



U.S. Department of Health and Human Services
Office of Inspector General

Questionable Billing for Compounded Topical Drugs in Medicare Part D

OEI-02-16-00440

August 2018

oig.hhs.gov

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Questionable Billing for Compounded Topical Drugs in Medicare Part D

What OIG Found

Medicare Part D spending for compounded topical drugs was 24 times higher in 2016 than it was in 2010. Compounded drugs are customized medications that may be necessary for patients whose medical needs cannot be met by commercially available drugs. Medicare Part D sponsors cover these drugs under certain circumstances. However, this explosive growth raises fraud, waste, and abuse concerns about whether compounded topical drugs are being billed appropriately.

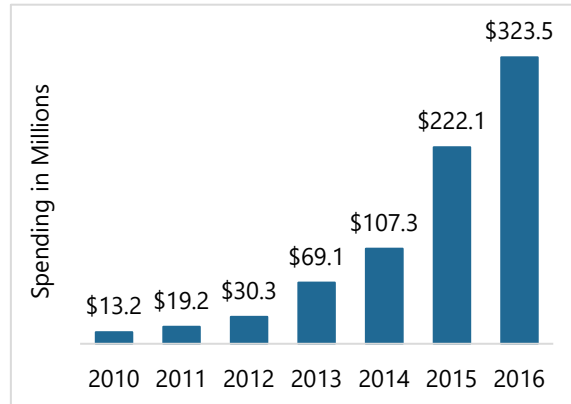
About 550 pharmacies had questionable Part D billing for compounded topical drugs in 2016. These pharmacies warrant further scrutiny. They each billed extremely high amounts for at least one of five measures that OIG has developed as indicators of possible fraud, waste, or abuse. For example, many of these pharmacies billed for compounded topical drugs for a high proportion of their beneficiaries. More than one-quarter of these pharmacies were located in four metropolitan areas.

In addition, 124 prescribers raise particular concern. Each of these prescribers ordered large amounts of compounded topical drugs dispensed by these pharmacies with questionable billing.

What OIG Recommends

We recommend that the Centers for Medicare & Medicaid Services (CMS) clarify Part D policies for coverage of compounded topical drugs and use of utilization management tools. Specifically, CMS should clarify that sponsors—the private companies that provide the Part D benefit—have the option to cover compounded topical drugs through an exceptions process. CMS should also clarify that sponsors may apply utilization management tools to compounded topical drugs, even if individual ingredients would not be subject to utilization management tools when dispensed individually. CMS should also conduct additional analysis on compounded topical drugs and conduct training for Part D sponsors on fraud schemes and safety concerns. Lastly, CMS should follow up on the pharmacies and prescribers identified in this report. CMS concurred with all four of our recommendations.

Part D spending for compounded topical drugs grew exponentially from 2010 to 2016.



Source: OIG analysis of Part D data, 2017.

Why OIG Did This Review

A dramatic increase in Medicare Part D spending for compounded topical drugs, the emergence of fraud cases, and safety concerns led the OIG to conduct this review.

In 2016, OIG called attention to significant growth in spending for compounded drugs (e.g., customized medications). Specifically, OIG found that Part D spending for compounded drugs grew by 625 percent from 2006 to 2015 and spending for topical compounded drugs—such as creams, gels, and ointments to, for example, relieve pain—grew at an even faster pace.

At the same time, OIG has been involved in an increasing number of fraud cases related to compounded drugs—including topical drugs—in Medicare and other health insurance programs.

There are also safety and effectiveness concerns related to compounded drugs, which are not FDA-approved. The quality standards for compounded drugs are generally lower than for FDA-approved drugs, leading to increased risks such as production of products with the wrong potency.

How OIG Did This Review

We analyzed Prescription Drug Event (PDE) records for compounded topical drugs from 2010 to 2016. With input from OIG investigators and CMS, we developed five measures to identify pharmacies with questionable billing for these drugs. We also identified prescribers associated with these pharmacies who warrant further scrutiny.

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BACKGROUND

Objectives

1. To describe Medicare Part D spending for compounded topical drugs.
2. To identify pharmacies with questionable billing for these drugs.
3. To identify prescribers associated with these pharmacies who raise particular concern.

The Office of Inspector General (OIG) recently called attention to the dramatic growth in Medicare Part D spending for compounded drugs, particularly compounded topical drugs. Compounded drugs are customized medications that may be necessary for patients whose medical needs cannot be met by commercially available drugs. From 2006 to 2015, spending for these drugs increased 625 percent and spending for compounded topical drugs—such as creams, gels, and ointments—grew at an even faster pace. Medicare Part D sponsors cover these drugs under certain circumstances. However, this explosive growth raises fraud, waste, and abuse concerns about whether compounded topical drugs are being billed appropriately.¹

OIG has been involved in an increasing number of investigations related to compounded drugs—including compounded topical drugs—in Medicare and other health insurance programs. In some cases, pharmacies pay kickbacks to physicians. In others, pharmacies bill Part D for more expensive compounded drugs than were actually dispensed. In one example, a pharmacy owner, who was also the pharmacist, admitted to bribing physicians for prescriptions for compounded topical drugs.² He was sentenced to 20 months in prison and ordered to pay more than \$3 million in restitution and tax penalties. In another case, a pharmacy compounded drugs with inexpensive bulk powders, which are not covered under

¹ OIG, *High Part D Spending on Opioids and Substantial Growth in Compounded Drugs Raise Concerns*, OEI-02-16-00290, June 2016.

² Department of Justice (DOJ), U.S. States Attorney's Office, District of New Jersey. November 4, 2015. *Compounding Pharmacist Sentenced to 20 Months In Prison For Paying Kickbacks For Referrals, Health Care Fraud* [Press release]. Accessed at <https://www.justice.gov/usao-nj/pr/compounding-pharmacist-sentenced-20-months-prison-paying-kickbacks-referrals-health-care>.

Medicare.³ The pharmacy submitted falsified records claiming that the drugs were made from expensive tablets and capsules. The owner was sentenced to 6 months of house arrest and agreed to pay a fine of \$2.5 million for submitting falsified documents.

According to the U.S. Food and Drug Administration (FDA), there are also safety and effectiveness concerns related to compounded drugs.⁴ Compounded drugs are not FDA-approved, meaning FDA has not evaluated them for safety, effectiveness, or quality before they are provided to patients. FDA does not oversee the day-to-day operations of most compounding pharmacies or ensure compliance with FDA's current good manufacturing practice requirements. In addition, quality standards for compounded drugs are generally lower than for FDA-approved drugs; therefore, compounded drugs can pose increased safety risks, such as being the wrong potency (i.e., too strong or too weak), being contaminated, or being ineffective. In addition to the New England Compounding Center case that led to a meningitis outbreak, there have been other examples of safety risks related to compounded drugs.⁵

- In unrelated cases, two women died after applying compounded topical anesthetics to their legs to lessen the pain of laser hair removal.⁶
- An individual who received compounded topical creams, sold as a part of a prescription drug fraud scheme, died from toxicity related to the ingredients in the creams.⁷

FDA also raised concern that prescribers and patients may not be aware of the potential risks—including the potential lack of effectiveness—associated with certain compounded topical drugs.⁸

³ DOJ, U.S. Attorney's Office, Northern District of Alabama. March 23, 2017. *NW Alabama Pharmacies Owner Sentenced to Six Month's [sic] Home Confinement for Obstructing Medicare Audit; Ordered to Pay \$2.5 million Fine* [Press release]. Accessed at <https://www.justice.gov/usao-ndal/pr/nw-alabama-pharmacies-owner-sentenced-six-month-s-home-confinement-obstructing-medicare>.

