Frequently Asked Questions (FAQs) About Drug Management Programs (DMPs)

Revised September 30, 2021

This FAQ document *replaces section IX of the 2021 Part D Drug Management Program Guidance memo issued December 23, 2020.* FAQs have been renumbered. New information has been added in red italics.

PACE and EGWPs

1) Does CMS expect EGWPs and PACE *organizations* to have DMPs?

Yes. *DMPs are mandatory for all Part D sponsors starting in CY 2022, consistent with section 2004 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (SUPPORT Act). The statute does not specify or contemplate exemptions based on Part D plan type. In 85 FR 33796, CMS amended language at 42 CFR § 423.153(f)(1) to account for Part D sponsors, including PACE organizations, that do not have their own or contracted P&T committee to comply with the DMP requirement by having written DMP policies and procedures that are approved by the Part D sponsor's medical director and applicable clinical and other staff or contractors, as determined appropriate by the medical director.*

Case Management

2) We are concerned about the time involved before beneficiaries can be determined to be at-risk under our plan's DMP, especially when they are new to our plan.

While the identification, case management, and notification process of DMPs takes some time, no beneficiary's Part D coverage of *frequently abused drugs (*FADs*)* should be limited under a DMP without a thorough review of their health care circumstances. *In addition, we have stated that DMPs should prioritize beneficiaries whose use of FADs puts them at the highest risk.* Also, some of this process may be shortened if the new plan receives a notice from the immediately prior plan that the beneficiary was identified as a PARB or ARB by the previous plan. Finally, keep in mind that all beneficiaries in a Part D prescription drug benefit plan are subject to their plan's formulary-level POS controls to address opioid overutilization. *S*ee the CMS webpage, "Improving Drug Utilization Review Controls in Part D," for additional guidance on other initiatives to reduce opioid overutilization in Medicare Part D: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html.

OMS Criteria

3) We discovered that a beneficiary does not meet the OMS criteria because the prescribers are in a group practice or the high opioid use was due to appropriate prescription overlap. What do we do?

A beneficiary who does not meet OMS criteria cannot be included in a DMP. The action that the sponsor should take depends upon when the sponsor discovers this information. If the sponsor

determines that the beneficiary does not meet the OMS criteria during case management, the sponsor is not permitted to limit the beneficiary's coverage of FADs under a DMP. Although this should not happen with thorough case management, if the sponsor learns that a beneficiary does not meet the OMS criteria after providing an Initial Notice to the beneficiary, the sponsor must send the beneficiary an Alternate Second Notice. If the sponsor obtains this information after a *coverage* limitation has been implemented, the sponsor must immediately remove the limitation and notify the beneficiary that it has done so. The sponsor must also update OMS*, by using the Sponsor Response Form (SRF),* and MARx, as applicable.

4) We have our own method for identifying group prescriber practices. Do we have to do it by the TIN numbers?

Given that there is no industry standard for identifying group practices through data analysis alone, a Part D sponsor can use any reasonably reliable method that it has developed to exclude beneficiaries from their DMPs. However, the sponsor should self-audit at reasonable intervals to test that its method is reasonably reliable, up-to-date, and that it has not overlooked potential ARBs who would benefit from its DMP.

5) A physician has requested that we "lock in" one of their patients to the physician for prescriptions for opioids; however, the patient is not under review in our DMP. Can we do so for the patient's safety?

While we understand the goal of patient safety, a sponsor may not implement a limitation on a beneficiary's access to coverage for FADs only in response to their physician's request. The sponsor must follow the Part D requirements of a DMP, including that the beneficiary must meet the current OMS criteria.

Exempted Beneficiaries

6) How should a DMP handle ARBs who move in and out of an LTC facility?

An ARB who moves into an LTC facility becomes an individual exempted from a DMP and a sponsor must remove the beneficiary from such program as soon as it reliably learns that the beneficiary has moved into an LTC facility, whether that be via the beneficiary, the facility, a pharmacy, a prescriber, or an internal or external report. A beneficiary who moves out of an LTC facility is no longer exempted unless he or she meets another prong of the definition of exempted beneficiary. Such beneficiary may be identified by OMS or by a sponsor as a PARB if they meet the OMS criteria.

Limitations on Access to Coverage for FADs

7) We intend to implement a pharmacy limitation on an ARB's access to coverage for opioids. However, while all 3 prescribers agree that the beneficiary is at-risk, 1 prescriber offered that they would not want their patient to be "locked-in" to a pharmacy. Can we proceed with the limitation?

