



PHARMACY AUDITS

An Important Tool for Fighting
Fraud, Waste, and Abuse and
Protecting Patients

JANUARY 2023

Health 
Σvaluations

PBMs use pharmacy audits to ensure patients receive high-quality services from network pharmacies and to verify that no FWA is taking place.

Key Findings

- » Pharmacy benefit managers (PBMs) are recognized technical experts in administering prescription drug benefits, including the investigation of pharmacy fraud, waste, and abuse (FWA).
- » Pharmacy FWA is not uncommon, costing an estimated \$3.5 billion annually, and can place patients at risk of physical harm.
- » PBM pharmacy audits are driven by both contractual requirements with payers and the regulatory requirements of government health care programs, such as Medicare Part D.
- » Audits require a thorough examination of pharmacy record details to investigate otherwise hidden FWA. Appeals processes allow for correcting the record if anything was missed in the audit. This is not about nit-picking.
- » Virtually all health care entities, including PBMs, are extensively audited. Pharmacies are not being treated differently.
- » Opportunities exist to reduce pharmacy audit burden by leveraging technology.

What Is a Pharmacy Benefit Manager (PBM) Pharmacy Audit?

Approximately 299.23 million Americans have health insurance coverage from a variety of sources, including self-insured employer or union plans, commercial group or individual market plans, and/or government sponsored plans (e.g., Medicare and Medicaid).¹ PBMs are the technical experts in the administration of prescription drug benefits for these plans. From a historical perspective, PBMs evolved from technical vendors (e.g., pharmacy claims processing firms), particularly in the late 1980s when most retail pharmacies began use of electronic data interchange capabilities.² As pharmacy benefits grew in both complexity and costs, payers (including government agencies) increasingly relied on the technical expertise of PBMs to manage prescription drug utilization, including implementing clinical programs that manage disease progression and auditing to limit FWA.

Today, PBMs typically provide the following services for payers:

- » Processing pharmacy claims;
- » Creating and administering retail pharmacy networks;
- » Administering clinical programs that focus on disease management and medication adherence;
- » Negotiating rebates with pharmaceutical manufacturers;
- » Developing and maintaining formularies, which are lists of covered drugs;
- » Providing mail-order pharmacy (i.e., prescription home delivery); and
- » Ensuring clinically appropriate drug use, which includes investigating pharmacies for potential FWA.³



PBMs use pharmacy audits to ensure patients receive high-quality services from network pharmacies and to verify that no FWA is taking place. PBMs conduct audits in accordance with contracted terms that are always shared and agreed to in advance and staffed by appropriately trained, licensed, and certified pharmacy technicians and/or pharmacists.

The reasons for conducting an audit typically involve contractual or regulatory requirements; referrals from persons who have alleged observing FWA; and/or as a result of patterns of suspected FWA detected in data analysis.⁴ Referrals can come from patients, prescribers, or pharmacy staff whistleblowers who allege that FWA has occurred. Data analytic approaches examine statistical patterns associated with FWA in order to target higher probability cases. For example, an analysis of claims and prescription data showing that a pharmacy is dispensing refills more times than the prescriber physician has authorized or without a valid prescription at all would present such a case.⁵ Enhancements in data analytic methods are widely cited as driving the detection of more FWA in the pharmacy and across the health care system.⁶ These data analytic detection methods usually require audit data to verify that FWA has taken place and to completely determine the size and scope of the problem.

Audits can be done in-person or remotely, with the reason for the audit driving the level of contact necessary.

The reasons for conducting an audit typically involve contractual or regulatory requirements; referrals from persons who have alleged observing FWA; and/or as a result of patterns of suspected FWA detected in data analysis.

Summary of Common Types of Pharmacy Audits

AUDIT TYPE	DESCRIPTION
Telephone Audit	Pharmacy is contacted by the PBM usually to correct billing on a small number of claims. This type of audit generally is not used for large volumes of claims.
Field/On-Site audit	Performed on site at the pharmacy where physical observations, prescription reviews, inventory, and other checks for compliance are performed. Unless there is an investigatory reason, a pharmacy selected for an on-site audit will receive an audit notification letter that specifies the date of the audit visit, and they are given an opportunity to reschedule.
Desk/Mail Audit	Automated means (e.g., data analytics) are used to review pharmacy claims and other clinical and administrative data received by the PBM. This type of audit may require the pharmacy to provide prescription records. Analytics are then performed to examine prescribing patterns, physician referral patterns, utilization overrides, ingredient cost integrity, geographic prescribing reports, and other metrics commonly used to identify possible FWA activity.
Virtual Audit	When the COVID-19 pandemic hit, pharmacies needed to take special measures to protect their customers and staff from exposure to the virus. This included limits on who was allowed inside the pharmacy. In response, virtual audits became the norm. These audits generally are a hybrid of traditional desk and on-site audit types. Pharmacy documents are submitted via fax, email, mail, or to a web-based portal. Brief (10-15 minutes) phone interviews are conducted to ask compliance questions.

