DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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CENTER FOR MEDICARE

DATE: October 17, 2022

TO: All Part D Plan Sponsors

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

SUBJECT: Termination of Pre-2019 Beneficiary-Specific Part D Opioid Point of Sale Claim Edits

This memorandum provides instructions to Part D sponsors regarding the termination of beneficiary-specific opioid point of sale (POS) claim edits implemented prior to January 1, 2019 ("pre-2019 edits"), both within sponsors' internal systems and in the Medicare Advantage and Prescription Drug System (MARx). Affected sponsors should make the necessary updates described in this memorandum no later than November 10, 2022.

Background

Section 1860D-4(c)(5)(A) of the Social Security Act ("the Act") requires Part D sponsors to have a drug management program (DMP) for beneficiaries at risk for misuse or abuse of frequently abused drugs (FADs). In the April 2019 final rule, "Medicare Program: Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs and the PACE Program" (83 FR 16440), CMS established the regulatory framework for Part D drug management programs (DMPs) at 42 CFR § 423.153(f). At that time, the existing Overutilization Monitoring System (OMS) policy was integrated into the new DMP framework. As part of that integration, sponsors were permitted to continue their pre-2019 edits, subject to certain requirements. In the preamble to the April 2019 final rule (83 FR 16455), CMS stated:

> [B]eneficiaries for whom Part D sponsors have implemented beneficiary-specific POS claim edits for opioids and/or benzodiazepines before January 1, 2019 can continue to be subject to those edits under the current policy after December 31, 2018, which means that they may remain in place unless removed under the current policy. For example, as the result of a coverage determination or appeal. To the extent that such a beneficiary is reported through OMS on January 1, 2019 or later to a sponsor with a drug management program, that sponsor must comply with the requirements we are finalizing in this rule.

In a subsequent HPMS memo, *Validate Opioid Point of Sale Claim Edit Information in the Medicare Advantage and Prescription Drug System*, dated July 20, 2018, CMS issued the following guidance:

> [S]ponsors may not change [pre-2019] edits except in compliance with the requirements in the [2019 final] rule. In other words, beneficiary-specific POS claim edits for opioids and/or benzodiazepines existing before January 1, 2019 can continue without change under the current policy after December 31, 2018 until they are terminated. To the extent that such a beneficiary is reported through OMS on January 1, 2019 or later to a sponsor with a drug management program, that beneficiary must be handled by the sponsor as any other beneficiary reported by OMS would under the sponsor's drug management program.

The Comprehensive Addiction and Recovery Act of 2016 (CARA) revised the Act at section 1860D-4(c)(5)(F), requiring CMS to develop standards for the termination of identification as an at-risk beneficiary, and giving CMS the authority to establish a maximum duration for such identification. At 42 CFR § 423.153(f)(14)(ii), CMS established a maximum duration for identification as an at-risk beneficiary of one year from the effective (start) date of the DMP limitation, with the ability to extend for one additional year, subject to re-review and additional notice to the affected enrollee.

The remaining active MARx records associated with pre-2019 edits do not have end dates and now far exceed the maximum duration permitted for such limitations under 42 CFR § 423.153(f)(14)(ii). As such, CMS expects Part D sponsors to end-date all remaining pre-2019 edits within their internal claims systems and in MARx no later than November 10, 2022.

Action: Systems Updates

To assist plans in making the necessary updates, CMS extracted beneficiary-level data for all pre-2019 edits that remain active in MARx as of October 14, 2022, and will provide this data to associated contracts through the Patient Safety web portal. Affected contracts will receive a separate email notification from our contractor, Acumen, LLC, about the availability of the file.

For each enrollee with an active pre-2019 edit, CMS expects sponsors to do the following:

1. ***Plan Systems:*** If the pre-2019 edit remains active in any of the plan's internal systems, including systems maintained by a downstream entity such as a PBM's claims adjudication system, terminate the edit. The effective date of the termination should be no later than November 10, 2022. CMS recognizes that some pre-2019 edits that remain active in MARx may have already been terminated in the plan's internal systems.
2. ***MARx:*** Through the MARx User Interface (UI) using the MCO CARA Status User role, or the batch submission process, update each affected enrollee's MARx record by adding an Implementation End-Date that reflects the date the edit is terminated in the plan's claims system, which should be no later than November 10, 2022. If possible, we recommend using the MARx UI to make these updates. To terminate an active pre-2019 (Legacy) record, only update the Implementation End-date field.

3. ***Notice:*** Sponsors are not expected to provide notice to affected enrollees or their prescribers regarding these actions.

Note: Pursuant to 42 CFR § 423.153(f)(2), plan sponsors must review any enrollee who has been identified in the most recent OMS report and for whom the plan has not provided a final response to CMS, regardless of whether any such enrollees also have an active pre-2019 edit. At the plan's discretion, pursuant to sections 4.2 and 4.3 of the DMP Guidance, plans are also permitted to apply minimum and/or supplemental OMS criteria and conduct case management for such enrollees. While the pre-2019 edit must be removed, the plan may implement a limitation for these enrollees under their DMP so long as it complies with all current requirements. In accordance with current guidance, Part D sponsors must enter information in OMS and MARx when they make a decision to implement a limitation under their DMP.

Guidance and other documents related to Part D DMPs are available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.

MARx technical guidance can be found in the Plan Communication User Guide: https://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-InformationTechnology/mapdhelpdesk/Plan_Communications_User_Guide.html.

General questions related to DMPs should be sent to PartD_OM@cms.hhs.gov. For technical questions related to the Patient Safety web portal user authorization process or access to the website or reports, contact Acumen at PatientSafety@AcumenLLC.com or by phone at (650) 558-8006.