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: April 17, 2019

TO: All Part D Plan Sponsors

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

SUBJECT: UPDATES - 2019 Medicare Part D Patient Safety and Overutilization Monitoring System Reports

The purpose of this memorandum is to announce the availability of the 2019 Patient Safety Reports on the Patient Safety Analysis Web Portal, updates to measure calculations, measure report modifications, and removal of older reports. We also discuss updates to the Medicare Part D Overutilization Monitoring System (OMS) for the April 2019 release.

To access the Patient Safety Reports, you must be an authorized user of the Patient Safety Analysis Web Portal. The access authorization process is described later in this memo. Requests for new user authorization to access the 2019 Patient Safety Reports must be received no later than April 26, 2019. Instructions can be found beginning on page 6 of this memorandum.

NOTE: PACE plans with a drug management program (DMP) are not exempt from the OMS reporting. PACE plans should assign authorized users of the Patient Safety Analysis Web Portal if they have not already done so.

Medicare Part D Patient Safety Measures

For 2019, CMS will report and update monthly 15 patient safety measures through the Patient Safety Analysis Web Portal. Each month, Part D sponsors should download and review their measure packages. These actionable measure packages include a summary contract-level report for each measure and additional beneficiary-level files. Part D sponsors should use the Patient Safety Reports to compare their performance to overall averages and monitor their progress in improving their measure rates.

Several measures are displayed on the Medicare.gov Plan Finder as Part D Star Ratings or on CMS.gov as display measures. Medicare beneficiaries can use this information to make informed enrollment decisions about available health and prescription drug plans.

The patient safety measures include:

- Medication Adherence for Cholesterol (Statins) (ADH-Statins)
- Medication Adherence for Hypertension (RAS Antagonists) (ADH-RAS)

- Medication Adherence for Diabetes Medications (ADH-Diabetes)
- Medication Adherence for HIV/AIDS (Antiretrovirals) (ADH-ARV)
- Drug-Drug Interactions (DDI)
- Statin Use in Persons with Diabetes (SUPD)
- Use of Opioids at High Dosage in Persons without Cancer (OHD)
- Use of Opioids from Multiple Providers in Persons without Cancer (OMP)
- Use of Opioids at High Dosage and from Multiple Providers in Persons without Cancer (OHDMP)
- Antipsychotic Use in Persons with Dementia, Overall (APD)
- Antipsychotic Use in Persons with Dementia, for Community-Only Residents (APD-COMM)
- Antipsychotic Use in Persons with Dementia, for Long-Term Nursing Home Residents (APD-LTNH)
- 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)

CMS expects sponsors to routinely monitor these data and immediately alert CMS if potential anomalies are identified, especially for measures used in the Star Ratings. Sponsors who wait to raise issues with their data during CMS' plan preview periods may find there is inadequate time for an investigation and resolution within the Star Ratings fall release schedule.

The Patient Safety Analysis Web Portal facilitates communication between CMS, Part D contracts, and our contractor, Acumen, LLC. Sponsors can view 'at-a-glance' Rate Summary and Performance Graphs for each measure, and respond directly to outlier notices. Patient Safety Analysis Web Portal User Guide, located under the Portal's Help Documents, includes the instructions for responding to outlier notices. Other information provided under Help Documents include each measure's Patient Safety Report User Guide, diagnosis codes, and the National Drug Code (NDC) / medication lists used to calculate the measures.

Reports across 18 measures will continue to be produced for the year of service of 2018 until July 2019.[1]

2019 Patient Safety Report Updates

CMS will begin releasing monthly Patient Safety Reports based on 2019 Prescription Drug Event (PDE) data with the April 2019 report release. The measures in these reports are calculated using 2019 PDE data processed up until one month before the release of the report. For example, the 2019 reports released on April 30, 2019 will contain PDE data for dates of service between January 1, 2019 and March 31, 2019, processed by March 31, 2019. Each monthly report is updated as more complete 2019 PDE data are received from Part D sponsors.

[1] See HPMS Memo, UPDATES - 2018 Medicare Part D Patient Safety and Overutilization Monitoring System Reports, April 6, 2018.

