Patient Safety Analysis

PDP/MA-PD Contracts
Overutilization Monitoring System User Guide
Implementation: January 1, 2022

Web Portal

https://PartD.ProgramInfo.US/PatientSafety

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Technical Support

If you need help accessing the Overutilization Monitoring System (OMS) or have questions about the content of the reports, please contact the Acumen, LLC help desk at:

Email	Phone
PatientSafety@AcumenLLC.com	(650) 558-8006

If you have questions related to the Medicare Part D drug management program requirements, send an email with "DMP" in the subject line to CMS at:

Email

PartD_OM@cms.hhs.gov

If you have questions related to MARx drug management program reporting, send an email with "MARx" in the subject line to CMS at:

Email

PartD_OM@cms.hhs.gov

1 Introduction

Since 2019, §1860D-4(c)(5)(A) of the Social Security Act permits Part D sponsors to establish Drug Management Programs (DMPs) for beneficiaries at-risk for misuse or abuse of frequently abused drugs (FADs). CMS established the regulatory framework under which Part D plan sponsors may establish a DMP at 42 CFR § 423.153(f),[1] which codified many aspects of the existing retrospective Part D Opioid Drug Utilization Review (DUR) and Overutilization Monitoring System (OMS) policies in place prior to 2019.

Beginning January 2022, based on additional changes to §1860D-4(c)(5) of the Act and corresponding regulatory changes,[2] all Part D sponsors are required to have a DMP, and beneficiaries with a history of opioid-related overdose are to be included in DMPs.

Sponsors must engage in the case management of each Potential At-Risk Beneficiary (PARB) reported through OMS and provide information related to their review within 30 days. In addition, sponsors must also report through OMS any sponsor-identified PARBs, and any newly enrolled PARBs or At-Risk Beneficiaries (ARBs) for which a sponsor received a transaction reply code (TRC) of '376' (New Enrollee CARA Status Notification) from the daily transaction reply report (DTRR).

DMP policy guidance, FAQs, and related information are posted on the CMS Part D Overutilization web page.

Information about navigating the Patient Safety Analysis Web Portal can be found in the Patient Safety Web Portal User Guide, located on the Help Documents page of the Patient Safety Analysis Web Portal.

1.1 Report Access

To access the Overutilization Monitoring (OM) reports (within the OMS Packages), an authorized user must be added to the Patient Safety Analysis Web Portal. A user's access to the OMS is limited to one of two levels, which is assigned by the Medicare Compliance Officer (MCO). Current authorized users of the Patient Safety Analysis Web Portal are automatically granted comparable access to OMS functionality. All authorized users can navigate the Web Portal and receive email notifications regarding report releases. The date (format = MMDDYYYY) in the file names represents the date the reports and packages were available on the Web Portal for authorized users to download. User access levels include:

1. Summary Report Only: User can access the OMS contract-level reports with summary information. Users with Summary Report Only permissions are not able to access beneficiary-level data:
    - The Summary OMS Package (.zip) is titled:

[1] https://www.govinfo.gov/content/pkg/FR-2018-04-16/pdf/2018-07179.pdf
[2] https://www.govinfo.gov/content/pkg/FR-2021-01-19/pdf/2021-00538.pdf

*ContractID*_Summary_Overutilization_Monitoring_Package_*MMDDYYYY.zip*

- The Summary OM report within the zip file is titled: *ContractID*_Summary_Overutilization_Monitoring_Report_*MMDDYYYY*.xlsx

2. Summary and Confidential Beneficiary Reports: User can access confidential beneficiary-level information in the Detail OMS report and the Summary OMS report:
   - The Detail OMS Package (.zip) is titled: *ContractID*_Detail_Overutilization_Monitoring_Package_*MMDDYYYY*.zip
   - The Detail OM report within the zip file is titled: *ContractID*_Detail_Overutilization_Monitoring_Report_*MMDDYYYY*.xlsx

MCO portal access instructions are available on the CMS Part D Overutilization web page under downloads. A contract's MCO authorizes the access level of each individual associated with a given contract up to five users (including her/himself) per contract. Authorization must be completed through Acumen's User Security Web Portal. The following link will take you to the Acumen User Security Web Portal.

At least one user from each contract must have access to Summary and Confidential Beneficiary Reports in order to view and respond to beneficiary-level reports and forms.

Users should request changes to their permission level through their contract's MCO.

Authorized users can download the OMS Package through the Download Files page. For more information about downloading reports, refer to the Patient Safety Web Portal User Guide on the Help Documents page of the Patient Safety Analysis Web Portal.

1.2 Report and Response Process

The contract-level OMS Package is provided once each quarter. Sponsors receive an email when the quarterly package is available for download. Each PARB identified by OMS is assigned a case number and is referred to in OMS as either a case or PARB. The case number is specific to the beneficiary and contract. All Part D contracts receive an OMS Package starting in 2022. Once the package is available, sponsors are to complete the following steps:

1. **Download the OMS Package(s)**. The OMS Package(s) is available for download on the Download Files page of the Patient Safety Analysis Web Portal on the last business day of the given quarter. The release and submission schedule is available on the Help Documents page of the Patient Safety Web Portal.
   - **The Summary OMS Package includes the following files:**
     i. *ContractID*_Summary_Overutilization_Monitoring_Report_*MMDDYYYY*.xlsx
     ii. *ContractID*_Sponsor_Response_Form_*MMDDYYYY*.xlsx (SRF)
     iii. Patient-Safety-Overutilization-Monitoring-System-User-Guide-*MONTH-YYYY*.pdf (OMS User Guide)

iv. ORF_and_SRF_Information – *YYYY_MM*.xlsx

- **The Detail OMS Package includes the following files:**

  i. *ContractID*_Detail_Overutilization_Monitoring_Report_*MMDDYYYY*.xlsx (Detail OM Report)

  ii. *ContractID*_Overutilization_Monitoring_Response_Form_*MMDDYYYY*.xlsx (ORF) – if the contract has open cases for review

  iii. *ContractID*_Sponsor_Response_Form_*MMDDYYYY*.xlsx (SRF)

  iv. *ContractID*_Verification_Response_Form_*MMDDYYYY*.xlsx (VRF) – if the contract has cases for review

  v. Patient-Safety-Overutilization-Monitoring-System-User-Guide-*MONTH-YYYY*.pdf (OMS User Guide)

  vi. ORF_and_SRF_Information – *YYYY_MM*.xlsx

2. **Review closed cases (Detail OM Report).** Cases are closed each quarterly report cycle dependent on sponsors' prior submitted responses or changes to a beneficiary's status.

3. **Review open cases (Detail OM Report).** Open cases are reported each quarter and require sponsor responses (refer to Step 6). Sponsors can use the beneficiary-level information provided in the Detail OM Report to assist in performing case management. Unless the sponsor determines that the beneficiary is exempt from the DMP or does not meet the minimum OMS criteria based on plan information, the sponsor must engage in case management through clinical contact with prescriber(s) to determine if the beneficiary is at risk and if a coverage limitation(s) is necessary.

4. **Review SRF cases (Detail OM Report).** All SRF cases reported by sponsors can be found in the Detail OM report. Sponsors review their SRF cases to verify all cases were successfully submitted and if any updates or deletions are necessary.

5. **Review VRF cases (VRF)**. Sponsor cases with potential data issues identified within the ORF and SRF, between the OMS and Medicare Advantage Prescription Drug System (MARx), or other data discrepancies are reported each quarter, if applicable. Sponsors compare their beneficiaries' MARx records with the last response submitted through OMS, refer to Section 4.5 Additional Clarifications: OMS Responses and MARx Coverage Limitations. If necessary, update the MARx record and/or submit the accurate final response(s) using the SRF. If different final responses are submitted in the SRF and the ORF for the same prior quarterly report and beneficiary, the sponsor should submit the accurate final response in the current SRF, if the beneficiary is not reported in the current ORF.

6. **Complete OMS Response Form (ORF) - if available.** Use the ORF to select the appropriate responses for each case. **Note**: this form is only available to contracts that have open cases in the given quarter. Refer to Section 4.2 for more information about the ORF, including instructions for completing the form.

7. **Complete Sponsor Response Form (SRF).** Sponsors must use the SRF to report any sponsor-identified PARBs or newly enrolled PARBs or ARBs for which a sponsor received a TRC of '376' (New Enrollee CARA Status Notification) from the DTRR and after requesting the prior contract's case management information. Refer to Section 4.3 for more information about the SRF, including instructions for completing the form.

    - Sponsor-identified cases meet either the minimum OMS criteria or the supplemental OMS criteria. Refer to Section 2.2 for more details regarding the criteria.

    - **Note:** Unlike the ORF, the SRF is made available to all sponsors each quarter. The SRF is expected to be completed by sponsors each quarter. If there are no cases to report in a given quarter, indicate so in the form.

8. **Complete Verification Response Form (VRF) - If available.** Sponsors use the VRF to provide an explanation for the potential data issues identified. The VRF will only be included in the Detail OMS Package if CMS has identified records that warrant further explanation. If the VRF is available in the Detail OMS Package, the sponsor will be notified when the OMS reports are released.

9. **Submit ORF (if available), SRF, and VRF (if available) through the Web Portal.** Once the responses are complete, upload the ORF, SRF, and/or VRF to the Patient Safety Analysis Web Portal.

    - Sponsors should verify that beneficiaries who meet the minimum OMS criteria are not reported in both the ORF and SRF in the same reporting cycle. If a beneficiary is identified by the sponsor and by CMS, the sponsor should only provide the ORF response.

