



Patient Safety Analysis

PDP/MA-PD Contracts

Overutilization Monitoring System User Guide

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Web portal

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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

PatientSafety@AcumenLLC.com

Phone

(650) 558-8006

If you have questions related to the Medicare Part D drug management program policies, 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

Section 704 of the Comprehensive Addiction and Recovery Act (CARA) of 2016 included provisions permitting Part D sponsors to establish Drug Management Programs (DMPs) for beneficiaries at-risk for misuse or abuse of frequently abused drugs (FADs). CMS published a final rule (CMS-4182-F) on April 16, 2018 (“final rule”) that established the framework under which Part D plan sponsors may establish a DMP. This rule codified the many aspects of 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 into the DMP provisions at 42 CFR § 423.153(f).

Starting January 2019, sponsors that adopt a DMP 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, 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).

Additional DMP guidance is available on the CMS Part D Overutilization website at: <https://www.cms.gov/Medicare/Prescription-Drug-coverage/PrescriptionDrugCovContra/RxUtilization.html>

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 OMS reports (called the Overutilization Monitoring Packages), an authorized user must be added to the Patient Safety Analysis Web portal. Currently authorized users of the Patient Safety Analysis web portal will be automatically granted comparable access to OMS functionality.

All authorized users can log on to navigate the web portal and receive email notifications regarding report releases. Access to the OMS is limited to two possible access levels for each user:

- **Summary Report Only**: User can access the OMS contract-level rate reports with summary information. Users with Summary Report Only permissions will not be able to access beneficiary-level data.
 - The Summary OMS report is titled:
ContractID_Summary_Overutilization_Monitoring_Report_MMDDYY.xlsx.
- **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 report is titled:
ContractID_Detail_Overutilization_Monitoring_Report_MMDDYY.xlsx.

A contract's Medicare Compliance Officer determines the access level of each individual associated with a given contract and can authorize "Summary and Confidential Beneficiary Reports" access for up to five users (including her/himself) per contract. Authorization must be completed through Acumen's User Security web portal at https://partd.programinfo.us/User_Security.

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 Medicare Compliance Officer.

Authorized users can download the Overutilization Monitoring Package through the Download Files page. For more information about downloading reports, see 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 Overutilization Monitoring Package is provided once each quarter. Sponsors will 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.

Once the package is available, sponsors should complete the following steps:

- 1. Download the Overutilization Monitoring Package(s).** The Overutilization Monitoring 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. Please see the Submission Schedule document on the Help Documents page of the Patient Safety web portal for exact report release dates. Only contracts with a DMP will receive an Overutilization Monitoring Package.
 - **The Summary OMS Package includes the following files:**
 - i. Summary OMS Report (.xlsx)
 - ii. Sponsor Report Form (SRF) (.xlsx)
 - iii. OMS User Guide (.pdf)
 - **The Detail OMS Package includes the following files:**
 - i. Detail OMS Report (.xlsx)
 - ii. OMS Response Form (ORF) – if the contract has open cases for review (.xlsx)
 - iii. Sponsor Report Form (SRF) (.xlsx)
 - iv. OMS User Guide (.pdf)

2. **Review closed cases (Detail Report only).** Cases are closed each quarterly report cycle dependent on prior sponsor responses or if a beneficiary no longer meets the minimum OMS criteria.
3. **Review open cases (Detail Report only).** Open cases that meet the minimum OMS criteria are reported each quarter. Sponsors should use the beneficiary-level information provided in the Detail Overutilization Monitoring Report to assist in performing case management. Unless the sponsor determines that the beneficiary is exempt from DMPs or does not meet the minimum OMS criteria based on plan information, the sponsor must engage in case management through clinical contact with the prescribers to determine if the beneficiary is at-risk and if a coverage limitation(s) is necessary.
4. **Complete OMS Response Form (ORF) - if available.** Use the ORF to select the appropriate responses for each case. **Note:** this form will only be made available to contracts that have open cases in the given quarter. See Section 4.1 for more information about the ORF, including instructions for completing the form.
5. **Complete Sponsor Report 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. See Section 4.2 for more information about the SRF, including instructions for completing the form.
 - Sponsor-reported cases meet either the minimum OMS criteria or the supplemental OMS criteria. See Section 2.1 for more details regarding the criteria.
 - **Note:** Unlike the ORF, the SRF is made available to 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, please indicate so in the form.
6. **Submit ORF (if available) and SRF through the web portal.** Once the responses are complete, upload the ORF and SRF to the Patient Safety Analysis web portal.
 - 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 will not be accepted via any other means.
 - Only completed forms will be 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, and the "Response Status" column for every applicable case.
 - Sponsors must provide responses for open ORF cases and sponsor-identified (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. Sponsors who do not submit by the deadline may be subject to compliance action by CMS. Once the submission deadline passes for that report cycle, sponsors may no longer update the responses for that quarter.

