



High Part D Spending on Opioids and Substantial Growth in Compounded Drugs Raise Concerns

The Office of Inspector General (OIG) has uncovered striking trends in Part D spending for opioids and compounded drugs that warrant further scrutiny. This data brief describes these trends. It also provides information that can assist efforts to ensure the appropriate use of these drugs, protect the integrity of the Part D program, and promote the safety of beneficiaries and others.

Key Takeaways:

- ✓ *Medicare spending for Part D drugs has continued to rise by more than \$10 billion a year*
- ✓ *Spending on commonly abused opioids exceeded \$4 billion in 2015*
- ✓ *Spending on compounded drugs has increased dramatically*
- ✓ *In particular, compounded topical drugs rose more than 3,400 percent since 2006*
- ✓ *These trends raise concerns about fraud and abuse and patient safety*

Prescription drug abuse, especially opioid abuse, remains a problem in this country. More people in the United States died from drug overdoses in 2014 than during any previous year on record. Opioids were associated with 60 percent of these overdose deaths—a total of 29,000 deaths.¹ Previous OIG work has highlighted the rapid growth in spending for commonly abused opioids and the problem of drug diversion—the redirection of prescription drugs for an illegal purpose, such as recreational use or illegal resale.²

At the same time, new concerns have emerged about compounded drugs. Compounded drugs are customized medications that are tailored to the needs of individual patients. Pharmacists and physicians create these medications by combining, mixing, or altering drug ingredients.³ A patient may need a compounded drug if no commercially available product meets that patient's needs. For

instance, a patient who is allergic to an ingredient in a commercially-available drug may require a special formulation to eliminate that ingredient, or a patient with swallowing difficulties may require a liquid instead of a commercially-available pill.

While compounded drugs are beneficial for certain patients, there are fraud and safety concerns. According to the Food and Drug Administration, compounded drugs may pose safety risks, such as being the wrong potency.⁴ Also, several cases involving private and public insurance programs illustrate a number of fraud schemes and safety issues related to these drugs. For example, in 2012, contaminated compounded drugs produced by a Massachusetts-based pharmacy caused an outbreak of fungal meningitis that sickened 753 patients and killed

64 patients.⁵ In addition, a physician and pharmacist were charged with involuntary manslaughter in a case in which a compounded pain cream allegedly contributed to the death of a baby. This physician and pharmacist are also accused of accepting illegal payments (i.e., kickbacks) involving compounded drugs.⁶ Further, a pharmacy in Florida agreed to pay over \$8 million to settle allegations that it billed for compounded drugs that were medically unnecessary and prescribed by physicians who had never seen the patients.⁷

Part D is the optional prescription drug benefit for Medicare beneficiaries. In 2014, over 40 million beneficiaries were enrolled in the Part D program.⁸ Private companies, known as plan sponsors, contract with the Centers for Medicare & Medicaid Services (CMS) to provide this benefit to those who choose to enroll. To be covered by Part D, prescription drugs—including opioids and compounded drugs—must meet certain requirements and be used for medically accepted indications.⁹

Since the Part D program went into effect in 2006, the Office of Inspector General (OIG) has had ongoing concerns about abuse and diversion of Part D drugs.¹⁰ In June 2015, OIG released a portfolio that provides a summary of its extensive body of Part D work and CMS's efforts to address weaknesses in program integrity that OIG identified.¹¹ OIG also released a data brief in June 2015, *Questionable Billing and Geographic Hotspots Point to Potential Fraud and Abuse in Medicare Part D*, which describes trends in Part D spending and identifies questionable billing by pharmacies.¹²

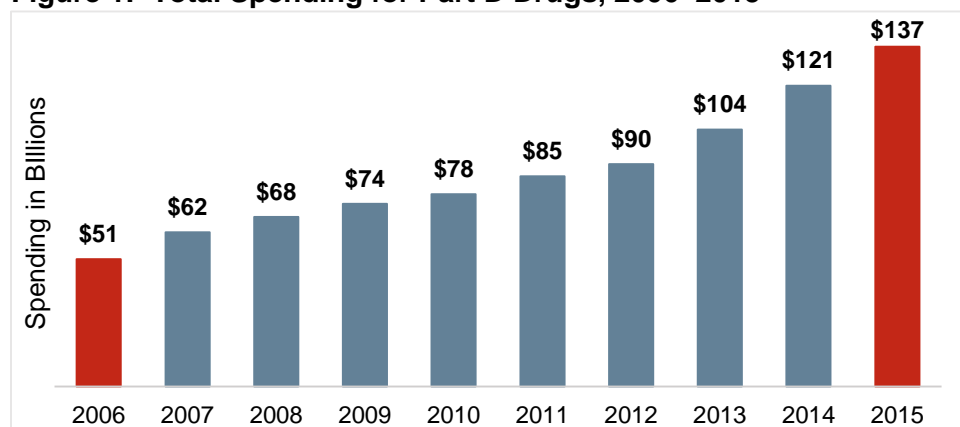
This current data brief builds on OIG's June 2015 data brief. In addition to updating information on Part D spending overall and Part D spending for opioids, it provides new information about spending for compounded drugs.

