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CENTER FOR MEDICARE

TO: All Part D Sponsors

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

SUBJECT: Additional Guidance on CY 2017 Formulary-Level Cumulative Morphine Equivalent Dose (MED) Opioid Point-of-Sale (POS) Edit

DATE: July 7, 2017

In the CY 2017 Call Letter, CMS notified Part D sponsors of the expectation to implement either soft and/or hard formulary-level cumulative opioid edits at point-of-sale (POS) based on morphine equivalent dose (MED) to prevent potentially unsafe opioid dosing. These real-time safety alerts at the time of dispensing are a prospective step to help ensure providers are aware that potentially high risk levels of opioids will be dispensed to their patients and to promote care coordination.

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 believe 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, as discussed more fully below, but instead to give physicians important additional information about their patients' opioid use.

Therefore, we are issuing this specific guidance regarding the appropriate use of these edits. Any sponsors that cannot comply with these practices should immediately turn off their hard edit or convert to a soft edit until they can implement the edit in a manner consistent with CMS' expectations as outlined below. The process for Part D sponsors to modify their MED POS edit parameters during the plan year is also described below.

Background

Please refer to the CY 2017 and CY 2018 Call Letter for detailed information on these edits. We expect Part D sponsors' Pharmacy and Therapeutics (P&T) committees to consider the case-load of enrollees in the development of their specific edits. Sponsors should identify a reasonable number of enrollees that the sponsors can appropriately manage in a timely manner.

We recommend that a soft edit threshold be set at levels no lower than 90 mg MED, and a hard edit threshold be set no lower than 200 mg MED to reduce initial beneficiary impact. Plans may not use these thresholds as prescribing limits and they can only function as a threshold to trigger the edit indicating potentially unsafe opioid use. In the case of a hard edit, if the only issue in

dispute is the MED, CMS expects the Part D sponsor to only rely on prescriber attestation that the higher MED is medically necessary to approve dosing that is higher than the hard edit when a coverage determination is requested. The edits should include additional criteria to minimize false positives by accounting for known exceptions, such as hospice care, certain cancer diagnoses, 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 through, for example, case management or the coverage determination and appeals process.

If sponsors decide to include a provider count criterion in the soft or hard edit specifications, we recommend a minimum threshold of two prescribers of active opioid prescriptions. To the extent possible, sponsors should prevent the edit from firing when the prescribers are from the same group practice. We also do not recommend a consecutive high-MED 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 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 MED involving one prescriber.

Additional Guidance

Q1: Are soft or hard MED edits safety edits?

A1: Yes. The cumulative MED edit is a safety edit, used to help fulfill concurrent drug utilization review (DUR) requirements outlined in 42 CFR § 423.153(c)(2). The edit should be implemented with minimal burden as possible on the prescribers and beneficiaries. The edit prompts prescribers to conduct additional safety review to determine what level of opioids is appropriate and medically necessary. The edit should not be implemented as a prescribing limit or as a substitute for the clinical judgment of the prescribers.

In addition, the MED edit is not intended to be a fraud, waste and abuse tool, although it may identify such activities.

Q2: Can the soft or hard MED edit be applied during a beneficiary's transition period?

A2: Yes. Since the MED 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.

Q3: When a hard MED edit is triggered and cannot be resolved at the pharmacy, must the beneficiary receive the pharmacy notice?

A3: Yes, 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).

Q4: When a beneficiary or prescriber appeals the hard MED edit, must the sponsor treat this request as a coverage determination?

A4: Yes. 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 MED edit, including the right to request an expedited coverage determination.

Sponsors are reminded that 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 determinations related to the MED edit to meet the criteria for expedited review, which means the plan sponsor must issue a decision within 24 hours of receipt of the coverage determination request.

Q5: Are Part D sponsors permitted to require that specific criteria or requirements be met, such as a referral to a pain specialist, prior to overriding the hard MED edit for a beneficiary?

A5: No.

The hard MED edit is 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 MED level is the intended and medically necessary dose for the beneficiary.

The authorization of the MED level should be considered an approved exception and be valid through the remainder of the plan year. The exception should apply to the cumulative MED 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 MED 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).

Q6: What is CMS' expectation with respect to training and outreach about the MED edits?

A6: 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 should be adequately trained with regard to these edits, including how pharmacists can override soft MED edits at POS using the appropriate NCPDP 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 requests

made by enrollees affected by hard MED edits, which should not be misclassified as inquiries or grievances. Plans are not permitted to instruct an enrollee who is requesting coverage that only their prescriber can initiate that request.

Sponsors should not refer to the MED edit with their enrollees as a "CMS requirement", "CMS mandate", or a prescribing limit. The edits trigger when one or more of the enrollee's opioid prescription(s) exceed a certain high amount of opioids (based on a cumulative MED), prompting additional safety review with prescriber(s) to ensure the amount of opioids is needed to manage the enrollee's pain.

Q7: Should sponsors submit cumulative MED edits even though CMS considers them to be safety edits?

A7: Yes. While safety edits typically are not submitted, in the absence of Food and Drug Administration (FDA) maximum dose labeling for opioids, we expect Part D sponsors to submit information on their cumulative MED safety edits using a template through HPMS. Guidance related to the HPMS submission of the cumulative MED safety edit is provided in Chapter 6 of the Medicare Prescription Drug Benefit Manual. CMS also supplements the guidance annually.

Q8: Are Part D sponsors permitted to modify their MED POS edit parameters during the plan year?

A8: Yes. We understand that some Part D sponsors may need to modify their edits based on additional data or experience that was gained through the implementation of the edit for CY 2017. Sponsors may request to revise their CY 2017 MED POS edit template during the plan year by sending an email to partdformularies@cms.hhs.gov with the subject line of "Cumulative MED POS Edit Request to Revise – [applicable contract ID number(s)]." The email should include:

a. The contract ID(s) associated with this change;
b. The proposed implementation date of the revised edit;
c. A justification for the mid-year change to the MED edit specifications;
d. The revised MED POS edit template that will be submitted to the Health Plan Management System (HPMS) as an attachment.

If the justification and review parameters are acceptable, CMS will notify the sponsor and open the gate for the revised template to be submitted to HPMS.

Q9: Are Part D sponsors permitted to include buprenorphine products in safety edits at POS?

A9: Yes, sponsors may establish safety edits (or prior authorization and quantity limits) for buprenorphine products based on the maximum daily dose in the FDA labeling.

This differs from the Overutilization Monitoring System (OMS) opioid list for retrospective drug utilization review in which all formulations of buprenorphine, except products with a pain indication, were removed. Similarly, we expect that buprenorphine

products for medication-assisted treatment (MAT) would be excluded from the soft or hard cumulative MED safety edit.

It is critical that Medicare beneficiaries who are in need of buprenorphine for MAT have appropriate access to these drugs in Part D.

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 MED POS edit information should be sent to partdformularies@cms.hhs.gov.

Thank you for your continued dedication to helping Medicare beneficiaries.