Analysis of Proposed Opioid Overutilization Criteria Modifications in Medicare Part D

Updated April 28, 2017[1]

Background

The Centers for Disease Control and Prevention (CDC) report that the U.S. prevalence of people experiencing chronic pain (lasting more than 3 months) is substantial and estimated at 11.2% of the adult population. Use of opioids to treat chronic pain should be based on a careful consideration of the benefits and risks of opioid use. Evidence supports short-term efficacy of opioids in randomized clinical trials lasting primarily 12 weeks or less but few studies have assessed the long-term benefits of opioids for chronic pain. The consequences of unrestrained opioid prescribing includes the risk of addiction, overdose and death. Opioid abuse remains a serious public health issue. Since 1999, the amount of prescription opioids sold in the U.S. nearly quadrupled, as did deaths from prescription opioids.[2,3] From 2000 to 2014 nearly half a million people died from drug overdoses and at least half of all opioid overdose deaths involved a prescription opioid.[4]

In 2013, CMS implemented a medication safety approach by which sponsors are expected to target and address egregious overutilization of opioids and maintain access to needed medications. Sponsors are expected to implement appropriate plan-level claim controls at point-of-sale (POS) for opioids, use improved retrospective drug utilization review to identify beneficiaries at high risk for an adverse event due to opioids, and perform case management with the identified beneficiaries' prescribers followed by beneficiary-specific POS edits to prevent Part D coverage of opioid overutilization, if necessary. In July 2013, CMS launched the Overutilization Monitoring System (OMS) to oversee sponsors' compliance with CMS guidance to address opioid overutilization.

CMS developed a comprehensive morphine equivalent dose (MED) approach to assist Part D sponsors in identifying high risk beneficiaries. Currently, the U.S. Food and Drug Administration (FDA) does not report a maximum opioid daily dose. Our approach was based on a promising method used in Washington State, and updated with the opioid product list and MED conversion factors maintained by the CDC. This cumulative MED approach to identify high risk use of opioids is now being widely adopted outside of Part D. Through the OMS, CMS reports quarterly to Part D contracts their members who may potentially be overutilizing opioids based on the following criteria:

> Use of opioids with cumulative daily MED exceeding 120 mg for at least 90 consecutive days with more than 3 prescribers and more than 3 pharmacies contributing to their opioid claims, during the most recent 12 months, excluding beneficiaries with cancer diagnoses and beneficiaries in hospice.

For each beneficiary identified in the OMS, Part D contracts provide an evaluation response to CMS with the result of their case review.

As reported in the 2017 Call Letter[5], Part D sponsors have significantly reduced the overutilization of opioids. From 2011 through 2015, there was a 47% decrease or 13,753 fewer Part D beneficiaries identified as potential opioid overutilizers. This represents a 57% decrease in the share of beneficiaries using opioids who are identified as potential opioid overutilizers (see Table 1).

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[1] The April 28, 2017 version updates the original report which was published on February 1, 2017 in conjunction with the draft 2018 Call Letter. This report corrects errors in the number of potential opioid overutilizers identified in Tables 6 through 8.

[2] Centers for Disease Control and Prevention. Morbidity and Mortality Weekly Report. Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6043a4.htm?s_cid=mm6043a4_w#fig2. Accessed August 17, 2015.

[3] CDC. Wide-ranging online data for epidemiologic research (WONDER). Atlanta, GA: CDC, National Center for Health Statistics; 2016. Available at http://wonder.cdc.gov

[4] Centers for Disease Control and Prevention. Increases in Drug and Opioid Overdose Deaths — United States, 2000–2014. MMWR 2015; 64;1-5.

[5] 2017 Call Letter. April 4, 2016. https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2017.pdf.

Table 1. OMS Part D Potential Opioid Overutilization Rates, 2011 – 2015*

Year	Total Part D Enrollees	Total Part D Enrollees Utilizing Opioids	% Part D Enrollees Utilizing Opioids	Total Beneficiaries with at Least 90 Consecutive Days >120 mg MED Daily AND > 3 Prescribers & > 3 Pharmacies for Opioid Claims	Difference Year-to-Year	Share of Opioid Utilizers Flagged as Outliers	Difference in Share Year-to-Year
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%	−0.08%
2014	39,982,962	12,308,735	30.8%	21,838	− 3,509	0.18%	−0.04%
2015	41,835,016	12,510,448	29.9%	**15,651**	− 6,187	0.13%	−0.05%

47% decrease

57% decrease

*Table 1 includes partial year inactive contracts, and hospice and cancer patients are excluded from utilizer and potential overutilizer counts. For these opioid utilization comparisons, CMS used OMS methodology and prescription drug event (PDE) TAP Data processed with cut-off dates in the early January of the following year.

