***Improving Drug Utilization Review Controls in Medicare Part D***

**Background on the Current Part D Opioid Overutilization Policy**

Opioid medications ("opioids"), particularly when used to treat pain in patients without active cancer or who are not in hospice care, have serious risks such as increasing tolerance, addiction, overdose, and death. In response to the growing national opioid epidemic, over time CMS has implemented a two-prong approach to specifically address opioid overuse in Medicare Part D from a medication safety perspective:

1. Retrospectively perform drug utilization review to identify potential opioid overutilizers and provide appropriate case management aimed at coordinated care.
2. Prospectively implement real-time safety alerts at the time of dispensing as a preventive step to ensure prescribers are aware that potentially high risk levels of opioids will be dispensed to their patients.

In the CY 2013 Call Letter and supplemental guidance, CMS described an opioid overutilization policy that focuses on cases that have the highest risk of adverse events, by which sponsors are expected to reduce beneficiary overutilization of opioids and maintain access to needed medications.[1] In July 2013, CMS launched the Overutilization Monitoring System (OMS) to help oversee sponsors' compliance with this CMS overutilization guidance.

CMS' approach has successfully given sponsors, pharmacists, and physicians the tools needed to identify potential opioid overutilizers in the Part D program and take appropriate steps to minimize risk for those beneficiaries. From 2011 through 2016, there was a 61% decrease (over 17,800 beneficiaries) in the number of Part D beneficiaries identified as potential very high risk opioid overutilizers (i.e., beneficiaries with at least 90 consecutive days with greater than 120 mg morphine equivalent dose (MED) daily with more than 3 prescribers and more than 3 pharmacies contributing to their opioid claims). (Table 19.)

[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 (https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html).

**Table 1: OMS Part D Potential Opioid Overutilization Rates, 2011 – 2016***

| 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% |
| 2016 | 43,569,035 | 12,885,620 | 29.6% | 11,594 | − 4,057 | 0.09% | −0.04% |

*61% decrease*

*69% decrease*

*Table 19 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.

CMS included proposals in the draft 2018 Call Letter to enhance both aspects of CMS' current Part D opioid overutilization policy; 1) to retrospectively better identify potential opioid overutilizers who may need case management; and 2) to increase focus on real-time safety alerts at the pharmacy. In addition, the Enhancements to the 2018 Star Ratings and Beyond section of the 2018 Call Letter discusses implementation of PQA-endorsed opioid overutilization measures.

### Additional Background on Part D Retrospective Drug Utilization Review and Case Management and OMS

CMS currently expects Part D sponsors to implement retrospective drug utilization review criteria to identify patients who are at risk of adverse events due to opioids, so that their cases may be further reviewed clinically. These criteria, established by the sponsors' Pharmacy and Therapeutics (P&T) committees within CMS guidance, should identify potential, non-borderline opioid overutilizers who may warrant case management and exclude beneficiaries with cancer or in hospice where the benefit may outweigh the risk associated with high opioid doses.

Once beneficiaries are identified, the Part D sponsors' clinical staff work with prescribers and beneficiaries to assess the potential risks. If medical necessity cannot be established due to unresponsive prescriber(s), or if misuse is verified with prescribers, sponsors may implement a beneficiary-specific claim edit at all network pharmacies that will result in the rejection of claims or rejection of quantities in excess of the opioid dosing deemed medically necessary.

The sponsor is expected to send a written notice to the beneficiary and prescriber(s) at least 30 days prior to implementing a beneficiary-specific claim edit. This allows time for the beneficiary and prescribers to request a coverage determination prior to the edit being implemented; however, a coverage determination may be requested at any time.

CMS developed specific criteria for retrospective drug utilization review and case management as part of its opioid overutilization guidance because the FDA – approved labeling for opioids generally do not contain maximum daily doses. Consequently, when developing the initial guidance in 2013, CMS also developed a comprehensive MED approach to assist CMS and Part D sponsors in identifying potentially unsafe doses in Medicare beneficiaries. We will

address later in this section how these criteria are now used by Part D sponsors for retrospective review and case management and focus here on the criteria used by OMS since its launch in July 2013, which are:

> 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.

In the draft 2017 Call Letter, CMS announced its intention to modify the OMS criteria 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). We proposed to reduce the measurement period to 6 months, use average MED rather than a count of 90 consecutive days of high MED, and group prescribers within the same practice. We received support for the proposed changes.

In response to the draft 2017 Call Letter, several stakeholders commented that CMS should revise the OMS criteria to align with the new CDC guideline issued in March 2016. Primarily due to timing constraints, CMS did not adopt the CDC guideline in the final 2017 Call Letter (issued in early April 2016), but stated that we would consider the suggestion for 2018.