AUDIT TYPE	DESCRIPTION
Investigational Audit	Pharmacies and/or prescribers are contacted, usually by telephone or mail, and asked to provide copies of specific documents and records related to claims paid during a specified period of time. Requested documentation may include copies of original prescriptions, signature logs, computer records, and invoices showing purchase or receipt of dispensed medications.
Purchase or Invoice Verification Audit	Pharmacies must purchase prescription drugs and related supplies from authorized sources (i.e., a wholesaler) under the law. The ordering of these products and supplies can be tracked using verifiable invoices and pedigree invoices. This is a type of investigational audit.
Prescriber/Member Audits	Prescriber audits have specific claim information submitted by the pharmacy that is thoroughly verified by a prescriber/physician to ensure complete alignment between both parties. They tend to be performed in the same manner as a Desk/Mail audit. Member audits are similar to the Prescriber Audit except the claims in question are verified with the patient or plan member.

Discrepancies in these claim details often is evidence of a type of FWA called drug diversion.

Sources: American Pharmacy Cooperative, "[Audit Information](#)," 2022; Florida House of Representatives, [Staff Final Bill Analysis for HB 357 Pharmacies and Pharmacy Benefit Managers](#), June 2022; Dhafer Almaklani, [Community Pharmacy Audits-Are you susceptible?](#), September 29, 2017; ExlService Holdings, Inc. and Affiliates, "[Innovation during pandemic results in successful virtual pharmacy audit program](#)," 2022; Thiede T, Westberg D. Tackling PBM audits collaboratively. Presented at: National Community Pharmacists Association 2022 Annual Convention; October 1-4, 2022; Kansas City, MO; [Humana Pharmacy Solutions Audit and Claim Review Guide](#), December 2022; [Prime Therapeutics Provider Manual for Pharmacy Providers](#), Effective January 1, 2023

Details Matter and Pharmacies May Appeal Audit Findings

Critics have claimed that PBM pharmacy audit final results are based on "nit-picky" standards that focus on minor administrative typographical errors (sometimes called scrivener's errors).⁷ However, uncovering FWA and ensuring regulatory and legal compliance requires a thorough examination of the records.

To illustrate the level of detail necessary in a pharmacy audit, consider that everything begins with a valid prescription. Thus, a prescription drug claim must have the correct prescriber's national provider identifier (NPI) and a prescription with the prescriber's signature and the date.⁸ Discrepancies in these claim details often is evidence of a type of FWA called drug diversion, which occurs when individuals redirect drugs from the legal supply chain to an illicit drug distribution without a legal and medically necessary purpose.⁹

When pharmacies disagree with initial audit findings, they have the opportunity to counter with additional evidence. In other words, pharmacies may submit an appeal, to dispute any audit findings they believe are inaccurate or not material. This usually takes place within 30 days of receiving the audit findings in writing.¹⁰

In certain states, a pharmacy may also appeal to a state agency or an independent review entity for a claims dispute, including those involved in pharmacy audit disputes.¹¹ For example, the Florida Agency for Health Care Administration leverages an independent review contractor to administer the Statewide Provider and Health Plan Claim Dispute Resolution Program, which assists all providers, including pharmacies, in resolving claim disputes.¹² According to the available annual reports from 2018 to 2021, there were numerous cases from physicians and hospitals, but



PBM pharmacy audits in New Jersey and New York uncovered approximately \$65 million in fraudulent billings involving prescription drugs that were never purchased from wholesalers and never dispensed to patients.

only one from a retail pharmacy.¹³ That one case was withdrawn by the pharmacy.¹⁴ Similarly, Washington State has a process where small pharmacies¹⁵ can submit an appeal to the Office of the Insurance Commissioner to review a PBM's decision regarding reimbursement.¹⁶ A review of the case records from 2021 (the most recent complete year available) finds that only three different pharmacies filed one or more appeals, but the cases centered around claims processing disputes and did not involve evidence from PBM audits of pharmacies.¹⁷