Opioid Overutilization Criteria

CMS' implementation of the OMS has led to significant reductions in the overuse of opioids in the Part D program. However, since implementation, we have also identified opportunities to improve the criteria used to identify beneficiaries who are at risk due to high use of opioids for whom focused case management may be appropriate.

In 2015, CMS performed outreach to assess Part D sponsors' compliance with CMS guidance and the appropriateness of their review processes. This effort included discussions with several Part D parent organizations (N=8) who were identified as outliers based on their evaluation responses to the potential opioid overutilizer cases reported to them within the OMS. For instance, several sponsors had high response rates for the response 'beneficiary did not meet internal criteria' and/or repeated use of the response 'overutilization resolved' for the same beneficiary.

Through our discussions, we found that sponsors were generally compliant with CMS guidelines, and we also identified methods used by the Part D sponsors to improve the utility of the OMS opioid overutilization criteria (i.e., reduce false positives). The compliant sponsors' internal criteria usually included a shorter measurement period, measured overuse more frequently (monthly), and averaged the MED milligram (mg) calculation across all opioid prescriptions. Some sponsors were also able to group chain pharmacies or group prescribers within the same practice as a single provider. We also learned that sponsors excluded beneficiaries whose drug regimen was consistent and showed no evidence of early refills.

In March 2016, the CDC published a guideline[6] for opioid prescribing to assist primary care providers in delivering safer, more effective chronic pain management for patients with pain outside of active cancer treatment, palliative care, and end-of-life care. In the guideline, CDC identifies 50 mg morphine milligram equivalents (MME)[7] daily dose as a threshold for increased risk of opioid overdose, and generally suggests avoiding increasing the dosage to 90 mg MME per day.

Based on our experience from compliance activities, additional analyses, and the CDC guideline, we announced in the 2017 Call Letter our plans to investigate potential modification of the criteria for implementation in 2018.

[6] CDC Guideline for Prescribing Opioids for Chronic Pain, http://www.cdc.gov/drugoverdose/prescribing/guideline.html

[7] Note: CDC's terminology, morphine milligram equivalents (MME), is equal to morphine equivalent dose (MED) in milligrams as used by CMS. Often calculated as a daily dose.

In this analysis, we assessed the following modifications to the OMS opioid overutilization criteria:

Modification	Rationale
Shorten the measurement period from 12 months to 6 months	A shortened measurement period better identifies current potential overutilizers, reduces the number of repeat cases reported by the OMS, and reduces the number of false positives.
Use average MED rather than a count of 90 consecutive days of high MED	By allowing gaps between prescription fills and days' supply in the calculation, the average MED methodology improves identification of beneficiaries who are chronic users of high opioid doses compared to evaluating consecutive days, and reduces false positives.
Lower the MED mg threshold (90 mg or 50 mg)	A lower MED threshold aligns with the CDC guideline (amount generally suggested to avoid increasing above) and may capture additional beneficiaries with egregious patterns of potential overutilization who may need additional monitoring or case management.
Group providers, such as physicians, within the same practice	Grouping providers reduces false positives by eliminating beneficiaries managed in the group practice setting.

Policy Goals

In modifying the criteria, we seek to:

- Improve the identification of inappropriate opioid use (i.e., reduce "false positives" related to overutilization that resolved recently and to better identify the most egregious cases of overuse),
- Align with the CDC guideline on opioid prescribing, and
- Define a target population for which the caseload would be manageable for Part D sponsors.

Methodology

Contract year 2015 Part D prescription drug event (PDE) data as of June 4, 2016 were used to study potential modifications to the opioid overutilization criteria. We continued to exclude beneficiaries in hospice or beneficiaries with a cancer diagnosis in 2015 as identified in the Risk Adjustment Processing System (RAPS) file. Beneficiaries who subsequently died remain in the counts. The potential criteria changes were applied to each measurement period to estimate the impact on the number of beneficiaries who would be identified in each scenario.