It is important to note that the purpose of the CDC guideline for opioid prescribing is 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 MME[2] daily dose as a threshold for increased risk of opioid overdose, and to generally avoid increasing the daily dosage to 90 MME. Thus, the guideline is not intended as an absolute prescribing limit.

Nevertheless, the guideline is helpful to CMS in establishing policy guidance, as it is the first national guideline developed by expert clinicians and researchers that identifies potentially dangerous levels of opioid prescribing. Therefore, after its publication, CMS commenced data analysis to assess if the additional caseload associated with any revisions to our targeting criteria would still be manageable for Part D sponsors.

**Changes to the OMS Opioid Overutilization Criteria for 2018**

Based on this analysis, CMS proposed in the draft 2018 Call Letter the following modifications to CMS' opioid overutilization criteria beginning in 2018:

[2] 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.

| Modification | Rationale |
|---|---|
| Shorten the measurement period from 12 months to 6 months | A shortened measurement period better identifies current potential overutilization, 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) | A lower MED threshold aligns 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. |

The full proposed criteria in the draft 2018 Call Letter was:

- During the most recent 6 months,
    - Use of opioids with an average daily MED greater than 90 mg for any duration; and
    - Received opioids from more than 3 prescribers and more than 3 pharmacies, OR from more than 4 prescribers regardless of the number of opioid dispensing pharmacies.
- Beneficiaries with cancer diagnoses and beneficiaries in hospice are excluded.
- Prescribers associated with the same single Tax ID Number (TIN) are counted as a single prescriber.

We estimated that 33,223 beneficiaries would meet the revised criteria using 2015 data (0.27% of all Part D opioid users; 0.08% of all Part D enrollees) The estimates are comparable to the number of beneficiaries identified in 2013 when the policy began (25,347 beneficiaries; 0.21% of all opioid users; 0.07% of all Part D enrollees).

We discovered an error with the estimates provided in the draft 2018 Call Letter. We had estimated that 33,223 beneficiaries would meet the revised criteria, which included beneficiaries who received opioids from more than 4 prescribers. Instead, this estimate is associated with the

inclusion of beneficiaries who received opioids from more than 5 prescribers. We find that over 52,000 beneficiaries would meet the criteria as proposed in the draft 2018 Call Letter.

CMS also solicited comments in the draft 2018 Call Letter for a more significant revision to target beneficiaries with more than 3 prescribers regardless of the number of opioid dispensing pharmacies (we estimated over 114,000 beneficiaries would be identified).

Most commenters on the draft 2018 Call Letter supported the proposed changes to the OMS criteria listed in the table above. A few commenters opposed lowering the MED threshold to 90 mg citing lack of evidence to support the CDC guideline on opioid prescribing. Generally, there was no support for the additional proposal to further expand the criteria to include beneficiaries who received their opioids from more than 3 prescribers regardless of the number of pharmacies citing concerns about caseload.

Based on the feedback we received which considered the caseload (over 33,000), CMS will implement these revised OMS criteria beginning in 2018:

- During the most recent 6 months,
    - Use of opioids with an average daily MED greater than 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 opioid dispensing pharmacies.
- Beneficiaries with cancer diagnoses and beneficiaries in hospice are excluded.
- Prescribers associated with the same single TIN are counted as a single prescriber.

After the 2018 Call Letter is published, we will post a revised analysis summary at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html

We wish to provide a point of clarification on the OMS criteria: Some commenters on the draft 2018 Call Letter asked for more information on the calculation of the average MED. As noted in the analysis summary document posted on CMS.gov (link provided above), 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 and the quantity dispensed is prorated for the same period. For example, if an opioid claim's quantity is 120 tablets with a day supply of 30 days (or 4 tablets

per day) and the opioid episode extends past the measurement period by 10 days, a prorated quantity of 80 tablets is included in the MED calculation. The denominator for the MED calculation is the opioid episode length.

We will continue to monitor the number and percent of potential opioid overutilizers based on the revised OMS criteria and the initial criteria (for historical purposes). Our goal was and continues to be a continued reduction in opioid overuse in the Medicare Part D program. In the absence of FDA dosing limits on opioids, we are using the CDC guideline to establish a threshold to identify potentially high risk beneficiaries who may benefit from closer monitoring, creating alignment between Government programs.

**Background and Changes to Part D Sponsors' Internal Opioid Criteria for Retrospective Identification of Opioid Overutilization and Subsequent Case Management**

Through the OMS, sponsors receive quarterly reports of Part D enrollees who may be potentially overutilizing opioids based on the criteria described above. In accordance with CMS guidance to date, CMS expects sponsors' clinical staff to work with the prescribing physician(s) and beneficiary to address the risks associated with overuse, and update CMS on actions taken.

