



March 5, 2018

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Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Baltimore, MD 21244

Re: Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2019 draft Call Letter

NCPDP is a not-for-profit ANSI-Accredited Standards Development Organization (SDO) consisting of more than 1,400 members who represent drug manufacturers, chain and independent pharmacies, drug wholesalers, insurers, mail order prescription drug companies, pharmaceutical claims processors, pharmacy benefit managers, physician services organizations, prescription drug providers, software vendors, telecommunication vendors, service organizations, government agencies, professional societies, and other parties 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 submits the following comments in response to the Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2019 draft Call Letter. We stand ready to assist by providing guidance that can be considered and used when developing opioid prescriptive and dispensing requirements.

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

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Sincerely,

A handwritten signature in black ink, reading 'Lee Ann C. Stember', enclosed within a rectangular box.

Lee Ann C. Stember  
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**Improving Drug Utilization Review Controls in Medicare Part D**  
**Part D Opioid Overutilization Policy** (pages 203-204)

*“In the CY 2013 Call Letter and supplemental guidance, CMS described the enhanced DUR policy that focuses on cases that have the highest risk of adverse events. Part D sponsors should identify potential opioid overutilizers and conduct retrospective reviews and case management. This approach can help identify beneficiaries at risk of adverse events due to prescription opioids. 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 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 Overutilization Management System (OMS) in July 2013. This system identifies those beneficiaries we consider at significant risk (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. Over time, CMS has 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 morphine milligram equivalent (MME) threshold cited in the CDC Guideline, which was developed by experts as the level that prescribers should generally avoid reaching with their patients. CMS considers plan and provider burden along with beneficiary impact in developing the OMS criteria. We have also continued to modify OMS in other ways as relevant information and guidelines have become available. For example, in October 2016, we added a flag to OMS indicating potential opioid overutilizers who have also been prescribed a benzodiazepine, which is known to increase risk of overdose when taken together.*

*Although these efforts have reduced very high risk overutilization of prescription opioids in the Part D program, given the urgency and scope of the national opioid epidemic, we will propose new strategies to more effectively address this issue in Part D. Most notably, these efforts will better manage chronic overuse among beneficiaries who are taking high levels of prescription opioids (e.g., beneficiaries with 90 MME or more without multiple prescribers and pharmacies who may not be addressed through the OMS) as well as opioid naïve patients. The proposals include:*

- *Enhancing the OMS by adding additional flags for high risk beneficiaries who use “potentiator” drugs (such as gabapentin and pregabalin) in combination with prescription opioids. OMS already flags concurrent benzodiazepine use.*
- *Implementing revisions to the PQA opioid quality measures used by CMS, and consideration of a new PQA measure, Concurrent Use of Opioids and Benzodiazepines. [See the Enhancements to the 2019 Star Ratings and Future Measurement Concepts section of the draft 2019 Call Letter]*
- *Expecting all sponsors to implement hard formulary-level cumulative opioid safety edits at point-of-sale (POS) at the pharmacy (which can only be overridden by the sponsor) at a dosage level of 90 MME per day, with a 7 days supply allowance.*
- *Implementing a days supply limit for initial fills of prescription opioids (e.g., 7 days) for the treatment of acute pain with or without a daily dose maximum (e.g., 50 MME per day).*
- *Expecting all sponsors to implement soft POS safety edits (which can be overridden by a pharmacist) based on duplicative therapy of multiple long-acting opioids, and request feedback on concurrent prescription opioid and benzodiazepine soft edits.*

*We welcome feedback on this important topic. All Part D sponsors are expected to have a documented, written strategy for addressing overutilization of prescription opioids given the public health crisis."*

**NCPDP comment:**

- NCPDP requests CMS define 'initial fill.' For example, first time that drug has been prescribed for that calendar year, first fill of that particular prescription or based on diagnosis/condition.
- NCPDP requests CMS clarify whether the initial fill limitation applies to short acting opioids, long acting opioids or both.
- Should the plan assume any short acting opioid prescribed during a transition fill eligible period is for an opioid naïve patient and only apply the 7 day limit not the 30 day transition fill?
- NCPDP recommends CMS allow an exemption to the initial fill limit for Long Term Care as there are business cases in which the Part D plan will not have access to previous claim data. For example, the opioid treatment may have been initiated under the Medicare Part A stay. Without this exemption patient access to care would be jeopardized.