To estimate the number of beneficiaries who would be identified and reported to sponsors, we applied the criteria modifications using 3 overlapping six-month measurement periods to align with the OMS quarterly reporting cycles (1/1 - 6/30, 4/1 - 9/30, and 7/1-12/31). We also report the total number of unique beneficiaries (based on a unique count of health insurance claim numbers (HICNs)) identified in 2015 from all 3 measurements periods. For example, a beneficiary that met the overutilization criteria in multiple six-month measurement periods is counted only once in the 2015 total. Reporting the number of unique overutilizers identified across all 3 periods provides an estimate of the expected total opioid overutilizers within 2015 for comparison with the current OMS criteria's one-year measurement period.

The consecutive criterion is defined as 90 or more days of opioid utilization meeting the MED threshold without any gaps in opioid days. Average MED is defined as the summation of total MED taken during the measurement period divided by the number of days between the first and last day of the opioid episode. An opioid episode is the number of days between the first opioid claim's date of service (DOS) and the last opioid claim's DOS plus the day supply of the last opioid claim within the measurement period. If the days supply extends the episode past the measurement period, the episode length is truncated to the measurement period end date.

Findings

Criteria Modifications: Six-month measurement periods and varying MED (mg) thresholds
Fixed Criteria: 90+ Consecutive MED days and greater than 3 prescribers and 3 pharmacies contributing to opioid claims

Table 2 illustrates the impact of shortening the measurement period to 6 months and modifying the MED threshold to 50 mg or more and 90 mg or more compared to the current MED threshold of greater than 120 mg. The consecutive MED day methodology and count of prescribers and pharmacies is consistent with the current OMS criteria. The provider count is set at greater than 3 prescribers and greater than 3 pharmacies contributing to the opioid claims within each six-month cycle.

Table 2. Comparison of Potential Opioid Overutilizer Counts by Varying MED Thresholds Using the Consecutive MED Methodology, 90+ Days Episode Length, and Six-month Cycles, CY 2015

> 3 Opioid Prescribers and >3 Pharmacies	Opioid Episode Length (Days)	MED Dosage (mg)	Opioid Overutilizer Count (1/1 - 6/30)	Opioid Overutilizer Count (4/1 - 9/30)	Opioid Overutilizer Count (7/1-12/31)	Unique Opioid Overutilizer Count (2015)
Yes	**90+**	**>120**	**2,578**	**3,533**	**3,138**	**7,265**
Yes	90+	>=90	4,329	5,853	5,426	12,085
Yes	90+	>=50	7,027	9,259	8,822	19,365

Changing the measurement period to six months but maintaining the current OMS criteria (>3 prescribers and pharmacies, 90+ days opioid episode length, >120 mg MED) results in 7,265 uniquely identified potential opioid overutilizers for 2015, compared to 15,651 beneficiaries targeted in 2015 using the 12-month look back period (Table 1). Overall, by shortening the measurement period from 12 months to 6 months, the analysis shows that the number of beneficiaries identified as potential overutilizers is decreased by more than a half. To understand the criterion that is most affected by shortening the measurement period, we selected a sample of 9 beneficiaries who met the opioid overutilization criteria using the 12-month measurement period in 2015 and then applied the same criteria to the last 6 months of 2015 (7/1-12/31). None of the 9 beneficiaries who met the criteria during the 12-month measurement period met the criteria in last six-months. One-third did not meet the high pharmacy and prescriber criterion, one-third did not meet the high-dose criterion, and one-third did not meet the overall overutilization criteria. Shortening the measurement period improved specificity by eliminating beneficiaries who are not currently overutilizing opioids.

Table 2 also shows the number of beneficiaries meeting the criteria and MED threshold in each six-month period and illustrates how the count fluctuates as new beneficiaries enroll into Part D, current beneficiaries disenroll from Part D (i.e., due to lapses in Part D premium payments, death, etc.), and fill patterns change. Overall, the highest overutilizer counts were identified during 4/1/2015 to 9/30/2015 cycle regardless of the MED threshold. Also, as expected, lowering the MED threshold to 90 mg MED (the CDC guideline recommended maximum dose) increases the total overutilizer count for 2015 to 12,085 beneficiaries and to 19,365 beneficiaries for 50 mg MED compared to 120 mg MED threshold.