Fraud, Waste and Abuse (FWA) Is Not Uncommon, and it Can Hurt Patients

Fraud, Waste, and Abuse Defined:

- » **Fraud** is knowingly submitting false pharmacy claims to obtain payment and/or receiving payment to induce or reward referrals for reimbursement;
- » **Waste** includes excessive and unnecessary quantities dispensed, dispensing inappropriate or ineffective prescription drugs for the medical condition of the patient, or high-cost prescription drugs when cheaper medically appropriate alternatives are available;
- » **Abuse**, in this context, generally involves a pharmacy knowingly dispensing medications that a person is utilizing for non-medical reasons.

Sources: CMS Medicare [Fraud & Abuse: Prevent, Detect, Report](#); American Academy of Managed Care Pharmacy, [Fraud, Waste, and Abuse in Prescription Drug Benefits](#); HHS OIG, [Prescribers With Questionable Patterns in Medicare Part D](#)

While the majority of pharmacies operate legally and ethically, pharmacy-related FWA is unfortunately too commonplace, adding an estimated annual cost of \$3.5 billion.¹⁸ There are currently over 3,900 pharmacies or individual pharmacists that the U.S. Department of Health and Human Services (HHS), Office of Inspector General (OIG) has prohibited from participation in federally-funded health care programs for FWA reasons.¹⁹

Numerous new cases of pharmacy FWA are reported each year by federal and state law enforcement and other government agencies (See Appendix for a partial list). For example, two New York pharmacy owners recently pleaded guilty to conspiracy involving fraudulent claims for high-cost cancer medications that were not prescribed by physicians, nor dispensed to patients.²⁰

Many of these reported cases involve evidence initially uncovered by pharmacy audits performed by PBMs.²¹ For example, PBM pharmacy audits in New Jersey and New York uncovered approximately **\$65 million in fraudulent billings** involving prescription drugs that were never purchased from wholesalers and never dispensed to patients.²² Ultimately, the pharmacy owner in that case was sentenced to prison, both for the fraud and for income tax evasion.²³ Similarly, a PBM pharmacy audit helped to uncover **\$3.8 million in false and fraudulent claims** for medically unnecessary foot bath medications and related medically unnecessary molecular diagnostic testing.²⁴

These cases are not just about added costs. Often these cases involve the potential for patient harm. For example, a Maryland pharmacy was recently charged with dispensing potentially dangerous controlled substances, including alprazolam, to patients who did not have a medically necessary reason to take the medication.²⁵ Alprazolam may cause physical dependence and can increase the risk of serious or life-threatening side effects, sedation, or coma if used along with certain prescription medications, alcohol and/or illegal drugs.²⁶ Thus, these drugs should never be dispensed without a valid prescription and a proper clinical treatment plan.

Pharmacy Audits Are Required by Payers and Government Programs

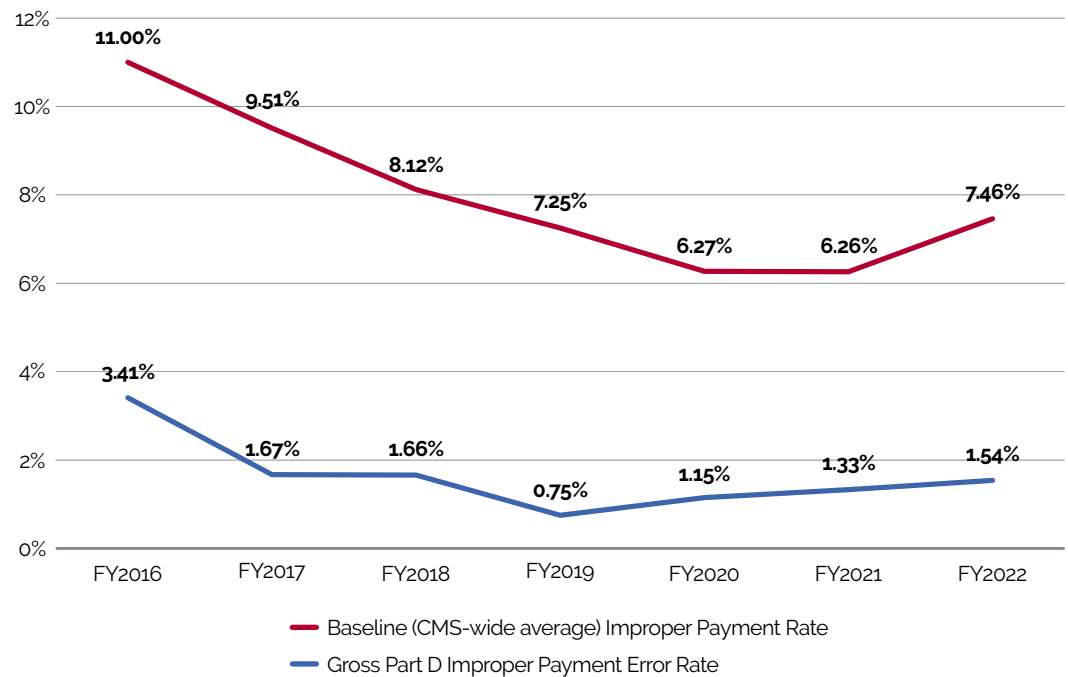
In large part due to the diligent efforts of PBMs, the improper payment error rate for Medicare Part D is significantly lower than for other CMS programs.