It depends. If a prescriber proactively alerts a plan sponsor that they do not believe that a pharmacy limitation is appropriate for a particular ARB, we expect the plan sponsor to take such information into consideration. In this case, the sponsor might inquire what the specific reason is

for the prescriber's opinion and take it into consideration. For example, if the prescriber states that the patient typically uses one pharmacy near their home and another pharmacy near where they work, a pharmacy limitation may not be the best approach for the beneficiary and the sponsor could ask if the prescriber would agree to a prescriber limitation instead. However, if the prescriber states that the reason is that the beneficiary splits their year between two homes in different states, the sponsor may be able to change the prescriber's opinion of a pharmacy limitation if the sponsor explains that the sponsor will limit the beneficiary to 2 pharmacies instead of 1 to provide reasonable access. If the prescriber does not change their mind, the sponsor must decide if it is reasonable to proceed with the pharmacy limitation and document their reasoning in the case file and should monitor if the pharmacy limitation is resolving the case without issues.

8) How do we handle a prescriber who insists that they must be able to continue to prescribe FADs for the beneficiary but will not agree to be the selected prescriber?

A sponsor is not permitted to limit a beneficiary's access to FADs to a prescriber who does not agree to be the selected prescriber. If another prescriber has agreed to serve as the selected prescriber, the unwilling prescriber cannot prescribe FADs for the beneficiary. A plan sponsor may reasonably need to ask the unwilling prescriber again if he or she would agree to be a selected prescriber for their patient who is under a prescriber limitation in certain scenarios.

For example, in order to ensure reasonable access, if a beneficiary has been obtaining opioids from multiple prescribers and benzodiazepines from one psychiatrist, a sponsor may have to permit an ARB to obtain opioids from the prescriber who agreed to the prescriber limitation and benzodiazepines from the psychiatrist, who initially did not agree, but ultimately does agree. Thus, the ARB would have a prescriber limitation to 2 prescribers.

9) Is a gaining plan sponsor required to immediately apply a coverage limitation to an ARB who was subject to one in the immediately prior plan?

No. A Part D sponsor is responsible for its own DMP and should take the action it believes is the most appropriate to promptly address opioid overutilization in their plans after case management or reviewing the case management documentation from the losing sponsor. As such, a sponsor may, but is not required to, immediately implement a coverage limitation if the requirements that apply to such cases are met. Gaining sponsors should be aware that if they do not take such action, the beneficiary may be later reported through OMS if the beneficiary meets the OMS criteria.

Beneficiary Preferences

10) We are hearing that Part D sponsors may refuse to cover any opioid drug under their DMPs that is not prescribed by a board-certified pain specialist, that is, a prescriber who has maintained certification in a pain subspecialty within American Boards of Medical Specialties (ABMS) of anesthesiology, family medicine, neurology, emergency medicine, neurology, or radiology. Is this true?

No. When a Part D sponsor limits an ARB's access to coverage for FADs through a pharmacy or prescriber coverage limitation, the sponsor's selection of a pharmacy and/or prescriber, as applicable, generally must be based on the beneficiary's preference.

11) As a Part D plan sponsor, we own some of our network pharmacies. Do we have to provide notification and confirmation when the selected pharmacy is one of our corporate network pharmacies?

If the corporate network pharmacy is a separate legal entity from the legal entity of the plan sponsor, then there should be a network agreement between these entities that covers such notifications and confirmations. If they are the same legal entity, then notification and confirmation are automatic.

12) Are there special considerations for ARBs who are entitled to fill prescriptions or receive services from Indian Health Service (IHS), Tribal, and Urban Indian (I/T/U) organization pharmacies and providers?

Yes, an IHS I/T/U pharmacy or prescriber may be the selected pharmacy or prescriber for such beneficiaries and they may go to such a pharmacy or prescriber pursuant to the reasonable access requirement, even if they are not in the plan sponsor's network.

13) If the selected pharmacy(ies) for an ARB is part of a chain that shares real-time electronic data, do we have to program every location into our claims processing system for that ARB?

Not necessarily. The name and location of the selected pharmacy(ies) will be in the Second Notice to the ARB (or in any subsequent notice to the ARB due to a change in selection), whether the beneficiary submitted preferences or not. ARBs must be able to access FADs at the selected pharmacy(ies) named in such notice. Some of these pharmacy(ies) will be part of a chain with multiple locations that share real-time electronic data. We do not have specific guidance on how sponsors implement the requirement operationally to collectively treat all such locations as one pharmacy, other than that sponsors must also provide ARBs who are subject to a pharmacy limitation with reasonable access to FADs. For example, sponsors may want to program in additional locations that the beneficiary has used occasionally in the past, or implement the requirement in some other reasonable way.

14) Similarly, if the selected prescriber(s) for an ARB is part of a group practice, do we have to program every prescriber of FADs in the group into our claims processing system for that ARB?

