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

CENTER FOR MEDICARE

TO: All Part D Sponsors

FROM: Amy Larrick Chavez-Valdez, Director, Medicare Drug Benefit and C & D Data Group

SUBJECT: Medicare Part D Overutilization Monitoring System (OMS) Update: Addition of the Concurrent Opioid-Benzodiazepine Use Flag

DATE: October 21, 2016

The Medicare Part D Overutilization Monitoring System (OMS) was implemented on July 31, 2013 to help CMS ensure that sponsors have established reasonable and appropriate drug utilization management programs to assist in preventing overutilization of prescribed medications as required by 42 C.F.R §423.153 et seq. Additional updates were applied to the OMS in subsequent releases.

The purpose of this memorandum is to announce an update to the OMS for the October 31, 2016 release. A new flag will be added to the OMS reports distributed to Part D sponsors quarterly to identify potential opioid overutilizers who are also receiving benzodiazepines concurrently.

Concurrent Use of Opioids and Benzodiazepines

In the 2017 final Call Letter, CMS expressed its concern over the high concurrent use of opioids and benzodiazepines in Medicare Part D. This concern is further emphasized by the Food and Drug Administration's (FDA) announcement on August 31, 2016 that requires boxed warnings and patient-focused Medication Guides for prescription opioid analgesics, opioid-containing cough products, and benzodiazepines with information about the serious risks associated with using these medications at the same time.[1] These combinations can cause extreme sleepiness and exacerbate respiratory depression, the primary factor in fatal opioid overdose. The risk of opioid-related morbidity and mortality is increased in all patients, even those who do not show signs of aberrant drug behavior. Furthermore, the Centers for Disease Control (CDC) advises clinicians to avoid prescribing opioids and benzodiazepines concurrently whenever possible.[2]

Our analysis of 2015 prescription drug event (PDE) data (as of March 2016) determined that almost 3.1 million beneficiaries were dispensed an opioid medication with at least one day overlap with a benzodiazepine medication, excluding beneficiaries enrolled in hospice or with a cancer diagnosis. This represented 24% of opioid users and 8% of Part D enrollees (non-hospice/non-cancer). A more recent analysis found that 64.9% of OMS identified potential opioid overutilizers in the July 2016 cycle received a benzodiazepine prescription and 99.7% of the use was concurrent.

[1] http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm518697.htm

[2] http://www.cdc.gov/drugoverdose/prescribing/guideline.html.

CMS, in the 2017 final Call Letter, encouraged Part D sponsors to evaluate their claims data and use drug utilization management tools that are available to them as necessary to help address the concurrent use of these drug classes. In an effort to assist Part D sponsors in addressing this issue, CMS is adding a concurrent benzodiazepine use flag to the OMS reports starting with the October 2016 cycle. A field will be added to the beneficiary current opioid overutilization issue report indicating if the beneficiary concurrently received a benzodiazepine (**Y**es/**N**o). In addition, we will add to the contract summary report the total number of beneficiaries with a potential opioid overutilization issue concurrently receiving a benzodiazepine. CMS' expectation is that Part D sponsors will consider benzodiazepine use within their opioid overutilization review process and include this information within their discussions with prescriber(s).

The changes described above will be included in the updated Overutilization Monitoring System User Guide on the Help Documents page of the Patient Safety Analysis Website by October 31, 2016.

For technical questions related to accessing the Patient Safety website, the user authorization process, or downloading or uploading OMS reports, please contact Acumen at PatientSafety@AcumenLLC.com or by phone at (650) 558-8006.

Additional Related Information:

FDA Opioid Action Plan Fact Sheet:
http://www.fda.gov/NewsEvents/Newsroom/FactSheets/ucm484714.htm

Drug Safety Communication:
FDA Drug Safety Communication: FDA warns about serious risks and death when combining opioid pain or cough medicines with benzodiazepines; requires its strongest warning
http://www.fda.gov/Drugs/DrugSafety/ucm518473.htm