

## **Frequently Asked Questions about Part D Drug Management Programs (DMPs)**

### **OMS Criteria**

- 1) **If a plan sponsor wants to target potential at-risk beneficiaries (PARBs) through its DMP by applying the Overutilization Monitoring System (OMS) criteria itself, can the sponsor initiate case management and send beneficiary notices before OMS reports the case to the sponsor?**

Yes. CMS identifies cases that meet the minimum OMS criteria and reports to Part D plan sponsors quarterly. Sponsors may apply the minimum OMS criteria more frequently than CMS does and / or apply the supplemental OMS criteria themselves. Sponsors must submit responses to OMS within 30 days after the most recent OMS report for each of the CMS-identified or sponsor-identified cases. Sponsors do not need to wait to receive an OMS report from CMS to initiate case management for sponsor-identified cases and send beneficiary notices, if applicable.

### **OMS Reports**

- 2) **Will a plan sponsor without a drug management program (DMP) receive OMS reports?**

No. Part D plan sponsors without a DMP will not receive reports from OMS and may not implement beneficiary-level POS edits, or prescriber and/or pharmacy limitations (i.e., “lock-in”) for frequently abused drugs (FADs = opioids or benzodiazepines) outside of a DMP starting January 1, 2019.

Sponsors without a DMP must comply with 42 CFR § 423.153(b)(2) which requires that a Part D sponsor have established a reasonable and appropriate drug utilization management (DUM) program that addresses the maintenance of policies and systems to assist in preventing overutilization of prescribed medication. Given the national opioid crisis, CMS expects such a program to focus on opioid overutilization, such as the potential overutilization reflected in the beneficiaries identified by the minimum OMS criteria. However, we do not have specific guidance for plan sponsors without a DMP to comply with 42 CFR § 423.153(b)(2).

- 3) **With the additional detail that sponsors are required to report through the OMS in 2019, would CMS extend the first OMS reporting deadline?**

No. Plan sponsors with DMPs must provide responses on new and pending cases in an OMS report within 30 days of that report. The first 2019 OMS report will be provided to sponsors at the end of January 2019. Initial notices may only be sent to a beneficiary if a sponsor has completed case management and intends to implement a coverage limitation for FADs. A beneficiary has 30 days to respond to an initial notice. CMS

expects that in many cases, sponsors will choose the response “Initial Review in Progress” for the first OMS report response deadline. Therefore, CMS does not believe an extension to the first OMS reporting deadline will be necessary.

**Prescriber Inquiry and Sponsor Information Transfer Templates**

- 5) **By what date are plan sponsors required to start using the prescriber inquiry and sponsor information transfer templates? Also, will CMS be providing any other templates?**

The prescriber inquiry and sponsor information transfer templates provided in the November 20, 2018 guidance memo are samples only. Plan sponsors can develop their own notices to communicate with prescribers and other sponsors with DMPs.

Sponsors must communicate with prescribers in writing when they initiate case management. Also, losing sponsors must transfer case management information to gaining sponsors as soon as possible but no later than 2 weeks from the gaining sponsor’s request when a PARB 2 or ARB 2 disenrolls from the losing sponsor’s plan and enrolls in a plan offered by the gaining sponsor; and the pending or implemented coverage limitation for FADs that the losing sponsor had entered into MARx for the beneficiary had not terminated before disenrollment. Sponsors should respond to such requests in writing. As it takes time for sponsors to implement coverage limitations and beneficiaries to change plans, CMS does not expect sponsors to have to respond to many such requests in the first quarter 2019. Finally, CMS will not be issuing a template for prescriber notification/agreement/confirmation.

**Transition from Pre-2019 Part D Opioid Overutilization Policy to DMPs in 2019**

- 6) **If an enrollee has an active beneficiary-specific POS claim edit (under pre-2019 opioid policy), can it remain in place?**

Yes. However, such beneficiaries will not be suppressed from OMS reporting. Also, if a beneficiary with an active edit implemented prior to 2019 meets the minimum OMS criteria, then the plan sponsor must review the beneficiary under its DMP. Based on this review, the sponsor must remove the edit if it determines the beneficiary does not meet the OMS criteria or is exempted from DMPs; however, the plan is not required to notify the beneficiary that the edit has been removed. If the sponsor intends to continue the edit, the sponsor must describe it (and any additional coverage limitations) in the Initial Notice to the beneficiary.