CMS also gives sponsors some flexibility in developing their internal criteria for retrospective identification of opioid overutilization for case management, as sponsors should not merely rely on OMS which is a compliance tool. Beginning in 2018, Part D sponsors are expected to lower their internal criteria to be no less restrictive than use of opioids with an average daily MED exceeding 90 mg for any duration during the measurement period. Sponsors may use a lower MED threshold and may vary other criteria including the number of prescribers and pharmacies. Sponsors also have flexibility to apply other methods to group prescribers within the same practice or not. As some commenters noted in response to the draft 2018 Call Letter, some sponsors do not have access to the TIN.

**Background on Real-Time Safety Alerts at the Pharmacy**

Although Part D sponsors' retrospective case management and CMS oversight through the OMS reduced very high risk overutilization of opioids in the Part D program, given the continuing national opioid epidemic, CMS believes that there may be additional opportunity for Part D sponsors to reduce such risk through safety alerts at the time of dispensing. Part D sponsors commonly implement safety edits to prevent the unsafe dosing of drugs at the time of dispensing as part of their concurrent drug utilization review requirements for all Part D drugs, such as drug-drug interactions, therapeutic duplication, or an incorrect drug dosage (e.g., doses above the FDA approved maximum dosing).

Based on our previous guidance, beginning in 2017, sponsors were expected to implement additional soft or hard formulary-level safety edits[3] for opioids based on a cumulative MED, as outlined and finalized in the 2017 Call Letter. Note that PACE organizations are expected to comply with these expectations unless they do not adjudicate claims at point of sale (POS). Some sponsors implemented hard edits in 2017.

**Changes to Real-Time Safety Alerts at the Pharmacy**

In the draft 2018 Call Letter, we proposed that all sponsors implement a formulary-level hard opioid safety edit based on a cumulative MED. We received a significant number of comments, including many personal letters from prescribers and patients. While there was some support, many commenters raised concerns about access, member disruption, and the approval process. A large number of physicians commented that the hard edits presented as payer-mandated prescribing controls that are at odds with the underlying purpose of the CDC guideline. Several organizations and sponsors discussed operational concerns, and requested continued flexibility for implementing either a soft or hard edit. Commenters suggested that beneficiary and prescriber education about these edits needed improvement.

Based on this feedback, we are not finalizing the proposal for all sponsors to implement a hard edit. As in 2017, we continue to expect sponsors to implement formulary-level soft and/or hard cumulative MED opioid safety edits for 2018, but hard edits are not required, and we reiterate past guidance. We recommend that if a soft opioid safety edit is implemented, the threshold be set at levels greater than 90 mg MED. We also recommend that if a hard opioid safety edit is implemented, the threshold be set at 200 mg MED or more. The edits should include additional criteria to minimize false positives by accounting for known exceptions, such as hospice care, certain cancer diagnoses, reasonable overlapping dispensing dates for prescription refills or new prescription orders for continuing fills, and high-dose opioid usage previously determined to be medically necessary such as through case management or the coverage determination and appeals process. We also encourage sponsors to include criteria to identify beneficiaries whose opioid prescriptions are written by multiple prescribers. Part D sponsors will continue to submit information on their cumulative MED safety edits using a template through HPMS. We will continue to monitor 2017 experience with these edits to inform this policy in the future.

Based on the comments to the draft 2018 Call Letter, we are providing additional background and guidance on formulary-level soft and hard safety edits for opioids based on a cumulative MED. CMS expects Part D sponsors to implement a soft and/or hard edit but only as a safety edit.

Cumulative MED edits may identify and prevent opioid misuse in real-time and give information to prescribers who may not be aware their patients are receiving such high cumulative levels of

[3] Soft edit rejections can be overridden by the pharmacist, while the hard edit requires prescriber attestation through the coverage determination process.

opioids or opioids from other doctors. However, such edits are not intended to substitute for physician judgment or dictate a prescribing limit. Rather, through this process, physicians can receive important information about their patients, which helps them make decisions about the care they are providing to their patients. Ultimately, such safety edits may proactively address potentially unsafe cumulative opioid levels with prescribers at the time of dispensing to promote care coordination, and before beneficiaries are identified by the OMS. Thus, if the only issue in dispute is the MED, CMS expects the Part D sponsor to only rely on prescriber attestation that the higher MED is medically necessary to approve dosing that is higher than the hard edit when a coverage determination is requested, and to not require additional clinical criteria. Sponsors that cannot implement a hard opioid safety edit in a manner consistent with CMS' expectations or without appropriate controls in place to minimize access issues are expected to implement only a soft edit.

