

**U.S. Department of Health & Human Services** 

### **Office of Inspector General**

### **Toolkit:**

Using Data Analysis To Calculate Opioid Levels and Identify Patients At Risk of Misuse or Overdose

June 2018 OEI-02-17-00560



### U.S. Department of Health & Human Services Office of Inspector General



## **Toolkit: Using Data Analysis To Calculate Opioid Levels and Identify Patients At Risk of Misuse or Overdose**

#### What is the toolkit?

This toolkit provides detailed steps for using prescription drug claims data to analyze patients' opioid levels and identify certain patients who are at risk of opioid misuse or overdose. It is based on the methodology that the Office of Inspector General (OIG) has developed in our extensive work on opioids.

This new OIG product provides highly technical information to support our public and private sector partners, such as Medicare Part D plan sponsors, private health plans, and State Medicaid Fraud Control Units. It is intended to assist our partners with analyzing their own prescription drug claims data to help combat the opioid crisis.

#### Why did OIG create the toolkit?

Opioid abuse and overdose deaths are at epidemic levels in the United States. As one of the lead Federal agencies fighting health care fraud, OIG is committed to supporting our public and private partners in their efforts to curb the opioid epidemic. These partners include Medicare Part D plan sponsors, other private health plans, State Medicaid Fraud Control Units, State prescription drug monitoring programs, and researchers. They can use this toolkit to analyze claims data for prescription drugs and identify patients who may be misusing or abusing prescription opioids and may be in need of additional case management or other followup. This toolkit can also be used to answer research questions about opioid utilization.

OIG most recently analyzed opioid levels in the data brief *Opioid Use in Medicare Part D Remains Concerning* (OEI-02-18-00220), which is being released alongside this toolkit. The data brief identified about 71,000 Part D beneficiaries who were at serious risk of misuse or overdose. Some of these beneficiaries received extreme amounts of opioids. Others appeared to be "doctor shopping," i.e., receiving high amounts of opioids from multiple prescribers and multiple pharmacies. The analysis identified beneficiaries who are at risk by calculating their opioid levels using Part D prescription drug data.

#### What does the toolkit include?

This toolkit provides steps to calculate patients' average daily morphine equivalent dose (MED), which converts various prescription opioids and strengths into one standard value. This measure is also called morphine milligram equivalent (MME). The toolkit includes a detailed description of the analysis and programming code that can be applied to the user's own data. The resulting data can be used to identify certain patients who are at risk of opioid misuse or overdose. Users can also

modify the code to meet their needs, such as identifying patients at varying levels of risk. The toolkit includes the following three chapters:

- 1. Analysis of Prescription Drug Claims Data
- 2. Explanation of the Programming Code To Conduct the Analysis
- 3. Programming Code

### **BACKGROUND**

In 2016, there were over 63,000 drug overdose deaths in the United States—an average of 174 deaths each day.<sup>1</sup> Two-thirds of these deaths—over 42,000—involved opioids. In addition to the risk of death from overdose, opioids carry a number of other health risks, including respiratory depression, confusion, increased drug tolerance, and physical dependence. Identifying patients who are at risk of misuse or overdose is integral to curbing this epidemic.

OIG has made fighting the opioid epidemic a top priority, forming a multidisciplinary team dedicated to protecting beneficiaries from prescription drug abuse and misuse. As a part of its efforts, OIG has conducted extensive data analysis, which is the basis of this toolkit. OIG developed this toolkit to provide detailed steps for using data from prescription drug claims to analyze patients' opioid levels and identify certain patients who are at risk of opioid misuse or overdose. The toolkit is intended to assist our partners—such as Medicare Part D plan sponsors, private health plans, and Medicaid Fraud Control Units—with analyzing their own prescription drug claims data to help combat the opioid crisis.

OIG most recently analyzed opioid levels in the data brief *Opioid Use in Medicare Part D Remains Concerning* (OEI-02-18-00220), which is being released alongside the toolkit.<sup>2</sup> This data brief found that nearly one in three Medicare beneficiaries received an opioid in 2017.<sup>3</sup> It also identified 71,000 beneficiaries who were at serious risk of opioid misuse or overdose. This included almost 58,000 beneficiaries who received extreme amounts of opioids for the entire year and about 15,000 beneficiaries who appeared to be doctor shopping—i.e., they received high amounts of opioids from multiple prescribers and pharmacies. See Exhibit 1 on the following page.

Patterns like these raise concern and warrant further scrutiny. They may indicate that a patient is receiving poorly coordinated care and requires additional case management. They may also indicate that a patient is addicted to opioids and at risk of overdose. Alternatively, they may indicate that a patient is receiving medically unnecessary drugs, which could be diverted for resale.

For this analysis, we identified beneficiaries on the basis of each patient's average daily morphine equivalent dose (MED), which is also known as morphine milligram equivalence (MME). MED is a unit of measurement that

<sup>&</sup>lt;sup>1</sup> CDC, Data Brief 294. Drug Overdose Deaths in the United States, 1999–2016, Accessed at <a href="https://www.cdc.gov/nchs/data/databriefs/db294">https://www.cdc.gov/nchs/data/databriefs/db294</a> table.pdf#page=1 on February 23, 2018.

<sup>&</sup>lt;sup>2</sup> OIG, Opioid Use in Medicare Part D Remains Concerning (OEI-02-18-00220), June 2018.