RESULTS

Spending for Part D drugs continues to rise

From 2006 to 2015, total spending for Part D drugs increased by 167 percent, growing from \$51.3 billion to \$137 billion.¹³ This is the amount that the Government, beneficiaries, and plan sponsors paid to pharmacies for Part D drugs. (See Figure 1.) In 2015 alone, total spending increased by \$15.6 billion, marking the third consecutive year that spending increases surpassed \$10 billion.

Figure 1: Total Spending for Part D Drugs, 2006–2015



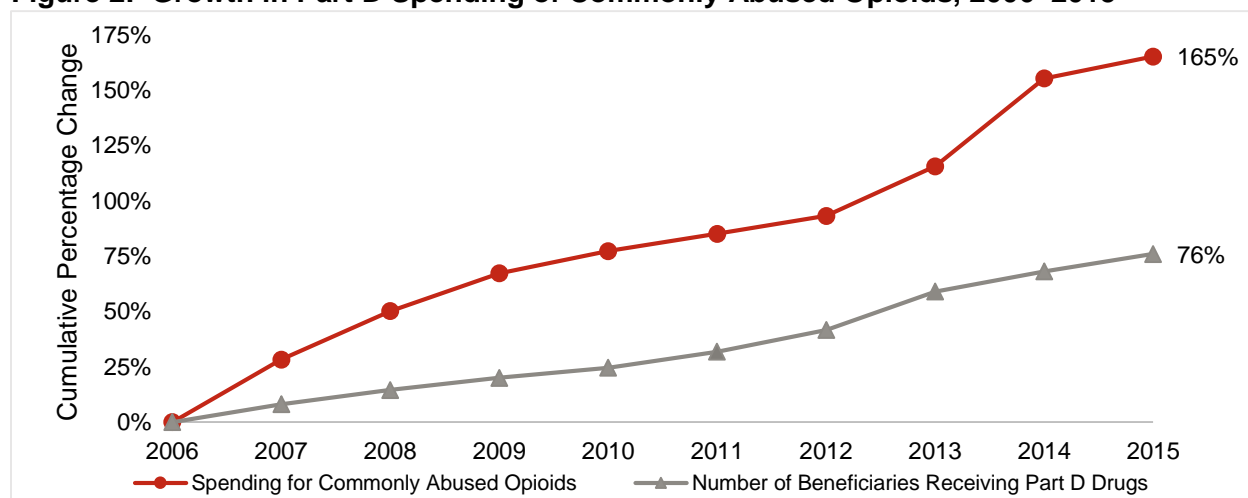
Source: OIG analysis of Medicare Part D data, 2016.

In 2015, controlled substances accounted for \$8.4 billion—or 6 percent—of all Part D spending.¹⁴ Controlled substances of particular concern are Schedule II and III opioids, hereafter referred to as “commonly abused opioids.”¹⁵ They are narcotics intended to manage pain from surgery, injury, and illness. They can create a euphoric effect, which makes them very vulnerable to abuse. In 2015, Part D spending for these opioids was highest for OxyContin (a brand-name version of oxycodone), hydrocodone-acetaminophen (a generic substitute for Vicodin), oxycodone-acetaminophen (a generic substitute for Percocet), and fentanyl.¹⁶

Spending for commonly abused opioids exceeded \$4 billion in 2015

Part D spending for commonly abused opioids reached \$4.1 billion in 2015, up from \$3.9 billion in 2014. Overall, spending for these drugs rose 165 percent from 2006 to 2015. (See Figure 2.) This greatly outpaced the growth in the number of beneficiaries who received Part D drugs, which was 76 percent.

