DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C1-26-16
Baltimore, Maryland 21244-1850

CENTER FOR MEDICARE

DATE: August 8, 2019

TO: All Part D Sponsors

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

SUBJECT: Submission Template - CY 2019 Opioid Safety Edit and Participation in Drug Management Programs

Background

In the CY 2019 Final Call Letter, CMS provided guidance regarding our expectation that Part D sponsors implement a real-time opioid Care Coordination safety edit, at the time of dispensing, as a proactive step to engage both patients and prescribers about overdose risk and prevention. This safety edit should be based on a cumulative morphine milligram equivalent (MME) threshold of 90 MME per day and may include prescriber/pharmacy counts. Sponsors will continue to have the flexibility to implement hard safety edits at a threshold of 200 MME or more, with or without prescriber/pharmacy counts. Additionally, to reduce the potential for chronic opioid use or misuse, CMS expects all Part D sponsors to implement a hard safety edit to limit initial opioid prescription fills for the treatment of acute pain to no more than a 7 day supply. Please refer to pages 234 – 251 of the CY 2019 Final Call Letter for detailed guidance.

Also, on April 16, 2018, CMS promulgated a final rule (CMS-4182-F) to implement the statutory provisions of the Comprehensive Addiction and Recovery Act of 2016 (CARA) that included new authority for Medicare Part D plans to establish drug management programs in 2019 for "at-risk beneficiaries." Please refer to pages 16442 – 16480 of the final rule. The rule codified many aspects of the current Part D Opioid Drug Utilization Review (DUR) Policy and the Overutilization Monitoring System (OMS), with adjustments as needed to comply with CARA, by integrating them into the drug management program provisions. Under drug management programs, sponsors may limit at-risk beneficiaries' access to coverage of opioids and benzodiazepines to a selected prescriber(s) and/or network pharmacy(ies) (i.e., "lock-in"), and they may still implement beneficiary specific claim edits for such drugs, for the safety of the beneficiary.

Submission Template

The current memorandum provides information regarding the template that Part D sponsors should utilize to submit information about CY 2019 opioid point-of-sale (POS) safety edit(s) and implementation of a drug management program to CMS via the Health Plan Management

System (HPMS). **A completed template must be submitted to HPMS between August 20, 2018 and 5:00 p.m. EDT on August 27, 2018.** Please note, PACE organizations only need to submit a template if they adjudicate claims at POS.

The template collects information concerning the specifications of a hard opioid safety edit the Part D sponsor intends to implement for 2019, as well as parameters for the sponsor's 2019 Care Coordination edits. For example, whether the sponsor will be including a prescriber count in the edit specification, and if so, the number of prescribers. The template also includes several attestations concerning 7 days supply edits and having a drug management program.

Detailed instructions regarding how to submit/revise the completed information via HPMS can be found on pages 118 – 126 of the CY 2019 HPMS Formulary Submission Module & Reports Technical Manual. Directions on how to complete the template are contained in the Appendix to this memorandum.

Please note that this template is solely for CMS data collection. The completion and submission of the core data elements contained within the template does not represent CMS' approval or denial of a plan's opioid safety edits or its drug management program.

If a sponsor wishes to revise their CY 2019 template after the initial submission window, they may do so by sending an email to PartDFormularies@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 specifications or drug management program; and
4. The revised template that will be submitted to the Health Plan Management System (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 PartDFormularies@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 **MME Opioid POS Edit – Upload** page by selecting the "View MME Opioid POS 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 must be included on the template and the template must not be altered in any way:

1. **Edit Type to be Implemented (Yes/No).** Select YES or NO for each Edit Type, to indicate which type of 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.
2. **Implementation Date (MM/DD/YYYY).** Enter the date the corresponding edit will be implemented. This field only accepts date values within the 2019 contract year.
3. **Cumulative MME Daily Dose Threshold (mg).** If implementing a cumulative MME hard edit, enter the daily cumulative MME threshold in milligrams (mg). This is a free text field that accepts only whole numerical values at or above 200 mg. For the Care Coordination edit, 90 MME should be entered.
4. **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 the 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.
5. **Number of Prescribers.** In the corresponding field, specify the minimum number of opioid prescribers for the hard and/or Care Coordination edit. 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) that cumulatively contribute to the MME Daily Dose Threshold in item #3. This is a free text field that accepts whole numerical values only.
6. **Number of Pharmacies Included in Edit? (Yes/No).** Select YES from the corresponding drop down if a number of 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.
7. **Number of Pharmacies.** In the corresponding field, specify the minimum number of pharmacies dispensing opioid prescriptions for the hard and/or Care Coordination edit that cumulatively contribute to the MME Daily Dose Threshold in item #3. 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.

8. **Opioid Naïve Edit Attestation.** Use the dropdown to attest to implementing the 7 day supply hard edit for opioid naïve patients. Select YES to indicate your organization is implementing this edit in CY 2019.
9. **Number of days to determine look-back 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.
10. **Drug Management Program.** Use the dropdown to attest to the organization's implementation of a drug management program. Select YES or NO to indicate whether your organization is implementing a drug management program in CY 2019.
11. **Contract ID.** Enter the contract ID(s) associated with the safety edits and drug management program in this field. This is a free text field.

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.