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**DATE:** September 30, 2021

**TO:** All Prescription Drug Plans, Medicare Advantage-Prescription Drug Plans, Section 1876 Cost Plans, Medicare-Medicaid Plans, and PACE Organizations

**FROM:** Amy Larrick Chavez-Valdez  
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**SUBJECT:** Contract Year 2022 Part D Drug Management Program Guidance

This memorandum provides updated information to Part D sponsors regarding contract year (CY) 2022 Drug Management Programs (DMPs).

Following is a summary of changes compared to the December 23, 2020 memorandum, “2021 Part D Drug Management Program Guidance.” New and revised text in the attached guidance is shown in red, italicized font.

- **Throughout:** Sections have been renumbered for clarity.
- **Throughout:** Updated guidance to reflect regulations codified through CMS-4190-F2, Medicare and Medicaid Programs; Contract Year 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly ([86 FR 5864](#)), including mandatory DMPs, inclusion of beneficiaries with a history of opioid-related overdose in DMPs, and beneficiaries with sickle cell disease as exempted beneficiaries.
- **Throughout:** Edits made to clarify existing policy. Content that was redundant of Overutilization Monitoring System (OMS) technical guidance was removed and cross references added.
- **Section 8.4:** Added section heading for appeals and updated related information.
- **Frequently Asked Questions (FAQs):** The FAQs have been removed and will be maintained as a separate document on the [CMS Part D Overutilization website](#). Some content originally in FAQs was integrated into the guidance document.

*The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law.*

Additional resources and guidance available on the [CMS Part D Overutilization website](#) include:

- Updated CY 2022 OMS technical guidance.
- Final rules CMS-4182-F ([83 FR 16440](#)) and CMS-4190-F2 ([86 FR 5864](#)) codifying the initial framework for DMPs and program updates, including mandatory DMPs, inclusion of beneficiaries with history of opioid-related overdose in DMPs, and exemption of beneficiaries with sickle cell disease exempt from DMPs.
- Updated standardized beneficiary notices, model prescriber inquiry letter, and model transfer memo associated with PRA package CMS-10141 (OMB Control No. 0938-0964) (will be posted upon approval).
- Frequently Asked Questions (FAQs) about DMPs.

Further information about appeals of at-risk determinations can be found in the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance posted here:

<https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/Downloads/Parts-C-and-D-Enrollee-Grievances-Organization-Coverage-Determinations-and-Appeals-Guidance.pdf>

We appreciate the continuing diligent efforts of Part D sponsors to operate DMPs. Questions about DMPs may be submitted to [PartD\\_OM@cms.hhs.gov](mailto:PartD_OM@cms.hhs.gov).

# PART D DRUG MANAGEMENT PROGRAMS

*Rev. 3, September 30, 2021  
Implementation: January 1, 2022*

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## **1. Introduction**

*Section 1860D-4(c)(5)(A) of the Social Security Act permits Part D sponsors to establish drug management programs (DMPs) for beneficiaries at-risk for misuse or abuse of frequently abused drugs (FADs). Sections 2004 and 2006 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act of 2018, amended sections 1860D-4(c)(5)(A) and (C) of the Social Security Act such that all Part D sponsors are required to have DMPs by January 1, 2022 and beneficiaries with a history of opioid-related overdose are to be included in DMPs. DMP requirements are codified at [42 CFR § 423.153\(f\)](#).*

*Throughout this guidance, we use the term “Overutilization Monitoring System (OMS) criteria” synonymously with the term “clinical guidelines” that is used in the applicable regulatory text. See [section 4](#) for more information about OMS.*

The goal of all DMPs must be to address overutilization of *frequently abused drugs* (FADs) while maintaining access to such drugs as medically necessary. DMPs review potential at-risk beneficiaries (PARBs) who meet the OMS criteria. Under such programs, Part D sponsors engage in case management of such beneficiaries through contact with their prescribers to determine if a beneficiary is at risk. After notification to the beneficiaries, sponsors may then limit at-risk beneficiaries’ (ARBs’) access to coverage of FADs to a selected network prescriber(s) (when applicable) and/or network pharmacy(ies) or through a beneficiary-specific point-of-sale claim edit for the safety of the ARB. In general, the beneficiary may select the prescriber and pharmacy.

## **2. Potential At-Risk Beneficiaries (PARBs) and At-Risk Beneficiaries (ARBs)**

*In [42 CFR § 423.100](#), a PARB is defined as a beneficiary who is not exempted from DMPs, meets the clinical guidelines described at [42 CFR § 423.153\(f\)\(16\)](#), or who was identified as a PARB by the sponsor of the beneficiary’s immediately prior Part D plan under its DMP and such identification had not been terminated before disenrollment.*

For purposes of this guidance, a PARB 1 refers to a beneficiary who meets the OMS criteria and is identified by CMS or *their current* sponsor. A PARB 2 refers to a beneficiary about whom a gaining plan sponsor receives notice upon the beneficiary’s enrollment through the *Medicare Advantage Prescription Drug (MARx)* system that the beneficiary was identified as potentially at-risk by the immediately prior plan sponsor under its DMP, but a coverage limitation on FADs had not yet been implemented by the prior plan before the beneficiary disenrolled.

In [42 CFR § 423.100](#), an ARB is defined as a beneficiary who meets the clinical guidelines described at [42 CFR § 423.153\(f\)\(16\)](#), is not exempted from DMPs, and is identified to be at-risk by their Part D plan sponsor under its DMP, or who was identified as an ARB by the sponsor of the beneficiary’s immediately prior Part D plan under its DMP and such identification had not been terminated before disenrollment.

For purposes of this guidance, an ARB 1 refers to a beneficiary who was identified as at-risk under their Part D plan's DMP. An ARB 2 refers to a beneficiary about whom a new plan sponsor receives notice upon the beneficiary's enrollment through the MARx system (*on the Daily Transaction Reply Report (DTRR)*) that the beneficiary was identified as at-risk by the immediately prior plan sponsor under its DMP and a coverage limitation(s) on FADs had been implemented by the prior plan before the beneficiary disenrolled.

*Note: If an ARB changes plans within a contract, CMS does not consider the beneficiary to be an ARB 2 and the beneficiary will not be reported by MARx.* If an ARB changes contracts, even if both *contracts* are held by the same legal entity or parent organization (*i.e., Part D sponsor*), CMS does consider the beneficiary to be an ARB 2 and the beneficiary will be reported by MARx.

*For more information about* notifications about PARB 2s and ARB 2s *to sponsors* through MARx system, see [\*section 11\*](#).

Under DMPs, the use of the special enrollment period (SEP) for dually- or other low-income subsidy (LIS)-eligible beneficiaries is limited for those LIS-eligible beneficiaries who are identified as PARBs or ARBs. Further information on the SEP limitation can be found in the enrollment guidance posted at: <https://www.cms.gov/medicare/eligibility-and-enrollment/medicarepresdrugeligenrol>.

### **3. Frequently Abused Drugs (FADs)**

Frequently abused drug, as defined at [42 CFR § 423.100](#), *is a controlled substance that the Secretary determines, based on several factors, is frequently abused or diverted. CMS has determined that* opioids (except buprenorphine for medication-assisted treatment [MAT] and injectables) and benzodiazepines are FADs for purposes of Part D DMPs. This means that methadone for pain is included in the definition of a FAD for purposes of Part D DMPs. CMS uses prescription opioids, including all formulations of buprenorphine for pain and MAT, to determine opioid prescribers and opioid dispensing pharmacies in the OMS criteria.