Criteria Modifications: Six-month measurement periods, using average MED calculation, varying MED (mg) thresholds and opioid episode length (90+ days versus < 90 days)
Fixed Criteria: Greater than 3 prescribers and 3 pharmacies contributing to opioid claims

In Table 3 we examine the impact of the six-month measurement periods along with the average MED calculation (rather than consecutive days) across all opioid claims, varying the length of the opioid episode (90 plus or less than 90 days) and the MED mg threshold. The number of providers remains consistent with the current OMS criteria (greater than 3 prescribers and 3 pharmacies). The beneficiary counts are reported for each six-month cycle and the total unique number for 2015.

Table 3. Comparison of Potential Opioid Overutilizer Counts Using Average MED by Varying MED Thresholds and Episode Lengths, Six-month Cycles, CY 2015

> 3 Opioid Prescribers and >3 Pharmacies	Opioid Episode Length (Days)	Average MED (mg)	Opioid Overutilizer Count (1/1 - 6/30)	Opioid Overutilizer Count (4/1 - 9/30)	Opioid Overutilizer Count (7/1-12/31)	Unique Opioid Overutilizer Count (2015)
Yes	**90+**	**>120**	**6,520**	**7,974**	**7,482**	**15,862**
Yes	90+	>=90	9,128	11,224	10,544	22,129
Yes	90+	>=50	16,821	20,343	19,413	40,062
Yes	<90	>120	57	43	64	157
Yes	<90	>=90	104	75	93	259
Yes	<90	>=50	320	266	288	808

A minimum episode length of 90 days and a MED greater than 120 mg results in six-month potential opioid overutilizer counts from 6,520 to 7,974. Calculating the MED using the average methodology across the entire opioid episode only slightly increased the beneficiary count from 15,651 (Table 1) to 15,862, an additional 211 beneficiaries. This suggests that only a few 120 mg MED users have gaps in their daily dose below the threshold. On the other hand, the consecutive day MED approach missed some beneficiaries whose average daily dose was high. Therefore using the average MED methodology should increase the measure's sensitivity for identifying high MED use.

Reducing the MED threshold to 90+ mg results in potential overutilizer counts ranging from 9,128 to 11,224 and reducing to 50+ mg from 16,821 to 20,343 beneficiaries for the 3 six-month cycles. As the MED threshold is lowered from 120 mg to 90 mg and 50 mg, the total unique beneficiary count for 2015 increases from 15,682 to 22,129 and 40,062, respectively. Changing the measurement period to 6 months and using the MED average calculation should better identify both current and chronic opioid overutilization. Using either the 120 mg or 90 mg MED threshold would maintain a similar case load, while using the 50 mg threshold would almost double it.

Interestingly, the number of additional overutilizers with an episode length less than 90 days for any of the MED dose thresholds analyzed ranges from only 57 to 320 beneficiaries, or 1% to 2% of the 90+ day episode opioid overutilizer count. This shows that some overutilizers reach the opioid MED and provider thresholds earlier suggesting a possible harmful opioid dose escalation within a shorter time. Although a portion of these beneficiaries may be newly enrolled into Medicare and therefore their prior opioid dose is unknown, the expectation is that the high use will continue and that sponsors should be monitoring their opioid use. In either instance, utilization patterns for these beneficiaries is disconcerting. Therefore, we suggest including these beneficiaries as potential opioid overutilizers.

Table 4 reports the unique count of potential opioid overutilizer identified in 2015 using the current opioid overutilization criteria and various combinations of the proposed modifications, while consistently maintaining the criteria of greater than 3 opioid prescribers and opioid dispensing pharmacies.

Table 4. Comparisons of Total Beneficiaries Identified as Overutilizers for the Current OMS Opioid Overutilizer Criteria and Proposed Modifications, CY 2015

MED Calculation	MED Threshold (mg)	> 3 Opioid Prescribers and >3 Pharmacies	Opioid Episode Length[8]	Measurement Period	Total Beneficiaries Identified as Overutilizers	% of Opioid Utilizers Flagged as Outliers*
Current OMS Criteria (Consecutive)	**>120**	**Y**	**90+**	**1-year**	**15,651**	**0.13%**
Consecutive	>120	Y	90+	6-month	7,265	0.06%
Average	>120	Y	All	6-month	16,019	0.13%
Consecutive	>=90	Y	90+	6-month	12,085	0.10%
Average	>=90	Y	All	6-month	22,388	0.18%
Consecutive	>=50	Y	90+	6-month	19,365	0.15%
Average	>=50	Y	All	6-month	40,870	0.33%

*The denominator is 12,510,448 (Table 1), the number of opioid users in 2015.