Again, not necessarily. The name of the selected prescriber(s) will be in the Second Notice to the ARB (or in any subsequent notice to the ARB due to a change in selection), whether the beneficiary submitted preferences or not. ARBs must be able to access FADs from the selected prescriber(s) named in such notice. Some of these prescriber(s) will be part of a group practice. We do not have specific guidance on how sponsors implement the requirement operationally to treat prescriber(s) in a group practice as one prescriber, other than that sponsors must also provide ARBs who are subject to a prescriber limitation with reasonable access to FADs. For example, sponsors may want to ask the selected prescriber(s) as part of the confirmation process, if there are other prescribers of FADs in their group practice with whom they coordinate care and from whom the selected prescriber(s) would want the ARB to be able to obtain prescriptions for FADs, such as when the selected prescriber is on vacation or otherwise has a colleague temporarily covering for them. If so, sponsors may want to program in such other prescribers' NPIs into their claims systems for the ARB, or implement the requirement in some other reasonable way.

Appeals

15) *P*rovide clarification around the following scenarios. Should the DMP staff address these issues or should they go to the grievance/appeals department?

- **When 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 the Initial Notice.**

  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.

Prescriber Inquiry *Letter* and Sponsor Information Transfer *Memo*

16) *A*re plan sponsors required to us*e* the prescriber inquiry *letter* and sponsor information transfer *memo*? Also, will CMS be providing any other templates?

The prescriber inquiry *letter* and sponsor information transfer *memo* are *model documents, not standardized materials*. Plan sponsors *may use all or part of the language in the models, modify the language, or* develop their own notices to communicate with prescribers and other sponsors. *CMS will not be issuing a template for prescriber notification / agreement / confirmation.*

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

17) 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 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 OMS criteria and the gaining plan determines that a coverage limitation is necessary for the beneficiary under the rules for DMPs.

18) 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.

Other

19) We understand the 569 reject code should be suppressed for claims that are rejected at the point of sale due to a coverage limitation implemented under our plan's DMP. However, when a claim also rejects for another reason that would normally trigger the 569 reject code, should the 569 code still be suppressed?

No. In such cases, the plan is still required to return the 569 reject code and instruct the network pharmacy to distribute a copy of the standardized pharmacy notice, "Medicare Prescription Drug Coverage and Your Rights" (CMS-10147) to the affected enrollee if the issue cannot be resolved at the point of sale.

20) Can beneficiaries in a DMP also be subject to their plan's formulary-level POS edits to address opioid overutilization?

Yes. Formulary and coverage rules apply to all enrollees (unless they obtain an exception) whether or not they are in the sponsor's DMP. A Part D sponsor's concurrent and retrospective DUR programs should be closely coordinated. In certain circumstances, it may be appropriate for a sponsor to make an at-risk determination through the DMP for a beneficiary who received an approved exception to a cumulative opioid MME safety edit, and as part of the at-risk determination, may determine that continuing the approved exception is no longer appropriate.

In the CY 2019 and 2020 final Medicare Parts C&D Call Letters, CMS provided guidance regarding our expectation that Part D sponsors implement a real-time opioid Care Coordination safety edit, at the time of dispensing, as a proactive step to engage both patients and prescribers about overdose risk and prevention. This safety edit should be based on a cumulative morphine milligram equivalent (MME) threshold of 90 MME per day and may include prescriber/pharmacy counts. Sponsors will continue to have the flexibility to implement hard safety edits at a threshold of 200 MME or more, with or without prescriber/pharmacy counts. Additionally, to reduce the potential for chronic opioid use or misuse, CMS expects all Part D sponsors to implement a hard safety edit to limit initial opioid prescription fills for the treatment of acute pain to no more than a

7 day supply. All current guidance regarding coverage of opioids under the Part D program can be found at the *CMS* Part D Overutilization website at: https://www.cms.gov/Medicare/Prescription- Drug-coverage/PrescriptionDrugCovContra/RxUtilization.html.

For example, a plan implemented a hard formulary-level cumulative MME opioid edit at 200 MME with 2 or more opioid prescribers. A beneficiary received their opioids from 2 prescribers and has a cumulative MME that exceeds 200 MME. They trigger the edit and request a coverage determination. The prescriber attests to medical necessity and the exception request is approved. At a later time, the beneficiary seeks opioids from 3 additional prescribers, and meets the OMS criteria.

21) If coverage of FADs is limited under a Part D DMP, does this mean that FADs are no longer covered Part D drugs?

No. Despite a DMP limitation, FADs are still considered covered Part D drugs as defined at 42 CFR § 423.100.