    - All forms must be submitted as an .xlsx or .zip file via the secure Upload Files feature of the Patient Safety Analysis Web Portal in order to be considered for submission. Forms are not accepted via any other means.

    - Only completed forms are accepted by the Patient Safety Analysis Web Portal. Sponsors can confirm whether a form is completed by checking the "Overall Form Status" cell at the top of each form (refer to Table 6), the "Response Status" column (refer to Table 8), and the "Validation Status" or "Preliminary Validation Status" columns (refer to Tables 8 and 9) for every applicable case.

    - Sponsors must provide responses for open ORF cases and SRF cases within 30 days of the OMS report release date. The submission deadline is provided in the email notification and in the Submission Schedule document on the Help Documents page of the Patient Safety Web Portal. Once the submission deadline passes for that report cycle, the OMS submission window is closed and sponsors who do not submit by the deadline may be subject to compliance action by CMS.

    - Sponsors are expected to submit their VRF within 30 days of the OMS report release date. If a sponsor has questions, send an email to:

PartD_OM@cms.hhs.gov with the subject “OMS-MARx DMP Outreach: <Part D contract number>”.

- Past OMS response forms (ORF, SRF, and VRF) are not accepted during a new OMS submission window.

10. **Confirm upload was successful.** After uploading the forms, view the Process Status on the Upload File History page to confirm the upload was successful. If the upload was successful the Process Status reads “Form(s) processed”.
11. **Confirm case response status.** Use the Case Tracking (Table 12) page to confirm that responses were submitted for each case identified in the ORF. The status of the case must be “Submitted”.

Additional information about completing each of these steps is provided in the following sections of this guide.

2 Methodology

This section describes the current methodology used to identify cases monitored through the OMS.

2.1 Update History

April 2022	Section 1.2 – 9. Submit ORF (if available), SRF, and VRF (if available) through the Web Portal. Updated first bullet. Section 2.4 – Part D enrollment, contract assignment, and death date exclusion changed from the last month of the measurement period to the OMS quarterly report release month. Table 9: SRF Response Codes – Clarified that S. Method of Identification response: M1 - Met Minimum OMS Criteria includes beneficiaries who met the MIN1 and/or MIN2 criteria.
January 2022	Section A.3 – A typographical error was fixed on page 33. In the Average MME formula, the numerator inside the parentheses was corrected from 1,300 to 1,380. The rest of the formula and the resulting calculations remain unchanged. Section 2.2 – Minimum OMS Criteria updated to include history of opioid-related overdose. All associated tables updated as necessary. Section 2.8 – Sickle Cell Disease (SCD) added as a DMP exemption and included in the ORF and SRF as Element K4 (Table 10). Section 3.1.2 – Table 3. Added Met MIN1 OMS and Met MIN2 OMS Criteria elements. Prior Contract(s) Contributed to Opioid Use element changed to a Y (Yes) and N (No) indicator. Section 4.2.1 – Table 8. Element B is now pre-populated with the contract's identification number in the ORF. Section 4.3.1 – Element B is now pre-populated within a dropdown menu to select the contract ID for each case in the SRF. Section 4.4 – Updated Suppression Rules to include history of opioid-related overdose. Table 10. Combined OMS Minimum Criteria Not Met exceptions (Elements; K6-K9) into a single exception Element K7. Tables 3, 4 and 5. Removed HICN field from the ORF and SRF.
April 2021	Section 1.2 – Updated language for potential data discrepancies reported in VRF. Section 2.1.5 – Updated active CARA status OMS reporting rules. Section 3.1.1 – Clarified "Open SRF Cases" column definition in Table 1.

January 2021	RAPS (RxHCC) is no longer a data source for identifying exempt beneficiaries. Implemented revised methodology to determine the number of opioid dispensing pharmacies. Verification Response Form (VRF) added to Detail OMS package. Modified SRF PARB reporting language (Section 4.3). Added Section 4.5 Additional Clarification, Appendix B Pharmacy Grouping Methodology, and Appendix C Prescriber Grouping Methodology.
January 2020	HICN is no longer reported or captured in any reports. Data entry to the HICN field is blocked. Medicare Advantage encounter data added to identify beneficiaries with exempt diagnoses. Clarified that the two palliative care outpatient claims are on different dates of service. Changed suppression rule for 'Review in Progress' responses to closed cases if the beneficiary has an exemption during the current period. Clarified definitions for the following response descriptions: J. Reason Coverage Limitation Unnecessary – "Wait and See" (O1). K. Exceptions -- K6, K7, and K9 E. Review Status -- Review in Progress (R1) for both the ORF and SRF.
April 2019	Imbedded Validation Check – Updated the ORF and SRF with a "Validation Status" column to check the validity of responses. All cases must have a "Complete" Response Status and a "Valid" Validation Status for the form to be successfully submitted by the 30-day reporting deadline. The validation status for SRF cases is preliminary, pending successful validation of the Medicare Beneficiary Identifier (MBI) fields. Validation Reports – The validity of response combinations is now checked within the ORF and SRF instead of through the Validation Reports. SRF cases with invalid MBI fields will be reported to sponsors as 'invalid' in the contract detail reports. Any 'invalid' SRF cases can be deleted and re-submitted through OMS during the next reporting cycle. SRF Deletion – A new response code 'DEL' was added to the Method of Identification element of the SRF. Selecting this response code and "NA" for all subsequent elements will result in deletion of the SRF case. Sponsors check your contract detail report for confirmation.

"Update" Response Code Removal – The R3. Update" response code for the Review Status element was removed. "R2. Review Complete" is used for completed reviews of new cases as well as updated responses to previously reported cases. "R1. Review in Progress" can still be used for cases pending completion.

2.2 OMS Criteria

2.2.1 Minimum OMS Criteria (MIN)

PARBs meeting the minimum OMS criteria are identified by CMS or sponsors based on the following specifications (criteria 1 OR criteria 2 must be met, however, PARBs may meet both types of criteria):

1) Level of opioid use from multiple prescribers/pharmacies (MIN1):
   - Use of opioids with average daily morphine milligram equivalents (MME) ≥ 90 mg for any duration during the most recent 6 months (refer to Section 2.3 Measurement Periods) AND either:
     - 3+ opioid prescribers AND 3+ opioid dispensing pharmacies; OR
     - 5+ opioid prescribers (regardless of the number of opioid dispensing pharmacies)
   - Prescribers within the same practice are counted as a single prescriber (refer to Section 2.7 Opioid Provider Count Methodology).
   - Pharmacies with multiple locations that share real-time data are counted as one pharmacy (refer to Section 2.7 Opioid Provider Count Methodology).

2) History of opioid-related overdose, beginning January 1, 2022 (MIN2):
   - A medical claim with a primary diagnosis of opioid-related overdose within the most recent 12 months (refer to Section 2.3 Measurement Periods); AND
   - A Part D opioid prescription (not including MAT) within the most recent 6 months.

2.2.2 Supplemental OMS Criteria (SUPP)

PARBs meeting the supplemental OMS criteria are identified by sponsors based on the following specifications:

- Use of opioids (regardless of average daily MME) during the most recent 6 months (refer to Section 2.3 Measurement Periods); AND
- 7 or more opioid prescribers OR 7 or more opioid dispensing pharmacies.
- Prescribers within the same practice are counted as a single prescriber.
- Pharmacies with multiple locations that share real-time data are counted as one pharmacy.

2.3 Measurement Periods

The measurement or lookback periods when applying the OMS criteria are:

- **6-month period** is the 6 months prior to the month of a given OMS quarterly report release. For example, the 6-month period for the OMS report released in January is July 1 to December 31 of the prior year.
- **12-month period** is the 12 months prior to the month of a given OMS quarterly report release. For example, the 12-month period for the OMS report released in January is January 1 to December 31 of the prior year.

Note: The 6-month period is always the last 6 months of the 12-month period.

2.4 Data Sources

Prescription Drug Event (PDE) – used for opioid claims and resident code

Common Medicare Environment (CME) – used for Part D enrollment and contract assignment (as of the month of the OMS quarterly report release), Low Income Subsidy (LIS) status, and demographic information

Medicare Enrollment Database (EDB) – used for hospice enrollment

Common Working File (CWF) and Encounter Data System (EDS) – used to identify medical claims with a primary diagnosis of opioid-related overdose and exemption diagnoses

First DataBank (FDB) – used for medication list information

Medi-Span – used for medication list information

Centers for Disease Control and Prevention (CDC)[3] – used to identify oral opioids and their conversion factors (CF) to calculate the MME of an opioid PDE

Medicare Provider Enrollment, Chain, and Ownership System (PECOS) – used for prescriber information

Health Plan Management System (HPMS) Data – used to identify contract-specific information

Medicare Advantage Prescription Drug (MARx) System – used to identify cases with an active CARA Status (i.e., an active Point of Sale (POS) Edit, Prescriber Limitation, and/or Pharmacy Limitation)

National Council for Prescription Drug Programs (NCPDP) – used for pharmacy information

[3] The following link will take you to the CDC Analyzing Prescription Data and Morphine Milligram Equivalents (MME) site.