<sup>&</sup>lt;sup>3</sup> Ibid.

converts various prescription opioids and strengths into one standard value. The Centers for Disease Control and Prevention (CDC) recommends that physicians consider a patient's MED level when prescribing opioids. Specifically, CDC recommends that when prescribing opioids to patients with chronic pain, prescribers use caution at any dosage, carefully consider any increases in daily dosages to 50 mg MED or more, and avoid increasing daily dosages to 90 mg MED or more.<sup>4</sup>

#### Exhibit 1: Opioids in Medicare Part D, 2017

### Nearly one in three Medicare Part D beneficiaries received a prescription opioid

• In total, 14.1 million beneficiaries received opioids.

### Almost 460,000 beneficiaries received high amounts of opioids in 2017

• Each of these beneficiaries had an average daily MED greater than 120 mg a day for at least 3 months and did not have cancer or a hospice stay in 2017.

### Almost 71,000 beneficiaries are at serious risk of misuse or overdose

- 58,000 beneficiaries received extreme amounts of opioids. Each had an average daily MED that exceeded 240 mg for the entire year. This amount is more than two and a half times the dose that CDC recommends avoiding.
- 15,000 beneficiaries appear to be doctor shopping. Each received a high amount of opioids (an average daily MED of 120 mg for at least 3 months) AND had four or more prescribers and four or more pharmacies in the year.
- None of these beneficiaries had cancer or were in hospice care in 2017.

Source: OIG, *Opioid Use in Medicare Part D Remains Concerning* (OEI-02-18-00220), June 2018.

Like OIG, CMS uses MED to identify Part D beneficiaries who are at high risk of overutilizing opioids and may be in need of case management.<sup>5</sup> This is

<sup>&</sup>lt;sup>4</sup> CDC, "CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016." MMWR Recomm Rep, March 18, 2016. Accessed at <a href="https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm">https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm</a> on January 16, 2018. Also see CDC, Calculating Total Daily Dose of Opioids for Safer Dosages. Accessed online at <a href="https://www.cdc.gov/drugoverdose/pdf/calculating-total-daily-dose-a.pdf">https://www.cdc.gov/drugoverdose/pdf/calculating-total-daily-dose-a.pdf</a> on February 14, 2018.

<sup>&</sup>lt;sup>5</sup> CMS uses the term "MME" to refer to MED. As noted earlier, they are equivalent.

the focus of CMS's Overutilization Monitoring System. CMS shares a list of these beneficiaries with Part D plan sponsors on a quarterly basis. Sponsors are instructed to conduct reviews of these beneficiaries to determine which beneficiaries require greater oversight or coordination of care.

This toolkit provides steps to calculate patients' average daily MED and gives a detailed description of the analysis and SAS programming code that can be applied to the user's own data.<sup>6</sup> Users can modify the code to meet their needs, such as identifying patients at varying levels of risk. The toolkit includes the following three chapters: (1) Analysis of Prescription Drug Claims Data; (2) Explanation of the Programming Code To Conduct the Analysis; and, (3) Programming Code.

#### Standards

This study was conducted in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

<sup>&</sup>lt;sup>6</sup> SAS and all other SAS Institute Inc. product or service names are registered trademarks or trademarks of SAS Institute Inc. in the United States and other countries.

### 1. ANALYSIS OF PRESCRIPTION DRUG DATA

This chapter provides an overview of the steps that are needed to conduct the analysis. It contains the following sections.

#### **Sections**

- 1.1 Collecting Prescription Drug Claims Data
- 1.2 Merging Data for MED Calculation
- 1.3 Conducting Quality Control Checks
- 1.4 Reviewing Patients With Certain Conditions
- 1.5 Identifying At-Risk Patients

# 1.1 Collecting Prescription Drug Claims Data

The first step is to collect the data needed for the analysis.

To calculate a patient's average daily MED over time, five data fields from the prescription drug claims are necessary:

- Unique Patient Identifier
- Prescription Fill Date
- Quantity Dispensed, or the number of units dispensed
- Days Supply
- National Drug Code (NDC)

It is also valuable to combine the MED analysis with additional patient-level data to further identify patients and patterns of concern. The following two additional fields may be particularly helpful:

- Unique Prescriber Identifier
- Unique Pharmacy Identifier<sup>7</sup>

Other data that may be helpful include patient-level medical data (e.g., data on diagnoses and medical services) and demographic data (e.g., date of birth and geographic location). These data can be used to conduct

<sup>&</sup>lt;sup>7</sup> The code in this toolkit includes an optional section that counts the number of pharmacies and the number of prescribers from which each patient received opioids. If unique identifiers for either the prescribers or pharmacies are not available, that portion of the code can be skipped.

additional analyses to better understand the at-risk patient population. They can also be used to identify—or to exclude from the analysis—beneficiaries who have cancer or are in hospice care.

Next, the timeframe for the analysis needs to be selected. A timeframe of at least 6 months is recommended.<sup>8</sup> In order to capture all prescriptions that a patient used in the timeframe, the analysis should include data for certain prescriptions dispensed before the timeframe. For example, for OIG's timeframe of January 1, 2017, to December 31, 2017, we included prescriptions that had a Prescription Fill Date in 2016, but had at least 1 day of supply in 2017. To identify these prescriptions, we calculated the last day of supply for each 2016 prescription using this calculation:

Last day of supply = Prescription Fill Date + Days supply -1

If the last day of supply was in 2017, we included the prescription in our analysis.

### 1.2 Merging Data for MED Calculation

The next step is to merge the prescription drug data with CDC's MME conversion data based on NDC. CDC's data include two fields—MME conversion factor and strength per unit—that are needed for the MED calculation. In addition, if users have prescription data that include opioids and other types of prescriptions drugs, merging the data with CDC's data will identify which prescriptions are opioids.