- Contact Acumen for assistance if an incorrect ORF or SRF was submitted.
7. **Confirm upload was successful.** After uploading the forms, view the Process Status on the Upload File History page to confirm the upload was successful. The Process Status will read “Form(s) processed” if the upload was successful.
 8. **Confirm case response status.** Use the Case Tracking page to confirm that responses were submitted for each case identified in the ORF. The status of the case must be “Submitted”.
 9. **Review ORF and SRF Validation Reports.** After the submission deadline, contracts will receive a report detailing the validation status of each submitted ORF and SRF case response. Use the Case Tracking page to confirm that responses were validated. The status of the case must be “Valid”.

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 OMS Identification Criteria

- **Minimum OMS Criteria:** Use of opioids with an average daily morphine milligram equivalent (MME) equal to or exceeding 90 mg for any duration during the most recent 6 months and either: 3 or more opioid prescribers and 3 or more opioid dispensing pharmacies OR 5 or more opioid prescribers, regardless of the number of opioid dispensing pharmacies. These cases are identified through OMS or by sponsors.
- **Supplemental OMS Criteria:** Use of opioids (regardless of average daily MME) during the most recent 6 months with 7 or more opioid prescribers OR 7 or more opioid dispensing pharmacies. These cases are identified by sponsors.

2.1.1 Measurement Period and Data Sources

Measurement Period: The 6 months previous to the month of a given quarterly report release. This includes Prescription Drug Event (PDE) data from all contracts that a beneficiary is (or was) enrolled in with a date of service during the 6 month period.

Data Sources:

- PDE Data
- Common Medicare Environment (CME) – used for enrollment, Low Income Subsidy (LIS) status, and demographic information
- Medicare Enrollment Database (EDB) – used for hospice enrollment
- Common Working File (CWF) – used for cancer diagnosis information
- Risk Adjustment Processing System (RAPS) – used for RxHCC cancer diagnoses
- First DataBank (FDB) – used for medication list information
- Medi-Span – used for medication list information
- Centers for Disease Control and Prevention (CDC) MME Conversion Factors (CF) – used for medication list information
- Medicare Provider Enrollment, Chain, and Ownership System (PECOS) – used for prescriber information

Health Plan Management System (HPMS) Data – used for contract information

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

CY 2019 Opioid Safety Edit Template – used to identify contracts with a DMP.

2.1.2 Medication Lists

The specific National Drug Codes (NDCs) included in the analysis are maintained by Acumen. The lists are created from Medi-Span and First DataBank (FDB) databases. The medication lists are created using the following methodology:

Opioid Product List:

- All opioid products with the same opioid ingredient, dosage form, and route of administration included on the Center for Disease Control and Prevention Oral MME List (CDC MME List) are identified from the Medi-Span and FDB databases.
- The CDC MME List contains specific exclusions: Opium tinctures, cough/cold products, and all opioids administered via injection, intravenous, intrathecal or epidural routes. These products are excluded from calculation of both the average MME and provider counts.
- Opioid products containing buprenorphine are excluded from the 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 CFs based upon the daily MME dose. An overview of the steps used to calculate MME can be reviewed in Section 2.1.3 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.¹

Benzodiazepine Product List:

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

¹ See CDC Analyzing Prescription Data and Morphine Milligram Equivalent (MME) <https://www.cdc.gov/drugoverdose/resources/data.html> or the Opioid Morphine EQ CF document found here; <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html>

Gabapentin and Pregabalin Product List:

- All products with 'gabapentin' or 'pregabalin' as one of their active ingredients and the route of administration as 'oral'.

