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DATE: October 23, 2018

TO: All Part D Sponsors

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

SUBJECT: Additional Guidance on Contract Year 2019 Formulary-Level Opioid Point-of-Sale Safety Edits

In the Final Contract Year (CY) 2019 Call Letter, CMS announced new strategies to further help Medicare Part D plan sponsors prevent and combat prescription opioid overuse through improved concurrent drug utilization review (DUR). CMS has tailored its approach to help the distinct populations of Medicare Part D opioid users, including new opioid users (opioid naïve), chronic opioid users, and those with potentially problematic concurrent medication use. CMS expects sponsors to implement the following formulary-level opioid safety edits ("opioid safety edits") at the point-of-sale (POS) in 2019:

- Soft edit for concurrent opioid and benzodiazepine use,
- Soft edit for duplicative long-acting (LA) opioid therapy,
- Care coordination edit at 90 morphine milligram equivalents (MME),
- Hard edit at 200 MME or more (optional), and
- Hard edit 7 day supply limit for initial opioid fills (opioid naïve).

Throughout the summer of 2018, CMS conducted a small, informal pilot with a few Part D sponsors. The purpose of the pilot was to test the opioid naïve and care coordination edit specifications, measure the impact and outcomes of those edits on beneficiaries, pharmacies, and prescribers, and assess industry readiness. We also evaluated information on beneficiary and provider education and pharmacy preparedness.

In response to the inquiries about the opioid safety edits, we are issuing these frequently asked questions (FAQs) as supplemental guidance along with a summary of preliminary lessons learned from the pilot. We also provide updates to the HPMS memorandum, *Additional Guidance on CY 2017 Formulary-Level Cumulative Morphine Equivalent Dose (MED) Opioid Point-of-Sale (POS) Edit*, dated July 7, 2017.

Background

The CY 2019 Call Letter provided detailed guidance on opioid safety edits.[1] The information in this memorandum builds upon and assumes knowledge of the contents of the Call Letter.

Our opioid safety edit policies for 2019 involve several types of POS edits, including soft edits and hard edits. As discussed in Chapter 6, Section 30.2.2.1, of the Medicare Prescription Drug Benefit Manual[2], soft edits can be overridden by the pharmacist at the POS, while hard edits generally require the Part D plan to take action before the claim can be adjudicated. Message-only edits give information to the pharmacist but do not stop the claim from adjudicating. While CMS has set forth expectations for the types of opioid safety edits to be implemented in 2019, Part D sponsors have flexibility and choices to make regarding specific approaches and specifications for doing so. As Part D sponsors develop their internal policies and procedures for implementing the new edits, CMS expects Part D sponsors' Pharmacy and Therapeutics (P&T) committees to consider observed overutilization of opioids among plan enrollees, as well as the plan's capacity to manage the potential workload associated with such edits, including timely claims processing and adjudication of coverage determination and appeal requests from enrollees and their prescribers. A summary of the 2019 opioid safety edits follows.

Concurrent opioid and benzodiazepine use soft edit

In 2016, the Food and Drug Administration (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.[3] Sponsors can help reduce the concurrent use of opioids and benzodiazepines, as well as other potentially problematic concurrent medication use though the use of POS safety edits. Beginning in 2019, we expect Part D sponsors to implement a concurrent opioid and benzodiazepine soft edit to prompt additional safety review at the time of dispensing. Sponsors have the flexibility to factor different prescribers, dose, or days supply in the edit specifications.

Duplicative LA opioid therapy soft edit

Both the use of LA opioids and the number of opioid prescriptions are associated with a higher risk of mortality.[4,5] Clinically, there is little support for maintaining a patient on multiple opioids and such use creates other health care issues. 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.[6] Beneficiaries who receive multiple LA opioids may lack coordinated care and be at higher risk for opioid overdose. Therefore, we expect all Part D plan sponsors to implement a

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[1] https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf - Improving Drug Utilization Review Controls in Medicare Part D
[2] https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals.html
[3] https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm518697.htm
[4] 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.
[5] 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.
[6] 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.

soft edit for duplicative LA opioid therapy beginning in 2019, with or without a prescriber count. 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.