2.5 Medication and Code List Workbook

The OMS medication and code workbook is available on the Help Documents page of the Patient Safety Analysis Web Portal: Overutilization Monitoring System→ Medication Lists. This workbook includes the applicable medication lists and additional codes used to identify history of opioid-related overdose and exclusions. The medication lists include the characteristics (i.e., product name, strength, strength units, route of administration, dosage form, and the opioid CFs) for opioids, benzodiazepines, gabapentin, and pregabalin. The exclusion code list includes International Classification of Diseases -10th Revision - Clinical Modification (ICD-10-CM) for cancer diagnoses, palliative care, and SCD as well as PDE codes used to identify long-term care (LTC) or intermediate care facility (ICF) residents.

The specific National Drug Codes (NDCs) included in the analysis are maintained by Acumen and are created from the Medi-Span and FDB databases. Due to Medi-Span and FDB licensing restrictions, the medication NDCs are not provided. The medication lists are created using the following methodology:

Opioid Medication List:

- All opioid products with the same opioid ingredient, dosage form, and route of administration included on the CDC opioid MME List are identified from the Medi-Span and FDB databases.
- The CDC opioid MME List excludes: opium tinctures, cough/cold products, powders, topical, and all opioids administered via intravenous, intrathecal, epidural, or injection (with the exception of buprenorphine subcutaneous prefilled syringe) routes of administration. These products are excluded from application of the OMS criteria.
- Opioid products containing buprenorphine are excluded from average MME calculations but are included when determining prescriber and pharmacy counts.
- Opioid products containing methadone do not have a static MME CF, but instead utilize a graduated MME CF based upon the daily MME dose. An overview of the steps used to calculate MME can be reviewed in Section 2.6 below.

When the quantity dispensed on PDE claims is counted as each, such as transdermal patches and nasal sprays, the MME CF is adjusted to reflect the units and doses billed.

Opioid-related Overdose Code List:

- Opioid-related overdose ICD-10-CM codes

Benzodiazepine Medication List:

- All benzodiazepine products with the same benzodiazepine ingredient, dosage form, route of administration, and strength included on the Patient Safety Concurrent Use of Opioids and Benzodiazepines Measure NDC list.

Gabapentin and Pregabalin Medication Lists:

- All products with ‘gabapentin’ or ‘pregabalin’ as an active ingredient and the route of administration is ‘oral.’

Exclusion Code List:

- Cancer ICD-10-CM codes
- Palliative Care ICD-10-CM codes
- SCD ICD-10-CM codes
- LTC and ICF PDE resident codes

2.6 Opioid MME Calculation

The steps below detail the average MME calculation process:

- To calculate the daily MME for each non-methadone opioid claim with a date of service (DOS) within the 6-month period, use the following equations:
    - Opioid dosage units per day = (opioid claim quantity) / (opioid claim’s days supply)
    - MME daily dose (mg) per claim = (number of opioid dosage units per day) × (opioid strength per unit) × (MME CF[4])
    - Daily MME = each claim’s MME is assigned to each calendar day spanning the DOS plus the days supply value minus one day.
- For Methadone claims, use the following equations:
    - Methadone dosage units per day = (methadone claim quantity) / (methadone claim’s days supply)
    - Methadone daily dose (mg) per claim = (methadone dosage units per day) × (methadone strength per unit)
    - Methadone daily dose per day = each Methadone claim’s daily dose is assigned to each calendar day spanning the DOS plus the days supply value minus one day.
- To calculate a beneficiary’s MME for each day of the 6-month period, use the following equations:
    - Non-methadone total daily MME = for a given day, sum the daily MME across all claims to get the total MME for that day. Repeat for each day of the period.
    - Methadone total daily MME = for a given day, sum the daily dose across all claims to get the total mg dose for that day. Repeat for each day of the period.

[4] Opioid MME CFs are on the Opioid Medication List available on the Help Documents page of the Patient Safety Analysis Web Portal.

Then, depending on the total daily dose for each day, multiply by the appropriate graduated methadone MME CF.[5]
    - Total daily MME = (non-methadone total daily MME) + (methadone total daily MME) for each given day of utilization
- The following equations are used to calculate the average MME for each opioid user:
    - Total MME = sum of total daily MME within the period[6]
    - Duration of opioid usage = number of days between first and last day of opioid use within the period (inclusive of first and last days of utilization)
    - Average MME = Total MME / Duration of opioid usage

A detailed example of the MME calculation can be found in Appendix A.

2.7 Opioid Provider Count Methodology

- Pharmacy Counts: To count the number of unique opioid dispensing pharmacies, the pharmacy National Provider ID (NPI) is taken from the 'service provider' and 'alternate service provider' IDs on the PDE data. If only the NCPDP pharmacy ID is available, an attempt is made to crosswalk the NCPDP to its NPI. Otherwise, the pharmacy ID found in the 'service provider' field is used. To group pharmacies with multiple locations that share real-time data, the minimum number of groupings identified between the number of unique Federal TINs, unique Chain Names, and unique Pharmacy Names among chain pharmacies is identified. This value is added to the unique number of Federal TINs among Franchise and Individual pharmacies. Refer to Appendix B for additional information.
- Prescriber Counts: To count the number of unique opioid prescribers, the prescriber NPI is taken from the 'prescriber ID' on the PDE. The PDE NPIs are then matched with the NPIs found in the PECOS database, where relationships between individuals and organizations can be established. Individual prescribers with the same single organizational TIN are grouped and counted as one prescriber. No grouping takes place if a relationship cannot be established or if the PDE does not contain an NPI. Refer to Appendix C for additional information.

2.8 Exclusions

Beneficiaries who meet any of the following criteria are not reported in the ORF:

- Beneficiaries with a LTC or ICF resident code ("03" and "09" respectively) on the last PDE within the 6-month period.
- Beneficiaries with a cancer diagnosis in the CWF or EDS during the 12-month period.

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[5] Methadone MME CFs are on the Opioid Medication List available on the Help Documents page of the Patient Safety Analysis web portal.

[6] By calculating a daily MME and limiting the total MME to days within the 6-month period, any days supply or quantity dispensed beyond the period is excluded.

- Beneficiaries with a SCD diagnosis in the CWF or EDS data during the 12-month period. Once identified, a beneficiary with SCD is permanently excluded from future OMS reports.
- Beneficiaries enrolled in hospice, according to EDB, at any point during the 6-month period.
- Beneficiaries with at least 1 inpatient or at least 2 outpatient claims on different dates of service with a Z51.5 (Encounter for palliative care) diagnosis code in the CWF or EDS data during the 6-month period.
- Beneficiaries with a death date in the CME as of the month of the OMS quarterly report release.
- Beneficiaries who are not Part D enrolled as of the OMS quarterly report release month.
- Beneficiaries with an active MARx CARA Status as of the end of the period i.e., an active CARA status for a POS Edit, Prescriber Limitation, and/or Pharmacy Limitation for any FAD and the last OMS response for H. Coverage Limitation Necessary is “Y” (Yes). Active MARx CARA status cases that may still be reported in the ORF include:
    - Cases reported in the previous ORF as having an ‘R1. Review in Progress’ status.
    - Current PARBs whose last reported ORF responses were “R2. Review Complete” and H. Coverage Limitation Necessary equals “N” or “NA”.
    - Current PARBs whose last reported SRF responses were “R2. Review Complete” and H. Coverage Limitation Necessary equals “N” or “NA”.
    - Newly identified PARBs that were never previously identified or reported in OMS.
- Beneficiaries suppressed due to an active ORF or SRF exception or sponsor response. Refer to Section 4 for more details regarding ORF and SRF exceptions and sponsor responses that suppress beneficiaries from OMS reporting.

2.9 Informational Metrics

The OMS reports include several metrics for Part D sponsors as supplemental information, including:

- **High Opioid Daily Dose (90 MME) Rate:** Calculated as the total number of opioid utilization days equal to or exceeding 90 MME per 1,000 opioid fill days for all Part D users enrolled in the contract during the 6-month period. No exclusions applied.
- **Total Open ORF Cases with Concurrent Potentiator Drug and Opioid Use:** Concurrent use is defined as at least 1 day of overlapping days supply of both the opioid and potentiator drug claim during the 6-month period. The concurrent opioid potentiator drug metrics are calculated for the following drugs: benzodiazepine, high dose gabapentin (>2,400 mg), and pregabalin.

3 OMS Report Structure

All Part D sponsors receive a contract-level Summary OM Report with information regarding the contract's enrollees and their opioid utilization. Sponsors with open cases also receive a Detail OM Report, which contains the same summary overview, along with beneficiary-level information for all open and closed ORF cases reported through OMS.

3.1 OMS Reports

This section outlines the levels of analysis included in the Detail OMS Report. Each sub-section contains a description of each metric, any related notes, and a table of key elements that are found in the corresponding worksheets.

3.1.1 Contract Summary

Worksheet Description: Includes the contract name and ID, organization-type, report date, 12-month and 6-month periods and summary of open and closed ORF cases reported through OMS. The Contract Summary worksheet provides two tables: a summary of the sponsor's current enrollees and open cases, as well as a historical (overall) summary of ORF and SRF cases reported. These summary metrics are broken out at the following beneficiary group levels: All Enrollees, Non-LIS Beneficiaries, and LIS Beneficiaries.

