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



CENTER FOR MEDICARE

DATE: July 5, 2023

TO: All Prescription Drug Plans, Medicare Advantage-Prescription Drug Plans,

Section 1876 Cost Plans, Medicare-Medicaid Plans, and PACE plans

FROM: Vanessa S. Duran

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SUBJECT: Contract Year (CY) 2024 Opioid Safety Edits – Submission Instructions

This memorandum provides instructions to Part D sponsors for submitting information about CY 2024 opioid point-of-sale (POS) safety edit(s) to CMS in the Health Plan Management System (HPMS).

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

Updates to the Submission Process

¹ Refer to the <u>2019</u> and <u>2020</u> 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 14, 2023 and 5:00 p.m. EDT on August 21, 2023. As a reminder, PACE organizations only need to submit opioid safety edit information if adjudicating claims at POS.

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 2024 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 Edits module.

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