*While* current OMS criteria (*as described in section 4*) only consider opioid use and not benzodiazepines for purposes of identifying PARBs, CMS will continue to flag PARBs through OMS who have concurrent opioid and benzodiazepine use to assist sponsors in determining whether such use is an issue, and if so, to address such use through their DMPs. *Thus, a* beneficiary who is determined to be at-risk based on *OMS criteria* could have a coverage limitation applied under a DMP to both opioids and benzodiazepines to manage current and future concurrent use. *It* is possible for a sponsor to apply a limitation only on an ARB's access to coverage for benzodiazepines. CMS expects to see this happen rarely in practice because the ARB would have to have met the OMS criteria, which look at opioid use that is potentially risky. Nevertheless, we acknowledge that prescriber agreement during case management could lead to such an outcome on occasion. For example, if *during case management, the benzodiazepine prescriber agrees to a coverage limitation* for benzodiazepines and no opioid prescriber agrees to a coverage limitation for opioids, but all but one opioid prescriber states they will no longer

prescribe opioids to the beneficiary, *then a coverage limitation on opioids may not be necessary.*

#### **4. OMS Criteria for Identification of PARBs**

OMS refers to the CMS system that reports PARBs to sponsors and which sponsors use to provide updates on each case to CMS.

*PARBs are the Part D beneficiaries whom CMS believes are **potentially** at the highest risk of **opioid-related** adverse events or overdose. **There are minimum criteria and supplemental criteria, as explained in sections 4.1 and 4.2. The **minimum** OMS criteria **that are based in part on morphine milligram equivalents (MME)** are not to be used as a maximum threshold for prescribing opioids or **used** to imply that a lower dosage is universally safe. Rather, in the absence of dosing limits in the FDA-approved labeling for opioids, **CMS uses** the Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain<sup>1</sup> to establish a threshold **in the minimum criteria** to identify PARBs who may benefit from better care coordination **and/or** closer monitoring and to create alignment between **government** programs. Under DMPs, decisions about the amount of FADs an ARB receives are made by the beneficiary's prescriber(s), **except when** no prescriber is responsive to the DMP's efforts to make clinical contact during case management. **In such cases, the amount may be set by the Part D sponsor that has decided to implement a beneficiary point-of-sale claim edit. See sections 7.3 and 7.4.*****

Of note, *while* benzodiazepines are a FAD for purposes of Part D DMPs, *they* are not a factor in OMS criteria. Similarly, buprenorphine products are not used to determine the beneficiary's average daily MME. However, prescription opioids, including all formulations of buprenorphine for pain and MAT, are used to determine opioid prescribers and opioid dispensing pharmacies under the minimum criteria. Similarly, sponsors *should* include all prescription opioids, including all buprenorphine products, to determine opioid prescribers and opioid dispensing pharmacies under the supplemental criteria.

A beneficiary who does not meet OMS criteria cannot be included in a DMP, *which also means that if the Part D sponsor determines that the beneficiary does not meet the OMS criteria during case management or otherwise, the Part D sponsor is not permitted to limit the beneficiary's coverage of FADs under a DMP.*

##### **4.1. Minimum OMS Criteria**

Sponsors must review all beneficiaries meeting the minimum OMS criteria. Also, OMS will only report beneficiaries meeting the minimum criteria. Unless the sponsor determines that the beneficiary is exempt from DMPs or does not meet the OMS criteria based on plan information, the sponsor must engage in case management with the prescribers of FADs for beneficiaries meeting the minimum OMS criteria (*see section 7.2*) and must report information to OMS (*see section 11.2*).

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<sup>1</sup> <https://www.cdc.gov/drugoverdose/prescribing/guideline.html>.

Minimum OMS criteria are based on the following specifications (criteria 1 **OR** 2 must be met; however, PARBs may meet both types of criteria):

- 1) *Level of opioid use from multiple prescribers/pharmacies:*
  - *Use of opioids with average daily MME  $\geq$  90 mg for any duration during the most recent 6 months AND either:*
    - *3+ opioid prescribers AND 3+ opioid dispensing pharmacies; OR*
    - *5+ opioid prescribers (regardless of the number of opioid dispensing pharmacies)*
  - *Prescribers associated with the same single Tax Identification Numbers (TIN) are counted as a single prescriber.*
  - *Pharmacies with multiple locations that share real-time data are counted as one pharmacy.*
  
- 2) *History of opioid-related overdose, beginning January 1, 2022:*
  - *A medical claim with a primary diagnosis of opioid-related overdose within the most recent 12 months; AND*
  - *A Part D opioid prescription (not including MAT) within the most recent 6 months.*

*Description of the methodology that CMS uses to identify group prescriber practices and pharmacies that share real-time data can be found in the OMS user guide available at <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization>.*

## **4.2. Supplemental OMS Criteria**

The supplemental *OMS* criteria provide flexibility for sponsors to address plan members who are receiving opioids from a large number of prescribers or pharmacies, but who do not meet a particular MME threshold.

*Supplemental OMS criteria are:*

- *Use of opioids (regardless of average daily MME) during the most recent 6 months; AND*
- *7+ opioid prescribers OR 7+ opioid dispensing pharmacies*
- *Prescribers associated with the same single Tax Identification Numbers (TIN) are counted as a single prescriber.*
- *Pharmacies with multiple locations that share real-time data are counted as one pharmacy.*

Sponsors may review beneficiaries who meet the supplemental OMS criteria at a level that is manageable for each sponsor. *Sponsors* that have *the* resources to conduct additional case management are encouraged to apply the supplemental OMS criteria *to their Part D member populations* to identify additional individuals at potential risk for prescription drug misuse or abuse who may benefit from the plan's DMP. Sponsors must report any beneficiaries who meet



the supplemental criteria that they review to OMS (*see section 11.2*).

### **4.3. Application of OMS Criteria by Part D Sponsors**

While Part D sponsors may not vary the OMS criteria to include more or fewer beneficiaries in their DMPs, they may apply the criteria more frequently than CMS currently does, which is quarterly. For example, sponsors may evaluate their enrollees using the *minimum* OMS criteria on a monthly basis. *Or, the sponsor may be aware of an opioid overdose or opioid utilization before it is accounted for by OMS.* With respect to identifying pharmacies with multiple locations that share real-time data or prescribers in a group practice, Part D sponsors may use any reasonably valid and reliable method when applying the OMS criteria; however, the sponsor should self-audit at reasonable intervals to test that its method is reliable and up-to-date. *Thus, sponsors may identify PARBs earlier than CMS.*

Sponsors must report any PARBs *that they identify through OMS within 30 days of the next OMS report (see section 11.2).* *Sponsors do not need to wait to receive an OMS report from CMS to initiate case management and send beneficiary notices, if applicable.*

## **5. Exempted Beneficiaries**

*According to the regulatory definition for exempted beneficiary at 42 CFR § 423.100, a beneficiary is automatically exempt from the DMP if the beneficiary:*

- 1) Is being treated for active cancer-related pain;
- 2) Has elected to receive hospice care or is receiving non-hospice palliative or end-of-life care;
- 3) Is a resident of a long-term care (*LTC*) facility, a facility described in section 1905(d) of the Act, or another facility for which FADs are dispensed for residents through a contract with a single pharmacy; *or*
- 4) *Has sickle cell disease (effective beginning CY 2022).*

*CMS attempts to remove exempted beneficiaries from OMS reporting (see exclusion methodology in the OMS user guide). Part D sponsors must use data available to them or obtained through case management to identify exempted beneficiaries, including those who are inadvertently reported by OMS or when the sponsor is reviewing cases pursuant to applying the OMS criteria themselves.*

*With respect to identifying enrollees with active cancer-related pain, Part D sponsors may refer to the CDC Guideline<sup>2</sup> as a reference that distinguishes active cancer treatment from cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, or are under cancer surveillance only.*

*Sponsors should refer to the Long-Term Institution (LTI) report, which CMS releases on a quarterly basis, to help them identify beneficiaries who are residents of LTC facilities.*

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<sup>2</sup> <https://www.cdc.gov/drugoverdose/prescribing/guideline.html>.