Opioid care coordination 90 MME edit

For 2019, CMS is implementing a policy that aims to balance 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.

The care coordination edit will trigger when a beneficiary's cumulative MME per day across their opioid prescription(s) reaches or exceeds 90 MME.[7] 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. The care coordination step distinguishes this edit from a traditional soft edit, which may or may not involve communication between the pharmacist and the prescriber.

Sponsors 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 recommend including a threshold of 2 or more opioid prescribers in these edit specifications.

MME hard edit (optional)

In 2019, sponsors will continue to have the flexibility to implement hard safety edits at a threshold of 200 MME or more, with or without prescriber/pharmacy counts.

We remind sponsors that they may not use MME thresholds as prescribing limits, nor are these thresholds meant to imply that a lower dosage is universally safe. They can only function as a threshold to trigger the edit, indicating potentially unsafe opioid use. If an enrollee or their prescriber requests a coverage determination and the only issue in dispute is the MME, CMS expects the Part D sponsor to approve the request if the prescriber attests that the higher MME is medically necessary, and not to apply additional requirements such as the execution of a pain management agreement.

To the extent possible, sponsors should prevent an MME edit from firing when the prescribers are from the same group practice. We also do not recommend a consecutive (i.e., no gaps in days of opioid use) high-MME days criterion because it does not allow gaps between prescription fills and days supply. While our concern is more focused on cases involving multiple prescribers who may not know about each other, we recognize that adding a prescriber count to an MME edit may significantly complicate the function of the edit, and that Part D sponsors may find it useful to confirm cases of very high cumulative MME involving one prescriber.

[7] https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf

Opioid naïve 7 days supply limit hard edit

Recommendation 6 of the CDC Guideline for Prescribing Opioids for Chronic Pain 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.[8]

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 a source for misuse and diversion.[9] 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.[10]

Therefore, we expect all Part D sponsors to implement a hard edit to limit initial opioid prescription fills for the treatment of acute pain to no more than a 7 days supply. Based on stakeholder feedback and data analysis, we recommend that sponsors use a look-back period of at least 60 days. Sponsors should include both SA and LA opioids, except buprenorphine for medication-assisted treatment (MAT). The 7 days supply edit should not include further restrictions around quantities or dosages (such as MME), outside of any other edit discussed above or quantity limit or prior authorization requirement previously approved by CMS. 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.

Lessons learned from the opioid safety edit pilot

We thank the sponsors and organizations involved in the opioid safety edit pilot. Some participants shared information on their implementation efforts while others began to live test the care coordination and/or opioid naïve 7 days supply limit edit. We expect testing to continue through 2018 during which time we will measure the impact and outcomes of those edits. We will release additional key takeaways at a later time as appropriate.

Where possible, lessons learned were included in the FAQs below. Additional lessons learned include:

Coordination internally and between the plan sponsor and its PBM or other downstream entities is crucial in implementing the opioid safety edits successfully. All involved parties should understand the goals of the edits, the status and timeline of developing the codes, what will happen when the edits are triggered at POS, and how to monitor for complaints or issues beginning January 1, 2019.

Education and training of partnering stakeholders such as health care providers, pharmacists, customer service representatives, and beneficiaries, with regard to the opioid safety edits is

[8] https://www.cdc.gov/drugoverdose/prescribing/guideline.html.
[9] 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.
[10] 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

vitally important. We encourage the education and training to be timely, consistent, comprehensive, and contextually relevant to each of the stakeholders so they can understand how best to operationalize the opioid safety edits into existing/or new processes and procedures going forward.

Some of the Part D sponsors in the pilot developed fax blasts, call center scripts, newsletters, or letters to beneficiaries, prescribers, or pharmacists, providing information on the new opioid safety edits. Pilot participants shared that repetitive and well-timed outreach to prescribers, pharmacies, and enrollees was helpful in reinforcing the new safety edits prior to going live.