Key Elements:

Table 1: Current PARB Summary

Key Element	Definition
Total Part D Enrollees	Total number of Part D beneficiaries enrolled in the contract as of the OMS quarterly report release month.
Total Opioid Users	Total number of beneficiaries with at least one prescription fill for an opioid during the 6-month period.
% of Part D Enrollees who are Opioid Users	Calculated as Total Opioid Users / Total Part D Enrollees
Total Open ORF Cases	Total number of enrollees identified as meeting the minimum OMS criteria (PARBs). This number may include beneficiaries who were identified in a previous OMS report, do not meet any exception criteria, and the prior OMS response did not result in suppression.
% of Opioid Users that are Open ORF Cases	Calculated as Total Open ORF Cases / Total Opioid Users
Total Open ORF Cases with Concurrent Benzodiazepine and Opioid Use	Total number of open ORF cases where the beneficiary has at least one day of concurrent benzodiazepine and opioid use.
Total Open ORF Cases with Concurrent High Dose Gabapentin (>2400 mg) and Opioid Use	Total number of open ORF cases where the beneficiary has at least one day of concurrent high dose gabapentin (> 2,400 mg) and opioid use.

Key Element	Definition
Total Open ORF Cases with Concurrent Pregabalin and Opioid Use	Total number of open ORF cases where the beneficiary has at least one day of concurrent pregabalin and opioid use.
High Opioid Daily Dose (90 MME) Rate	Total number of opioid utilization days with at least a 90 MME daily dose per 1,000 opioid utilization days for all opioid users. No exclusions applied.
Total Open SRF Cases	Total number of enrollees identified as open SRF cases. An open SRF case is one that has not been excluded (e.g., deceased), exempted (e.g., exempt facility), or suppressed (e.g., coverage limitation) and submitted within the past year. This column is for informational purposes only, and does not represent any further action required from the sponsor.

Table 2: Overall PARB Summary

Key Element	Definition
Open ORF Cases - Response Expected	Total number of enrollees identified as meeting the minimum OMS criteria (PARBs). This number may include beneficiaries who were identified in a previous OMS report and do not meet any exception criteria.
Total ORF Cases Reported Since Month-YYYY	Total number of enrollees ever identified as meeting the minimum OMS criteria. This number includes all open and closed cases.
Total Closed ORF Cases Since Month-YYYY	Total number of enrollees previously identified as meeting the minimum OMS criteria, but currently closed.
Total SRF Cases Since Month-YYYY	Total number of enrollees ever identified by sponsors via SRF. This number includes all open and closed SRF cases.

3.1.2 Open ORF Cases

Worksheet Description: Lists all currently open ORF cases requiring a response along with the minimum OMS criteria met and opioid utilization information for each case.

Key Elements:

Table 3: Open ORF Cases

Key Element	Definition
Case Number	The unique contract case identifier assigned to a beneficiary.
MBI	The beneficiary's Medicare Beneficiary Identifier.
DOB	The beneficiary's date of birth.
PBP ID	The beneficiary's plan benefit package (PBP) ID number.
LIS Status	The beneficiary's low-income subsidy (LIS) status. "Y" indicates the beneficiary ever had LIS status and "N" indicates the beneficiary never had LIS status during their Part D enrollment within the 6-month period.
Date First Reported	The first OMS report that the beneficiary was reported to the sponsor. (format: YYYY_MM)

Key Element	Definition
Met MIN1 OMS Criteria	Met MIN1 OMS Criteria: Level of opioid use from multiple prescribers/pharmacies (Y=Yes/N=No)
Met MIN2 OMS Criteria	Met MIN2 OMS Criteria: History of opioid-related overdose (Y=Yes/N=No)
Prior Contract(s) Contributed to Opioid Use	Y (Yes) if any of the PDEs contributing to the beneficiary's opioid fills were covered by a prior contract. N (No) if all the PDEs were filled through this contract.
Duration of Opioid Use	Number of days between first and last opioid fill during the period (calculated as days from the first opioid fill DOS to the last day of opioid use during the 6-month period).
Total MME	Total MME dispensed to the beneficiary during the 6-month period.
Average Daily MME	The Average Daily MME, calculated as Total MME divided by Duration of Opioid Use.
Concurrent Benzodiazepine and Opioid Use	Concurrent usage of a benzodiazepine and an opioid for at least one day. (N=No and Y=Yes)
Concurrent High Dose Gabapentin (>2400 mg) and Opioid Use	Concurrent usage of high dose gabapentin (> 2,400 mg) and an opioid for at least one day. (N=No and Y=Yes)
Concurrent Pregabalin and Opioid Use	Concurrent usage of pregabalin and an opioid for at least one day. (N=No and Y=Yes)
Number of Pharmacies Contributing to Opioid Claims	Total number of opioid dispensing pharmacies applying the grouping methodology.
Number of Prescribers Contributing to Opioid Claims	Total number of opioid prescribers applying the grouping methodology.
Prior Submitted Review Status	The last review status reported by the contract for a case (PARB) reported to the contract through OMS. Refer to Table 8. Element E. Review Status Codes (R1-R2). New cases have a review status "NA".

3.1.3 Closed ORF Cases

Worksheet Description: Presents a list of all previously identified but currently closed cases along with the reason for the closed status.

Key Elements:

Table 4: Closed ORF Cases Key Elements

Key Element	Definition
Case Number	The unique identifier assigned to a beneficiary for the given contract.
MBI	The beneficiary's Medicare Beneficiary Identifier.
DOB	The beneficiary's date of birth.
PBP ID	The beneficiary's plan benefit package (PBP) ID number.
LIS Status	The beneficiary's low-income subsidy (LIS) status. The beneficiary ever had LIS status during their Part D enrollment within the 6-month period. (N=No and Y=Yes)
Date Closed	Indicates the report date that the case was closed.

Key Element	Definition
Current Exclusion: Death or Lacks Part D Eligibility	Case closed due to death, Part D disenrollment, or disenrollment from contract associated with case number. “Y” indicates the case was closed for this reason and “N” indicates that it was not applicable.
Current Exemption: Cancer, SCD, Hospice, Palliative Care, or Facility	Case closed due to cancer diagnosis, SCD, hospice enrollment, palliative care diagnosis, or residence in an exempt facility. “Y” indicates the case was closed for this reason and “N” indicates not applicable.
Does Not Meet Minimum OMS Criteria	Case closed as beneficiary does not meet minimum OMS criteria at the time of the report. “Y” indicates the case was closed for this reason and “N” indicates not applicable.
Suppressed from OMS due to Sponsor Prior Response	Case closed due to sponsor provided response in the ORF. “Y” indicates the case was closed for this reason and “N” indicates not applicable.
Active CARA Status in MARx	Case closed due to active CARA Status in MARx (i.e., FAD notification or implementation of a coverage limitation) and the last OMS response is H. Coverage Limitation Necessary response = “Y” (Yes). A “Y” indicates the case was closed for this reason and “N” indicates that it was not applicable.
Prior Submitted Review Status	The last review status reported by the contract for a case previously reported to the contract through OMS. Refer to Table 8. Element E. Review Status Codes (R1-R2).

Note: Cases with a “Review Complete” status are closed when the beneficiary no longer meets the minimum OMS criteria, regardless if the Part D contract previously reported that the beneficiary had an OMS exception (refer to Table 10). Similarly, cases with a “Review in Progress” status where a new DMP exemption (refer to Table 10. K1-K4) is identified during the current period are closed and not re-reported to the sponsor. However, if the sponsor subsequently sent an initial notice to the beneficiary identifying them as a PARB, the sponsor must notify the beneficiary that they are no longer a PARB, submit the appropriate limitation end-date in MARx within 7 days, and provide an updated OMS response within 30 days of the most recent OMS report release. Refer to Section 4.5 for further information on updating cases.

3.1.4 SRF Cases

Worksheet Description: Presents a list of all submitted SRF cases.

Key Elements:

Table 5: SRF Cases

Key Element	Definition
MBI	The beneficiary’s Medicare Beneficiary Identifier.
DOB	The beneficiary’s date of birth.
PBP ID	The beneficiary’s plan benefit package (PBP) ID number.
LIS Status	The beneficiary’s low-income subsidy (LIS) status. “Y” indicates the beneficiary ever had LIS status and “N” indicates the beneficiary never had LIS status during their Part D enrollment within the 6-month period.
Submission Date	The date the SRF case was submitted.
Validation Status	The case’s validation status. “Y” indicates that the MBI is valid and “N” indicates the MBI is invalid. Invalid cases are not used.

4 Contract Responses

Sponsors must respond to each case identified by OMS using the OMS Response Form (ORF) included in the downloadable Detail OMS Package. Additionally, sponsors must report internally identified cases using the Sponsor Response Form (SRF). This section describes the process and instructions for completing and submitting both the ORF and the SRF. Table 6 provides an overview of the key status definitions within the ORF and SRF.

Table 6: ORF and SRF Status Definitions

Key Element	Definition
Overall Form Status	**Incomplete** = One or more cases have a missing response code, one or more cases have invalid response combinations, or one or more of the Responder Identification fields are blank. **Note**: All acceptable response codes are provided in the drop-down menus within the response forms. Incomplete forms will not be accepted by the Web Portal. **Complete** = All cases have a "Complete" Review and "Valid" Validation Status (for ORFs) or Preliminary Validation Status (for SRFs).
# of Cases	Number of cases requiring a response in the given form.
# of Valid Cases	Number of cases with a "Complete" Review Status and a "Valid" Validation (for ORFs) or Preliminary Validation (for SRFs) Status in the given form. **Note:** For the SRF, submission of invalid MBIs lead to individual cases being deemed "Invalid".

Additional information, including flowcharts that provide a visual illustration for completing the response form(s), response form layouts and formats for each data element, and full descriptions of the response codes, can be found in the ORF and SRF Information workbook included in the OMS packages, on the Help Documents page of the Patient Safety Web Portal, and on CMS Part D Overutilization page.