The MME conversion factor reflects the potency of each opioid prescription drug. For example, hydrocodone has a conversion factor of 1, meaning that its potency is similar to that of morphine. Hydromorphone, on the other hand, has a conversion factor of 4, meaning that it is about 4 times more potent than morphine.

The "strength per unit" field contains a numeric value that indicates the strength of the opioid in each drug. For example, a 30-mg tablet of oxycodone hydrochloride (HCl) has a strength per unit of 30. For combination drugs in this analysis, the strength per unit is the strength of the opioid ingredient. For example, what is called a "10-325 mg" tablet of oxycodone-acetaminophen contains 10 mg of oxycodone and 325 mg of acetaminophen, so the strength per unit is 10.

Toolkit: Using Data Analysis To Calculate Opioid Levels and Identify Patients At Risk of Misuse or Overdose OEI-02-17-00560

<sup>&</sup>lt;sup>8</sup> The analysis is conducted over 90-day periods; a 6-month timeframe allows the user to detect patterns using a substantive amount of data.

CDC publishes these data on its website. The data are available for download in both SAS and Excel versions at <a href="https://www.cdc.gov/drugoverdose/resources/data.html">https://www.cdc.gov/drugoverdose/resources/data.html</a>.

The Documentation tab in the CDC's Excel spreadsheet contains important information about the conversion factors. A few things to note:

- CDC updates the conversion factor data about once a year. These updates add new NDCs and occasionally change some drugs' conversion factors.
- The CDC's spreadsheet excludes certain opioids, such as some cough and cold formulations, injectable opioids, intravenous (IV) opioids, and drugs not typically used in outpatient settings.
   As a result, claims for these opioids will not match with an MME conversion factor and will therefore need to be excluded from the MED analysis.
- The CDC's spreadsheet includes buprenorphine products; however, in the 2017 version, CDC removed the MME conversion factor for these drugs. Although buprenorphine is an opioid, a number of the products containing buprenorphine are indicated for the treatment of opioid dependence rather than pain. (Such treatment is known as medication-assisted treatment.) Depending on the objectives of their analysis, users should consider options for how to handle buprenorphine products.
- CDC's spreadsheet includes an MME conversion factor for methadone. Methadone is indicated both for pain and for treatment of opioid addiction. Users should determine whether these drugs are included in their data and then assess whether to include them in their analysis.

CDC's spreadsheet also contains information (e.g., NDCs, drug names) for benzodiazepines, muscle relaxants, stimulants, and zolpidem.<sup>10</sup> These data may be helpful for additional analysis. Benzodiazepines, for example, are known potentiator drugs—i.e., drugs that increase the euphoria when mixed with opioids and increase the risk of overdose.

<sup>&</sup>lt;sup>9</sup> The files are called "Oral MMEs—SAS Data File" and "Oral MMEs—Excel Data File." They can be merged using the NDC.

<sup>&</sup>lt;sup>10</sup> Zolpidem is a sedative sold under the brand name Ambien.

# 1.3 Conducting Quality Control Checks

Next, it is important to conduct quality control checks on the prescription drug claims data. There are many ways to check for errors in the data. The most appropriate methods depend on the data. Two steps that may be helpful are to check for missing or zero values and to check for erroneous values that may impact the MED calculation.<sup>11</sup>

Missing/Zero Values: Missing or zero values may underestimate a patient's average daily MED. We addressed this issue by excluding prescription drug claims data that had missing or zero values for the following fields that affect the MED calculation: Unique Patient Identifier, Prescription Fill Date, Quantity Dispensed, and Days Supply.

Erroneous Values: Erroneous data may cause inaccuracies in the MED calculation. Users should assess their own data and determine the best way to identify erroneous values. One method is to calculate the ratio of the Quantity Dispensed field to the Days Supply field and identify outliers. Both of these fields impact the MED calculation.

Once these outlier values are identified, it is important to review the data and determine the next steps. If the outliers appear to be erroneous values, one way to address this is to exclude them from the analysis. Excluding such values reduces the risk of inappropriately flagging some patients; however, it may also underestimate the amounts of opioids taken by these patients.

# 1.4 Reviewing Patients With Certain Conditions

It is important to review patient diagnosis codes and medical claims data—if available—to identify patients with certain conditions. Patients at the end of their lives or those with certain conditions, such as active cancer-related pain, may have different patterns of opioid use. It may be helpful to exclude these types of patients from the analysis or to flag them for separate analysis.

For instance, we excluded patients who were receiving hospice care. To identify these patients, we looked for hospice claims in the timeframe. We also excluded patients who had diagnoses of cancer. In its Overutilization Monitoring System, CMS excludes patients that it identifies as having hospice care or a diagnosis of cancer. The Pharmacy Quality Alliance provides ICD-10 codes that can be used to identify patients with cancer.<sup>12</sup> See Exhibit 2.

<sup>&</sup>lt;sup>11</sup> OIG conducted a number of quality control checks. These two steps are not a complete

<sup>&</sup>lt;sup>12</sup> ICD-10 diagnosis codes became effective in October 2015. For analysis of data prior to October 2015, ICD-9 diagnosis codes are needed.