The education and training of all stakeholders on the new opioid safety edits will help minimize workflow disruption and ensure beneficiaries have access to their medications in a timely manner. For instance, pharmacists might be trained on how and when to process a claim by entering either an override code or contacting the plan sponsor to authorize the claim. Plan sponsors will need to develop a clear plan and process for training pharmacists on using reject and override codes appropriately. CMS encourages education and consistent messaging across all pharmacies to minimize confusion on which reject and override codes to use. Pharmacists also need to be trained to provide the beneficiary with the "Medicare Prescription Drug Coverage and Your Rights" (CMS-10147) notice that explains the beneficiary's right to request a coverage determination from the Part D sponsor if a prescription cannot filled as written and the issue is not resolved at the POS.

In parallel, customer service representatives may need new protocols to triage calls from beneficiaries who are confused about why their opioid prescriptions are not being filled for the full days supply as written or why the pharmacist needs to consult with the prescriber first prior to dispensing the opioid medication. Beneficiaries will need to be notified of the additional safety checks that will be performed when they present an opioid prescription at the pharmacy and their right to request a coverage determination from the plan.

Part D sponsors should outreach to their network prescribers, if applicable, to make them aware of the new policies, and steps they can take to minimize disruption for their patients, including proactive steps like requesting coverage determinations in advance for chronic pain patients and communication with dispensing pharmacists as needed for the care coordination edit. CMS will help supplement plan sponsors' education efforts through resources such as a beneficiary education brochure and a Medicare Learning Network (MLN) Matters article for prescribers this fall.

Misconceptions were discovered during the pilot regarding the new opioid safety edits. CMS emphasizes that the opioid naïve 7 days supply limit and the care coordination safety edits are not intended to overburden the pharmacist. We do not expect additional, cumbersome documentation requirements surrounding the care coordination edit consultation or redundant consultations as discussed below. We also do not expect the pharmacist to do extra work to identify exclusions if not already known. CMS expects that the new opioid safety edits will fit within the current pharmacy workflow, and will continue to work with the National Council for Prescription Drug Programs (NCPDP) to develop coding and messaging to improve efficiency of the pharmacy workflow.

Frequently Asked Questions (FAQs)

Q1: Are the new edits described in the 2019 Final Call Letter safety edits?

A1: Yes. The care coordination edit and opioid naïve 7 days supply limit hard edit are safety edits, used to help fulfill concurrent DUR requirements outlined in 42 CFR § 423.153(c)(2). The hard MME edit, soft concurrent opioid and benzodiazepine edit, and soft duplicative LA opioid therapy edit are also safety edits.

The purpose of the edits is to prompt prescribers and pharmacists to conduct additional safety review to determine if the enrollee's opioid use is appropriate and medically necessary. The edits should not be implemented as a prescribing limit or as a substitute for clinical judgment. Plan sponsors are expected to implement the edits in a manner that minimizes any additional burden on prescribers, pharmacists, and beneficiaries.

In addition, the edits are not intended to be a fraud, waste, and abuse tool, although they may identify such activities.

Q2: Are PACE organizations expected to apply the opioid safety edits?

A2: Yes. PACE organizations are expected to comply with the opioid safety edit guidance unless they do not adjudicate claims at POS.

Q3: Can the opioid safety edits be applied during a beneficiary's transition period?

A3: Yes. Since the opioid edits are safety edits, they 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. We encourage plan sponsors to utilize the opioid safety edits during transition fills.

Q4: Are Part D sponsors permitted to include buprenorphine products in the opioid safety edits at POS?

A4: No. It is very important that beneficiaries' access to MAT, such as buprenorphine, is not impacted. Sponsors should not include buprenorphine for MAT in the opioid safety edits.

However, sponsors may establish separate safety edits (or prior authorization and quantity limits upon approval by CMS) for buprenorphine products based on the maximum daily dose in the FDA labeling. Sponsors are also encouraged to implement a soft POS edit when an opioid prescription is presented following the initiation of buprenorphine for the treatment of opioid use disorder. It is very important that a sponsor should only implement this edit if it has the technical ability to not reject buprenorphine claims.

Q5: Which beneficiaries should be excluded from the opioid safety edits?