When the current OMS criteria were applied using 3 six-month look back periods versus a one-year measurement period, the total potential opioid overutilizer count for all of 2015 decreased by half (15,651 to 7,265). Using six-month measurement periods and the average 120 mg MED calculation (rather than a consecutive MED calculation), on the other hand, only slightly increased the total overutilizer count to 16,019 regardless of the episode length. Although the consecutive MED would result in a lower caseload regardless of the MED thresholds, we believe that the average MED methodology will improve the sensitivity of the measure since gaps in a person's opioid use that still averages above the MED threshold will be identified. As would be expected, lowering the MED threshold increases the potential opioid overutilizer counts regardless of the MED calculation method.

Following peer review of the findings, we concluded that aligning the MED dose threshold with the CDC guideline's maximum opioid dose (90 mg), using the average MED methodology, and not limiting the opioid episode length within six-month measurement periods had the maximum face validity. Therefore, the remaining analyses are limited to beneficiaries with an average MED of 90 mg or more for any opioid episode length within a six-month measurement period. These potential opioid overutilizers are referred to as Opioid High Dose (Opioid-HD) users in the remainder of the paper.

Criteria Modifications: Number of pharmacy and prescribers contributing to opioid claims
Fixed Criteria: Six-month measurement periods, average MED 90 mg threshold and all opioid episode lengths

Table 5 examines the impact of the opioid pharmacy provider count on the distribution of unique opioid prescribers among Opioid-HD users. Distributions were calculated for all 3 six-month measurement periods within 2015 with similar results. Therefore, we only report the prescriber count distribution within the 7/2015 to 12/2015 measurement period (Table 5).

[8] An episode length of '90+' means a minimum of 90 consecutive days of opioid use without gaps in use. Episode lengths of 'ALL' mean no restrictions are placed on the length of the opioid episode.

Table 5. Opioid-HD Users' Prescriber Count Distribution by Pharmacy Count, 7/2015 - 12/2015

Pharmacy Count	Opioid-HD Users		Prescriber Mean	High Dose User Prescriber Count Distribution, Percentiles					
	#	%		25	50	75	90	99	Max
Total	727,016								
1	469,350	64.6%	1.60	1	1	2	3	5	14
2	161,683	22.2%	2.05	1	2	3	4	6	16
3	60,298	8.3%	2.36	1	2	3	4	7	14
4+	35,685	4.9%	2.97	1	2	4	6	10	31

A total of 727,016 Part D beneficiaries were identified as Opioid-HD users during the six-month cycle. The majority of beneficiaries (64.6%) received opioids from a single pharmacy. Among the Opioid-HD users, as the number of pharmacies increased so did the mean number of opioid prescribers from 1.60 to 2.97. Fifty percent of the Opioid-HD users, regardless of the pharmacy count, only had one or two opioid prescribers. At the 75% percentile or within the top 25% of Opioid-HD users, the number of prescribers begins to separate as the number of pharmacies increases. This divergence is the most prominent at the 99th percentile where 1% of Opioid-HD users, regardless of the number of pharmacies, received opioids from a minimum of 5 prescribers with a maximum of 31 prescribers associated with 4 or more pharmacies and a maximum of 14-16 prescribers among 1 to 3 pharmacy providers. Consequently, requiring a pharmacy threshold may result in the exclusion of Opioid-HD users who receive opioid prescriptions from an aberrantly high number of prescribers.

Criteria Modifications: Number of pharmacies contributing to opioid claims
Fixed Criteria: Six-month measurement periods, average MED 90 mg threshold, all opioid episode lengths and more than 3 prescribers of opioids, annual unique beneficiary count

Table 6 examines the impact of lowering the number of opioid dispensing pharmacies on the number of Opioid-HD Users when the prescriber count is maintained at greater than 3.