⁴ See FDA, *Compounding and the FDA: Questions and Answers*. Accessed at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339764.htm> on September 13, 2017.

⁵ See DOJ, *New England Compounding Center Pharmacist Sentenced for Role in Nationwide Fungal Meningitis Outbreak*, January 31, 2018. Accessed at <https://www.fda.gov/ICECI/CriminalInvestigations/ucm594800.htm> on March 13, 2018.

⁶ FDA, *Public Health Advisory: Life-Threatening Side Effects with the Use of Skin Products Containing Numbing Ingredients for Cosmetic Procedures*, February 6, 2007.

⁷ DOJ, *Leader of \$17 Million Health Insurance Fraud Scheme Ordered to Prison*, July 17, 2017.

⁸ FDA, *Statement from FDA Commissioner Scott Gottlieb, M.D., on agency's continued efforts relating to compounded drugs for patients who cannot use an FDA-approved drug* [Press Release]. Accessed at <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm612193.htm> on July 31, 2018.

These safety issues, combined with the increases in spending for compounded topical drugs and the emergence of new fraud cases, highlight the need to further examine Part D billing for these drugs. This study builds on previous OIG work. It describes Part D billing for compounded topical drugs and identifies pharmacies with questionable billing and associated prescribers who warrant further scrutiny.

This study focuses on pharmacies that compound drugs but are not registered with FDA as outsourcing facilities. Drugs compounded by pharmacies that register as outsourcing facilities are subject to different requirements and are not the focus of this report.⁹

Compounded Drugs

Licensed pharmacists or licensed physicians create compounded drugs by combining, mixing, or altering drug ingredients. Compounded drugs may be necessary for certain patients when commercially available drugs cannot meet that patient's clinical needs. For example, a patient who is allergic to an inactive ingredient, such as a dye, in a commercially available drug may require a special formulation to eliminate that ingredient.

Unlike the drugs made by conventional manufacturers that require FDA approval, compounded drugs are not evaluated by FDA for safety, effectiveness, or quality before they are marketed. Most compounded drugs are exempt from the new-drug approval process, current good manufacturing practice, and other FDA requirements. To be exempt, drugs must generally be compounded by a licensed pharmacist or licensed physician, for an identified individual patient, and based on the receipt of a valid prescription.¹⁰ Compounded drugs that are essentially copies of commercially available drug products and compounded regularly or in inordinate amounts are not exempt.¹¹

Medicare Part D Coverage of Compounded Drugs

Part D is an optional prescription drug benefit for Medicare beneficiaries. Private companies, known as Part D sponsors, contract with the Centers for Medicare & Medicaid Services (CMS) to provide this benefit to beneficiaries

⁹ 21 U.S.C. § 353b.

¹⁰ 21 U.S.C. § 353a(a). Under certain circumstances, drugs may be compounded in limited quantities prior to the pharmacy receiving a valid prescription for an individual patient. Also see FDA, *Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act*. Accessed at <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM469119.pdf> on February 27, 2018.

¹¹ 21 U.S.C. § 353a(b)(1)(D). Also see FDA, *Compounded Drug Products that Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act*. Accessed at <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM510154.pdf> on January 30, 2018.

who choose to enroll. Sponsors also contract with pharmacies to dispense prescription drugs to the beneficiaries enrolled in their plans. These pharmacies can be independently owned or part of a chain.

To be covered under Medicare Part D, prescription drugs must meet certain requirements. For example, a drug must be FDA-approved and used for medically accepted indications.¹² Compounded drugs are not FDA-approved and, therefore, do not meet the definition of a “Part D covered drug.” However, CMS permits sponsors to cover a compounded drug if the compounded drug:

- contains at least one active ingredient that meets the definition of a Part D drug—meaning that it would be covered by Part D if it were dispensed separately; and
- does not contain any ingredients that would be covered under Medicare Part B.¹³

If a compounded drug meets these criteria, then the sponsor must determine whether it will treat the drug as “on-formulary” (i.e., on its list of covered drugs) or “non-formulary.” If the sponsor opts to treat a compounded drug as “on-formulary,” the sponsor may use utilization management tools, such as prior authorization. If the sponsor opts to treat a compounded drug as “non-formulary,” the beneficiary may go through an exceptions process to request coverage. The sponsor can choose to treat the compounded drug as “non-formulary” even if the individual ingredients of the compounded drug are on the sponsor’s formulary.

In addition, the sponsor must follow certain guidelines for determining the amount it will pay for a compounded drug. Specifically, CMS requires that the sponsor pay for all ingredients that independently meet the definition of a Part D drug.¹⁴ Bulk powders—active pharmaceutical ingredients for compounding—do not meet this definition and are not covered by

¹² 42 U.S.C. § 1395w-102(e).

¹³ CMS, *Medicare Prescription Drug Benefit Manual*, Chapter 6, Section 10.4. Accessed at <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf> on September 13, 2017. Also see 42 C.F.R. § 423.120(d). For more information about compounded drugs covered under Part B, see OIG, *Compounded Drugs Under Medicare Part B: Payment and Oversight*, OEI-03-13-00270, April 2014.

¹⁴ 42 CFR § 423.120(d).

Part D.¹⁵ Sponsors receive a list of all the ingredients in each compounded drug from the pharmacy.¹⁶

Detecting and Deterring Part D Fraud, Waste, and Abuse

CMS relies on Part D sponsors to be the first line of defense against fraud, waste, and abuse. Each sponsor is required to implement a comprehensive compliance plan to identify and prevent Part D fraud, waste, and abuse.¹⁷ As a part of these compliance plans, CMS expects sponsors to monitor pharmacies.¹⁸ CMS also encourages sponsors to use data analysis to identify billing patterns that pose the greatest risk to the program.

In addition, CMS contracts with a private company to serve as the National Benefit Integrity (NBI) Medicare Drug Integrity Contractor (MEDIC) to detect and prevent fraud, waste, and abuse in Part D. The MEDIC's responsibilities include identifying and investigating potential fraud and abuse and referring cases to law enforcement, as appropriate.

Concerns about Topical Compounded Drugs in Other Programs

The growth of spending for compounded drugs, including topicals, has also raised concerns in other Federal programs. TRICARE, the Department of Defense's military insurance program, has had rapid increases in spending for compounded drugs.¹⁹ In response, TRICARE implemented new controls on payments for compounded drugs that reduced its costs.

