but possess one of the five relevant factors for informational purposes only. No action will be required for those sponsors.

Improving Drug Utilization Review Controls in Medicare Part D

Part D Opioid Overutilization Policy

Opioid medications ("opioids") have serious risks such as addiction, overdose, and death. CMS is deeply concerned about the magnitude of the opioid misuse epidemic and its impact on our communities, and is committed to a comprehensive and multi-pronged strategy to combat this public health emergency. It is a top priority of this Administration to address the opioid epidemic.

We value stakeholder input as we undertake multiple efforts to reduce the negative impacts of the opioid epidemic on our communities. While most beneficiaries utilize and clinicians prescribe opioids in ways that are medically appropriate, opioid overutilization is nonetheless a significant concern for the Medicare Part D program, and CMS is helping plans identify individuals potentially at risk for opioid abuse.

In the 2019 draft Call Letter, CMS announced a number of new strategies to further help Medicare plan sponsors prevent and combat opioid overuse. We received a significant number of comments in response to the draft guidance from patients, clinicians, plan sponsors, advocates, and associations, which we carefully considered before finalizing the policies in this Call Letter. The policies give health plans additional tools to employ more effective drug utilization review (DUR) programs to reduce overutilization of opioids and maintain access to needed medications for beneficiaries.

Furthermore, we recognize that a "one size fits all" approach does not take into account different circumstances related to opioid use. Therefore, while the strategies collectively work towards the same goal, an overall reduction in opioid overuse and overdoses, we have tailored each approach to address the distinct populations of Medicare Part D prescription opioid users (e.g., new opioid users; chronic users; those with uncoordinated care; those that concurrently use opioids with benzodiazepines, etc.). We also recommend that beneficiaries who are residents of a long-term care facility, in hospice care[37] or receiving palliative or end-of-life care, or being treated for active cancer-related pain be excluded from these interventions. In addition, it is also very

[37] We remind Part D sponsors that drugs and biologicals covered under the Medicare Part A per-diem payments to a Medicare hospice program are excluded from coverage under Part D. For a prescription drug to be covered under Part D for a beneficiary who has elected hospice, the drug must be for treatment unrelated to the terminal illness or related conditions. This is because drugs and biologicals covered under the Medicare Part A per-diem payments to a Medicare hospice program are excluded from coverage under Part D. Therefore, in 2014, we strongly encouraged sponsors to place beneficiary-level PA requirements on only four categories of prescription drugs including analgesics. Please see the most recent CMS guidance, "Update on Part D Payment Responsibility for Drugs for Beneficiaries Enrolled in Medicare Hospice", issued on November 15, 2016.

important that beneficiaries' access to medication-assisted treatment (MAT), such as buprenorphine, is not impacted.

Discussed in greater detail in the following pages, a summary of the 2019 opioid overutilization policies is as follows:

1. Opioid naïve patients: To reduce the potential for chronic opioid use or misuse, we expect all Part D sponsors to implement a hard[38] safety edit to limit initial opioid prescription fills for the treatment of acute pain to no more than a 7 days supply.

2. High risk opioid users: We are building upon and expanding the Overutilization Monitoring System (OMS), which has already significantly reduced the number of high risk beneficiaries. The OMS retrospectively identifies those beneficiaries we consider at significant risk (using high levels of opioids from multiple prescribers and pharmacies). Sponsors review these cases and perform case management with the beneficiaries' prescribers.

   We proposed to implement the Comprehensive Addiction and Recovery Act of 2016 (CARA) drug management program in 2019 and integrating those policies with the OMS process. Part D sponsors will be able to limit at-risk beneficiaries' coverage for frequently abused drugs to certain prescribers and pharmacies ("lock-in") and apply beneficiary-specific point-of-sale (POS) claim edits. The OMS will also be enhanced to include revised metrics to track high opioid overuse and to provide additional information to sponsors about high risk beneficiaries who take opioids and "potentiator" drugs (which when taken with an opioid increase the risk of an adverse event).

3. Chronic opioid users: We expect all sponsors to implement real-time safety edits at the time of dispensing as a proactive step to engage both patients and prescribers about overdose risk and prevention. We recognize that a tailored approach is needed to better address chronic opioid overuse at the POS. Some patients are using opioids where prescribers are considering increasing the opioid dosage above 90 morphine milligram equivalent (MME) per day or where prescribers may be unaware their patients are receiving high levels of opioids from additional prescribers. Other patients are already receiving higher opioid dosages long-term where the benefits and risks of maintaining or the decreasing opioid dosage should be carefully considered. Opioid withdrawal,

[38] See Chapter 6 of the Prescription Drug Benefit Manual: Hard reject: stops the pharmacy from processing a claim unless or until an override is entered or authorized by a plan representative; soft reject: stops the pharmacy from processing a claim unless or until a pharmacist-submitted drug utilization review (DUR)/prospective payment system (PPS) code is entered.

disruptions in care, obtaining opioids from other sources, and suicide risk affect clinical decisions.

4. We expect all sponsors to implement an opioid care coordination edit at 90 MME per day. This formulary-level safety edit would trigger when a beneficiary's cumulative MME per day across their opioid prescriptions reaches or exceeds 90 MME. In implementing this edit, sponsors should instruct the pharmacist to consult with the prescriber, document the discussion, and if the prescriber confirms intent, use an override code that specifically states that the prescriber has been consulted. Sponsors will have the flexibility to include a prescriber and/or pharmacy count in the opioid care coordination edit. Sponsors will also have the flexibility to implement hard safety edits and set the threshold at 200 MME or more and may include prescriber/pharmacy counts.

5. Opioid users also taking duplicate or key potentiator drugs: Lastly, we expect sponsors to implement additional soft safety edits to alert the pharmacist about duplicative opioid therapy and concurrent use of opioids and benzodiazepines.

6. Overall: CMS also uses quality measures to track trends in opioid overuse across the Medicare Part D program. To drive performance improvement among plan sponsors, CMS will implement technical revisions to the Pharmacy Quality Alliance (PQA) opioid overuse measures and add a new PQA measure, Concurrent Use of Opioids and Benzodiazepines.

