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**DATE:** July 9, 2021

**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) 2022 Opioid Safety Edits – Submission Instructions

This memorandum provides instructions to Part D sponsors for submitting information about CY 2022 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.<sup>1</sup>

### **Updates to the Submission Process**

For CY 2022, Part D sponsors should submit opioid safety edit information in the new Opioid Safety Edits module in HPMS. The module replaces the Excel templates used for opioid safety edit submissions in prior years. Authorized HPMS users may locate the module under **Plan Formularies → Opioid Safety Edits**. The Plan User Guide for CY 2022, with detailed

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<sup>1</sup> 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>.

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 16, 2021 and 5:00 p.m. EDT on August 23, 2021**. 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 days 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 2022 opioid safety edits after the initial submission window, they may do so by sending an email to [PartD\\_OM@cms.hhs.gov](mailto: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 acceptable, CMS will notify the sponsor and open the gate for the Opioid Safety Edits module.

For questions related to this memorandum or revisions to the HPMS module, or for assistance completing the initial submission, email [PartD\\_OM@cms.hhs.gov](mailto:PartD_OM@cms.hhs.gov).