In addition, a U.S. Postal Service Office of Inspector General report found dramatic increases in workers' compensation costs for compounded drugs, the most common of which were topical drugs.²⁰ The report called for the implementation of controls to reduce these costs.

Related Work

This report is part of OIG's body of work on compounded drugs. In a separate report, OIG plans to determine the extent to which hospitals obtain

¹⁵ CMS, *Medicare Prescription Drug Benefit Manual*, Chapter 6, Section 10.4. Accessed at <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf> on September 13, 2017.

¹⁶ 76 Fed. Reg. 21521 (Apr. 15, 2011). Accessed at <https://www.gpo.gov/fdsys/pkg/FR-2011-04-15/pdf/2011-8274.pdf> on May 17, 2018.

¹⁷ 42 C.F.R. § 423.504(b)(4)(vi).

¹⁸ CMS, *Prescription Drug Benefit Manual*, Chapter 9, §§ 40 and 50.6.9, January 2013. Accessed at <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Chapter9.pdf> on September 13, 2017.

¹⁹ U.S. Department of Defense Office of Inspector General, *Controls Over Compound Drugs at the Defense Health Agency Reduced Costs Substantially, but Improvements are Needed*, DODIG-2016-105, July 2016.

²⁰ U.S. Postal Service Office of Inspector General, *Workers' Compensation Compound Drug Costs*, HR-MA-16-003, March 2016.

compounded sterile preparations from compounders, including outsourcing facilities that have registered with the FDA.²¹

Methodology

Scope

This report focuses specifically on compounded topical drugs because of the extreme increases in spending for these drugs that we identified in our prior work. The analysis in this report on questionable billing does not include entities that registered with the FDA as outsourcing facilities because they are subject to different requirements.²²

Analysis

We based this study on an analysis of CMS's Prescription Drug Event (PDE) records. Part D sponsors submit a PDE record to CMS each time a drug is dispensed to a beneficiary enrolled in one of their plans.

We first analyzed all PDE records with dates of service from January 1, 2010, to December 31, 2016. We matched the National Drug Code (NDC) on the PDE records to First DataBank to identify topical compounded drugs and other compounded drugs. We then calculated the total spending for compounded topical drugs, for other types of compounded drugs, and for all Part D drugs for 2010 to 2016.

Next, with input from OIG investigators and CMS, we developed five measures to identify pharmacies with questionable billing for compounded topical drugs in 2016. These measures are based on current fraud schemes involving compounded topical drugs that have been uncovered by OIG investigators. Examples of these schemes include pharmacies that pay kickbacks to physicians for prescribing unnecessary compounded topical drugs to patients and referring these patients to the pharmacies. Other schemes involve pharmacies billing for more expensive ingredients than are actually dispensed or pharmacies billing for the same compounded drug for multiple beneficiaries, even though compounded drugs are intended to be customized medications to meet individual patient needs.

In total, we analyzed the billing of 2,388 pharmacies.²³ Together, these pharmacies billed for 93 percent of all compounded topical drugs in 2016. We analyzed these data to identify pharmacies that have questionable

²¹ OIG, *Hospitals' Reliance on Drug Compounding Facilities*, OEI-01-17-00090.

²² As of June 2017, 71 entities nationwide had registered as outsourcing facilities. For more information, see FDA, Registered Outsourcing Facilities. Accessed at <https://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/pharmacycompounding/ucm378645.htm> on September 13, 2017.

²³ We focused our analysis on 2,388 pharmacies that billed for more than 10 compounded topical drugs and \$1,000 for these drugs in 2016. As mentioned earlier, this analysis does not include pharmacies that registered with the FDA as outsourcing facilities because they are subject to different requirements.

Measures Indicating Possible Fraud or Abuse Related to Compounded Topical Drugs

1. Percent of beneficiaries for whom the pharmacy billed at least one compounded topical drug.
2. Number of beneficiaries for whom the pharmacy billed for identical compounded topical drugs.
3. Average dollar amount billed per compounded topical drug.
4. Number of compounded topical drugs ordered by a single prescriber.
5. Percent increase in total amount billed for compounded topical drugs from 2015 to 2016.

billing. We determined that a pharmacy had questionable billing if it was an extreme outlier on one or more of the five measures.

Lastly, we identified prescribers who were associated with these pharmacies and prescribed high amounts of compounded topical drugs. These prescribers each ordered more than \$250,000 of compounded topical drugs dispensed at these pharmacies in 2016.

See Appendix A for a detailed description of the methodology.

Limitations

We did not independently verify the data for this study, including the PDE records and other data from CMS. Also, the PDE record contains the NDC of the most expensive ingredient in each compound; it does not contain a list of all ingredients used in each compounded drug. As a result, we were unable to determine how the amounts billed to Part D were related to the individual ingredients in each compounded drug. In addition, we designed this study to identify pharmacies and associated prescribers who warrant further scrutiny. None of the measures we analyzed confirms that a particular pharmacy or prescriber is engaging in fraudulent or abusive practices.

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.

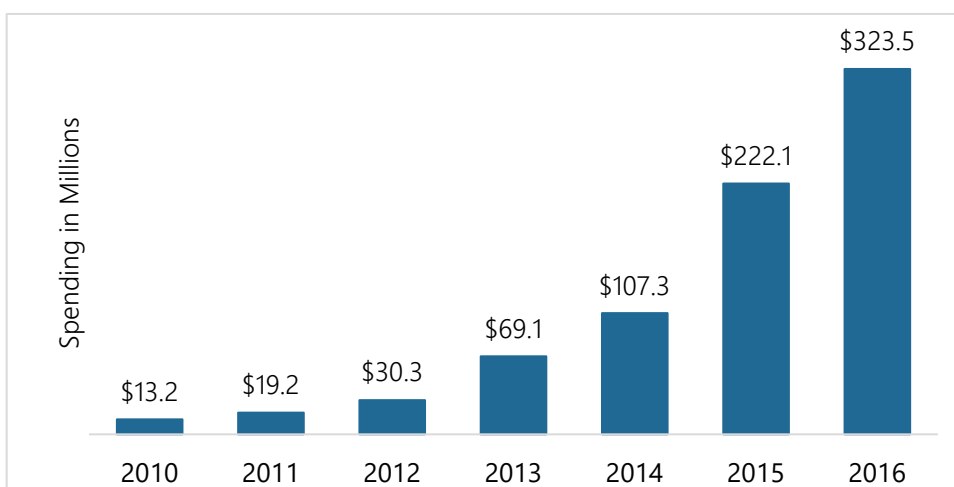
FINDINGS

Part D spending for compounded topical drugs was 24 times higher in 2016 than it was in 2010

Part D spending for compounded topical drugs increased 2,353 percent from 2010 to 2016, rising from \$13.2 million to \$323.5 million. Much of this growth occurred from 2014 to 2016, when spending increased by more than \$200 million. See Exhibit 1.