4.1 ORF and SRF Information

Before responding to each case identified by OMS in the ORF or internally identified cases in the SRF, it is recommended that sponsors review the ORF and SRF Information Workbook. This workbook helps sponsors ensure that the ORF and SRF forms are populated completely with valid response combinations for each case. This workbook contains the following information:

Table 7. ORF and SRF Information Workbook Layout

Workbook Tab	Description
ORF Flowchart	Depicts the logic tree for the ORF reporting process and all response codes.
SRF Flowchart	Depicts the logic tree for the SRF reporting process and all response codes.
Response File Layouts	Lists the detailed descriptions of each data element, as well as each data element's format and possible values.
Response Codes	Lists detailed descriptions of all ORF and SRF response codes.
ORF Valid Cases	Lists all expected valid response code combinations for ORF cases.
SRF Valid Cases	Lists all expected valid response code combinations for SRF cases.

Following the flowcharts, response file layouts, response codes descriptions, and the list of valid response code combinations as described in the ORF and SRF Information workbook ensure that your submitted responses are processed and receive a Validation (for ORFs) or Preliminary Validation (for SRFs) Status of 'Valid'.

4.2 OMS Response Form (ORF)

All Part D contracts with PARBs or open ORF cases receive an ORF within the Detail OMS Package that is prepopulated with the case number, contract ID, MBI, and DOB for each case. If there are no open cases, an ORF is not provided.

Sponsors must use the current ORF to respond to all open cases. That is, respond to new cases or update pending cases (i.e., where previous response was 'Review in Progress' and no exemptions are identified). **Note:** If the ORF is submitted multiple times during the 30-day submission window, only the complete or valid responses in the most recent ORF are used.

4.2.1 Completing the ORF

Table 8 and the accompanying notes provide an overview of the response codes that must be selected in the ORF for a given case for elements E through K. If a response code is not applicable to a particular aspect of a given case, "NA" must be selected in the field to have a valid response. Only one Final Response code, as indicated in the Response Description column below, can be selected for each case number, except for element K. Multiple "Y" or "N" responses are acceptable for K.1-7 Exceptions (refer to Table 10). Use the Response Status field to check the completeness of a case's responses and the Validation Status field to check the validity of a case's response combination.

Table 8: ORF Response Codes

Table Element. Response Category	Response Code	Response Name	Response Description
A. Case Number	**–**	**–**	CMS-assigned case number at the beneficiary-contract level.
B. Contract ID	**–**	**–**	Part D Contract ID
C. MBI	**–**	**–**	Medicare Beneficiary Identifier
D. DOB	**–**	**–**	Date of Birth
E. Review Status	**R1**	Review in Progress	Sponsor's review is pending and no clinical contact (either written report or further attempted contact) was made with prescribers. For example, the sponsor's review of the case has not started, or the sponsor is still reviewing internal data to determine if the beneficiary has a DMP exemption, does not meet the minimum OMS criteria, or has another exception. All subsequent element responses are "NA." **Final Response***

Table Element. Response Category	Response Code	Response Name	Response Description
E. Review Status (Cont.)	**R2**	Review Complete	Sponsor's review of a newly identified or an in-progress case from a prior report is complete. **Proceed to F. Clinical Contact Status**
F. Clinical Contact Status	**C1**	Clinical Contact - Only Written Report Sent to Prescriber(s)	Only written information and inquiry letter sent to prescriber(s). **Proceed to G. Prescriber Verification**
	C2	Further Clinical Contact Attempted	Further clinical contact attempted with prescribers (in addition to required written information), such as a phone call. **Proceed to G. Prescriber Verification**
	C3	Other - No Clinical Contact Due to Exception(s)	No clinical contact is made with prescribers because the sponsor identified from internal data that the beneficiary has an exception(s). **Proceed to K. Exceptions**
	NA	Not Applicable	If E. Review Status = "R1"
G. Prescriber Verification	**Y**	Yes	Prescriber(s) verified that the beneficiary is at-risk. **Proceed to H. Coverage Limitation Necessary**
	N	No	Prescriber(s) verified that the beneficiary is NOT at-risk. **Proceed to H. Coverage Limitation Necessary**
	NR	No Response	No response from prescriber(s). **Proceed to H. Coverage Limitation Necessary**
	NA	Not Applicable	If F. Clinical Contact Status = "C3" or "NA"
H. Coverage Limitation Necessary	**Y**	Yes	Sponsor decided that a coverage limitation(s) is necessary. **Proceed to I. Prescriber Agreed to Coverage Limitation**
	N	No	Sponsor does not intend to implement a coverage limitation(s). **Proceed to J. Reason Coverage Limitation Unnecessary**
	NA	Not Applicable	If G. Prescriber Verification = "NA"
I. Prescriber Agreed to Coverage Limitation	**Y**	Yes	Prescriber agreed that a coverage limitation(s) was necessary. **Final Response***
	N	No	Prescriber did not agree that a coverage limitation was necessary. **Final Response***
	NR	No Response	No response from prescriber(s). **Final Response***
	NA	Not Applicable	If H. Coverage Limitation Necessary = "N" or "NA"
J. Reason Coverage Limitation Unnecessary	**O1**	Wait and See	After written information is sent to the prescriber, sponsor is taking a "wait and see" approach to monitor the beneficiary's FAD use to see if the prescribers adjust their patient's care or respond to the sent information before making a determination. **Final Response***
	O2	Prescriber(s) Agreed During Clinical Contact to Manage/Coordinate Care	Coverage limitation is not necessary; the prescriber is aware of the beneficiary's history of opioid-related overdose (if applicable) with prescription opioid use and will manage/coordinate the beneficiary's FAD use. **Final Response***

Table Element. Response Category	Response Code	Response Name	Response Description
J. Reason Coverage Limitation Unnecessary (Cont.)	**O3**	Prescriber(s) Attested During Clinical Contact that the Medication Regimen is Appropriate	Coverage limitation is not necessary, prescriber verified that the total FAD regimen is medically necessary and is aware of the beneficiary's history of opioid-related overdose (if applicable) with prescription opioid use. **Final Response***
	O4	Sponsor Determined Coverage Limitation is Not Necessary	The Part D sponsor determined that a coverage limitation is not necessary and closed the case. This response should be used after written information is sent to the prescriber or further clinical contact attempted, there is no response from the prescriber. **Final Response***
	O5	Clinical Contact Determined has a Beneficiary Exception(s)	During case management it was determined the beneficiary has an exception. **Proceed to K. 'Exceptions'**
	NA	Not applicable	If H. Coverage Limitation Necessary = "Y" or "NA"
K. 1-7 Exceptions (refer to Table 10)	**Y**	Yes	The beneficiary has a DMP exemption, does not meet the OMS criteria, or has an exception. **Final Response(s)****
	N	No	The beneficiary does not have the exception. **Final Response(s)****
	NA	Not Applicable	If J. Reason Coverage Limitation Unnecessary is NOT "O5" AND F. Clinical Contact Status is NOT "C3"
Response Status	**Complete/ Incomplete**	Checks that acceptable response codes are populated for each element. Only the responses in the drop-down box are accepted for each element. A correctly populated row has a "Complete" Response Status while a row with any missing or unacceptable responses has an "Incomplete" Response Status.	
Validation Status	**Valid/ Invalid**	A Validation Status of "Valid" confirms that that the response combination in the row meets the current validation logic.	

*Only one Final Response code, as indicated in the Response Description column, can be selected for each case number except for element K.
**Multiple "Y" or "N" responses are acceptable for K. 1-7 Exceptions (refer to Table 10).

Notes:

- If the Overall Form Status is "Incomplete" the form is not processed or recorded.
- If multiple ORFs are received for a given case number, the most recent "Complete" and "Valid" response received by the submission due date is used.
- If an ORF from a previous reporting cycle is submitted during a current cycle, responses for the cases are not processed.

4.3 Sponsor Response Form (SRF)

Sponsors must also report to CMS PARBs identified by the sponsor who met either the minimum OMS criteria or the supplemental OMS criteria, and through the case management process, the sponsor determined that a coverage limitation was necessary (meaning they did or will send the initial notice) or was not necessary. Thus, the reported review status is complete. Sponsors must also report newly enrolled beneficiaries for which a sponsor received a TRC of '376' (New Enrollee CARA Status Notification) from the daily transaction reply report (DTRR). Sponsors may report these cases as in progress or complete depending on when they received the enrollment request and when the OMS report is due. In addition, if the sponsor determines that a currently closed ORF case's status necessitates updating in OMS (e.g., a coverage limitation is deemed necessary) the sponsor should report the beneficiary and responses in the SRF using the MBI.

Note: The SRF is independent of the ORF, and the two forms cannot be used interchangeably. The SRF that is provided in a given quarter must be used in that quarter (i.e., previous versions of the SRF from different quarters are not processed by the Web Portal). If the SRF is submitted multiple times during a given quarter, only the most recent valid responses are used.

4.3.1 Completing the SRF

This section details the data elements and response codes that are specific to the SRF. All other data elements and response codes from the ORF section apply to SRF in the same manner.

First, after completing the responder information portion of the form, answer the question in Cell B13: 'Has the sponsor internally identified any cases?'

- **If N (No)**, then leave the remainder of the SRF blank, save the form to your desktop, and upload the form to the Patient Safety Analysis Web Portal using the Upload Files page
- **If Y (Yes)**, then populate the form with the sponsor identified cases using the remainder of this section as a guide

For each SRF case, the MBI, Contract ID, and the DOB fields must be populated by the sponsor. If the DOB is not available to the sponsor, populate the element with "NA". Additionally, the sponsor must select the contract ID for each case from the pre-populated dropdown menu.

