



CENTER FOR MEDICARE

Date: December 23, 2020

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
Director, Medicare Drug Benefit and C&D Data Group

Subject: 2021 Part D Drug Management Program Guidance

This memorandum provides updated information to Part D sponsors regarding contract year (CY) 2021 Drug Management Programs (DMPs).

Following is a summary of changes compared to the November 20, 2018 memorandum, “Part D Drug Management Program Policy Guidance”, which applied to CYs 2019 and 2020. New and revised text in the attached guidance is shown in red, italicized font.

- Section IV. Includes updated information on program size based on 2019 data. Adds description of new OMS methodology to identify pharmacies with multiple locations that share-real time data.
- Section V. Updates data sources for identifying beneficiary exemptions.
- Sections VIII and IX. Reflects a new requirement that if a Part D sponsor affirms an at-risk determination on appeal, the case must be automatically forwarded to the Part D Independent Review Entity (IRE) for review and resolution.
- Section IX. Incorporates Frequently Asked Questions (FAQs) about DMPs, with updates for 2021.

The updated 2021 OMS technical guidance is also available on the CMS Part D Overutilization website at: <https://www.cms.gov/Medicare/Prescription-Drug-coverage/PrescriptionDrugCovContra/RxUtilization.html>.

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.

PART D DRUG MANAGEMENT PROGRAMS

*Rev. 2, December 23, 2020,
Implementation: January 1, 2021*

I. INTRODUCTION	4
II. POTENTIAL AT-RISK BENEFICIARIES (PARBs) AND AT-RISK BENEFICIARIES (ARBs) (42 CFR §423.100)	5
III. FREQUENTLY ABUSED DRUGS (FADs) (42 CFR §423.100).....	5
A. <i>Opioids and Benzodiazepines</i>	<i>5</i>
B. <i>Additional Information about Benzodiazepines.....</i>	<i>5</i>
IV. OVERUTILIZATION MONITORING SYSTEM (OMS) CRITERIA (CLINICAL GUIDELINES) / ESTIMATED PROGRAM SIZE (42 CFR §§423.100 and 423.153(f)(16)).....	6
A. <i>OMS Criteria are not Dosing Limits.....</i>	<i>6</i>
B. <i>Minimum and Supplemental OMS Criteria</i>	<i>7</i>
1. <i>Minimum OMS Criteria</i>	<i>9</i>
2. <i>Supplemental OMS Criteria.....</i>	<i>9</i>
C. <i>Frequency of Application of OMS Criteria.....</i>	<i>9</i>
D. <i>OMS Criteria and Group Practices / Chain Pharmacies</i>	<i>9</i>
1. <i>Group Practices</i>	<i>9</i>
2. <i>Pharmacy Grouping.....</i>	<i>9</i>
V. EXEMPTED BENEFICIARIES (42 CFR § 423.100)	10
A. <i>Active Cancer-Related Pain.....</i>	<i>10</i>
B. <i>Hospice, Palliative or End-of-Life Care</i>	<i>11</i>
C. <i>Residents of Long-Term Care (LTC) and Other Facilities</i>	<i>11</i>
D. <i>Beneficiaries in a DMP who become Exempt.....</i>	<i>11</i>
E. <i>Effect of Being an Exempt Beneficiary</i>	<i>11</i>
VI. BENEFICIARIES ENROLLING IN A PART D PLAN WHOSE COVERAGE OF CONTROLLED SUBSTANCES WAS LIMITED UNDER THEIR PRIOR PLAN (BUT NOT THROUGH A DMP).....	12
A. <i>Non-Part D Prescription Drug Benefit Coverage</i>	<i>12</i>
B. <i>Part D Prescription Drug Benefit Coverage: Beneficiary-Specific POS Claim Edits for Opioids Prior to 2019 ...</i>	<i>12</i>
VII. MEDICAID AND DUAL ELIGIBLES	13
VIII. REQUIRED FRAMEWORK OF DRUG MANAGEMENT PROGRAMS (§423.153(a) & (f))	13
A. <i>Written Policies and Procedures (42 CFR §423.153(f)(1))</i>	<i>13</i>
B. <i>Case Management / Clinical Contact / Prescriber Verification (42 CFR §423.153(f)(2)).....</i>	<i>14</i>

C.	<i>Limitations on Access to Coverage for FADs (42 CFR §423.100(f)(3))</i>	16
D.	<i>Requirements for Implementing Limitations on an ARB’s Access to Coverage for FADs (42 CFR § 423.153(f)(4))</i>	18
E.	<i>Notices (42 CFR § 423.153(f)(5)-(7))</i>	31
1.	Initial Notice (42 CFR § 423.153(f)(5))	32
2.	Second Notices (42 CFR § 423.153(f)(6)-(f)(7))	33
F.	<i>Notices: Timing and Exceptions (42 CFR § 423.153(f)(8))</i>	34
G.	<i>Overview of Selection Process for Prescribers and Pharmacies</i>	35
1.	Beneficiary Preferences (42 CFR § 423.153(f)(9))	35
2.	Reasonable Access Considerations	36
3.	Actual Selection of Prescribers and Pharmacies (42 CFR § 423.153(f)(12))	37
4.	Sponsor Exception to Beneficiary Preferences (42 CFR § 423.153(f)(10))	38
5.	Notification and Confirmation of Selection(s) (42 CFR § 423.153(f)(13)).....	38
H.	<i>Effective and Termination Dates and Extensions of Identification as an ARB (42 CFR § 423.153(f)(14))</i>	39
1.	Effective Dates.....	39
2.	Termination Dates.....	39
3.	Extensions	40
I.	<i>Data Disclosure (42 CFR § 423.153(f)(15))</i>	41
1.	By CMS through OMS and MARx.....	41
2.	By Part D Sponsors through OMS, MARx and Manually	41
IX.	FREQUENTLY ASKED QUESTIONS (FAQs)	43
	ATTACHMENT A	52
	ATTACHMENT B	54

I. INTRODUCTION

Section 704 of the Comprehensive Addiction and Recovery Act (CARA) of 2016 contained provisions permitting Part D sponsors to establish drug management programs (DMPs) for beneficiaries at-risk for misuse or abuse of frequently abused drugs (FADs). In a final rule (CMS-4182-F) published in the Federal Register on April 16, 2018 (“final rule”), CMS established the framework under which Part D sponsors may implement a DMP. This rule codified the retrospective Part D Opioid Drug Utilization Review (DUR) Policy and Overutilization Monitoring System (OMS) with adjustments as needed to comply *with* CARA, by integrating them with the DMP provisions now at 42 CFR § 423.153(f). While DMPs are voluntary *in 2021*, these regulations place requirements on DMPs when established by sponsors.

The goal of all DMPs must be to address overutilization of FADs while maintaining access to such drugs as medically necessary. DMPs will review potential at-risk beneficiaries (PARBs) who meet the OMS criteria. Under such programs, Part D sponsors will 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 for their safety 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.

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 the links below:

Medicare Managed Care Manual - <http://www.cms.gov/Medicare/Eligibility-and-Enrollment/MedicareMangCareEligEnrol/index.html> and Medicare Prescription Drug Benefit Manual - <https://www.cms.gov/Medicare/Eligibility-and-Enrollment/MedicarePresDrugEligEnrol/index.html>.