Complete OMS medication lists for opioids, benzodiazepines, gabapentin, and pregabalin, including medication characteristics (i.e., product name, strength, strength units, route of administration, dosage form and the opioid CFs) are available on the Help Documents page of the Patient Safety Analysis web portal. The medication NDCs are not listed due to Medi-Span and FDB licensing restrictions.

2.1.3 Opioid MME Calculation

The steps below detail the average MME calculation process.

- To calculate the daily MME for each non-methadone opioid claim, use the following equations:
 - Opioid dosage units per day = (opioid claim quantity) / (opioid claim days supply)
 - MME daily dose (mg) per claim = (number of opioid dosage units per day) × (opioid strength per Unit) × (MME CF²)
 - Daily MME = Each claim's MME is assigned to each calendar day spanning the date of service (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 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 measurement 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 measurement 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 measurement period. Then, depending on the total daily dose for each day, multiply by the appropriate graduated methadone MME CF³.

² Opioid MME CFs are on the Opioid Medication List available on the Help Documents page of the Patient Safety Analysis web portal.

³ Methadone MME CFs are on the Opioid Medication List available on the Help Documents page of the Patient Safety Analysis web portal.

- 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 measurement period⁴
 - Duration of opioid usage = number of days between first and last day of opioid use within the measurement 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.

2.1.4 Opioid Provider Count Methodology

- Buprenorphine PDE claims contribute towards a beneficiary's opioid prescriber and opioid dispensing pharmacy counts.
- To count the number of unique opioid prescribers, the prescriber National Provider ID (NPI) is taken from the 'prescriber ID' on the PDE data. 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 organizational Tax Identification Number (TIN) are grouped and counted as a single prescriber. No grouping will take place if a relationship cannot be established or if the PDE does not contain an NPI.
- To count the number of unique opioid dispensing pharmacies, the pharmacy NPI is taken from the 'service provider' and 'alternate service provider' IDs on the PDE data. If only the National Council for Prescription Drug Programs (NCPDP) pharmacy ID is available, an attempt will be made to crosswalk the NCPDP to a NPI ID. Otherwise, the pharmacy ID found in the 'service provider' field is used.

2.1.5 OMS Report Exceptions

Beneficiaries that meet any of the following criteria are not reported:

- Beneficiaries with a long-term care (LTC) or intermediate care facility (ICF) resident code ("03" and "09" respectively) on the last PDE of the 6 month measurement period.
- Beneficiaries with a cancer diagnosis in the CWF during the 12 months prior to the end of the measurement period or identified with a cancer RxHCC in the RAPS.
- Beneficiaries enrolled in hospice, according to EDB, at any point during the 6 month measurement period.
- Beneficiaries with at least 1 inpatient or at least 2 outpatient claims with a Z51.5 ("Encounter for palliative care") diagnosis code in the CWF during the 6 month measurement period.
- Beneficiaries with a death date in the CME.
- Beneficiaries who are not Part D enrolled as of the OMS report date.

⁴ By calculating a daily MME and limiting the total MME to days within the measurement period, any days supply or quantity dispensed beyond the measurement period is excluded.

- Beneficiaries with an active CARA Status as of the end of the measurement period i.e., an open period for a POS Edit, Prescriber Limitation, and/or Pharmacy Limitation in MARx for any FAD.
- Beneficiaries suppressed due to an active ORF or SRF exception or sponsor response. See Sections 4.3 and 4.4 for more details regarding ORF and SRF exceptions and sponsor responses that suppress beneficiaries from OMS reporting.

2.1.6 Informational Report 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 utilization days for all Part D enrolled beneficiaries within the contract during the 6-month measurement period.
- **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 measurement period. The concurrent opioid-potentiator drug metrics are calculated for the following drugs: benzodiazepine, high dose gabapentin (>2,400 mg), and pregabalin.

