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CENTER FOR MEDICARE

TO: All Part D Sponsors

FROM: Cynthia G. Tudor, Ph.D., Director, Medicare Drug Benefit and C & D Data Group

SUBJECT: Medicare Part D Overutilization Monitoring System

DATE: July 5, 2013

Summary

This memorandum provides information about the new Medicare Part D Overutilization Monitoring System (OMS). The OMS will help CMS to ensure that sponsors have established reasonable and appropriate drug utilization management programs to assist in preventing overutilization of prescribed medications as required 42 C.F.R §423.153 et seq.

Beneficiaries with potential opioid or acetaminophen (APAP) overutilization issues identified through analyses of PDE and beneficiaries referred by the CMS Center for Program Integrity (CPI) due to possible utilization issues will be reported to sponsors on a quarterly basis. Sponsors will be required to respond to CMS within 30 days on the status of the review of each beneficiary case. The first reports will be available on July 31, 2013.

Additional information about the OMS will be presented during a CMS Part C&D User Group call on July 17, 2013.

Background

In the section entitled, "Improving Drug Utilization Review Controls in Part D" of the Final CY 2013 Call Letter issued on April 2, 2012 and in supplemental guidance issued on September 6, 2012, CMS described how Medicare Part D sponsors can comply with drug utilization management (DUM) requirements of 42 C.F.R §423.153 et seq. to prevent overutilization of opioids. The guidance addressed the following expectations for sponsors effective January 1, 2013:

- Appropriate controls at point of sale (POS), including safety edits and quantity limits.
- Improved retrospective drug utilization review (DUR) to identify at-risk beneficiaries.
- Case management with the beneficiaries' prescribers.
- Data-sharing between Part D sponsors when a beneficiary for whom a beneficiary-level claim edit has been implemented move from one Part D plan to another.

The guidance included sample methodology that sponsors could use to identify a narrow target population of beneficiaries who are at high risk due to the nature of their chronic opioid use and for whom focused case management would be appropriate. Sponsors were also reminded that they should prevent the dispensing of more than the FDA daily maximum APAP dose of 4 grams

(http://www.fda.gov/Drugs/DrugSafety/ucm239821.htm) to any beneficiary. A Black Box Warning highlighting the potential for severe liver injury and death is included in the labeling of all prescription drug products that contain acetaminophen.

Black Box Warning
These products contain acetaminophen. Acetaminophen has been associated with cases of acute liver failure, at times resulting in liver transplant and death. Most of the cases of liver injury are associated with the use of acetaminophen at doses that exceed 4,000 milligrams per day, and often involve more than one acetaminophen-containing product.

Through extensive analyses of APAP usage reported in PDE, CMS identified the APAP overutilization threshold described below to select beneficiary cases for initial review through OMS.

Sponsors may implement POS edits to control access to medications containing opioids or APAP either in agreement with the prescribers to assist in managing the patient or when the prescribers are non-responsive to case management to help protect the beneficiary. The guidance also stated that CMS will develop monitoring protocols to ensure sponsors are implementing effective but appropriate controls against opioid overutilization, and that sponsors that establish inappropriate controls may be subject to a compliance action.

Overutilization Monitoring System

CMS has developed the OMS to monitor the performance of Part D sponsors to ensure they are implementing effective and appropriate controls against opioid and APAP overutilization and for review of beneficiaries referred by the CPI for possible utilization issues. The OMS adds new functionality to the Patient Safety Analysis Website. Contract-level reports of beneficiaries with potential overutilization issues will be available quarterly to Part D sponsors, and sponsors will be required to send responses to CMS describing the status of the review of each beneficiary's case. Sponsors will be notified by email when the reports are available for download. The first reports will be available through the Patient Safety Analysis Website at the end of July 2013, with sponsors' responses due within thirty days. Sponsors are reminded that while we are providing reports that identify potential outliers in drug use, sponsors are required to develop their own targeting criteria to identify which beneficiaries should be subject to case management.

Note that the OMS identifies potential outlier drug utilization issues at the beneficiary level, and is not related to the current Patient Safety Outlier Reporting process, which tracks contract-level outliers for Patient Safety Measures. The OMS uses a separate process for reporting and collecting responses to beneficiaries identified with potential drug utilization issues.