Table 6. Opioid-HD Users with Greater than 3 Opioid Prescribers by Minimum Opioid Pharmacy Counts, CY 2015

Minimum Opioid Pharmacy Count	Opioid-HD Users w/ >3 Opioid Prescribers Count	Increase Over Standard Percent
4 or more (Standard)	**22,280**	
3 or more	43,147	93.7%
2 or more	75,786	240.2%
1 or more	113,247	408.3%

Reducing the minimum count of opioid dispensing pharmacies results in significant increases in the total number of potential opioid overutilizers. The number of overutilizers almost doubles from 22,280 to 43,147 when the minimum pharmacy count is reduced to 3 or more. Further reductions in the minimum pharmacy count to two or more and one or more than triples (N=75,786) and quadruples (N=113,247), the number of overutilizers from the standard 4 or more pharmacy count, respectively. CMS expects that a pharmacy count criterion of less than 4 pharmacies associated with the criterion of less than 4 prescribers would also result in too many potential overutilizers for case management review and a significant burden on Part D plans. We will seek input from stakeholders to inform additional changes to the pharmacy counts.

During CMS' outreach with Part D sponsors, several sponsors noted that some prescribers were within the same practice and therefore, the sponsor counted the practice as a single prescriber. To address this issue we investigated methods to group prescribers within the same practice. CMS maintains the Provider Enrollment, Chain and Ownership System (PECOS) that includes physicians, non-physician practitioners and provider and supplier organization's Medicare

enrollment information. The PECOS data include a group or an individual provider organizational Tax ID Number (TIN), which identifies a business with the IRS, and their National Provider Identifier (NPI), which identifies a business or provider within the health care system, along with other information. The NPI is unique to a prescriber and is required to be submitted on every Part D claim. Prescribers that work within the same practice should have the same TIN; therefore, we grouped NPIs in PECOS that had the exact same single TIN and counted the group as one provider.

Table 7 compares the count of beneficiaries identified as Opioid-HD users with greater than 3 prescribers by either the unique NPI, or TIN grouping within PECOS.

Table 7. Opioid-HD Users with Greater than 3 Opioid Prescribers Identified Using either NPI or PECOS TIN by the Minimum Opioid Pharmacy Counts, CY 2015

Minimum Opioid Pharmacy Count	Opioid-HD Users with >3 Prescribers Count		Percent Change: NPI versus TIN Method
	NPI	TIN	
4 or more	**22,280**	21,443	-3.8%
3 or more	43,147	41,042	-4.9%
2 or more	75,786	71,269	-6.0%
1 or more	113,247	105,332	-7.0%

Using the TIN reduced the number of Opioid-HD users identified by 3.8% to 7.0% compared to using unique NPIs depending on the pharmacy counts. On the other hand, the TIN grouping did not markedly shift the number of potential opioid overutilizers associated with higher pharmacy counts, therefore, CMS suggests that the pharmacy and prescriber count criteria should remain at greater than 3 within a six-month measurement period with the 90 mg MED threshold regardless of the opioid episode length. Although the TIN methodology reduces the number of Opioid-HD users by a small percent, CMS believes grouping prescribers with the same TIN as a single prescriber will improve the utility of the criteria to identify of opioid overutilizers.

CMS, however, was still concerned with the number of Opioid-HD users with multiple prescribers who were excluded by the greater-than-three pharmacy requirement. Table 8 evaluates the total count of beneficiaries in 2015 meeting the modified opioid overutilization criteria including Opioid-HD users with 5 or more opioid prescribers and fewer than 4 opioid pharmacy providers.

Table 8. Modified Potential Opioid Overutilizers or High Number of Opioid Prescriber Beneficiary Counts, CY 2015

Six-month Measurement Periods, Average MED >=90 mg and Any Opioid Episode Length	Potential Opioid Overutilizers (2015)		Part D Enrollees Flagged as Outliers	Part D Opioid Utilizers Flagged as Outliers
	TIN		N = 41,835,016	N = 12,510,448
Provider Overuse Definitions	Count	Additional Count above Standard	Percent	Percent
Standard*	**21,443**		0.05%	0.17%
Standard* or only 5+ Prescribers	52,998	+31,555	0.13%	0.42%
Standard* or only 6+ Prescribers	33,059	+11,616	0.08%	0.26%
Standard* or only 7+ Prescribers	25,729	+4,286	0.06%	0.21%
Standard* or only 8+ Prescribers	23,096	+1,653	0.06%	0.18%
Standard* or only 9+ Prescribers	22,101	+658	0.05%	0.18%