Each of these policies is described in detail below. We are contemplating pilot testing the opioid naïve 7 days supply limit and care coordination safety edits in 2018 with Part D sponsors to further develop best practices and technical guidance for implementation in 2019.

Furthermore, CMS has significantly expanded its oversight of Medicare Part D plans to ensure compliance with requirements that protect beneficiaries, and can help prevent and address opioid overutilization. All Part D sponsors are expected to have a documented, written strategy for addressing overutilization of prescription opioids given the public health crisis.

Days Supply Limits for Opioid Naïve Patients

Recommendation 6 of the CDC Guideline for Prescribing Opioids for Chronic Pain[39] states that opioids prescribed for acute pain should be limited to 3 days or fewer, and that more than a 7 days supply is rarely necessary. Clinical evidence cited by the CDC review found that opioid use for acute pain is associated with long-term opioid use, and that a greater amount of early opioid exposure is associated with greater risk for long-term use.

[39] See https://www.cdc.gov/drugoverdose/prescribing/guideline.html.

Because the amount of opioid prescribed can often be in excess of the amount needed to treat an acute event, leftover supplies of opioids can become the source for misuse and diversion.[40] Limiting the initial amount of prescription opioids dispensed may reduce the risk that patients develop an affinity for these drugs and transition to chronic use or misuse.[41] At least sixteen states currently have, or plan to add by statute or agency rule, limits on the initial days supply (e.g. 5 or 7 days) and/or daily dose of opioids clinicians can prescribe for acute pain.[42] Several large prescription benefit plans are also implementing similar restrictions within their commercial lines, employer health plans, and Medicaid clients.[43,44]

To reduce the potential for chronic opioid use or misuse, CMS is establishing a days supply limitation policy for opioid-naïve patients. In the draft 2019 Call Letter, we solicited comment on guidance that all sponsors should implement a hard safety edit for initial opioid prescription fills that exceed 7 days for the treatment of acute pain. We also solicited comment on whether a days supply limit with or without a daily dose maximum (e.g., 50 MME per day) would be more effective.

In response to the draft 2019 Call Letter, most commenters supported a 7 days supply limitation policy, but there was no consensus on adding a daily dose (MME) maximum. Some commented that adding an MME threshold would cause confusion and add complexity. Beginning in 2019, we expect all Part D sponsors to implement a hard safety edit to limit initial opioid prescription fills for the treatment of acute pain to no more than a 7 days supply. After sponsors gain experience in implementing this policy in Medicare Part D, we will reassess if an MME edit for opioid naïve patients would be feasible or effective. Several commenters also raised technical questions.

Therefore, we recommend the following in implementing these edits:

- Sponsors should exclude beneficiaries who are residents of a long-term care facility, in hospice care or receiving palliative or end-of-life care, or being treated for active cancer-related pain.

- Some commenters recommended that an opioid naïve patient be defined as a patient with an opioid prescription who has not received an opioid fill over the past 30 days or longer.

---

[40] Centers for Disease Control and Prevention (CDC). Adult use of prescription opioid pain medications—Utah, 2008. MMWR Morb Mortal Wkly Rep. 2010;59(6):153-157.

[41] Bateman, BT, Choudhry, NK. Limiting the Duration of Opioid Prescriptions: Balancing Excessive Prescribing and the Effective Treatment of Pain. JAMA Intern Med. 2016;176(5):583-584. doi:10.1001/jamainternmed.2016.0544

[42] http://www.astho.org/StatePublicHealth/A-Look-at-State-Legislation-Limiting-Opioid-Prescriptions/2-23-17/

[43] https://cvshealth.com/thought-leadership/fighting-opioid-abuse-our-pbms-approach

[44] http://drugtopics.modernmedicine.com/drug-topics/news/express-scripts-limits-opioid-prescriptions

In analyzing 2017 PDE data, we found that 95% of opioid Part D fills were for 30 days supply or less. Based on stakeholder feedback and data analysis, we recommend that sponsors use a look-back period of at least 60 days. Other commenters suggested a look-back period of 108 days[45].

- Sponsors should include both short-acting and long-acting opioids, except buprenorphine for MAT.

Furthermore, we clarify:

- Since the 7 days supply limit for opioid naïve patients is a safety edit, it can be applied during transition. See Section 30.4.8, "Edits for Transition Fills", Chapter 6, Part D Drugs and Formulary Requirements, Medicare Prescription Drug Benefit Manual.

- If the claim is rejected by the plan due to a days supply greater than 7 days, and the patient does not receive a covered fill of the full days supply as written, then consistent with 42 CFR § 423.128(b)(7)(iii), the sponsor is required to notify its network pharmacy to distribute a written copy of the standardized CMS pharmacy notice to the enrollee ("Medicare Prescription Drug Coverage and Your Rights", CMS-10147, OMB Approval No. 0938-0975; see also Section 40.3.1 of Chapter 18 of the Medicare Prescription Drug Benefit Manual).

- An enrollee, the enrollee's representative, or the enrollee's prescriber has the right to request a coverage determination from the plan for a drug or drugs subject to the days supply limit, including the right to request an expedited coverage determination.

- In the absence of other submitted and approved utilization management requirements, the sponsor should approve coverage for the full days supply once the prescriber attests that the days supply is the intended and medically necessary amount for the beneficiary.

A hard edit is not generally resolvable at POS without the Part D sponsor's explicit authorization of the claim. We recognize that plans may not always be able to automatically apply all of the exemptions to this edit through claims data or identify initial versus continuing use for new enrollees at the beginning of the plan year. Pharmacists may be able to provide this information to the plan sponsor to avoid the beneficiary or their prescriber from having to request a coverage determination on this particular fill. We expect sponsors to allow pharmacists to communicate this information through the plan's help desk or through override codes for plan authorization. CMS expects sponsors' network pharmacies and customer service representatives to be adequately trained with regard to these edits.

---

[45] For consistency with the look-back period described in Chapter 6, Section 30.4.3, of the Prescription Drug Benefit Manual Chapter 6 regarding transition.

