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

CENTER FOR MEDICARE

TO: All Part D Plan Sponsors

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

SUBJECT: UPDATES - 2018 Medicare Part D Patient Safety and Overutilization Monitoring System Reports

DATE: April 6, 2018

The purpose of this memorandum is to announce the availability of the 2018 Patient Safety Reports on the Patient Safety Analysis Website, including updates to the measure calculations, addition of new measure reports, and removal of older reports. We also discuss updates to the Medicare Part D Overutilization Monitoring System (OMS) for the April 2018 release.

Requests for new user authorization to access the 2018 Patient Safety Reports must be received no later than April 15, 2018. Instructions can be found beginning on page 5 of this memorandum.

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

For 2018, CMS will report eighteen patient safety measures through the Patient Safety Analysis Website. Several measures are also displayed on the Medicare.gov Plan Finder as Part D Star Ratings or on CMS.gov as Display Measures so that Medicare beneficiaries have the information necessary to make informed enrollment decisions by comparing available health and prescription drug plans. They also provide measures of quality across Part D sponsors. The patient safety measures include:

- High Risk Medication (HRM)
- Medication Adherence (ADH) for Cholesterol (Statins)
- Medication Adherence (ADH) for Hypertension (RAS Antagonists)
- Medication Adherence (ADH) for Diabetes Medications
- Medication Adherence (ADH) for HIV/AIDS (Antiretrovirals)
- Drug-Drug Interaction (DDI)
- Diabetes Medication Dosing (DMD)
- Statin Use in Persons with Diabetes (SUPD)
- Use of Opioids at High Dosage (OHD)
- Use of Opioids from Multiple Providers (OMP)

- Use of Opioids at High Dosage and from Multiple Providers (OHDMP)
- Antipsychotic Use in Persons with Dementia, Overall (APD),
- Antipsychotic Use in Persons with Dementia, in Community-Only Residents (APD-COMM)
- Antipsychotic Use in Persons with Dementia, in Long-Term Nursing Home Residents (APD-LTNH)
- Acetaminophen High Daily Dose (APAP-HD)
- Concurrent Use of Opioids and Benzodiazepines (COB)
- Polypharmacy Use of Multiple Anticholinergic (ACH) Medications in Older Adults (Poly-ACH)
- Polypharmacy Use of Multiple Central Nervous System (CNS)-Active Medications in Older Adults (Poly-CNS)

Part D sponsors currently have access to monthly Patient Safety Reports to compare their performance to overall averages and monitor their progress in improving their measure rates. These actionable monthly reports include summary contract-level reports for each measure, additional detail-level reports, and outlier reports. CMS expects sponsors to routinely monitor these data and immediately alert CMS if potential anomalies are identified, especially measures used in the Star Ratings. Sponsors who wait to raise issues with their data until CMS' plan preview periods may find there is inadequate time for an investigation and resolution within the Star Ratings fall release schedule.

In addition to downloading monthly reports, sponsors can view 'at-a-glance' Rate Summary and Performance Graphs for each measure, and respond to outlier notices directly on the website. Instructions for responding to outlier notices can be found in the Patient Safety Analysis Website User Guide available on the Patient Safety Analysis Website under Help Documents.

The Patient Safety Analysis Website also includes the Medicare Part D OMS. The OMS helps CMS ensure that sponsors have established reasonable and appropriate drug utilization management programs to assist in preventing overutilization of 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, the plans, 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 National Drug Code (NDC) / medication lists used to calculate the Patient Safety measures and used for the OMS are available on the Patient Safety Analysis Website under Help Documents.

2018 Patient Safety Reports

CMS will begin releasing monthly Patient Safety Reports based on 2018 Prescription Drug Event (PDE) data with the April 2018 report release through the Patient Safety Analysis Website. The measures in these reports are calculated using 2018 PDE data processed up until one month before

the release of the report. For example, the 2018 reports released on April 30, 2018 will contain PDE data for dates of service between January 1, 2018 and March 31, 2018, processed by March 31, 2018. Each monthly report is updated as more complete 2018 PDE data are received from Part D sponsors.