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>

The final rule and the DMP guidance are available on the CMS Part D Overutilization website at: <https://www.cms.gov/Medicare/Prescription-Drug-coverage/PrescriptionDrugCovContra/RxUtilization.html>. Questions may be submitted to PartD_OM@cms.hhs.gov.

II. POTENTIAL AT-RISK BENEFICIARIES (PARBs) AND AT-RISK BENEFICIARIES (ARBs) (42 CFR §423.100)

A PARB is a beneficiary who meets the OMS criteria 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. (See below section, "Overutilization Monitoring System (OMS) Criteria (Clinical Guidelines) / Estimated Program Size").

For purposes of this guidance, a PARB 1 refers to a beneficiary who meets the OMS criteria and is identified by CMS or a sponsor. A PARB 2 refers to a beneficiary about whom a new plan sponsor receives notice upon the beneficiary's enrollment through the 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. (See below section, "Limitations on Access to Coverage for FADs.")

An ARB is a beneficiary who meets the OMS criteria, 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** 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.*

Sponsors receive notifications about PARB 2s and ARB 2s through MARx system. See below section, "Data Disclosure."

III. FREQUENTLY ABUSED DRUGS (FADs) (42 CFR §423.100)

A. Opioids and Benzodiazepines

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. Please note that 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. (See below section, "Overutilization Monitoring System (OMS) Criteria (Clinical Guidelines) / Estimated Program Size"). Any changes in the drugs that CMS determines to be FADs for purposes of Part D DMPs **will be addressed through rulemaking, as necessary.**

B. Additional Information about Benzodiazepines

It is also important to note that the **current** OMS criteria only consider opioid use, and not benzodiazepines, for purposes of identifying PARBs. However, 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.

This means that a beneficiary who is determined to be at-risk based on OMS criteria that look at the beneficiary's opioid use could have a coverage limitation applied under a DMP to both opioids and benzodiazepines to manage current and future concurrent use. For example, a sponsor could require an ARB to obtain both opioids and benzodiazepines from one selected pharmacy. (See next sections, "Overutilization Monitoring System (OMS) Criteria (Clinical Guidelines) / Estimated Program Size" and "Requirements for Implementing Limitations on an ARB's Access to Coverage for FADs").

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, however, 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 no opioid prescriber agrees to a beneficiary-specific POS claim edit for opioids, but all but one state they will no longer prescribe opioids to the beneficiary, then a limit on coverage of opioids may not be necessary. However, the benzodiazepine prescriber agrees to such an edit for benzodiazepines.

If a sponsor implements a coverage limitation for both opioids and benzodiazepines, the sponsor may have to permit the ARB to obtain FADs from more than one pharmacy and/or more than one prescriber in order to provide reasonable access. (See section further below, "Reasonable Access Considerations.")

IV. OVERUTILIZATION MONITORING SYSTEM (OMS) CRITERIA (CLINICAL GUIDELINES) / ESTIMATED PROGRAM SIZE (42 CFR §§423.100 and 423.153(f)(16))

OMS refers to the *CMS* system that reports PARBs to sponsors and which sponsors use to provide updates on each case to CMS. CMS uses the term "OMS criteria" instead of the statutory term "clinical guidelines" for purposes of describing the standards used to identify individuals to be included in DMPs. We will develop future OMS criteria *with* stakeholder input by applying the standards in 42 CFR 423.153(f)(16) *through the rule-making process, as necessary*. Please also refer to the Section "Data Disclosure" below for information about OMS reports.

A. OMS Criteria are not Dosing Limits

The OMS criteria identify the Part D beneficiaries whom CMS believes are at the highest risk of adverse events or overdose due to their level of opioid use and/or obtaining them from multiple prescribers/pharmacies. The OMS criteria are not to be used as a maximum threshold for prescribing opioids or meant to imply that a lower dosage is universally safe. Rather, in the absence of dosing limits in the FDA-approved labeling for opioids, we are using the Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain² to establish a threshold to identify PARBs who may benefit from better care coordination / closer monitoring and to create alignment between Government programs. Under DMPs,

decisions about the amount of FADs an ARB should receive are made by the beneficiary's prescriber(s), and only in limited cases may the amount be set by the Part D sponsor through a beneficiary point-of-sale claim edit when no prescriber is responsive to the DMP's efforts to make clinical contact during case management. (See below sections, "Case Management / Clinical Contact / Prescriber Verification" and "Requirements for Implementing Limitations on an ARB's Access to Coverage for FADs.")

B. Minimum and Supplemental OMS Criteria

To provide sponsors with information on actual program size (compared to estimates provided previously), the OMS criteria applied in 2019 and the number of PARBs identified are included in Table 1. Part D sponsors may not modify the OMS criteria; however, they may apply the criteria more frequently (See below Section Frequency of Application of OMS Criteria).

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

**TABLE 1: CLINICAL GUIDELINES / OMS CRITERIA* FOR IDENTIFYING PARBs
AND NUMBER OF BENEFICIARIES IDENTIFIED IN 2019**

Minimum Criteria Applied (Sponsors with Drug Management Programs Must Review)	<i>PARBs Identified in 2019</i>
<p>Use of opioids with average daily MME \geq 90 mg for any duration during the most recent 6 months and either:</p> <p>3+ opioid prescribers <u>AND</u> 3+ opioid dispensing pharmacies</p> <p><u>OR</u></p> <p>5+ opioid prescribers (regardless of the number of opioid dispensing pharmacies)</p> <p>Prescribers associated with the same single Tax Identification Numbers (TIN) are counted as a single prescriber.</p> <p>Pharmacies with multiple locations that share real-time data are counted as one pharmacy.</p>	<p><i>In 2019, a total of 32,675 unique Part D beneficiaries who met the minimum OMS criteria were reported in OMS.</i></p> <ul style="list-style-type: none"> <i>Of that total, CMS reported 22,347 unique beneficiaries as PARBs to Part D sponsors for case management Sponsors identified and reported 10,328 PARBs to CMS.</i> <p><i>Note: CMS was unable to group pharmacies with multiple locations that share-real time data as one pharmacy.</i></p>
Supplemental Criteria Applied (Sponsors with Drug Management Programs May Review as Many as Manageable)	<i>PARBs Identified in 2019</i>
<p>Use of opioids (regardless of average daily MME) during the most recent 6 months and:</p> <p>7+ opioid prescribers <u>OR</u> 7+ opioid dispensing pharmacies</p> <p>Prescribers associated with the same single Tax Identification Numbers (TIN) are counted as a single prescriber.</p> <p>Pharmacies with multiple locations that share real-time data are counted as one pharmacy.</p>	<p><i>Sponsors identified and reported to CMS 611 PARBs who met the supplemental OMS criteria, of which 604 were newly identified PARBs.</i></p>

* Benzodiazepines are a FAD for purposes of Part D DMPs but are not a factor in these clinical guidelines/OMS criteria. 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 must include all prescription opioids, including all buprenorphine products, to determine opioid prescribers and opioid dispensing pharmacies under the supplemental criteria.