Compounded topical drugs include creams, gels, and ointments that are customized to meet specific needs of individual patients. They are intended for use by patients when commercially available drugs do not meet their clinical needs. For example, a patient who is allergic to an inactive ingredient, such as a dye, in a drug may require a special formulation to eliminate that ingredient. However, the explosive growth of compounded topical drugs raises concerns that the drugs that were billed to Part D were not always dispensed or medically necessary. This is of particular concern, as FDA does not approve compounded drugs or verify their safety or effectiveness.

Exhibit 1: Part D spending for compounded topical drugs grew exponentially from 2010 to 2016.



Source: OIG analysis of Part D data, 2017.

Part D spending for compounded topical drugs grew at a much faster rate than spending for all Part D drugs and for other types of compounded drugs. From 2010 to 2016, spending for compounded topicals increased 2,353 percent while spending for all Part D drugs increased 89 percent and spending for other types of compounded drugs, such as intravenous, injectable, and oral drugs, grew 225 percent.²⁴

²⁴ Note that these numbers and others presented in this report are rounded. Because our calculations are based on unrounded numbers, they cannot always be recreated from the numbers presented in the report.

A main driver of the spending increase for compounded topicals appears to be the substantial increase in the average cost per drug. In 2010, the average Part D cost per compounded topical was \$54, but by 2016 it was \$422. This increase of 676 percent significantly outpaced the cost increases for all drugs (41 percent) and for other types of compounded drugs (79 percent).

Other drivers of the spending increase appear to be growth in the number of beneficiaries receiving compounded topicals and growth in the number of compounded drugs billed to Part D. The number of beneficiaries increased 167 percent from 2010 to 2016, while the number of prescriptions for compounded topical drugs increased 216 percent. The growth for both outpaced the growth in the number of beneficiaries and prescriptions for all drugs and for other compounded drugs.

About 550 pharmacies had questionable billing for compounded topical drugs

A total of 547 pharmacies had questionable billing for compounded topical drugs in 2016. These pharmacies each billed extremely high amounts for at least one measure indicating possible fraud or abuse. See Exhibit 2 for these measures. These pharmacies billed Part D a total of \$300.3 million for compounded topicals in 2016—more than 90 percent of all Part D billing for these drugs nationwide. Although some of this billing may be legitimate, all of these pharmacies warrant further scrutiny.

Exhibit 2: 547 pharmacies had questionable billing on at least 1 measure, indicating possible fraud or abuse related to compounded topical drugs in 2016.*

Measure	Median	Threshold for Questionable Billing	Number of Pharmacies With Questionable Billing
Percent of beneficiaries for whom the pharmacy billed at least one compounded topical drug	2%	38%	246
Number of beneficiaries for whom the pharmacy billed for identical compounded topical drugs	2	21	246
Average dollar amount billed per compounded topical drug	\$124	\$934	222
Number of compounded topical drugs ordered by a single prescriber	14	131	204
Percent increase in total amount billed for compounded topical drugs from 2015 to 2016	6%	483%	110
Total Number of Pharmacies with Questionable Billing			547**

* This analysis includes pharmacies that billed for more than 10 compounded topical drugs and \$1,000 for these drugs in 2016. For more information, see Appendix A.

** A number of pharmacies exceeded thresholds for multiple measures. As a result, the sum does not equal 547 pharmacies.

Source: OIG analysis of Part D data, 2017.

Exhibit 3: Many of the 547 pharmacies had questionable billing for multiple measures.

Number of Measures	Number of Pharmacies with Questionable Billing
1	270
2	123
3	114
4	30
5	10
Total	547

Source: OIG analysis of Part D data, 2017.

More than half these pharmacies—277—billed extremely high amounts for 2 or more measures. Ten pharmacies billed for extremely high amounts for all five measures.²⁵ See Exhibit 3.

Pharmacies with questionable billing primarily billed for compounded topical drugs containing ingredients common in pain creams. Eight out of every ten compounded topical drugs these pharmacies billed for contained lidocaine-prilocaine, lidocaine, or diclofenac sodium. Lidocaine and lidocaine-prilocaine are both anesthetics. Diclofenac sodium is a nonsteroidal anti-inflammatory drug. OIG has previously raised concern about potential fraud and abuse related to both diclofenac and lidocaine.²⁶

Compounded topical drugs containing these three ingredients were, on average, more expensive than non-compounded topical drugs with these same ingredients. The difference is most striking with drugs containing diclofenac sodium. On average, Medicare Part D paid \$751 per compounded topical containing lidocaine, \$276 per compounded topical containing lidocaine-prilocaine, and \$1,506 per compounded topical containing diclofenac sodium. For non-compounded topical drugs, Part D paid an average of \$445 for lidocaine, \$59 for lidocaine/prilocaine, and \$128 for diclofenac sodium.

Independent pharmacies were about seven times more likely than chain pharmacies to have questionable billing for compounded topical drugs. Specifically, 30 percent of independent pharmacies that billed for compounded topicals had questionable billing for these drugs, compared to only 4 percent of chain pharmacies that billed for compounded topicals. OIG has previously raised concerns that independent pharmacies are more likely than chain pharmacies to have questionable billing for Part D drugs.²⁷

Nearly 250 pharmacies billed for compounded topical drugs for an extremely high percentage of beneficiaries

A total of 246 pharmacies billed for compounded topical drugs for an extremely high percentage of their Part D beneficiaries. Each of these pharmacies billed for compounded topicals for more than 38 percent of the beneficiaries they served, far higher than the median of 2 percent for

²⁵ We considered pharmacies that were above the 75th percentile plus three times the interquartile range on one or more measures to have questionable billing. This means that these pharmacies were extreme outliers on one or more measures.

²⁶ In 2014, OIG raised concerns about diclofenac potassium, Solaraze (a brand-name version of diclofenac sodium gel), and Lidoderm (a lidocaine patch). These three drugs had significantly higher Medicare payments in certain geographic areas compared to the Nation, pointing to potential fraud and abuse. OIG, *Questionable Billing and Geographic Hotspots Point to Potential Fraud and Abuse in Medicare Part D*, OEI-02-15-00190, June 2015.

²⁷ OIG, *Retail Pharmacies with Questionable Part D Billing*, OEI-02-09-00600, May 2012.

pharmacies nationwide. Further, 79 percent of these pharmacies—194 of 246—billed for extremely high amounts on at least one other measure.

When a pharmacy bills for compounded topical drugs for a high percentage of their beneficiaries it may mean that the pharmacy is billing for unnecessary compounded topical drugs or that it is billing for drugs that were not dispensed. It may also mean that the beneficiary identification numbers used to bill for the drugs had been stolen or sold.

Among these pharmacies, 29 stand out. Each billed for compounded topicals for more than 90 percent of the beneficiaries they served. For these 29 pharmacies' billing to be appropriate, almost every one of the Part D beneficiaries they served would have had to have had specific needs that required customized topical medications.