All measures are calculated using Pharmacy Quality Alliance (PQA) measure specifications and NDC lists, except for the APAP-HD measure. The PQA updates their NDC lists two times per year, usually in February and July. CMS reviews the NDC lists and communicates findings to the PQA. Once the NDC lists are finalized, CMS implements the revised NDC lists into the Patient Safety Reports. The April 2018 reports use the most recent updated PQA NDC lists for both PDE 2017 and 2018 data. In between PQA NDC list updates, sponsors may observe some differences between their internal monitoring reports and the patient safety reports especially if they are applying more real-time NDC changes or capturing PDE data not yet submitted to or processed by CMS. The APAP-HD measure NDC lists are created using the Medi-Span and First Databank drug databases by CMS and are also updated bi-annually similar to the other patient safety measures.

The final 2018 Patient Safety Reports will be released in July 2019, one month after the submission deadline for 2018 PDE records to CMS using the NDC list provided by the PQA in early 2019 (e.g., February). The final 2018 contract rates will be used to calculate 2020 Part D Star Ratings and/or Display Measures. If the updated RxHCCs are available in September, the final 2020 Display Measures that include diagnoses will use the newly updated RxHCCs.

The updated 2018 NDC lists for all measures are available under Help Documents » NDC Lists » 2018 NDC Lists. Applicable inclusion and exclusion diagnosis codes are included in the associated NDC file. To access the Patient Safety Reports, you must be an authorized user of the Patient Safety Analysis Website. The access authorization process is described in this memo.

Patient Safety Measure Report Updates

The following changes will be implemented with the release of the April 2018 reports using 2018 data unless otherwise specified.

New Measures: We will add the following new measures to the Patient Safety Reports: COB, Poly-ACH, and Poly-CNS.

Medicare Beneficiary Identifier (MBI). Beneficiary-level analyses will include both beneficiary Health Insurance Claim Number (HICN) and MBI as reported on the PDE.

Opioid Product List for OHD, OMP, and OHDMP. The PQA removed all buprenorphine NDCs for the OHD, OMP, and OHDMP measures because there is no longer an MME conversion factor for buprenorphine in the most recent CDC Morphine Milligram Equivalent (MME) conversion factor file.

Days Supply. An updated methodology will be implemented for the patient safety measures that calculate total days supply, per the 2018 PQA Measure Manual (Technical Specifications for PQA-Endorsed Measures, February 2018). The measures include: OHD, OMP, OHDMP, APD, APD-COMM, APD-LTNH, Poly-ACH, Poly-CNS, and COB.

When calculating a beneficiary's total days supply, the following specifications will be applied:

- Any days supply that extends beyond the end of the measurement period will be excluded,
- In the case of multiple prescription claims with the same date of service, total days supply will only include the supply of the claim with the longest days supply, and
- In the case of multiple overlapping claims with different dates of service, there will be no adjustments for early fills or overlapping days supply.

The revised days supply methodology will not apply to HRM which will continue to sum the days supply for all relevant claims, regardless of overlap or extension beyond the measurement period, to determine whether a beneficiary meets the measurement's threshold.

However, the PQA did revise the specifications for the HRM numerator: beneficiaries with at least two fills of the same HRM drug on different dates of service. Per the 2019 Call Letter, this revision will be applied to both the year of service 2017 and 2018 reports.

Hospice Exclusions. The following measures will exclude beneficiaries who elected to receive hospice care at any time in the measurement period: ADH for Cholesterol (Statins), Hypertension (RAS Antagonists), Diabetes Medications, and HIV/AIDS (Antiretrovirals), Poly-ACH, Poly-CNS, and COB.

Medication Adherence Proportion of Days Covered (PDC) Adjustment. The PDC is currently adjusted for inpatient (IP) stays and hospice enrollment for MA-PDs and PDPs, and skilled nursing facility (SNF) stays for PDPs. The day of discharge will now be counted in the PDC adjustment. As such, beneficiaries with stays that span the entire measurement period are not included. Per the 2019 Call Letter, this revision will be applied to both the year of service 2017 and 2018 reports for all four ADH measures. Also, as noted above, beneficiaries in hospice will be excluded from the 2018 ADH measures (versus applying a PDC adjustment).

ESRD Exclusion. (ADH) for Cholesterol (Statins). ADH for Cholesterol (Statins) will exclude beneficiaries with an ESRD diagnosis at any time during the measurement period.