Figure 2: Growth in Part D Spending of Commonly Abused Opioids, 2006–2015

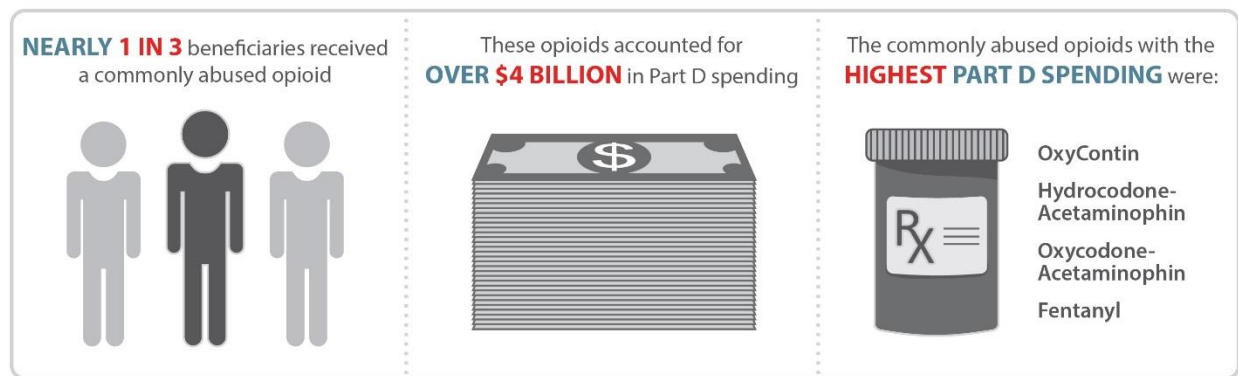


Source: OIG analysis of Medicare Part D data, 2016.

Spending for commonly abused opioids remained high in 2015, although the annual growth rate slowed to 4 percent. This slower growth rate appears to be due to a relatively small increase in the number of beneficiaries receiving commonly abused opioids and a decrease in the average number of prescriptions per beneficiary. In 2015, the total number of beneficiaries receiving these opioids grew by 1 percent while the average number of prescriptions per beneficiary decreased by 7 percent.

A high proportion of Part D beneficiaries continued to receive commonly abused opioids, which also raises concerns. In 2015, almost 12 million beneficiaries—30 percent—received at least one of these drugs.¹⁷ On average, each of these beneficiaries received five prescriptions for commonly abused opioids during the year.

Figure 3: Use of Commonly Abused Opioids in Part D, 2015



Source: OIG analysis of Medicare Part D data, 2016.

In several States, the proportion of beneficiaries receiving commonly abused opioids was higher. Alabama had the highest proportion, with 42 percent. Similarly, Mississippi, Tennessee, Oklahoma, and Arkansas each had approximately 40 percent of beneficiaries receiving commonly abused opioids. The lowest proportions were in Hawaii and New York, where 21 percent of beneficiaries received commonly abused opioids.

Part D Spending for Compounded Drugs Has Increased Significantly, Particularly for Topical Medications

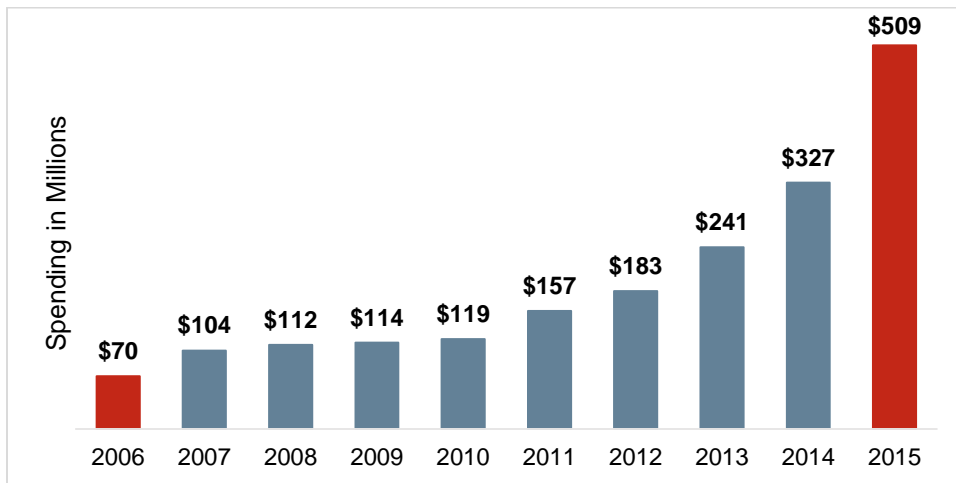
By 2015, Part D spending on compounded drugs was seven times what it was in 2006

Between 2006 and 2015, Part D spending for compounded drugs climbed from \$70.2 million to \$508.7 million, an increase of 625 percent. (See Figure 4.) Compounded drugs can take many forms, the most common of which are topical drugs, intravenous drugs, oral drugs, and injectable drugs.

The growth in spending for compounded drugs far outpaced the growth in spending for all Part D drugs (167 percent). The biggest jump in spending for compounded drugs occurred in 2015,

when it rose by \$182 million. This was an increase of 56 percent. Growth in the number of beneficiaries receiving compounded drugs (154 percent) outpaced growth in the number of beneficiaries receiving Part D drugs (76 percent).