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 and must report information to OMS. (Please refer to the sections “Case Management / Clinical Contact / Prescriber Verification,” “Exempted Beneficiaries,” and “Data Disclosure” sections).

2. Supplemental OMS Criteria

The supplemental 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. Sponsors may review beneficiaries who meet the supplemental OMS criteria at a level that is manageable for each sponsor.

Plans that have resources to conduct additional case management are encouraged to apply the supplemental OMS criteria 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. (Please refer to the “Case Management / Clinical Contact / Prescriber Verification” and “Data Disclosure” sections.)

C. Frequency of Application of OMS Criteria

While Part D sponsors may not vary the minimum 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 using a 6-month look back period. For example, sponsors may evaluate their enrollees using the OMS criteria on a monthly basis. This may result in sponsors identifying PARBs earlier. Sponsors must report to OMS any PARBs identified by applying the minimum criteria more frequently.

D. OMS Criteria and Group Practices / Chain Pharmacies

1. Group Practices

Under the OMS criteria, prescribers with the same tax identification number (TIN) are counted as one prescriber, unless any of the prescribers are associated with multiple TINs. *Thus*, when reporting PARBs through OMS, CMS counts prescribers with the same TIN as one prescriber, unless any of the prescribers are associated with multiple TINs. Specifically, we use the National Provider Identifier (NPI) to first identify single prescribers, and then we further group single prescribers with the same single TIN. *More detail about this methodology is provided in the updated 2021 OMS technical guidance.*

2. Pharmacy Grouping

As discussed in the preamble to the 2018 final rule (83 FR 16451), when a pharmacy has multiple locations that share real-time electronic data, all locations are treated as one pharmacy under the OMS criteria used by CMS to identify PARBs. Beginning in 2021, CMS will implement an improved OMS methodology that includes identifying pharmacies with multiple locations.

This change is intended to reduce burden on plans by minimizing potential false positives in OMS reporting; that is, beneficiaries who appear to meet the OMS criteria of 3 or more opioid prescribing pharmacies but in fact are using multiple locations of a single pharmacy or pharmacy chain that share real-time data. The new methodology maps pharmacy NPIs and National Council for Prescription Drug Programs (NCPDP) pharmacy IDs to Federal TINs, chain names, and Doing Business As (DBA) names, and will be applied prior to issuing OMS reports. A detailed example applying this methodology is provided in the updated 2021 OMS technical guidance. We estimate that the new methodology will reduce the number of PARBs reported by OMS to sponsors by 18%.

For PARBs included in OMS reporting and identified by sponsors applying the minimum or supplemental criteria, sponsors without the capability to group prescribers using the TIN through data analysis or determine whether the pharmacy is part of a chain that shares real-time electronic data are expected to continue to make these determinations during case management. If a sponsor finds that the multiple opioid prescribers for a beneficiary are from a single group practice, or that the beneficiary is using multiple locations of a pharmacy that share real-time data, and therefore, the beneficiary does not meet the OMS criteria, the beneficiary may not be included in the sponsor's DMP. If a sponsor discovers this information after it has provided the Initial Notice to the beneficiary, the sponsor would send the beneficiary an Alternate Second Notice to indicate that the sponsor has determined that the beneficiary is not an ARB. (See the later section, "Notices.")

V. EXEMPTED BENEFICIARIES (42 CFR § 423.100)

A beneficiary is automatically exempt from any 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; or
- 3) Is a resident of a long-term care facility, of a facility described in section 1905(d) of the Act, or of another facility for which FADs are dispensed for residents through a contract with a single pharmacy.

Part D sponsors that have a DMP must identify exempted beneficiaries through data they have and case management, including those who are inadvertently reported by OMS. (Please refer to the sections "Case Management / Clinical Contact / Prescriber Verification," "Exempted Beneficiaries," and "Data Disclosure" sections).

A. Active Cancer-Related Pain

CMS attempts to remove beneficiaries who are being treated for active cancer-related pain from OMS reporting. Beneficiaries with ICD-10 cancer diagnoses in the Common Working File (CWF) *and Medicare Advantage Encounter Data System (EDS)* during the 12 months prior to the end of the measurement period or cancer RxHCCs in the latest Risk Adjustment Processing System (RAPS) are removed from OMS reporting. *Beginning in 2021, CMS will no longer use the cancer RxHCCs reported in the RAPS to identify exempted beneficiaries. The diagnosis information used to calculate the RxHCC is captured at least two years prior to the measurement period, and therefore may not accurately identify active cancer-related pain. While there may*

continue to be a reporting lag in the current year diagnosis data in the CWF and EDS, this change removes the data that is most outdated.

Plan sponsors may have more recent cancer diagnosis information or learn this information through clinical contact with prescribers during case management. Plan sponsors may refer to the CDC Guideline 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.

B. Hospice, Palliative or End-of-Life Care

CMS will identify and remove beneficiaries who have a hospice stay in the Medicare Enrollment Database (EDB) during the measurement period. CMS will also remove beneficiaries receiving palliative care with 1 or more inpatient or 2 or more outpatient claims with a Z51.5 ("Encounter for palliative care") diagnosis code in the CWF *or EDS* during the 6-months measurement period.

CMS is otherwise not able to remove beneficiaries who are receiving non-hospice and end-of-life care from OMS reporting. Therefore, Part D sponsors that have a DMP must identify exempted beneficiaries through the case management process, if they are inadvertently reported through OMS or when the sponsor is reviewing cases pursuant to applying the minimum OMS criteria more frequently than CMS and the supplemental OMS criteria.

C. Residents of Long-Term Care (LTC) and Other Facilities

CMS will remove beneficiaries residing in LTC and other facilities from OMS reports based on the Prescription Drug Event (PDE) data with dates of service during the measurement period. If the Patient Residence Code on the last PDE record during the measurement period equals 3 (Nursing Facility) or 9 (Intermediate Care Facility/Mentally Retarded) the beneficiary is identified as exempt.

Sponsors should also refer to the Long-Term Institution (LTI) report, which CMS releases on a quarterly basis, to identify beneficiaries who are residents of LTC facilities, as well as their own data, in order to determine which beneficiaries are exempt from DMPs. Beneficiaries serviced by LTC pharmacies, but who are not residents of the LTC, do not meet the LTC resident exemption but beneficiaries may meet the exemption by residing in facilities for which FADs are dispensed to residents through a contract with a single pharmacy.

D. Beneficiaries in a DMP who become Exempt

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.

E. Effect of Being an Exempt Beneficiary

Exempted beneficiaries cannot be placed in a Part D sponsor's DMP. Thus, sponsors cannot implement beneficiary-specific POS claim edits for FADs on exempt beneficiaries, nor can sponsors limit their access to coverage of FADs to only selected prescribers and pharmacies.

While these 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 § 423.153, and could implement a beneficiary-specific POS claim edit for drugs other than FADs, if necessary to comply with those obligations. We do 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. In addition, sponsors may also still 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.