Example of a pharmacy that billed for compounded topicals for a high percentage of its beneficiaries

One Oregon pharmacy billed for compounded topicals for 91 percent of its beneficiaries. This pharmacy billed a total of \$2.9 million for compounded topicals for 3,289 beneficiaries, averaging \$891 per beneficiary. Almost all of these compounded topicals contained lidocaine-prilocaine cream. This pharmacy also billed identical compounded topicals for an extremely high number of beneficiaries and billed for an extremely high number of compounded topical drugs ordered by a single prescriber.

Close to 250 pharmacies billed for identical compounded topical drugs for an extremely high number of their beneficiaries

A total of 246 pharmacies billed for identical compounded topicals for an extremely high number of beneficiaries. These pharmacies each billed identical drugs for more than 21 different beneficiaries, far more than the median of just 2 beneficiaries per pharmacy nationwide. Sixteen of the pharmacies are particularly noteworthy; each billed identical drugs for 200 or more beneficiaries.

Compounded drugs are meant to be customized to meet an individual patient's needs. When a pharmacy bills for an identical drug for many different beneficiaries, it raises questions as to whether the beneficiaries needed, or even received, the drug. It also raises questions as to whether the pharmacy was mass-producing these drugs and potentially marketing unapproved drugs in violation of the Federal Food, Drug, and Cosmetic Act. Federal law generally requires that pharmacies compound drugs only for identified individual patients and based on the receipt of a valid

prescription.²⁸ This requirement helps ensure that pharmacies, which are not held to the same requirements as conventional manufacturers, compound drugs only for patients who have a medical need. If a pharmacy provides the identical, mass-produced compounded topical drug to scores of beneficiaries, it would have far reaching consequences if the drug was unsafe or ineffective. As previously mentioned, FDA does not review the safety, effectiveness or quality of compounded drugs, which makes them higher-risk than FDA-approved drugs.

Examples of pharmacies that billed for identical compounded topicals for a high number of beneficiaries

A Tennessee pharmacy billed for identical compounded topicals for 588 different Part D beneficiaries. For each of these beneficiaries, the pharmacy billed for a 40-day supply of a compounded topical containing lidocaine-prilocaine cream. Each prescription—1,082 in all—cost exactly \$383.26. These drugs were ordered by 564 different prescribers for beneficiaries living in 22 different States.

In a similar example, a New York pharmacy billed for identical compounded topicals for 535 different beneficiaries. For each of these beneficiaries, the pharmacy billed for a 30-day supply of a compound containing lidocaine 5% ointment, costing exactly \$643.96. Raising additional concern, this pharmacy billed Part D \$8.8 million for compounded topicals in 2016, the second highest amount in the Nation.

Over 200 pharmacies billed extremely high dollar amounts per compounded topical drug

A total of 222 pharmacies each billed a high average dollar amount for compounded topical drugs. They each billed more than \$934 per drug, on average, far more than the median of \$124 per drug for pharmacies nationwide. Of note, 23 of the pharmacies billed more than \$2,000 for each drug, on average.

Billing unusually high amounts for compounded topicals is another sign of possible fraud or abuse. It may indicate that pharmacies are adding medically unnecessary ingredients or using more expensive ingredients than necessary to increase reimbursement. It may also indicate that pharmacies are billing for different ingredients than those used in the compound. For instance, pharmacies may be using low-cost bulk powders to make

²⁸ Under certain circumstances, drugs may be compounded in limited quantities prior to the pharmacy receiving a valid prescription for an individual patient. 21 U.S.C. § 353a(a). Only entities registered as outsourcing facilities, which are not included in this analysis, may under certain circumstances, distribute compounded drugs without obtaining prescriptions for identified individual patients. 21 U.S.C. § 353b.

compounds, but billing as if they used more expensive FDA-approved creams. As noted earlier, Part D does not pay for bulk powders.

Examples of pharmacies that billed high dollar amounts per compounded topical drug

A pharmacy in Florida billed \$1,752 per compounded topical drug, on average. In total, it billed Part D \$1.1 million for compounded topicals. This pharmacy's top prescriber was a family medicine physician located over 180 miles away from the pharmacy. Raising additional concern, the pharmacy billed Part D for compounded topical drugs for beneficiaries in 25 different States.

A Texas pharmacy billed \$2,447 per compounded topical drug, on average. In total, this pharmacy billed Part D \$1.1 million for compounded topicals. Three-quarters of this pharmacy's compounded topical drugs were prescribed by the same neurologist, and the majority contained diclofenac sodium 3% gel.

About 200 pharmacies billed for an extremely high number of compounded topicals from a single prescriber

In total, 204 pharmacies billed for an extremely high number of compounded topicals ordered by a single prescriber. Each pharmacy billed Part D for more than 131 compounded topicals from a single prescriber. In contrast, the median for pharmacies was 14 compounded topicals from a single prescriber. Eighteen of the pharmacies with questionable billing raise particular concern because each billed Part D for over 1,000 prescriptions from a single prescriber.

Billing for a high number of drugs that are ordered by a single prescriber may indicate that the pharmacy and prescriber are working together to bill for drugs that are medically unnecessary or never provided to the beneficiary. These schemes could involve kickbacks to the prescriber to induce him or her to write prescriptions for compounded topicals and to direct patients to fill them at a particular pharmacy. Alternatively, this billing pattern could indicate that the pharmacy is using a prescriber identification number without the prescriber's knowledge.

Examples of pharmacies that billed a high number of compounded topical drugs from a single prescriber

A pharmacy in New York billed Part D for 5,342 compounded topicals—totaling \$1.6 million—ordered by a single podiatrist in 2016. This pharmacy also billed for over 1,000 compounded topicals each from five other podiatrists. In total, the pharmacy billed Part D \$6.4 million for compounded topicals in 2016.

A different New York pharmacy billed Part D for 2,775 compounded topicals—totaling \$1.3 million—ordered by a single podiatrist. This pharmacy also billed for over 1,400 compounded topicals each from two other podiatrists. Of particular concern, one of these podiatrists was also a top prescriber in the example above. In total, this pharmacy billed Part D \$7.3 million for compounded topicals in 2016.

More than 100 pharmacies greatly increased the total amount they billed for compounded topical drugs from 2015 to 2016

There were 110 pharmacies that greatly increased their billing for compounded topicals over the course of just 1 year. Each of these pharmacies increased their billing for these drugs by more than 483 percent from 2015 to 2016. Of note, 20 of these pharmacies increased their billing by more than 10,000 percent.

An extreme increase in a pharmacy's billing may indicate fraud and abuse, especially when the spike is related to a particular type of drug. This may indicate that the pharmacy is billing for drugs that are not medically necessary or never dispensed.

Examples of pharmacies with extreme increases in billing

A California pharmacy billed Part D \$7.2 million for compounded topicals in 2016 after billing just \$61,199 for these drugs in 2015. This was an increase of over 11,600 percent in only 1 year. Of great concern, this pharmacy was questionable on every measure in our analysis.