3 Report Structure

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

3.1 OMS Reports

This section outlines the levels of analysis included in the Detail Overutilization Monitoring Report Package. 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: Presents a summary of open and closed cases reported through OMS at the contract-level. The Contract Summary worksheet provides two tables: a summary of the sponsor's current enrollees and open cases, as well as an 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 Summary Key Elements

| Key Element | Definition |
|---|--|
| Total Part D Enrollees | Total number of Part D beneficiaries enrolled in contract during the period measured. |
| Total Opioid Utilizers | Total number of beneficiaries with at least one prescription fill for an opioid. |
| % of Enrollees who are Opioid Utilizers | Calculated as Total Opioid Utilizers / Total Part D Enrollees |
| Total Open ORF Cases | Total number of beneficiaries identified as a case (PARBs) by meeting the minimum OMS criteria. This number may include beneficiaries who were identified as a case in a previous OMS report and do not meet the exception criteria. |
| % of Opioid Users that are Open ORF Cases | Calculated as Total Open ORF Cases / Total Opioid Utilizers |
| 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 utilizers. |
| Total Open SRF Cases | Total number of beneficiaries identified as open SRF cases. |

Table 2: Overall Summary Key Elements

| Key Element | Definition |
|--|---|
| Open ORF Cases - Response Expected | Total number of beneficiaries meeting the minimum OMS criteria (PARBs) and cases whose initial review from prior reports is still in progress and do not meet the exception criteria. |
| Total ORF Cases Reported Since Mon-YYYY | Total number of beneficiaries ever identified as a case (PARB) according to the minimum OMS criteria. This number includes all open and closed cases. |
| Total Closed ORF Cases Since Mon-YYYY | Total number of beneficiaries previously identified as a case (PARB) by meeting the minimum OMS criteria, but currently closed. |
| Total SRF Cases since Mon-YYYY | Total number of beneficiaries ever identified by sponsors via SRF. This number may include closed, as well as open SRF cases. |

3.1.2 Open ORF Cases

Worksheet Description: Presents a list of all currently open ORF cases requiring a response along with opioid utilization information for each case.

Key Elements:

Table 3: Open ORF Cases Key Elements

| Key Element | Definition |
|--|---|
| Case Number | The unique identifier assigned to a beneficiary for the given contract. |
| HICN | The beneficiary's Health Insurance Claim Number. |
| 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 measurement period. |
| Date First Reported | Indicates the date that the beneficiary was first reported to the sponsor. |
| Measurement Period | Indicates the period in which the beneficiary was identified as a case (PARB). |
| Prior Contracts Contributing to Utilization | List of beneficiary's prior contracts from PDE data that contributed to the beneficiary's utilization. If this field is empty, all claims contributing to the beneficiary's utilization were filled through the contract on the report. |
| Duration of Opioid Use | Number of days between first and last opioid use during the measurement period (calculated as days from the first opioid fill date of service to the last day of opioid use during the measurement period) |

| Key Element | Definition |
|---|--|
| Total MME | Total MME utilized by the beneficiary during the measurement 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 distinct pharmacies that filled opioid claims. |
| Number of Prescribers Contributing to Opioid Claims | Total number of distinct prescribers with different Tax IDs that were attributed to opioid prescriptions. |
| Prior Submitted Review Status | The last review status reported by the contract for a case (PARB) reported to the contract through OMS. See Table 6. Element E. Review Status Codes (R1-R3). New cases will 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 Cases Key Elements

| Key Element | Definition |
|---|---|
| Case Number | The unique identifier assigned to a beneficiary for the given contract. |
| HICN | The beneficiary's Health Insurance Claim Number. |
| MBI | The beneficiary's Medicare Beneficiary Identifier. |
| DOB | The beneficiary's date of birth. |
| 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 measurement period. |
| PBP ID | The beneficiary's plan benefit package (PBP) ID number. |
| Date Closed | Indicates the report date that the case was closed. |
| Current Exclusion: Death or Lacks Part D Eligibility | Case closed due to death or Part D disenrollment. |
| Current Exemption: Cancer, Hospice, Palliative Care, or Facility | Case closed due to cancer diagnosis, hospice enrollment, palliative care diagnosis, or residence in an exempt facility. |
| Does Not Meet Minimum OMS Criteria | Case closed as beneficiary does not meet minimum OMS criteria at the time of the report. |

| Key Element | Definition |
|--|---|
| Suppressed from OMS due to Sponsor Prior Response | Case closed due to sponsor provided response in the ORF. |
| Active CARA Status in MARx | Case closed due to active CARA Status in MARx (i.e., FAD notification or implementation of a coverage limitation). |
| Prior Submitted Review Status | The last review status reported by the contract for a case (PARB) previously reported to the contract through OMS. See Table 6. Element E. Review Status Codes (R1-R3). |

Note: A prior case meeting the exception criteria listed in Section 2.1.5 in the current OMS report will be closed. Cases with an 'Initial Review Complete' or 'Update' status will also be closed regardless of any active exceptions if their drug utilization no longer meets the minimum OMS criteria. Cases with an 'Initial Review in Progress' status that do not meet any of the exception criteria will be re-reported to sponsors regardless of their drug utilization.