VI. BENEFICIARIES ENROLLING IN A PART D PLAN WHOSE COVERAGE OF CONTROLLED SUBSTANCES WAS LIMITED UNDER THEIR PRIOR PLAN (BUT NOT THROUGH A DMP)

A. Non-Part D Prescription Drug Benefit Coverage

As discussed later in this guidance, in order for a sponsor to immediately implement a coverage limitation under its DMP for a beneficiary who is newly enrolled, the plan from which the beneficiary most recently disenrolled must have been a Part D plan in which they were determined to be an ARB under that previous plan's DMP and the ARB identification was not terminated before disenrollment.

Because DMPs are new to Part D *as of* 2019, no Part D sponsor could have had a Part D DMP before 2019. This means that a beneficiary with a limitation on their opioid coverage that was implemented before 2019 could not have had such a limitation imposed under a Part D DMP. Thus, beneficiaries with these opioid coverage limitations in a prior plan who switch plans could only be subject to a coverage limitation in the new plan through the required DMP process detailed in this guidance.

To the extent the new Part D plan sponsor is aware or discovers based on reliable information 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 a beneficiary is an ARB under its DMP. In other words, 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.

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

Beneficiaries for whom Part D sponsors have implemented beneficiary-specific POS claim edits for opioids and/or benzodiazepines before January 1, 2019 can continue to be subject to those edits under the pre-2019 opioid overutilization policy after December 31, 2018. 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 the 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 on January 31, 2019 (the date of the first 2019 OMS report) or later 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.

VII. MEDICAID AND DUAL ELIGIBLES

An ARB's coverage of FADs will be limited in some way under a Part D DMP. FADs are still covered Part D drugs. Therefore, to the extent coverage of FADs is limited for the ARB, such FADs are not coverable under Medicaid.

VIII. REQUIRED FRAMEWORK OF DRUG MANAGEMENT PROGRAMS (§423.153(a) & (f))

A. Written Policies and Procedures (42 CFR §423.153(f)(1))

Part D sponsors must document their programs in written policies and procedures that are approved by the applicable Pharmacy & Therapeutics 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.
- The necessary and appropriate contents of case management files, which must include documentation of the substance of prescriber, beneficiary, and pharmacy contacts.
 - 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.

(See the sections further below, "Requirements for Implementing Limitations on an ARB's Access to Coverage for FADs" "Notices," and "Notification and Confirmation of Selection(s).")

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

(Please refer to the section “Data Disclosure” below).

B. Case Management / Clinical Contact / Prescriber Verification (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 engaging in clinical contact with the prescribers of FADs, verifying whether the beneficiary is at-risk for abuse or misuse of FADs, and obtaining agreement to a coverage limitation on FADs, if a limitation is deemed necessary and agreement is required. The goal of case management under a DMP is to achieve a consensus among multiple prescribers 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, particularly if they are 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 prescribers that the 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
- Include in the written information the beneficiary’s actual total utilization of opioids and/or benzodiazepines, if available to the sponsor
- Elicit information and opinions from the prescribers 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
 - 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

We have attached a sample prescriber letter for this purpose as Attachment A *that Part D sponsors may use to communicate with prescribers*. Please also refer to the sections, “Exempted Beneficiaries” and “Limitations on Access to Coverage for FADs.”

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 prescribers respond to sponsors’ outreach.

Sponsors may take a “wait and see” approach in cases, as appropriate. In some cases, after sponsors send the prescribers of FADs the required written information described just above about the beneficiary’s status as a PARB and total utilization of FADs, if available, the sponsors

may prefer to wait and see if the prescribers adjust their care of their patient, such that the beneficiary no longer meets the OMS criteria and additional outreach to the prescriber is therefore unnecessary. However, the goal of case management is the same from case-to-case: the information that the sponsor sends to prescribers and elicits from them is intended to assist a sponsor with understanding why the beneficiary meets the OMS criteria and if a limitation on access to coverage for FADs is warranted for the safety of the beneficiary. Thus, we expect sponsors to address all cases without unreasonable delay and to accelerate their review of the most egregious 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. Sponsors will use the information they obtain from case management to choose standardized responses in OMS and submit information to MARx about any limitations that the sponsor notified the beneficiary about and implemented for the beneficiary's safety. One of the standardized responses will allow sponsors to report to CMS that the case is under review ("Review In Progress"). Please refer to the "Data Disclosure" section later in this guidance, 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>.

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:

- Education of prescribers about the opioid overutilization crisis, the CDC Guideline for Prescribing Opioids for Chronic Pain, *co-prescribing of naloxone*, and the role their DMPs play in reducing overutilization of FADs in the Part D program. We expect this additional information to enhance the requirements of case management and requirements that must be met to implement limitations on ARBs' access to FADs.
- Encouragement of 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.
- Use of 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.

Prescribers who do not Respond to Case Management. In cases where 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 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 and apparent lack of coordinated care.

In doing so, a 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. We suggest that sponsors make 3 outreach attempts to contact prescribers over 10 business days during case management, because documentation of 3 or more attempts is sufficient for the sponsor to demonstrate that a prescriber is not responsive in cases when the sponsor wants to implement a coverage limitation on a beneficiary's access to FADs under their DMPs. (See section, "Requirements for Implementing Limitations on an ARB's Access to Coverage for FADs").

Exception to case management. If a beneficiary was identified as a PARB 2 or ARB 2 by his or her most recent prior plan, MARx will report such beneficiaries to their new plan sponsors, if such identification was not terminated before the beneficiary disenrolled from the previous plan. To distinguish between the two, the sponsor must contact the sponsor of the Part D plan in which the beneficiary was most recently enrolled. Plans should refer to the applicable Overutilization Contact listed in HPMS and posted on the CMS Part D Overutilization website. See Attachment B for a sample memo that a former sponsor may use to provide such information to a new sponsor, when the new sponsor requests it.

The sponsor does not have to engage in case management for PARB 2s and ARB 2s, so long as the sponsor obtains case management information from the previous 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 has already been performed by a prior Part D sponsor under a DMP. See also the Section, "Data Disclosure."

C. Limitations on Access to Coverage for FADs (42 CFR §423.100(f)(3))

If the requirements to do so are met, a Part D plan sponsor may limit an ARB's access to coverage for FADs under a DMP in the following ways:

1. **Beneficiary-Specific POS Claim Edit:** Implement a *POS* claim edit for FADs that is specific to an ARB. This means that the 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.
 - Example: The sponsor will cover only certain Part D prescription opioid medications or benzodiazepines for the ARB.
 - Example: The sponsor will not cover any prescription opioid medications or benzodiazepines for the ARB.
 - Example: The sponsor will cover up to a certain level (e.g., MME, quantity) of prescription opioid medications for the ARB.
2. **Prescriber Limitation:** Limit an ARB's access to coverage for FADs to those that are prescribed for the beneficiary by one or more selected prescribers. This means that the sponsor covers FADs for the ARB only when they are obtained from the selected prescriber(s).

3. **Pharmacy Limitation:** Limit an ARB's access to coverage for FADs to those that are dispensed for the beneficiary by one or more selected network pharmacies. This means that the sponsor covers FADs for the ARB only when they are obtained from the selected pharmacy(ies).