*Beneficiaries serviced by LTC pharmacies who are not residents of the LTC facility do not meet the LTC resident exemption, but beneficiaries who reside in facilities for which FADs are dispensed to residents through a contract with a single pharmacy are exempt. Under the applicable regulatory definition, an enrollee is not exempted solely because they reside in an assisted-living facility (ALF); however, if a sponsor learns during case management that a beneficiary resides in an ALF that dispenses drugs through a contract with a single pharmacy, the sponsor must exempt such resident from its DMP.*

*When applying the OMS criteria to a beneficiary who previously resided in a LTC facility during any part of the relevant lookback period but no longer resides in a LTC facility, CMS does not exclude such time periods in determining whether the criteria are met, and sponsors should do the same. For example, if a beneficiary resided in an LTC for the first 2 months of a 6-month lookback, their Part D opioid utilization during those 2 months should be included when calculating MME and prescriber/pharmacy count.*

*Exempted beneficiaries cannot be placed in a Part D sponsor's DMP.* A sponsor must remove an exempted beneficiary from a DMP as soon as it reliably learns that the beneficiary is exempt, whether that be via the beneficiary, the facility, a pharmacy, a prescriber, or an internal or external report.

While *exempted* beneficiaries are exempt from DMPs, they are not exempt from retrospective DUR processes. Part D sponsors still must comply with other utilization management obligations in 42 CFR § 423.153, and could implement a beneficiary-specific POS claim edit for drugs other than FADs, if necessary to comply with those obligations. *CMS does* not have specific guidance for such edits for non-FADs, but we would expect the sponsor to employ the same level of diligence and documentation with respect to beneficiary-specific POS claim edits for non-FADs that we require for DMPs. Sponsors may not implement a prescriber limitation or pharmacy limitation for non-FADs. *However, they* may review the use of FADs by exempt beneficiaries, such as those in LTC facilities, and work with such facilities to identify patterns of inappropriate or medically unnecessary prescription drug use among enrollees.

## **6. Beneficiaries Whose Coverage of *FADs* Was Limited Under Their Prior Plan But Not Through a DMP**

### **6.1. Non-Part D Prescription Drug Benefit Coverage**

To the extent the new Part D plan sponsor is aware or discovers that a beneficiary who meets the OMS criteria was subject to an opioid or benzodiazepine coverage limitation specific to the beneficiary, such as prescriber or pharmacy lock-in or a beneficiary-specific POS edit under a state Medicaid or EGWP plan, that plan sponsor may consider that information in deciding whether to determine that the beneficiary is an ARB under its DMP. For example, when a new enrollee comes from a non-Part D plan in which the beneficiary was subject to lock-in, the sponsor can consider the prior lock-in if it learns or knows of it based upon reliable information which is legally available to the sponsor in conjunction with the information it gathers from the case management process, the beneficiary, and the sponsor's other relevant internal sources and data.

## **6.2. Part D Prescription Drug Benefit Coverage: Beneficiary-Specific POS Claim Edits for Opioids Prior to 2019**

Beneficiaries for whom Part D sponsors 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 pre-2019 opioid overutilization policy after December 31, 2018, *provided the individual remains continuously enrolled in the plan*. This means that such edits may remain in place unless removed pursuant to the pre-2019 policy, for example, as the result of a coverage determination or appeal. However, MARx will not alert a new plan if the beneficiary had a pre-2019 beneficiary-specific POS claim edit in the prior plan.

In addition, these beneficiaries will not be suppressed from OMS reporting if they meet the OMS criteria after January 1, 2019. To the extent that such a beneficiary is reported through OMS to a sponsor with a DMP, that sponsor must comply with the requirements at [42 CFR § 423.153\(f\)](#), including case management and beneficiary notices.

## **7. Required Framework of Drug Management Programs**

### **7.1. Written Policies and Procedures**

*Consistent with 42 CFR § 423.153(f)(1)*, Part D sponsors must document their programs in written policies and procedures that are approved by the applicable committee and reviewed and updated as appropriate. These policies and procedures must address all aspects of the sponsors' DMPs, including but not limited to:

- The appropriate credentials of the clinical staff conducting case management.
  - Staff must have a current and unrestricted license to practice within the scope of their profession in a *state, territory, Commonwealth of the United States* (that is, Puerto Rico), or the District of Columbia.
  - *CMS expects clinical staff conducting case management as part of a Part D plan sponsor's DMP would be a physician and/or other appropriate health care professional with sufficient expertise to conduct medical necessity reviews related to potential opioid overutilization.*
- The necessary and appropriate contents of case management files, which must include documentation of the substance of *the contact with the* prescriber, beneficiary, and pharmacy.
  - Example: The sponsor must document if a prescriber verbally agreed with the sponsor to implement a limit on the beneficiary's access to coverage for FADs.
  - Example: The sponsor documents if the beneficiary calls the sponsor to provide his or her preferences for pharmacy or prescriber limitations.
  - Example: In the case of a prescriber limitation, while a prescriber's confirmation to serve as a selected prescriber can be verbal, to the extent possible, CMS recommends that sponsors also provide an advance written confirmation statement to a prescriber, which can memorialize prescriber agreement, notice and confirmation, and include a

copy of such statement in their case management file.

- Monitoring reports and notifications about incoming enrollees who meet the definitions of a PARB and an ARB.
  - Respond to requests from other Part D sponsors for information about PARBs and ARBs who recently disenrolled from the Part D sponsor's prescription drug benefit plans and document such communications and transfers of information.

## **7.2. Case Management / Clinical Contact / Prescriber Verification**

*Requirements for case management, clinical contact, and prescriber verification for the purposes of DMPs are described at 42 CFR § 423.153(f)(2).* The Part D sponsor's clinical staff must conduct case management for PARB 1s reported by OMS or identified by the sponsor, and for PARB 2s and ARB 2s reported by MARx (unless the case management exception discussed below applies). This case management serves the purpose of *1) engaging in clinical contact with the prescriber(s) of FADs, 2) verifying with the prescriber(s) whether the beneficiary is at-risk for abuse or misuse of FADs, and 3) obtaining agreement from the prescriber(s) to a coverage limitation on FADs, if a limitation is deemed necessary and prescriber agreement is required.*

*A prescriber must verify that a beneficiary is at risk, which serves as their opinion that a Part D plan sponsor takes into account during case management. However, it is the Part D sponsor that determines if a beneficiary is an ARB under its DMP after conducting case management and accounting for the enrollee response to the Initial Notice.*

The goal of case management under a DMP is to *ascertain the clinical relevance of the prior overdose, if applicable, and* achieve a consensus *with the* prescriber(s) as to the appropriate, medically necessary, and safe dosage of FADs, and if there is no consensus, to facilitate one. Sponsors should make every attempt to identify a prescriber who is willing to provide input about the beneficiary's utilization of FADs. Sponsors must determine for themselves the usefulness of attempting to call or contact all prescribers of FADs when there are many, *such as* emergency room providers.

Unless the exception to case management described below applies, the sponsor must also do the following as part of case management:

- Send written information to the beneficiary's prescriber(s) that the *Part D* sponsor's DMP is reviewing the beneficiary as potentially at-risk because the beneficiary meets the OMS criteria due to obtaining opioids from multiple prescribers and/or pharmacies *or due to history of opioid-related overdose;*
- Include in the written information the beneficiary's actual total utilization of opioids, benzodiazepines, *or both*, if available to the *Part D* sponsor; *and*

- Elicit information and opinions from the prescriber(s) in writing and verbally, as necessary, about any factors in the beneficiary’s treatment that are relevant to a determination whether the beneficiary is an ARB, such as:
  - Whether the beneficiary is an exempted beneficiary;
  - Whether the prescribed medications are appropriate, medically necessary, and safe for the beneficiary’s medical conditions;
  - Any other relevant treatment factors; *and*
  - Agreement, if necessary, as to whether a limitation on the beneficiary’s access to coverage of FADs is warranted for the safety of the beneficiary.