Payers, including government programs, often drive PBM pharmacy audit contract provisions by placing certain payment integrity contractual requirements on PBMs. Publicly available state and local government requests for proposals (RFPs) provide transparency and insight into this dynamic. For example, a recent RFP for the Tennessee state employee benefits plan requires any PBM they contract with to “detect and prevent errors, fraud or abusive pharmacy utilization by Members, pharmacies or prescriber” and the PBM “shall contact pharmacies with aberrant claims or trends to gain an acceptable explanation for the finding or to submit a corrected claim.”²⁷ Similar provisions are commonplace in RFPs for both Medicaid and employee pharmacy benefits plans in other states. See, for example, RFPs in California, New Jersey, Louisiana, and Wisconsin.²⁸

Federal programs have very rigorous regulatory requirements around payment that impact pharmacy audits. For example, Medicare Part D plan sponsors and their PBMs are expected to utilize “procedures and a system for promptly responding to compliance issues as they are raised,” which includes among other things, “reporting payment suspensions pending investigations of credible allegations of fraud by pharmacies; information related to the inappropriate prescribing of opioids and concerning investigations and credible evidence of suspicious activities of a provider of services (including a prescriber) or supplier.”²⁹ **CMS has been clear that Part D plans and their PBMs should work towards the detection of FWA trends via daily claims reviews, outlier reports, and pharmacy audits.**³⁰

Moreover, federal programs place on plan sponsors and their PBMs the additional expectation to limit improper payments.³¹ This can be a higher standard than what would typically be considered FWA because it includes both payments that should not have been made and also legitimate payments that have some “element made incorrectly under statutory, contractual, administrative, or other applicable requirements.”³² For example, a claim that is paid on a valid prescription, but has incorrect key information on it (e.g., wrong quantity or days' supply) could be considered an improper payment. Some in the pharmacy space may allege this is ‘nit-picking,’ but it is a long-standing federal program requirement applied to all stakeholders, including PBMs themselves. In large part due to the diligent efforts of PBMs, the improper payment error rate for Medicare Part D is significantly lower than for other CMS programs.³³ Figure 1 compares the average payment error rates in Part D to that average across all CMS programs, finding the Part D rate, at 1.5 percent, dramatically lower than the 7.5 percent rate across federal programs.

Figure 1: Comparison of CMS Program Average Improper Payment Error Rates and Medicare Part D, FY2016 to FY2022



Pharmacy audits do not single out pharmacies or create large burdens.

Sources: Analysis of CMS data available online at <https://www.cms.gov/research-statistics-data-and-systems/monitoring-programs/medicare-fs-compliance-programs/cert/additionaldata> and <https://www.cms.gov/research-statistics-data-and-systems/improper-payment-measurement-programs/medicare-part-d>

Everyone in Health Care Is Regularly Audited

Pharmacy audits do not single out pharmacies or create large burdens. The truth is virtually all health care stakeholders are regularly audited in detail.³⁴ To put in context the scale of audit activities, the federal government alone has been spending over \$2 billion per fiscal year since 2019 on audits and related oversight activities of the various providers and entities participating in Medicare, Medicaid, and other government programs.³⁵

In other words, pharmacies are no different than other entities in the health care system. Again, everyone in health care is extensively audited and reviewed. For example, in select states³⁶ since June 1, 2019, CMS has required home health agencies to make one of the following challenging choices: 1) Pre-claim review of **all** claims; 2) Post-payment review of **all** claims; or 3) Minimal review with 25% payment reduction.³⁷ Thus, these home health agencies must have all claims audited or take a 25% payment cut. These home health claims reviews require submission of extensive medical records evidence to support each claim.³⁸

To be clear, plan sponsors and their PBMs are rigorously audited, analyzed, and reviewed as well.³⁹ For example, the Medicare Advantage and Part D program audits alone require an estimated 500+ hours of plan and PBM staff time to complete.⁴⁰ The reality is that compliance with detailed audits is just part of being in the health care business.



