Concerns About Opioid Use in Medicare Part D in the Appalachian Region

The opioid crisis has been declared a public health emergency. In 2016, there were more than 42,000 opioid-related overdose deaths in the United States—115 deaths per day. Nearly 7,000 of these deaths occurred in 5 States in the Appalachian region—Alabama, Kentucky, Ohio, Tennessee, and West Virginia. All five of these States had high opioid prescribing rates and four reported opioid-related overdose death rates that far exceeded that of the Nation. Identifying patients at risk of overdose or abuse is key to addressing this crisis.

Opioids include narcotics intended to manage pain from surgery, injury, or illness. They can create a euphoric effect, which makes them vulnerable to abuse and misuse (i.e., taking opioids in a way other than prescribed). Although opioids can be appropriate under certain circumstances, the Office of Inspector General (OIG) and others are concerned about fraud, abuse, and misuse of opioids, as well as drug diversion—the redirection of prescription drugs for an illegal purpose, such as recreational use or resale. These concerns extend to opioids obtained under Medicare Part D, the optional prescription drug benefit for Medicare beneficiaries. In 2017, Part D covered about 45 million beneficiaries.

In addition to these concerns, opioid use carries a number of health risks. Side effects from using opioids may include respiratory depression, confusion, increased tolerance, and physical dependence. For seniors, long-term use of prescription opioids also increases the likelihood of falls and fractures.

The Centers for Disease Control and Prevention (CDC) published guidelines on prescribing opioids to patients with chronic pain. The guidelines recommend that prescribers use caution when ordering opioids at any dosage and avoid increasing dosages to the equivalent of 90 mg or more of morphine a day for chronic pain.

This data brief is part of a larger strategy by OIG to fight the opioid crisis and protect beneficiaries from prescription drug misuse and abuse. As part of this strategy, OIG is partnering with other law enforcement agencies in the Appalachian Regional Prescription Opioid Strike Force, bringing together resources and expertise to fight the opioid crisis in five States.
This data brief focuses on those five States: Alabama, Kentucky, Ohio, Tennessee, and West Virginia. OIG has also released a data brief on opioid use in the Ohio Medicaid program. In addition, OIG recently issued factsheets that describe Tennessee’s and West Virginia’s oversight of opioid prescribing and monitoring of opioid use. OIG has also reviewed opioid use in Part D nation-wide and has ongoing studies focused on access to care.

RESULTS

In five States in the Appalachian region, 36 percent of Part D beneficiaries received a prescription opioid in 2017

In 2017, more than one in three beneficiaries in five States in the Appalachian region—Alabama, Kentucky, Ohio, Tennessee, and West Virginia—received at least one prescription opioid through Medicare Part D. About 1.7 million beneficiaries received opioids out of the approximately 4.7 million who were enrolled in Medicare Part D in these States. Part D paid for 10.1 million opioid prescriptions for beneficiaries in these States in 2017—an average of 6 prescriptions per beneficiary receiving opioids. Part D paid a total of $410 million for these opioids. Tramadol, hydrocodone-acetaminophen, and oxycodone-acetaminophen were the most commonly prescribed opioids for the beneficiaries in the five States during the year.

Of the five States, Alabama had the highest proportion of beneficiaries receiving opioids. In Alabama, 44 percent of the Part D beneficiaries received an opioid in 2017. Tennessee was next with 40 percent, followed by Kentucky with 37 percent, West Virginia with 35 percent, and Ohio with 30 percent. Nation-wide, 31 percent of Part D beneficiaries received a prescription opioid.

Exhibit 1: Alabama had the highest proportion of Part D beneficiaries receiving opioids.

<table>
<thead>
<tr>
<th>State</th>
<th>Proportion of Part D beneficiaries who received at least one opioid in 2017</th>
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<tbody>
<tr>
<td>Alabama</td>
<td>44%</td>
</tr>
<tr>
<td>Tennessee</td>
<td>40%</td>
</tr>
<tr>
<td>Kentucky</td>
<td>37%</td>
</tr>
<tr>
<td>West Virginia</td>
<td>35%</td>
</tr>
<tr>
<td>Ohio</td>
<td>30%</td>
</tr>
</tbody>
</table>

Almost 49,000 of these beneficiaries received high amounts of opioids, far exceeding levels CDC says to avoid.