*A model prescriber letter that Part D sponsors may use to communicate with prescribers is posted on the [CMS Part D Overutilization website](#).*

CMS expects sponsors to diligently engage in case management, but there is no deadline for sponsors to complete it. CMS recognizes that every case is unique and that the needed time for case management will vary depending on many factors, such as the complexity of the case, and the promptness with which, *and whether*, prescribers respond to sponsors’ outreach.

*Part D sponsors may take a “wait and see” approach in cases, as appropriate. In some cases, after Part D sponsors send the prescribers of FADs the required written information described just above about the beneficiary’s status as a PARB and available utilization of FADs, the Part D sponsors may prefer to wait and see if the prescribers adjust their care of their patient and additional outreach or action regarding the beneficiary is therefore unnecessary. The sponsors may wait and see if the beneficiary no longer meets the OMS criteria (due to a reduction in MME, number of prescribers, and/or number of pharmacies), or if there is a noteworthy change in the beneficiary’s opioid regimen in the prescription drug claims data. The sponsor may also wait and see if the beneficiary receives naloxone, MAT, or other relevant treatment. CMS expect sponsors to actively monitor the case when taking a wait and see approach.*

*While the approach to case management may vary based on the facts and circumstances of the case, the general goal of case management is to understand why the beneficiary meets the OMS criteria and whether a limitation on access to coverage for FADs is warranted for the safety of the beneficiary. Thus, Part D sponsors are expected to address all cases without unreasonable delay and to triage their review of the most concerning cases to the extent possible.*

While there is no deadline to complete case management, there are deadlines to report information about the case to OMS and MARx, and CMS will monitor OMS for outliers in terms of time taken to complete case management and take action as appropriate. Part D sponsors use the information they obtain from case management to choose standardized responses in OMS about the case and submit information to MARx about any coverage limitations that the sponsor notified the beneficiary about and implemented for the beneficiary’s safety. Refer to the “Data Disclosure” [section 11](#), as well as the OMS technical guidance and the MAPD Plan Communications User Guide (PCUG) on the CMS Part D Overutilization website at: <https://www.cms.gov/Medicare/Prescription-Drug-coverage/PrescriptionDrugCovContra/RxUtilization.html>.

*If sponsors have identified PARBs on their own consistent with [section 4.3](#), sponsors do not need to wait to receive an OMS report from CMS to initiate case management and send beneficiary notices, if applicable.*

While not required, to the extent possible, CMS encourages Part D sponsors to incorporate the following into case management, and in the case of MA-PD plans, through network provider agreements:

- *Educate* prescribers about the opioid overutilization crisis, *the risk of overdose or repeat opioid overdose*, the CDC Guideline for Prescribing Opioids for Chronic Pain, co-prescribing of naloxone, and the role DMPs play in reducing overutilization of FADs in the Part D program;
- Encourage prescribers to perform, or refer their patient for, a comprehensive substance abuse disorder screening and/or assessment, and if indicated, prescribe MAT, or refer their patient for follow-up treatment with a pain specialist or addiction treatment provider; *and*
- Use all reliable sources legally available to them, such as prescription drug monitoring programs (PDMPs), to which they may have access under applicable state law, to obtain an accurate account of a PARB's or ARB's utilization of FADs.

### ***7.2.1. Prescribers who do not Respond to Case Management***

In cases when prescribers have not responded to case management, the sponsor must make reasonable attempts to communicate with the prescribers telephonically and/or by another effective communication method designed to elicit a response from the prescribers within a reasonable period after sending the written information. The idea is that the *Part D* sponsor will escalate the steps they take to engage in clinical contact with the prescribers, given that the OMS criteria identify beneficiaries who are potentially at-risk for serious adverse health events, including death, due to their opioid use, apparent lack of coordinated care *and/or history of opioid-related overdose*.

In doing so, a *Part D* sponsor should balance on a case-by-case basis the competing priorities of diligently addressing opioid overutilization through the required case management, which may necessitate multiple outreach attempts to prescribers, while being cognizant of the need to be judicious in contacting prescribers telephonically in order to not unnecessarily disrupt their practices. CMS suggests that *Part D* sponsors make *three* outreach attempts to contact prescribers over 10 business days during case management, because documentation of *three* or more attempts is sufficient for the *Part D* sponsor to demonstrate that a prescriber is not responsive in cases when the *Part D* sponsor wants to implement a coverage limitation on a beneficiary's access to FADs under their DMPs (*see [section 7.4](#)*).

### ***7.2.2. Exception to Case Management***

If a beneficiary was identified as a PARB 2 or ARB 2 by his or her most recent prior plan, *and the beneficiary enrolls in a new plan*, MARx will report such beneficiaries to their new plan



sponsors, if such identification was not terminated before the beneficiary disenrolled from the *most recent prior* plan. To distinguish between the two *possible beneficiary statuses*, the *gaining* sponsor must contact the *losing* sponsor. *The losing sponsor must transfer case management information to the gaining sponsor as soon as possible but no later than two weeks from the gaining sponsor's request. Sponsors should make and respond to such requests in writing. Part D sponsors* should refer to the applicable Overutilization Contact listed in HPMS and posted on the [CMS Part D Overutilization website](#). *This list contains contact information for the personnel at each contract to whom correspondence about DMPs should be addressed. The CMS Part D Overutilization page also provides a sample transfer memo that a losing sponsor may use to provide such information to a gaining sponsor, when the new sponsor requests it.*

The Part D sponsor *is not required* to engage in case management for PARB 2s and ARB 2s *before implementing a coverage limitation under a DMP*, so long as the *Part D* sponsor obtains case management information from the *most recent Part D* sponsor and such information is still clinically adequate and up to date. The purpose of this exception is to avoid unnecessary burden on Part D sponsors and health care providers when additional case management outreach is not necessary, because it *was* performed by *the most recent* prior Part D sponsor under a DMP.

*See note in section 2 for information on identification of ARB 2s.*

### **7.3. Limitations on Access to Coverage for FADs (“Coverage Limitations”)**

If the requirements [at 42 CFR § 423.153\(f\)\(4\)](#) are met, a Part D sponsor may limit an ARB's access to coverage for FADs under a DMP in the following ways, *as described at 42 CFR § 423.153(f)(3)*. *The requirements at 42 CFR § 423.153(f)(4) are described in section 7.4.*

**Beneficiary-Specific POS Claim Edit:** *A Part D sponsor may implement a POS claim edit for FADs that is specific to an ARB. A Part D sponsor must not cover FADs for the ARB in excess of the edit, unless the edit is terminated or revised based on a subsequent determination, including a successful appeal. A sponsor should not implement an edit at a dosage that is lower than the highest dosage a prescriber asserts is medically necessary, or as determined by the sponsor's appropriate clinical staff when no prescriber is responsive.*

- Example: The *Part D* sponsor will cover only certain Part D prescription opioid medications or benzodiazepines for the ARB.
  - Example: The *Part D* sponsor will not cover any prescription opioid medications or benzodiazepines for the ARB.
  - Example: The *Part D* sponsor will cover up to a certain level (e.g., MME, quantity) of prescription opioid medications for the ARB.
2. **Prescriber Limitation:** *A Part D sponsor may limit an ARB's access to coverage for FADs to those that are prescribed for the beneficiary by one or more selected prescribers such that the Part D sponsor covers FADs for the ARB only when they are obtained from the selected prescriber(s).*

3. **Pharmacy Limitation:** *A Part D sponsor may limit an ARB's access to coverage for FADs to those that are dispensed for the beneficiary by one or more selected network pharmacies, such that the Part D sponsor covers FADs for the ARB only when they are obtained from the selected pharmacy(ies).*

In applying a prescriber and/or pharmacy limitation, the *Part D* sponsor must also comply with the requirements regarding beneficiary preferences and to provide an ARB with reasonable access to coverage for FADs *as described in section 9.2.*

*Part D* sponsors may implement more than one coverage limitation for a single ARB. These limitations may be concurrent *for the entire or part of the time*, or overlapping due to the case not resolving as expected with the *first* limitation(s). Periods of overlapping coverage limitations are independent of each other. If a beneficiary changes *contracts*, any limitation period associated with a coverage limitation placed on an ARB *2 under* the new *Part D contract* is also independent of the limitation period(s) associated with the coverage limitation(s) implemented *under* the prior *contract*.

