DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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CENTER FOR MEDICARE

TO: All Part D Plan Sponsors

FROM: Jennifer R. Shapiro, Acting Director, Medicare Drug Benefit and C & D Data Group

SUBJECT: UPDATES - 2018 Medicare Part D Overutilization Monitoring System

DATE: January 19, 2018

The purpose of this memorandum is to discuss updates to the Medicare Part D Overutilization Monitoring System (OMS) for the January 2018 release, including revisions to the OMS criteria as finalized in the 2018 Final Call Letter.

NOTE: PACE plans are not exempt from the OMS reporting. PACE plans should assign authorized users of the Patient Safety Analysis Website if they have not already done so.

Background

The OMS (within the Patient Safety Analysis Website) helps CMS ensure that sponsors have established reasonable and appropriate drug utilization management programs to assist in preventing overutilization of prescription opioids. Through the OMS, sponsors receive quarterly contract-level reports of Part D enrollees who may be potentially overutilizing opioids. In accordance with CMS guidance to date, CMS expects sponsors' clinical staff to work with the prescribing physicians and beneficiaries to address the risks associated with overuse, and update CMS on actions taken. Sponsors can also report potential opioid overutilization by beneficiaries identified through sponsors' own internal criteria and review, but not previously identified by the OMS.

The Patient Safety Analysis Website facilitates communication between CMS, sponsors, and our contractor, Acumen, LLC. Sponsors are required to use the website and should be engaged in performance monitoring. For additional information, Report User Guides, diagnosis codes, and the medication lists used for the OMS are available on the Patient Safety Analysis Website under Help Documents.

Overutilization Monitoring System Updates

The updates described below will be incorporated into the next quarterly OMS reports, available on **January 31, 2018**.

Sponsors will receive an email when their Overutilization Monitoring Report Package is available for download. The email will indicate which contracts have detail-level reports, including OMS-identified and sponsor-identified potential beneficiary overutilization issues from the current or

previous reporting periods. Instructions for downloading the Overutilization Monitoring Package of reports and submitting responses to the OMS are available in the Overutilization Monitoring System User Guide available on the Patient Safety Analysis Website under Help Documents. The deadline for submitting responses is generally 30 days after the report date.

Terminology. CMS will use the Centers for Disease Control and Prevention (CDC) term morphine milligram equivalent (MME) going forward instead of morphine equivalent dose (MED), which CMS has used to date. We will update CMS documents that currently refer to MED as soon as practicable.

OMS Opioid Overutilization Criteria. As announced in the 2018 Final Call Letter, CMS is implementing revised OMS criteria beginning in 2018. The new criteria[1], starting with the January 2018 reports, are as follows:

- During the most recent 6 months,

    o Use of opioids with an average daily MME greater than or equal to 90 mg for any duration; and

    o Received opioids from more than 3 prescribers and more than 3 pharmacies, OR from more than 5 prescribers regardless of the number of opioid dispensing pharmacies.

- Beneficiaries with cancer diagnoses and beneficiaries in hospice are excluded.

- Prescribers associated with the same single Tax ID Number (TIN) are counted as a single prescriber.

Opioid Product List. All formulations of buprenorphine, including those for pain, have been removed from the most recent CDC MME conversion factor file[2]. Based on input from the CDC, all formulations of buprenorphine will be removed from the OMS.

OMS Response Code. For the PS1 response code (Beneficiary-level POS edit determined necessary: No drugs in the class allowed) for the opioid drug class, buprenorphine products with a Food and Drug Administration (FDA) indication for pain only may be included in the edit.

It is also very important that sponsors implement these edits in a way that beneficiaries' access to medication-assisted treatment (MAT) is not impacted. Sponsors should not include buprenorphine products that are indicated for MAT in this edit.

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[1] More information on the methodology is provided in the Patient Safety Overutilization Monitoring System User Guide (January 2018) on the Patient Safety Analysis Website under Help Documents.
[2] https://www.cdc.gov/drugoverdose/data-files/CDC_Oral_Morphine_Milligram_Equivalents_Sept_2017.xlsx

Access to the Patient Safety Analysis Web Portal

To access the Patient Safety and Overutilization Monitoring Reports, you must be an authorized user of the Patient Safety Analysis Web Portal. CMS' contractor, Acumen, LLC, currently manages the Patient Safety Analysis Web Portal. The web portal is accessible only to authorized participants, with each sponsor utilizing a secure space on the site that is separate from all other sponsors.

Only the Medicare Compliance Officer is authorized to grant access to Acumen's web portals for each contract. To streamline this process, Acumen has developed the User Security Web Portal – a web tool that allows Medicare Compliance Officers to manage their users on the Acumen web portals.

In order for contract users to gain access to the Patient Safety Analysis Web Portal, the Medicare Compliance Officer must complete the following steps:

1. **Identify individuals who should have access to the Patient Safety Analysis Web Portal.**

   If the contract is continuing from 2017, previously authorized users will retain their access to the Patient Safety Analysis Web Portal. The Medicare Compliance Officer may choose to keep the same users or modify users.

   If the contract is new in 2018, the Medicare Compliance Officer must authorize users for the Patient Safety Analysis Web Portal. The Medicare Compliance Officer may choose to authorize users who currently have access to other Acumen web portals. However, the Medicare Compliance Officer must complete the user authorization process again, specifically for the Patient Safety Analysis Web Portal.