A5: Part D sponsors are expected to develop specifications that 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 all of the opioid safety edits. Sponsors should use all information available to them to reasonably exclude these beneficiaries from triggering the edits at POS in the first place. Sponsors are also encouraged to work with their P&T committees to identify other vulnerable patient populations for exclusion from the edits to avoid impeding critical access to needed medication. For example, the CDC Guideline for Prescribing Opioids for Chronic Pain stated that "given the challenges of managing the painful complications of sickle cell disease, readers are referred to the NIH National Heart, Lung, and Blood Institute's Evidence Based Management of Sickle Cell Disease Expert Panel Report for management of sickle cell disease".[11] CMS also recently released a report on the challenges of pain management for beneficiaries with Sickle Cell Disease.[12]

Sponsors should also apply specifications to account for known exceptions, such as 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 coverage determinations, prior authorization, case management, or appeal processes.

Q6: Are pharmacists expected to do extra work to determine if a beneficiary who triggered one of the opioid safety edits at POS should be excluded?

A6: No. We expect Part D plan sponsors to use available information to remove excluded beneficiaries prior to a POS rejection, but we recognize that sponsors may not always be able to automatically apply exclusions through claims data in all cases. In addition, for the opioid naïve edit, sponsors may be limited in their ability to identify initial versus continuing use for new enrollees at the beginning of the plan year.

Pharmacists are not expected to do extra work contacting prescribers or patients to find exclusions outside of the normal pharmacy workflow. Rather, pharmacists may have existing knowledge or information that a beneficiary is not opioid naïve or meets one of the opioid safety edit exclusions (such as through pharmacy drug claims history, knowledge of the enrollee's diagnosis and/or the prescriber's specialty). Also, the pharmacist may learn through a care coordination consult with the prescriber that a beneficiary should be excluded.

Sponsors should instruct pharmacists on how to communicate to the plan that the enrollee is excluded (e.g., through a transaction response code or by contacting the pharmacy help desk) to override the edit or to avoid the beneficiary or their prescriber from having to request a coverage determination on this particular fill. Plans are expected to accept this information in real-time so the claim can adjudicate. The NCPDP will be releasing

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[11] National Heart Lung and Blood Institute. Evidence-based management of sickle cell disease. Expert Panel report. Washington, DC: National Institutes of Health; 2014.

[12] https://www.cms.gov/About-CMS/Agency-Information/OMH/research-and-data/information-products/data-highlights/Understanding-Pain-Management-in-Medicare-Beneficiaries-with-Sickle-Cell-Disease-.html

updated telecommunications standards guidance to support the new Part D opioid safety edits.

Q7: Are Part D sponsors permitted to require that specific criteria or requirements be met, such as a referral to a pain specialist, prior to approving a coverage determination request related to an opioid safety edit?

A7: No. The opioid safety edits are not intended to be a means to apply additional clinical criteria for the use of opioids, such as being managed by a pain specialist, having a signed pain contract, or having a treatment plan in place. In the absence of other submitted and approved utilization management requirements, the sponsor should allow the beneficiary to access his/her medication(s) once the prescriber(s) attests that the identified cumulative MME level or days supply is the intended and medically necessary amount for the beneficiary.

For the MME edits, 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. For the hard opioid naïve edit, a request for a longer supply for an opioid naïve patient would be considered an exception request. If during the coverage determination process it becomes known that the patient is not opioid naïve, he or she should be excluded from the opioid naïve edit.

The sponsor should also remove the edit if it is determined that the beneficiary meets their established criteria for opioid safety edit exclusions (such as cancer, palliative or end-of-life care, long-term care or hospice) discussed above.

Q8: Could multiple opioid POS rejections occur at the same time?

A8: Yes. For example, it is possible that a claim could trigger both the opioid naïve edit and the care coordination 90 MME edit. It is also possible that an opioid claim may be subject to a Part D sponsor's CMS-approved formulary utilization management edits. We recommend that sponsors' P&T committees determine a hierarchy to manage multiple opioid claim rejects to reduce confusion.

Q9: After a first fill of a 7 days supply, would the opioid naïve edit still apply if the beneficiary attempts to fill another opioid prescription?

A9: No. For a beneficiary who attempts to fill another opioid prescription after the initial 7 days fill and is still within the lookback window designated by the Part D sponsor, CMS does not expect the opioid naïve edit to trigger again. The beneficiary may be subject to additional edits and CMS-approved formulary utilization management criteria.

