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

TO: All Part D Plan Sponsors

FROM: Amy K. Larrick, Acting Director, Medicare Drug Benefit and C & D Data Group

SUBJECT: UPDATES - 2015 Medicare Part D Patient Safety, Overutilization Monitoring
            System Reports and MARx POS Edit User Interface

DATE: April 8, 2015

The purpose of this memorandum is to announce the availability of the 2015 Patient Safety
Reports on the Patient Safety Analysis Website, including updates to the measure calculations
and removal of older reports, discuss updates to the Medicare Part D Overutilization Monitoring
System for the April 2015 release, and announce the availability of the MARx POS Edit User
Interface.

Requests for new user authorization to access the April 2015 Patient Safety and OMS reports
must be received no later than April 17, 2015.

Background

Performance and quality measures are used by CMS so 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. As part of
this effort, CMS currently calculates and reports on eight patient safety measures:

- High Risk Medication (HRM) measure*
- Diabetes Treatment (DT) measure*
- Medication Adherence (ADH) for Cholesterol (Statins)*
- Medication Adherence (ADH) for Hypertension (RAS Antagonists)*
- Medication Adherence (ADH) for Diabetes Medications*
- Drug-Drug Interaction (DDI) measure**
- Diabetes Medication Dosage (DMD) measure**
- Medication Adherence for HIV/AIDS (Antiretrovirals)***

  *Part D Plan Rating on the Medicare.gov Plan Finder   **Part D Display Measure on CMS.gov   ***Part D Patient Safety Report (only)

Part D sponsors currently have access to monthly Patient Safety Reports via the Patient Safety
Analysis Website to compare their performance to overall averages and monitor their progress in
improving the prescription drug patient safety measures. These actionable reports include
summary contract-level Patient Safety Reports for each measure, additional detail-level reports,

and outlier reports. In addition to downloading monthly reports, sponsors can also view 'at-a-glance' Rate Summary and Performance Graphs for each measure, and respond to Outlier Reporting directly on the website.

The Patient Safety Analysis Website includes the Medicare Part D Overutilization Monitoring System (OMS). The OMS helps CMS ensure that sponsors have established reasonable and appropriate drug utilization management programs to assist in preventing overutilization of certain prescribed medications. Contract-level reports of beneficiaries with potential overutilization issues (i.e., acetaminophen, opioid, and Center for Program Integrity referrals) are available quarterly to Part D sponsors, and sponsors are expected to send responses to the OMS describing the status of the review of each beneficiary's case. Sponsors can also report potential opioid overutilization by beneficiaries identified through sponsors' own internal criteria and reviewed, 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, User Guides and the medication lists used to calculate the Patient Safety and the OMS measures are available on the Patient Safety Analysis Website under Help Documents.

2015 Patient Safety Reports

CMS will begin releasing monthly Patient Safety Reports based on 2015 Prescription Drug Event (PDE) data during the April 2015 report release.

The measures in these reports are calculated using 2015 PDE data processed up until one month before the release of the report. For example, the 2015 reports released on April 30, 2015 will contain PDE data for dates of service between January 1, 2015 and March 31, 2015, processed by March 31, 2015. Each monthly report is updated as more complete 2015 PDE data are received from Part D sponsors. The final 2015 Patient Safety Reports will be released in July 2016, one month after the submission deadline for 2015 PDE records to CMS. The final 2015 rates will be used to calculate the 2017 Part D Star Ratings and/or Display Measures.

CMS will also continue producing Patient Safety Reports based on 2014 PDE data through July 2015, when the final 2014 reports will be released. The final 2014 rates will be used to calculate the 2016 Part D Star Ratings and/or Display Measures.

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. **The deadline for new user authorization is no later than April 17, 2015.**

Patient Safety Measure and Report Updates

The Patient Safety Measures were adapted from measures developed by the Pharmacy Quality Alliance (PQA). As announced in the 2016 Final Call Letter, CMS adopted certain PQA

revisions to its specifications and made other changes to the Patient Safety Measures, which are described below.

Medication Adherence for Diabetes Medications. For both year of service (YOS) 2014 and 2015 reports, beneficiaries reported with end-stage renal disease (ESRD) coverage in the Medicare Enrollment Database (EDB) will be excluded from the denominator of the diabetes medication adherence measure for the entire year. Also, when available in the Common Medicare Environment (CME), the exact death date will be used rather than the CME disenrollment date as the end of the beneficiary's measurement period.

Medication Adherence for Hypertension. For both YOS 2014 and 2015 reports, beneficiaries reported with ESRD coverage in the EDB will be excluded from the denominator of the hypertension medication adherence measure for the entire year. Also, when available in the CME, the exact death date will be used rather than the CME disenrollment date as the end of the beneficiary's measurement period.

Medication Adherence for Cholesterol. For both YOS 2014 and 2015 reports, the cholesterol medication adherence measure will use the exact death date when available in the CME rather than the CME disenrollment date as the end of the beneficiary's measurement period.

Diabetes Treatment. The Diabetes Treatment (DT) measure will be retired after completing the YOS 2014 reports through July 2015. This measure will not be included in YOS 2015 reports or remaining YOS 2014 outlier reports. Beneficiaries reported with ESRD coverage in the EDB will be excluded from the denominator of the DT measure for the entire year.

Statin Use in Persons with Diabetes. This new PQA-endorsed measure, Statin Use in Persons with Diabetes (SUPD), calculates the percentage of patients between 40 and 75 years old who received at least two diabetes medication fills and also received a statin medication during the measurement period. Beneficiaries in hospice according to the EDB will be excluded from the denominator of the SUPD measure for the entire year. The SUPD measure will be included in YOS 2015 reports. The Patient Safety Analysis Website will be updated with the SUPD measure and a SUPD user guide will be available under the Help Documents page of the website.

