September 18, 2018

Mr. Demetrios Kouzoukas
Principal Deputy Administrator for Medicare and Director
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Washington, DC

Re: Medicare Part C and Part D CY 2019 Final Call Letter

Mr. Kouzoukas:

The National Council for Prescription Drug Programs (NCPDP) is a not-for-profit ANSI-Accredited Standards Development Organization (SDO) consisting of more than 1,400 members who are interested in electronic standardization within the pharmacy services sector of the healthcare industry. NCPDP provides a forum wherein our diverse membership can develop solutions, including ANSI-accredited standards, and guidance for promoting information exchanges related to medications, supplies, and services within the healthcare system.

For over 40 years NCPDP has been committed to furthering the electronic exchange of information between healthcare stakeholders. The NCPDP Telecommunication Standard is the standard used for eligibility, claims processing, reporting, and other functions in the pharmacy services industry as named in HIPAA. The NCPDP SCRIPT Standard, Telecommunication Standard, and the Formulary and Benefit Standard are the standards in use in electronic prescribing as named in MMA.

NCPDP has completed an extensive review of the opioid requirements in the Medicare Part C and Part D CY 2019 Final Call Letter and has published recommendations for standardization of claims processing that support a comprehensive foundation for opioid utilization patient safety measures. We are requesting 1) confirmation of our understanding of CMS' intent and 2) NCPDP recommended solutions address the intent. Additionally, to reinforce standardization across the industry, we request CMS reference the NCPDP recommendations in the *Telecommunication Version D and Above Questions, Answers and Editorial Updates* in future CMS guidance.

Based on the 2019 Final Call Letter, it is NCPDP's understanding that CMS expects all Medicare Part D plan sponsors to implement a formulary-level, real-time opioid care coordination safety edit, to trigger at the time of dispensing when an enrollee's cumulative morphine milligram equivalent (MME) per day across their opioid prescription(s) reaches or exceeds 90 MME. As part of this:

- Plan sponsors should develop specifications to ensure that care coordination edits are not triggered for beneficiaries who are residents of a long-term care facility, in hospice care, receiving palliative or end-of-life care, or being treated for active cancer-related pain.

- When the care coordination edit is triggered at the point of sale, but the affected enrollee is known to the pharmacist as meeting one or more of the exemptions described above, the pharmacist should be instructed on how to communicate to the plan that the enrollee is exempt (e.g., through a claim transaction code value or by contacting the pharmacy help desk). Plans are expected to accept this information in real-time so the claim can adjudicate. An enrollee's exempt status may be known to the pharmacist, for example, through drug claims history, knowledge of the enrollee's diagnosis and/or the prescriber's specialty. Pharmacists are not expected to do extra work to "find" exemptions by contacting prescribers or patients outside of the care coordination process.
- Outside of a known exemption, when the care coordination edit is triggered, the pharmacist is expected to consult with the enrollee's prescriber to confirm intent. One of the following is likely to occur at point of sale:
    - Prescriber confirms intent, and the pharmacist enters an override code indicating that intent was confirmed.
    - Prescriber provides information that the enrollee is exempt, and the pharmacist enters an override code indicating that the enrollee is exempt.
    - Pharmacist is unable to reach prescriber.
    - Prescriber is consulted but does not confirm intent.
- When the care coordination edit is triggered and the issue cannot be resolved at the point of sale (for example, if the prescriber cannot be reached or the pharmacist elects not to fill the prescription based on clinical judgment), the plan sponsor must arrange with the network pharmacy to provide the enrollee with a written copy of the standardized pharmacy notice, "Medicare Prescription Drug Coverage and Your Rights" (CMS-10147). See Chapter 18, Section 40.3.1 of the *Medicare Prescription Drug Benefit Manual* for additional information about the pharmacy notice.
- 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 are expected to be consistent with current pharmacist workflow and professional practices.
- Part D plan sponsors should take steps to prevent the care coordination edit from triggering for enrollees who meet one or more of the exemption criteria. In addition, they should have policies and procedures in place to prevent the edit from triggering on applicable future claims once the plan is aware that care coordination has taken place.
- If a claim submission triggers the care coordination edit or the prescriber confirms intent, it should not negate the pharmacist's ability not to fill the prescription based on their clinical judgment.
- As with other soft edits, care coordination edits that have been overridden by the pharmacist will not later be overturned by the plan unless such claims are found to be fraudulent or otherwise not coverable under Part D. It is expected that the existing guidance in Chapter 6, Section 30.2.2.1 of the *Medicare Prescription Drug Benefit Manual* related to soft edits will be updated as needed in the next revision of the chapter.
- A beneficiary with a cancer diagnosis, who resides in a long-term care facility, is receiving palliative or end of life care, or is in hospice would be exempted from all opioid point of sale edits. This includes the days supply limit for opioid naïve patients hard edit, care coordination edit, cumulative MME hard edit, long-acting opioid duplicative soft edit, and concurrent use with benzodiazepines soft edit. Note: It is NCPDP's understanding that any one of the above conditions would exclude the beneficiary from all Part D point of sale opioid overutilization edits.

- In reference to the opioid naïve patients edit, pharmacists may be able to provide information on a beneficiary's exempt status to the plan sponsor to avoid the beneficiary or their prescriber from having to request a coverage determination on this particular fill. The pharmacist's communication of an exempt status of a beneficiary to the plan sponsor is appropriate for all opioid point of sale edits.

NCPDP has identified methods for clarification of exemptions or care coordination on point of sale claims that will mitigate patient access to care concerns. Below are additional steps we believe address CMS' intent to minimize the number of beneficiaries impacted by these requirements through proactive management.

