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

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TO: All Part D Plan Sponsors

FROM: Tracey McCutcheon, MHSA, MBA
Acting Director, Medicare Drug Benefit and C & D Data Group

SUBJECT: UPDATES - 2014 Medicare Part D Patient Safety and Overutilization Monitoring System Reports

DATE: April 9, 2014

The purpose of this memorandum is to announce the availability of 2014 Patient Safety Reports, discuss updates to the measure calculations, notify sponsors of the upcoming removal of older Patient Safety Reports from the Patient Safety Analysis Website, and discuss updates to the Medicare Part D Overutilization Monitoring System (OMS) for the April 2014 reports. Requests for new user authorization to access the April 2014 Patient Safety and OMS reports must be received no later than April 18, 2014.

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**
- Part D 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.

In July 2013, new functionality was added to the Patient Safety Analysis Website with the addition of 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 CPI 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. Beginning in January 2014, sponsors can also report internally-identified potential opioid overutilization issues for inclusion in 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.

2014 Patient Safety Reports

CMS will begin releasing monthly Patient Safety Reports based on 2014 Prescription Drug Event (PDE) data during the April 2014 report release.

The measures in these reports are calculated using 2014 PDE data processed up until one month before the release of the report. For example, the 2014 reports released on April 30, 2014 will contain PDE data for dates of service between January 1, 2014 and March 31, 2014, processed by March 31, 2014. Each monthly report is updated as more complete 2014 PDE data are received from Part D sponsors. The final 2014 Patient Safety Reports will be released in July 2015, one month after the submission deadline for 2014 PDE records to CMS. The final 2014 rates will be used to calculate the 2016 Part D Star Ratings and/or Display Measures.

CMS will also continue producing Patient Safety Reports based on 2013 PDE data through July 2014, when the final 2013 reports will be released. The final 2013 rates will be used to calculate the 2015 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 18, 2014.**

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 2015 Final Call Letter, CMS adopted certain PQA

revisions to its specifications for 2014 and made other changes to the Patient Safety Measures, which are described below.

High Risk Medication (HRM). Beginning with year-of-service (YOS) 2013 reports, the label for the HRM measure that is based on the American Geriatrics Society (AGS) recommendations to the Beers List will be changed from "HRM–2015SR" to "HRM."

Medication Adherence for Diabetes Medications. For both YOS 2013 and 2014 reports, the diabetes medication adherence measure will include adjustments for hospice and skilled nursing facility (SNF) stays. The SNF adjustment will only apply to PDPs because SNF data are not currently available for MA-PD organizations.

Beginning with YOS 2014 reports, a new drug class, sodium glucose co-transporter 2 (SGLT2) inhibitors, will be added to the measure calculations; patients with End-Stage Renal Disease (ESRD) as reported in the Medicare Enrollment Database (EDB) will be excluded from the calculations of this measure; and the overlap adjustment for common generic ingredient will also apply to single ingredients contained in combination products.

Medication Adherence for Cholesterol. For both YOS 2013 and 2014 reports, the cholesterol medication adherence measure will include adjustments for hospice and SNF stays. The SNF adjustment will only apply to PDPs because SNF data are not currently available for MA-PD organizations. Beginning with the YOS 2014 reports, the overlap adjustment for common generic ingredient will also apply to single ingredients contained in combination products.

Medication Adherence for Hypertension. For both YOS 2013 and 2014 reports, the hypertension medication adherence measure will include adjustments for hospice and SNF stays. The SNF adjustment will only apply to PDPs because SNF data are not currently available for MA-PD organizations. Beginning with YOS 2014 reports, patients with ESRD as reported in the EDB will be excluded from the calculations of this measure, and the overlap adjustment for common generic ingredient will also apply to single ingredients contained in combination products.

Medication Adherence for HIV/AIDS. Beginning with YOS 2014 reports, the shifting of days supply will be based on the common generic ingredient name as in the other adherence measures, and the overlap adjustment for common generic ingredient will also apply to single ingredients contained in combination products. YOS 2013 reports will continue to use Generic Code Number (GCN) for purposes of shifting the days supply for both single ingredient and multi-ingredient products.

