Section III – Part D

Improving Drug Utilization Review Controls in Medicare Part D

In this section, we describe the results of sponsors' implementation of improved drug utilization controls to prevent overutilization of medications in Part D, and our additional expectations for further reductions of opioid overutilization in the Medicare Part D program. We appreciate the comments and suggestions submitted by sponsors, patient advocates, and other organizations about the proposals to strengthen the overutilization policy in order to reduce the unsafe overutilization of medications by Part D beneficiaries.

Background

In the Final 2013 Call Letter, published April 2012, and supplemental guidance, published September 2012, CMS described several methods for Part D sponsors to prevent overutilization of prescribed medications.[1] CMS' expectations beginning January 1, 2013 generally were outlined as follows: 1) Sponsors were to improve their safety controls at the point-of-sale (POS), in particular with respect to acetaminophen (APAP), and their formulary utilization management designs; 2) Sponsors were to implement improved retrospective drug utilization review to detect egregious cases of opioid overutilization and apply case management principles to targeted cases in accordance with CMS guidance. After case management, sponsors would implement beneficiary-level POS claim edits if necessary to prevent continued overutilization of opioids. Lastly, sponsors that implemented such POS claim edits would share certain data with a new sponsor when the beneficiary moves to another plan in accordance with applicable law.

Since the general overutilization policy was announced, CMS has taken several steps to make sure that sponsors were implementing it effectively and appropriately, beginning with the launch of the Overutilization Monitoring System (OMS). The OMS provides quarterly reports to sponsors on beneficiaries with potential opioid or APAP overutilization issues identified through analyses of PDE data from the previous 12 months and through CMS program integrity investigations; sponsors should respond to the OMS within 30 days on the status of their review for each beneficiary case. In January 2014, the OMS was enhanced to collect potential opioid overutilization issues and the status of each beneficiary case that was identified through Part D sponsors' own internal criteria and reviewed by the sponsors, but not previously identified by CMS. In February 2014, CMS enhanced the MARx system to accept beneficiary-level opioid POS edit data and to alert sponsors when a newly-enrolled beneficiary was subject to a

[1] An excerpt from the Final 2013 Call Letter, the supplemental guidance and additional information about the OMS are available on the CMS webpage, Improving Drug Utilization Controls in Part D (http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html).

beneficiary-level opioid POS edit in their prior plan.[2] For CY 2015, CMS announced its expectation that sponsors use the 120 mg morphine equivalent dose (MED) and 90 consecutive day threshold as the basis for their internal opioid criteria for improved drug utilization review and case management.[3]

Results

We believe the Part D overutilization policy has played a key role in reducing opioid and APAP overutilization in the program. A comparison of overutilization in 2011, 2013, and 2014 shows a significant reduction of opioid and APAP overutilization in Part D since the overutilization policy went into effect. Although the total number of Part D enrollees and the count of beneficiaries who used opioids increased from 2011 through 2014, the number of potential opioid overutilizers, based on the CMS definition in the OMS, decreased from 29,404 in 2011 to 21,838 in 2014 (see Table 1).

Table 1. OMS Part D Potential Opioid Overutilization Rates, 2011 - 2014 YOS (Comparable OPIOID Methodology)

YOS	Total Part D Enrollees	Total Part D Enrollees Utilizing Opioids	% Part D Enrollees Utilizing Opioids	Total Beneficiaries with at least 90 Consecutive Days >120mg MED Daily AND > 3 Prescribers & > 3 Pharmacies for Opioid Claims	Difference Year-to-Year	Share of Opioid Utilizers Flagged as Outliers
2011*	31,483,841	10,049,914	31.9%	29,404		0.29%
2013†	37,842,632	11,794,908	31.2%	25,347	- 4,057	0.21%
2014‡	39,982,962	12,308,735	30.8%	21,838	- 3,509	0.18%

Table 1 includes partial year inactive contracts, and hospice and cancer patients are excluded from utilizer and potential overutilizer counts. Results slightly differ from prior analyses due to these methodological changes.