Pharmacy audits are an important tool that PBMs use to help combat fraud, waste, and abuse, protecting payers and patients.

The Future of Pharmacy Audits

While the prevalence of pharmacy audits has not been extensively studied, experts supporting pharmacies in their audit responses have noted that “an extensive audit of prescription records and purchase history generally occurs every 2 to 3 years.”⁴¹ A more recent report from a third-party pharmacy audit assistance firm suggested that the number of audits declined during 2020, but that newer virtual audits required the submission of more prescription claims.⁴² It is likely that pre-audit analytics are facilitating more targeted audits (thus less audit volume). Data analytic approaches generally require more data and the total number of prescriptions filled continues to grow—reaching 6.4 billion in 2021, up from 5.9 billion in 2017.⁴³ To the extent that there are opportunities to reduce the number of audits or the data required, discussions need to be evidence driven and include both payers and regulators.

Ultimately, leveraging technology to automate the storage and transmission of the data used in the pharmacy audits could help reduce burden. This is especially true as more audits shift to a virtual format. Fortunately, key pieces of this are already in place. For example, nearly all (94%) prescriptions now are electronically transmitted, up from just 73% in 2013.⁴⁴ This means that pharmacies rarely will have to scan or photocopy paper prescriptions to submit to auditors. Moreover, Pharmacy Services Administrative Organizations (PSAOs) often have analytic tools that can integrate into pharmacy practice management systems to aid with compliance.⁴⁵

Conclusion

Pharmacy audits are an important tool that PBMs use to help combat fraud, waste, and abuse, protecting payers and patients. FWA is not uncommon, and high-profile examples in multiple states highlight the need for continued action. Additionally, PBMs are often required by contractual or regulatory means to regularly audit their pharmacy partners. Technology used in audits continues to advance, making compliance by both PBMs and pharmacies easier.

Appendix

Recent Illustrative Pharmacy Fraud Cases⁴⁶

YEAR	CASE IN STATE	CASE SUMMARY
2022	California	The owner and pharmacist-in-charge of a pharmacy was convicted of health care fraud and illegal drug diversion conspiracy involving Medicaid of California (Medi-Cal) and Medicare for prescription drugs that were never dispensed to beneficiaries, but rather were provided to co-conspirators to sell illegally.
2021	California	California announced the sentencing of a pharmacy owner for defrauding the Medi-Cal and Medicare programs. An audit found that the number of drugs the owner claimed to have purchased and billed the programs for was not supported by the actual inventory records. Fraudulent over-billing totaled more than \$1.8 million.
2022	Florida	Pharmacy owners were alleged to have paid kickbacks and bribes to telemarketers and telemedicine providers to secure orders for medically unnecessary prescriptions that were billed to Medicare. Claims were made to Medicare for medically unnecessary medications, sometimes through multiple pharmacies they owned and controlled and were reimbursed for a total of \$8.3 million.
2022	Florida	A specialty pharmacy entered into a deferred prosecution agreement and agreed to pay a \$1.31 million civil settlement to resolve allegations that it submitted fraudulent claims to Medicare for Evzio, a high-priced drug used in rapid reversal of opioid overdoses. The pharmacy completed Evzio prior authorizations forms in place of the prescribing physicians, including instances in which pharmacy staff signed the forms without the physician's authorization and listed the pharmacy's contact information as if it were the physician's information. These prior authorization requests also contained false clinical information to secure approval for the expensive drug.
2019	Georgia	Georgia announced that a pharmacist and the owner and operator of a retail pharmacy located in Atlanta, Georgia pled guilty to seeking reimbursement from the Georgia Medicaid program for medications that were not dispensed.
2021	Maryland	Maryland's attorney general announced charges filed against a licensed pharmacist who owned and operated an independent retail pharmacy in New Carrollton. It is alleged that beginning in October 2013 the pharmacy knowingly filled fraudulent prescriptions and dispensed controlled dangerous substances, including oxycodone and alprazolam, to customers who presented the fraudulent prescriptions, many of whom were Medicaid recipients.
2021	Massachusetts	An \$800,000 settlement with a retail pharmacy in Jamaica Plain for allegedly billing the state's Medicaid program, MassHealth, was announced. The pharmacy automatically refilled prescription medications for a costly prescription multivitamin that was not provided to patients, and other prescriptions that were not authorized by a physician.
2021	Michigan	A pharmacist along with two specialty pharmacies that the pharmacists formerly owned and operated agreed to pay the United States \$1 million to resolve allegations that they submitted false claims for the drug Evzio. Evzio was an injectable form of naloxone hydrochloride indicated for use to reverse opioid overdose. Evzio was the highest-priced version of naloxone on the market, and insurers frequently required the submission of prior authorization requests before they would approve coverage for Evzio.
2020	Michigan and Ohio	Nine pharmacists were charged in three separate indictments unsealed last week for their alleged participation in a \$12.1 million health care fraud scheme executed in Detroit and southern Ohio. The indictments allege that, using the pharmacies, the defendants billed Medicare, Medicaid, and Blue Cross Blue Shield (BCBS) for prescription medications that were neither purchased nor dispensed. The indictments further allege that the defendants billed Medicare and Medicaid for medications that were often medically unnecessary and for some medications that were purportedly dispensed to deceased beneficiaries after their dates of death.