4 Contract Responses

Sponsors must respond to each case identified by OMS using the OMS Response Form (ORF) included in the downloadable Detail Overutilization Monitoring Report Package. This section describes the process and requirements for completing and submitting both the ORF and the Sponsor Report Form (SRF).

Detailed instructions on how to correctly fill out the ORF and SRF are included in the sections below. Additional information, including flowcharts that provide a visual illustration for completing the response form, response form layouts with descriptions and formats for each data element, and full descriptions of the response codes, can be found on the Help Documents page of the Patient Safety web and on CMS.gov at: <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html>

Table 5 provides an overview of the key status definitions within the ORF and SRF.

Table 5: ORF and SRF Status Definitions

| Key Element | Definition |
|---------------------|---|
| Overall Form Status | Incomplete = The Responder Information portion of the form is incomplete, one or more response elements are missing, or an unacceptable response code is present for any case in the response form. Note: all acceptable response codes are provided in the drop-down menus within the response forms. Complete = All response elements are populated and acceptable response codes are present for each case in the response form. |
| # of Cases | Number of cases requiring a response in the given form. |
| # of Complete Cases | Number of cases with a complete status in the given form. |

4.1 OMS Response Form (ORF)

If the sponsor has any open cases identified by OMS, the Detail Overutilization Monitoring Package includes an ORF that has been prepopulated with the case number, MBI, HICN, and DOB for each case. If there are no open cases, an ORF will not be provided.

Sponsors must use one ORF to respond to all open cases. That is, respond to new cases or update pending cases (i.e., where previous response was 'Initial Review in Progress'). **Note:** the ORF that is provided in a given quarter must be used in that quarter (i.e., previous versions of the ORF from different quarters will not be processed by the web portal). If the ORF is submitted multiple times during the 30 day submission period, only the responses in the most recent ORF will be used.

4.1.1 Completing the ORF

Table 6 and the accompanying notes provide an overview of the response codes that must be selected in the ORF for a given case. 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.

Table 6: ORF Response Codes

| Table Element. Response Category | Response Code | Response Name | Response Description |
|---|------------------|--|---|
| A. Case Number | - | - | CMS-assigned case number associated at the beneficiary-contract level. |
| B. MBI | - | - | Medicare Beneficiary Identifier |
| C. HICN | - | - | Health Insurance Claim Number |
| D. DOB | - | - | Date of Birth |
| E. Review Status | R1 | Initial Review in Progress | Sponsor's review is pending. All subsequent element responses should be NA. Final Response* . |
| | R2 | Initial Review Complete | Sponsor's review of a newly identified or an in-progress case from the prior report is complete. Proceed to 'F. Clinical Contact Status' |
| | R3 | Update | Update to a previously reported and reviewed case. Proceed to 'F. Clinical Contact Status' |
| F. Clinical Contact Status | C1 | Clinical Contact - Only Written Report Sent to Prescriber(s) | Only written information and a Prescriber Inquiry Letter sent to prescriber(s). Proceed to 'G. Prescriber Verification' . |
| | C2 | Further Clinical Contact Attempted | Further clinical contact attempted with prescribers, such as a phone call. Proceed to 'G. Prescriber Verification' . |
| | C3 | Other - No Clinical Contact Due to Exception(s): Exemption, OMS Criteria not met, or Administration Exclusion Identified | No clinical contact is made with prescribers because the sponsor identified from internal data that the beneficiary has an exemption, does not meet the OMS criteria, or has an administrative exclusion. 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 'E. Review Status' = 'R1' Or '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' . |

