A Retrospective Analysis of Medicare Part D Compounded Products: Evaluating the Utilization of Compounded Products and the Limitations of Claims Data Reporting

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BACKGROUND

Pharmaceutical compounding of medications is a fundamental component of pharmacy practice defined as the combining, mixing, or altering of ingredients of a drug to create a medication tailored to an individual patient's needs.[1,3] While pharmaceutical compounding serves important medical needs, individualized preparations do not have the same regulatory oversight as commercially available products, posing risks to patients. A 2016 report by the Office of the Inspector General states the prevalence of Medicare beneficiaries receiving a compounded product has increased by 281% from 2006-2015 with spending increasing by 625%, yet there are no universal requirements for pharmacies to register as compounding pharmacies nor report on the types of products compounded.[2] Furthermore, while there are guidelines from the National Council for Prescription Drug Programs on how to bill for compounded products, there are no standardized pricing structures for compounded products. The lack of oversight and exponential growth of compounded drugs raise significant fraud, waste, and abuse concerns.[4]

PURPOSE & OBJECTIVES

Evaluate the utilization of Medicare Part D compounded drugs and identify limitations in pharmacy claims data reporting to develop the framework for future studies to improve regulatory oversight and cost transparency. Additional aims of this study include evaluating the total and per-patient costs of compounded drugs and the impact of data limitations on outcomes research.

METHODS

Retrospective observational analysis using a 20% nationally representative sample of 2017-2019 Medicare claims data. Beneficiaries enrolled in a Part D plan who received at least one compounded product during the study period were included. The Part D Event (PDE) File identified unique compounded drug claims and was used to obtain the active ingredients, dosage form, pharmacy service type, fill number, and costs per compound. Beneficiary-level demographic and chronic condition data were derived from the Master Beneficiary Summary File (MBSF) and the Chronic Conditions Segment Files (CCS) and were correlated to the Master Beneficiary ID (BENE_ID) associated with each PDE claim. Claims were subcategorized by therapeutic area modeled after USP Medicare Model Guidelines v6.0 (USP).

RESULTS

- A total of 1,062,637 unique PDE compounded drug claims were identified. There was a 32% reduction in compounded drug claims from 2017-2019 (21% reduction from 2017-2018; 9% reduction from 2018-2019). On average, compounded drugs represent 0.25% of all prescription claims.

Table 1: Beneficiary Characteristics

	2017 (n = 126,242)	2018 (n = 105,036)	2019 (n = 93,136)
Age (Mean (SD))	70.9 (13.0)	71.0 (12.8)	70.3 (12.7)
Male (%)	45.7	45.7	45.3
Female (%)	54.3	54.3	54.7
White (%)	79.6	79.2	78.9
Black (%)	10.7	10.7	10.7
Asian (%)	2.4	2.5	2.6
Hispanic (%)	2.9	3.0	3.1
Native (%)	0.5	0.5	0.4
Other (%)	2.1	2.12	2.1

Table 2: Frequency of Chronic Conditions (%)

	2017	2018	2019
Hypertension	70.9	68.3	66.3
Hyperlipidemia	64.6	62.0	60.2
Anemia	57.2	55.9	54.8
Rheumatoid Arthritis/ Osteoarthritis	56.4	53.3	50.7
Ischemic Heart Disease	46.7	44.9	43.3
Cataract	46.5	43.5	41.6
Depression	46.2	44.4	43.3
Diabetes	43.7	42.3	41.9
Chronic Kidney Disease	37.7	37.8	38.1
Heart Failure	32.4	31.2	30.7

- The average proportion of compound drug users within the study population was 2.8%, and there was a 27.6% reduction in the number of beneficiaries using compounded products over the three-year study period.

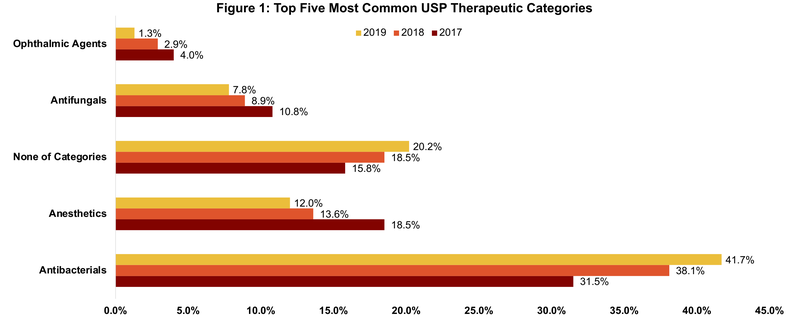
Table 3: Frequency of Compounded Claims, by Year

	Compounded Claims	Total PDE Claims	Frequency
2017	411,051	300,110,926	0.14%
2018	340,316	301,180,099	0.11%
2019	311,270	305,491,313	0.10%

RESULTS CONT.

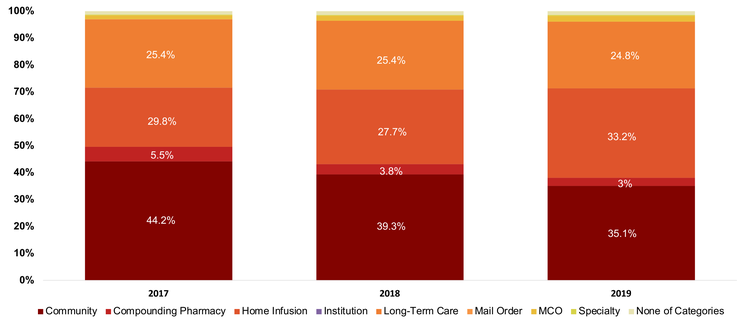
- An average of 18.15% of all compounded claims contained ingredients classified as “None of Categories,” consisting of various inactive ingredients (i.e., excipients, solvents, buffering agents).