Figure 4: Part D Spending for Compounded Drugs, 2006–2015



Source: OIG analysis of Medicare Part D data, 2016.

This high growth raises concerns that some compounded drugs may not have been medically necessary or may not have been dispensed. These concerns are most pronounced with regard to compounded topical drugs.

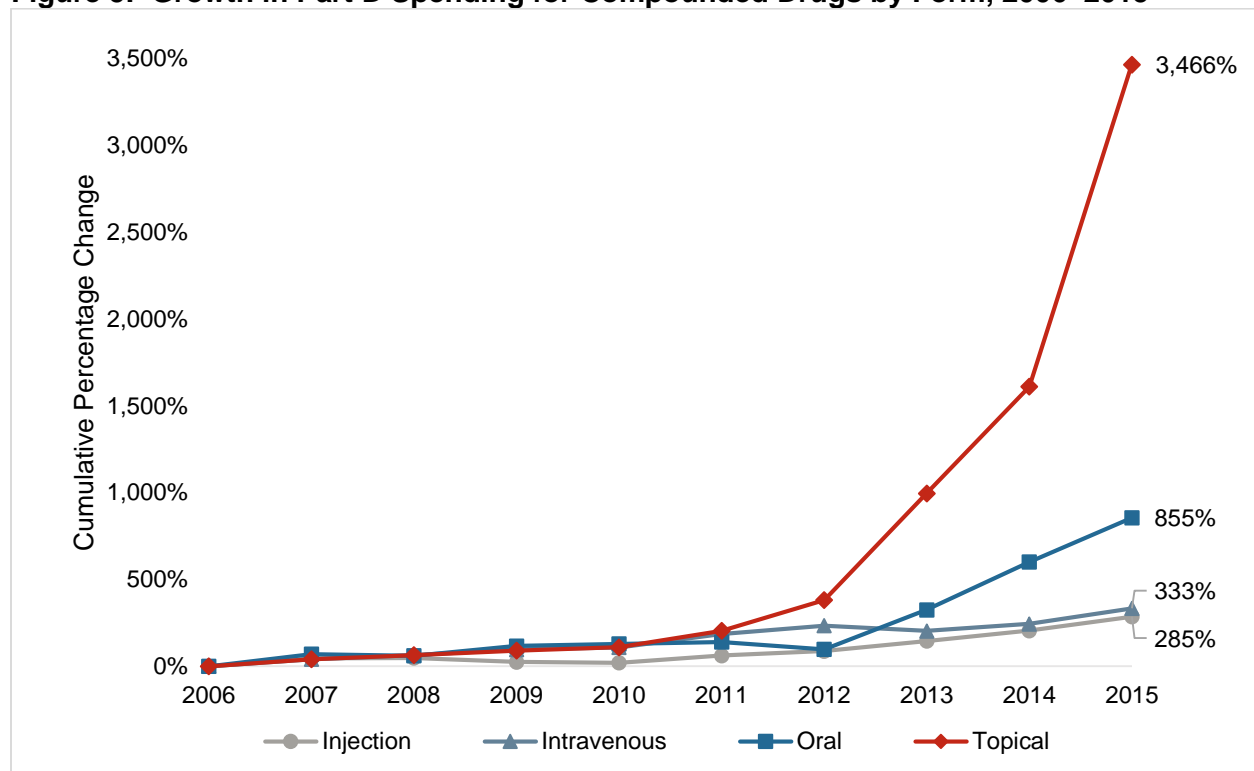
Spending for compounded topical drugs has risen more than 3,400 percent since 2006

Part D spending for compounded topical drugs, which include creams, gels, and ointments, increased 3,466 percent since 2006. (See Figure 5.) In 2015, spending was the highest for lidocaine-prilocaine, which is a local anesthetic, and diclofenac, which is an anti-inflammatory.

Spending for other forms of compounded drugs also increased significantly during that time. Spending for compounded oral drugs increased by 855 percent. These compounds included various types of medications, such as muscle relaxants, antivirals and anti-inflammatories. Spending for compounded intravenous drugs, such as parenteral nutrition and antibiotics, increased by 333 percent, while spending for compounded injectable drugs increased by 285 percent.

Although significant, the growth in these other forms of compounded drugs does not come close to the monumental growth in compounded topical drugs. In 2006, these topical drugs accounted for 9 percent of all spending for compounded drugs, but by 2015 they were closer to half. Part D spending for compounded topical drugs reached \$224.3 million in 2015, representing 44 percent of total spending for compounded drugs for the year.