A pharmacy in Florida billed Part D \$1.8 million for compounded topical drugs in 2016 after billing just \$7,468 for them in 2015, an increase of 24,000 percent. Almost every compounded topical billed to Part D by this pharmacy—1,002 of 1,085—was ordered by a nurse practitioner who practiced 50 miles away.

More than one quarter of the pharmacies with questionable billing were in the New York, Houston, Detroit, and Los Angeles areas

Of the 547 pharmacies with questionable billing for compounded topical drugs, 154 were located in the New York, Houston, Detroit, and Los Angeles metropolitan areas. These four metropolitan areas had the highest numbers of pharmacies with questionable billing of any metropolitan areas in the Nation.

The New York area had 81 pharmacies with questionable billing. Together, these pharmacies billed \$67.6 million for compounded topical drugs, which is 21 percent of the total amount billed in the Nation. The majority of the pharmacies (51 of 81) each billed for an extremely high number of compounded topicals from a single prescriber.

The Houston area had 32 pharmacies with questionable billing. These pharmacies accounted for two-thirds of the pharmacies in the area (32 of 48) that billed for compounded topicals. Many of the pharmacies with questionable billing (23 of 32) billed for extremely high dollar amounts per compounded topical drug.

The Detroit area had 22 pharmacies with questionable billing. This represented almost half of the pharmacies (22 of 47) in the area that billed for compounded topicals. Like Houston, many of the pharmacies billed for extremely high prices. In fact, 18 Detroit-area pharmacies each billed more than \$934 per compounded topical, on average.

The Los Angeles area had 19 pharmacies with questionable billing. This represented almost half of the pharmacies in the area that billed for compounded topicals (19 of 45). Many of these pharmacies (17 of 19) billed for a high number of beneficiaries who received identical compounded topical drugs.

124 prescribers associated with these pharmacies raise particular concern

A total of 124 prescribers raise concern. Each of these prescribers ordered more than \$250,000 of compounded topicals dispensed by the pharmacies identified in this report as having questionable billing, for a total of \$73.1 million.²⁹ This amount accounted for almost a quarter—23 percent—of all Part D spending for compounded topical drugs in 2016.

Although there are legitimate reasons for prescribing compounded topicals, the large amounts ordered by these prescribers at pharmacies with questionable billing raise particular concern. When a prescriber is associated with pharmacies with questionable billing, it may indicate that a fraud scheme is occurring. All these prescribers warrant further scrutiny.

Some of these 124 prescribers also raise concerns about fraud and abuse for additional reasons. Notably, one-fifth of these prescribers—27 of the 124—

²⁹ These 124 prescribers represent 0.31 percent of all 39,666 prescribers who ordered at least one compounded topical drug that was dispensed by a pharmacy with questionable billing. The majority of the 39,666 prescribers ordered less than \$2,000 worth of compounded topicals dispensed by pharmacies with questionable billing.

each ordered compounded topicals for beneficiaries in four or more States. This raises concerns that the prescribers may not have had legitimate doctor-patient relationships with the beneficiaries. In addition, more than one-third of these prescribers—43 of 124—were podiatrists. It is worth noting that podiatrists account for 35 percent of prescribers of particular concern, yet make up just 10 percent of all prescribers who ordered compounded topicals dispensed by pharmacies with questionable billing.³⁰

Examples of prescribers who raise concerns

A California podiatrist ordered 2,646 compounded topicals dispensed at four pharmacies with questionable billing. These drugs averaged \$857 each. In total, Part D paid nearly \$2.3 million for them.

A California family medicine physician ordered \$2.1 million worth of compounded topicals dispensed at three pharmacies with questionable billing. The drugs—1,193 in all—were ordered for 113 Part D beneficiaries. On average, Part D paid nearly \$18,500 per beneficiary for these drugs.

A Texas podiatrist ordered compounded topicals for 319 Part D beneficiaries dispensed at two pharmacies with questionable billing. Every one of the 1,319 drugs that this podiatrist ordered contained lidocaine 5% ointment. These drugs averaged \$1,061 each. In total, Part D paid \$1.4 million for these drugs.

³⁰ After podiatrists, the next most frequent specialty was internal medicine. A total of 13 of the 124 prescribers were internal medicine physicians.

CONCLUSION AND RECOMMENDATIONS

Compounded drugs are meant to be customized for individuals whose needs cannot be met by commercially available drugs. The explosive growth in Part D payments for compounded topical drugs is cause for concern. Payments for these drugs were 24 times higher in 2016 than in 2010. Nearly 550 pharmacies nationwide have questionable billing for compounded topicals. Each of these pharmacies billed extremely high amounts on one or more measures that indicate possible fraud, waste, or abuse. For example, many billed for identical compounded topicals for a high number of beneficiaries or billed for high numbers of these drugs ordered by a single prescriber. More than a quarter of the pharmacies with questionable billing were located in four metropolitan areas: New York City, Houston, Detroit, and Los Angeles. In addition, 124 prescribers associated with these pharmacies raise particular concern. Each of these prescribers ordered high amounts of compounded topical drugs dispensed by pharmacies with questionable billing.

These pharmacies and the associated prescribers all warrant further scrutiny. The patterns may indicate fraud, waste, and abuse. They might include cases in which the beneficiaries' or prescribers' identification numbers were stolen or used without their knowledge to obtain drugs that were not needed or not even received by the beneficiaries.

OIG is committed to working with CMS to follow up on the pharmacies and prescribers identified in this review as appropriate. OIG will also work with FDA to follow up on any pharmacies that may have compounding practices that warrant further scrutiny. In addition, CMS and Part D sponsors need to more effectively prevent fraud, waste, and abuse related to compounded topical drugs, while also ensuring access to needed drugs.

We recommend that CMS:

Clarify Part D policies for coverage of compounded topical drugs and use of utilization management tools

CMS must ensure that sponsors cover only medically necessary compounded topical drugs. To do this, CMS should clarify that sponsors have flexibility in their coverage of compounded topical drugs and use of utilization management tools, such as prior authorization and quantity limits, for these drugs. This will also help sponsors limit fraud, waste, and abuse for compounded topical drugs and protect beneficiaries' safety. CMS should also work with sponsors to address any questions related to these policies.

Specifically, CMS should clarify that sponsors have the option to treat compounded drugs as if they are "on-formulary" drugs or "non-formulary"

drugs. CMS should also clarify that, even if individual ingredients in the compound are on their formulary (i.e. their list of covered drugs), sponsors may still opt to treat a compound as “non-formulary.” If the sponsor opts to treat a compounded drug as “non-formulary,” it does not need to pay for the drug unless the beneficiary goes through an exceptions process and their request is approved.

