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DATE: April 20, 2021

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

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SUBJECT: UPDATES - 2021 Medicare Part D Patient Safety Reports

The purpose of this memorandum is to announce the availability of the 2021 Patient Safety Reports on the Patient Safety Analysis Web Portal on April 30, 2021, updates to measure calculations, measure report modifications, and removal of older reports.

To access the Patient Safety Reports, you must be an authorized user of the [Patient Safety Web Portal](#). The access authorization process is described later in this memo. We encourage requests for new user authorization to access the 2021 Patient Safety Reports to be submitted by April 27, 2021. Instructions can be found beginning on page 4 of this memorandum.

Medicare Part D Patient Safety Measures

For 2021, CMS will report and update monthly 13 patient safety measures through the Patient Safety Analysis Web Portal. Each month, Part D sponsors may 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 can 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)
- 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)
- Antipsychotic Use in Persons with Dementia, Overall (APD)
- 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)
- Initial Opioid Prescribing for Long Duration (IOP-LD)

Sponsors may monitor their data in the reports and alert CMS if potential errors or anomalies are identified. 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. CMS encourages sponsors to review the outlier notices; however, it is optional for Part D sponsors to respond.

The Patient Safety Analysis Web Portal User Guide is located under the Portal’s Help Documents tab. Other information provided under the Help Documents tab 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 the sixteen year of service (YOS) 2020 measures will continue to be produced with YOS 2020 data until July 2021.¹

2021 Patient Safety Report Updates

CMS will begin releasing monthly Patient Safety Reports based on 2021 Prescription Drug Event (PDE) data with the April 2021 report release. The measures in these reports are calculated using 2021 PDE data processed up until one month before the release of the report. For example, the 2021 reports released on April 30, 2021 will contain PDE data for dates of service between January 1, 2021 and March 31, 2021, submitted by March 31, 2021. Each monthly report is updated as more complete 2021 PDE data are received from Part D sponsors.

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

- Updated exclusion files for SUPD based on the newly added denominator exclusions from diagnosis codes and NDC Value Sets for the YOS 2021 measure that will contain a list of beneficiaries excluded from the SUPD measure and the reason for exclusion.

All measures are calculated based on Pharmacy Quality Alliance (PQA) measure specifications and National Drug Code (NDC) Value Sets. The PQA updates their NDC lists biannually, usually in

¹ See HPMS Memo, UPDATES - 2020 Medicare Part D Patient Safety and Overutilization Monitoring System Reports, April 20, 2020.

February and July. The April 2021 reports use the most recent updated PQA NDC lists and the ICD-10 diagnoses codes for both PDE 2020 and 2021 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 YOS 2021 Patient Safety Reports will be released in July 2022, one month after the submission deadline for 2021 PDE records to CMS using the NDC list provided by the PQA in early 2022 (e.g., February). The final YOS 2021 contract rates will be used to calculate 2023 Part D Star Ratings and/or display measures.

Patient Safety Measure Updates

The following changes will be implemented with the release of the April 2021 reports using 2021 data unless otherwise specified, consistent with the Announcement of Calendar Year (CY) 2022 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies published on January 15, 2021.²

Retired Measures. (1) Drug-Drug Interactions, (2) Antipsychotic Use in Persons with Dementia, for Community-Only Residents, and the (3) Use of Opioids at High Dosage and from Multiple Providers in Persons without Cancer measures will be retired from Patient Safety reports after the completion of measurement year 2020 and will not be reported as display page measures for 2022.

Measure Specification Updates. Updated measure specifications will be implemented for the following patient safety measures:

SUPD:

- The index prescription start date (IPSD) is defined as the earliest date of service for a diabetes medication during the measurement period and must occur at least 90 days prior to the end of the measurement year or end of enrollment episode to be considered in the measure rate.
- Beneficiaries with rhabdomyolysis or myopathy; pregnancy, lactation, or fertility; liver disease; pre-diabetes; and polycystic ovary syndrome (PCOS) will be excluded from the SUPD measure for the measurement year. See the SUPD Measure Report User Guide for specifics on these diagnoses.

Poly-CNS and Poly-ACH:

- The injectable and inhalation routes of administration will be removed from both polypharmacy measures' NDC medication lists provided by the PQA in an effort to improve accuracy in estimating days' supply.

Poly-CNS:

- The serotonin-norepinephrine reuptake inhibitors (SNRIs) and antiepileptics medication classes will be added to the Poly-CNS NDC medication list.

² See [Announcement of Calendar Year \(CY\) 2022 Medicare Advantage \(MA\) Capitation Rates and Part C and D Payment Policies](#).

- Beneficiaries with a seizure disorder diagnosis during the measurement year will be excluded from the Poly-CNS measure.

Removal of Older Patient Safety Reports

As of April 30, 2021, the Patient Safety Analysis Web Portal will no longer display Performance Graphs or Rate Summary pages for 2018 Patient Safety Reports.

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 2018 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 2018 measures.

Access to the Patient Safety Analysis Web Portal

To access the Patient Safety Reports, you will need to 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.

To complete User Authorization, the MCO will need to:

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](#). 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 [Patient Safety Web Portal](#).
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 may 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 2020**, your MCO may 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 2021**, your MCO may 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 may 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 Reports with summary information on contract-level data for each Patient Safety measure. 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 Reports, in addition to the summary versions of the Patient Safety 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 issues.

Important Date: To ensure timely access to the Web Portal for patient safety reporting, we recommend that MCOs complete all steps of the user authorization process **by April 27, 2021**. However, if you are unable to access the Web Portal by April 27, 2021, please contact Acumen when possible. Acumen will provide assistance to ensure that sponsors gain access to the Web Portal in a timely manner.

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 [Part C&D Performance Data website](#).

Any general questions related to the Patient Safety Analysis project should be sent via email to PartCandDStarRatings@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.