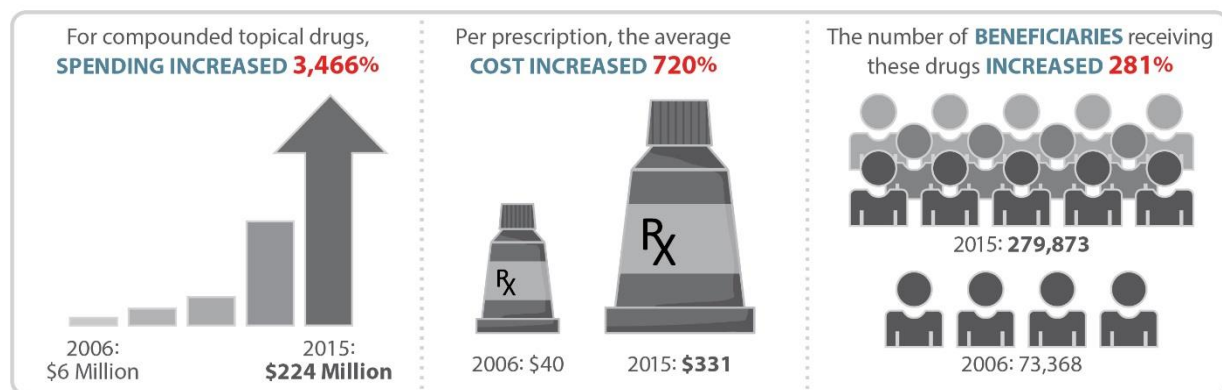
Figure 5: Growth in Part D Spending for Compounded Drugs by Form, 2006–2015



Source: OIG analysis of Medicare Part D data, 2016.

The large growth in compounded topical drugs appears to be driven by both an increase in the average cost of prescriptions and an increase in the number of beneficiaries receiving these drugs. The average cost increased 720 percent since 2006—from \$40 to \$331. The largest increase was in 2015, when the average cost grew 77 percent. The number of beneficiaries receiving compounded drugs also grew sharply—281 percent—since 2006. (See Figure 6.)

Figure 6: Growth of Compounded Topical Drugs in Part D, 2006–2015



Source: OIG analysis of Medicare Part D data, 2016.

Some areas have unusually high spending for compounded topical drugs

Several areas of the country stand out as having unusually high spending for compounded topical drugs. In the McAllen, Texas area, average Part D spending for compounded topical drugs per beneficiary was 5 times higher than the national average in 2015.¹⁸ McAllen also had 4 times more beneficiaries receiving compounded topical drugs than the national average.

Spending for compounded topical drugs also was high in the areas of Jacksonville, Florida, New York, New York and San Antonio, Texas. In each of the areas, spending for these drugs per beneficiary was more than three times the national average. The number of beneficiaries receiving compounded topical drugs was 2.5 times higher in the Jacksonville and New York areas and 2 times higher in the San Antonio area than the national average.

Further, the New York area accounted for the largest proportion of the overall Part D spending for compounded topical drugs. Eighteen percent of all Part D spending for compounded topical drugs—\$41.5 million—was in New York. Yet, New York had 6 percent of the Nation's Part D beneficiaries.

Recent cases have heightened fraud and abuse concerns regarding compounded drugs

OIG is involved in a growing number of cases related to compounded drugs. These cases include civil and criminal actions taken against pharmacies since July 2015 that represent over \$20 million in expected recoveries. Many of these cases involve pharmacies paying kickbacks for prescriptions or filling prescriptions that should not have been filled. They involve Medicare and other public insurance programs. In one case, a pharmacy agreed to pay more than \$4.7 million to resolve allegations that it paid kickbacks to marketers and filled prescriptions for compounded drugs that were not legitimate.¹⁹

A similar case involved a New Jersey pharmacy. Its owner, who was also the pharmacist, admitted to arranging for a middleman to pay tens of thousands of dollars in cash bribes to physicians for prescriptions for compounded topical drugs. The drugs were then billed to Medicare Part D as well as other public and private insurance programs. He was sentenced to 20 months in prison and ordered to pay more than \$3 million in restitution and tax penalties.²⁰

In another case, a Minnesota physician was indicted for writing prescriptions for compounded topical pain creams as part of a large-scale Medicare and Medicaid fraud scheme. The physician allegedly received kickbacks for writing unwarranted prescriptions and referring virtually every patient prescribed topical pain cream to a single pharmacy. The pharmacist also was charged in the case. He is accused of using inexpensive bulk drug ingredients—which generally are not covered by Medicare Part D—to make these pain creams, but billing Medicare and Medicaid for more expensive ingredients.²¹

In a fourth case, four physicians and two pharmacies agreed to pay approximately \$10 million to resolve a group of related compounded drug cases in Jacksonville, Florida.²² The physicians allegedly had an incentive to write prescriptions that were filled at the pharmacies. These physicians, including a neurologist and a cardiologist, wrote hundreds of prescriptions for pain

and scar creams while receiving hundreds of thousands of dollars. Investigators found that often the patients did not even use the drugs.