Exhibit 2: With Cand	ICD-10 Codes That Can Be Used To Identify Patients
C00–C14	Malignant neoplasms of lip, oral cavity, and pharynx
C15–C26	Malignant neoplasms of digestive organs
C30-C39	Malignant neoplasms of respiratory and intrathoracic organs
C40–C41	Malignant neoplasms of bone and articular cartilage
C43	Malignant melanoma of skin
C4A	Merkel cell carcinoma
C45-C49	Malignant neoplasms of mesothelial and soft tissue
C50	Malignant neoplasms of breast
C51–C58	Malignant neoplasms of female genital organs
C60-C63	Malignant neoplasms of male genital organs
C64-C68	Malignant neoplasms of urinary tract
C69–C72	Malignant neoplasms of eye, brain, and other parts of central nervous system
C73–C75	Malignant neoplasms of thyroid and other endocrine glands
C7A	Malignant neuroendocrine tumors
С7В	Secondary neuroendocrine tumors
C76–C80	Malignant neoplasms of ill-defined, other secondary and unspecified sites
C81–C96	Malignant neoplasms of lymphoid, hematopoietic and related tissue
D37-D48	Neoplasms of uncertain behavior, polycythemia vera and myelodysplastic syndromes
D49	Neoplasms of unspecified behavior
Q85.0	Neurofibromatosis (nonmalignant)

Source: Pharmacy Quality Alliance ICD Code Value Sets, Cancer Exclusion

### 1.5 Identifying At-Risk Patients

The next step is to select the opioid levels for review. The resulting data can be used to identify certain patients who are at risk of opioid misuse or overdose. Users can also modify the code to meet their needs, such as identifying patients at varying levels of risk.

Depending on the purpose of the analysis, users may opt to identify patients at different opioid levels. For example, if the purpose of the analysis is to identify patients who would benefit from additional case management, the user may choose an MED level that is lower than if the purpose of the analysis were to identify patients to be investigated for possible drug diversion. A lower MED level may also be appropriate when

identifying patients who are mixing opioids with potentiator drugs, such as benzodiazepines.

To identify at-risk patients in Medicare Part D, OIG used the following three measures: (1) patients who received high amounts of opioids (i.e., an average daily MED greater than 120 mg) for any 90-day period in the year; (2) patients who received extreme amounts of opioids (average daily MED greater than 240 mg) for the entire year; and (3) patients who appear to be doctor shopping (i.e., those with high amounts of opioids (as described above) AND four or more prescribers and four or more pharmacies in the year). There may be other patients who are also at risk, but do not meet these criteria.

OIG's third measure uses criteria similar to those that CMS's Overutilization Monitoring System uses to identify high-risk patients. From 2013 to 2017, CMS considered patients to be "high risk" if they had a daily MED exceeding 120 mg for at least 90 consecutive days and received opioids from four or more prescribers and four or more pharmacies in 12 months. For 2018, CMS revised its criteria for identifying high-risk patients.<sup>13</sup> It is also planning additional revisions for 2019.<sup>14</sup>

After identifying at-risk patients, it is important to conduct additional followup. For example, this followup may include contacting the patient's prescriber or conducting additional data analyses to determine the best course of action.

<u>Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2018.pdf</u> on April 24, 2018. <sup>14</sup> See 83 Fed. Reg. 16452 (April 16, 2018). Accessed at <a href="https://www.gpo.gov/fdsys/pkg/FR-2018-04-16/pdf/2018-07179.pdf">https://www.gpo.gov/fdsys/pkg/FR-2018-04-16/pdf/2018-07179.pdf</a> on April 18, 2018.

<sup>&</sup>lt;sup>13</sup> For 2018, CMS considers patients to be "high risk" if, during the previous 6 months, they have had an average MED greater than 90 mg for any period of time and received opioids from more than three prescribers and more than three pharmacies OR more than five prescribers regardless of the number of pharmacies. Beginning in 2018, CMS also considered multiple prescribers with associated the same Tax Identification Number to be a single prescriber. For more information, see CMS, *Announcement of Calendar Year (CY) 2018 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter and Request for Information*. Accessed at https://www.cms.gov/Medicare/Health-

### 2. EXPLANATION OF PROGRAMMING CODE

This chapter explains the SAS code. The code uses two macros and creates three patient-level datasets:

- 1) Overview MED dataset—provides an overview of each patient's opioid utilization.
- 2) Daily MED dataset—provides detailed daily MED amounts for selected patients.
- 3) At-Risk MED dataset—identifies at-risk patients who had certain MED levels.

#### **Sections**

- 2.1 Macro To Create Overview of Each Patient's Opioid Utilization
- 2.2 Macro To Create Detailed Patient Data
- 2.3 Code To Identify At-Risk Patients

# 2.1 Macro To Create Overview of Patient's Opioid Utilization

The first macro creates the "Overview MED" dataset. For each Unique Patient Identifier, it creates three fields:

- 1. Number of Days of Opioid Use (OPIOID\_DAYS)
- 2. Average Daily MED for the entire study timeframe (ALL\_AVG\_MED)
- 3. Highest Average Daily MED for any 90 days (MAX\_AVG\_MED\_90)

First, the macro calculates each patient's "Daily MED" for each day within the timeframe. The Daily MED includes all opioid prescriptions a patient received on a given day. To calculate this, the macro uses a temporary array for each patient. The array creates a field for each day in the study timeframe (*D1*, *D2*, *D3*, etc.) It begins by assigning a value of zero to each day.

For each of the patient's prescriptions, the macro calculates the MED. The MED converts opioids of different ingredients, strengths, and forms into equivalent milligrams of morphine. It is calculated by using the following equation. See Exhibit 3.