When a hard MED edit is triggered and the issue cannot be resolved at the pharmacy, the sponsor is required to notify their network pharmacy to distribute a written copy of the standardized CMS pharmacy notice to the enrollee. The pharmacy notice explains the enrollee's right to ask for a coverage determination from his or her plan, including an expedited coverage determination. CMS expects plan sponsors to ensure that appropriate staff are adequately trained to identify coverage determination requests, including verbal requests made by enrollees affected by hard MED edits. Plans are also reminded that the timeframe for expedited coverage determination requests applies when the prescriber indicates, or the plan decides, that applying the standard timeframe may seriously jeopardize the enrollee's life, health, or ability to regain maximum function. We generally expect coverage determinations related to the MED edit to meet the criteria for expedited review, which means the plan sponsor must issue a decision within 24 hours of receipt of the coverage determination request.

CMS expects to issue a HPMS memo that reiterates our expectations and this guidance, and that provides additional guidance for how existing and new hard MED edits are implemented and resolved. CMS will also do additional outreach to the physician community to ensure their awareness that the Part D sponsor should only rely on prescriber attestation and no additional clinical criteria should be used to approve the MED above the hard edit threshold. We are exploring opportunities to provide more information to beneficiaries about these edits, including via a note within the Medicare Plan Finder. We will also continue to monitor complaints and appeals related to these edits and take compliance actions as warranted.

CMS believes that Medicare Advantage Organizations and Part D sponsors, working with prescribing physicians, are in the best position to identify and employ best practices and the most appropriate care management interventions for enrollees using high dosage opioids. We expect all Part D sponsors to focus on improving the coordination of care among these beneficiaries using high dosage of opioids, and MA-PDs in particular should consider expanding the care management they provide enrollees.

### 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 and best practices for care management, such as the following information:

- ***CDC Guideline for Prescribing Opioids for Chronic Pain*** provides recommendations about the appropriate prescribing of opioid pain relievers and other treatment options to improve pain management and patient safety; provides other resources to facilitate communication between providers and patients (https://www.cdc.gov/drugoverdose/prescribing/guideline.html).

- ***Designing and Implementing Medicaid Disease and Care Management Programs: A User's Guide*** is designed to be a resource for decision makers involved with designing and implementing care management programs in Medicaid; these best practices could be useful for other health and drug plans. https://www.ahrq.gov/professionals/systems/long-term-care/resources/hcbs/medicaidmgmt/index.html

### A Note about the Comprehensive Addiction and Recovery Act of 2016

Section 704 of the Comprehensive Addiction and Recovery Act of 2016 (CARA) (Pub. L. 114-198) includes provisions that permit Part D sponsors to establish drug management programs for at-risk beneficiaries under which Part D sponsors may limit such beneficiaries' access to frequently abused drugs to certain prescribers and pharmacies. CMS' implementation of Section 704 for plan year 2019 in accordance with the statutory provisions is underway. The effect of implementation on the Part D opioid overutilization policy will be addressed as soon as possible as we continue with the rulemaking process.

### Addressing Chronic Use of Benzodiazepine Sedative-Hypnotics in the Medicare Part D Population

There continue to be concerns regarding the risks and benefits of benzodiazepine use, especially in the elderly due to an increased risk of falling.[4]

Therefore, we analyzed and tested the PQA measure, *Use of Benzodiazepine Sedative-Hypnotic Medications in the Elderly (BSH)*, to assess the chronic use of these medications in the elderly enrolled in Part D.

The BSH rate measures the percent of Part D enrollees 65 years of age and older who received two or more prescription fills for any BSH medication for a cumulative period of more than 90

[4] Cumming RG, Miller JP, and Kelsey JL. et al. Medications and multiple falls in elderly people: the St. Louis OASIS study. Age Ageing. 1991 20:455–461.

days. We calculated BSH rates across all Part D contracts using 2014 PDE data, adjusted for member-years.

We found that the average BSH measure rate across all Part D contracts was low (~1%) during 2014. The number of elderly Part D beneficiaries with chronic BSH use was about 300,000. Overall, 73% of Part D contracts' BSH rates did not exceed 0.97%, the aggregate average rate, and 10% had rates more than double the average, from 2% to more than 17%. BSH rates were lowest for community-only beneficiaries compared to long-term nursing home (NH) residents, 0.93% and 1.27%, respectively.

We do not plan to add the measure to the Star Ratings or display measures at this time since the overall use of BSH medications in the elderly is not an absolute contraindication per the Beers Criteria and the BSH rates were low for most Part D contracts. We will continue to monitor BSH rates, and we will consider outreach to outlier contracts in the future if necessary.

We strongly encourage Part D sponsors to evaluate their claims data and use drug utilization management tools to monitor beneficiaries' BSH use before it becomes chronic. We also recommend that sponsors assess prescriber rates to identify outliers for educational or administrative interventions.