- Example: An ARB may have a beneficiary-specific POS claim edit and a pharmacy limitation for opioids, and the *Part D* sponsor terminates the pharmacy limitation early or after 12 months, but leaves the POS edit in place or extends it for an additional 12 months. However, once the POS edit ends, a *Part D* sponsor may only implement additional coverage limitations if the beneficiary meets the OMS criteria again.
- Example: A beneficiary-specific POS claim edit for opioids is implemented, and then a few months later, a prescriber limitation is implemented, perhaps because the beneficiary is obtaining opioids from multiple prescribers and the opioid dosage keeps getting adjusted upward.
- Example: A sponsor implements a pharmacy limitation for opioids for a beneficiary who had been obtaining FADs from multiple prescribers and pharmacies. The ARB continues to obtain FADs from multiple prescribers, *and the sponsor also implements a prescriber limitation*. Before pursuing a prescriber limitation, however, the sponsor should investigate why a selected network pharmacy is filling opioid prescriptions for an ARB from multiple prescribers.
- Example: A sponsor implements a prescriber limitation for opioids with a network prescriber, who has been substantially increasing the opioid dose and the ARB is filling the prescriptions at multiple unrelated network pharmacies. Again, such a scenario may merit additional scrutiny by the sponsor before pursuing the pharmacy limitation.

These examples demonstrate how concurrent and overlapping limitations would work, but they also demonstrate why CMS believes that the instances in which more than one limitation would be warranted would be infrequent. Therefore, while *Part D* sponsors are permitted to make such additions and terminations to coverage limitations on FADs for an ARB, CMS strongly discourages sponsors from making frequent changes, as such changes might also be disruptive or confusing for the beneficiary.

If the sponsor determines that overlapping coverage limitations are warranted, for each additional limitation, it must comply with the requirements, i.e., repeat the case management



process, including prescriber verification and prescriber agreement, if applicable, and Initial and Second Notice requirements. Also, with each new limitation, the beneficiary has 60 calendar days from the date of the Second Notice of the limitation to request an appeal. CMS will closely monitor information submitted by sponsors in OMS and MARx and complaint data to make sure sponsors are not inappropriately disrupting beneficiary access to coverage for FADs by making frequent changes to coverage limitations through their DMPs.

When processing pharmacy claims or beneficiary requests for reimbursement for FADs for a beneficiary who is subject to a coverage limitation for FADs, the sponsor must process the claim/request in accordance with all other coverage benefits and requirements of the beneficiary's prescription drug benefit plan.

#### **7.4. Requirements for Implementing Limitations on an ARB's Access to Coverage for FADs**

A sponsor may not limit the access of an ARB to coverage for FADs unless the sponsor has done all of the following, *consistent with 42 CFR § 423.153(f)(4)*:

1. Conducted the required case management, *in accordance with 42 CFR § 423.153(f)(2) and described in section 7.2*, and updated it, if necessary;
2. Obtained the agreement of at least one prescriber of FADs for the beneficiary that the specific limitation is appropriate, *except in the case of a pharmacy limitation or a beneficiary-specific POS claim edit where the prescriber is not responsive (see section 7.4.1)*; and
3. Provided the required notices to the beneficiary after case management is complete (*see section 8*).

##### **7.4.1. Limitation-Specific Exceptions**

*The requirements outlined in section 7.4 apply in order to implement a coverage limitation on FADs, with the following exceptions listed in 42 CFR § 423.153(f)(4), specific to the type of limitation.*

**Beneficiary-Specific POS Claim Edit:** *The Part D sponsor must attempt to obtain a prescriber's agreement for this limitation, but is authorized to implement the limitation if a prescriber does not respond to the Part D sponsor after three attempts by the sponsor to contact them within 10 business days. In this scenario, the sponsor has demonstrated that the prescriber is not responsive and may proceed with a beneficiary-specific POS claim edit.*

**Prescriber Limitation:** *There is no exception to prescriber agreement to implement a prescriber limitation. Sponsors must obtain the agreement of at least one prescriber of FADs for the enrollee that the specific limitation is appropriate. A sponsor cannot implement a prescriber limitation unless a prescriber agrees to be the selected prescriber, which constitutes agreement with the limitation, as well as notification and confirmation about serving as the selected*

*prescriber (see [section 9.5.2](#)). However, sponsors are not required to obtain agreement from all prescribers of FADs for the enrollee. A sponsor may not implement a prescriber limitation if no prescriber was responsive.*

***Pharmacy Limitation:*** *While a prescriber agreement is not required for a sponsor to implement a pharmacy limitation for an enrollee, sponsors should attempt to engage with prescriber(s). Only after a minimum of 3 attempts to contact a prescriber within 10 business days may the sponsor consider the prescriber to be non-responsive. In the event no prescriber is responsive, sponsors may proceed with a beneficiary-specific POS claim edit.*

## **8. Notices**

CMS regulations *at [42 CFR § 423.153\(f\)\(5-8\)](#)* set forth the specific content that must be included in the written notices that Part D sponsors are required to send to beneficiaries under a DMP, *as well as the timing for issuing notices.*

A Part D sponsor must not send any beneficiary notices until initial case management has been completed, which may have been conducted under the DMP of the beneficiary's immediately prior plan, if an exception applies (*see [section 7.2.2](#)*). Sponsors must make reasonable efforts to provide the beneficiary's prescriber(s) of FADs with a copy of the notices.

### **8.1. Initial Notice**

After completion of the required case management, a Part D sponsor that intends to limit a beneficiary's access to coverage for FADs must provide an initial written notice to the PARB, *consistent with [42 CFR § 423.153\(f\)\(5\)](#)*, unless an exception applies. The Initial Notice does the following:

- 1) Notifies the PARB that they have been identified as potentially at-risk for misuse or abuse of FADs, and that the sponsor intends to limit their access to FADs under its DMP;
- 2) Describes the specific coverage limitation(s) the sponsor intends to implement and the timeframe for its decision;
- 3) Explains how the PARB or their prescriber can provide additional information if they do not agree with the plan's intended action, including the PARB's preferences for the selected pharmacy and/or prescriber, if applicable;
- 4) Provides information about resources and plan benefits designed to address prescription drug abuse;
- 5) Explains that the beneficiary will have the right to appeal if the plan determines the beneficiary is at-risk and implements a limitation under the DMP; and
- 6) Informs the PARB with LIS of the limitation on the availability of the special enrollment period (SEP).

It is important to note that although a prescriber has verified that the beneficiary is at-risk (unless no prescriber was responsive) during the case management that the sponsor has already

conducted, the beneficiary is *still* considered a PARB when the sponsor provides the Initial Notice.

*If the beneficiary disagrees with the intended action stated in the Initial Notice, the beneficiary may respond to the plan sponsor by providing documentation that may be material to the plan's determination about whether the beneficiary is an ARB.*

The Part D sponsor must also make reasonable efforts to provide a copy of the Initial Notice to the beneficiary's prescriber(s) of FADs. This gives prescribers more information about the sponsor's intent with respect to their patient for treatment purposes. In cases where a prescriber has not responded to case management, this information may motivate the prescriber to contact the *Part D* sponsor.