   For security purposes, each contract is limited to five authorized users for the Patient Safety Analysis Web Portal.

2. **Log onto the User Security Web Portal**
   (https://PartD.ProgramInfo.us/User_Security).

   Access to the Patient Safety Analysis Web Portal is managed by each contract's Medicare Compliance Officer through Acumen's User Security Web Portal (https://PartD.ProgramInfo.us/User_Security). The latest Medicare Compliance Officer on record for each contract in HPMS has been granted access to the User Security Web Portal.

   If the contract is continuing from 2017, the current Medicare Compliance Officer should already have access to the User Security Web Portal through existing work with Acumen. The Medicare Compliance Officer may log in to the User Security Web Portal using the same username and password.

   If the contract is new in 2018, your contract must update the Medicare Compliance Officer's contact information in HPMS to reflect the appropriate individual. Acumen will then disseminate login credentials to the updated Medicare Compliance Officer.

   To access the User Security Web Portal:

1. Navigate to the Web Portal at https://PartD.ProgramInfo.us/User_Security.
2. Agree to the Warning Notice.
3. Enter your username and login password.

If you are a Medicare Compliance Officer and do not have access to the User Security Web Portal or have never logged on, please contact Acumen at PatientSafety@AcumenLLC.com.

3. **Designate Users and Authorize Access Permissions.**

After the Medicare Compliance Officer logs on to the User Security Web Portal, he or she must review the current user access settings, then designate users and authorize access permissions as necessary.

If the contract is continuing from 2017, the Medicare Compliance Officer must log in to the User Security Web Portal to review the list of individuals currently authorized to access information on the Patient Safety Analysis Web Portal. The Medicare Compliance Officer may choose to keep the same user access settings or modify access as necessary.

If the contract is new in 2018, the Medicare Compliance Officer must log in to the User Security Web Portal to add new users and authorize access permissions or choose to authorize existing users to access the contract's information.

To designate users and authorize access permissions to the Patient Safety Analysis Web Portal, the Medicare Compliance Officer must complete the following steps through the User Security Web Portal:

1. Add an existing and/or new user.
2. Select the Web Portal and contract(s) for each user.
3. Authorize access permissions for each user.

Medicare Compliance Officers may also designate themselves as one of the five authorized users to gain immediate access to the Patient Safety Analysis Web Portal.

All authorized users can log on to navigate the web portal and receive email notifications regarding report releases. However, access to the Patient Safety Analysis Web Portal can vary according to two possible access levels for each user:

- *Summary Report Only*: User can access a version of the Patient Safety and Overutilization Monitoring Reports with summary information on contract-level data for each Patient Safety measure and Overutilization Issue Type. Users with *Summary Report Only* permissions will not be able to access beneficiary-level data.
- *Summary and Confidential Beneficiary Reports:* User can access confidential beneficiary-level information in the detail version of the Patient Safety and Overutilization Monitoring Reports, in addition to the summary versions of the Patient Safety and Overutilization Monitoring Reports.

At least one user from each contract must have access to Summary and Confidential Beneficiary Reports in order to view and respond to beneficiary-level overutilization issues.

Important Date: To ensure timely access to web portal and the January OMS reports, Medicare Compliance Officers must complete all steps of the user authorization process **by January 31, 2018.**

Following the user authorization process, Acumen will send the following to each newly authorized Patient Safety Analysis Web Portal user:

- A Welcome Email with the Patient Safety Analysis Web Portal user guide and Web Portal URL.
- A Credential Email with a unique One-Time Password Link and login username.

MARx Opioid POS Edit Database

We remind sponsors that in accordance with current guidance they should enter information in the Medicare Advantage and Prescription Drug System (MARx) when they have made a decision to implement a beneficiary-level opioid POS claim edit. To facilitate data sharing between Part D sponsors, CMS expects sponsors to submit POS edit notifications into MARx within seven (7) business days of the date on the beneficiary's written advance notice. CMS also expects sponsors to submit implementation, termination, and modification dates of such POS edits within seven (7) business days of the event.

MARx then alerts a new sponsor when a beneficiary identified in this manner by the previous sponsor enrolls in the new sponsor's plan. If the new contract decides to immediately continue the beneficiary-level POS edit, the new contract should enter the POS edit information into MARx. The beneficiary's new contract enrollment date may be entered as both the POS edit notification and implementation date if the POS edit is active on that date. It is still expected that the new contract provide the beneficiary with notification of the continuing POS edit. This guidance applies in cases where the beneficiary changes contracts within the same or different parent organizations.

Technical guidance on the MARx POS Edit Database can be found in the Plan Communication User Guide found here:
https://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/mapdhelpdesk/Plan_Communications_User_Guide.html

HPMS memos and other documents related to the OMS and drug utilization management (DUM) guidance regarding opioid overuse are available on CMS.gov:
https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html

Any general questions related to the Overutilization Monitoring System should be sent to PartD_OM@cms.hhs.gov. For technical questions related to the user authorization process or access to the website or reports, please contact Acumen at PatientSafety@AcumenLLC.com or by phone at (650) 558-8006.

Thank you for your continued dedication to helping our beneficiaries.