*Standard =Four or more opioid pharmacies and four or more opioid prescribers

Adding potential opioid overutilizers with 5 or more opioid prescribers (Standard or only 5+ row in Table 8) regardless of the number of opioid dispensing pharmacies to the standard criteria (greater than 3 opioid prescribers and pharmacies) more than doubles the beneficiary count from 21,443 to 52,998, a 31,555 person increase. On the other hand, adding potential opioid overutilizers with 6 or more opioid prescribers regardless of the number of opioid dispensing pharmacies to the standard criteria increases the beneficiary count to 33,059, an 11,616 person increase. The percentage of Part D beneficiaries identified as potential opioid overutilizers increases from 0.05% to 0.08%. Less than 4,300 and 1,700 beneficiaries are added if the opioid prescriber count is increased to 7 or more and 8 or more, respectively. The number of beneficiaries added decreases to less than 700 when the prescriber count increases above eight. We recommend including beneficiaries who received opioids from 6 or more prescribers in the opioid overutilization criteria. CMS believes that multiple opioid prescribers can lead to adverse events and will periodically re-evaluate this proposed threshold.

Number of Unique Opioids (opioid and dosage form excluding strength)

CMS also examined the relationship between the number of unique opioids and the number of prescribers among the Opioid-HD users as a proxy for a consistent regimen. A unique opioid was defined at Medispan's™ GPI 12 that groups National Drug Codes (NDCs) at the unique opioid and dosage form excluding strength. The same opioid with different strengths was grouped to exclude instances when a beneficiary was taking different strengths of the same opioid in the morning and evening or to meet a particular dose that is not commercially available. A high number of GPIs would suggest an inconsistent opioid regimen. Eighty-three percent of potential opioid overutilizers with one to 3 opioid prescribers, using unique NPIs, received only one or two unique opioids. When the number of prescribers increased to 4 or 5 prescribers only 53% and 37% Opioid-HD users received one or two opioids, respectively (data not shown). This suggests that Opioid-HD users with 4 or more opioid prescribers are more likely to receive multiple opioids placing the beneficiary at a higher risk for medication mismanagement that may result in overdose. In addition, multiple prescribed opioids can result in unused medications that may contribute to drug diversion. Although we did not assess if the multiple opioids were concurrent or consecutive, the prescribing of multiple opioids within a short period of time should prompt at least a cursory review.

Summary

Beginning in 2013, CMS implemented an opioid overutilization policy and established criteria to assist Part D sponsors to effectively target and address egregious overuse of opioids. CMS oversees sponsors' compliance with the guidance through the OMS which allows sponsors to provide feedback to CMS on beneficiaries meeting the opioid overutilization criteria. Evidence suggested that modifications to the OMS criteria were necessary to improve the utility of the criteria to identify potential opioid overutilizers. In early 2016, the CDC published opioid use guidelines for the treatment of chronic pain. Consequently, CMS decided it was necessary to revisit the opioid overutilization criteria ahead of the 2018 Call Letter.

We investigated modifying the measurement period, the MED calculation methodology and daily dose threshold, and the opioid episode length along with assessing the relationship between the number of opioid dispensing pharmacies and opioid prescribers. Reducing the measurement period to 6 months, lowering the MED threshold to 90 mg, and using an average MED calculation, while maintaining the number of provider counts to greater than 3 opioid pharmacies and 3 prescribers, resulted in improving the utility of the criteria to identify a reasonable number of potential opioid overutilizers (N=22,280) for inclusion in a Part D sponsor's enhanced drug utilization review (DUR) program to reduce overutilization.

Examination of lowering the opioid pharmacy count minimum below 4 revealed a small percentage but important group of Opioid-HD users who received opioids from between 5 and 16 prescribers. Multiple prescribers may suggest drug-seeking behavior and/or poor pain management that places a patient at risk for an adverse event. This is supported by

Baumblatt et al. who found both an increased risk of opioid-related overdose death associated with 4 or more prescribers, as well as, 4 or more pharmacies.[9] Based on the number of beneficiaries that would be added to sponsors' enhanced DUR program with a prescriber only criteria we believe that including beneficiaries who received opioids from 6 or more prescribers regardless of the number of opioid dispensing pharmacies is reasonable and should assist in identifying beneficiaries at risk for an adverse event. Additional analysis also found that beneficiaries who saw more than 4 prescribers were more likely to receive multiple (greater than two) opioids, which may also suggest risky behavior and/or lack of drug monitoring.

