NCPA summary of 2019 final Call Letter

On April 2, 2018, the Centers for Medicare and Medicaid Services ("CMS") issued its 2019 Call Letter (the "Call Letter"). Every year CMS issues a call letter outlining various requirements for plan sponsors to participate in the Medicare Part C and D programs for the upcoming contract year. This document will analyze the relevant issues important to community pharmacists.

Changes that will impact your pharmacy

CMS requires plans to include hard safety edits on 7-day initial fills for opioid prescriptions for the treatment of acute pain. The pharmacy will be stopped from processing a claim unless or until an override is entered or authorized by a plan representative.

CMS states that plans must implement an opioid care coordination edit at 90 MME per day for all beneficiaries. CMS outlines how the care coordination edit could work including instructing the pharmacist to consult with the prescriber, documenting the discussion, and using an override code indicating that the prescriber has confirmed intent.

CMS did not make changes to the Part D mail-order refill consent policy, which currently requires patient consent for refills in a mail order program. NCPA submitted information including survey results from community pharmacists which demonstrates that CMS should not relax its current policy.

Enhancements to the 2019 star ratings and future measurement concepts

Potential new measures for 2020 and beyond

Use of opioids from multiple providers and/or at high dosage in persons without cancer (Part D)

In the Final Call Letter, CMS implements the following changes beginning with the 2017 Patient Safety reports (note these measures will not be included in the formal Star Ratings program):

Measure 1: Use of Opioids at High Dosage in Persons without Cancer (OHD)
Measure 2: Use of Opioids from Multiple Providers in Persons without Cancer (OMP)
Measure 3: Use of Opioids at High Dosage and from Multiple Providers in Persons without Cancer (OHDMP)

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PQA's Measure Update Panel and Quality Metrics Expert Panel approved the following changes:

- Each rate will have a separate title.
- The term "morphine equivalent dose" will be changed to "morphine milligram equivalents."
- The opioid treatment period for Measures 1 and 3 must be 90 days or more.
- ICD-9 and ICD-10 codes were changed to align with the American Medical Association (AMA) Physician Consortium for Performance Improvement (PCPI) cancer value set.
- All buprenorphine products indicated for medication-assisted treatment (MAT) are excluded.

CMS states that it will continue to report all three measures to Part D plan sponsors through the Patient Safety reports and only add the OHDMP measure to the 2019 Part D display page (2017 data). In the Final Call Letter, CMS also asserts that it will monitor updates to PQA's measure specifications and consider adopting the revised measure through a future Call Letter. CMS will also re-assess incorporating the existing measures in the display page and in the Star Ratings as PQA updates them.

Polypharmacy measures (Part D)

PQA established and endorsed three measures that identify potentially harmful concurrent drug use or polypharmacy. In the Final Call Letter, CMS assessed these measures for possible inclusion in Patient Safety reporting, display page, or Star Ratings in the future.

The first measure is the Use of Multiple Anticholinergic (ACH) Medications in Older Adults (Poly-ACH). This measure evaluates the "percentage of individuals 65 years and older with concurrent use of two or more unique ACH medications."[1] The second measure is the Use of Multiple Central Nervous System (CNS)-Active Medications in Older Adults (Poly-CNS). This measure evaluates the "percentage of individuals 65 years or older with concurrent use of three or more unique CNS-active medications."[2] Lastly, the third measure addresses the concurrent use of opioids and benzodiazepines. It evaluates the "percentage of individuals 18 years or older with concurrent use of opioids and benzodiazepines."[3] CMS will begin reporting these measures in the Patient Safety reports for 2018 and will add it to the display page for 2021 (2019 data) and 2022 (2020 data).

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[1] *Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter*, Apr. 2, 2018, *available at* https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf.

[2] Id. at 171.

[3] Id. at 172.

CMS will consider including this measure in 2023 Star Ratings (2021 data), and that will be proposed through future rulemaking.

Measurement and methodological enhancements

CMS states that it will continue to analyze existing ratings measures to evaluate whether measure scores are "topped out" or show high performance across all contracts. CMS states that it is exploring measurement concepts such as functional status and use of non-pharmacological or non-opioid pain management interventions that will require the use of non-claims data. NCPA asked that CMS recognize PQA's efforts to develop pharmacy level measures. Specifically, NCPA asserted that no methodology exists to evaluate the quality of a community pharmacy or to compare pharmacies within a network. However, CMS did not address this in the Final Call Letter.

Improving drug utilization review controls in Medicare Part D

CMS states that about 28% of Medicare Part D enrollees currently utilize opioids (about 12,619,655 enrollees), with about 6,931 beneficiaries that meet OMS criteria for potential opioid overutilization. OMS criteria is met when the patient falls under the definition that "during the previous 12 months, beneficiaries with at least 90 consecutive days with greater than 120 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.[4] CMS has indicated that the number of enrollees utilizing opioids has steadily decreased over the past 6 years due to CMS' proposals for plan sponsors to utilize claim edits and lock-in programs in its drug benefit. For example, CMS' current DUR policy allows plan sponsors to implement beneficiary-specific point-of-sale edits at all network pharmacies that will result in the rejection of claims or quantities more than the opioid dosing deemed medically necessary. CMS touted that these programs have experienced great success and the percent of opioid users has steadily decreased from about 32% to 28%, and a 76% decrease in the number of Part D beneficiaries identified as potential very high risk opioid users.[5]

In the Final Call Letter, CMS outlines several new policies with which plan sponsors are either required or encouraged to implement to continue the trend of less opioid usage for Part D enrollees. The following are points that are particularly applicable to community pharmacies.