Diabetes Medication Dosing. For both YOS 2013 and 2014 reports, a minimum age criteria of 18 years of age will apply to this measure.

Diabetes Treatment. Beginning with YOS 2014 reports, a new drug class, sodium glucose co-transporter 2 (SGLT2) inhibitors, will be added to the measure calculations and patients with ESRD as reported in the EDB will be excluded from the calculations of this measure

Obsolete NDCs. Beginning with YOS 2014 reports, we will implement the PQA's 2014 specification change to account for obsolete NDCs. Obsolete NDCs will be included in the measure calculation if the obsolete date is within the measurement period or within six months prior to the beginning of the measurement year.

Removal of Older Patient Safety Reports

As of April 30, 2014, the Patient Safety Analysis Website will no longer display Performance Graphs or Rate Summary pages for 2011 Patient Safety Reports. In addition, the summary contract-level and detail-level 2011 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 2011 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 2011 measures.

April 2014 Overutilization Monitoring Reports

The April OMS reports will be available on April 30, 2014. 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 potential beneficiary overutilization issues identified through the OMS in the current or previous reporting periods. All contracts will receive a summary report including a Sponsor-Identified Potential Overutilization Issue (SPI) Reporting Form.

Overutilization Monitoring System Updates

Incorporation of Sponsor-Identified Potential Overutilization Issues (SPIs) into the OMS. Beginning with the January 2014 OMS submission cycle, sponsors can use the SPI Reporting Form to report beneficiaries with potential opioid overutilization issues identified through the sponsor's internal criteria. Reported SPIs are verified to determine if the submitted data are complete and properly formatted. Verified SPIs will be incorporated into the OMS reports.

Sponsors should respond to all current ticket-issues identified through the OMS using the OMS Response Form. The SPI Reporting Form is not interchangeable with the OMS Response Form and cannot be used to respond to or update the response code for a current OMS ticket-issue. SPIs may close previously reported OMS ticket-issues with prior incomplete responses only if those issues have been resolved in the PDE data. SPIs reported with response codes that identify known exceptions and have never been reported through OMS may be excluded from future OMS reports if identified as potential overutilization issues through the regular OMS process.

Duplicate Responses. Beginning with the April 2014 OMS reports, duplicate responses will be processed as follows:

- If a single SPI Reporting Form contains multiple response codes for the same beneficiary, the beneficiary will not be verified for inclusion in OMS reports. If multiple OMS Response Forms or multiple SPI Reporting Forms are received for a given OMS ticket-issue or SPI, the most recent complete response received for that ticket-issue/SPI at the close of the submission period will be analyzed. An incomplete response uploaded after a complete response will not replace the latest complete response for that ticket-issue/SPI.
- If the sponsor reports different response codes for the same beneficiary and issue type on the OMS Response Form and the SPI Reporting Form, the response code submitted through the OMS will take priority.

Deceased Beneficiaries. Beginning with the April 2014 OMS cycle, beneficiaries with newly identified potential overutilization issues who have a death date observed in the Common Medicare Environment (CME) as of the end of the measurement period will be excluded from reporting. Due to data lags, sponsors may still receive ticket-issues for deceased beneficiaries, and should respond using the BDC response code in these cases.

Terminated Contract IDs. Beginning with the April 2014 OMS cycle, contracts with a termination date observed in HPMS before or as of the reporting month will not receive an Overutilization Monitoring Package.

Part D sponsors may also be interested in a new publication from the Centers for Disease Control and Prevention (CDC), *Recommendations in Opioid Prescribing Guidelines for Chronic Pain,* which is available at CDC.gov (http://www.cdc.gov/HomeandRecreationalSafety/overdose/guidelines.html).

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 2013, 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 2014, 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 2013, 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 2014, 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 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 for new or additional users 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 18, 2014**.

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 PartDMetrics@cms.hhs.gov, and general questions related to the Overutilization Monitoring System should be sent to PartDPolicy@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.