| Table Element. Response Category | Response Code | Response Name | Response Description |
|---|------------------|--|---|
| H. Coverage Limitation Necessary <i>(continued)</i> | N | No | Sponsor does not intend to implement a coverage limitation(s). Proceed to 'J. Reason Coverage Limitation Unnecessary' |
| | NA | Not Applicable | If E. Review Status = R1 or F. Clinical Contact Status = C3 or 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 'E. Review Status' = 'R1' Or 'F. Clinical Contact Status' = 'C3' or 'NA' Or 'H. Coverage Limitation Necessary' = 'N' or 'NA' |
| J. Reason Coverage Limitation Unnecessary | O1 | Wait and See | Sponsor is monitoring beneficiary's FAD use to see if the prescribers adjust their care of their patient such that the beneficiary no longer meets the OMS criteria. Final Response* . |
| | O2 | Prescriber(s) Agreed During Clinical Contact to Manage/Coordinate Care | Coverage limitation is not necessary, prescriber will manage/coordinate the beneficiary's FAD use. Final Response* . |
| | O3 | Prescriber(s) Attested During Clinical Contact that the Medication Regimen is Appropriate | Coverage limitation is not necessary, prescriber verified that FAD regimen is medically necessary. Final Response* . |
| | O4 | Clinical Contact Determined Beneficiary Exception(s): Exemption, OMS Criteria not Met, or Administrative Exclusion | During case management it was determined the beneficiary has an exemption, does not meet the OMS criteria, or has an administrative exclusion. Proceed to K. 'Exceptions' . |
| | NA | Not applicable | If 'E. Review Status' = 'R1' Or 'F. Clinical Contact Status' = 'C3' or 'NA' Or 'H. Coverage Limitation Necessary' = 'Y' |
| K. 1-9 Exceptions (see Table 8) | Y | Yes | The beneficiary has an exception. Final Response(s)** . |
| | N | No | Beneficiary does not have an exception. Final Response(s)** . |
| | NA | Not Applicable | If 'F. Clinical Contact Status' is NOT 'C3' AND 'J. Reason Coverage Limitation Unnecessary' is NOT 'O4'. |

| Table Element. Response Category | Response Code | Response Name | Response Description |
|--|------------------|---------------|---|
| Response Status | Complete | | 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 will have a 'Complete' status while a row with any unacceptable responses will have an 'Incomplete Response' status. Note: this check only determines whether an acceptable response is populated in each individual element, not if the responses meet the current validation logic (see Section 4.4 for additional response validation information) |

*Only one 'Final Response' code, as indicated in the Response Description column, can be selected for each case number.

**Multiple 'Y' or 'N' responses are acceptable for 'K. 1-9 Exceptions' (see Table 8).

Notes:

- If the Overall Form Status is "Incomplete" the form will not be processed and the responses will not be recorded.
- If multiple ORFs are received for a given case number, the most recent complete response received by the close of the submission period will be used. An incomplete response uploaded after a complete response will not replace the latest complete response for that case.
- If an ORF from a previous reporting cycle is submitted during a current cycle, responses for the cases will not be processed.

4.2 Sponsor Report Form (SRF)

Sponsors must also report to CMS beneficiaries who meet either the minimum OMS criteria or the supplemental OMS criteria identified by the sponsor. These cases should be reported only after case management and the reported review status is complete. Sponsors must also report newly enrolled PARBs or ARBs 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 previous OMS identified case that the sponsor was monitoring now needs a coverage limitation, the sponsor should report the beneficiary and responses in the SRF.

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 will not be processed by the web portal). If the SRF is submitted multiple times during a given quarter, only the most recent responses will be used.

4.2.1 Completing the SRF

This section details 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', 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', then populate the form with the SRF cases that have been identified using the remainder of this section as a guide

For each SRF case, the MBI or HICN and DOB fields must be populated by the sponsor. The SRF includes all the elements in the ORF (see Table 6) plus Elements **S. Method of Identification** and **T. Prior Sponsor Beneficiary CARA Status**. Some responses in the SRF are not valid in the ORF. Key differences in elements are noted below:

Table 7: SRF Response Codes

| Table Element / Response Category | Response Code | Response Name | Response Description |
|---|--|---|---|
| S. Method of Identification | M1 | Met Minimum OMS Criteria | The sponsor identified a PARB who met the minimum OMS criteria. Proceed to 'E. Review Status'. |
| | M2 | Met Supplemental OMS Criteria | The sponsor identified a PARB who 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'. |
| T. Prior Sponsor Beneficiary CARA Status <i>Only applies if the response to S. = M3</i> | 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 Plan | 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 | See Table 6 for response codes and definitions | | |
| F. Clinical Contact Status | C1 | Clinical Contact - Only Written Report Sent to Prescriber(s) | Only written information and a Prescriber Inquiry Letter sent to the prescriber(s). Proceed to 'G. Prescriber Verification'. |

| Table Element / Response Category | Response Code | Response Name | Response Description |
|--|--|--|--|
| F. Clinical Contact Status <i>(continued)</i> | C2 | Further Clinical Contact Attempted | Further clinical contact attempted with prescribers, such as phone call. Proceed to 'G. Prescriber Verification'. |
| | C3 | Other - No Clinical Contact due to Exception(s): Exemption, OMS Criteria not Met, or Administration Exclusion Identified | No clinical contact is made with prescribers because the sponsor identified from internal data that the beneficiary has an exemption, does not meet the OMS criteria, or has an administrative exclusion. Proceed to 'K. Exceptions'. |
| | C4⁵ | Exempt from Case Management | Sponsor obtained case management information from the previous sponsor and such information is still clinically adequate and up to date. Proceed to 'H. Coverage Limitation Necessary'. |
| | NA | Not Applicable | If 'E. Review Status' = 'R1' |
| G. Prescriber⁶ Verification | See Table 6 for response codes and definitions | | |
| Complete remaining elements in Table 6 and Table 8. | | | |

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, see the Patient Safety Website User Guide on the Help Documents page of the Patient Safety Analysis web portal.

4.3 Suppression Rules

The following is the list of potential exceptions that a sponsor may identify for a particular case based on internal data or through case management. 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 contract. If the sponsor’s response to ‘**F. Clinical Contact Status**’ = ‘**C3**’ or ‘**J. Reason Coverage Limitation Unnecessary**’ = ‘**O4**’, sponsors respond to the ‘**K. Exception**’ elements 1-9 with ‘Y’ or ‘N’. Otherwise, sponsors should populate the ‘**K. Exceptions**’ elements with ‘NA’. In addition, if the supplemental OMS criteria was used by the sponsor to identify a case, a response of ‘NA’ would be appropriate for K8 and K9 since MME is not applicable. **Note:** this table applies to both the ORF and SRF. It includes the OMS exception reasons, plus additional exceptions that can only be identified by the Part D sponsor.

⁵ Note: For the SRF only, this code applies only to beneficiaries in which the Method of Identification = ‘M3’ (Notice Upon Enrollment – Active CARA Status), for which the plan has received case management information from the beneficiary’s prior plan and it is still clinically adequate and up-to-date.

⁶ Note: For the SRF only and Method of Identification = ‘M3’ (Notice Upon Enrollment – Active CARA Status) the response selected is either based on the prior or the current sponsor’s case management information.

Table 8. 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, of 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 | 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 up to 1 year, 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 up to 1 year, DOD or disenrollment. |
| K4. | Administrative Exclusion: Deceased | Beneficiary is deceased. | Exclude from OMS reporting based on CME. |
| K5. | Administrative Exclusion: Disenrolled or Lacks Part D Eligibility | Beneficiary disenrolled or lacks Part D enrollment | Exclude from OMS reporting based on CME. |
| K6. | OMS Criteria Not Met: Prescriber(s) in a Group Practice | OMS prescriber criterion not met because several prescribers are within the same group practice and treated as one prescriber | Y=Suppressed up to 1 year, DOD or disenrollment. |
| K7. | OMS Criteria Not Met: Pharmacies share Real-Time Electronic Data | OMS pharmacy criterion not met because pharmacies with multiple locations that share real-time electronic data are treated as one pharmacy | Y=Suppressed up to 1 year, DOD or disenrollment. |
| K8. | OMS Criteria Not Met: MME Approved Due to Favorable Coverage Determination or Appeal | OMS MME criterion not met because of a favorable coverage determination or appeal | Y=Suppressed up to 1 year, DOD or disenrollment. |
| K9. | OMS Criteria Not Met: MME for Other Reasons | OMS MME criterion not met for other reasons (e.g., MME is due to appropriate prescription fill overlap, data entry error, an acute/temporary short-term use that has resolved or dosage was reduced) | None |