(See next section "Requirements for Implementing Limitations on an ARB's Access to Coverage for FADs").

In applying a prescriber and/or pharmacy limitation, the sponsor must also comply with the requirements regarding beneficiary preferences and to provide an ARB with reasonable access to coverage for FADs. (Please refer to the "Beneficiary Preferences" and "Reasonable Access Considerations" sections later in this guidance).

Sponsors will be permitted to implement beneficiary-specific POS claim edits, prescriber limitations, and pharmacy limitations for FADs only through a Part D DMP in 2019 and beyond. A sponsor may not implement a beneficiary-specific claim edit for FADs outside of a DMP after 2018.

Sponsors may implement more than one coverage limitation for a single ARB. These limitations may be concurrent or overlapping due to the case not resolving as expected with the other limitation(s) in place. Periods of overlapping coverage limitations are independent of each other. If a beneficiary changes sponsors, any limitation period associated with a coverage limitation placed on an ARB 2 by the new sponsor is also independent of the limitation period(s) associated with the coverage limitation(s) implemented by the prior plan sponsor.

- Example: An ARB may have a beneficiary-specific POS claim edit and a pharmacy limitation for opioids, and the 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 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. 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 plan 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. (See next section “Requirements for Implementing Limitations on an ARB’s Access to Coverage for FADs” and the section, “Date Disclosure”).

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.

*D. Requirements for Implementing Limitations on an ARB’s Access to Coverage for FADs
(42 CFR § 423.153(f)(4))*

A sponsor may not limit the access of an ARB to coverage for FADs unless the sponsor has done all of the following:

- 1) Conducted the required case management and updated it, if necessary.
 - a) Obtained verification from a prescriber that the beneficiary is at-risk. 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 case management and providing an Initial Notice and 30 day time period for the beneficiary’s response. See “Case Management / Clinical Contact / Prescriber Verification”).
 - b) Obtained the agreement of at least one prescriber of FADs for the beneficiary 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 also “Notification and Confirmation of Selections” section later in this guidance).
- 2) Provided the required notices to the beneficiary after case management is complete.

Exceptions (please also refer to Table 2):

- Prescriber agreement is not required for a pharmacy limitation.

- If a prescriber does not respond after 3 attempts by the sponsor to contact them within 10 business days, then the sponsor has demonstrated that the prescriber is not responsive and may proceed with a beneficiary-specific POS claim edit.
- A sponsor may not implement a prescriber limitation if no prescriber was responsive.

TABLE 2: REQUIREMENTS FOR LIMITING ACCESS TO COVERAGE OF FADS

Coverage Limitation on FADs	Prescriber Verification Beneficiary is At-Risk**	Prescriber Agreement**** for Coverage Limitation (Initial 12 months)	Prescriber Agreement for Coverage Limitation (Extend Additional 12 months)
Beneficiary-Specific POS Claim Edit	Yes**	Yes**	Yes**
Pharmacy Limitation	Yes**	No*	No*
Prescriber Limitation	Yes***	Yes***	Yes***

**If prescriber rejects a pharmacy limitation, the sponsor should take this into consideration.*

***If prescriber does not respond to case management, the sponsor may proceed with this limitation.*

****If prescriber does not respond to case management, the sponsor may not proceed with this limitation.*

***** (See also “Notification and Confirmation of Selections” section later in this guidance).*

E. Notices (42 CFR § 423.153(f)(5)-(7))

CMS regulations 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. Part D sponsors should consult the regulations for compliance purposes.

A Part D sponsor must not send any beneficiary notices until initial case management has been completed, as described earlier in this guidance, which may have been conducted under the DMP of the beneficiary’s immediately prior plan, if an exception applies, as also described earlier in this guidance. (See “Case Management / Clinical Contact / Prescriber Verification”).

Sponsors must make reasonable efforts to provide the beneficiary’s prescriber(s) of FADs with a copy of the notices.

Beginning January 1, 2021, if a Part D sponsor upholds its at-risk determination on appeal, the sponsor must automatically forward the case to the IRE for review. Sponsors are also required to include information about automatic forwarding in beneficiary notices.¹ CMS has proposed corresponding revisions to the content of the Initial Notice and Second Notice described below. The current notices², which expire on November 30, 2021, will be updated pending approval by the Office of Management and Budget (OMB) under control number 0938-0964 (CMS-10141).

¹ SUPPORT Act, P.L. 115-271, § 2007

² Notices and instructions available at <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Drug-Management-Program-Notices-.zip>.

1. Initial Notice (42 CFR § 423.153(f)(5))

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, unless an exception applies. The Initial Notice does the following:

- i) 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;
- ii) Describes the specific coverage limitation(s) the sponsor intends to implement and the timeframe for its decision;
- iii) 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;
- iv) Provides information about resources and plan benefits designed to address prescription drug abuse;
- v) 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
- vi) 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 considered a PARB when the sponsor provides the Initial Notice. The beneficiary may provide information to the sponsor that may be material to the plan's determination about whether the beneficiary is an ARB.

As indicated above, the Part D plan 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 plan sponsor.

The Initial Notice is also used for ARB 2s when a gaining 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 plan 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. (See the previous section, "Requirements for Implementing Limitations on an ARB's Access to Coverage for FADs").

2. Second Notices (*42 CFR § 423.153(f)(6)-(f)(7)*)

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 plan sponsor to the Initial Notice, there are two possible outcomes. The sponsor will either determine the beneficiary is at-risk for abuse or misuse of FADs and will proceed with the coverage limitation under its DMP, or the 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. (See next section, “Notices: Timing and Exceptions”).

a) Second Notice (*42 CFR § 423.153(f)(6)*)

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.

The Second Notice does the following:

- i) 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;
- ii) Describes the coverage specific limitation(s) the sponsor is implementing, including the effective and end dates and the selected pharmacy and/or prescriber, if applicable;
- iii) Explains how the beneficiary can submit preferences for the selected pharmacy and/or prescriber, if applicable;
- iv) Explains the beneficiary’s right to a redetermination, including the right to an expedited redetermination, and how to request one; and
- v) 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. (See Section, “*Notices: Timing and Exceptions*” just below.)

The Part D plan 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 “Notification and Confirmation of Selections” section below).

b) Alternate Second Notice (42 CFR § 423.153(f)(7))

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, the 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. (See Section, "*Notices: Timing and Exceptions*" just below).

The Alternate Second Notice informs the beneficiary that:

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

The Part D plan 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.

F. *Notices: Timing and Exceptions (42 CFR § 423.153(f)(8))*

Upon making the determination that the beneficiary is at-risk for abuse or misuse of FADs or not, a Part D sponsor must provide the beneficiary a Second Notice or the Alternate Second Notice, as applicable, no sooner than 30 days from the date of the Initial Notice, and no later than 60 days from the date of the Initial Notice.

Exception: A gaining plan 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.

We note that if an ARB changes plans within a contract, CMS does not consider the beneficiary's status in a DMP to have changed and thus the beneficiary will not be reported by MARx. However, if the new plan does not have the 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. If an ARB changes contracts - even if both are held by the same legal entity or parent organization - CMS does consider the beneficiary to be an ARB 2 and the beneficiary will be reported by MARx.