In addition, CMS should clarify that sponsors may apply utilization management tools to compounded topical drugs, even if individual ingredients would not be subject to utilization management tools when dispensed individually. Utilization management tools, such as prior authorization and quantity limits, can help to prevent fraud, waste, and abuse and ensure patient safety. Prior authorization requires additional information from a prescriber before a Part D sponsor approves payment for a particular drug, allowing the sponsor to better determine if the drug is medically necessary. For example, a sponsor could use the prior authorization process to ensure that the compound is being prescribed because the beneficiary’s needs cannot be met by a commercially available drug. Quantity limits cap the amount of a drug a beneficiary can receive, which can help reduce overutilization and limit fraud, waste, and abuse.

CMS should reiterate that, in order to be covered by Part D, at least one of the ingredients must meet the definition of a Part D covered drug and none of the ingredients in a compounded drug may be covered under Part B. CMS should also reiterate that Part D does not pay for bulk powders.

Conduct additional analysis on compounded topical drugs

To strengthen its program integrity efforts for compounded topical drugs, CMS should instruct the NBI MEDIC to conduct additional analysis of compounded topical drugs. The NBI MEDIC currently conducts analysis of certain pharmacies with a high risk of billing fraud, waste, and abuse for compounded drugs and shares this information with Part D sponsors. Future analysis should include other pharmacy types and the measures in this report, as well as others it deems appropriate, to identify additional pharmacies and prescribers with questionable patterns that warrant further scrutiny. CMS should share the results of this analysis with sponsors and other partners, as appropriate. These additional data will allow sponsors and others to take action on these pharmacies and prescribers, which is critical to CMS’s Part D program integrity efforts.

Conduct training for Part D sponsors on fraud schemes and safety concerns related to compounded topical drugs

CMS should conduct training for Part D sponsors that informs them about the fraud schemes and the safety concerns related to compounded topical drugs. It should also reiterate that sponsors have flexibility in their coverage of compounded topical drugs and use of utilization management tools for these drugs, as described above.

More specifically, the training for Part D sponsors should include how to monitor and detect pharmacies with questionable billing for compounded topical drugs. It should include information on proactive data analysis as well as methods to investigate pharmacies. These methods include scrutinizing all of the ingredients in compounded topical drugs and performing inventory audits, which compare the quantities of the drug ingredients that they billed for with the quantities that they purchased. These efforts can help to reduce fraud, waste, and abuse related to compounded topical drugs under Part D.

Follow up on pharmacies with questionable Part D billing and the prescribers associated with these pharmacies

In a separate memorandum, we will refer to CMS the pharmacies identified as having questionable Part D billing for compounded topical drugs, as well as the associated prescribers identified in this report. CMS should review this information in conjunction with its ongoing efforts and take appropriate action.

AGENCY COMMENTS AND OIG RESPONSE

In response to the draft report, CMS concurred with all four recommendations.

Specifically, CMS concurred with the first recommendation to clarify Part D policies for coverage of compounded topical drugs and use of utilization management tools. CMS states that it will continue to work with Part D sponsors to clarify the policies and use of utilization management tools.

CMS concurred with the second recommendation to conduct additional analysis on compounded topical drugs. CMS states that it will continue to monitor the billing of Part D drugs, including compounded topical drugs, as well as take additional measures as appropriate.

CMS also concurred with the third recommendation to conduct training for Part D sponsors on fraud schemes and safety concerns related to compounded topical drugs. CMS states that it will incorporate this training into ongoing training programs.

Lastly, CMS concurred with the fourth recommendation to follow up on pharmacies with questionable Part D billing and the prescribers associated with these pharmacies. CMS states that it will review the referrals and take action as appropriate. It may also share this information with plan sponsors or make referrals to law enforcement.

For the full text of CMS's response, see Appendix B.

APPENDIX A: Detailed Methodology

We based this study on an analysis of CMS's PDE records. Part D sponsors submit a PDE record to CMS each time a drug is dispensed to a beneficiary enrolled in one of their plans. Each PDE record contains information about the drug and beneficiary, as well as the identification numbers for both the pharmacy and the prescriber. It also indicates if the drug was compounded.³¹

Analysis of total drug spending for compounded drugs

We analyzed all PDE records with dates of service from January 1, 2010 to December 31, 2016. This amounts to between 1.1 billion and 1.5 billion PDE records per year. We used a field on the PDE records to identify whether a drug was compounded. Then, to identify the type of compounded drug—e.g., topical, intravenous, injectable, or oral—we matched the NDC in the PDE records to First Databank.³²

We then calculated the total drug spending for compounded topical drugs, other types of compounded drugs, and all Part D drugs for each year from 2010 to 2016. To determine this amount, we summed four fields on the PDE records—ingredient cost, dispensing fee, sales tax, and the vaccine administration fee. We also calculated the average price per drug for compounded topicals, other types of compounded drugs, and all Part D drugs by dividing the total spending for each group by the total number of PDE records. Lastly, we calculated the total number of beneficiaries who received at least one drug in each of these groups for each year.

Analysis of pharmacies and prescribers

To identify pharmacies with questionable billing for compounded topical drugs, we developed a set of measures and analyzed PDE records for each pharmacy in our analysis. We included pharmacies that billed Part D for more than 10 compounded topical drugs and more than \$1,000 for these drugs. In total, we analyzed the PDE records for 2,388 pharmacies.³³ This

³¹ Compounded drugs often contain multiple drug ingredients. The PDE record lists the NDC for only the most expensive drug ingredient covered by Part D included in each compounded drug. For more information, see 76 Fed. Reg. 21521 (Apr. 15, 2011). Accessed at <https://www.gpo.gov/fdsys/pkg/FR-2011-04-15/pdf/2011-8274.pdf> on September 13, 2017.

³² The PDE records contain a field that indicates if a drug is compounded. To identify topical drugs, we used the route of administration listed in First DataBank for the NDC on the PDE record. In total, we identified a total of 766,870 PDE records for compounded topical drugs in 2016. The study did not include topical compounded drugs that were billed with NDCs with other routes of administration, such as an oral drug, which is crushed and put into a cream.

³³ A total of 15,290 pharmacies billed for at least one compounded topical drug in 2016.

analysis is based on pharmacies that did not register with the FDA as outsourcing facilities.³⁴

With input from OIG investigators and CMS, we developed five measures. These measures aim to capture current fraud schemes involving compounded topical drugs.

For each pharmacy, we calculated the following measures:

1. Percent of beneficiaries for whom the pharmacy billed at least one compounded topical drug

For each pharmacy, we determined the percent of its Part D beneficiaries for whom it billed at least one compounded topical drug in 2016.³⁵

2. Number of beneficiaries for whom the pharmacy billed for identical compounded topical drugs

For each pharmacy, we calculated the total number of its beneficiaries who received identical drugs. We considered drugs to be identical if they had identical values for seven fields in the PDE records—NDC, ingredient cost, dispensing fee, sales tax, vaccine administration fee, days supply, and quantity dispensed.³⁶ If a pharmacy billed multiple different identical drugs for beneficiaries, we reported the largest number of beneficiaries for whom the pharmacy billed for an identical compounded topical drug.