#### **Exhibit 3: MED Calculation for a Prescription**

$$MED = \frac{(Strength \ per \ unit) \times (Quantity \ dispensed) \times (MME \ conversion \ factor)}{(Days \ supply)}$$

The macro assigns the MED to the appropriate day based on the Prescription Fill Date and Days Supply. <sup>15</sup> If the day already has an MED value greater than zero, the macro sums the two MED values.

Second, the macro calculates the days of opioid use. To do this, it counts the number of days during the timeframe that the patient has a daily MED that is greater than zero.

Third, the macro calculates the average daily MED over the entire timeframe for the patient. See Exhibit 4.

#### Exhibit 4: Calculation for Patient's Average Daily MED

$$Average \ daily \ MED \ = \frac{Total \ MED \ of \ all \ prescriptions \ in \ the \ time frame}{Total \ number \ of \ days \ in \ the \ time frame}$$

Fourth, the macro calculates the average daily MED for the patient over every 90-day time period. The denominator for this calculation is 90, which is the number of days in the timeframe. (The denominator is *not* the number of days within the 90-day period on which the patient received opioids.) The macro then outputs the highest average of any 90-day period. See Exhibit 5.

### Exhibit 5: Determining Each Patient's Highest Average Daily MED for 90 Days

1. For the first 90-day period, the average daily MED over 90 days is:

90-Day Average MED = 
$$\frac{D1 + D2 + D3 + ... + D98 + D89 + D90}{90}$$

2. For the second 90-day period, the average daily MED over 90 days is:

90-Day Average MED = 
$$\frac{D2 + D3 + D4 + ... + D89 + D90 + D91}{90}$$

3. This repeats until the last possible 90-day combination. Then the highest average for any 90 days outputs as MAX\_AVG\_MED\_90.

Toolkit: Using Data Analysis To Calculate Opioid Levels and Identify Patients At Risk of Misuse or Overdose OEI-02-17-00560

<sup>&</sup>lt;sup>15</sup> The MED calculation assumes that the patient took the full prescription as prescribed each day starting on the Prescription Fill Date until the last day of the supply.

# 2.2 Macro To Provide Detailed Daily Patient Data

The second macro creates the Daily MED dataset. This dataset provides the daily MED for each day in the study timeframe for selected patients. This macro can be used to look more closely at the daily MED for selected patients with concerning patterns. For example, if a patient has an average daily MED that is extremely high, this data will show on which days during the timeframe the patient received the highest amounts. It can also be used to identify the drugs associated with those days. For an analysis with 365 days, the data would contain the daily MED for day 1 (*D1*) through day 365 (*D365*). See Exhibit 6.

Exhibit 6: Example of Daily MED Output								
Patient ID	D1	D2	D3	•••	D364	D365		
X12345	525	525	525		495	495		

#### 2.3 Code To Identify At-Risk Patients

Using the data created with the step above, the next section of the code identifies patients who—based on their average daily MED—are at risk of opioid misuse or overdose.

The code identifies patients who met the criteria for the measures used in OIG's data brief *Opioid Use in Medicare Part D Remains Concerning* (OEI-02-18-00220). These include:

- Patients who received high amounts of opioids: Patients with an average daily MED greater than 120 mg for any 90-day period and had at least 90 days of opioid use (*HIGH\_MED*).
- Patients who received extreme amounts of opioids: Patients with an average daily MED that was greater than 240 mg for the entire year and had at least 360 days of opioid use (EXTREME\_MED).
- Patients who appear to be doctor shopping: Patients with high amounts of opioids—i.e., an average daily MED greater than 120 mg for any 90-day period—and who received opioid prescriptions from four or more prescribers AND four or more pharmacies during the year (DOCTORSHOP\_MED).<sup>16</sup>

<sup>&</sup>lt;sup>16</sup> To identify these patients, the code includes an optional section that calculates the total number of prescribers and pharmacies that dispensed opioids to each patient during the timeframe.

There may be other patients who are also at risk, but do not meet these criteria. This section of the code can be adjusted depending on each user's needs. For example, if the purpose of the analysis is to identify patients who may benefit from additional case management, the MED levels can be lowered. If the purpose is to refer incidents of possible drug diversion to law enforcement, the MED levels can be increased. Similarly, if the user's analysis is based on a timeframe shorter or longer than 1 year, the days of opioid use can be changed.

#### **Notice**

Note that the Office of Inspector General (OIG) is providing this toolkit, including the associated SAS programming code, to assist users in analyzing large datasets of prescription drug claims to identify individuals at risk of potential opioid abuse or misuse. This toolkit was prepared as a technical resource and is not intended to, and does not, create any rights, privileges, or benefits, substantive or procedural, enforceable by a party against the United States; its agencies or instrumentalities; its officers or employees; or any other person. The toolkit is provided in "as-is" condition, and OIG and its employees, agents, and staff disclaim any express or implied representation, warranty, or quarantee, including, but not limited to, the implied warranties of merchantability and fitness for a particular purpose. In particular, no representation is made that the information included in the toolkit, or any data the toolkit produces, is error free. The toolkit should not be used as the sole basis to determine whether an individual is abusing or overdosing on opioids or other prescription drugs, or in any determinations of coverage or dispensing by an insurer, pharmacy, provider, or other individual or organization. The toolkit is not intended to be used to determine compliance with any laws, regulations or other guidance. In no event shall OIG or its employees, agents, or staff be liable for any claim, damages, or liability, whether in an action of contract, tort or otherwise, and including direct, indirect, incidental, special, exemplary, or consequential damages, however caused, and on any theory of liability, arising in any way out of the use of this toolkit or its associated code, even if advised of the possibility of such damage. Compatibility of the toolkit with any user systems is not quaranteed, and any manipulation or alteration of the code is the sole responsibility of the user.