High Risk Opioid Use and the Overutilization Monitoring System (OMS)

Background on the OMS

In the CY 2013 Call Letter and supplemental guidance, CMS described the enhanced retrospective DUR policy that focuses on cases that have the highest risk of adverse events.[46] Part D sponsors should identify potential opioid overutilizers, conduct retrospective reviews, and perform case management with beneficiaries' prescribers aimed at coordinated care. These efforts do not include beneficiaries with cancer or in hospice. Under our current policy, if sponsors cannot establish medical necessity due to unresponsive prescriber(s), or if misuse is verified with prescribers, with the prescribers' agreement, sponsors may implement a beneficiary-specific point-of-sale (POS) claim edit at all network pharmacies that will result in the rejection of claims or quantities in excess of the opioid dosing deemed medically necessary.

To facilitate compliance with this policy, CMS developed the OMS in July 2013. This system identifies those beneficiaries we consider at significant risk (using high levels of opioids with potential coordination-of-care issues due to obtaining opioids from multiple prescribers and pharmacies). CMS expects plans to report back to us their results of implementing the review and case management policies through the OMS. In 2018, CMS modified the OMS opioid overutilization criteria based on stakeholder feedback and on the CDC Guideline for Prescribing Opioids for Chronic Pain. With regard to the latter, the OMS criteria incorporate a 90 MME threshold[47], cited in the CDC Guideline as the level that prescribers should generally avoid reaching with their patients, to establish a threshold to identify potentially high risk beneficiaries who may benefit from closer monitoring and case management.

To date, CMS's oversight through OMS has reduced very high-risk overutilization of prescription opioids in the Part D program. Despite increasing Medicare enrollment from 2011 to 2017, 31.5 to 45.2 million beneficiaries, the percent of opioid users has steadily decreased from about 32% to 28% (Table 27.). In addition, we concurrently observed a 76% decrease (almost 22,500 beneficiaries) in the number of Part D beneficiaries identified as potential very high risk opioid users (outliers) with the greatest decrease observed from 2016 to 2017 (40%). Likewise,

---

[46] 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).

[47] During the most recent 6 months, beneficiaries with an average daily MME greater than or equal to 90 mg 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 Tax Identification Number (TIN) are counted as a single prescriber.

the percentage of opioid users identified as outliers has steadily decreased from 0.29% to 0.05%, a decrease of 81%.

Table 27: OMS Part D Potential Opioid Overutilization Rates, 2011 – 2017*

Year	Total Part D Enrollees	Total Part D Enrollees Utilizing Opioids	% Part D Enrollees Utilizing Opioids	Total Beneficiaries Meeting OMS Criteria**	Year-to-Year % Change	Share of Opioid Utilizers Flagged as Outliers	Year-to-Year Share % Change
2011 (Pre-policy /pilots)	31,483,841	10,049,914	32%	29,404	***76% decrease***	0.29%	***81% decrease***
2013	37,842,632	11,794,908	31%	25,347	−14%	0.21%	−28%
2014	39,982,962	12,308,735	31%	21,838	−14%	0.18%	−14%
2015	41,835,016	12,510,448	30%	15,651	−28%	0.13%	−28%
2016	43,569,035	12,885,620	30%	11,594	−26%	0.09%	−31%
2017	45,218,211	12,619,655	28%	6,931	−40%	0.05%	−39%

*Table 27 includes partial year inactive contracts. Hospice and cancer patients are excluded from the opioid utilizer and OMS criteria counts. For these opioid utilization comparisons, CMS used OMS methodology as of 2013 and prescription drug event (PDE) TAP Data processed with cut-off dates in the early January of the following year.
**2013 – 2017 OMS criteria: During the previous 12 months, beneficiaries with at least 90 consecutive days with greater than 120 mg morphine milligram equivalent (MME) dose daily with more than 3 prescribers and more than 3 pharmacies contributing to their opioid claims excluding beneficiaries with cancer and in hospice.

Comprehensive Addiction and Recovery Act of 2016 and the OMS

Through the parallel rule-making process (82 FR 56336), CMS proposed to implement requirements under Section 704 of the Comprehensive Addiction and Recovery Act of 2016 (CARA) (Pub. L. 114-198) to permit Part D sponsors to establish drug management programs for beneficiaries who are at-risk of overuse and limit beneficiaries' coverage for frequently abused drugs to certain prescribers and pharmacies ("lock-in"). We also proposed to codify the Medicare Part D OMS and current enhanced retrospective DUR policy by integrating both with the drug management program provisions required by CARA.

This proposed integration would mean that Part D plan sponsors implementing a drug management program could limit an at-risk beneficiary's access to coverage of frequently abused drugs beginning 2019 through a beneficiary-specific POS claim edit and/or by requiring the beneficiary to obtain frequently abused drugs from a selected pharmacy(ies) and/or prescriber(s) after case management and notice to the beneficiary. To do so, the beneficiary will have to meet clinical guidelines based on the level of opioids they are taking and the fact that they are obtaining them from multiple pharmacies and prescribers. We will consider the comments we received that were submitted in response to the notice of proposed rule-making. We plan to publish a final rule with sufficient time for Part D sponsors to consider it in preparing their 2019 bid proposals.

OMS Metrics

Since January 2016, the OMS reports to Part D sponsors have included an Opioid Daily Dose metric for informational purposes:

- 120 MME Opioid Daily Dose rate: # opioid days > 120 MME/1000 Opioid utilization days during the last 12 months.

Since the January 2016 OMS report, we have observed a 10% decrease in the Opioid Daily Dose rate across all Part D contracts, from 122.4 to 109.7 per 1,000 opioid utilization days[48].

Beginning with the April 2018 OMS reports, we will report two Opioid Daily Dose metrics. A 90 MME Opioid Daily Dose metric will be added with a 90 MME threshold and a 6-month measurement period to align with the revised OMS criteria implemented in 2018. The original 120 MME Opioid Daily Dose metric will be revised to use a 6-month measurement period.

- 90 MME Opioid Daily Dose rate: # opioid days > 90 MME/1000 Opioid utilization days during the last 6 months.
- 120 MME Opioid Daily Dose rate: # opioid days > 120 MME/1000 Opioid utilization days during the last 6 months.

We plan to discontinue reporting the 120 MME Opioid Daily Dose rate (with 6-month measurement period) in the 2019 OMS reports.

Opioid Potentiator Drugs

As previously mentioned, the OMS identifies and reports to Part D sponsors beneficiaries we consider at significant risk and may need case management because they use high levels of opioids and obtain their opioids from multiple prescribers and pharmacies.