In the case of the opioid naïve edit, we generally expect that either:

- The beneficiary will receive an initial fill for a 7 days supply. Upon reassessment by the prescriber, if the beneficiary needs additional acute pain treatment, the

prescriber will write another opioid prescription. The opioid naïve edit would not trigger again if additional prescriptions are presented within the plan's lookback period; OR

- The beneficiary will not receive any medication and instead will request a coverage determination from the plan for the full amount as written.

Q10: If an opioid prescription's smallest available marketed package size exceeds a 7 day supply, does CMS expect plans to allow more than the 7 day supply?

A10: No. As stated in the 2019 Draft Call Letter[13], we are not aware of any State laws or labeling that would prohibit prescription opioids from being dispensed in a smaller quantity.

Q11: How does the daily cost-sharing rate regulation at 42 CFR § 423.153(b)(4) relate to the opioid naïve edit?

A11: When a prescription is dispensed for less than the approved month's supply, a daily cost-sharing rate applies. Thus, if a solid, oral opioid prescription is written for 30 days, and the beneficiary receives a 7 days supply due to the opioid naive edit, the daily cost-sharing rule applies. If the copayment for a month's supply is $30, the copayment for a 7 days supply would be $7.

Q12: Does CMS intend for a soft reject to also occur for a benzodiazepine claim if concurrent history of an opioid exists?

A12: Yes. We expect the concurrent use of opioid and benzodiazepine soft edit to be bidirectional, meaning that edit would be applied to both opioid and benzodiazepine claims.

Q13: What are CMS's expectations for pharmacists' when the care coordination edit is triggered, including documentation of the care coordination consultation with the prescriber?

A13: Outside of a known exclusion, when the care coordination edit is triggered, the pharmacist is expected to consult with the beneficiary's prescriber to confirm intent. We generally expect the consultation to be consistent with current pharmacy practice to verify the prescription with the prescriber and to validate its clinical appropriateness.

These consultations are also an opportunity for pharmacists to inform the prescriber of other opioid prescribers or increasing level (MME) of opioids. As such, they may help reinforce CDC Guideline recommendations for improved clinician and patient communications about the risks and benefits of opioid therapy, and create an opportunity for prescribers to reassess the patients' opioid use and look for opportunities for opioid discontinuation or alternative treatment options.

One of the following is likely to occur at POS when consulting with the prescriber:

[13] https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2019Part2.pdf

- Prescriber confirms intent.
- Prescriber provides information that the enrollee is excluded.
- Prescriber does not confirm medical necessity of the prescription.
- Pharmacist is unable to reach prescriber.

Pharmacists should be provided the appropriate override codes 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. While Part D plan sponsors are required to oversee and monitor their network pharmacies to ensure compliance with Part D program rules, any documentation requirements established by plans related to care coordination consultations are expected to be minimally burdensome and consistent with current pharmacist workflow and professional practices. For example, the documentation may include the date, time, name of prescriber, and brief note that the prescriber confirmed intent, did not confirm intent, provided information on beneficiary exclusion, or could not be reached after 'X' number of attempts.

Also, whether a prescription triggers the care coordination edit or whether the prescriber confirms intent does not negate the pharmacist's ability to not to fill the prescription based on the pharmacist's clinical judgment.

Q14: If the pharmacist recently consulted with the beneficiary's prescriber when verifying the prescription, is an additional care coordination consultation necessary?

A14: Generally, no. If the pharmacist recently consulted with the prescriber and the pharmacist has up to date clinical information (e.g. Prescription Drug Monitoring Program (PDMP) system or other records), an additional consultation with the prescriber is not expected. Pharmacies should maintain documentation of the recent consultation and enter the appropriate override code.

It is also possible that a beneficiary may meet the conditions of the care coordination edit multiple times in a given month or year. 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).

Q15: May sponsors continue to use message-only alerts with the same parameters as the care coordination edit after the resolution of the care coordination edit?