Counting the number of unique NPIs is a common method for identifying the number of prescribers for a beneficiary when using prescription claims data. During our outreach, sponsors often reported that a beneficiary was not identified as a potential overutilizer due to the prescribers being within the same practice. To address this circumstance we examined the use of the PECOS and TIN to group prescribers within the same practice. The TIN method reduced the number of potential overutilizers by 3.8% for beneficiaries with 4 or more prescribers and pharmacies and appears to be a useful methodology to address this issue. If implemented, we will continue to monitor sponsors' responses to the OMS and state our expectations that reporting 'beneficiary did not meet internal criteria' should be reduced.

Overall, including prescriber and/or pharmacy count criteria to identify beneficiaries at the highest risk for an opioid related adverse event is common. However, evidence suggest that MEDs exceeding 90 mg even from a single prescriber and pharmacy can increase an individual's risk for an adverse event without any additional pain-relief benefit and/or improved functionality. CMS believes opioid use at doses greater than 90 mg MED, excluding cancer pain treatment, should be limited and future criteria may focus more on the MED.

Conclusion

Based on this analysis, CMS recommends modifying the OMS criteria to improve the identification of current opioid overutilizers and to align with the recently published CDC guidelines.

Current Opioid Overutilization Criteria:

- Use of opioids with cumulative daily MED exceeding 120 mg for at least 90 consecutive days with more than 3 prescribers and more than 3 pharmacies contributing to their opioid claims, during the most recent 12 months, excluding beneficiaries with cancer diagnoses and beneficiaries in hospice.

Revised Opioid Overutilization Criteria:

- During the most recent six months,
  - Use of opioids with an average daily MED equal to or exceeding 90 mg for any duration, and
  - Received opioids from more than 3 prescribers and more than 3 pharmacies, OR from more than 5 prescribers regardless of the number of dispensing pharmacies.
- Beneficiaries with cancer diagnoses and beneficiaries in hospice are excluded.
- Prescribers associated with a single TIN are counted as a single prescriber.

[9] Gwira Baumblatt JA, Wiedeman C, Dunn JR, Schaffner W, Paulozzi LJ, Jones TF. High-Risk Use by Patients Prescribed Opioids for Pain and Its Role in Overdose Deaths, JAMA Intern Med. doi:10.1001/jamainternmed. 2013.12711
Published online March 3, 2014.

Based on 2011 data, we estimated that 22,222 beneficiaries (0.07% of all Part D enrollees) would meet the initial opioid overutilization criteria[10]. Using 2013 data, the first year of OMS implementation, 25,347 beneficiaries were identified as potential opioid overutilizers, which represented 0.21% of all opioid users. The number of potential opioid overutilizers was reduced to 15,651 beneficiaries in 2015 (0.13% of Part D opioid users).

The estimated number of beneficiaries in Part D meeting the revised criteria in 2015 is 33,059, or 0.26% of all Part D opioid users. This also represents 0.08% of all Part D enrollees, similar to our initial estimates using 2011 data (0.07%). After 3 years' experience, we believe that the revised criteria will more effectively identify beneficiaries with possible overutilization of opioids and who are at an increased risk for an adverse event, and still be manageable for sponsors to use to trigger additional patient-specific utilization review and case management.

Furthermore, beginning in 2017, Part D sponsors are expected to implement formulary-level cumulative opioid edits at point-of-sale to prospectively prevent opioid overutilization. This change could further reduce the number of beneficiaries identified through retrospective drug utilization review for case management, not to mention the impact of many other Federal and State opioid initiatives.

Modifications to the opioid overutilization criteria were proposed in the draft 2018 Call Letter (https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2018.pdf) and finalized in the final 2018 Call Letter (https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2018.pdf). This summary was originally published as a companion to the draft 2018 Call Letter. An update to Table 1 was also included in the final 2018 Call Letter.

[10] Supplemental Guidance Related to Improving Drug Utilization Review Controls in Part D, HPMS memo, September 6, 2012. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/HPMSSupplementalGuidanceRelated-toImprovingDURcontrols.pdf. Accessed September 29, 2016.