[4] Id. at 240.
[5] Id. at 240.

CMS requires plans to include hard safety edits for opioid prescription initial fills for the treatment of acute pain to 7 days or less

For opioid naïve patients, CMS expects all plan sponsors to implement a hard safety edit (or hard reject) to limit initial opioid prescription fills for the treatment of acute pain to no more than a 7 days' supply. A hard reject is defined in the Prescription Drug Benefit Manual that a pharmacist "stops the pharmacy from processing a claim unless or until an override is entered or authorized by a plan representative."[6]

In implementing these edits, CMS states sponsors should exclude beneficiaries in long-term care and hospice settings as well as beneficiaries receiving palliative or end-of-life care or who are being treated for active cancer-related pain. Sponsors should also use a look-back period of at least 60 days to determine who is an opioid naïve patient. This means an opioid naïve patient is a patient with an opioid prescription who has not received an opioid fill in the past 60 days.

Edits can be applied during a transition. If a claim is rejected following a hard edit, the plan sponsor is required to notify its network pharmacy to distribute a written copy of the standardized CMS pharmacy notice to the enrollee. Pharmacies should be aware of this requirement following a denial of a claim after a hard edit.

Finally, CMS recognizes the technical difficulties with hard edits, specifically that plans may not be able to automatically apply exemptions to a hard edit through claims data or identify initial versus continuing use for new enrollees at the beginning of the plan year. CMS expressly states, "we expect sponsors to allow pharmacists to communicate this information through the plan's help desk or through override codes for plan authorization." Pharmacies should ensure plan sponsors have communicated how this information should be communicated to the plan sponsor. CMS further states plan sponsor's representatives should be "adequately trained" to facilitate this communication.[7]

[6] Id. at 235.
[7] Id. at 238.

CMS expects all sponsors to implement real-time safety edits at the time of dispensing for chronic opioid users and states that plans must implement an opioid care coordination edit (different from a traditional soft edit) at 90 MME per day for all beneficiaries

For chronic pain users, CMS expects all sponsors to implement real-time safety edits at the time of dispensing.[8] Currently, POS edits are triggered at the pharmacy when a patient's opioid dose across all their adjudicated prescriptions reaches or exceeds a certain MME level per day. About 50% of contracts in 2017 and 2018 utilized a hard edit utilizing the above criteria.[9]

Now, CMS expects all plan sponsors to implement an opioid care coordination edit at 90 MME per day. CMS states, "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."[10] CMS also states that plan 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."[11] The instructions should be sent through messaging though the claim billing transaction communications.

CMS specifically states, "pharmacies should be provided the override code without needing to contact the plan sponsor, or sponsor 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."[12]

Other requirements or recommendations include:

- CMS gives sponsors the flexibility to include a prescriber/pharmacy count in the opioid care coordination edit and implementation of hard safety edits to set threshold at 200 MME or more.
- Pharmacists are encouraged to review the patient's record in their state's Prescription Drug Monitoring Programs to detect further opioid abuse.[13]
- CMS recommends, but does not require, patients who are residents of an LTC 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.[14]

[8] Id. at 236.
[9] Id. at 244.
[10] Id. at 247.
[11] Id. at 236.
[12] Id. at 247.
[13] Id. at 248.
[14] Id.

- The safety edit can be applied during transition.[15]

Finally, if the pharmacist does not fill the prescription based on a care coordination edit, the sponsor is required to notify their network pharmacy to distribute a written copy of the standardized CMS pharmacy notice to the enrollee.

CMS signals sponsors are expected to use additional soft safety edits

CMS states that it expects sponsors to implement additional soft safety edits to inform the pharmacist about duplicative opioid therapy and concurrent use of opioids and benzodiazepines.[16]

CMS states plan sponsors should integrate policies in the CARA drug management program that includes a prescriber/pharmacy "lock-in"

Per CARA, Part D sponsors will integrate OMS policies. Specifically, 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 claim edits.

CMS signals potential pilot testing to work out hard and soft edits

CMS has finally noted that it may pilot test the 7-day supply limit for acute pain and the care coordination safety edits for 90 MME per day to develop best practices and technical guidance for the above requirements to be appropriately implemented in 2019.

Part D mail-order refill consent policy-solicitation for comments

CMS did not make changes to the Part D mail-order refill consent policy, which currently requires patient consent for refills in a mail order program

In the draft version of the Call Letter, CMS solicited comments on potential changes to CMS' current policy on mail-order patient consent which requires mail-order programs to obtain patient consent before adding a patient to a refill setting. In response to this solicitation for comments, NCPA submitted information including survey results from community pharmacists which demonstrates that CMS should not relax its current policy.

[15] Id. at 250.
[16] Id. at 251.

The survey results demonstrate that changes in CMS' mail order policies in 2014 (that is, mail order programs were required to obtain prior patient consent for new prescriptions and refills) positively impacted the flow of patients coming into pharmacies with unwanted mail order prescriptions while CMS' 2016 policy (the policy now requires mail order programs to only obtain prior patient consent for refills, not new prescriptions) resulted in a negative change. NCPA remains vigilant that CMS may change its current policy in upcoming contract years and will focus on providing more information to CMS to prevent this change.