The SRF includes all the elements in the ORF (refer to Table 8) plus Elements **S**. **Method of Identification** and **T. Prior Sponsor Beneficiary CARA Status**. Some responses in the SRF are not valid in the ORF.

Cases with a **S. Method of Identification** response code of "DEL" that do not match a previously submitted case are invalid and are excluded from OMS. The sponsor should review the invalid information and re-submit the accurate information during the next OMS report submission.

Table 9: SRF Response Codes

Table Element / Response Category	Response Code	Response Name	Response Description
S. Method of Identification	**M1**	Met Minimum OMS Criteria	The beneficiary met the minimum OMS criteria, which includes MIN1 and/or MIN2. **Proceed to E. Review Status.**
	M2	Met Supplemental OMS Criteria	The beneficiary met the supplemental OMS criteria. **Proceed to E. Review Status.**
	M3	Notice Upon Enrollment – Active CARA Status	The sponsor received an active CARA Status notification for the beneficiary. **Proceed to T. Prior Sponsor Beneficiary CARA Status.**
	DEL	Delete SRF Case	The beneficiary is no longer identified as an SRF case and is deleted. **Final Response***
T. Prior Sponsor Beneficiary CARA Status *Only applies if the response to S. = M3*	**P1**	At-Risk Beneficiary with a Coverage Limitation Implemented	Indicates that successful communication was established with the prior Part D sponsor and the beneficiary had an implemented coverage limitation(s) under the prior contract. **Proceed to E. Review Status.**
	P2	No Response from Prior Sponsor	Indicates that attempted contact with the prior Part D sponsor was unsuccessful. **Proceed to E. Review Status.**
	P3	Potential At-Risk Beneficiary with No Coverage Limitation Implemented	Indicates successful communication was established with the prior Part D sponsor and the beneficiary coverage limitation(s) were pending. **Proceed to E. Review Status.**
	NA	Not Applicable	If S. Method of Identification = “M1” or “M2”.
E. Review Status	**R1**	Review in Progress	Only applicable to “M3 Notice Upon Enrollment – Active CARA Status”. Sponsor’s review is pending and no clinical contact (either written report or further attempted contact) was made with prescribers. For example, the current contract is in the process of contacting the prior contract, or gathering or reviewing the information from the prior contract. **Final Response***
	R2	Review Complete	Sponsor’s review of a case is complete. **Proceed to F. Clinical Contact Status**
	NA	Not Applicable	If S. Method of Identification = “DEL”.

Table Element / Response Category	Response Code	Response Name	Response Description
F. Clinical Contact Status	**C1**	Clinical Contact – Only Written Report Sent to Prescriber(s)	Only written information and an inquiry letter sent to the prescriber(s). **Proceed to G. Prescriber Verification.**
	C2	Further Clinical Contact Attempted	Further clinical contact attempted with prescribers (in addition to required written information), such as phone call. **Proceed to G. Prescriber Verification.**
	C3	Other – No Clinical Contact due to Exception(s)	No clinical contact is made with prescribers because the sponsor identified from internal data that the beneficiary has an exception(s). **Proceed to K. Exceptions.**
	C4[7]	Exempt from Case Management	Sponsor obtained case management information from the previous sponsor and such information is clinically adequate and up to date. **Proceed to H. Coverage Limitation Necessary.**
	NA	Not Applicable	If E. Review Status = “R1” or “NA”
G. Prescriber Verification	**Y**	Yes	If F. Clinical Contact Status = “C1” or “C2” AND Prescriber(s) verified that the beneficiary is at-risk. **Proceed to H. Coverage Limitation Necessary.**
	N	No	If F. Clinical Contact Status = “C1” or “C2” AND Prescriber(s) verified that the beneficiary is NOT at-risk. **Proceed to H. Coverage Limitation Necessary.**
	NR	No Response	If ‘F. Clinical Contact Status’ = “C1” or “C2” AND No response from prescriber(s). **Proceed to H. Coverage Limitation Necessary.**
	NA	Not Applicable	If F. Clinical Contact Status = ”C3”, “C4”, or “NA”
Complete remaining elements in Table 8 and Table 10.			

[7] Note: A response of F. Clinical Contact Status = “C4” (Exempt from Case Management) can only be selected if S. Method of Identification = ”M3” (Notice Upon Enrollment - Active CARA Status).

Table Element / Response Category	Response Code	Response Name	Response Description
Response Status	**Complete/ Incomplete**	Checks that acceptable response codes are populated for each element. Only the responses in the drop-down box are accepted for each element. A correctly populated row has a “Complete” status while a row with any missing or unacceptable responses has an “Incomplete.” status.	
Preliminary Validation Status	**Valid/ Invalid**	A Validation Status of “Valid” confirms that the response combination in the row meets the current validation logic. Note if the MBI element is populated incorrectly, the case is deemed “Invalid”.	

Once the form is complete, save the form to your desktop, and upload the file to the Patient Safety Analysis Web Portal using the Upload Files page. For detailed information about the using the Upload Files and Upload File History pages, refer to the Patient Safety Web Portal User Guide on the Help Documents page of the Patient Safety Analysis Web Portal.

4.4 Suppression Rules

The following is the list of ORF and SRF exceptions that a sponsor may identify for a particular case based on internal data or through case management. The exceptions generally include three types: DMP required exemptions, administrative exclusions, and other exceptions related to the beneficiary not meeting the minimum OMS criteria. Select “Y” for all the exceptions that apply to the case. The list also includes the maximum time that a case is suppressed from OMS reporting while the beneficiary is enrolled in the same contract.

If the sponsor’s response to **F. Clinical Contact Status** = **C3** or **J. Reason Coverage Limitation Unnecessary** = **O5** at least one **K. Exception** element 1-7 is populated with “**Y**.” Otherwise, sponsors populate the **K. Exceptions** elements with “**NA**.”

Modification of the 1-year suppression rule for non-exemption responses. For PARBs who met the MIN2 criteria with a response that suppresses the beneficiary for 1 year for reasons other than an exemption (“K1”-“K4”): the beneficiary is no longer suppressed if they meet the MIN2 criteria again based on additional opioid-related overdose claim(s) with a DOS after the 12-month period in which they were originally identified. For example, the beneficiary met the MIN2 criteria and was included in the contract’s January 2022 OMS report (12-month period from January 1, 2021 to December 31, 2021 and 6-month period from July 1, 2021 to December 31, 2021). The contract submitted “O3” (Prescriber(s) attested during clinical contact that the medication regimen is appropriate). The beneficiary would be suppressed for 1 year unless an additional opioid-related overdose claim is identified with a DOS after December 31, 2021 and there is an opioid PDE during the 6-month period, after which the case is re-reported to the sponsor in the current OMS report.

Table 10. List of OMS Report Exceptions and Suppression Rules

Element	Exception	Description	Suppression Rule
K1.	Exemption: Resident of an Exempt Facility	Beneficiary is a resident of a long-term care facility, a facility described in section 1905(d) of the Act, or of another facility for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy.	Y=Exclude from OMS reporting if last PDE Patient Resident Code is 3 or 9.
K2.	Exemption: Active Cancer-Related Pain	Beneficiary is being treated for active cancer-related pain.	Y=Suppressed for 1 year, date of death (DOD) or disenrollment.
K3.	Exemption: Hospice, Palliative or End-of-Life Care	Beneficiary has elected to receive hospice care or is receiving palliative or end-of-life care.	Y=Suppressed for 1 year, DOD or disenrollment.
K4.	Exemption: Sickle Cell Disease	Beneficiary has Sickle Cell Disease.	Y=Exclude from OMS reporting
K5.	Administrative Exclusion: Deceased	Beneficiary is deceased.	Y=Exclude from OMS reporting based on CME.
K6.	Administrative Exclusion: Disenrolled or Lacks Part D Eligibility	Beneficiary not enrolled in a Part D plan or lacks Part D eligibility.	Y=Exclude from OMS reporting based on CME.
K7.	OMS Criteria Not Met	OMS criteria not met for one or more of the following reasons: 1) the number of prescribers is below the prescriber count threshold, 2) the number of pharmacies is below the pharmacy count threshold, 3) there is a favorable coverage determination or appeal, 4) the MME is below the threshold after accounting for appropriate prescription fill overlap, data entry error, or an acute/temporary short-term use, or changes in opioid use in a recent 6 month period, or 5) the beneficiary does not have a history of opioid-related overdose due to data-entry error.	Y=Suppressed for 1 year, DOD, disenrollment, or until additional history of opioid-related overdose is identified, whichever occurs first.

4.4.1 Additional Sponsor Responses and Suppression Rules

Other sponsor responses that result in the case being suppressed from OMS reporting include the following:

Table 11. Additional Sponsor Responses and Suppression Rules

Element	Final Response	Description	Suppression Rule
H. Coverage Limitation Necessary	Yes	Sponsor intends to implement a coverage limitation(s).	The beneficiary has an active CARA Status (i.e., coverage limitation notification or implementation period for a FAD) in MARx as of the last day in the 6-month period.
J. Reason Coverage Limitation Unnecessary	O2	Prescriber(s) agreed during clinical contact to manage/coordinate care.	Y=Suppressed for 1 year, DOD, disenrollment, or until additional history of opioid-related overdose is identified, whichever occurs first.
	O3	Prescriber(s) attested during clinical contact that the medication regimen is appropriate.	Y=Suppressed for 1 year, DOD, disenrollment, or until additional history of opioid-related overdose is identified, whichever occurs first.
	O4	Plan determined coverage limitation is not necessary.	Y=Suppressed for 1 year, DOD, disenrollment, or until additional history of opioid-related overdose is identified, whichever occurs first.
	O5 and at least one K.1-7 response is Y = Yes	Clinical contact determined beneficiary exception: exemption, OMS criteria not met, or administrative exclusion identified.	Y=Suppression rules apply as described in Table 10.