PROACTIVE AUTHORIZATIONS

If plans invoke new MME edits they should have a clinical review process in place for any patients that have opioid claim history that would trigger the new edit.

1. The clinical review process would validate the patient's condition (e.g., cancer-related pain) and allow or disallow future claims when the MME limit exceeds that of the original MME.
2. When possible, the plan's process should address all applicable future claims and not require pharmacy intervention.
3. CMS should recommend a historic look back period for this activity.

Note: Plans would not be able to support proactive authorization in situations where the edit is invoked as a result of changes in the prescribed therapy (e.g., change in dose), changes in the number of opioid prescribers or pharmacies, or changes in enrollee location.

EXEMPTION OPTIONS

Utilization of Prescriber Specialty

The use of prescriber specialty by the plan or the pharmacy is appropriate to bypass an edit. Plans may leverage best available evidence to determine the prescriber specialty to allow point of sale claims to bypass MME limits.

1. Use of prescriber specialty, license types or taxonomy that contains descriptions of "Oncology," "Palliative Care" and "Hospice" specialties may be utilized for exemptions where appropriate.
2. NCPDP requests CMS to confirm that use of NPPES taxonomy codes is considered best available evidence and PDEs should not be rejected based on a taxonomy code that is self-reported by the prescriber and relied upon by the plan.

Additionally, plans should utilize pharmacy provided information where the pharmacy is aware the provider is one of the exempt provider types. This information can be submitted on a claim in the Result of Service Code field. Note: The earliest availability of this new code value is October 2019.

Exempt Level of Care and Clinical Conditions

When the prescribed therapy is known to be related to hospice, palliative care or cancer, applicable result of service and/or diagnosis codes can be submitted on the claim. NCPDP recommends:

1. Once information submitted on a claim is used to override the MME edits, plans should have processes in place to bypass future edits, where applicable, without the need for pharmacy intervention.
2. The submitted diagnosis code should be used by payers and processors to allow for an override at point of sale when the diagnosis code value submitted meets the exception

criteria (e.g., cancer). If the diagnosis code is not available to submit on the claim, or the diagnosis code does not align to the allowed exception criteria (e.g., hospice, palliative care), the fields within the Drug Use Review (DUR)/Professional Pharmacy Services (PPS) segment of the claim request may be used to support a point of sale override.

3. If the pharmacist has knowledge that the patient has cancer, is in hospice or palliative care, the pharmacist may submit the applicable DUR result of service code.

Value	Description
4B	Dispensed, Palliative Care
4C	Dispensed, Hospice
4D	Dispensed, Cancer Treatment

4. Long-term care patients should be identified using Patient Residence values 3 – Nursing Facility or 9 – Intermediate Care Facility/Individuals with Intellectual Disabilities.

While the condition of hospice care is an exemption within the opioid guidance, drugs related to hospice care are not covered under Part D. As a result, when the hospice value is submitted on point of sale claims, the plan should return a rejected response including reject code A3 – This Product May Be Covered Under Hospice - Medicare A.

Care Coordination

If the plan has not already received or identified an exemption for the patient and the claim meets the plan's criteria for prescriber care coordination, the plan should reject the claim with the applicable reject codes and DUR reason for service codes as outlined within Section 7 of the NCPDP *Telecommunication Version D and Above Questions, Answers and Editorial Updates.*

If no exemption exists, the pharmacy should consult with the prescriber to confirm clinical appropriateness and, when applicable, submit the appropriate exemption/diagnosis codes or the professional service and result of service codes that reflect the outcome of the clinical review.

NCPDP encourages CMS to recommend that plans should return appropriate reject codes, reason for service codes and the total MME in the message field to clearly specify the clinical safety information as determined by the plan. Using the correct code set values is necessary for the pharmacist and prescriber to distinguish whether the MME limit has been exceeded on the current fill or across multiple fills within the plan's claim history. Since the pharmacist and/or prescriber may not have access to this claims history (e.g., different pharmacy, different prescriber), this detail should be represented in the claim response for appropriate clinical reviews to occur. Without this detail, the prescriber may need to initiate the coverage determination process.

It is important to note the pharmacy may not be able to contact and/or receive confirmation from the prescriber on a timely basis. It might be a weekend, after hours or the pharmacy has not received a response. Since resubmitting a claim for informational purposes is not consistent with NCPDP standards, there is no mechanism to communicate to the plan that the prescriber could not be consulted. CMS should not require a pharmacy/pharmacist coordinate care beyond the beneficiary's "Medicare Prescription Drug Coverage and Your Rights" notification.

Plans should accept the pharmacy's documentation process as proof of prescriber outreach. Use of the appropriate professional service code/result of service code indicating the prescriber has been

contacted and claim is clinically appropriate should not trigger an audit unless fraud, waste or abuse is suspected.

Hard Reject- Coverage Determination May Be Required

As indicated in the Call Letter, "Plans may implement hard safety edits and set the threshold at 200 MME." For plans that wish to implement a hard edit, NCPDP recommends the rejected response include reject code G4 – Prescriber Must Contact Plan. All exemption options identified in the Exemption Options Section above should override this rejection.

All Medicare Part D opioid-related rejections should also include reject code 569 – Provide Notice: Medicare Prescription Drug Coverage And Your Rights and, when unable to resolve at point of sale, the pharmacy should provide the notice to the beneficiary.

Thank you for the opportunity to comment on the Medicare Part D opioid utilization requirements. NCPDP looks forward to continuing our work with CMS on this very important topic to ensure patient safety, appropriate access to care and standardization of processes.

For direct inquiries or questions related to this letter, please contact
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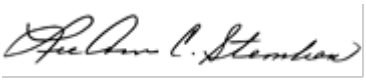
Sincerely,



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