*2011 PDE TAP Data (PDEs processed through 7JAN2012). For this comparison, CMS applied the revised 2013 opioid methodology, including the expanded drug list from CDC, and comparable PDE cut-off dates to 2011 data.

†2013 PDE TAP Data (PDEs processed through 4JAN2014)

‡2014 PDE TAP Data (PDEs processed through 3JAN2015)

In addition, from 2011 through 2014, the number of beneficiaries identified as potential APAP overutilizers, based on the CMS definition in the OMS, notably decreased from 76,581 in 2011 to 6,286 in 2014 (see Table 2).

Table 2. OMS Part D Potential APAP Overutilization Rates, 2011 - 2014 YOS (Comparable APAP Methodology)

[2] The Medicare Advantage and Prescription Drug Plan Communications User Guide (PCUG): http://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-technology/mapdhelpdesk/Plan_Communications_User_Guide.html

[3] Sponsors may lower the MED or number of consecutive days threshold and may vary other factors, such as the number of prescribers and pharmacies as described in the CY 2015 Call Letter.

YOS	Total Part D Enrollees	Total Part D Enrollees Utilizing APAP	% Part D Enrollees Utilizing APAP	Total Beneficiaries with daily APAP dose exceeding 4g for 30 or more days within any six-month period with at least one day exceeding 4g within the most recent calendar quarter.	Difference Year-to-Year	Share of APAP Utilizers Flagged as Outliers
2011*	31,483,841	9,449,693	30.0%	76,581		0.81%
2013†	37,842,632	10,591,651	28.0%	26,122	- 50,549	0.25%
2014‡	39,982,962	10,845,499	27.1%	6,286	- 19,836	0.06%

*2011 PDE TAP Data (PDEs processed through 13AUG2012). For this comparison, CMS applied the 2014 OMS APAP methodology, including the 6-month measurement period, which reduced the potential APAP overutilization counts as compared to the prior 2011 analysis

†2013 PDE TAP Data (PDEs processed through 04JAN2014)

‡2014 PDE TAP Data (PDEs processed through 03JAN2015)

Acetaminophen (APAP)

As described in the 2015 Call Letter, sponsors are expected to implement soft formulary-level edits in 2015 to reduce overutilization of APAP. However, we stated that if the soft formulary-level POS edits did not significantly reduce overutilization of APAP, we would consider announcing an expectation that Part D sponsors use hard edits for CY 2016. We are pleased that there has been a significant reduction in APAP overutilization observed through 2014 in the Part D program, as noted above. Therefore, CMS is not expecting sponsors to implement hard APAP formulary edits in CY 2016, but we still encourage sponsors to implement hard APAP formulary edits to prevent doses at egregious levels for which there would be no reasonable medical or dispensing explanation.[4]

Opioids

Although the use of improved drug utilization review, case management, and beneficiary-level POS edits have reduced overutilization of opioids in the Part D program, CMS believes that Part D sponsors should take additional steps to further reduce opioid overutilization, and suggested that sponsors implement a soft, formulary-level POS edit based on cumulative daily MED. CMS recommended potential specifications for the POS edit, including options for the MED and number of prescribers thresholds, and methods to minimize false positives to reduce the impact on beneficiaries at POS.

Although several commenters supported the proposed soft opioid POS edit, few offered recommendations on the edit specifications, and many raised concerns such as difficulties

[4] More information about soft and hard rejects and edits is available from the National Council for Prescription Drug Programs: "Telecommunication Version D and Above Questions, Answers and Editorial Updates," *NCPDP*, February 2014, http://www.ncpdp.org/NCPDP/media/pdf/VersionD-Editorial.pdf (accessed 1/22/2015).

developing the edit as specified in time for the formulary submission and implementing it by CY 2016, as well as the potential impact on beneficiaries at the pharmacy. We will delay specifying the parameters for the POS edit until additional testing can be completed, but we continue to encourage sponsors to implement a soft, formulary-level cumulative MED POS edit and build the capacity for a more sophisticated POS edit in preparation for CY 2017. Sponsors who are interested in pilot testing the soft formulary-level POS edit should send an email to the new Part D Overutilization Management mailbox (PartD_OM@cms.hhs.gov).