CONCLUSION

Spending for Part D drugs continues to rise by more than \$10 billion every year. In 2015, it totaled \$137 billion. The high level of spending for commonly abused opioids and the tremendous growth in spending for compounded drugs are of particular concern.

Part D spending for commonly abused opioids and the rate of utilization among beneficiaries remain high. Nearly 1 in 3 beneficiaries received commonly abused opioids in 2015 and Part D spending for these drugs exceeded \$4 billion. Although the growth rate slowed in 2015, the high level of spending raises concerns about the misuse of these drugs. Opioid use can be appropriate in some cases. However, misuse of opioids not only has serious financial costs but also human costs, including deaths from overdoses. Moreover, these continuing high rates provide further evidence of this crisis facing our Nation.

Although not as high as opioid spending, the spending for compounded drugs is just as striking. The tremendous growth in spending for compounded drugs, particularly topical medications, raises concerns. Part D spending for compounded drugs has grown more than 600 percent since 2006, while spending for compounded topical drugs increased more than 3,400 percent. The extremely high rate of growth raises questions as to whether all of the drugs were medically necessary or even dispensed to the beneficiary. These concerns are buttressed by a growing number of fraud cases. Together, the spending trends and cases involving compounded drugs signal the need for action. The issues are not exclusive to Part D, but as the recent sharp increases attest, this opportunity should be seized so that spending and potential safety issues do not go unchecked in Part D.

Ensuring the appropriate use of opioids and compounded drugs is essential to protecting the safety of Medicare beneficiaries; it is also critical to ensuring the integrity of the Medicare program. OIG is committed to continuing to conduct investigations and reviews to help address the ongoing problems created by opioid abuse and the emerging problems linked to compounded drugs. CMS has taken a number of steps to combat the multi-faceted problems associated with commonly abused opioids. For example, CMS now identifies both high-risk beneficiaries and outlier prescribers and shares that information with Part D plan sponsors.²³ However, it needs to take additional action, including fully implementing OIG's previous recommendations.²⁴ CMS also needs to assess the implications of the compounded drug trends identified in this data brief and take action where needed to protect the integrity of the program.

METHODOLOGY

We based this data brief on an analysis of prescription drug event (PDE) records for Part D drugs from 2006 to 2015. Plan 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. It also indicates if the drug was compounded.²⁵

To obtain descriptive information about the drugs, we matched the PDE records to data from First Databank and Medi-Span. First DataBank contains information about each drug, such as the drug name, strength of the drug, the therapeutic class (e.g., an opioid), and the form (i.e., topical, intravenous, oral, and injections). First DataBank and Medi-Span also indicate whether a drug is a controlled substance and if so, which schedule the drug is on (i.e., Schedule II or III). For this study, the term “prescription” refers to one PDE record.

Trend Analysis

We identified all PDE records for Part D drugs with dates of service from January 1, 2006, to December 31, 2015. For each year, we calculated the number of beneficiaries who received Part D drugs and the Part D spending for each of the following: all drugs, all controlled substances, commonly abused opioids, and compounded drugs. To determine total spending for each of these categories, we summed four fields on the PDE records that represent the total gross drug costs: ingredient cost, dispensing fee, vaccine administration fees, and sales tax.

For commonly abused opioids, we also determined the annual growth in spending. In addition, we calculated the average number of prescriptions for commonly abuse opioids per beneficiary and the proportion of beneficiaries who received these opioids nationally and in each State, using the beneficiary’s ZIP code.

For compounded drugs, we calculated total Part D spending by form (i.e., topical, intravenous, oral, and injections) for each year.²⁶ We also identified the drugs with the highest Part D spending for compounded topical drugs in 2015. Finally, we calculated the total spending for compounded topical drugs and the average Part D spending per beneficiary for compounded topical drugs for each Core Base Statistical Area (CBSA) and for the Nation. We then identified the CBSAs with the highest Part D spending per beneficiary.²⁷

Limitations

We did not independently verify the accuracy of the PDE records or the data from First DataBank or Medi-Span.

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.

ACKNOWLEDGEMENTS

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ENDNOTES

¹ CDC, *Increases in Drug and Opioid Deaths—United States, 2000-2014*, January 1, 2016. Accessed at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm?s_cid=mm6450a3_w on April 27, 2016.

² Maxwell, Ann, Assistant Inspector General for Evaluations and Inspections, Office of Inspector General, U.S. Department of Health and Human Services, *Opioid Use Among Seniors—Issues and Emerging Trends* (Congressional testimony) February 24, 2016. Also see, Cantrell, Gary, Deputy Inspector General for Investigations, Office of Inspector General, U.S. Department of Health and Human Services, *Fraud in Medicare* (Congressional testimony) March 24, 2015.