### 3. PROGRAMMING CODE

This SAS code can also be downloaded at oig.hhs.gov/oei/reports/oei-02-17-00560.asp.

```
/* U.S. Department of Health & Human Services
Office of Inspector General (OIG)
Office of Evaluation and Inspections
```

Toolkit: Using Data Analysis To Calculate Opioid Levels and Identify Patients At Risk of Misuse or Overdose OEI-02-17-00560, June 2018

This code uses prescription drug data to analyze patients' opioid levels and identify patients who are at risk of opioid misuse or overdose. It is based on the methodology OIG developed for its data brief Opioid Use in Medicare Part D Remains Concerning (OEI-02-18-00220), which was released in June 2018 alongside this toolkit.

This code is being shared as part of the OIG Toolkit: Using Data Analysis To Calculate Opioid Levels and Identify Patients At Risk of Misuse or Overdose (OEI-02-17-00560). Please read the full toolkit. It provides important information about preparing the data for the analysis, including how to merge data from the Centers for Disease Control and Prevention. The toolkit may be accessed at www.oig.hhs.gov/oei/reports/oei-02-17-00560.asp.

The code calculates patients' average daily morphine equivalent dose (MED), which converts various prescription opioids and strengths into one standard value: equivalent milligrams of morphine. This measure is also called morphine milligram equivalent (MME). Users can use these data to identify patients at varying levels of risk.

The code uses two macros and creates three patient-level datasets:

- 1) OVERVIEW MED dataset provides an overview of each patient's opioid utilization.
- 2) DAILY MED dataset provides detailed daily MED amounts for selected patients.
- 3) AT RISK MED dataset identifies at-risk patients who had certain MED levels.

```
/* Enter name of cleaned dataset of opioid prescription data. Please note that
       the code does not exclude cancer and hospice patients. Please see the
       toolkit text for more information about excluding these patients from the
       analysis.*/
%let DATA CLEANED = work.data cleaned ;
   /* Enter Prescription Fill Date field name. Note: The code requires the
       prescription fill date field to be in the SAS date format. */
%let PRESCRIPTION FILL DATE = prescription fill date ;
   /* Enter Unique Patient Identifier field name. Note: The analysis relies on
       each patient having a unique identifier. If the prescription drug data
       do not contain a unique identifier for each patient, additional steps
       should be taken to create one. */
%let PATIENT ID = patient id ;
   /* Enter Strength per Unit field name */
%let STRENGTH PER UNIT = strength per unit ;
   /* Enter Quantity Dispensed field name */
%let QUANTITY DISPENSED = quantity dispensed;
   /* Enter Morphine Milligram Equivalent (MME) Conversion Factor field name */
%let MME CONVERSION FACTOR = mme conversion factor;
   /* Enter Days Supply field name */
%let DAYS SUPPLY = days supply ;
   /* If available: Enter pharmacy unique identifier field name. Note: This
       field is optional. */
%let PHARMACY ID = pharmacy id ;
   /* If available: Enter prescriber unique identifier field name. Note: This
       field is optional. */
%let PRESCRIBER ID = prescriber id ;
/* 1) OVERVIEW MED MACRO
   This macro provides an overview of each patient's opioid utilization. The
   output data contains the following fields for each patient:
    PATIENT ID Unique patient identifier.
    OPIOID DAYS Days of opioid use, or the number of days during the
                  timeframe when the patient has a daily MED that is
                  greater than zero.
    ALL AVG MED
                  Average daily MED for the entire study timeframe. For
                   example, for a timeframe of 1 year, this is the
                   patient's average daily MED for that year.
    MAX_AVG_MED_90 Highest average daily MED for any 90 days. This is the
                   maximum average daily MED over any 90-day period in the
                   timeframe.
   Brief explanation of the code:
   a. PROC SORT sorts the prepared data of opioid prescription claims by
```

```
patient ID. The code analyzes the data by patient ID.
      ARRAY creates a field for each day in the timeframe (D1, D2, D3, etc.)
            for each patient ID.
    c. DAILY MED calculates the daily MED for each opioid prescription =
            (Quantity dispensed * Strength per unit * MME conversion factor)/
            (Days supply).
            The daily MED is assigned to the appropriate day (D1, D2, etc.) in
            the timeframe based on the Date of Service and Days Supply. If the
            day already has an MED value greater than zero, the macro sums the
            two values. When the code reaches the last opioid prescription for a
            patient, each day field contains that patient's total MED for that
    d. OPIOID_DAYS is days of opioid use. When the code reaches the last opioid
            prescription for a patient, it counts the number of days during
            the timeframe when the patient has a daily MED that is greater than
    e. ALL AVG MED calculates the average daily MED over the entire timeframe
            for the patient. ALL AVG MED = (Total MED of all prescriptions
    in the timeframe) / (Total number of days in the timeframe).
    f. MAX_AVG_MED_&SELTIME becomes MAX_AVG_MED_90, or highest average daily MED
            for any 90 days. It calculates the average daily MED for the patient
            over every 90-day time period in the timeframe and outputs the highest
*/
%macro overview med;
%let seltime = 90;
                      /* 90-day periods */
proc sort data=&DATA CLEANED;
   by &PATIENT ID;
run:
                            &PATIENT ID
data overview med (keep =
                            opioid days
                            all avg med
                            max avg med &seltime);
    set &data cleaned (keep = &PRESCRIPTION FILL DATE
                                &PATIENT ID
                                &STRENGTH PER UNIT
                                &QUANTITY DISPENSED
                                &MME CONVERSION FACTOR
                                &DAYS SUPPLY);
   by &patient id;
/* b */
   array d{&DAYS IN TIMEFRAME} _temporary_;
    if first. & PATIENT ID then do;
        do i = 1 to &DAYS IN TIMEFRAME;
        d\{i\} = 0;
        end;
    end;
/* c */
    daily med = (&QUANTITY DISPENSED * &STRENGTH PER UNIT *
        &MME CONVERSION FACTOR) / &DAYS SUPPLY;
    do i = 1 to &DAYS IN TIMEFRAME;
        if &PRESCRIPTION FILL DATE <= mdy(&FIRST DATE) + (i - 1)
            <= &PRESCRIPTION FILL DATE + (&DAYS SUPPLY - 1) then do;
                d\{i\} + daily med;
            end;
    end:
/* d */
```

```
if last.&PATIENT ID then do;
       opioid days = 0;
       totl time med &DAYS IN TIMEFRAME = 0;
       do i = 1 to &DAYS IN TIMEFRAME;
           if d\{i\} > 0 then opioid days = opioid days + 1;
           totl time med &DAYS IN TIMEFRAME =
               totl time med &DAYS IN TIMEFRAME + d{i};
       end;
/* e */
       all avg med = totl time med &DAYS IN TIMEFRAME / &DAYS IN TIMEFRAME;
/* f */
       max avg med & seltime = 0;
       totl time med &seltime = 0;
       do s = 1 to ((&DAYS IN TIMEFRAME - &seltime) + 1);
           totl time med &seltime = 0;
           do i = s to (s + (\&seltime - 1));
               totl time med &seltime = totl time med &seltime + d{i};
           end;
           avg_med_&seltime = totl_time_med_&seltime / &seltime;
           if avg_med_&seltime > max_avg_med_&seltime
           then max_avg_med_&seltime = avg med &seltime;
       end;
       if last.&PATIENT ID then output;
   end;
run;
%mend overview med;
%overview_med
/* 2) DAILY MED MACRO
   This macro provides the daily MED for each day in the study timeframe for
   selected patients. This macro can be used to look more closely at the daily
   MED for selected patients with concerning patterns. For example, if a
   patient has an extremely high average daily MED, these data will show which
   days during the timeframe the patient received the highest amounts.
   The output data contains the following fields:
    PATIENT ID
                          Unique patient identifier.
                           The day in the timeframe. Each day in the timeframe
    D1 to D[N]
                           has that day's total daily MED. N is the number of
                           days in the timeframe.
   For example, for a patient with 365 days in the timeframe, the output data
   contain 366 fields: PATIENT ID, D1, D2, D3 ... D363, D364, and D365. The
   field names correspond to the day in the analysis. D1 is day 1 in
   the timeframe, and D365 is day 365 in the timeframe.
   The code works similarly to OVERVIEW MED. It uses the ARRAY and DAILY MED code
   from the OVERVIEW MED macro.
%macro daily med(PATIENT);
data daily med &PATIENT (keep = &PATIENT ID d1-d&DAYS IN TIMEFRAME);
   set &DATA CLEANED (keep = &PRESCRIPTION FILL DATE
                               &PATIENT ID
                               &STRENGTH PER UNIT
                               &QUANTITY DISPENSED
```

```
&MME CONVERSION FACTOR
                             &DAYS SUPPLY);
   where &PATIENT ID = &PATIENT;
   by &PATIENT ID;
   array days arr{&DAYS IN TIMEFRAME} d1-d&DAYS IN TIMEFRAME;
   if first. & PATIENT ID then do;
       do i = 1 to &DAYS IN TIMEFRAME;
       days arr\{i\} = 0;
       end;
   end;
   daily med = (&QUANTITY DISPENSED * &STRENGTH PER UNIT *
       &MME CONVERSION FACTOR) / &DAYS SUPPLY;
   do i = 1 to &DAYS IN TIMEFRAME;
       if &PRESCRIPTION FILL DATE <= mdy(&FIRST DATE) + (i - 1)
          <= &PRESCRIPTION FILL DATE + (&DAYS SUPPLY - 1) then do;
              days arr{i} + daily med;
              end;
   end;
   if last.&PATIENT ID then output;
%mend daily med;
   /* Insert patient ID of specific patients. If the patient ID is a character
   field, then place the patient ID in quotes. */
% daily med(PATIENT)
/* 3) AT RISK MED CODE
```

This code identifies patients who, based on their average daily MED, are at risk of opioid misuse or abuse. The code identifies patients who met the criteria in the measures used in OIG's data brief, *Opioid Use in Medicare Part D Remains Concerning* (OEI-02-18-00220). This analysis used calendar year 2017 as the timeframe.

This section of the code can be adjusted depending on each user's needs. For example, if the purpose of the analysis is to identify patients who may benefit from additional case management, the MED thresholds can be lowered. If the purpose is to refer incidences of possible drug diversion to law enforcement, the MED thresholds can be increased. Similarly, if the user's analysis is based on a shorter or longer timeframe than 1 year, the days of opioid use can be changed.

The code identifies patients who appear to be doctor shopping. This analysis requires unique pharmacy identifiers and unique prescriber identifiers in the opioid prescription data. For each patient, it counts the number of distinct pharmacies and prescribers that had at least 1 opioid prescription with a fill date in the timeframe. As noted below, this section of the code is optional and should be skipped if these unique identifiers are not available.