4.3.1 Additional Sponsor Responses and Suppression Rules

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

Table 9. 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 measurement period. |
| J. Reason Coverage Limitation Unnecessary | O2 | Prescriber(s) agreed during clinical contact to manage/coordinate care | Y=Suppressed up to 1 year, DOD or disenrollment. |
| | O3 | Prescriber(s) attested during clinical contact that the medication regimen is appropriate | Y=Suppressed up to 1 year, DOD or disenrollment. |
| | O4 and at least one K.1-8 response is Yes | Clinical contact determined beneficiary exception: exemption, OMS criteria not met, or administrative exclusion identified | Y=Suppressed up to 1 year, DOD or disenrollment. |

4.4 ORF and SRF Response Validation

After the submission deadline has passed, the ORF and SRF responses will be validated. The MBI and HICN elements on the SRF will also be validated to ensure that they are in the correct format and can be mapped to a beneficiary. The following logic checks for both ORF and SRF responses will be made to determine if a response is valid:

- Each case may only have a single 'Final Response' code except for responses to K. Exceptions 1-9.
- Every element must be populated (not applicable data elements must be populated with 'NA')
- Contradictory responses are not allowed (For example, selecting 'O4' but selecting 'N' or 'NA' for all the 'K. Exceptions' data elements)

Contracts will receive an ORF and SRF Response Validation Report with indicators for which responses were considered valid or invalid. CMS expects sponsors to correct invalid responses and resubmit the case responses to OMS. Further information will be provided to sponsors with the release of the Validation reports.

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, see 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 cases identified in OMS requiring a response in the given reporting period, all fields will be populated with zero.

5.2 Case Tracking Page

The Case Tracking page allows sponsors to view status information for ORF cases and any submitted responses. The three main statuses on the Case Tracking Page 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' will be populated with the Review Status value from the submitted ORF. This value can be 'R1', 'R2', or 'R3'. See Section 4.1 for more information regarding these response codes.
- **Validation Status** – After the Response Validation Reports are sent out to sponsors, the 'Validation Status' will be updated to indicate whether a submitted response is considered 'Valid' or 'Invalid'. See Section 4.4 for more information regarding the validation process.

Note: Before the ORF is submitted, the three statuses will default to "Not Submitted". After the ORF is submitted and processed successfully, the Validation Status will be "Pending" until the validation process is complete.

Appendix A: Average MME Calculation:

This appendix outlines the steps that are used to calculate 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 is 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 MME CF is left out of the daily dose per claim calculations for methadone claims.

A.1.1 Non-Methadone Claims:

In the first row of Table 10, 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:

$$\text{Dosage units per day: } (10/2) = \mathbf{5}$$

$$\text{MME daily dose per claim: } (5 \times 30 \times 1) = \mathbf{150}$$

Table 10: 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 11, 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:

$$\text{Dosage units per day: } (8/4) = \mathbf{2}$$

$$\text{Daily dose per claim: } (2 \times 10) = \mathbf{20}$$

Table 11: 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 measurement 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 12 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 measurement period.

Table 12: 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 12, 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 13 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 12, the total daily dose is calculated by summing up the daily dose per claim (mg) for each day within the measurement 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 13, 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: $20 \times 4 = 80$. On 1/4/2019, the methadone daily dose falls in the range that is associated with a CF of 8.

Table 13: 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 | $20 \times 4 = 80$ | $20 \times 4 = 80$ | $20 \times 4 = 80$ | $35 \times 8 = 280$ | - | $20 \times 4 = 80$ | $20 \times 4 = 80$ |

A.2.3 Daily MME Calculation:

Finally, the daily MME for both methadone and non-methadone claims for each day in the measurement period is summed to calculate the total daily MME. Table 14 calculates the total daily MME for each day by summing up the methadone and non-methadone rows.

Table 14: 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 measurement period, the average MME is calculated by totaling the MME dispensed within the measurement 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:

$$\text{Total MME: } (230 + 230 + 220 + 380 + 0 + 240 + 80) = \mathbf{1,380}$$

$$\text{Duration of Opioid Usage: } \mathbf{7}$$

$$\text{Average MME: } (1,380/7) = \mathbf{197.14}$$