4.5 Additional Clarifications

Based on monitoring OMS and MARx reporting, here are additional clarifications to sponsor's reporting via the OMS:

1. OMS Responses and MARx Coverage Limitations

   If the sponsor submits for a case (PARB) a response of either "No" or "N/A" for H. Coverage Limitation Necessary (e.g., case may be complete at that time, or may be "Review in Progress" or "Wait and See"), and the sponsor later determines that a coverage limitation is necessary, the sponsor sends the beneficiary the initial notice and must submit the information to MARx within 7 days of the initial notice date. The sponsor should then also update OMS with the new response within 30 days of the most recent OMS report release date (i.e., the OMS report submission due date).

2. Medication-Assisted Treatment (MAT) Prescribers

   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 MIN1 criteria. Therefore, sponsors should not exclude the MAT prescriber(s) or pharmacy(ies) when determining if the beneficiary's opioid use meets the MIN1 criteria.

Case management under DMPs provides an opportunity to improve care coordination and treatment for the beneficiary. CMS recommends that Part D sponsors consider if the beneficiary was switched to MAT but is still taking non-MAT opioids concurrently. If a MAT opioid prescriber is a new prescriber, sponsors may want to consider reporting "Review in Progress" while working to verify that non-MAT opioids are not continued as appropriate, or while performing case management outreach to non-MAT prescribers to coordinate care. If a coverage limitation is determined NOT necessary, submit the appropriate OMS response and reason. Furthermore, if there is no prescriber response after clinical contact, the sponsor may want to consider a "Wait and See" approach to observe if the MAT treatment continues with or without concurrent non-MAT opioid use.

3. Acute Short-Course of Opioids

As reiterated above, all opioids should be included when determining the number of opioid prescribers or pharmacies. If the MME remains **above** the MIN1 criteria threshold after accounting for a short-course of opioids, and the beneficiary meets the pharmacy and prescriber counts, the beneficiary meets the OMS criteria and the sponsor must review the case unless the beneficiary has a DMP exemption. Sponsors should not report OMS Criteria Not Met (refer to Table 10. K7) exception. Inappropriate responses would result in the beneficiary being suppressed from the OMS for 1 year despite the OMS criteria being met.

If the MME is **below** the MME threshold after accounting for a short-course of opioids, the beneficiary does not meet the OMS criteria and the sponsor should report 'OMS Criteria Not Met'.

4. Failure to Submit ORF and SRF by Deadline

Contracts that fail to timely submit their ORF are out of compliance with the data disclosure requirements found at 42 CFR § 423.153(f)(15). Once the OMS report submission deadline has passed, the OMS submission window is closed for that OMS quarterly cycle and the associated response forms are no longer accepted or valid. Open cases associated with the prior missing ORF will be re-reported to the contract in the next quarterly OMS report's ORF. If an ORF case(s) with a missing response is not reported in the next quarterly OMS report's ORF and the sponsor wants the response(s) recorded in OMS, the sponsor should submit the case(s) using their SRF.

If the sponsor also failed to submit their SRF by the OMS submission deadline, it must submit sponsor identified PARBs and cases for which a sponsor received a transaction reply code of TRC 376 from the DTRR using the current SRF. However, if the missing SRF case was identified by the sponsor using the minimum OMS criteria and is identified in the next quarterly OMS report's ORF, the sponsor must provide a response in the ORF and should not report the case in the SRF.

5 Summary and Case Tracking

In addition to downloading reports and uploading forms, sponsors can use the OMS to track ORF cases over time. The following sections provide an overview of the Summary Tracking and Case Tracking pages, and describe how to use these pages to monitor the contract's progress in responding to OMS.

For more information about the using the Summary Tracking and Case Tracking pages, refer to the Patient Safety Web Portal User Guide on the Help Documents page of the Patient Safety Analysis Web Portal.

5.1 Summary Tracking Page

The Summary Tracking page provides sponsors with an overview of the number of unique ORF cases requiring a response for a given report date, by contract. If a contract did not have any ORF cases requiring a response in the given submission period, all fields are populated with zero.

5.2 Case Tracking Page

The Case Tracking page allows sponsors to view status information for ORF cases and the submitted responses. The Case Tracking Page includes three status fields that are described below:

- Submission Status – This status indicates whether a response was successfully "Submitted" or "Not Submitted" for the given case.
- Review Status – If the Submission Status is "Submitted," then the Review Status is populated with the Review Status value from the submitted ORF. This value can be "R1" or "R2." Refer to Section 4.2 for more information regarding these response codes.
- Validation Status – This status indicates whether the response combination is deemed "Valid"' or "Invalid."

Note: Before the ORF is submitted, the three statuses fields default to "Not Submitted". Table 12 provides more information about the information displayed on the Case Tracking page.

Table 12. Case Tracking

Data Element	Element Description
Contract	CNNNN
Case Number	CNNNN_NNNNNNN
Submission Status	Not Submitted / Submitted
Review Status	Not Submitted / R1 / R2
Validation Status	Not Submitted / Pending / Valid / Invalid
Date Reported	MM/DD/YYYY
Deadline	MM/DD/YYYY
Last Update	MM/DD/YYYY

Appendix A: Average MME Calculation:

This appendix outlines the steps that are used to calculate the average MME for one beneficiary example. For the purposes of this appendix, the beneficiary example that is referenced throughout the remaining sections is assumed to have received three methadone claims and four non-methadone claims.

A.1 Step 1: Calculate Dosage Units per Day and Daily Dose per Claim

First, the dosage units per day are calculated for both non-methadone and methadone claims. Dosage units per day is calculated by dividing quantity supplied by days supply. Second, the MME or daily dose per claim is calculated as the dosage units per day multiplied by the strength and MME CF, if applicable. For non-Methadone claims, the MME CF is used in the daily dose per claim calculation. Methadone claims use a graduated MME CF that is implemented in Step 2, thus the methadone MME CF is left out of the daily dose per claim calculation.

A.1.1 Non-Methadone Claims:

In the first row of Table 13, the quantity supplied is 10, the days supply is 2, the strength is 30, and the MME CF is 1. The dosage units per day and MME daily dose per claim for this row is calculated as follows:

Dosage units per day: (10/2) = **5**

MME daily dose per claim: (5x30x1) = **150**

Table 13: Non-Methadone Dosage Units per Day and Daily Dose per Claim Examples

Claim	Fill Date	Days Supply	Quantity Supplied	Strength	MME CF	Dosage Units per Day	MME Daily Dose (mg) per Claim
Morphine #1	01/01/2019	2	10	30	1	**5**	**150**
Morphine #2	01/03/2019	2	20	10	1	**10**	**100**
Morphine #3	01/03/2019	1	4	10	1	**4**	**40**
Morphine #4	01/06/2019	1	16	10	1	**16**	**160**

A.1.2 Methadone Claims:

In the first row of Table 14, the quantity supplied is 8, the days supply is 4, and the strength is 10. The dosage units per day and daily dose per claim for this row is calculated as follows:

Dosage units per day: (8/4) = **2**

Daily dose per claim: (2x10) = **20**

Table 14: Methadone Dosage Units per Day and Daily Dose per Claim Examples

Claim	Fill Date	Days Supply	Quantity Supplied	Strength	Dosage Units per Day	Daily Dose (mg) per Claim
Methadone #1	01/01/2019	4	8	10	**2**	**20**
Methadone #2	01/04/2019	1	3	5	**3**	**15**
Methadone #3	01/06/2019	2	4	10	**2**	**20**

A.2 Step 2: Calculate Daily MME

Next, the daily dose for both the methadone and non-methadone claims are assigned across each calendar day with utilization as described below:

- Start Day = Fill Date
- End Day = Fill Date + Days Supply - 1
- Utilization Days = Start Day to End Day

A total daily MME is then calculated by summing up the daily dose for all claims for each day in the period. A graduated MME conversions factor is applied to calculate the total daily MME for methadone claims in this step.

A.2.1 Daily Non-Methadone MME Calculation:

The Morphine #2 and Morphine #3 claims have one day of overlap. This means that the beneficiary filled their third Morphine prescription before their second Morphine claim's day supply ended. The Morphine #1 and Morphine #4 claims do not overlap with any other non-methadone prescriptions.

Table 15 assigns MME daily dose per claim (mg) across the usage days. The total daily MME is calculated by summing up the MME daily dose for all claims for each day in the t period.

Table 15: Daily MME for Non-Methadone Claims Examples

Claim	Metric	1/1/2019	1/2/2019	1/3/2019	1/4/2019	1/5/2019	1/6/2019	1/7/2019
Morphine #1	MME daily dose	150	150	-	-	-	-	-
Morphine #2	MME daily dose	-	-	100	100	-	-	-
Morphine #3	MME daily dose	-	-	40	-	-	-	-
Morphine #4	MME daily dose	-	-	-	-	-	160	-
Non-Methadone	**Total Daily MME**	**150**	**150**	**140**	**100**	**-**	**160**	**-**

In Table 15, rows 2 and 3 contain Morphine #2 and Morphine #3 prescriptions that have a 1 day overlap on 1/3/2019. The total Daily MME for 1/3/2019 is calculated by summing the MME daily dose for each claim (100+40=140).