*A gaining sponsor also uses* the Initial Notice for ARB 2s when *the* sponsor wishes to implement a coverage limitation for FADs, but is not able to continue the same limitation(s) that the beneficiary had under their previous plan. For example, the gaining sponsor wishes to continue a pharmacy limitation, but does not have the previously selected pharmacy in its network. In such a situation, the sponsor must provide the beneficiary with an Initial Notice, which in this example would include a request that the beneficiary state their preference for a selected pharmacy.

If the Part D sponsor subsequently intends to make a change to the terms of an ongoing coverage limitation(s), including the intention to impose an additional limitation on the ARB, the sponsor must comply with the requirements to implement a coverage limitation, including the requirements for beneficiary notices.

## **8.2. Second Notices**

After a 30-day period has passed from the date on the Initial Notice, whether or not a PARB has provided a response to the *Part D* sponsor to the Initial Notice, there are two possible outcomes. The *Part D* sponsor will either determine *that* the beneficiary is *an ARB* and will proceed with the coverage limitation under its DMP, or the *Part D* sponsor will determine that the beneficiary is not an ARB. In the former case, the sponsor must provide the ARB with the Second Notice. In the latter case, the sponsor must provide the beneficiary with the Alternate Second Notice.

### **8.2.1. Second Notice**

When a plan makes a determination that a beneficiary is an ARB and limits the ARB's access to coverage for FADs, the plan must give the Second Notice to the beneficiary, as soon as possible after the end of the beneficiary's 30 day response period but no later than 60 days from the date on the Initial Notice, *as described in [42 CFR § 423.153\(f\)\(6\)](#).*

The Second Notice does the following:

- 1) Notifies the ARB that the sponsor has identified them as at risk for misuse or abuse of FADs, and that the sponsor is limiting their access to FADs under its DMP;

- 2) Describes the *specific* coverage limitation(s) the sponsor is implementing, including the effective and end dates and the selected pharmacy and/or prescriber, if applicable;
- 3) Explains how the beneficiary can submit preferences for the selected pharmacy and/or prescriber, if applicable;
- 4) Explains the beneficiary's right to a redetermination, including the right to an expedited redetermination, and how to request one; and
- 5) Informs the ARB with LIS that the limitation on the SEP continues.

Sponsors may provide the Second Notice immediately for ARB 2s when the gaining sponsor continues the same limitation from the ARB 2's previous plan, with the same prescriber or pharmacy, as applicable.

The Part D sponsor must make reasonable efforts to provide a copy of the Second Notice to the beneficiary's prescriber(s) of FADs for patient treatment purposes. When implementing a prescriber limitation, the sponsor may wish to incorporate the agreement and notification and confirmation process into its efforts to provide this notice to the prescriber who is selected to be the selected prescriber to consolidate communications, to the extent possible. (See [section 9.5.2](#)).

### **8.2.2. Alternate Second Notice**

After providing an Initial Notice to a beneficiary, if a Part D sponsor determines that the PARB is not an ARB and will thus not limit the beneficiary's access to FADs under the DMP, *consistent with 42 CFR § 423.153(f)(7)*, the *Part D* sponsor must provide an Alternate Second Notice to the beneficiary. This notice must be provided to the beneficiary as soon as possible after the end of the beneficiary's 30-day response period but no later than 60 days after the date on the Initial Notice.

The Alternate Second Notice informs the beneficiary that:

- 1) The sponsor has determined that the beneficiary is not an ARB;
- 2) The sponsor will not limit the beneficiary's access to coverage for FADs under its DMP; and
- 3) The SEP limitation no longer applies for ARBs with LIS.

The Part D sponsor must make reasonable efforts to provide a copy of the Alternate Notice to the beneficiary's prescriber(s) of FADs for patient treatment purposes.

### **8.3. Exceptions to Providing Notice**

A gaining *Part D* sponsor may forgo providing the Initial Notice and may immediately provide a Second Notice to an ARB 2, if the sponsor is implementing either of the following coverage limitations:

- 1) A beneficiary-specific POS claim edit, if the edit is the same as the one that was implemented in the losing sponsor.
- 2) A pharmacy or prescriber limitation, if such limitation would require the ARB 2 to obtain FADs from the same location of pharmacy and/or the same prescriber, as applicable, that served as the selected pharmacy/prescriber under the losing sponsor.

*See note in [section 2](#) for information on identification of ARB 2s.*

## **8.4. Appeals**

*If a beneficiary does not agree with the plan's at-risk determination, under 42 CFR § 423.580 they have 60 days from the date of the Second Notice to request a redetermination. Additionally, if a Part D sponsor upholds its at-risk determination on appeal, the sponsor must automatically forward the case to the IRE for review pursuant to 42 CFR § 423.590(i). Sponsors are also required to include information about automatic forwarding in beneficiary notices consistent with 42 CFR §§ 423.153(f)(5)(ii)(C)(3) and 423.153(f)(6)(ii)(C)(4)(iii). CMS has proposed corresponding revisions to the content of the Initial Notice and Second Notice described below. The current notices<sup>3</sup> will be updated pending approval by the Office of Management and Budget (OMB) under control number 0938-0964 (CMS-10141).*

*For information about DMP appeals, see [Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance](#).*

## **9. Overview of Selection Process for Prescribers and Pharmacies**

*Sections 9.1 through 9.5 detail the prescriber and pharmacy selection process that a Part D sponsor must follow for cases involving prescriber coverage limitations, pharmacy coverage limitations, or both. In such cases, the prescriber(s), pharmacy(ies), or both from which an ARB must obtain FADs are called “selected prescriber(s)” and “selected pharmacy(ies),” respectively. Part D sponsors are required to include a selected prescriber, selected pharmacy, or both, as applicable, that ensures the beneficiary has reasonable access to FADs in the Initial Notice to the beneficiary and to solicit the beneficiary's preference(s) consistent with 42 CFR § 423.153(f)(9) (after notification and confirmation with the prescriber/pharmacy about the selection).*

*The selections a Part D sponsor ultimately makes and includes in the Second Notice or later are based on the beneficiary's preferences, unless:*

- The beneficiary does not submit preferences;
- The beneficiary's preferences do not comply with the “network policy” described in [section 9.1](#); or
- The sponsor takes exception to the beneficiary's preferences, as also described in [section 9.4](#).

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<sup>3</sup> Notices and instructions available at <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Drug-Management-Program-Notices-.zip>.

## 9.1. Beneficiary Preferences

If an ARB submits preferences for a selected pharmacy(ies) or prescriber(s) or both, the sponsor must review the preferences and must generally select or change the selection based on the ARB's preferences. See [section 7.4.1](#). However, there are some parameters, caveats, and exceptions, discussed in [sections 9.1-4](#).

If the beneficiary is enrolled in a stand-alone *PDP* and specifies a prescriber(s) or network pharmacy(ies), or both, the sponsor must select or change the selection of the prescriber(s) or network pharmacy(ies), or both, for the beneficiary based on beneficiary's preference(s).

If the beneficiary is enrolled in an MA-PD plan and specifies a network prescriber(s) or network pharmacy(ies), or both, the sponsor must select or change the selection of prescriber(s) or pharmacy(ies), or both, for the beneficiary based on the beneficiary's preference(s).

This means that the selected *prescriber or selected* pharmacy must be a network *prescriber* or network *pharmacy*, unless the ARB is in a *PDP* or an MA-PD plan that is not network-based. In such cases, the prescriber would not be a network prescriber, because such plans do not have prescriber networks. The reason for this "network policy" is that the selection of network prescribers and pharmacies *best facilitates* the *Part D* sponsor's *ability* to coordinate the beneficiary's care going forward in light of the demonstrated concerns with the beneficiary's utilization of FADs.