In October 2016, we began reporting the concurrent use of benzodiazepines among potential opioid overutilizers to Part D sponsors through the OMS. Sponsors may use this information in the case management process. We found that 64% of potential opioid overutilizers had a claim(s) for a benzodiazepine. A year later, the percent dropped to 62%. Although the trend is going in the right direction, we find that the continued high use of benzodiazepines within this high-risk population to be of concern and will continue to identify this use for Part D sponsors' review.

[48] Compares 122.4 rate from the January 2016 OMS reported (measurement period: January 1, 2015 – December 31, 2015) to 109.7 rate from the October 2017 OMS report (measurement period: October 1, 2016 – September 30, 2017).

We have been working with the Office of the Inspector General (OIG) to identify other potentiator[49] drugs that may pose safety risks when misused with opioids. Gabapentin, a gapapentinoid, has been identified as an independent risk factor for opioid-related deaths and is reportedly misused due to the euphoria associated with use at high doses.[50,51] The increasing use of gabapentin for off-label indications, despite the lack of evidence from clinical trials, has been documented in the literature.[52,53] One such off-label indication is non-specific chronic lower back pain, which is on the rise.[54] As the focus on opioid use is intensifying, clinicians and patients may be looking for alternatives for their pain treatment.[55] Currently, gabapentin is FDA-approved for the treatment of postherpetic neuralgia in adults and the treatment of partial onset seizures.

From 2015 to 2017, the rate of gabapentin users increased by 14% from 93 to 108 users per 1,000 Medicare Part enrollees based on 6-month measurement periods. Higher gabapentin use was observed among opioid users. From January to June 2017, there were 308 gabapentin users per 1,000 Part D chronic opioid users[56], and 452 gabapentin users per 1,000 OMS potential opioid overutilizers.[57] From January - June 2015 to January - June 2017, we observed a change in the percent of gabapentin users receiving very high (> 2,400 mg) doses among opioid users and chronic opioid users of 7.5% and 8.5%, respectively. CMS is concerned that the increase in gabapentin use and higher doses among opioid users may place beneficiaries at a higher risk for adverse events. These safety concerns extend to pregabalin, which is also a gapapentinoid.

---

[49] A drug potentiator is defined as a chemical, herb, or other drug that is used to increase the effects of a substance and consequently, increasing both the substance and the potentiators abuse potential.

[50] Gomes T, Juurlink DN, Antoniou T, Mamdani MM, Paterson JM, van den Brink W. "Gabapentin, opioids, and the risk of opioid-related death: A population-based nested case–control study." PLoS Med 14(10): e1002396.

[51] Evoy KE, Morrison MD, Saklad SR. Abuse and misuse of pregabalin and gabapentin. Drugs 2017;77:403-26.

[52] Mack, A. "Examination of the Evidence for Off-Label Use of Gabapentin" J Manag Care Spec Pharm, 2003 Nov;9(6):559-568.

[53] Fukada, Christine et al. "Prescribing Gabapentin off Label: Perspectives from Psychiatry, Pain and Neurology Specialists." Canadian Pharmacists Journal : CPJ 145.6 (2012): 280–284.e1. PMC. Web. 17 Nov. 2017.

[54] Shanthanna, Harsha et al. "Benefits and Safety of Gabapentinoids in Chronic Low Back Pain: A Systematic Review and Meta-Analysis of Randomized Controlled Trials." Ed. Alexander C. Tsai. PLoS Medicine 14.8 (2017): e1002369. PMC. Web. 3 Nov. 2017.

[55] Goodman, CW, Brett, AS. "Gabapentin and Pregabalin for Pain — Is Increased Prescribing a Cause for Concern?" DOI: 10.1056/NEJMp1704633.

[56] Opioid users are beneficiaries with at least one opioid claim; chronic opioid users are beneficiaries with an opioid episode of 90 days or more.

[57] Based on analysis using the revised 2018 OMS criteria (e.g., beneficiaries with average MME > = 90 mg, 4 or more prescribers and pharmacies, or 6 or more prescribers).

We will add a concurrent opioid-gabapentin/pregabalin flag to the OMS reports to Part D sponsors for informational purposes. However, based on feedback received in response to the draft 2019 Call Letter, we will only identify OMS at-risk beneficiaries who receive high dose gabapentin (> 2400mg). Part D sponsors commented that this information would be useful since these beneficiaries may have coordination-of-care issues due to receiving opioids from multiple providers along with other drugs that can potentiate the risk of overdose. We expect that when sponsors perform case management they would consider the use of other drugs (e.g., benzodiazepines, gabapentin and pregabalin) in their review process.

Sponsors also commented that information on OMS potential opioid overutilizers who concurrently use other potentiator drugs would be useful, such as muscle relaxants (e.g., carisoprodol) or sedative hypnotics (e.g., zolpidem, zalepron and eszopiclone). We will perform additional analyses and consider enhancements to OMS in the future.

Real-Time Care Coordination Safety Edits to Address Chronic Opioid Use

Part D sponsors commonly implement safety edits to prevent the unsafe dosing of drugs at the time of dispensing as part of their concurrent DUR requirements for all Part D drugs, such as drug-drug interactions, therapeutic duplication, or an incorrect drug dosage (e.g., doses above the maximum dosing in the FDA-approved labeling).

We will strengthen this aspect of the current Part D opioid overutilization policy as follows. We note that PACE organizations are expected to comply with these policies unless they do not adjudicate claims at POS.

Background on Current Cumulative MME Safety Edit Policy

Sponsors are currently expected to implement either soft and/or hard formulary-level safety edits for opioids based on a cumulative MME at POS to prevent potentially unsafe opioid dosing, as outlined and finalized in the 2017 and 2018 Call Letters. Plans may set any soft cumulative opioid claim edit MME threshold at or above 90 mg per day and any hard cumulative opioid claim edit at or above 200 mg per day.

These POS edits provide real-time information to help ensure providers are aware that potentially high-risk levels of opioids will be dispensed to their patients. Specifically, the POS edits are triggered at the pharmacy when a patient's total opioid dose across all of their adjudicated prescriptions reaches or exceeds a certain MME level per day. The pharmacist receives an alert and then action must be taken before the prescription can be covered.