A.2.2 Daily Methadone MME Calculation:

The beneficiary also has two methadone claims that have 1 day of overlap. This means that the beneficiary filled the second methadone claim before the first methadone supply expired. The third claim does not overlap with the first two claims.

Table 15 assigns the daily dose per claim (mg) across the usage days. Rows 1 and 2 contain Methadone #1 and Methadone #2 claims that have a day of overlap on 1/4/2019. Similar to what is done for non-methadone claims in Table 14, the total daily dose is calculated by summing up the daily dose per claim (mg) for each day within the 6-month period.

An additional step is used for methadone claims, in which the total daily MME is calculated by multiplying the total daily dose with the appropriate graduated methadone CF. The graduated methadone CF that is used is determined by the total daily dose. The graduated methadone CFs can be found in the OMS Medication List that is made available on the Help Documents page of the Patient Safety Analysis Web Portal.

For example, on 1/1/2019 in Table 16, a daily dose of 20 is associated with a graduated methadone CF of 4. As a result, the total daily MME for 1/1/2019 is: 20x4 = 80. On 1/4/2019, the methadone daily dose falls in the range that is associated with a CF of 8.

Table 16: Daily MME for Methadone Claims Examples

Claim	Metric	1/1/2019	1/2/2019	1/3/2019	1/4/2019	1/5/2019	1/6/2019	1/7/2019
Methadone #1	Daily Dose	20	20	20	20	-	-	-
Methadone #2	Daily Dose	-	-	-	15	-	-	-
Methadone #3	Daily Dose	-	-	-	-	-	20	20
Methadone	**Total Daily Dose**	**20**	**20**	**20**	**35**	**-**	**20**	**20**
Methadone	**Total Daily MME**	**20x4 = 80**	**20x4 = 80**	**20x4= 80**	**35x8 = 280**	**-**	**20x4 = 80**	**20x4 = 80**

A.2.3 Daily MME Calculation:

Finally, the daily MME for both methadone and non-methadone claims for each day in the period is summed to calculate the total daily MME. Table 17 calculates the total daily MME for each day by summing up the methadone and non-methadone rows.

Table 17: Total Daily MME Examples

Claim	Metric	1/1/2019	1/2/2019	1/3/2019	1/4/2019	1/5/2019	1/6/2019	1/7/2019
Methadone	Total Daily MME	80	80	80	280	-	80	80
Non-Methadone	Total Daily MME	150	150	140	100	-	160	-
All	**Total Daily MME**	**230**	**230**	**220**	**380**	**0**	**240**	**80**

A.3 Step 3: Calculate Average MME

After calculating the total daily MME for the beneficiary on each day of the period, the average MME is calculated by totaling the MME dispensed within the period and dividing it by the duration of opioid usage. The duration of opioid usage is calculated by counting the number of days from the first and last day of opioid usage, including the first and last days. Despite not having any opioid utilization on 1/5/2019, this day is still included in duration of opioid usage.

The average MME calculation for the example beneficiary is as follows:

Total MME: (230 + 230 + 220 + 380 + 0 + 240 + 80) = **1,380**

Duration of Opioid Usage: **7**

Average MME: (1,380/7) = **197.14**

Appendix B: Pharmacy Grouping Methodology

When a pharmacy has multiple locations that share real-time electronic data, all locations of the pharmacy must be counted as one pharmacy under the OMS criteria. CMS maps the National Provider Identifier (NPI) or National Council for Prescription Drug Programs (NCPDP) pharmacy ID to the NCPDP data file. The number of pharmacies is determined using the minimum number of groupings among chain pharmacies identified between the number of unique Federal Tax Identification Numbers (TIN), chain pharmacy names, and pharmacy 'Doing Business As' (DBA) names (i.e., name with store numbers removed) and adding this value to the number of unique TINs among franchise and individual pharmacies. An example of this pharmacy grouping methodology as it applies to a beneficiary who receives multiple opioid prescriptions is shown in Table 18 below.

Table 18: Pharmacy Information

Pharmacy ID/NPI	TIN	Chain Name[8]	DBA Name	Cleaned DBA Name	Pharmacy Type
111111111	111111111	n/a	TBD Pharmacy	TBD Pharmacy	Individual Pharmacy
211111112	123456789	ABCD Pharmacy	ABCD Pharmacy #1234	ABCD Pharmacy	Chain
311111113	123456789	ABCD Pharmacy	ABCD Pharmacy #1345	ABCD Pharmacy	Chain
411111114	222222222	XYZ Pharmacy, INC	XYZ Pharmacy #1001	XYZ Pharmacy	Chain
511111115	333333333	n/a	PQRS Pharmacy at Lake DR	PQRS Pharmacy at Lake DR	Individual Pharmacy
611111116	333333333	n/a	PQRS Pharmacy at River DR	PQRS Pharmacy at River DR	Individual Pharmacy
711111117	987654321	LMNOP Pharmacy	LMNOP Pharmacy #011	LMNOP Pharmacy	Chain
811111118	999654321	LMNOP Pharmacy	LMNOP Pharmacy #012	LMNOP Pharmacy	Chain

In the Table 18 example above, the beneficiary received 8 opioid prescriptions during the 6-month period. Each prescription was associated with a different pharmacy NPI, which matched the fictitious NCPDP information reported in the table. To count the number of pharmacies in this example, the following steps are followed:

- Step 1a: Calculate the unique number of TINs among chain pharmacies. In the Table 18 example, there are 4 unique TINs among the chain pharmacies: 123456789, 222222222, 987654321, and 999654321.
- Step 1b: Calculate the unique number of chain names among chain pharmacies. In the Table 18 example, there are 3 unique chain names among chain pharmacies: ABCD Pharmacy INC, XYZ Pharmacy INC, and LMNOP Pharmacy INC.
- Step 1c: Calculate the unique number of cleaned DBA names among chain pharmacies. In the Table 18 example, there are 3 unique cleaned (i.e., store numbers removed) DBA

[8] Chain and Franchise names are only used for grouping if the relationship ID found in the NCPDP data associated with the pharmacy TIN has a relationship type of 'Chain' or 'Franchise.'

names among chain pharmacies: ABCD Pharmacy, XYZ Pharmacy, and LMNOP Pharmacy.

- Step 1d: Determine the Chain pharmacy count. The Chain pharmacy count is the minimum between calculated values in Steps 1a-1c. In the Table 18 example, the minimum value is derived from either Step 1b or 1c, 3 unique Chain names and 3 unique cleaned DBA names, respectively.

After the Chain pharmacy count is determined, the unique number of TINs for Franchise and Individual pharmacies are counted and added to the total pharmacy count:

- Step 2. Calculate the unique number of TINs among individual/franchise pharmacies. In the Table 18 example, there are 2 unique TINs among the individual/franchise pharmacies: 111111111 and 333333333.

Once the Franchise and Individual pharmacies are counted, the totals from Step 1d and Step 2 are added together for the final pharmacy count:

- Step 3. Determine the total pharmacy count. This final calculation is the sum of the chain pharmacy count (Step 1d) and the unique number of TINs among individual/franchise pharmacies (Step 2). In the Table 18 example, the resulting sum is 3 (Step 1d) + 2 (Step 2) = 5

In summation, this example beneficiary received opioids from five pharmacies using the OMS pharmacy grouping methodology, and hence meets the minimum OMS criteria pharmacy count requirement.

Appendix C: Prescriber Grouping Methodology

To count prescribers under the OMS criteria, individual prescribers are grouped when a relationship between individual opioid prescribers and organizations can be established. Individual prescribers who share the same organizational Tax Identification Number (TIN) are grouped and counted as one prescriber.

Table 19: Prescriber Grouping Example 1

Prescriber NPI	Organization TIN	Group/Individual Determination
111111111	123456789	Prescriber Group 1
111111112	123456789	Prescriber Group 1
111111113	123456789	Prescriber Group 1
111111114	523456799	Individual Prescriber 2
111111115	993456788	Individual Prescriber 3

In Table 19, the individual prescriber NPI and Organization TIN associated with each opioid prescriber is provided. Assume the beneficiary meets the MME criterion and received opioid prescriptions from 3 prescribers in the same group practice and 2 independent opioid prescribers (1 group practice + 2 individual prescribers = 3 total prescribers) and filled the prescriptions at 4 opioid dispensing pharmacies that do not share real-time electronic data. In this example, the beneficiary has 3 total prescribers after grouping and meets the other qualifying criteria. Thus, the beneficiary meets the minimum OMS criteria.

Table 20: Prescriber Grouping Example 2

Prescriber NPI	Organization TIN	Group/Individual Determination
222222222	123498765	Prescriber Group 1
222222223	223456789	Individual Prescriber 2
222222224	123498765	Prescriber Group 1
222222225	123498765	Prescriber Group 1

In Table 20, assume that the beneficiary meets the MME criterion and received opioid prescriptions from 3 prescribers in the same group practice and 1 independent opioid prescriber (1 group practice + 1 individual prescriber = 2 prescribers) and filled the prescriptions at 4 opioid dispensing pharmacies that do not share real-time electronic data. In this example, the beneficiary does not meet the minimum OMS criteria as they have only two prescribers after grouping.