***Cumulative Morphine Milligram Equivalent Daily Dose (MME) Safety Edits for High, Chronic Prescription Opioid Users*** (pages 210 – 211)

*"To balance beneficiary access to medically necessary drug regimens and reduce the potential for any unintended consequences for patients already on higher doses of opioids such as withdrawal symptoms, we propose that sponsors should implement these edits in 2019 to allow beneficiaries to receive a 7 days supply of the prescription that triggered the hard edit as written. This would provide a short term supply to patients to allow time to pursue coverage through the exceptions process. However, if the exception request is approved, the patient may need to obtain a new prescription from their prescriber for amounts beyond the 7 days supply. Alternatively, the patient could elect not to receive the partial 7 days supply fill (e.g., they are not out of the medication) and go through the exceptions process. In that case, if approved, the original prescription could be filled. Also, in the case of opioid prescriptions that trigger the 90 MME hard edit where the packaging is only available in a days supply greater than 7 days, we would not expect any supply to be provided. The beneficiary would need to obtain an approved exception in order to get the medication. Nonetheless, we are not aware of any State laws or labeling that would prohibit prescription opioids from being dispensed in a smaller quantity.*

*We additionally propose to only allow the 7 days supply once. That is, if the beneficiary attempts to fill a prescription for another opioid that triggers the MME hard edit, another 7 days supply would not be allowed. We request comment on this concept and stakeholder feedback on its operational feasibility. Should we finalize a policy whereby the 7 days supply is only available once after the 90 MME hard edit is triggered during a specific time period, if a patient presents at the pharmacy with multiple opioid prescriptions on the same day, if only one 7 days supply was allowed, the pharmacist would help assess the immediate needs of the patient to help determine which prescription should be filled for a 7 days supply. We further seek comment on when and how to best communicate to beneficiaries that the one-time 7 days supply would not be available for future prescriptions should the MME level remain at 90 mg or higher.*

*To estimate the number of beneficiaries who may be impacted by a cumulative MME edit at 90 MME per day, we analyzed 2016 PDE data across all Part D sponsors. In 2016, almost 1.6 million beneficiaries (3.8% of Part D enrollees) met or exceeded 90 MME for at least one day, 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 seek feedback on whether all sponsors have the capacity to implement hard edits at 90 MME as well as the 7 days allowance proposal for 2019. We also request comment on other solutions to address prescription opioid overuse while balancing access to medically necessary drug regimens and reducing the potential for unintended consequences.*

*Furthermore, we reiterate that when the MME edit is triggered and cannot be resolved at the pharmacy, consistent with Section 40.3.1 of Chapter 18 of the Medicare Prescription Drug Benefit Manual, 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 their 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 within 24 hours of receipt of the prescriber’s supporting statement (attestation).*

*Consistent with current guidance, if the only issue in dispute is the MME, CMS expects the Part D sponsor to only rely on prescriber attestation that the higher MME is medically necessary to approve dosing that is higher than the hard 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 known exceptions (such as cancer or hospice).”*

**NCPDP comment:**

1. For the scenario below, NCPDP’s interpretation of the guidance is the claim must be rejected. We believe this is not the intent and CMS would allow the smallest unbreakable package size.
  - 7 day initial fill limit
  - 90 MME is exceeded
  - Unbreakable package of greater than 7 day supply

For the scenario below, there is no guidance; however NCPDP believes the intent is to allow the smallest unbreakable package size.

- 7 day initial fill limit
  - Unbreakable package of greater than 7 day supply
2. NCPDP does not recommend a MME limit for initial prescriptions. Having different MME hard rejects with a 7 day supply limit will cause confusion for the beneficiary, prescriber and the pharmacist as there is no clear way to communicate the difference between the two types of edits.