*There are a few caveats to this guidance. A* sponsor may have to permit an ARB in a network-based MA-PD plan to obtain FADs from a non-network prescriber, if needed to provide the ARB with reasonable access, as discussed in [section 9.2](#). The same is true regarding a non-network pharmacy for an ARB in an MA-PD plan or stand-alone *PDP*. Finally, a *Part D* sponsor can take exception to a beneficiary's preference for a selected *prescriber, a selected* pharmacy, *or both*, as detailed in [section 9.4](#).

The sponsor must inform the beneficiary of the selection or change in:

- The Second Notice; or
- If the Second Notice is not feasible due to the timing of the beneficiary's submission of preference, then in a subsequent written notice, issued no later than 14 days after receipt of the submission.

There is no limit on how many times a beneficiary can submit their preferences. A beneficiary may change a prescriber preference because they have developed a new health condition, or change pharmacy preference because they have moved, for example. A change in beneficiary preferences *should* generally not *be* sufficient reason to extend the original one-year time period for the applicable coverage limitation. However, if an ARB changes their preferences so frequently such that there is strong evidence that this behavior is inappropriate and is contributing to prescription drug abuse or diversion, the sponsor may take exception to the beneficiary's preferences and change the selection, as described in [section 9.4](#). The sponsor may

also consider this information when the sponsor determines whether there is a clinical basis to extend a coverage limitation at the end of the original one-year period.

## 9.2. Reasonable Access Considerations

When making pharmacy and prescriber selections, a Part D sponsor must ensure that the beneficiary continues to have reasonable access to FADs, taking into account all relevant factors, including but not limited to—

- The beneficiary’s preference(s);
- The beneficiary’s predominant usage of a prescriber or pharmacy, or both, for FADs;
- Geographic location;
- Reasonable travel time;
- Whether the beneficiary has multiple residences;
- The beneficiary’s health conditions;
- The impact on cost-sharing;
- Natural disasters and similar situations; and
- The provision of emergency services.

A beneficiary’s preferences for *a* selected prescriber, *selected* pharmacy, *or both*, prevail over the other factors, unless: *1)* the beneficiary’s preferences do not comply with the “network policy” described in [section 9.1](#), or *2)* the *Part D* sponsor takes exception to the beneficiary’s preferences.

When the beneficiary’s preferences are not available, in weighing these factors, CMS expects the *Part D* sponsor *to* select the network *prescriber(s)* (*or non-network prescriber in the case of a plan without a provider network*), *network* pharmacy(ies), or *both*, that the beneficiary predominantly uses for FADs, if predominant use can be discerned. The sponsor must also take into account whether more than one prescriber or pharmacy is necessary to provide the ARB with reasonable access to FADs due to the ARB’s health care or housing situation in accordance with the next section of this guidance. With regard to emergency services, CMS expects sponsors to have reasonable policies in place to ensure the ARB has access to coverage of FADs without a delay that may seriously jeopardize the life and health of the ARB or the ARB’s ability to function. If the beneficiary’s predominant use of prescriber or pharmacy cannot be ascertained, then the sponsor *should* weigh the remaining reasonable access factors in the manner the sponsor deems most appropriate for the case.

## 9.3. Actual Selection of Prescribers and Pharmacies

When making prescriber and pharmacy selections, whether the beneficiary’s preferences are available, a Part D sponsor must do the following *consistent with* [42 CFR § 423.153\(f\)\(12\)](#):

- In the case of a prescriber limitation, an MA-PD sponsor must select one, or more than one, network prescriber(s) as the selected prescriber(s) who is authorized to prescribe FADs for the ARB, if the sponsor determines it *is* necessary to ensure the ARB has



reasonable access to FADs. Also, selection of an out-of-network provider may be necessary to provide the ARB with reasonable access to FADs. A stand-alone PDP must select one, or more than one, selected prescriber who is authorized to prescribe FADs for the ARB if the sponsor determines it necessary to ensure the ARB has reasonable access to FADs. Also, in the case of a group practice, regardless of the type of Part D sponsor, sponsors *must* treat all prescribers of the group practice as one prescriber.

- In the case of a pharmacy limitation, an MA-PD and stand-alone PDP sponsor must select one, or more than one, network pharmacy as the selected pharmacy that may dispense FADs for the ARB, unless selection of an out-of-network pharmacy is necessary to ensure the ARB has reasonable access to FADs. Also, in the case of a pharmacy that has multiple locations that share real-time electronic data, *Part D* sponsors *must* treat *all* such locations of the pharmacy as one pharmacy.

Whether the selection of more than one pharmacy or prescriber is necessary for reasonable access depends upon the facts and circumstances of the case. Below are examples as to when selection of more than one prescriber/pharmacy may be necessary:

- In the case of a pharmacy limitation, if an ARB lives 6 months in one area of the country and 6 months in another, the sponsor would have to select two pharmacies, one in each geographic area, unless there is a location of the same pharmacy in both areas that share real-time electronic data, which would only count as one pharmacy but would suffice for reasonable access. However, if the beneficiary prefers not to use such a pharmacy, and the sponsor does not have a basis on which to take exception to the beneficiary's preference, then the sponsor would have to accept the beneficiary's preference for two selected pharmacies.
- 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 primary care physician and benzodiazepines from the psychiatrist, in order to ensure the ARB has reasonable access to FADs.

*If an ARB changes plans within a contract and* the new plan does not have the *ARB's* previously selected pharmacy or prescriber in its network, the sponsor must request the beneficiary to provide their preference for a selected pharmacy or prescriber, as applicable.

#### **9.4. Sponsor Exception to Beneficiary Preferences**

*Consistent with 42 CFR § 423.153(f)(10)*, if the Part D sponsor determines that the selection or change of a prescriber or pharmacy would contribute to prescription drug abuse or drug diversion by the ARB, the sponsor may change the selection without regard to the beneficiary's preferences if there is strong evidence of inappropriate action by the prescriber, pharmacy, or beneficiary. If the sponsor changes the selection, the sponsor must provide the beneficiary with at least 30 days advance written notice of the change and a rationale for the change.

With regard to this exception, if a sponsor asserts that a beneficiary's preference for a network



prescriber or pharmacy would contribute to prescription drug abuse or diversion because of strong evidence of inappropriate action by the prescriber or pharmacy, CMS would question why the prescriber or pharmacy is in the sponsor's network. Thus, CMS would not expect to see sponsors asserting this exception very often.

## **9.5. Notification and Confirmation of Selection(s)**

### **9.5.1. Prescribers and Pharmacies**

*Consistent with 42 CFR § 423.153(f)(13)*, before selecting a prescriber or pharmacy, a Part D sponsor must notify the prescriber, *pharmacy, or both*, as applicable, that the beneficiary has been identified for inclusion in a DMP and that the prescriber, pharmacy, or both, is(are) being selected as the beneficiary's selected prescriber, *selected* pharmacy, or both, for FADs. The *Part D* sponsor must also receive confirmation from the prescriber(s), pharmacy(ies), *or both*, as applicable, that the selection is accepted before conveying this information to the ARB *in the Initial Notice*.

We note that nothing in this guidance supersedes a provider or pharmacy's right under state law to refuse treatment to a patient or customer.