The output dataset contains the following fields in addition to the fields from the  ${\tt OVERVIEW\_MED}$  dataset:

```
HIGH_MED Patients who received high amounts of opioids. Patients with an average daily MED greater than 120 mg for any 90-day period and had at least 90 days of opioid use.
```

```
1=Yes, 0=No.
    EXTREME MED
                       Patients who received extreme amounts of opioids. Patients
                       with an average daily MED that was greater than 240 mg
                       for the entire year and had at least 360 days of
                       opioid use. 1=Yes, 0=No.
    DOCTORSHOP MED
                       Patients who appear to be doctor
                       shopping. Patients with a high amount of opioids (i.e.,
                       average daily MED greater than 120 mg for any 90-day
                       period) and who received opioid prescriptions from four
                       or more prescribers and four or more pharmacies during
                       the year. 1=Yes, 0=No. */
proc sql; /* Do not run this SQL step if unique pharmacy identifier or unique
               patient identifier are not available */
   create table pharm presc counts as
   select &PATIENT ID,
           count(distinct (case when &PRESCRIPTION FILL DATE between
               mdy(&FIRST DATE) and (mdy(&FIRST DATE) + &DAYS IN TIMEFRAME - 1)
               then &PHARMACY ID end))
               as PHARMACY_COUNT,
           count(distinct (case when &PRESCRIPTION FILL DATE between
               mdy(&FIRST DATE) and (mdy(&FIRST DATE) + &DAYS IN TIMEFRAME - 1)
               then &PRESCRIBER ID end))
               as PRESCRIBER COUNT
           &DATA CLEANED
   group by &PATIENT ID;
   create table overview med as
   select a.*,
           b.PHARMACY COUNT,
           b.PRESCRIBER COUNT
           overview med a
   from
           left join pharm presc counts b
           on a.&PATIENT ID = b.&PATIENT ID;
quit;
data AT RISK MED;
   set overview med;
   if max avg med 90 > 120 and
                                  /* The MED and days of opioid use may */
        opioid days ge 90
                                   /* be adjusted as needed */
       then high med = 1;
       else high med = 0;
                                  /* The MED and days of opioid use may */
   if all avg med > 240 and
                                  /* be adjusted as needed */
       opioid days ge 360
       then extreme med = 1;
       else extreme med = 0;
/* Do not run the IF/THEN condition for DOCTORSHOP MED if pharmacy and
       prescriber counts are not available */
   if max_avg_med_90 > 120 and /* The MED and days of opioid use may */
                                  /* be adjusted as needed */
       opioid days ge 90 and
       pharmacy count ge 4 and
                                 /*Criteria for prescribers and pharmacies */
       prescriber count ge 4
                                  /* may be adjusted as needed */
       then doctorshop med = 1;
       else doctorshop med = 0;
run;
```

/\*Note that the Office of Inspector General (OIG) is providing this toolkit, including this associated SAS programming code, to assist users in analyzing large datasets of prescription drug claims to identify individuals at risk of potential

opioid abuse or misuse. This toolkit was prepared as a technical resource and is not intended to, and does not, create any rights, privileges, or benefits, substantive or procedural, enforceable by a party against the United States; its agencies or instrumentalities; its officers or employees; or any other person. The toolkit is provided in "as-is" condition, and OIG and its employees, agents, and staff disclaim any express or implied representation, warranty, or guarantee, including, but not limited to, the implied warranties of merchantability and fitness for a particular purpose. In particular, no representation is made that the information included in the toolkit, or any data the toolkit produces, is error free. The toolkit should not be used as the sole basis to determine whether an individual is abusing or overdosing on opioids or other prescription drugs, or in any determinations of coverage or dispensing by an insurer, pharmacy, provider, or other individual or organization. The toolkit is not intended to be used to determine compliance with any laws, regulations, or other guidance. In no event shall OIG or its employees, agents, or staff be liable for any claim, damages, or liability, whether in an action of contract, tort or otherwise, and including direct, indirect, incidental, special, exemplary, or consequential damages, however caused, and on any theory of liability, arising in any way out of the use of this toolkit or its associated code, even if advised of the possibility of such damage. Compatibility of the toolkit with any user systems is not guaranteed, and any manipulation or alteration of the code is the sole responsibility of the user. \*/

### **ACKNOWLEDGMENTS**

Miriam Anderson served as the team leader for this study. Others in the Office of Evaluation and Inspections who conducted the study include Margaret Himmelright and Jason Kwong. Office of Evaluation and Inspections staff who provided support include Althea Hosein, Christine Moritz, Berivan Demir Neubert, and Meghan Riggs. We would also like to acknowledge the contributions of other Office of Inspector General staff, including Robert Gibbons.

This report was prepared under the direction of Jodi Nudelman, Regional Inspector General for Evaluation and Inspections in the New York regional office; Nancy Harrison, Deputy Regional Inspector General; and Meridith Seife, Deputy Regional Inspector General.

### ABOUT THE OFFICE OF INSPECTOR GENERAL

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

### Office of Audit Services

The Office of Audit Services (OAS) provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These assessments help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

### Office of Evaluation and Inspections

The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness of departmental programs. To promote impact, OEI reports also present practical recommendations for improving program operations.

#### Office of Investigations

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in all 50 States and the District of Columbia, OI utilizes its resources by actively coordinating with the Department of Justice and other Federal, State, and local law enforcement authorities. The investigative efforts of OI often lead to criminal convictions, administrative sanctions, and/or civil monetary penalties.

# Office of Counsel to the Inspector General

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG's internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, and civil monetary penalty cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the health care industry concerning the anti-kickback statute and other OIG enforcement authorities.