3. Average dollar amount per compounded topical drug

For each pharmacy, we calculated the average dollar amount per drug. To determine the amount paid to the pharmacy at the point of sale, we summed four fields on the PDE record—ingredient cost, dispensing fee, sales tax, and vaccine administration fee.

³⁴ These facilities are subject to different requirements related to compounding. To identify outsourcing facilities, we used FDA's publically available list of Registered Outsourcing Facilities and CMS's online National Plan & Provider Enumeration System (NPPES) National Provider Identifier (NPI) Registry.

³⁵ Because this measure is based on a percentage of beneficiaries, we included pharmacies that had more than 100 beneficiaries who received at least one topical compounded drug. In total, 2,276 of the 2,388 pharmacies met this criteria.

³⁶ We were not able to match all ingredients that were included in each compounded drug because the PDE record lists the NDC for only the most expensive drug ingredient covered by Part D. For more information, see 76 Fed. Reg. 21521 (Apr. 15, 2011). Accessed at <https://www.gpo.gov/fdsys/pkg/FR-2011-04-15/pdf/2011-8274.pdf> on September 13, 2017.

4. Number of compounded topical drugs ordered by a single prescriber

For each pharmacy, we determined the total number of compounded topical drugs ordered by each prescriber. We then determined the highest number of compounded topical drugs ordered by a prescriber.

5. Percent increase in total amount billed for compounded topical drugs from 2015 to 2016

For each pharmacy, we determined the percent change in the total amount billed for compounded topical drugs from 2015 to 2016.³⁷

We calculated each of these five measures for each of the pharmacies in our review. To identify pharmacies that had questionable billing for compounded topical drugs, we used a standard technique to identify outliers, known as the Tukey method. We considered pharmacies that were outliers (i.e., above the 75th percentile plus three times the interquartile range) on one or more measures to have questionable billing.

Next, we determined whether pharmacies with questionable billing had certain characteristics in common. To do this, we matched each pharmacy's NPI to data from the National Council for Prescription Drug Program (NCPDP). We then determined the proportion of pharmacies with questionable billing that were independent and the proportion that were part of a chain.³⁸ We also determined whether the pharmacies with questionable billing were located in certain metropolitan areas, i.e., Core Based Statistical Areas (CBSA).³⁹

Lastly, we identified prescribers associated with pharmacies with questionable billing who raise concern. We considered a prescriber to raise concern if they ordered more than \$250,000 of compounded topical drugs from pharmacies with questionable billing. We then determined total Part D spending for compounded topicals ordered by these associated prescribers at pharmacies with questionable billing. Next, we used

³⁷ To be considered to have questionable billing, the pharmacy also had to have an increase of more than \$10,000 in Part D billing for topical compounded drugs from 2015 to 2016.

³⁸ For the purposes of the report, we used the definitions of chain and independent pharmacies from the NCPDP. Accordingly, chain pharmacies are part of a group of four or more pharmacies under common ownership. Independent pharmacies are one to three pharmacies under common ownership. We included franchise pharmacies with independent pharmacies because they are independently owned. For this analysis, we were unable to determine whether 82 pharmacies were independent or chain. An additional 27 pharmacies had other ownership types, such as government pharmacies. These 109 pharmacies were included in a third category of "other" for this analysis.

³⁹ A CBSA is a region around an urban center with at least 10,000 people. See U.S. Census Bureau, *Metropolitan and Micropolitan Statistical Areas*. Accessed at <https://www.census.gov/programs-surveys/metro-micro/about.html> on November 8, 2017.

beneficiaries' ZIP codes to determine where the each prescriber's beneficiaries were located. We also determined the specialty of these prescribers using CMS's NPPES.⁴⁰

⁴⁰ NPPES contains information about prescribers, such as their name, address, and taxonomy.

APPENDIX B: Agency Comments



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

200 Independence Avenue SW
Washington, DC 20201

DATE: MAY - 3 2018

TO: Daniel R. Levinson
Inspector General

FROM: Seema Verma *SV.*
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: Questionable Billing for
Compounded Topical Drugs in Medicare Part D (OEI-02-16-00440)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the draft report from the Office of Inspector General (OIG). CMS is committed to program integrity and beneficiary safety in Medicare Part D.

Compounded drugs are customized to meet the needs of patients who cannot use commercially available drugs, for example, due to an allergy to an inactive ingredient. Medicare Part D covers compounded drugs if they contain at least one active ingredient that would be covered by Part D if dispensed separately. Access to compounded drugs is essential for patients with allergies and other unique healthcare needs.

CMS routinely monitors pharmacy billing and utilization, including that of compounded drugs. CMS has many initiatives underway specifically examining compounding pharmacies, including a Compounded Prescription Drug Pharmacy Data Analysis project, which uses outlier detection to identify high-risk pharmacies billing Medicare Part D for compounded prescription drugs. This analysis is informed by known compounding pharmacy fraud and abuse schemes. CMS shares the results of this project with plan sponsors. The metrics used in this analysis are frequently updated, and most recently, in February 2018, CMS updated risk factors and broadened the scope of the pharmacy population used for this analysis.

It is important to note that pharmacies that specialize in compounded drugs may have billing patterns that differ from traditional pharmacies and may not be indicative of fraud. The updated project now utilizes a data-driven approach based on prescription drug event records to identify pharmacies of interest.

In addition, the Quarterly Drug Trend Analysis that CMS provides to plan sponsors broadly analyzes Part D drugs, including topical compounded drugs, and their associated payments as well as changes and trends in utilization and price.

CMS takes seriously its responsibility to oversee beneficiary safety, as exemplified by the many efforts currently underway, and appreciates the OIG's additional review into this area. OIG's recommendations and CMS's responses are below.

OIG Recommendation

We recommend that CMS clarify Part D policies for coverage of compounded topical drugs and use of utilization management tools.

CMS Response

CMS concurs with this recommendation and will continue to work with Part D sponsors to clarify Part D policies for coverage of compounded topical drugs and use of utilization management tools.

OIG Recommendation

We recommend that CMS conduct additional analysis on compounded topical drugs.

CMS Response

CMS concurs with this recommendation. CMS will continue efforts to monitor the billing of Part D drugs, which include compounded topical drugs, as well as utilizing additional measures as appropriate. CMS notes that risk factors based on volume would identify large compounding pharmacies rather than pharmacies with current fraud schemes and questionable billing patterns.

OIG Recommendation

We recommend that CMS conduct training for Part D sponsors on fraud schemes and safety concerns related to compounded topical drugs.

CMS Response

CMS concurs with the recommendation to conduct training for Part D sponsors on fraud schemes and will incorporate this training into ongoing training programs.

OIG Recommendation

We recommend that CMS follow up on pharmacies with questionable Part D billing and the prescribers associated with these pharmacies.

CMS Response

CMS concurs with this recommendation. CMS will review the referral sent by the OIG and take action as appropriate, in accordance with CMS policies and procedures. CMS may share this information with plan sponsors or make referrals to law enforcement.

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 Kevin Farber and Meghan Riggs.

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.

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

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