Overutilization Issue Types

Beneficiaries with potential overutilization issues will be identified initially using three types of outlier metrics:

1. Opioid outliers: Excluding patients with cancer or receiving hospice care, beneficiaries whose daily morphine equivalent dose ("MED") is greater than 120 mg for at least 90 consecutive days, and who used more than 3 prescribers and more than 3 pharmacies.
2. APAP outliers: Beneficiaries who may be taking more than 4 g of APAP per day for more than 30 days.
3. CPI referral outliers: Beneficiaries referred by the Medicare Center for Program Integrity for review of possible utilization issues. These referrals involve potential fraud or abuse of prescriptions in the Part D program and may include non-opioid cases.

Outliers will be identified based on analysis of Prescription Drug Event (PDE) data with dates of service within the previous two calendar quarters. The first OMS reports in July 2013 will include beneficiary outliers based on PDE data submitted and received by CMS as of June 30, 2013 with dates of service between January 1, 2013 and June 30, 2013. For example, the quarterly report available in October 2013 will be based on PDE data submitted and received as of September 30, 2013 with dates of service between April 1, 2013 and September 30, 2013.

Overutilization Monitoring Reports

Sponsors will have access to Overutilization Monitoring Reports at the contract and beneficiary levels. The OMS summary reports will include contract-level information only. The OMS detail reports will also include beneficiary-level data for each overutilization issue type, as well as closed overutilization issues.

A ticket number will be generated for each beneficiary with potential overutilization issues. A beneficiary may be identified as an outlier for one or more overutilization issue types on a ticket. Sponsors will be required to submit responses to close each beneficiary ticket number and issue type.

Overutilization Issue Response Form

The OMS will include pre-populated contract-level response forms, which will identify each beneficiary ticket and overutilization issue(s), excluding beneficiaries for whom a known exception has been previously identified in the OMS, such as if the utilization was deemed medically necessary or the beneficiary was diagnosed with cancer, or for whom the sponsor has notified CMS that a POS edit has been implemented. After downloading the Overutilization Issue Response Form and comparing the outlier data for each beneficiary on the form with Part D plan records, sponsors will select the appropriate response from a drop-down list of options that describe the status of the sponsor's review for each beneficiary's overutilization issue(s) (e.g., No further review planned: <reason>, Review in progress, POS edit determined necessary, POS edit not determined necessary: <reason>). When the response form is completed, the sponsor will upload the file to the Patient Safety Analysis Website through the secure Upload Files feature.

Additional information will be available on the Patient Safety Analysis Website under Help Documents, including an OMS User Guide and National Drug Code (NDC) medication lists used to identify the opioid and APAP overutilization issues.

Access to the Overutilization Monitoring System

To access the OMS, 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. Currently authorized users of the Patient Safety Analysis Website will be automatically granted comparable access to OMS functionality.

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.*

The Medicare Compliance Officer may choose to keep the same users, modify users, 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.

NOTE: PACE plans are <u>not</u> exempt from the CMS overutilization requirements. Like any Part D plan, each PACE plan will have to investigate and respond concerning outliers identified through the OMS. PACE plans must assign authorized users of the Patient Safety website if they have not already done so.

2. *Access the User Security Website.*

The current Medicare Compliance Officer should already have access to the User Security Website through existing work with Acumen.

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 versions of the Patient Safety and OMS reports with summary information on contract-level rates for each Patient Safety measure and OMS outlier 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 OMS reports, in addition to the summary versions of the Patient Safety and OMS reports. Note that at least one user from each contract must have access to Summary and Confidential Beneficiary Reports to view and respond to beneficiary-level overutilization issues.

To ensure timely access to the OMS, Medicare Compliance Officers must complete all steps of the user authorization process to add new users or modify users' access **by July 16, 2013**. No action is required if a Medicare Compliance Officer wishes to retain current user access levels to the Patient Safety Analysis Website, including the Patient Safety and OMS reports.

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 login password via USPS

Any general questions related to the CMS overutilization management requirements should be sent via email to PartDPolicy@cms.hhs.gov. For questions related to the Medicare Part D Overutilization Monitoring System, send an email with "OMS" in the subject line 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.