



## **CENTER FOR MEDICARE**

TO: All Part D Plan Sponsors

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

SUBJECT: Validate Opioid Point of Sale Claim Edit Information in the Medicare Advantage and Prescription Drug System

DATE: July 20, 2018

The purpose of this memorandum is to prompt Part D sponsors to review and update current opioid point of sale (POS) beneficiary-specific claim edit information in the Medicare Advantage and Prescription Drug System (MARx) by August 31, 2018 in preparation for implementation of the new drug management programs taking effect in 2019.

### **Background**

On April 16, 2018, CMS promulgated a final rule that implements the statutory provisions of the Comprehensive Addiction and Recovery Act of 2016 (CARA) that included new authority for Medicare Part D plans to establish drug management programs effective on or after January 1, 2019. Through this final rule, CMS has established a framework under which Part D plan sponsors may establish a drug management program for beneficiaries at risk for prescription drug abuse or misuse, or “at-risk beneficiaries.”

Under drug management programs, Part D plans will engage in case management of potential at-risk beneficiaries through contact with their prescribers. Potential at-risk beneficiaries meet clinical guidelines / Overutilization Monitoring System (OMS) criteria that take into account the dosage of opioids and the existence of multiple opioid prescribers and multiple pharmacies dispensing the opioids. After case management and notification, sponsors may limit at-risk beneficiaries’ access to coverage of controlled substances that CMS determines are “frequently abused drugs” (i.e., opioids and benzodiazepines) to a selected prescriber(s) and/or network pharmacy(ies), or they may implement beneficiary specific claim edits for such drugs, for the safety of the beneficiary. Thus, as we stated in the rule, the rule codified many aspects of the current Part D Opioid Drug Utilization Review (DUR) Policy and OMS by integrating them into the drug management program provisions.

Part D sponsors have implemented beneficiary specific POS claim edits for opioids and benzodiazepines under the current policy, which was adopted in contract year 2013. With respect to these edits, in the final rule, we 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.” 16440 Fed. Reg. 16455 (April 16, 2018).

We wish to add to this guidance that sponsors may not change such existing edits except in compliance with the requirements in the 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.

In accordance with current guidance<sup>1</sup>, Part D sponsors should enter information in MARx when they have made a decision to implement a beneficiary-specific POS edit for opioids, including the notification, implementation, and termination dates of such POS edits.

### **Action: Data Validation**

In order for MARx to accurately distinguish beneficiaries with current, active opioid POS edits from those who are subject to opioid and / or benzodiazepine coverage limitations, including edits, through a drug management program beginning in 2019, the data in MARx related to these current edits must be accurate and up-to-date. This is especially important because beneficiaries with current edits are not subject to a limitation on the use of the special enrollment period (SEP) under the current policy. In contrast, however, the final rule limits the use of the SEP for dually- or other low income subsidy (LIS)-eligible beneficiaries by those who will be identified as at-risk or potentially at-risk for prescription drug abuse under a drug management program starting in 2019. This limitation will be operationalized through the use of MARx data.

Therefore, we are asking Part D sponsors to conduct validation of the current opioid POS edit MARx data. To facilitate this data validation, CMS extracted current opioid POS edit data from MARx as of July 10. Within the July 2018 Detail OMS report package that will be distributed at the end of this month, an additional file will be made available to contracts with a list of beneficiaries with current opioid POS edit information from MARx. Your contract will also receive a separate email notification from our contractor, Acumen, LLC, about the availability of the file.

For each beneficiary with an active opioid POS edit, review the data that has been entered in MARx and verify that the information is correct. If any information for a given beneficiary requires updating, please do so within the MARx system. No additional response via the OMS response form or email is needed for this ad hoc data review. For example,

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<sup>1</sup> HPMS Memo, UPDATES – 2018 Medicare Part D Overutilization Monitoring System, January 19, 2018.

- For beneficiaries with a notification date and no implementation date, enter the implementation date in MARx or a termination date as appropriate.
- For beneficiaries with a notification date and an implementation date, validate that the opioid POS edit is still active and the dates entered are correct.
  - If still active, no further action needed.
  - If no longer active, enter a termination date.

If your contract did not receive the file through OMS or a separate email notification, and you do not have any beneficiaries with active opioid POS edits, no further action is needed. However, if you do have beneficiaries with active opioid POS edits, make sure the information is entered in MARx.

We request that Part D sponsors complete this data validation by August 31, 2018.

Technical guidance on the MARx POS Edit Database can be found in the Plan Communication User Guide found here:

[https://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/mapdhelppdesk/Plan\\_Communications\\_User\\_Guide.html](https://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/mapdhelppdesk/Plan_Communications_User_Guide.html)

HPMS memos and other documents related to the OMS and drug utilization management (DUM) guidance regarding opioid overuse are available on CMS.gov:

<https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html>

Any general questions related to the OMS should be sent to [PartD\\_OM@cms.hhs.gov](mailto:PartD_OM@cms.hhs.gov). For technical questions related to the user authorization process or access to the website or reports, please contact Acumen at [PatientSafety@AcumenLLC.com](mailto:PatientSafety@AcumenLLC.com) or by phone at (650) 558-8006.

Additional guidance will be released in Fall 2018 on CARA drug management programs, including updates to MARx.