As shown in Table 28, in 2017, the first year that sponsors were expected to have either a soft and/or hard edit, 51% of contracts (320 contracts) utilized a hard edit. In 2018, 50% of contracts (341 contracts) implemented a hard edit.

Table 28: Counts of Part D contracts with soft and/or hard MME edits

Contract	Contracts with Hard Edit only		Contracts with Soft Edit only		Contracts with both Hard and Soft edits		Total contracts
Year	Number	Percent	Number	Percent	Number	Percent	Number
2018	160	23.5%	340	49.9%	181	26.6%	681
2017	172	27.3%	310	49.2%	148	23.5%	630

Most contracts have implemented soft edits at 90 MME and hard edits at 200 MME, which are the "floor" of CMS's guidance. Of those contracts with hard edits, 76% in 2017 and 67% in 2018 set a threshold at the minimum recommended MME of 200 mg. Furthermore, 95% of contracts with a soft edit set an MME threshold from 90 – 120 MME in 2017 and 2018. In 2018, the proportion of contracts with 90 MME thresholds increased from 3% in 2017 to 40% in 2018.

Table 29: Counts of Part D contracts with soft edits by MME level

Contract Year	90	100	120	200-300	>300	Total contracts with soft edits
2018	209 (40%)	119 (23%)	166 (32%)	26 (5%)	1 (0%)	521
2017	16 (3%)	92 (20%)	326 (71%)	2 (0%)	22 (5%)	458

Table 30: Counts of Part D contracts with hard edits by MME level

Contract Year	200	>200-300	360	>360	Total contracts with hard edits
2018	227 (67%)	49 (14%)	61 (18%)	4 (1%)	341
2017	244 (76%)	10 (3%)	50 (16%)	16 (5%)	320

In the July 7, 2017 HPMS memo, Additional Guidance on CY 2017 Formulary-Level Cumulative Morphine Equivalent Dose (MED) Opioid Point-of-Sale (POS) Edit, we provided additional guidance to sponsors regarding appropriate use of these edits. As we stated in the

guidance memo, through review of complaints received via the CMS Complaint Tracking Module (CTM) during the first months of 2017, discussions with Part D sponsors, and receipt of questions from other stakeholders, we believed that some sponsors implemented these edits beyond their intended use as a safety edit. For example, the edits are not intended as a means to implement a prescribing limit or apply additional clinical criteria for the use of opioids, but instead to give physicians important additional information about their patients' opioid use. Since that time, we have observed few complaints per month in the CTM related to these edits.

Draft 2019 Call Letter Cumulative MME Safety Edit Policy Guidance Comments

Given the public health emergency and the fact that half of sponsors are already implementing hard MME edits, sponsors can and should do more to address chronic, high prescription opioid overuse. Therefore, in the draft 2019 Call Letter, we solicited comment on guidance that all sponsors should implement a hard edit in 2019 that is triggered when a beneficiary's cumulative daily MME reaches or exceeds 90 mg (meaning the MME threshold should only be set at 90 MME) without multiple prescriber or multiple pharmacy criteria, and to allow beneficiaries to receive a 7 days supply of the prescription that triggered the hard edit as written. Based on an analysis of 2016 PDE data across all Part D sponsors, we estimated that almost 1.6 million beneficiaries (3.6% of Part D enrollees) met or exceeded 90 MME for at least one day[58], excluding those with cancer, in hospice care, or with overlapping dispensing dates for timely continued fills for the same opioid (e.g., false positives).

We received more than 1000 comments, and the 90 MME hard edit guidance was strongly opposed by nearly all stakeholder groups for a variety of reasons. Physician groups opposed the forcible/non-consensual dose reductions due to the risks for patients of abrupt discontinuation and rapid taper of high dose opioid use. Similarly, we received hundreds of letters from patients who have taken opioids for long periods of time and are afraid of being forced to abruptly reduce or discontinue their medication regimens with sometimes extremely adverse outcomes, including depression, loss of function, quality of life, and suicide. Plan sponsors and other organizations expressed support for CMS's goal to aggressively address opioid overuse. However, the overall consensus was that a 90 MME-per-day hard edit threshold would have little clinical impact against opioid overuse (evidenced by high appeal approval rates, as data from one sponsor that implemented hard edits in 2018 showed that 93% of beneficiaries who hit their hard edit at 200 MED requested a coverage determination, and the vast majority were approved). Sponsors requested flexibility to set their own MME thresholds and the ability to include provider counts in the hard edit specifications. There was also much opposition for the 7 days supply allowance guidance as this may be very confusing for beneficiaries, and the systems capabilities do not

[58] The estimate is based on the MME daily dose calculated per opioid prescription. The daily dose is assigned to the prescription's covered days and calculated from the dispensing date and the days supply, and summed per day across all overlapping opioid fills. Methodology differs from the OMS average MME calculated from all opioid prescriptions dispensed during the measurement period.

currently exist today. Numerous operational challenges would need to be addressed to reduce disruption and potential beneficiary harm. Therefore, we are not implementing guidance for sponsors to implement hard 90 MME safety edits with a 7 days supply allowance.

New Opioid Care Coordination Safety Edit for 2019

The CDC Guideline states that tapering opioids for patients already taking high dosages of opioids after years on high dosages can be very challenging because of physical and psychological dependence. Furthermore, experts noted that "patients tapering opioids after taking them for years might require very slow opioid tapers as well as pauses in the taper to allow gradual accommodation to lower opioid dosages." Therefore, we are implementing a policy that aims to strike a better balance between addressing opioid overuse without a negative impact on the patient-doctor relationship, preserving access to medically necessary drug regimens, and reducing the potential for unintended consequences.

We recognize that a tailored approach is needed to better address chronic opioid overuse at POS and to support the recommendations described in the CDC Guideline. For example, in some cases, prescribers may be unaware their patients are receiving high levels of opioids from additional prescribers. In addition, some patients are using opioids where prescribers are considering increasing the opioid dosage. The CDC Guideline recommended against increasing opioid dosages above 90 MME per day in most cases in patients not yet receiving higher opioid dosages. Given that there may be some circumstances when the benefits of increasing opioids to higher dosages might outweigh the risks, the recommendation statement includes the option to "carefully justify a decision to titrate dosage to ≥90 MME/day." The supporting text for this recommendation outlines some factors that might be considered in individualized decisions about benefits and risks of increasing opioid dosages above ≥90 MME/day, including "diagnosis, incremental benefits for pain and function relative to harms as dosages approach 90 MME/day, other treatments and effectiveness, and recommendations based on consultation with pain specialists."