Specific instructions for sponsors to submit information to MARx *is* in the MAPD PCUG available *on* the CMS Part D overutilization website at:

<https://www.cms.gov/Medicare/Prescription-Drug->

[coverage/PrescriptionDrugCovContra/RxUtilization.html](https://www.fda.gov/coverage/PrescriptionDrugCovContra/RxUtilization.html) once released.

G. Overview of Selection Process for Prescribers and Pharmacies

This section summarizes multiple subsections below about the prescriber and pharmacy selection process that a Part D sponsor must follow for cases involving prescriber and/or pharmacy coverage limitations. In such cases, the pharmacy(ies) and prescriber(s) from which an ARB must obtain FADs are called “selected pharmacy(ies)” and “selected prescriber(s).” Sponsors are required to include a selected pharmacy and/or prescriber, as applicable, that ensures the beneficiary has reasonable access to FADs in the Initial Notice to the beneficiary and solicit the beneficiary’s preference(s) (after notification and confirmation with the prescriber/pharmacy about the selection).

It is important to note, however, that 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 a subsection below; or
- the sponsor takes exception to the beneficiary’s preferences, as also described in a later subsection.

1. Beneficiary Preferences (42 CFR § 423.153(f)(9))

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. However, there are some parameters, caveats, and exceptions, discussed in this subsection and later in this section. The sponsor must do the following:

- If the beneficiary is enrolled in a stand-alone prescription drug benefit plan 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 pharmacy or prescriber must be a network pharmacy or network prescriber, unless the ARB is in a stand-alone prescription drug benefit plan (PDP) or in an MA-PD plan that is not network-based. In such a case, 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 puts the sponsor in the best possible position to coordinate the beneficiary’s care going forward in light of the demonstrated concerns with the beneficiary’s utilization of FADs.

A few caveats to this guidance are that 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 a subsection below. The same is true regarding a non-network

pharmacy for an ARB in an MA-PD *plan* or stand-alone PDP. Finally, a sponsor can take exception to a beneficiary's preference for a selected pharmacy and/or prescriber, as detailed in a later subsection.

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.

(See earlier section, "Second Notice.")

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 is generally not 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 the guidance below. 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.

2. Reasonable Access Considerations

When making pharmacy and prescriber selections, a Part D plan 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.

As discussed earlier, a beneficiary's preferences for selected prescriber and pharmacy prevail over the other factors, unless the beneficiary's preferences do not comply with the "network policy" described in this section or the sponsor takes exception to the beneficiary's preferences.

When the beneficiary's preferences are not available, in weighing these factors, CMS expects the sponsor will select the network pharmacy(ies) and/or the network prescriber(s) (or non-network prescriber in the case of a plan without a provider network) 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 must weigh the remaining reasonable access factors in the manner the sponsor deems most appropriate for the case.

3. Actual Selection of Prescribers and Pharmacies (42 CFR § 423.153(f)(12))

When making prescriber and pharmacy selections, whether the beneficiary's preferences are available or not, a Part D sponsor must do the following:

- a) 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 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 shall treat all prescribers of the group practice as one prescriber.
- b) 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, sponsors shall treat such locations of the pharmacy collectively 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.

4. Sponsor Exception to Beneficiary Preferences (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.

5. Notification and Confirmation of Selection(s) (42 CFR § 423.153(f)(13))

a) Prescribers and Pharmacies

Before selecting a prescriber or pharmacy, a Part D plan sponsor must notify the prescriber and/or pharmacy, as applicable, that the beneficiary has been identified for inclusion in a DMP and that the prescriber or pharmacy or both is(are) being selected as the beneficiary's selected prescriber or pharmacy or both for FADs. The sponsor must also receive confirmation from the prescriber(s) and/or pharmacy(ies), as applicable, that the selection is accepted before conveying this information to the ARB.

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.

i) Prescribers

As described earlier, the sponsor should initially select the prescriber who will serve as the beneficiary's selected prescriber during case management, although the beneficiary may later express a different preference, which then must be taken into account. As also described earlier in the "Case Management" section, the 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 sponsor can identify the prescriber in the Initial Notice it provides to the beneficiary. If the beneficiary provides the sponsor with a different selection, then the sponsor would contact the alternate prescriber and obtain their agreement to serve as the beneficiary's selected prescriber, which again 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.

ii) *Pharmacies*

Similar to selected prescribers, the 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 then must be taken into account. In the case of a pharmacy limitation, the sponsor and network pharmacies should negotiate 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. For out-of-network pharmacies, or network pharmacies *that* have not negotiated how to be notified, the sponsor must notify 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.

H. *Effective and Termination Dates and Extensions of Identification as an ARB (42 CFR § 423.153(f)(14))*

1. Effective Dates

The effective date of a coverage limitation implemented under a DMP is the date of the Second Notice.

2. Termination Dates

The identification of an ARB as such must terminate on whichever of the following 2 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 1 year period calculated from the effective date of the limitation, unless the limitation is extended, or
 - the date that is the end of a 2 year period calculated from the effective date of the limitation, if the limitation was extended.

Regarding extensions to coverage limitation periods, please see the next section. As we noted earlier, the time periods of overlapping limitations are independent of each other. Also, as noted earlier, if a beneficiary changes sponsors, any coverage limitation period placed on an ARB 2 by the new sponsor is independent of the original limitation period implemented by the prior plan sponsor.

Additionally, a beneficiary's identification of an ARB also terminates as soon as a sponsor discovers that the beneficiary is exempted or did not meet the OMS criteria to begin with, as also discussed earlier in this guidance.

Finally, a plan 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.

3. Extensions

As just noted, 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
 - A sponsor may not extend a prescriber limitation if no prescriber agreed
- Provide another Second Notice to the ARB.

The clinical basis to extend a coverage limitation should be the sponsor's assessment whether an ARB demonstrates that the 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 plan sponsor extends an ARB's coverage limitation, the ARB, their representative, or their prescriber on behalf of the ARB is not precluded from requesting 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.

Please refer to Table 2 regarding prescriber agreement and prescribers who are not responsive in the context of extensions of coverage limitations.

I. *Data Disclosure (42 CFR § 423.153(f)(15))*

Data disclosure by CMS and Part D sponsors is essential to the operation of DMPs. CMS has updated OMS responses to allow sponsors to provide more detail about case management, and we have also updated MARx to accommodate information about the two required beneficiary notices. Please refer to the OMS technical guidance for DMPs *and MAPD PCUG for MARx reporting* available on the CMS Part D Overutilization website at: <https://www.cms.gov/Medicare/Prescription-Drug-coverage/PrescriptionDrugCovContra/RxUtilization.html>.

1. By CMS through OMS and MARx

CMS systems disclose the following data to Part D sponsors:

- OMS identifies PARB 1s *who are enrolled in Part D plans that* have a DMP.
- OMS *reports* PARB 1s to Part D sponsors with DMPs quarterly on the last business day of the month. Sponsors may also identify PARB 1s by applying the OMS criteria.
- MARX identifies PARB 2s and ARB 2s to Part D sponsors *with DMPs*.

