DEPARTMENT OF HEALTH & HUMAN SERVICES Centers for Medicare & Medicaid Services 7500 Security Boulevard

Baltimore, Maryland 21244-1850



CENTER FOR MEDICARE

DATE: April 24, 2024

TO: All Prescription Drug Plans, Medicare Advantage-Prescription Drug

Plans, Section 1876 Cost Plans, and PACE plans

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SUBJECT: UPDATES - 2024 Medicare Part D Patient Safety Reports

The purpose of this memorandum is to announce the availability of the 2024 Patient Safety Reports on the Patient Safety Analysis Web Portal on April 30, 2024, updates to measure calculations, changes to measure specifications, new measures, and archiving of older reports.

To access the Patient Safety Reports, you must be an authorized user of the <u>Patient Safety Web Portal</u>. The access authorization process is described later in this memo. Instructions can be found in the "Access to the Patient Safety Analysis Web Portal" section of this memorandum.

Medicare Part D Patient Safety Measures

For measurement year 2024, CMS will report and update monthly 17 Patient Safety measures through the Patient Safety Analysis Web Portal. Each month, Part D sponsors may download and review their measure packages. These 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 Rating measures or on CMS.gov as display page measures. Medicare beneficiaries can use this information to make informed enrollment decisions about available health and prescription drug plans.

The Patient Safety measures include:

- Star Ratings Medication Adherence for Cholesterol (Statins) (ADH-Statins)
- Star Ratings Medication Adherence for Hypertension (RAS Antagonists) (ADH-RAS)
- Star Ratings Medication Adherence for Diabetes Medications (ADH-Diabetes)
- Display Page Medication Adherence for Cholesterol (Statins) with Sociodemographic

- Status Adjustment (ADH-Statins SDS)
- Display Page Medication Adherence for Hypertension (RAS Antagonists) with Sociodemographic Status Adjustment (ADH-RAS SDS)
- Display Page Medication Adherence for Diabetes Medications with Sociodemographic Status Adjustment (ADH-Diabetes SDS)
- 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)
- Persistence to Basal Insulin (PST-INS)

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. Sponsors may review their underlying measure data in the reports and alert CMS if potential errors or anomalies are identified in the rate calculations per the measure specifications. If you have questions regarding your rate calculations, diagnosis codes or exclusions, or underlying data, contact PatientSafety@AcumenLLC.com. Provide detailed information about the potential issue or question. Your request will be reviewed and if appropriate, a secure submission window will be opened in the Patient Safety Analysis Web Portal for you to submit a small, demonstrative sample of beneficiaries (i.e., claims for no more than one or two beneficiaries per Part D contract and measure that demonstrate the potential issue) for a review of the administrative data. We may request a larger sample depending on the results of the review.

The Patient Safety Analysis Web Portal User Guide is located under the Web Portal's navigation menu Help Documents web page link. Other information provided on the Help Documents web page includes links to each measure's Patient Safety Report User Guide, diagnosis codes, and the National Drug Code (NDC) medication lists used to calculate the measures.

The 14 measure reports for year of service (YOS) 2023¹ will be produced until July 2024 using 2023 data submitted by the <u>annual prescription drug event (PDE) submission deadline</u> for the annual Part D payment reconciliation.

¹ See HPMS memorandum, "UPDATES - 2023 Medicare Part D Patient Safety Reports, April 20, 2023."

2024 Patient Safety Report Update

CMS will begin releasing monthly Patient Safety Reports using 2024 Prescription Drug Event (PDE) data with the April 2024 report release. The measures in these reports are calculated using 2024 PDE, fee-for-service claims, and encounter data processed up until one month before the release of the report. For example, the 2024 reports released on April 30, 2024, will contain PDE data for dates of service between January 1, 2024, and March 31, 2024, submitted by March 31, 2024. Each monthly report is updated as more complete 2024 data are submitted and processed.

The 2024 Patient Safety Reports and User Guides include the following updates:

- An updated user guide for continuous enrollment will be provided for the following measures: ADH-Statins, ADH-RAS, ADH-Diabetes, SUPD, Poly-ACH, Poly-CNS, and COB.
- A new user guide for the following new display page measures: ADH-Diabetes SDS, ADH-RAS SDS, and ADH-Statins SDS.
- A new user guide for the ADH-ARV measure.
- The Measure Summary worksheet within the Contract-Level Report includes the contract-level data stratified by the low-income subsidy (LIS) status. A beneficiary is considered LIS if they are partial or full LIS status at any time during the measurement year.

All measures are calculated based on Pharmacy Quality Alliance (PQA) measure specifications and Value Sets, which include NDCs. The PQA updates their Value Sets biannually, usually in February and July. The April 2024 reports use the most recent updated PQA NDC lists and the ICD-10 diagnoses codes for both 2023 and 2024 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 2024 Patient Safety Reports will be released in July 2025, one month after the submission deadline for 2024 PDE records to CMS and use the NDC list provided by the PQA in early 2025 (e.g., February). The final YOS 2024 contract rates will be used to calculate 2026 Part D Star Ratings and/or display page measures.