Removal of Older Patient Safety Reports

As of April 29, 2018, the Patient Safety Analysis Website will no longer display Performance Graphs or Rate Summary pages for 2015 Patient Safety Reports. In addition, the summary contract-level and detail-level 2014 Patient Safety Reports will no longer be available for download.

The reports will be archived and available only by request. Sponsors that currently have access to these reports may use the following website features to download this data before it is permanently archived:

- Use the Download Files feature to download 2015 contract-level and detail-level reports.
- Use the Export All Rate Measures feature on the Rate Summary page to download the final summary contract-level data for all 2015 measures.

Overutilization Monitoring System Report Updates

Please refer to the January 19, 2018 HPMS memo, UPDATES - 2018 Medicare Part D Overutilization Monitoring System. We described changes to the OMS beginning with the January 2018 release, including implementing the revised OMS criteria as finalized in the 2018 Call Letter. We will make additional updates to the OMS for the April 2018 release as described below.

Opioid Product List. As mentioned in the January memo, all formulations of buprenorphine, including those for pain, were removed from the most recent CDC MME conversion factor file and subsequently, were removed from the OMS. Based on additional feedback from the CDC, beginning with the April 2018 OMS report, buprenorphine will continue not to be used to calculate the beneficiary's average daily morphine milligram equivalent (MME) due to the removal of the conversion factor, but all forms of buprenorphine, for MAT and pain, will be used to determine the count of opioid prescribers and opioid dispensing pharmacies in the OMS criteria.

High Opioid Daily Dose Rates. Per the 2019 Call Letter, the 2018 OMS reports will now include two Opioid Daily Dose rates for informational purposes.

- 90 MME Opioid Daily Dose rate: # opioid days > 90 MME/1000 Opioid utilization days during the last 6 months.

- 120 MME Opioid Daily Dose rate: # opioid days > 120 MME/1000 Opioid utilization days during the last 6 months.

Medicare Beneficiary Identifier (MBI). OMS reports will include both the beneficiary HICN and MBI as reported on the PDE.

Sponsors will receive an email when their quarterly 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.

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 (MCO to manage their users on the Acumen web portals.

To complete User Authorization, the MCO must:

1. Identify individuals who require access to the Patient Safety Analysis web portal for each contract.
    a. Contracts are limited to **five** authorized users.
    b. All authorized web portal users will have the ability to view all contract-specific portal content and transfer data for their designated contract and permission level.
    c. All authorized web portal users will also be able to discuss any data concerns with Acumen and CMS through contract-specific discussion boards.
2. Log on to the User Security Web Portal.
3. Complete the Add User steps to designate users and authorize access permissions.

Accessing the User Security Web Portal

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

- **If your MCO already has an Acumen ProgramInfo web portal account**, he/she may log in to the User Security Web Portal using the same username and password.
- **If your MCO does not have an Acumen ProgramInfo web portal account**, your contract must update your MCO's contact information in HPMS to reflect the appropriate individual. Acumen will then disseminate login credentials to the updated MCO.

To access the User Security Web Portal:
1. Navigate to the Web Portal at https://partd.programinfo.us/usersecurity.
2. Agree to the Warning Notice.
3. Enter your username and login password.

Designating Users and Authorizing Access Permissions

After your organization's MCO logs in to the User Security Web Portal, he/she must review and/or update the current user access settings, or authorize access permissions for new users. Each contract is limited to a maximum of five users on the Patient Safety Analysis Web Portal.

- **If your contract is continuing from CY 2017**, your MCO must log in to the User Security Web Portal to review the list of individuals currently authorized to access your contract's information on the Patient Safety Analysis Web Portal. Your MCO may choose to keep the same user access settings or modify access as necessary.
- **If your contract is new in CY 2018**, your MCO 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 your contract's information.

To designate users and authorize access permissions, MCOs 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.

MCOs may also designate themselves as one of the five authorized users on the Patient Safety Analysis Monitoring 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 the web portal for patient safety reporting, Medicare Compliance Officers must complete all steps of the user authorization process **by April 15, 2018**. For OMS reports, this process should have already occurred.

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.

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 Patient Safety Analysis project should be sent via email to PartCandDStarRatings@cms.hhs.gov, and 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.