A15: Yes. We encourage the use of 90 MME message-only alerts similar to sponsors' care coordination edit parameters once the care coordination edit has been resolved; that is, has been overridden at the POS or no longer triggers as the result of a coverage determination or appeal. The use of message-only alerts at POS avoids duplicating the care coordination effort. At this time, we do not recommend additional soft cumulative 90 MME edits after resolution of the care coordination edit.

Q16: When an opioid safety edit is triggered and the issue cannot be resolved at the pharmacy, is the pharmacy required to provide the enrollee with a copy of the notice "Medicare Prescription Drug Coverage and Your Rights" (CMS-10147)?

A16: Yes. Consistent with 42 CFR § 423.128(b)(7)(iii) and Section 40.3.1 of Chapter 18 of the Medicare Prescription Drug Benefit Manual[14], 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). 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.

This includes situations when the beneficiary does not receive a covered fill of the full days supply as written on the prescription due to the opioid naïve 7 days supply limit edit, or when the hard MME edit or care coordination 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 confirm 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).

Q17: What is the expectation for Part D sponsors if a dispensing pharmacist does not fill a prescription based on clinical judgment or other reasons (e.g. suspected fraud or opioid abuse)?

A17: As discussed above, if the pharmacist chooses not to fill a prescription that triggers one or more opioid safety edits, the pharmacy notice must be provided to the enrollee. CMS also expects plan sponsors to assist enrollees in locating a network pharmacy that will fill prescriptions for all medications covered under the plan's Part D benefit.

Q18: When an enrollee or their prescriber contacts the plan to dispute the application of an opioid safety edit, how should the request be processed?

A18: The request must be processed as a coverage determination. An enrollee, the enrollee's representative, or the enrollee's prescriber on the enrollee's behalf has the right to request a coverage determination for a drug or drugs subject to the opioid safety edits, including the right to request an expedited coverage determination. A coverage determination may be requested at any time, including prior to the enrollee presenting a prescription at the pharmacy (for example, if the enrollee is filling a prescription for pain medication in advance of a surgical procedure).

Q19: Must all coverage determination requests seeking an exception to an opioid safety edit be expedited?

A19: No. Part D plan sponsors are required to process a coverage determination request under the expedited timeframe when the prescriber indicates, or the plan decides, that applying

[14] https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/index.html

the standard timeframe may seriously jeopardize the enrollee's life, health, or ability to regain maximum function. CMS generally expects coverage determinations related to any opioid safety edits to meet the criteria for expedited review. However, there is no blanket requirement that all of these requests must be expedited. It is based on the facts and circumstances of the individual case. If the request meets the criteria for expedited review by the plan, the plan must make its decision and notify the enrollee as expeditiously as their health condition requires, but no later than 24 hours after receipt of the prescriber's supporting statement. See Chapter 18, Sections 40 and 50 of the Prescription Drug Benefit Manual for more information.

Q20: What is CMS' expectation with respect to training and outreach about the opioid safety edits?

A20: 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. Pharmacists should also be instructed how they can override the opioid safety edits at POS using the appropriate codes.

CMS also expects sponsors to ensure that their staff are trained to appropriately identify and process enrollee requests for a coverage determination. This includes verbal coverage determination requests made by enrollees, which should not be misclassified as inquiries or grievances. Plans are not permitted to instruct an enrollee who is requesting a coverage determination that only their prescriber can initiate that request.

Q21: Should sponsors submit opioid safety edits via HPMS even though CMS considers them to be safety edits?

A21: Yes. While safety edits typically are not submitted, in the absence of dosing limits in the FDA-approved labeling for opioids, we expect Part D sponsors to submit information on their opioid naïve safety edit, care coordination safety edit, and optional hard MME edit using a template through HPMS. Guidance memos related to the HPMS submission of the opioid safety edits are provided annually. See most recent HPMS memo, *Submission Template - CY 2019 Opioid Safety Edit and Participation in Drug Management Programs*, from August 8, 2018. The memo also includes instructions if a sponsor wishes to revise their CY 2019 template after the initial submission window.

Any general questions related to the Medicare Part D opioid overutilization policy may be sent to PartD_OM@cms.hhs.gov. Questions related to submission of opioid safety edit information should be sent to partdformularies@cms.hhs.gov.

Thank you for your continued dedication to helping Medicare beneficiaries.