Other patients are already receiving higher opioid dosages long-term where the benefits and risks of maintaining or the decreasing opioid dosage should be carefully considered. Routine monitoring is important to review periodically for efficacy and safety of the regimen. Opioid withdrawal, disruptions in care, adverse effects, obtaining opioids from other sources, and suicide risk affect clinical decisions. Because of these considerations and because of challenges clinicians and patients face when reducing opioid dosages, the supporting text for Recommendation 5 of the CDC Guideline advises a different approach for patients already receiving long-term high dosages of opioids:

"Established patients already taking high dosages of opioids, as well as patients transferring from other clinicians, might consider the possibility of opioid dosage reduction to be anxiety-provoking, and tapering opioids can be especially challenging after years on high dosages

because of physical and psychological dependence. However, these patients should be offered the opportunity to re-evaluate their continued use of opioids at high dosages in light of recent evidence regarding the association of opioid dosage and overdose risk. Clinicians should explain in a nonjudgmental manner to patients already taking high opioid dosages (≥90 MME/day) that there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages. Clinicians should empathically review benefits and risks of continued high-dosage opioid therapy and should offer to work with the patient to taper opioids to safer dosages. For patients who agree to taper opioids to lower dosages, clinicians should collaborate with the patient on a tapering plan (See Recommendation 7).”

Tapering is most likely to be effective when there is patient buy-in and collaboration, tapering is gradual, and clinicians provide support. All of these elements require time. To support clinicians in tapering opioids when appropriate, the CDC offers a tapering pocket guide, a mobile app mobile app and online training with motivational interviewing components, and information about non-opioid treatments for pain. These resources are available at https://www.cdc.gov/drugoverdose/prescribing/resources.html.

To support these efforts, in 2019, we expect all sponsors to implement a real-time opioid care coordination safety edit at the time of dispensing as a proactive step to engage both patients and prescribers about overdose risk and prevention. This opioid care coordination safety edit should be based on a cumulative MME threshold of 90 MME per day. This formulary-level safety edit would trigger when a beneficiary’s cumulative MME per day across their opioid prescription(s) reaches or exceeds 90 MME.

In implementing this edit, sponsors should instruct the pharmacist (e.g., through messaging to the pharmacist through the claim billing transaction communications) to consult with the prescriber, document the discussion, and if the prescriber confirms intent, use an override code that indicates the prescriber has been consulted. These extra care coordination steps are what distinguish the new care coordination edit from a traditional soft edit. Use of a common process across all sponsors will improve sponsors’ ability to monitor and improve this type of drug utilization review in their pharmacy networks. The same clinical discussions can occur with patients and prescribers, without the fear of acute withdrawal or unintended consequences from a hard edit at 90 MME.

Pharmacies should be provided the override code without needing to contact the plan sponsor, or sponsors should allow the pharmacist to call the plan’s help desk for the plan to put in an override in real time if the plan sponsor does not have the capability to utilize automated codes. Plan sponsors should make it clear to pharmacies to only use the override code upon completion and documentation of the care coordination activities, and plan sponsors may consider auditing pharmacies’ documentation. Furthermore, even if the prescriber confirms intent, consultation with the prescriber does not supersede what is ultimately the pharmacist’s decision to fill the prescription or not based on professional judgment.

Sponsors will have the flexibility to include a prescriber and/or pharmacy count in the edit, in which case the edit would trigger if the cumulative MME threshold across the patient's opioid prescription(s) was met or exceeded, and the patient was receiving the opioid prescription(s) from a certain number of prescribers and/or pharmacies set by the plan sponsor. We are allowing this flexibility based on comments received in response to the draft 2019 Call Letter, in which we did not initially recommend provider counts. Many commenters noted that in the circumstance where a beneficiary at 90 MME per day or more hits an edit and only has one prescriber, the claim would virtually always be approved because the single prescriber would attest that the opioid dosage was medically necessary, thereby delaying beneficiary access. For this reason, we believe it would be appropriate for a plan sponsor to elect to have the edit not trigger in such a case. If sponsors decide to include a provider count criterion in the hard edit specifications, we recommend a minimum threshold of two prescribers of active opioid prescriptions.

Additionally, it is possible that the care coordination edit may trigger multiple times for a patient in a given month or calendar year if the conditions for the edit are still met. We expect sponsors to implement reasonable logic to remove the likelihood of redundant or duplicative coordination edits from triggering multiple times and necessitating repeated pharmacist-prescriber consultations (e.g., after they receive the prescriber attestation via a coverage determination request or confirmation from the pharmacy that the prescriber was consulted).

These edits would also serve to support the current pharmacist workflow by providing real-time information on risk complementing their review of the States Prescription Drug Monitoring Program (PDMP) systems to promote coordination and education with respect to opioid prescribing. We encourage pharmacists to review the patient's records in their State's PDMP (See Medicare Learning Network (MLN) Matters® Article SE1250: Prescription Drug Monitoring Programs: A Resource to Help Address Prescription Drug Abuse and Diversion: https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnmattersarticles/downloads/se1250.pdf).

Sponsors will continue to have the flexibility to implement hard safety edits and set the threshold at 200 MME or more with or without prescriber/pharmacy counts. CMS expects sponsors' Pharmacy and Therapeutics (P&T) committees to develop the safety edit specifications based on the observed opioid overutilization in their Part D plans, to take into account other formulary and utilization management controls already in place by the plan, and to identify a reasonable number of enrollees that the sponsors can appropriately manage in a timely manner to avoid disruptions in access.