Obsolete NDCs. Beginning with YOS 2014 reports, we will implement the PQA's 2014 specification change to account for obsolete NDCs. The revised obsolete date methodology includes the following steps:
- Query the MediSpan and First DataBank databases to develop an NDC list.
- Cross-check the NDC list developed at step 1 against the FDA's Comprehensive NDC Structured Product Labeling (SPL) Data Elements File (NSDE) and its effective dates.
- Include the NDC in the file if:
  - There is no obsolete date noted by MediSpan, or First DataBank, or NSDE; or
  - The obsolete date in any of the databases is within the measurement year; or
  - The obsolete date is within six months prior to the beginning of the measurement year.

Removal of Older Patient Safety Reports

As of April 30, 2015, the Patient Safety Analysis Website will no longer display Performance Graphs or Rate Summary pages for 2012 Patient Safety Reports. In addition, the summary contract-level and detail-level 2012 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 2012 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 2012 measures.

April 2015 Overutilization Monitoring Reports

The April OMS reports will be available on April 30, 2015. Sponsors will receive an email when their Overutilization Monitoring 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. All contracts will receive a summary report package including a Sponsor-Identified Potential Overutilization Issue (SPI) Reporting Form.

Overutilization Monitoring System Updates

Opioid Product List Change. Based on input from the Centers for Disease Control and Prevention (CDC), combination products containing buprenorphine and naloxone (e.g., Bunavail™, Suboxone®, Zubsolv®) will be removed from the OMS opioid list effective April 2015. We are taking this action because these products are indicated for treatment of opioid dependence and the recommended daily target dose exceeds the OMS opioid threshold of 120 mg morphine equivalent dose (MED).

New Processing Logic for OMS Point-of-Sale (POS) Response Codes. Effective April 2015, the known exception logic for PS1 and PS2 Response Codes will be based on the actual implementation date submitted in MARx for the POS edit, rather than the notification date. This change in processing logic is necessary because a proposed POS edit described in the beneficiary notice may be reversed, due to reasons such as a coverage determination or appeal. All sponsors should regularly update the POS edit information in MARx to include the actual implementation date.

Website Update. Beginning with the April 2015 OMS cycle, the Patient Safety Analysis Website will no longer accept OMS Response Forms and SPI Reporting Forms in .xls format. Only forms uploaded in .xlsx format will be processed.

New Part D Overutilization Management Mailbox. A new Part D Overutilization Management mailbox (PartD_OM@cms.hhs.gov) is available for submission to CMS of any questions or suggestions related to overutilization management in Part D, the OMS, or POS edit information in MARx. Sponsors should also send copies of non-opioid, beneficiary-specific POS edit notices to this new mailbox rather than the CMS Part D Policy mailbox, in addition to sending copies to their CMS account manager.

Access to the Patient Safety Analysis Website

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

In accordance with Federal Information Security Management Act (FISMA) regulations, only the Medicare Compliance Officer is authorized to give access to the website for each contract. To streamline this process, Acumen has developed the User Security Website – a web tool that allows Medicare Compliance Officers to manage their users on the Acumen websites.

In order for contracts to gain access to the Patient Safety Analysis Website, the Medicare Compliance Officer must complete the following steps:

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

   If the contract is continuing from 2014, previously authorized users will retain their access to the Patient Safety Analysis Website. The Medicare Compliance Officer may choose to keep the same users or modify users.

   If the contract is new in 2015, the Medicare Compliance Officer must add new users or choose to authorize existing users who currently have access to other Acumen websites.

   For security purposes, contracts are limited to five authorized users per website.

2. **Access the User Security Website.**

   If the contract is continuing from 2014, the current Medicare Compliance Officer should already have access to the User Security Website through existing work with Acumen.

   If the contract is new in 2015, the Medicare Compliance Officer should have received login credentials and a User Security Website user guide via email and USPS.

   To access the User Security Website:

   1. Navigate to the User Security Website at https://partd.programinfo.us/usersecurity.
   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 Website or have never logged on, please contact Acumen at (650) 558-8006.

3. **Designate and authorize users.**

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

To designate users and authorize access permissions to the Patient Safety Analysis Website, the Medicare Compliance Officer must:

1. Submit an Add User Request Form for each new user.
2. Designate users for each contract individually.
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 Website.

All authorized users can log on to navigate the websites and receive email notifications regarding report releases. However, access to the Patient Safety Analysis Website 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.

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

To ensure timely access to the website, Medicare Compliance Officers must complete all steps of the user authorization process **by April 17, 2015**.

Once users have been added, Acumen will send these authorized Patient Safety Analysis Website users:
- An email with the login username and website user guide
- A letter with the login password via USPS

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.

MARx POS Edit User Interface

A user interface (UI) is now available in MARx for updating the POS edit data; this change was first described in the HPMS memo dated November 12, 2014: Announcement of the February 2015 Software Release for information regarding the change to the MARx POS edit database.

To access the UI, sponsors' users must first obtain a MCO POS Edit User role and password by registering in the Enterprise Identity Management (EIDM) system. The Plan's External Point of Contact (EPOC) is responsible for approving their users' access in accordance with established EIDM policies. Authorized users will have access to two new screens:

- M254 – Update POS Drug Edit
- M255 – POS Drug Edit Detail

For additional information, see the Medicare Advantage and Prescription Drug Plan Communications User Guide (PCUG) Section 2.1: http://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-technology/mapdhelpdesk/Plan_Communications_User_Guide.html. The EIDM User's Guide is also available via the web at: https://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/IACS/Downloads/IACS-EIDM-Migration-User-Guide.pdf.