Also, please note that if a beneficiary with an active edit implemented prior to 2019 enrolls in a different Part D plan after January 1, 2019, a New Enrollee CARA Status Notification will not be reported to the gaining plan indicating the beneficiary had an existing edit in the prior plan, and the edit may not continue unless the beneficiary meets the 2019 OMS criteria and the gaining plan determines that a coverage limitation is necessary for the beneficiary under the rules for DMPs.

- 7) **If enrollee remains in the same Part D plan and wants to dispute or change an active beneficiary-specific POS claim edit that was implemented prior to 2019, should the request be handled as a coverage determination (per pre-2019 Part D opioid overutilization policy) or as a redetermination (per 2019 DMP rules)? What if the prescriber wants to change the MME level for the edit?**

For a beneficiary-specific POS claim edit implemented prior to the 2019 plan year that the enrollee wants to change or dispute, the plan sponsor should attempt to resolve the issue via case management. If the matter can't be resolved in the enrollee's favor via case management, the request is processed as a coverage determination (which the enrollee has the right to request at any time). An enrollee's prescriber can also request a coverage determination on the enrollee's behalf if the prescriber believes the MME should be modified.

- 8) **May a sponsor implement a beneficiary-specific POS claim edit in 2019 if the beneficiary was sent a letter in 2018 with an effective edit date in 2019?**

No. A plan sponsor must not implement a new beneficiary-specific POS claim edit for opioids or benzodiazepines in 2019 under the pre-2019 Part D overutilization policy. Any coverage limitations for opioids and benzodiazepines implemented in 2019 must be done under a DMP.

### **Exemptions**

- 9) **If a beneficiary was a resident of a long-term care (LTC) facility and is now at home, and a sponsor is applying the OMS criteria itself, when reviewing the previous 6 months, should the sponsor include the prescribers/pharmacies from the beneficiary's time in the LTC facility or is that period exempt?**

CMS does not exempt any periods when applying the OMS criteria and neither should sponsors.

## **Appeals**

- 10) **If an enrollee appeals after 60 days from receiving the second notice, can this be handled through case management? We read that a member can request a coverage determination at any point.**

An enrollee has 60 calendar days from the date of the second notice to request a redetermination. The plan sponsor has the discretion to extend the timeframe for filing a redetermination if the plan sponsor finds good cause for late filing. If the 60 calendar day timeframe has lapsed, the plan sponsor should attempt to resolve the issue via case management. If the matter can't be resolved in the enrollee's favor via case management, process it as a coverage determination.

- 11) **If a prescriber responds to initial written outreach that the medications are safe, medically necessary and appropriate and patient is not at-risk, and the plan determines to not implement a coverage limitation, does the DMP clinical staff still have to speak to the provider as part of case management to fulfill the other educational suggestions of PDMP use, SUD screenings/assessments, and CDC Guideline?**

No. We encourage Part D plan sponsors to undertake these suggestions as they see appropriate, but they are not required at this time. Also, we note that if a sponsor marks a case as resolved, the case may be suppressed from OMS reporting for a defined period of time. See OMS User Guide for the suppression rules.

- 12) **Please provide clarification around the following scenarios. Should the DMP staff address these issues or should they go to the grievance/appeals department?**

- **When an enrollee calls to request a change in pharmacy and/or prescriber limitations or a provider calls to request a change in a beneficiary-specific POS claim edit:**

DMP staff, assuming the time to request an appeal on the issue has lapsed. The plan sponsor should attempt to resolve the issue via case management. If the matter can't be resolved in the enrollee's favor via case management, process as a coverage determination.

- **When an enrollee calls because they don't agree with their Initial Notice determination.**

DMP staff; at this point in the process, the enrollee can submit additional information if the enrollee disagrees with the intended action.

- **When an enrollee calls because they don't agree with their Second Notice determination.**

Appeals department, assuming the time to request an appeal has not lapsed. The enrollee has 60 calendar days from the date of the second notice to request a redetermination. The plan sponsor has the discretion to extend the timeframe for filing a redetermination if the plan sponsor finds good cause for late filing, if the time to request an appeal has lapsed. See 12a.