In 2017, a total of 48,584 beneficiaries in these 5 States in the Appalachian region received high amounts of opioids through Medicare Part D; this number does not include beneficiaries who had cancer or were in hospice care. Each of the 48,584 beneficiaries received an average morphine equivalent dose (MED) of greater than 120 mg a day for at least 3 months in 2017. MED is a measure that converts all the various opioids and strengths into one standard value. A daily MED of 120 mg is equivalent to taking 12 tablets a day of Vicodin 10 mg or 16 tablets a day of Percocet 5 mg. These dosages far exceed the amounts that the manufacturers recommend for both of these drugs. They also exceed the MED level that CDC recommends avoiding for patients with chronic pain.

To help inform prescribers, the CDC published guidelines on prescribing opioids to patients with chronic pain. The guidelines recommend that prescribers use caution when ordering opioids at any dosage and avoid increasing dosages to the equivalent of 90 mg or more MED a day for chronic pain.

The most commonly prescribed opioids for beneficiaries with high amounts were oxycodone-acetaminophen 10 mg and oxycodone 15 mg. Nearly one-quarter of all beneficiaries who received high amounts of opioids had at least one prescription for oxycodone-acetaminophen 10 mg, while 22 percent had a prescription for oxycodone 15 mg. Eleven percent of beneficiaries who received high amounts of opioids had at least one prescription for fentanyl patch 50 mcg/hr. Oxycodone and fentanyl are among the most common opioids involved in law enforcement cases.

Fentanyl is 80 to 100 times more powerful than morphine and is sometimes mixed with other drugs, such as cocaine or heroin, which increases the risk of overdose.

Although beneficiaries may receive opioids for legitimate purposes, these amounts raise concern. Opioids carry health risks, including respiratory depression, constipation, drowsiness, and confusion. Older adults may also be at an increased risk of injury, as research has shown that the risk of fracture may increase as drug dosage increases.

Nearly 6,000 beneficiaries in these States are at serious risk of opioid misuse or overdose.

Two groups of beneficiaries who are at serious risk of opioid misuse or overdose are beneficiaries who receive extreme amounts of opioids—i.e., an average daily MED greater than 240 mg for 12 months—and beneficiaries who appear to be doctor shopping—i.e., receive a high amount of opioids (an average daily MED greater than 120 mg for 3 months) and have four or more prescribers and four or more pharmacies. Other Part D beneficiaries also may be at serious risk of opioid misuse or overdose but do not meet these criteria.
In 5 States in the Appalachian region, 5,929 beneficiaries were in one of these two groups in 2017 and, therefore, at serious risk. This does not include beneficiaries who had cancer or were in hospice care. Specifically, 4,556 beneficiaries received extreme amounts of opioids in these States and 1,451 beneficiaries appeared to be doctor shopping. A total of 78 beneficiaries were in both groups. See Appendix A for data on Part D beneficiaries in the Appalachian region receiving opioids.

Most of the beneficiaries at serious risk were under the age of 65. These individuals may have qualified for Medicare because they have disabilities or end-stage renal disease. Seventy-five percent of beneficiaries at serious risk were under 65 years old, 21 percent were between 65 and 75, and 4 percent were over 75.17

**Examples of Beneficiaries at Serious Risk of Opioid Misuse or Abuse**

A beneficiary from Ohio received more than a year’s supply of fentanyl patches and over 3,000 pills containing oxycodone in 2017. This beneficiary had a total of 54 opioid prescriptions from 5 prescribers and 4 pharmacies, giving him an average daily MED of more than 1,100 mg for the year. This is 12 times the amount CDC recommends avoiding.

A beneficiary from Tennessee had an average daily MED that topped 1,400 mg for the year, which is over 15 times the amount CDC recommends avoiding. This beneficiary also had 5 prescribers and used 5 pharmacies in 2017. She received 27 opioid prescriptions totaling more than 6,000 pills, almost all of which contained two high strengths of oxycodone, 80mg and 30mg.

In the first month of 2017, a beneficiary in Kentucky received 5 opioid prescriptions amounting to 22 pills per day. These prescriptions included 1-month supplies each of three strengths of oxycodone (80 mg, 30 mg, and 20 mg), methadone 10 mg and Subsys (a fentanyl spray). This beneficiary went on to receive a total of 54 opioid prescriptions during the year, resulting in an average daily MED that exceeded—by 17 times—the level that CDC says to avoid. Over the course of the year, he received more than 6,400 pills containing oxycodone.