2. By Part D Sponsors through OMS, MARx and Manually

CMS has established the following rules to require Part D sponsors to disclose data about their decisions to impose coverage limitations and the limitations imposed. CMS has also established the following procedures under which sponsors must share information about *PARBs and ARBs*.

a) OMS

A Part D sponsor must provide information to CMS through OMS on the case management status for:

- i) Each PARB 1 identified through OMS to the sponsor within 30 days of receiving an OMS report.
- ii) Each PARB 1 that the sponsor identifies within 30 days from the date of the most recent OMS report.
- iii) 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 daily transaction reply report (DTRR) within 30 days from the date of the most recent OMS report.

b) MARx

A Part D sponsor must provide coverage limitation information to CMS about *PARBs* and *ARBs* by entering information into MARx as soon as possible but not later than 7 days from the:

- i) Date of the Initial Notice to a PARB: Notification start-date.

- ii) Date of the Second Notice to an ARB: Implementation start-date (i.e., effective date).
- iii) Date that the sponsor terminates a PARB status or an ARB's coverage limitation(s) for FADs before the original termination date: Notification end-date or implementation end-date.

c) *Sponsor-to-Sponsor Information Transfer*

A losing sponsor must provide information to the gaining sponsor by transferring case management information as soon as possible but no later than 2 weeks from the gaining sponsor's request when—

- i) 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
- ii) The pending or implemented coverage limitation for FADs that the losing sponsor had entered into MARx for the beneficiary had not terminated before disenrollment.

See Attachment B for a sample memo that a losing sponsor may use to provide case management information to a gaining sponsor, when the gaining sponsor requests it.

IX. FREQUENTLY ASKED QUESTIONS (FAQs)

This FAQ document integrates information from the HPMS memo, “Part D Drug Management Program Policy Guidance,” released on November 20, 2018, and the “Frequently Asked Questions about Part D Drug Management Programs (DMPs)” document that was posted on the Part D Overutilization website. FAQs have been renumbered. New information has been added in red italics.

PACE and EGWPs

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

Yes. Given the national opioid crisis, we expect all Part D sponsors to implement DMPs.

- 2) *Are PACE plans waived from the DMP provisions at § 423.153(f)?*

Because of the voluntary nature of the provisions under § 423.153(f), a waiver of these provisions is not necessary for PACE organizations. However, to the extent that PACE organizations implement beneficiary-specific POS claim limits on opioids and/or benzodiazepines, or require a beneficiary to obtain such prescriptions drugs only from a specific provider or pharmacy, which limitations are not imposed on the general membership of the PACE organization, the PACE organization must comply with the Part D DMP provisions. In addition, CMS will monitor beneficiaries meeting the OMS criteria who are in PACE organizations. If a PACE organization does not have a DMP, CMS may ask the PACE organization to demonstrate what alternate drug utilization review process it has in place to prevent prescription drug overutilization.

Case Management

- 3) *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, these requirements are in place for two reasons: 1) DMPs should focus on beneficiaries whose use of FADs puts them at the highest potential risk; and 2) no beneficiary’s Part D coverage of FADs should be limited under a DMP without a thorough review of their health care circumstances. 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, please 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. Please see 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>

- 4) *In addition to a current and unrestricted license to practice within the scope of their profession, what specific credentials must the clinical staff have who are conducting case management?*

While there is no requirement for particular credentials for clinical staff, CMS expects that such

clinical staff conducting case management as part of a Part D plan sponsor's DMP would be a physician or other appropriate health care professional with sufficient expertise to conduct medical necessity reviews related to potential opioid overutilization.

OMS Criteria

- 5) *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. Thus, the sponsor should not provide the Initial Notice to the beneficiary. 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 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 and MARx, as applicable.

- 6) *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.

- 7) *Can plans apply their own method for identifying pharmacies with multiple locations that share real-time data?*

The methodological changes that CMS will implement in OMS in 2021 are expected to improve identification of pharmacy grouping before PARBs are reported to plans. While there is currently no commercially available database that captures information specific to which pharmacies share real-time data, a Part D sponsor wishing to apply minimum or supplemental OMS criteria to their own data may use any reasonably valid and reliable method that it has developed. However, the sponsor should self-audit at reasonable intervals to test that its method is reliable and up-to-date.

- 8) *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.

- 9) *If a plan sponsor wants to target PARBs through its DMP by applying the OMS criteria itself, can the sponsor initiate case management and send beneficiary notices before OMS reports the case to the sponsor?*

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

OMS Reports

- 10) *Will a plan sponsor without a DMP receive OMS reports?*

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

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

Exempted Beneficiaries

- 11) *Are beneficiaries resident in an assisted living facility (ALF) exempted?*

Unless such beneficiary meets one of the specific exemptions, the beneficiary is not exempted solely because they reside in an **ALF**. However, if a sponsor learned during case management that a beneficiary resides in an ALF that does dispense drugs through a contract with a single pharmacy, for example, then the sponsor must exempt such resident from its DMP.

- 12) *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.

- 13) *If a beneficiary was a resident of a LTC facility and is now at home, and a sponsor is applying the OMS criteria itself, when reviewing the previous 6 months, should the sponsor include the prescribers/pharmacies from the beneficiary’s time in the LTC facility*

or is that period exempt?

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

*14) We have discovered that a beneficiary is exempt because they have elected hospice. What does this mean for a beneficiary-level **prior authorization (PA)** on drugs in the 4 classes (analgesic, anti-nausea, laxative, anti-anxiety)?*

The PA should be reinstated or not removed because a Part D sponsor must still make sure that drugs and biologicals covered under the Medicare Part A per-diem payments to a Medicare hospice program are excluded from coverage under Part D. Please see the most recent CMS guidance, “Update on Part D Payment Responsibility for Drugs for Beneficiaries Enrolled in Medicare Hospice,” issued on November 15, 2016.

Limitations on Access to Coverage for FADs

15) 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.

16) Do we have to obtain agreement from the prescriber that a beneficiary prefers for a prescriber limitation?

Generally, yes. The prescriber who agrees to a prescriber limitation for a beneficiary should be identified, and their agreement obtained by the plan sponsor through case management. If a beneficiary submits a preference for a different prescriber in response to the Initial Notice or later, the sponsor will have to obtain that prescriber’s agreement, unless the sponsor asserts that an exception applies to the beneficiary’s preference.

17) 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.

18) 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 Notices

19) Are plan sponsors required to copy the CMS account manager on beneficiary notices?

No. While we expected the plan to copy their CMS account manager on all beneficiary notices implementing a beneficiary-specific point of sale edit under the previous Part D overutilization policy, it is no longer expected.

Beneficiary Preferences

*20) 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.

21) 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.

22) 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.

23) 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.

24) 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

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

No. We encourage Part D plan sponsors to undertake these suggestions as they see appropriate,

but they are not required at this time. Also, we note that if a sponsor marks a case as resolved, the case may be suppressed from OMS reporting for a defined period of time. See OMS User Guide for the suppression rules.

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

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

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

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

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

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

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

Prescriber Inquiry and Sponsor Information Transfer Templates

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

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

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

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

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

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

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

29) 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

30) 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.