We recommend that sponsors exclude beneficiaries who are residents of a long-term care facility, in hospice care or receiving palliative or end-of-life care, or being treated for active cancer-related pain from the opioid care coordination edit or other hard edits. Sponsors should also apply specifications to account for known exceptions, such as reasonable overlapping

dispensing dates for prescription refills[59] or new prescription orders for continuing fills; and high-dose opioid usage previously determined to be medically necessary such as through coverage determinations, prior authorization, case management, or appeals processes. It is also very important that sponsors implement these edits in a way that beneficiaries' access to MAT, such as buprenorphine, is not impacted. Sponsors should not include buprenorphine products for MAT in this edit.

As stated above, CMS provided additional guidance to sponsors regarding appropriate use of hard edits. Any sponsors that cannot comply with these practices should immediately turn off their hard edit until they can implement the edit in a manner consistent with CMS's expectations.

When the coordination MME edit or the hard MME edit is triggered and cannot be resolved at the pharmacy (e.g., prescriber cannot be reached for care coordination edit consultation, prescriber consulted due to care coordination edit but does not verify the medical necessity of the prescription, pharmacist does not fill the prescription based on clinical judgment or other reasons, or due to hard edit reject), consistent with 42 CFR § 423.128(b)(7)(iii) the sponsor is required to notify their network pharmacy to distribute a written copy of the standardized CMS pharmacy notice to the enrollee ("Medicare Prescription Drug Coverage and Your Rights", CMS-10147, OMB Approval No. 0938-0975; see also Section 40.3.1 of Chapter 18 of the Medicare Prescription Drug Benefit Manual). This notice instructs enrollees on how to contact their plan and explains their right to obtain a coverage determination from the plan, including information about the exceptions process.

Sponsors are reminded that an enrollee, the enrollee's representative, or the enrollee's prescriber has the right to request a coverage determination for a drug or drugs subject to the MME edit, including the right to request an expedited coverage determination. 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 determination requests seeking exceptions to the MME edit to meet the criteria for expedited review, which means the plan sponsor must issue a decision no later than 24 hours from receipt of the prescriber's supporting statement (attestation). As with any other request for benefits, the Part D sponsor should determine the need for the expedited timeframe based on the facts and the circumstances of the case. See section 40 and 50 of Chapter 18 of the Prescription Drug Benefit Manual for more information.

---

[59] Prescription opioids are controlled substances under the Controlled Substances Act (CSA) and are assigned to Schedule II through V. Schedules are assigned based on the abuse potential and the severity of the psychological or physical dependence of the prescription opioid. A complete list of the schedules is published annually in Title 21 Code of Federal Regulations (C.F.R.) §§ 1308.11 through 1308.15. Schedule II opioids require a new prescription for each fill while prescriptions for schedule III through V do not and therefore, can include refills.

Consistent with current guidance, if the only issue in dispute is the MME, CMS expects the Part D sponsor to rely on prescriber attestation that the higher MME is medically necessary to approve dosing that is higher than the edit when a coverage determination is requested. The authorization of the higher MME level should be considered an approved exception and be valid through the remainder of the plan year. The exception should apply to the cumulative MME level for the beneficiary, not just one specific drug, or one prescriber. In order to minimize unnecessary disruptions in therapy, Part D sponsors should consult with the prescriber(s) to determine whether dose escalation for the beneficiary is imminent, and authorize an increased MME accordingly. The sponsor should also remove the edit if it is determined that the beneficiary meets their established criteria for exclusions (i.e., cancer, hospice, etc.).

Since the MME edit is a safety edit, it can be applied during transition. See Section 30.4.8, "Edits for Transition Fills", Chapter 6, Part D Drugs and Formulary Requirements, Medicare Prescription Drug Benefit Manual. As outlined in 42 CFR § 423.120(b)(7), a Part D sponsor that uses a formulary under its qualified prescription drug coverage must establish policies and procedures to educate and inform health care providers and enrollees concerning its formulary. Accordingly, CMS expects sponsors' network pharmacies and customer service representatives to be adequately trained with regard to these edits to ensure affected beneficiaries are given timely and appropriate information and instruction. It is important that these edits be implemented in a manner that minimizes disruption to beneficiaries. It is integral that sponsors have the ability to process associated exceptions and appeals, including expedited requests, within the required timeframes. Plans are not permitted to instruct an enrollee who is requesting coverage that only their prescriber can initiate the request. CMS expects sponsors to ensure that their staff are trained to appropriately identify enrollee requests for a coverage determination, including verbal requests made by enrollees affected by hard MME edits.

The CDC Guideline for Prescribing Opioids for Chronic Pain and accompanying recommendations are intended to "improve communication between clinicians and patients about the risks and benefits of opioid therapy for chronic pain, improve the safety and effectiveness of pain treatment, and reduce the risks associated with long-term opioid therapy, including opioid use disorder, overdose, and death." The care coordination edit and other opioid-related strategies implemented for Part D beneficiaries discussed in this Call Letter support adoption of the Guideline. MA-PDs are in a unique position and CMS believes it is important that MA-PDs set expectations for prescribers to implement the CDC's recommendations as a best practice through their provider contracts. As the CDC points out, periodic reassessment by prescribers of patient opioid use is important to assess patient goals, to look for opportunities for opioid discontinuation or alternative nonopioid treatment options, and to develop patient-specific care plans. PDPs should also reinforce these messages through DUR interactions with prescribers such as OMS/case management and care coordination edits. We expect these interactions to be an integral component of sponsors' drug utilization management programs.

Furthermore, we believe it is important Part D sponsors offer Medication Therapy Management (MTM) services to beneficiaries who are at risk of adverse events due to opioid overutilization or opioid users who are also taking key potentiator drugs. These beneficiaries may benefit from MTM services including a Comprehensive Medication Review, targeted medication reviews, and interventions with their prescribers. We will monitor progress in reducing prescription opioid overuse through data analysis and quality metrics. We are particularly concerned with protracted, high risk use without routine reassessment, care coordination, and tapering opioids to a lower dosage or to taper and discontinue opioids where appropriate. If the strategies finalized in this Call Letter do not result in an overall reduction in prescription opioid overuse in Medicare Part D, or if we do not see improvement in the management and treatment of pain through uptake of the CDC's recommendations, CMS will evaluate the need for alternative approaches again in the future.