Revisions to the Overutilization Monitoring System Methodology

The OMS has proven to be a valuable tool to make certain that sponsors have established reasonable and appropriate drug utilization management programs to monitor beneficiaries who are at-risk for adverse events due to potential overutilization of opioids and APAP as described above. With input from Part D sponsors and other stakeholders, CMS has revised the OMS and related systems (e.g., MARx). In the draft version of this Call Letter, CMS described potential enhancements to the OMS, including two new metrics and four new measures:

- Opioid Daily Dose rate: # opioid days > 120mg MED/1000 Opioid utilization days
- APAP Daily Dose rate: # APAP days > 4g/1000 APAP utilization days
- High-dose opioids in opioid naïve patients
- More than 90mg cumulative MED daily of short-acting opioids for greater than 90 consecutive days
- Concurrent buprenorphine and opioid use for more than 90 consecutive days
- Concurrent opioid and other CNS depressant use from multiple prescribers

Several entities submitted comments and questions about the proposed rates and measures, including what action CMS expected from sponsors in response to the new rates, requests for more details of the measure specifications, and suggestions for measure specifications. While there was support for the two concurrent opioid use measures as useful indicators of potentially unsafe practices, some commenters recommended a measure based on the concurrent use of benzodiazepines, opioids and skeletal muscle relaxants rather than concurrent use of opioids and CNS depressants. Therefore, for CY 2016, the new Opioid and APAP Daily Dose rates will be added to the OMS for informational purposes only. CMS will also investigate the concurrent use of buprenorphine and opioids in Part D as a potential new measure for the OMS for CY 2016.

See additional discussion regarding opioid overutilization measures in Enhancements to the 2016 Star Ratings and Beyond, Potential new measures, Opioid Overutilization section of the Call Letter.

Improved Drug Utilization Controls for Other Drug Classes

Now that sponsors have more experience in implementing the overutilization policy, and CMS has more experience in overseeing compliance with the policy, we solicited feedback on expanding the Part D overutilization policy to other drugs or classes of drugs. The comments submitted were mixed concerning expansion of the Part D overutilization policy to other drugs or classes of drugs. A few commenters offered suggestions regarding other drugs and classes, such as the concomitant use of opioids, benzodiazepines, and muscle relaxants, which we will investigate or pilot test for future expansion of the policy. For CY 2016, we will not expand our overutilization policy beyond the opioid class. We note that current CMS guidance is that sponsors may adapt Part D overutilization policy to non-opioid medications, including HIV drugs, as long as they use the same level of diligence and documentation that CMS expects with respect to opioids, including written notice to the beneficiary when implementing POS claim edits.

Research, Guidelines, and Training Materials

CMS encourages Part D sponsors and members of their P&T committees to keep abreast of current research, guidelines, and training materials related to the appropriate use of opioids, such as the following information:

- *Common Elements in Guidelines for Prescribing Opioids for Chronic Pain*, published by the Centers for Disease Control and Prevention (CDC) at CDC.gov (http://www.cdc.gov/HomeandRecreationalSafety/overdose/guidelines.html)
- *The Effectiveness and Risks of Long-Term Opioid Treatment of Chronic Pain*, Publication No. 14-E005-EF, September 2014, published by the Agency for Healthcare Research and Quality (AHRQ) at AHRQ.gov (http://www.ahrq.gov/research/findings/evidence-based-reports/opoidstp.html)
- *Opioids for chronic noncancer pain*, A position paper of the American Academy of Neurology, published in the September 30, 2014 issue of the journal *Neurology*, and available at AAN.com (https://www.aan.com/uploadedFiles/Website_Library_Assets/Documents/6.Public_Policy/1.Stay_Informed/2.Position_Statements/3.PDFs_of_all_Position_Statements/Position%20and%20Policy%20Documents.pdf)
- *NIDAMED: Medical & Health Professionals* provides tools, resources, continuing education and training for medical and health professions through the website of the National Institute on Drug Abuse (http://www.drugabuse.gov/nidamed-medical-health-professionals)