31) 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 sponsors' 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 Part D Overutilization website at: [https://www.cms.gov/Medicare/Prescription- Drug-coverage/PrescriptionDrugCovContra/RxUtilization.html](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.

ATTACHMENT A

Sample Part D Drug Management Program Prescriber Inquiry Letter

Instructions: This sample could be used to notify prescribers of frequently abused drugs that the plan's records show that one of their patient's utilization pattern of frequently abused drug(s) is potentially unsafe, which has triggered a review under the plan's Drug Management Program to determine whether the patient is at risk for prescription drug abuse or misuse. The sponsor may replace <Plan Name> with either "the Plan" or "our Plan" throughout the notice.

<DATE>

<PRESCRIBER NAME>

<ADDRESS>

<CITY, STATE ZIP>

<RE: BENEFICIARY NAME AND CASE NO. [###]>

Dear <PRESCRIBER>:

<Plan Name> is sending you this letter to request your assistance and response. We have important clinical information about your patient's utilization of prescription <<opioids> <and benzodiazepines>> for use in your treatment of this patient. <Plan Name> is the Medicare prescription drug benefit plan for your patient, <Patient Name>. Our Drug Management Program <, name of program, if applicable,> reviews utilization by our plan enrollees that involve multiple prescribers and/or pharmacies, and flags for case management utilization that is potentially unsafe.

We would appreciate your review of the total prescription drug utilization of your patient, <Name of Patient,> your opinion whether your patient is at risk for prescription drug abuse or misuse, and information about any relevant treatment factors, such as whether your patient is being treated for active cancer-related pain or is receiving hospice, palliative, or end-of-life care services. If so, we would like to work with you <and the other prescribers of these drugs> to determine how your patient's utilization of these drugs should be more closely managed.

<We have <listed below> <attached> information about the <opioid> <and benzodiazepine> medications prescribed for <Patient Name> of which we are aware, such as the prescribers, dosage(s) (quantities and days' supply) prescribed, dispensing dates and time period we are reviewing.> <We have <also> <listed below><attached> the criteria that <Name of Patient>'s opioid utilization met to trigger our review. Please provide us with information about this drug utilization by completing the options below and returning this page to us by <fax at ###> <indicate other method>:

When multiple prescribers are involved, the goal of our <Drug Management Program><, name of program, if applicable,> is to achieve a consensus among all prescribers as to the appropriate,

medically necessary, and safe dosage for <Patient Name>, and if there is no consensus, to facilitate one.

We thank you for your assistance in addressing this matter and urge you to be responsive. If we are unable to establish through communication with the prescriber(s) of these drugs that the current dosage of opioid medication(s) is appropriate, medically necessary, and safe for <Patient Name>, we may have to place a limitation on <Patient Name's> access to coverage of some or all of these medications. In addition, a limitation may assist you in managing <Patient's Name> safe use of opioids <and benzodiazepines>. Therefore, your input is imperative.

Should you have any questions, or if you need additional, please contact me at <Contact Information> during the hours of <LIST HOURS> and please refer to the file number above.

Sincerely,

<NAME AND CREDENTIAL OF CLINICAL STAFF>

[Insert beneficiary identifying information]

[List or attach the pertinent prescription information].

PLEASE COMPLETE ALL THAT APPLY. THANK YOU FOR YOUR COOPERATION.

___ I would like <Plan Name> <Name of Drug Management Program, if applicable> to contact me further to discuss this case, including relevant treatment information.

___ I, <Prescriber Name> am of the opinion 1) that all these medications are appropriate, medically necessary, and safe for my patient, <Patient Name>; and 2) that <Patient Name> **IS NOT** at-risk for prescription drug abuse or misuse.

___ I <Prescriber Name> am of the opinion: 1) that all of these medication are NOT appropriate, medically necessary, and safe; 2) that <Patient Name> **IS** at-risk for prescription drug abuse or misuse.

___ I think <Plan Name> should be aware of the following relevant treatment information:

ATTACHMENT B

Sample Part D Drug Management Program Sponsor Information Transfer Memorandum

Instructions: This memorandum could be used by a former sponsor to respond to a new sponsor that has requested case management information about a potential at-risk or at-risk beneficiary who disenrolled from the former sponsor's plan. It is intended to convey information about the former sponsor's findings about the beneficiary's prior opioid and/or benzodiazepine utilization, and to provide the new sponsor with the records and actions generated by the former sponsor's review of the beneficiary under its Drug Management Program.

DATE: <Date>
TO: New Sponsor
FROM: Former Sponsor
RE: Drug Management Program Information for <Beneficiary Name>

The purpose of this memo is to highlight certain information that <Former Sponsor Plan Name> is providing in response to a request that we received on <Date> from <New Sponsor Plan Name> to transfer case management information and associated records for <Beneficiary Name> from our Drug Management Program. <New Sponsor> received notice from <Former Sponsor> on <Date, if known by Former Sponsor> through MARx that <Beneficiary Name> had an Active CARA Status when they disenrolled from <Former Sponsor Plan Name> and enrolled in <New Sponsor Plan Name> effective <Date>.

<Beneficiary Name> had the status of [*Select one as applicable:* <potential at-risk beneficiary> <at-risk beneficiary>] under <Former Sponsor Plan Name's> Drug Management Program. [*Select one, as applicable:* <We notified this potential at-risk beneficiary of their status> <We implemented a coverage limitation on frequently abused drugs for this at-risk beneficiary>] on <date>.

The limitation(s) that <Former Sponsor> [*Select one, as applicable:* <intended to implement> <implemented>] on <Beneficiary Name's> access to coverage for [*Select as applicable:* <opioids> <and benzodiazepines>] is:

[[*Select if applicable:* Prescriber Limitation for [*Select as applicable:* <opioids> and <benzodiazepines>.] The selected prescriber is <Prescriber Name> and their individual NPI is <NPI #>. The contact information we have for the prescriber is <FILL IN>].]

[[*Select if applicable:* Pharmacy Limitation for [*Select as applicable:* <opioids> and <benzodiazepines>]. The selected pharmacy is <Pharmacy Name> and its organizational NPI is <NPI #>. The address we have for the pharmacy is <FILL IN>].]

[[*Select if applicable:* Beneficiary-specific POS claim edit for [*Select as applicable:* <Only
<Drug Name> <drug strength><quantity> is covered every <Number> days>].]]

More detail is included in the documents accompanying this memorandum, which contain copies of the applicable beneficiary notice(s) and of the records from the case management that was conducted under <Former Sponsor's> Drug Management Program upon which the decision to implement the coverage limitation(s) was based. Specifically, the following minimum necessary records are permitted to be transferred under applicable law and include:

[List the records that are included. Examples of records that could be included are:

- a) notation whether the beneficiary met the minimum or supplemental OMS criteria;
- b) copies of medical records;
- c) beneficiary drug utilization history;
- d) correspondence with prescribers and the beneficiary;
- e) notes documenting telephone conversations; and
- f) documentation of the decision arrived at through case management.

If you have any questions concerning this memorandum, please contact <Name> <Title> at
<Contact Information.>

[Insert beneficiary identifying information]