### **9.5.2. Prescribers**

As described *previously*, the *Part D* sponsor should initially *identify* the prescriber who will serve as the beneficiary's selected prescriber during case management, *if the sponsor intends to implement a prescriber limitation*, although the beneficiary may later express a different preference which the *sponsor* must *review*. As also described in the *section 7.2*, the *Part D* sponsor must obtain the prescriber's agreement to the prescriber limitation, i.e., to serve as the selected prescriber. Such agreement also logically constitutes prescriber notification and confirmation; therefore, the *Part D* sponsor can identify the prescriber in the Initial Notice it provides to the beneficiary. If the beneficiary provides the *Part D* sponsor with a different selection, then the *Part D* sponsor would contact the alternate prescriber and obtain their agreement to serve as the beneficiary's selected prescriber, which also constitutes prescriber notification and confirmation.

While a prescriber's confirmation to serve as a selected prescriber can be verbal, CMS strongly recommends that sponsors also provide an advance written statement to a prescriber, to the extent possible, which can memorialize prescriber agreement, notice and confirmation. A copy of such statement should be included in the case management file.

An MA-PD plan sponsor may address DMPs in their network contracts with providers, including how notifications and confirmations will be executed. However, the contracts may not substitute for case-by-case notifications and confirmations to ensure that the selected prescriber has actively agreed to manage a particular ARB's use of FADs.

### **9.5.3. Pharmacies**

Similar to selected prescribers, the *Part D* sponsor should initially select the pharmacy that will

serve as the beneficiary's selected pharmacy during case management, although the beneficiary may later express a different preference, which the *sponsor must review*. In the case of a pharmacy limitation, *CMS suggests that Part D* sponsors and network pharmacies should negotiate *in their contracts* how to notify a network pharmacy that a beneficiary has been identified for inclusion in a DMP, that the network pharmacy is the beneficiary's selected pharmacy for FADs, and how the pharmacy confirms its selection. *The sponsor must notify* out-of-network pharmacies, or network pharmacies who have not negotiated how to be notified on a case-by-case basis, which CMS strongly suggests be done in writing.

The sponsor must receive confirmation from a pharmacy that the selection is accepted before conveying this information to the ARB, unless the agreement specifies how the pharmacy will be notified by the sponsor of its selection and the pharmacy has agreed in advance in a network agreement with the sponsor to accept all such selections.

CMS strongly recommends that sponsors provide advance written notifications, which could be via electronic messaging, to pharmacies for each case, to the extent possible, so that the selected pharmacy is best prepared for each ARB it will serve. In the case of a non-network pharmacy, CMS strongly suggests that it receive an advance written confirmation from the pharmacy, to the extent possible, accepting its selection and to include it in the case management file.

## **10. Effective and Termination Dates and Extensions of Identification as an ARB**

### **10.1. Effective Dates**

*Consistent with 42 CFR § 423.153(f)(14)*, the effective date of a coverage limitation implemented under a DMP is the date of the Second Notice.

### **10.2. Termination Dates**

*Consistent with 42 CFR § 423.153(f)(14)*, the identification of an ARB as such must terminate on whichever of the following *two* possible dates is earliest:

- a) The date the beneficiary demonstrates that they are no longer likely to be at risk for abuse or misuse of FADs without the limitation through a subsequent determination, including but not limited to, a successful appeal; or
- b) The date that is the end of:
  - The *one*-year period calculated from the effective date of the limitation, unless the limitation is extended, or
  - The date that is the end of a *two*-year period calculated from the effective date of the limitation, if the limitation was extended.

Regarding extensions to coverage limitation periods, see *section 11.4*. As noted *previously*, the time periods of overlapping limitations are independent of each other. As noted *previously*, if a

beneficiary changes sponsors, any coverage limitation period placed on an ARB 2 by the new *Part D* sponsor is independent of the original limitation period implemented by the prior *Part D* sponsor.

Additionally, a beneficiary's identification *as* an ARB also terminates as soon as *the Part D* sponsor discovers that the beneficiary is exempted or does not meet the OMS criteria, as discussed in [section 5](#).

Finally, a *Part D* sponsor is not prevented from identifying a beneficiary as an ARB after the beneficiary's coverage limitation terminates if the beneficiary again meets the OMS criteria.

### **10.3. Extensions**

*Pursuant to 42 CFR § 423.153(f)(14)(ii)(B), a* Part D sponsor may extend a coverage limitation if certain requirements are met. The sponsor must do the following:

- Determine at the end of the one-year limitation period that there is a clinical basis to extend the limitation
- Obtain the agreement of a prescriber of FADs for the ARB that the limitation should be extended, except that:
  - Prescriber agreement is not required to extend a pharmacy limitation;
  - If no prescriber was responsive after 3 attempts by the sponsor to contact the prescribers within 10 business days, the sponsor does not need a prescriber's agreement to extend a beneficiary-specific POS edit; *or*
  - A sponsor may not extend a prescriber limitation if no prescriber agreed; *and*
- Provide another Second Notice to the ARB.

The clinical basis to extend a coverage limitation should be the sponsor's assessment whether an ARB is likely to continue to be an ARB in the absence of the coverage limitation. This assessment might include a review of medical records, rejected claims for FADs at non-selected pharmacies, or prescription drug monitoring program data, if available to the sponsor.

If a *Part D* sponsor extends an ARB's coverage limitation, the ARB (*or the ARB's* representative, or prescriber on *their* behalf) *may request* that the plan revisit its determination that the beneficiary is an ARB or the term of any limitation imposed on the ARB under the sponsor's DMP.

Refer to [section 7.4](#) regarding prescriber agreement and prescribers who are not responsive in the context of extensions of coverage limitations.

## **11. Data Disclosure**

Data disclosure by CMS and Part D sponsors is essential to the operation of DMPs. CMS has

*developed* OMS responses to allow *Part D* sponsors to provide *information* about case management, and has *programmed* MARx to accommodate information about the required beneficiary notices. Refer to the OMS technical guidance for DMPs and MAPD PCUG for *Reporting Beneficiaries Identified with a Drug Management Program* available on the CMS Part D Overutilization website at: <https://www.cms.gov/Medicare/Prescription-Drug-coverage/PrescriptionDrugCovContra/RxUtilization.html>.

### **11.1. By CMS through OMS and MARx**

CMS systems disclose the following data to Part D sponsors:

- OMS reports PARB 1s to *their* Part D sponsors quarterly on the last business day of the month *following that quarter*.
- *MARx* identifies PARB 2s and ARB 2s to *their* Part D sponsors *upon enrollment, through the DTRR*.

### **11.2. By Part D Sponsors through OMS, MARx and Manually**

Pursuant to [42 CFR § 423.153\(f\)\(15\)\(ii\)](#), Part D sponsors *are required* to disclose *information* about *PARBs and ARBs enrolled in their plan, including* their decisions to impose coverage limitations *under a DMP* and the limitations imposed. CMS has established the following procedures under which sponsors must share information about PARBs and ARBs:

#### OMS

*Within 30 days of receiving an OMS report*, Part D sponsors must provide information on the case management status for:

- Each PARB 1 identified through OMS to the sponsor
- Each PARB 1 that the sponsor identifies
- Each PARB 2 or ARB 2 for which a sponsor received a transaction reply code of TRC 376 (New Enrollee CARA Status Notification) from the DTRR

#### MARx

*As soon as possible but not later than 7 days from the date the action is taken*, Part D sponsors must provide *the following* information *in MARx* about PARBs and ARBs *enrolled in their plan*:

- *The date* of the Initial Notice to a PARB (Notification start-date)
- *The date* of the Second Notice to an ARB (Implementation start-date (i.e., effective date)).
- *The date* that the sponsor terminates an “*active CARA status*” (see [OMS technical guidance](#)), *including terminating* an ARB’s coverage limitation(s) *sooner than* the original termination date (Notification end- date or implementation end-date).

### Sponsor-to-Sponsor Information Transfer

A losing sponsor must provide *case management* information to the gaining sponsor 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 another prescription drug 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.

*A model case management transfer memo that sponsors may use to provide this information is located on the [CMS Part D Overutilization page](#).*