DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

CENTER FOR MEDICARE

DATE: July 3, 2025

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

FROM: Vanessa S. Duran
Director, Medicare Drug Benefit and C & D Data Group

SUBJECT: Contract Year (CY) 2026 Medicare Part D Opioid Safety Edits – Submission Instructions, Recommendations, and Reminders

This memorandum provides instructions to Part D sponsors for submitting information about CY 2026 opioid point-of-sale (POS) safety edit(s) to CMS in the Health Plan Management System (HPMS) and helpful reminders and recommendations.

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 (opioid naïve), and an optional hard MME edit at 200 MME per day or more.[1]

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 work with their P&T committees to identify other vulnerable patient populations for exemption from the opioid safety edits.

[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*, the December 19, 2022 memorandum: *Medicare Part D Opioid Safety Edit Reminders and Recommendations and Frequently Asked Questions (FAQs)*, 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.

Submission Process

For CY 2026, 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 2026, with detailed instructions on how to submit and revise opioid safety edits, is in the module under **Documentation**.

Sponsors should submit opioid safety edits in the HPMS module **between August 12, 2025, and 5:00 p.m. EDT on August 19, 2025.**

All PACE Organization contracts should submit opioid safety edit information in HPMS regardless of how pharmacy claims are adjudicated. Refer to the 2026 HPMS Plan User Guide for more information on how PACE contracts that do not adjudicate claims at POS should submit opioid safety edit data through HPMS (see page 10, 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 2026 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

- 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-

prescriber 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]

- 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.

- Outside of a known exemption, when the care coordination edit is triggered, the pharmacist is expected to consult with the beneficiary's prescriber to confirm intent. We generally expect the consultation to be consistent with current pharmacy practice to verify the prescription with the prescriber and to validate its clinical appropriateness. These consultations are also an opportunity for pharmacists to inform the prescriber of other opioid prescribers or increasing level (MME) of opioids. As such, they may help reinforce Centers for Disease Control and Prevention (CDC) recommendations[3] for improved clinician and patient communications about the risks and benefits of opioid therapy and create an opportunity for prescribers to reassess the patients' opioid use and look for opportunities for opioid discontinuation or alternative treatment options.

    - One of the following is likely to occur at POS when consulting with the prescriber:
        - Prescriber confirms intent.
        - Prescriber provides information that the enrollee is exempt.
        - Prescriber does not confirm medical necessity of the prescription.
        - Pharmacist is unable to reach prescriber.

    - Pharmacists should be provided the appropriate override codes without needing to contact the plan sponsor, or sponsors should allow the pharmacist to call the plan's help desk for the plan to put in an override in real-time if the plan sponsor does not have the capability to utilize automated codes. While Part D plan sponsors are required to oversee and monitor their network pharmacies to ensure compliance with Part D program rules, any documentation requirements established by plans related to care coordination consultations are expected to be minimally burdensome and consistent with current pharmacist workflow and professional practices. For example, the documentation may include the date,

[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

time, name of prescriber, and brief note that the prescriber confirmed intent, did not confirm intent, provided information on beneficiary exemption, or could not be reached after 'X' number of attempts. Regardless of whether a prescription triggers the care coordination edit or whether the prescriber confirms intent, a pharmacist retains the ability to not fill a prescription based on their clinical judgment.

- 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 POS based on information from the prescriber or otherwise known to the pharmacist that an enrollee is exempt.

- 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.

- 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.