3. Prior to the coverage determination outcome, the patient will obtain a reduced days supply. NCPDP would like to verify the intent is to allow the patient to obtain the remainder of the originally prescribed amount once the coverage determination is approved by the plan. Processing claim transactions for multiple fills for CII medications triggers several concerns that need to be considered to ensure standardization of processes. We ask CMS to consider the following:
  - The absence of the Quantity Prescribed field hinders the payer’s ability to validate the total dispensed quantity does not exceed the total quantity prescribed.
  - The process flow and associated claim identifiers to support a 7 day supply and initiate the coverage determination process for the remaining prescribed quantity are unclear. For example:
    1. Claim is submitted for a 30 day supply and a daily dose >90MME, where exception condition is not available to the Part D plan.
    2. Part D plan rejects the claim using the new MME reject codes that will be available for use as of January 1, 2019 and Pharmacy Notice reject code 569.
    3. If the Part D plan is expected to allow a 7 day supply, will this be part of the reject messaging where the pharmacy would resubmit the claim for a 7 day supply when applicable? Should standardized messaging be developed to facilitate consistency to support patient access to care?
    4. If a claim for 7 day supply is accepted, how is the coverage determination process initiated to support coverage of the prescription as written? Will the plan sponsor need to make the outreach to the prescriber? If so, how will the pharmacy be alerted to the outcome to know whether the remaining quantity on the prescription can be dispensed and billed to the Part D plan? Conversely, how will the pharmacy know that the remaining quantity on the prescription is no longer valid as the script is considered to be inactive?
  - Based on these open concerns that will require technical and operational changes to support both a 7 day supply and the coverage determination process, the January 1, 2019 compliance date will be challenging to meet.
4. Should residents of LTC facilities also have the same exemption as indicated for cancer and hospice?

***Days Supply Limits for Opioid Naïve Patients, page 212***

*“The sixth recommendation of the CDC Guideline states that opioids prescribed for acute pain should be limited to three days or fewer, and that seven days are 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. 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. 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. Currently, at least sixteen States have or plan to add by statute or agency rule days supply (e.g., 5 or 7 days) and/or daily dose limits on the initial amount of opioids that*



*clinicians can prescribe for ‘acute’ pain. In addition, several large prescription benefit plans are implementing similar restrictions within their commercial, health plan, employer, and Medicaid clients.*

*In addition to the strategies described above to help better manage high, chronic prescription opioid use, CMS intends to establish a days supply limitation policy for opioid naïve patients in this year’s final 2019 Call Letter that balances reducing the harm posed by opioids with an individual’s need for access to appropriate pain relief. Ultimately, we seek to align our policy with other Government programs. For example, the FDA is seeking stakeholder input (82 FR 58572) on how the FDA might, under its Risk Evaluation and Mitigation Strategy (REMS) authority, improve the safe use of opioid analgesics by curbing overprescribing to decrease the occurrence of new addictions and limit misuse and abuse of opioid analgesics.*

*We expect all Part D sponsors to implement a hard safety edit for initial opioid prescription fills that exceed 7 days for the treatment of acute pain. CMS understands that implementing such restrictions may create important challenges. Any restrictions should not compromise appropriate pain treatment or result in an excessive burden on clinicians and their patients. We request feedback from stakeholders, especially Part D sponsors, providers, and PBMs, on the implementation of a days supply limitation at 7 days or if an alternative days supply limit would be more appropriate (such as 3 days or 5 days), including their experience with such limitations or the basis for their recommendations. We also solicit 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 particular, we request information on both inclusions and exceptions for specific clinical situations (i.e., whether and to what extent a supply limit could be based on specific indications or other criteria) and other parameters and what safeguards should be in place to protect appropriate beneficiary access.”*

**NCPDP Comment:**

Regarding the request for information on both inclusions and exceptions for specific clinical situations, NCPDP has developed additional override codes (available for use in January 2019) which would allow the pharmacist to communicate the following potential exemptions to the payer:

- palliative care
- hospice
- cancer
- chronic pain
- per prescriber
- surgery
- trauma
- hospital discharge

While available, these codes are not required for implementation by January 2019. NCPDP encourages CMS to consider a delay in the compliance date if these codes are recommended for usage.