The following changes will be made to the Patient Safety reports and documented in the applicable Patient Safety Measure User Guide:

- To reduce duplication, the beneficiary-level files will be removed and all applicable information will be added to the denominator files.
- Exclusion files will be produced for the Star Ratings measures based on feedback during the plan preview periods from sponsors. Separate files will be created for the SUPD and ADH, and these files will contain a list of all beneficiaries excluded from the measures and the reason for exclusion. The exclusion files for the Star Ratings measures will also be added to the year of service 2018 reports.
- Some commenters to the draft 2020 Call Letter requested additional information to assist with understanding the inpatient (IP) and skilled nursing (SNF) stay adjustments within the adherence measures. Therefore, we will add the number of adjustment days for IP and/or SNFs stays to the denominator files.
- Certain files will be removed to streamline the content:
    - The prescriber-level files from the SUPD and DDI measures.
    - The drug class tabs from the SUPD, DDI, and ADH measures.
    - The claim-level files from the DDI measure.
- Stratification reports will be included for Hypertension (ADH-RAS), Diabetes (ADH-Diabetes), and Cholesterol (ADH-Statins) adherence measures for the overall and contract rates by: gender, LIS/Dual eligibility status, disability status, and age groupings.

All measures are calculated using Pharmacy Quality Alliance (PQA) measure specifications and NDC lists. The PQA updates their NDC lists biannually, usually in February and July. The April 2019 reports use the most recent updated PQA NDC lists and the ICD-10 diagnoses codes for both PDE 2018 and 2019 data. Between NDC list updates, sponsors may observe differences between their internal monitoring reports and the patient safety reports, especially if applying more real-time NDC changes or capturing PDE data not yet submitted to or processed by CMS.

The final 2019 Patient Safety Reports will be released in July 2020, one month after the submission deadline for 2019 PDE records to CMS using the NDC list provided by the PQA in early 2020 (e.g., February). The final 2019 contract rates will be used to calculate 2021 Part D Star Ratings and/or display measures.

Patient Safety Measure Updates

The following changes will be implemented with the release of the April 2019 reports using 2019 data unless otherwise specified.

Retired Measures. We will no longer report the following measures in the Patient Safety reports for the 2019 measurement period: HRM and DMD.

Discontinue Acetaminophen High Daily Dose (APAP-HD) Metric: The APAP-HD metric measured the proportion (XX out of 1,000) of total days of APAP utilization of Medicare Part D beneficiaries

that exceeded a daily dose of 4 grams.[2] Since CMS began to report this contract-level metric, the rates have remained very low and continued to decrease. The rates across all Part D contracts decreased from 1.74 days in 2016 to 1.08 days in 2018. CMS will continue to monitor APAP overutilization and re-assess if needed.

Medication Adherence (ADH) Proportion of Days Covered (PDC) Adjustment. Using the Common Working File (CWF), the PDC is adjusted for IP stays and hospice enrollment for MA-PDs and PDPs, and SNF stays for PDPs. The days of relevant stays occurring during the measurement period are excluded from the numerator and denominator of the PDC calculation. SNF stay data from the CWF, if available for MA beneficiaries and MA-PDs, will be included in the PDC adjustment methodology.

Measure Specification Updates. An updated methodology will be implemented for the following patient safety measures:

- *ADH-ARV*: The measure will evaluate the PDC of ≥ 3 unique antiretroviral medications (ARVs) at 90% PDC threshold.

- *SUPD*: The eligible population/denominator requirement of ≥ 2 prescription claims must have different dates of service and can be for any diabetes medication.

- *COB, OHD, OMP, and OHDMP:* When calculating the denominator requirement of ≥ 15 total days supply of opioid medication the following steps are applied: i) when dispensed on different days, the days supply is summed for the total days supply, and ii) in the case of multiple prescriptions dispensed on the same day, total days supply will only include the supply of the prescription with the longest days supply.

- *OHD*: The percentage of individuals ≥ 18 years of age who received prescriptions for opioids with an average daily dosage of ≥ 90 morphine milligram equivalents (MME) over a period of ≥ 90 days (which does not need to be 90 consecutive days or longer). The average daily MME calculated will be rounded to the nearest hundredth.

- *OMP*: The percentage of individuals ≥ 18 years of age who received prescriptions for opioids from ≥ 4 prescribers and ≥ 4 pharmacies within ≤ 180 days.

- *OHDMP*: The percentage of individuals ≥ 18 years of age who received prescriptions for opioids with an average daily dosage of ≥ 90 MME and who received prescriptions for opioids from ≥ 4 prescribers and ≥ 4 pharmacies within ≤ 180 days. The average daily MME calculated will be rounded to the nearest hundredth.

