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DATE: July 17, 2020

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

FROM: Amy Larrick Chavez-Valdez, Director Medicare Drug Benefit and C & D Data Group

SUBJECT: Submission Template – Contract Year (CY) 2021 Opioid Safety Edits

This memorandum provides information regarding the template that Part D sponsors should utilize to submit information about CY 2021 opioid point-of-sale (POS) safety edit(s) to CMS via 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 edit¹.

Submission Template

A completed template should be submitted to HPMS **between August 17, 2020 and 5:00 p.m. EDT on August 24, 2020**. As a reminder, PACE organizations only need to submit a template if adjudicating claims at POS.

Using the template, sponsors should provide information on: the parameters for the opioid care coordination edit, such as whether the sponsor will include an opioid prescriber count in the edit

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

specification and the number of prescribers; specifications for a hard MME safety edit (if applicable); and implementation of the 7 days supply opioid naïve edit. Please note that the submission of the template aids in CMS's monitoring and does not represent approval or denial of a sponsor's opioid safety edits.

Detailed instructions regarding how to submit or revise the information via HPMS can be found on pages 145 – 152 of the CY 2021 HPMS Formulary Submission Module & Reports Technical Manual. Directions on how to complete the template are contained in the Appendix to this memorandum.

If a sponsor wishes to revise their CY 2021 template 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 Template Request to Revise – [applicable contract ID number(s)]." The email should include:

1. The contract ID(s) associated with this change;
2. The proposed implementation date of the revision;
3. A justification for the mid-year change to the opioid safety edit; and
4. The revised template that will be submitted to HPMS as an attachment.

If the justification and review parameters are acceptable, CMS will notify the sponsor and open the gate for the revised template to be submitted to HPMS.

For questions related to this memorandum or if you need assistance completing the template, please email PartD_OM@cms.hhs.gov.

Appendix. Submission Template Completion Instructions

The attached Microsoft[®] Excel Workbook is to be used to create the file that will be submitted to CMS. It will also be available to download via HPMS on the **Opioid Safety Edit – Upload** page by selecting the “View Opioid Safety Edit File Template” link. This workbook utilizes macros that *must* be enabled before editing the template by clicking on the “Enable Content” box.

The following information should be included in the template, and the template cannot be altered in any way:

- 1. Contract ID.** Enter the contract ID(s) associated with the opioid safety edits included in template. This is a free text field.
- 2. MME Edit Type to be Implemented (Yes/No).** Select YES or NO to indicate which type of MME edit (or both) your organization will implement. If NO is chosen, the remainder of the column will be greyed out and should not be completed. YES should be selected for the care coordination edit and either YES or NO may be selected for the hard edit.
- 3. MME Implementation Date (MM/DD/YYYY).** Enter the date the corresponding MME edit will be implemented. This field only accepts date values within the 2021 contract year. We expect the initial submission template for CY 2021 will indicate 01/01/2021. If the sponsor submits a revision, the effective date of the modified specifications should be entered.
- 4. Cumulative MME Daily Dose Threshold.** Enter the daily cumulative MME threshold. This is a free text field that accepts only whole numerical values at or above 200 MME for the hard edit. For the care coordination edit, 90 MME should be entered.
- 5. Number of Prescribers Included in Edit? (Yes/No).** Select YES from the corresponding drop down if a prescriber count is included in the hard and/or care coordination edit specifications. Select NO from the corresponding drop down if a prescriber count is not included in the hard and/or care coordination edit specifications. If NO is selected, the number of prescribers field below will be greyed out and should not be completed.
- 6. Number of Prescribers.** In the corresponding field, specify the minimum number of opioid prescribers for the hard and/or care coordination edit that cumulatively contribute to the MME daily dose threshold in item #4. This value should be 2 or greater. For example, if 3 is entered into this field, the hard and/or care coordination edit will trigger at POS if the member receives opioid prescriptions from 3 or more prescribers (in addition to meeting the other specifications). This is a free text field that accepts whole numerical values only.
- 7. Number of Pharmacies Included in Edit? (Yes/No).** Select YES from the corresponding drop down if a number of opioid dispensing pharmacies threshold is included in the hard and/or care coordination edit specifications. Select NO if the number of pharmacies threshold is not included in the hard and/or care coordination edit

specifications. If NO is selected, the number of pharmacies field below will be greyed out and should not be completed.

- 8. Number of Pharmacies.** In the corresponding field, specify the minimum number of opioid dispensing pharmacies for the hard and/or care coordination edit that cumulatively contribute to the MME daily dose threshold in item #4. This value should be 2 or greater. For example, if 3 is entered into this field, the hard and/or care coordination edit will trigger at POS if the member fills concurrent opioid prescriptions at 3 or more pharmacies (in addition to meeting the other specifications). This is a free text field that accepts whole numerical values only.
- 9. Implementing a 7 day supply hard edit for opioid naïve patients (Yes/No).** Use the dropdown to indicate (YES) that your organization will implement the 7 day supply hard edit for opioid naïve patients.
- 10. Opioid Naïve Edit Implementation Date (MM/DD/YYYY).** Enter the date the corresponding opioid naïve edit will be implemented. This field only accepts date values within the 2021 contract year. We expect the initial submission template for CY 2021 will indicate 01/01/2021. If the sponsor submits a revision, the effective date of the modified specifications should be entered.
- 11. Number of days to determine lookback for opioid naïve patients.** Indicate the number of days that will be used for the look back period to determine if a beneficiary is opioid naïve. This is a free text field that accepts whole numerical values only.

Once all of the applicable fields of the template have been completed:

1. The “Form Status” indicator will change from “INCOMPLETE” to “COMPLETE.”
2. Select the “Create HPMS Upload” button to create an Excel file to be uploaded to HPMS.
3. As a result, a copy of the template as a Microsoft[®] Excel .xlsx file will be saved in the same directory with the current date added to the file name.
4. Submit this newly created file to HPMS using the instructions above. Please do not submit the original template consisting of macros.