Part D sponsors will continue to submit information on their cumulative MME safety edits using a template through HPMS. We will monitor implementation of these edits including complaints data and the effectiveness of the care coordination edits. In addition, Part D sponsors report implementation outcomes of their MME POS edits, such as number of claims rejected due to edits, number of beneficiaries impacted, and number of rejected claims overridden or processed through the Part D reporting requirements. CMS will analyze these data once reported and validated. The first data collection will be in February 2018 for 2017 reporting requirements data and validated data by September 2018.[60]

Additional Opioid Safety Edits

Concurrent Use of Opioids and Benzodiazepines Soft Edits

In 2016, the FDA added a boxed warning to prescription opioid analgesics, opioid-containing cough products, and benzodiazepines with information about the serious risks associated with using these medications concurrently.[61] Sponsors can reduce the concurrent use of opioids and benzodiazepines, as well as other potentially problematic concurrent medication use at POS. Prospective drug use review can identify and evaluate the appropriateness of concurrent use prior to dispensing. We expect that Part D sponsors implement a concurrent opioid and benzodiazepine soft POS safety edit (which can be overridden by the pharmacist) to prompt additional safety review at the time of dispensing beginning in 2019, which commenters largely supported. Sponsors have the flexibility to factor different prescribers, dose or days supply in the edit specifications.

---

[60] See Part D reporting requirements: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxContracting_ReportingOversight.html

[61] https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm518697.htm

Duplicative Therapy Soft Edits

Both the use of long-acting (LA) opioids and the number of opioid prescriptions are associated with a higher risk of mortality.[62,63] Clinically, there is little support for maintaining a patient on multiple different opioids and such use creates other health care issues. First, the use of multiple opioids that compete for similar pain receptors may provide little improvement in analgesia while increasing the risk of adverse events. In addition, prescriptions for multiple opioids (whether LA or short-acting (SA)) and/or multiple strengths increases the supply of opioids available for diversion and abuse, as well as the opportunity for self-medication and dose escalation.[64] Commenters agreed that additional DUR controls at the POS like a soft edit might help reduce excess opioid supplies and reduce adverse events. Beneficiaries who receive multiple LA opioids may lack coordinated care and be at higher risk of opioid overdose. Therefore, we expect all Part D plan sponsors to implement a soft POS safety edit (which can be overridden by the pharmacist) for duplicative LA opioid therapy beginning in 2019, with or without a multiple prescriber criterion. Plans have the flexibility to define duplicative therapy at the drug or class level and should, when possible, consider situations when beneficiaries switch between doses.

When such an edit is triggered for concurrent use of opioids and buprenorphine, the soft edit should only reject the opioid prescription following the buprenorphine claim and should not impede access to buprenorphine for MAT. It is very important that a sponsor should only implement this edit if it has the technical ability to not reject buprenorphine claims.

We also recognize that multiple opioid POS edits could potentially generate a combination of messages and soft or hard rejects that may cause confusion. Therefore, we recommend that industry develop and adopt more specific reject codes, and sponsors' P&T committees determine a hierarchy to manage multiple opioid POS edits to reduce confusion.

Quality Measures

CMS also uses quality measures developed by the PQA to track trends in opioid overuse across the Medicare Part D program.

See the Enhancements to the 2019 Star Ratings and Future Measurement Concepts section of the 2019 Call Letter. We will implement changes to the PQA-endorsed opioid overutilization

---

[62] Ray WA, Chung CP, Murray KT, Hall K, Stein CM. Prescription of Long-Acting Opioids and Mortality in Patients with Chronic Noncancer Pain. JAMA. 2016 Jun 14;315(22):2415-23.

[63] Baumlatt JA, Wiedeman C, Dunn JR, Schaffner W, et al. High-risk use by patients prescribed opioids for pain and its role in overdose deaths. JAMA Intern Med. 2014 May; 174(5):796-801.

[64] Manchikanti, L. Helm II, S, Fellows, B. Janata, J.W. Pampati,V., Grider, J.S. Boswell, M.V. Opioid Epidemic in the United States. Pain Physician 2012; 15:ES9-ES38

measures in the Patient Safety reports and on the display page, and add a new PQA measure, Concurrent Use of Opioids and Benzodiazepines to the reporting.

Since 2016, sponsors have received monthly Patient Safety reports based on the PQA opioid measures. We communicate with plans about their performance on these quality measures, including sharing information about specific beneficiaries identified, and plan sponsors with the lowest rating on each measure should report actions they will take to improve performance.

Sponsors may use the reports to supplement their DUR programs to address overutilization of opioids across a population broader than OMS. CMS expects sponsors to routinely monitor these data to compare their performance to overall averages and assess their progress in reducing the number of beneficiaries using high doses of opioids, with or without multiple providers and pharmacies.

Access to Medication-Assisted Treatment

While CMS continues to work closely with Part D sponsors and other stakeholders to help combat inappropriate opioid utilization, it is imperative to also ensure that Medicare beneficiaries have appropriate access to medication-assisted treatment (MAT). As noted in previous Call Letter guidance, CMS will closely scrutinize formulary and benefit submissions with respect to formulary inclusion, utilization management criteria, and cost-sharing of Part D drugs indicated for MAT. Benefit designs that would substantially discourage enrollment by beneficiaries who need these therapies will not be approved. We continue to expect Part D sponsors to include products in preferred formulary tiers, and to avoid placing generic drugs indicated for MAT in brand tiers. As noted in previous Call Letter guidance, PA criteria that duplicates those requirements already set forth in the FDA Risk Evaluation and Mitigation Strategies and Drug Addiction Treatment Act of 2000 for applicable MAT products will not be approved.

On September 20, 2017, FDA announced that they recently had strengthened labeling requirements for buprenorphine MAT products to emphasize that treatment may be required indefinitely, as long as the use contributes to the intended treatment goals (https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm576752.htm). Consistent with FDA's position, CMS will not approve PA criteria that requires a beneficiary to need an authorization any more frequently than once during a plan year for buprenorphine MAT products. Further, when a sponsor has authorized MAT for a beneficiary in the prior plan year, we expect that the sponsor would carry that authorization through to the next plan year.

Coordination of Benefits (COB) User Fee

CMS is authorized to impose user fees on Part D sponsors for the transmittal of information necessary for benefit coordination between sponsors and other entities providing prescription drug coverage. We review and update this user fee annually to reflect the costs associated with