Figure 1: Top Five Most Common USP Therapeutic Categories



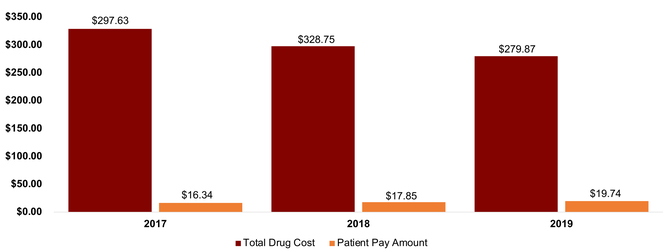
- Compounding pharmacies dispensed an average of 4.1% over the three-year period.

Figure 2: Trends in Dispense Location, By Year



- The percent difference in mean total drug costs observed a 16% reduction over the three-year period. The range of total drug costs varied and incurred a standard deviation exceeding $850. Patient pay amount remained relatively consistent throughout the study and only incurred a standard deviation of approximately $80. On average, patients paid about 16% of the compounded drug's total cost.

Figure 3: Average Compounded Drug Total Drug & Patient Costs, By Year



	Mean	SD	Median	Max	Upper Q	Lower Q
2017	328.74	931.25	112.27	40,806.90	263.15	33.80
2018	297.63	869.43	96.55	40,964.90	208.54	30.58
2019	279.87	933.93	93.02	54,688.82	202.86	27.26

	Mean	SD	Median	Max	Upper Q	Lower Q
2017	16.3398	78.06	1.2	6356.34	8.25	0
2018	17.84634	80.67	1.25	6413.36	8.55	0
2019	19.74454	80.87	1.25	5315.14	9.44	0

DISCUSSION

- Our findings identify gaps in available claims data. Compounded preparations do not have the same regulatory oversight as commercially available products, posing efficacy and safety risks to patients.
- While the practice of compounding has typically been regulated at the state level, FDA has raised concerns regarding the risks associated with compounded medications distributed with minimal assurance of having met appropriate safety and legal requirements.[2]
- Compounded drugs may encompass a combination of active and inactive ingredients, and different formulations have varying sterility parameters.[2] Unlike commercially available drug products, there are no specific billing codes for compounded drugs dispensed in an outpatient setting as they lack national drug codes (NDC) to identify the active ingredients in the preparation.[2] PDE claims data only lists one ingredient of a multi-ingredient preparation, making it difficult to correlate ingredients to costs, verify that the beneficiary received the correct medications, and determine if payers were appropriately billed.
- The limitations of available data also raise questions about the cost of compounded drugs. Medicare Part D plan sponsors vary in their payment practices in whether they pay pharmacies for bulk substances or each FDA-approved ingredient and may not submit these payments as part of the claims data that the Center for Medicare & Medicaid Services (CMS) uses to determine federal Part D payments.[2]
- In recent years, insurers have discontinued payment for these substances due to increasing costs of ingredients not covered by Part D, including bulk substances.[2] Medicare Part D plan sponsors calculate pharmacy payments based on individual FDA-approved ingredients or bulk substances used in the preparation.[2] Without detailed data collection of the inactive and active ingredients used in the preparations, it is difficult for the CMS to confirm if they are accurately paying for compounded drugs.

STUDY LIMITATIONS

- Due to the inherent limitations of information about compounded medications in prescription claims data, the results needs to be interpreted with caution.
- The drug-level characteristics do not account for preparations with multiple active ingredients; a substantial proportion of the claims lists an inactive ingredient as the sole ingredient.
- The beneficiary-level characteristics may offer some insight into patient population that utilizes compounded medications but are purely descriptive.
- The data does not confirm whether a claim is indicated for a specific chronic condition, making it difficult to determine intended use. The limitations of compounding claims data raise challenges in assessing whether pharmacies are preparing compounded drugs for individual patients in large quantities without prescriptions, whether compounded products are being sold to facilities in multiple sites, and trace for possible contamination of products.

REFERENCES

1. American Society of Health System Pharmacists. ASHP guidelines on compounding sterile preparations. Am J Health Syst Pharm. 2014;71(2):145-166. doi:10.2146/sp140001
2. “Compounded Drugs: Payment Practices Vary across Public Programs and Private Insurers, and Medicare Part B Policy Should Be Clarified.” U.S. Government Accountability Office, 10 Oct. 2014, https://www.gao.gov/assets/gao-15-85.pdf.
3. Huffman DC, Holmes ER. Specialty compounding for improved patient care: 2006 national survey of compounding pharmacists. Int J Pharm Compd. 2008;12(1):74-82.
4. McPherson T, Fontane P, Iyengar R, Henderson R. Utilization and Costs of Compounded Medications for Commercially Insured Patients, 2012-2013. J Manag Care Spec Pharm. 2016;22(2):172-181. doi:10.18553/jmcp.2016.22.2.172