A beneficiary in West Virginia used 15 pharmacies to fill opioid prescriptions from 22 prescribers. The prescribers were in 10 different States: Georgia, Maryland, Michigan, Missouri, New Hampshire, New York, Ohio, Virginia, Vermont, and West Virginia.
CONCLUSION

Opioid abuse and overdose deaths are at epidemic levels in the United States. In five States in the Appalachian region—Alabama, Kentucky, Ohio, Tennessee, and West Virginia—36 percent of Part D beneficiaries received a prescription opioid in 2017. In comparison, 31 percent of Part D beneficiaries nation-wide received a prescription opioid. Almost 49,000 of beneficiaries in the 5 States received amounts that far exceed manufacturer recommendations and the levels that CDC says to avoid. Raising additional concern, nearly 6,000 beneficiaries in these States are at serious risk of opioid misuse or overdose because they received extreme amounts of opioids, or they appeared to be doctor shopping.

The use of opioids described in this study may indicate that opioids in the Appalachian region are being prescribed for medically unnecessary purposes and then diverted for resale or recreational use. It may also indicate that the beneficiary is receiving poorly coordinated care or that the beneficiary’s care may need to be reassessed. In addition, it raises questions as to whether prescribers are checking State prescription drug monitoring databases or whether these databases have current information.

The severity of the crisis makes it imperative that the Department of Health and Human Services (the Department), including the Centers for Medicare & Medicaid Services (CMS) and OIG, continue to work with its partners to address this epidemic. As the Department has highlighted—strengthening public health surveillance, advancing the practice of pain management, improving access to treatment and recovery services, targeting availability and distribution of overdose-reversing drugs, and supporting cutting-edge research—all need to be part of the strategy to fight the opioid crisis in the Appalachian region and the Nation.18

OIG is committed to fighting the opioid crisis and protecting beneficiaries from prescription drug abuse and misuse. We are working with our law enforcement partners to bring resources and expertise to these five States through the Appalachian Regional Prescription Opioid Strike Force. The mission of the Strike Force is to prevent patient harm and identify and investigate healthcare fraud related to medically unnecessary prescribing and illegal distribution of opioids, with a particular focus on medical professionals.

OIG also recently released an opioid analysis toolkit to assist our public and private sector partners.19 The toolkit provides detailed step-by-step instructions for using prescription drug data to identify patients who are at risk of opioid misuse or overdose. In addition, OIG is conducting a series of reviews on opioid utilization in Medicaid and producing factsheets on
selected States’ oversight of opioid prescribing and monitoring of opioid use.\textsuperscript{20} OIG also has ongoing reviews about key opioid initiatives at the Department, including access to buprenorphine for opioid use disorder; controls on opioid treatment programs, and grants for prescription drug monitoring programs.

Further, OIG supports States’ efforts nation-wide to combat the opioid crisis. OIG supports States’ efforts to implement and enforce strong prescription drug monitoring programs that require prescribers and pharmacies to check the State database before prescribing and dispensing opioids. Further, we encourage States to provide greater access to these data, including sharing these data with entities such as State Medicaid agencies. We also encourage States to analyze these data to help identify patients who may be at risk and to promote appropriate opioid prescribing practices. For example, States could provide reports to prescribers about their opioid prescribing patterns. By working together and expanding our efforts, we can help curb the opioid crisis in our Nation.
METHODOLOGY

We based this data brief on an analysis of prescription drug event (PDE) records for Part D drugs. This data brief includes prescriptions that beneficiaries in five States in the Appalachian region—Alabama, Kentucky, Ohio, Tennessee, and West Virginia—received through Part D. It does not include prescriptions paid through other programs, prescriptions paid for in cash, or illicitly purchased drugs. Part D sponsors submit a PDE record to CMS each time a drug is dispensed to a beneficiary enrolled in their plans. Each record contains information about the drug and beneficiary, as well as the identification numbers for the pharmacy and the prescriber.

We matched PDE records to data from the First DataBank, National Claims History File, Part C Encounter Data, CDC’s Morphine Milligram Equivalent (MME) conversion file, National Plan and Provider Enumeration System (NPPES), and the National Council for Prescription Drug Programs (NCPDP) database to obtain descriptive information about the drugs, beneficiaries and pharmacies. First DataBank contains information about each drug, such as the drug name, strength of the drug, and therapeutic class (e.g., an opioid.) The National Claims History File contains claims data from Medicare Parts A and B, including diagnosis codes. Part C Encounter Data contains medical claims data, including diagnosis codes, for beneficiaries enrolled in Medicare Advantage plans. CDC’s MME conversion file contains information about each opioid’s drug morphine milligram equivalence. NPPES contains information about prescribers, such as their name and address. The NCPDP database contains information about pharmacies, such as their names and addresses. For the purposes of this study, we use the term “prescription” to mean one PDE record.