Patient Safety Measure Updates

As finalized in the April 12, 2023 final rule, "Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly" (88 FR 22265-22270), and consistent with the Announcement of Calendar Year (CY) 2025 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment

Policies published on April 1, 2024,² the following changes are implemented with the release of the April 2024 reports using 2024 data unless otherwise specified.

New Display Page Measures

ADH-Diabetes SDS/ADH-RAS SDS/ADH-Statins SDS. SDS risk adjustment will be implemented for the three adherence measures on the display page. The SDS risk adjustment is based on SDS characteristics (age, gender, dual eligibility/LIS status, and disability status) according to the PQA specifications which were endorsed by the National Quality Forum (NQF). These measures will first be added to the display page since the SDS risk adjustment is a substantive update to the measures while the legacy measures are maintained on the Star Ratings. In addition to the SDS risk adjustment, the medication adherence measures on the display page will also incorporate non-substantive updates to fully align with the PQA measure specification such as continuous enrollment (CE) and removal of the skilled nursing facility (SNF) and inpatient (IP) stay adjustment. The legacy adherence measures will be maintained in the Star Ratings until 2028 (2026 measurement year).

Measure Specification Updates

ADH-Diabetes/ADH-RAS/ADH-Statins. CE will be implemented for the current legacy medication adherence measures in the Star Ratings to align with the PQA specifications and no longer adjust for member-year (MY) enrollment which was used to account for partial enrollment. For more information on the CE methodology, please refer to the Medication Adherence measure user guides.

SUPD. To align with the PQA measure specifications, CMS will use CE, no longer adjust for MY, and align with the PQA age eligibility criteria. Therefore, based on the PQA's age criteria, beneficiaries will be eligible for the measure based on their age criteria at the start of the measurement year regardless of whether the beneficiary ages in or out during the measurement year.

Poly-ACH/Poly-CNS/COB. To align with the PQA measure specifications, CMS will use CE and no longer adjust for MY.

Poly-ACH. Per the updated PQA measure specifications, 14 medications were removed from the NDC Medication Value Sets: belladonna alkaloids, carbinoxamine, clemastine, dexbrompheniramine, dexchlorpheniramine, dispropyramide, loxapine, methoscoplamine, propantheline, protriptyline, pyrilamine, thioridazine, trifluoperazine, and trimipramide. These medications were removed from the Poly-ACH measure by the PQA to align with the American Geriatrics Society (AGS) Beers Criteria which provides the recommendation to avoid concurrent use of two or more anticholinergic medications in older adults. The updated AGS Beers Criteria identified 14 medications for removal due to very low usage or the medications were no longer available on the United States market.

² Referred to as the 2025 Rate Announcement and available at: https://www.cms.gov/files/document/2025-announcement.pdf.

Poly-CNS/Poly-ACH. The PQA updated the measure specifications by removing the index prescription start date (IPSD) for both polypharmacy measures. The intent of the IPSD in the polypharmacy specifications, which required the earliest date of service for a target medication to occur 30 or more days from the last day of the measurement year, was to limit and define the eligible population for the polypharmacy measures to beneficiaries who can potentially meet the numerator criteria. The PQA revised the measure specifications to apply to instances of 2 or more prescription claims for the same target medication on different dates of service when determining if the earliest date of service for any target medication is 30 or more days from the last day of the measurement year. CMS will implement this update for both polypharmacy measures.

Poly-ACH/Poly-CNS/COB/OHD/OMP. Based on the PQA CE measure specifications, these measures previously included an anchor date. The anchor date required the beneficiary to be enrolled and to have a benefit on a specific date. Additionally, the allowable gap must not have included that date specified in the measure as the anchor date. The PQA removed the anchor date for these measure specifications for calendar year (CY) 2024. Therefore, as these measures transition from MY to CE, CMS will not implement the anchor date with the CE methodology beginning with the 2024 measurement year, since the anchor date from the eligible population definition was removed by the PQA as of CY 2024.

ADH-Diabetes/ADH-RAS/ADH-Statins/ADH-ARV/ OHD/OMP/PST-INS/COB/IOP-LD/Poly-CNS/Poly-ACH. As described in the 2025 Rate Announcement, we will use the Common Medicare Environment (CME) to identify beneficiaries with a hospice stay and/or ESRD status (ESRD dialysis coverage dates) as applicable to the measure specifications. The Enrollment database (EDB) is part of the CME database, and accessing enrollment information through the CME will improve data availability for the monthly Patient Safety Reports for these Patient Safety measures. Additionally, the CME database includes Medicare beneficiary enrollment and demographic data, as well as integrates different types of beneficiary data from CMS legacy systems.

Removal of Older Patient Safety Reports

As of April 30, 2024, the Patient Safety Analysis Web Portal will no longer display Performance Graphs or Rate Summary pages for 2021 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 2021 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 2021 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 contractspecific 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, they 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, they 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 2023, 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 2024, 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 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.

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.