

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SUBJECT: Contract Year (CY) 2025 Medicare Part D Opioid Safety Edits – Submission Instructions, Recommendations, and Reminders

This memorandum provides instructions to Part D sponsors for submitting information about CY 2025 opioid point-of-sale (POS) safety edit(s) to CMS in the Health Plan Management System (HPMS) and helpful reminders and recommendations. We are also releasing an 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 POS or point of distribution as described in 42 CFR § 423.153(c)(2). To help prevent and combat prescription opioid overuse through improved concurrent DUR, sponsors are expected to implement opioid safety edits at the POS, including a care coordination edit based on a cumulative morphine milligram equivalent (MME) threshold of 90 MME per day, a hard safety edit to limit initial opioid prescription fills for the treatment of acute pain to no more than a 7 day supply, and an optional hard MME edit.[1]

Submission Process

For CY 2025, Part D sponsors should submit opioid safety edit information in the Opioid Safety Edits module in HPMS. Authorized HPMS users may locate the module under **Plan Formularies → Opioid Safety Edits**. The Opioid Safety Edits Module Plan User Guide for CY 2025, with detailed instructions on how to submit and revise opioid safety edits, is in the module under **Documentation**.

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

Sponsors should submit opioid safety edits in the HPMS module **between August 13, 2024, and 5:00 p.m. EDT on August 20, 2024.**

PACE Organization contracts should submit opioid safety edit information in HPMS regardless of how pharmacy claims are adjudicated. Refer to the 2025 HPMS Plan User Guide for more information on how PACE contracts that do not adjudicate claims at POS should submit opioid safety edit data (see page 11, section 3. Submit Data, number 6).

Using the module, sponsors should provide information on: the opioid care coordination edit, such as whether the sponsor will include an opioid prescriber and/or pharmacy count, and the number of prescribers and/or pharmacies; an MME hard edit (if applicable); and the opioid naïve 7 day supply edit. Please note that the submission of the opioid safety edit information aids in CMS' monitoring and does not represent approval or denial of a sponsor's opioid safety edits.

If a sponsor wishes to revise their CY 2025 opioid safety edits after the initial submission window, they may do so by sending an email to PartD_OM@cms.hhs.gov with the subject line "Opioid Safety Edit Request to Revise – [applicable contract ID number(s)]." The email should include:

1. The contract ID(s) associated with this change;
2. The intended revisions to the opioid safety edit(s);
3. The proposed implementation date of the revision; and
4. A justification for the mid-year change to the opioid safety edit(s).

If the justification and revisions are accepted, CMS will notify the sponsor to allow edits in the HPMS Opioid Safety module.

Reminders and Recommendations

Part D sponsors should refer to the December 19, 2022 HPMS memorandum "Medicare Part D Opioid Safety Edit Reminders and Recommendations and Frequently Asked Questions (FAQs)", which can be found on the CMS Part D Overutilization website: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html, for helpful reminders and recommendations, as well as additional information below.

- CMS implemented changes to the Part D Drug Management Programs (DMPs) beginning January 1, 2025, as outlined in the final rule (89 FR 30448) issued on April 4, 2024.[2] Based on the 2022 CDC Clinical Practice Guideline for Prescribing Opioids for Pain[3] applicability in individuals with cancer, we amended the regulatory definition of ''exempted beneficiary'' at 42 CFR §423.100 by replacing the reference to ''active cancer-related pain'' with ''cancer-related pain.'' We expanded the definition of

[2] The April 2024 final rule is available at: https://www.federalregister.gov/public-inspection/2024-07105/medicare-program-medicare-advantage-and-the-medicare-prescription-drug-benefit-program-for-contract
[3] https://www.cdc.gov/mmwr/volumes/71/rr/rr7103a1.htm

exempted beneficiary to more broadly refer to enrollees being treated for cancer-related pain to include beneficiaries undergoing active cancer treatment, as well as cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, or are under cancer surveillance only.

To continue to align Medicare Part D prescription opioid policies, Part D sponsors should update the exemptions for the opioid safety edits for CY 2025. 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 cancer-related pain. Sponsors are encouraged to identify other vulnerable patient populations for exemption from the opioid safety edits.

- In developing opioid safety edit programming, Part D sponsors are encouraged to refer to the list of commonly prescribed opioids for pain management and their MME conversion factors in the 2022 CDC Guideline Table, which are also used in the DMP Overutilization Monitoring System (OMS) MME calculations.[4] As of the January 2024 OMS reports, fentanyl patch claims are assigned a daily value of 1 patch per day, which is multiplied by the patch strength and a conversion factor of 2.4 to calculate the daily MME for the duration of the claim.

- 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.

Summary

CMS will continue to monitor all available data and current literature to evaluate the need for potential modifications or development of additional approaches for Medicare Part D prescription opioid policies.

For questions related to this memorandum or for assistance completing the initial submission, email PartD_OM@cms.hhs.gov.

[4] Refer to the CY 2024 OMS Technical Guidance available on the CMS Part D Overutilization website at https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html.