Analysis of Part D Opioid Utilization and Spending
We identified all PDE records for opioids that beneficiaries received in 2017. We calculated the total number of Part D beneficiaries in Alabama, Kentucky, Ohio, Tennessee, and West Virginia who received opioids in 2017. For beneficiaries in these five States, we then calculated the total number of opioid prescriptions paid for by Part D in 2017 and the average number of opioid prescriptions per beneficiary. We also calculated the proportion of beneficiaries who received opioids in each of these States in 2017. We based this analysis on the PDE records and Medicare enrollment data.

Beneficiary Analysis
Next, we determined the amount of opioids that each beneficiary in these five States received in 2017. To do this, we calculated each beneficiary’s average daily morphine equivalent dose (MED). The MED converts opioids of different ingredients, strengths, and forms into equivalent...
milligrams of morphine. It allows us to sum dosages of different opioids to determine a beneficiary’s daily opioid level.

To calculate each beneficiary’s average daily MED, we first calculated the MED for each prescription (i.e., PDE record). To do this, we used the following equation:

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

Next, we summed each beneficiary’s MED for each day of the year based on the dates of service and days supply on each PDE record. We refer to this as the daily MED. We excluded from this analysis beneficiaries with a diagnosis of cancer or a hospice stay at any point in 2017.

We analyzed the MED data using the same criteria that we used in our previous national analyses of Part D data from 2016 and 2017. We began by determining the extent to which beneficiaries received high amounts of opioids. To do this, we calculated each beneficiary’s average daily MED over each 90-day period in 2017. We determined that a beneficiary received high amounts of opioids if he or she exceeded an average daily MED of 120 mg for any 90-day period and had received opioids for 90 or more days in the year. We used these criteria because they closely align with the criteria used by CMS in 2016 and 2017 for its Overutilization Monitoring System. The MED of 120 mg also exceeds the level CDC recommends avoiding for patients with chronic pain—an MED of 90 mg.

We then determined the extent to which beneficiaries received extreme amounts of opioids. We calculated each beneficiary’s average daily MED over the entire year. We considered a beneficiary who exceeded an average daily MED of 240 mg for the entire year and had received opioids for 360 days or more to have received an extreme amount of opioids.

Next, we determined the extent to which beneficiaries appeared to be doctor shopping. To do this, we calculated the total number of prescribers and pharmacies from which each beneficiary received opioids in 2017. We considered beneficiaries to have appeared to be doctor shopping if they exceeded an average daily MED of 120 mg for any 90-day period, received opioids for 90 or more days in the year, and received opioids from four or more prescribers and four or more pharmacies.

**Limitations**

This analysis is based on Part D prescription drug event records; it is not based on a review of medical records. The analysis does not include data on opioids that beneficiaries may have received from sources other than Part D.
Standards

We conducted this study in accordance with the Quality Standards for Inspection and Evaluation issued by the Council of the Inspectors General on Integrity and Efficiency.
**APPENDIX A: DATA ON PART D BENEFICIARIES IN THE APPALACHIAN REGION RECEIVING OPIOIDS**

**Exhibit A-1:** Almost 49,000 beneficiaries in 5 States in the Appalachian region received high amounts of opioids, far exceeding levels CDC says to avoid.*

<table>
<thead>
<tr>
<th>Number of Beneficiaries in 2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beneficiaries who received amounts that far exceed levels CDC says to avoid</td>
</tr>
</tbody>
</table>


* These five States are Alabama, Kentucky, Ohio, Tennessee, and West Virginia.

**Exhibit A-2:** Nearly 6,000 beneficiaries in these States are at serious risk of opioid misuse or overdose.*

<table>
<thead>
<tr>
<th>Number of Beneficiaries in 2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beneficiaries who received an extreme amount of opioids</td>
</tr>
<tr>
<td>Beneficiaries who appear to be doctor shopping</td>
</tr>
<tr>
<td>Total beneficiaries at serious risk</td>
</tr>
</tbody>
</table>


* These five States are Alabama, Kentucky, Ohio, Tennessee, and West Virginia.

** A total of 78 beneficiaries were in both groups in 2017.
ACKNOWLEDGMENTS

Miriam Anderson served as the team leader for this study. Other Office of Evaluation and Inspections staff from the New York regional office who conducted the study include Margaret Himmelright and Jason Kwong. Office of Evaluation and Inspections staff who provided support include Adam Freeman. We would also like to acknowledge the contributions of other Office of Inspector General staff, including Robert Gibbons and Lauren McNulty.