The current lack of standardization among State and Federal requirements causes confusion in the industry and impedes efficiencies. Therefore, NCPDP recommends the exchange of clinical information using diagnosis codes (ICD-10) to communicate specific clinical situations in a standardized manner. Plans would be able to implement edits based on criteria for exceptions based on specific diagnosis codes.

**Opioid Duplicative Therapy Safety Edits**, pages 214- 215:

*“Of the beneficiaries who used LA opioids in 2016, over 250,000 (or almost 20% of LA opioid users) had at least one fill of an LA opioid before 75% of prior claims’ days supply expired (criteria #2). Next, we identified how many of these beneficiaries had duplicative LA opioid therapy, meaning fills for different LA opioids at the generic entity, dosage form, and strength (criteria #3). This yielded over 200,000 beneficiaries (15.6%). Lastly, we recognize that multiple LA opioid prescriptions of different strengths can be clinically appropriate so we examined the impact of requiring different opioid prescribers (criteria #4). Of those beneficiaries with duplicative LA opioid therapy, over 66,000 (5.1%) were from different prescribers. Some additional key findings from the analysis included: (1) more than half of MA-PD contracts and more than 70% of PDP contracts had greater than 100 beneficiaries with duplicative LA opioid therapy (criteria #3), and (2) adding different prescribers to the overlapping criteria (criteria #4) decreased the number of contracts with greater than 100 beneficiaries identified to less than 10% of MA-PD contracts and less than 40% of PDP contracts.*

*Based on these findings, we expect all Part D plan sponsors to implement a soft POS edit for duplicative LA opioid therapy beginning in 2019, with or without a multiple prescriber criterion. 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.*

*Ultimately, such safety edits may proactively address potentially unsafe cumulative opioid regimens at the time of dispensing to promote care coordination, and before beneficiaries are identified by the OMS. 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 contracts create a hierarchy for the opioid POS edit messaging in an effort to reduce confusion.*

*We are requesting feedback from stakeholders, especially Part D sponsors and PBMs, on the proposed expectation that sponsors to implement a soft duplicative LA opioid therapy POS edit (e.g., current experience in implementing such edits or concerns with the complexity or capacity to be able to implement for 2019) and recommendations on the most effective edit specifications (e.g., the specifications used in CMS’s analysis or other specifications). We also seek feedback on how best to manage multiple opioid POS edits that a single prescription may trigger, for instance, a duplicative therapy and cumulative MME POS edit. In addition, we request feedback on extending the specifications in the future to include SA opioids and defining duplicative therapy as previously described for LA opioids (i.e., generic entity, dosage form, strength and/or differing prescribers) or another unique drug classification scheme (e.g., removing strength). We will delay specifying the parameters for the duplicate SA opioid POS edit until additional testing can be completed and we have a better idea of the feasibility and operational considerations for such edits.”*

**NCPDP comment:**

NCPDP recommends a standardized method of communicating this information throughout the prescribing process (from prescriber to pharmacy to plan) using diagnosis codes (ICD-10) as noted in the NCPDP Recommendations for Standardized Communications to Address the Opioid Epidemic.

Regarding how best to manage multiple opioid POS edits that a single prescription may trigger, NCPDP has developed more specific reject codes (available for use in January 2019) which can be used to report multiple edits and/or reasons for rejects.

- Morphine Equivalent Dose Exceeds Limits
- Morphine Equivalent Dose Exceeds Limits for Patient Age
- Cumulative dose exceeded across multiple prescriptions
- Initial Fill Days Supply Exceeds Limits
- Initial Fill Days Supply Exceeds Limits For Patient Age
- Days Supply Limitation For Product/Service for Patient Age
- Cumulative Fills Exceed Limits