³ According to the Food and Drug Administration (FDA), compounding is a practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient. See FDA, *Compounding and the FDA: Questions and Answers*. Accessed at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339764.htm> on April 25, 2016.

⁴ Compounded drugs, if made using poor quality practices, can be the wrong potency (i.e., too strong or too weak.) They can also be contaminated or otherwise adulterated. See FDA, *Compounding and the FDA: Questions and Answers*. Accessed at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339764.htm> on April 25, 2016.

⁵ In 2013, Congress passed the Compounding Quality Act, 113 Pub. L. No. 113-54, §§ 101-107. The Act allows entities that compound sterile drugs to register with the FDA as outsourcing facilities. Facilities that register are monitored by FDA. Sterile drugs include drugs that are intended for parenteral administration, an ophthalmic or oral inhalation drug in aqueous format, or a drug that is required to be sterile under Federal or State law. This law does not apply to all compounded drugs. 21 U.S.C. § 353b. Also, see FDA, *FDA Implementation of the Compounding Quality Act*. Accessed at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm375804.htm> on May 13, 2016. For more information on the outbreak, see CDC, *Healthcare-associated Infections (HAIs): Multistate Outbreak of Fungal Meningitis and Other Infections*. October 30, 2015. Accessed at <http://www.cdc.gov/HAI/outbreaks/meningitis.html> on April 27, 2016.

⁶ Christine Mai-Duc, O.C. *Grand Jury Indicts 15 People in Alleged Healthcare Scam*, *Los Angeles Times*, June 24, 2014. Accessed at <http://www.latimes.com/local/orangecounty/la-me-0625-obama-donor-indictment-20140625-story.html> on April 27, 2016.

⁷ This case was related to the TRICARE program, the Department of Defense's military insurance program that provides civilian benefits for military personnel, retirees and their dependents. Federal Bureau of Investigations, Tampa Division, *United States Settles False Claim Act Allegations Against Jacksonville-Based Compounding Pharmacy for More Than \$8 Million*, July 15, 2015. Accessed at <https://www.fbi.gov/tampa/press-releases/2015/united-states-settles-false-claims-act-allegations-against-jacksonville-based-compounding-pharmacy-for-more-than-8-million> on April 27, 2016.

⁸ The Boards of Trustees, Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, *2015 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medicare Insurance Trust Funds*, p. 184. Accessed at <https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/reportstrustfunds/downloads/tr2015.pdf> on April 27, 2016.

⁹ 42 U.S.C. § 1395w-102(e). Also see C.F.R. § 423.120(d). Compounded drugs that contain any ingredients that—as prescribed and dispensed or administered—are covered by Medicare Part B may not be covered under Part D. For other compounded drugs, Part D covers only the ingredients that independently meet the definition of a Part D drug. Bulk powders (i.e., active pharmaceutical ingredients for compounding) do not satisfy the definition of a Part D drug and are not covered by Part D. Medicare Prescription Drug Benefit Manual, Pub. No. 100-18, Chapter 6, section 10.4.

¹⁰ For example, OIG raised concerns that some Part D sponsors did not identify any incidents of potential fraud and abuse in the first 6 months of 2007. See OIG, *Medicare Drug Plan Sponsors' Identification of Potential Fraud and Abuse*, October 2008. Subsequent OIG reviews revealed questionable billing associated with pharmacies,

prescribers, and beneficiaries involving both opioids and other prescription drugs. OIG, *Retail Pharmacies With Questionable Part D Billing*, OEI-02-09-00600, May 2012; OIG, *Prescribers With Questionable Part D Billing*, OEI-02-09-00603, May 2013; and OIG, *Part D Beneficiaries With Questionable Utilization Patterns for HIV Drugs*, OEI-11-00170, August 2014.

¹¹ OIG, *Ensuring the Integrity of Medicare Part D*, OEI-03-15-00180, June 2015.

¹² OIG, *Questionable Billing and Geographic Hotspots Point to Potential Fraud and Abuse in Medicare Part D*, OEI-02-15-00190, June 2015.

¹³ This represents the negotiated price paid to the pharmacy. It is not adjusted for any rebates, coverage gap discounts, or other Direct and Indirect Remuneration paid to the sponsors. Note that these numbers and others presented in the data brief are rounded. Because our calculations are based on unrounded numbers they cannot always be recreated from the numbers presented in the data brief.

¹⁴ Controlled substances are drugs regulated by the Controlled Substances Act, which established five schedules based on the medical use and the potential for abuse. See 21 U.S.C. §§ 801 et seq.