- *APD, APD-COMM, APD-LTNH*: The denominator requirement of ≥ 2 prescription claims must have different dates of service. PQA clarified that > 60 days supply is cumulative for any cholinesterase inhibitor or NMDA receptor antagonist. The days' supply of eligible antipsychotic drugs in the numerator is cumulative. When calculating the numerator and

[2] CMS initially reported the number of potential APAP over utilizers through the OMS, but saw a significant decrease of 94% (76,681 to 4,539 beneficiaries) from 2011 to 2015. See Final 2016 Call Letter. CMS switched to report the contract-level metric in 2016, but overutilization has remained very low.

denominator total days' supply requirements the following steps specifications are applied: i) when dispensed on different days, the days supply is summed for the total days supply, and ii) in the case of multiple prescriptions dispensed on the same day, total days supply will only include the supply of the prescription with the longest days supply.

- *Cancer Exclusion*. CMS adopted PQA's revised cancer exclusion value set for these measures: COB, OMP, OHDMP, and OHD.

Removal of Older Patient Safety Reports

As of April 30, 2019, the Patient Safety Analysis Web Portal will no longer display Performance Graphs or Rate Summary pages for 2016 Patient Safety Reports. In addition, the summary contract-level and detail-level 2015 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 Web Portal features to download this data before it is permanently archived:

- Use the Download Files feature to download 2016 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 2016 measures.

Overutilization Monitoring System (OMS)

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 potential at-risk beneficiary cases 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 Web Portal under Help Documents. The deadline for submitting responses is 30 days after the report date.

Part D sponsors can refer to the following resources for more information on the DMPs available at: https://www.cms.gov/Medicare/Prescription-Drug-coverage/PrescriptionDrugCovContra/RxUtilization.html

- 2019 Part D Drug Management Program Policy Guidance Memo
- Frequently Asked Questions About Part D Drug Management Programs
- 2019 OMS Technical Guidance

Part D Drug Management Program Notices technical instructions for submitting to the Medicare Advantage and Prescription Drug System (MARx) can be found in the MAPD Plan Communications User Guide (PCUG) https://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/mapdhelpdesk/Plan_Communications_User_Guide.html.

OMS Report Updates

The following changes will be implemented with the release of the April 2019 reports.

Cancer Exclusion. CMS adopted PQA's revised cancer exclusion value set.

Opioid product list. Buprenorphine solution (Sublocade®) will be added to the OMS medication drug list in order to better align with the CDC medication list.[3] Buprenorphine products are included in the OMS medication list for the identification of opioid prescribers and pharmacies only, as there is no conversion factor for MME calculation.

Imbedded Validation Checker. The ORF and SRF will be updated with a 'Validation Status' column to check the validity of responses. All cases must have a 'Complete' Response Status and a 'Valid' Validation Status for the form to be successfully submitted by the 30-day reporting deadline. The validation status for SRF cases are preliminary, pending successful validation of the health insurance claim number (HICN) or Medicare Beneficiary Identifier (MBI) fields.

Validation Reports. The validity of responses will be checked within the ORF and SRF instead of through the Validation Reports. SRF cases with invalid HICN and MBI fields will be reported to sponsors as 'invalid' in the contract detail reports. Any 'invalid' SRF cases should be re-submitted through OMS during the next reporting cycle.

SRF Deletion. A new response code 'DEL' will be added to the 'Method of Identification' element of the SRF. Selecting this response code and 'NA' for all subsequent elements will result in deletion of the SRF case. Sponsors should check their contract detail report for confirmation.

'Update' Response Code Removal. The 'R3. Update' response code for the 'Review Status' element will be removed. 'R2. Review Complete' should be used for completed reviews of new cases as well as updated responses to previously reported cases. 'R1. In Progress' should still be used for cases pending completion.

Documentation. Updated documentation will be posted to both the Patient Safety Analysis Web Portal and CMS Part D Overutilization website (https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html) before April 30.

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 (MCO) for a given contract may authorize user access to Acumen's Patient Safety Web Portal for that contract. To streamline this process, Acumen has developed the User Security Web Portal – a web tool that allows MCOs to manage their users on the Acumen web portals.

[3] https://www.cdc.gov/drugoverdose/resources/data.html

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 2018**, 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 2019**, 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 26, 2019**. 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.

Additional Resources

Part D sponsors can refer to the CMS Part D Overutilization website: 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 Web Portal or reports, please contact Acumen at PatientSafety@AcumenLLC.com or by phone at (650) 558-8006.

Thank you for your continued dedication to helping Medicare beneficiaries.