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

To obtain additional information concerning this report or to obtain copies, contact the Office of Public Affairs at Public.Affairs@oig.hhs.gov.
ENDNOTES


2 In 2016, the opioid prescribing rate nation-wide was 66.5 prescriptions per 100 persons. Alabama (121 prescriptions per 100 persons), Tennessee (107.5), Kentucky (97.2), West Virginia (96.0), and Ohio (75.3) all had higher prescribing rates than that of the Nation. In total, there were 6,864 opioid-related overdose deaths in these 5 States in the Appalachian region in 2016. The age-adjusted opioid-related overdose death rate was 13.3 per 100,000 persons for the Nation in 2016. West Virginia (43.4 deaths per 100,000 persons), Ohio (32.9), Kentucky (23.6), and Tennessee (18.1) all had higher rates than the Nation. Alabama reported a rate of 7.5. See CDC, Annual Surveillance Report of Drug-Related Risk and Outcomes, 2017. Accessed at https://www.cdc.gov/drugoverdose/pdf/pubs/2017-cdc-drug-surveillance-report.pdf on February 27, 2019. See National Institute on Drug Abuse, Opioid Summaries by States, February 2018. Accessed at https://www.drugabuse.gov/drugs-abuse/opioids/opioid-summaries-by-state on February 20, 2019.


6 Ibid. p. 16. The CDC guidelines recommend that prescribers avoid increasing opioids to morphine equivalent dosages of greater than or equal to 90 mg a day or carefully justify the decision to increase to this level.


10 The five most commonly dispensed opioids included tramadol 50 mg, hydrocodone-acetaminophen 10–325 mg, hydrocodone-acetaminophen 5–325 mg, hydrocodone-acetaminophen 7.5–325 mg, and oxycodone-acetaminophen 10–325 mg.

11 According to the manufacturer labels, the maximal daily dose for Percocet 5 mg is 12 tablets and the daily dosage for Vicodin 10 mg should not exceed 6 tablets. For more information about Percocet, see Endo Pharmaceuticals, PERCOCET® (Oxycodone and Acetaminophen Tablets, USP), p. 2. Accessed at https://www.accessdata.fda.gov/drugsatfda_docs/label/2006/040330s015,040341s013,040434s003lbl.pdf; for Vicodin, see page 20 at http://www.rxabbvie.com/pdf/vicodin_apap_300mg_hydrocodone_5mg-7_5mg-10mg_PI.pdf.
13 Ibid, p. 16.
19 OIG, Toolkit: Using Data Analysis To Calculate Opioid Levels and Identify Patients At Risk of Misuse or Overdose, OEI-02-17-00560, June 2018.
21 These files contain MME conversion factors for each National Drug Code. MED and MME are interchangeable terms.
22 To identify PDE records for opioids, we matched the NDCs on the PDE records with two files—First DataBank and CDC’s MME conversion file.
23 We used the beneficiary’s address on the PDE record to identify the State. For beneficiaries who resided in more than one State during the year, we included the beneficiary in the analysis for each of those States.
25 To ensure that we included all opioids received by each beneficiary in 2017, we included opioids dispensed in 2016 with days of use in 2017. Also, for beneficiaries who resided in more than one State during the year, we included all the opioids they received regardless of where they resided. Note that we did not include PDE records for injection, intravenous, and intrathecal opioids because CDC does not publish MME conversion factors for these opioids. We also did not include opioids indicated for medication-assisted treatment.
26 We identified beneficiaries with a cancer diagnosis or hospice stay using CMS’s National Claims History File and Part C Encounter data.
27 OIG, Opioids in Medicare Part D: Concerns About Extreme Use and Questionable Prescribing, OEI-02-17-00250, July 2017. OIG, Opioid Use in Medicare Part D Remains Concerning, OEI-02-18-00220.
28 Through 2017, CMS’s Overutilization Monitoring System identified beneficiaries who had a daily MED of 120 mg for 90 days plus 4 or more prescribers and 4 or more pharmacies. Note that the guidance uses the term “more than 3 prescribers and more than 3 pharmacies” which is the equivalent to “4 or more prescribers and 4 or more pharmacies.” The criteria for the Overutilization Monitoring System changed in 2018. 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, April 2017. Accessed at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvvtqSpecRateStats/Downloads/Announcement2018.pdf on February 26, 2019.