¹⁵ For the purposes of this data brief, we refer to Schedule II and III opioids as “commonly abused opioids.” According to the National Institute on Drug Abuse—part of the National Institutes of Health—prescription opioids are among the most commonly abused drugs. We limited our review to Schedule II and III opioids because they have the highest potential for abuse among legally available drugs, according to the Drug Enforcement Agency (DEA). For more information on commonly abused drugs, see National Institute on Drug Abuse, *Commonly Abused Drug Charts*, February 2016. Accessed at <https://www.drugabuse.gov/drugs-abuse/commonly-abused-drugs-charts> on April 27, 2016.

¹⁶ In 2015, Medicare Part D paid: \$932 million for 1.8 million prescriptions of OxyContin; \$727 million for 29.5 million prescriptions of hydrocodone-acetaminophen; \$515 million for 10.3 million prescriptions for oxycodone-acetaminophen; and \$330 million for 3.1 million prescriptions for fentanyl.

¹⁷ The proportion of beneficiaries receiving commonly abused opioids slightly decreased slightly from 2014 to 2015, going from 31.5 percent to 30.4 percent.

¹⁸ We conducted this analysis based on the Core Based Statistical Area (CBSA) of the beneficiary. A CBSA is a region around an urban center that has at least 10,000 people. U.S. Census Bureau, Metropolitan and Micropolitan Statistical Areas. Accessed at <http://www.census.gov/population/www/metroareas/aboutmetro.html> on April 28, 2016.

¹⁹ Department of Justice (DOJ), U.S. Attorney’s Office Middle District of Florida, *United States Announces New Round of Compound Pharmacy Settlements Expected to Result in More than \$30 Million In Fines And Repayments*, November 25, 2015. Accessed at <https://www.justice.gov/usao-mdfl/pr/united-states-announces-new-round-compound-pharmacy-settlements-expected-result-more-30> on April 28, 2016.

²⁰ DOJ, U.S. States Attorney’s Office District of New Jersey, *Compounding Pharmacist Sentences to 20 Months In Prison For Paying Kickbacks For Referrals*, Health Care Fraud, November 4, 2015. Accessed at <https://www.justice.gov/usao-nj/pr/compounding-pharmacist-sentenced-20-months-prison-paying-kickbacks-referrals-health-care> on April 28, 2016.

²¹ Federal Bureau of Investigations, Minneapolis Division, *Bloomington Pain Management Doctor Indicted for Accepting Kickbacks as Part of Large-Scale Health Care Fraud Scheme*, September 23, 2015. Accessed at <https://www.fbi.gov/minneapolis/press-releases/2015/bloomington-pain-management-doctor-indicted-for-accepting-kickbacks-as-part-of-large-scale-health-care-fraud-scheme> on May 13, 2016.

²² DOJ, U.S. Attorney’s Office Middle District of Florida, *United States Announces Approximately \$10 Million Settlement With Four Physicians and Two Compounding Pharmacies*, February 11, 2016. Accessed at <https://www.justice.gov/usao-mdfl/pr/united-states-announces-approximately-10-million-settlement-four-physicians-and-two> on April 28, 2016.

²³ CMS identifies beneficiaries who are at high-risk for opioid overutilization. On a quarterly basis, CMS provides each plan sponsor with a list of these beneficiaries through its Overutilization Monitoring System. CMS also recently identified outlier prescribers for Schedule II drugs and sent reports to half of these prescribers about their outlier patterns. CMS also shared a list of outlier prescribers with the plan sponsors. For more information, see Sean Cavanaugh, Deputy Administrator and Director Center For Medicare, Centers for Medicare & Medicaid, U.S. Department of Health and Human Services, *Opioid Use Among Seniors—Issues and Emerging Trends* (Congressional Testimony) February 24, 2016. Also see, Shantanu Agrawal, M.D., Deputy Administrator and

Director Center for Program Integrity, Centers for Medicare & Medicaid Services, U.S. Department of Health and Human Services, *The Medicare Part D: Measures Needed to Strengthen Program Integrity* (Congressional Testimony) July 14, 2015.

²⁴ OIG, Compendium of Unimplemented Recommendations, April 2016. Accessed at: <http://oig.hhs.gov/reports-and-publications/compendium/index.asp> on May 3, 2016. Also see, OIG, *Ensuring the Integrity of Medicare Part D*, OEI-03-15-00180, June 2015.

²⁵ Compounded drugs often contain multiple drug ingredients. The PDE record lists the National Drug Code (NDC) for only the most expensive drug ingredient covered by Part D included in each compounded drug.

²⁶ To determine the form of the compounded drug, we matched the NDC listed on the PDE record to First Databank.

²⁷ We focused this analysis on CBSAs with at least 2,000 beneficiaries receiving a compounded topical drug.