YEAR	CASE IN STATE	CASE SUMMARY
2022	Mississippi	A former Mississippi pharmacist was sentenced to 10 years for a multimillion-dollar scheme to defraud TRICARE and private insurance companies by paying kickbacks to distributors for the referral of medically unnecessary prescriptions. The conduct resulted in more than \$180 million in fraudulent billings, including more than \$50 million paid by federal health care programs.
2020	Mississippi	Two pharmacy owners were convicted for conspiring to commit health care fraud and conspiring to commit money laundering and tax evasion. They recruited TRICARE beneficiaries and paid them a percentage of the revenue for each prescription in order to induce the beneficiaries to accept millions of dollars of compounded medications.
2020	Mississippi	A Mississippi businessman pleaded guilty for his role in a multimillion-dollar scheme to defraud TRICARE, the health care benefit program serving U.S. military, veterans, and their respective family members, as well as private health care benefit programs, by paying kickbacks to practitioners and distributors for the prescribing and referring of fraudulent prescriptions for not medically necessary compounded medications that were ultimately dispensed by his pharmacies, as well as for his role in a scheme to launder the proceeds of the fraud scheme. Between 2012 and 2016, the scheme defrauded TRICARE and other health care benefit programs by distributing compounded medications that were not medically necessary in the amount of \$287,659,569.
2021	Missouri	The owner of pharmacy and an employed pharmacy technician, were both indicted for forging prescriptions that were billed to the Missouri Medicaid program.
2022	New Jersey	A New Jersey pharmacy admitted its role in a conspiracy to illegally distribute prescription opioids and to give kickbacks to health care providers. From 2015 through 2019, the pharmacy sent controlled substances and other prescription medications to patients via mail throughout the United States, including highly addictive and dangerous transmucosal immediate release fentanyl (TIRF) medications. The pharmacy admitted that its violations of the statute caused a loss to federally funded health care programs of over \$4.5 million.
2022	New Jersey	New Jersey's attorney general announced shutting down the pharmacy of a Hudson County pharmacist who was arrested on charges of selling falsified COVID-19 vaccination record cards and fraudulently reporting the administration of COVID-19 vaccines to a state-managed vaccination registry without having administered the vaccine.
2022	New Jersey	New Jersey's attorney general announced charges against 19 individuals for their alleged participation in an \$11 million "medicine-for-cash" insurance fraud scheme that was run by a Manhattan pharmacy owner and operated across New York and New Jersey. The investigation also resulted in the recovery of more than \$6.8 million in diverted prescription medications and more than \$4 million in alleged illegal profits from the scheme impacting the New Jersey's Medicaid program.
2022	New York	Two individuals pled guilty to using New York pharmacies to submit millions of dollars in fraudulent claims to Medicare, including during the COVID-19 pandemic. These fraudulent claims included claims for expensive cancer medications, Targretin Gel 1% and Panretin Gel 0.1%, that were not prescribed by physicians or dispensed to patients, and that were purportedly dispensed during periods when certain pharmacies were closed. Co-conspirators exploited the COVID-19 emergency for their own financial gain by using COVID-19-related "emergency override" billing codes to submit additional fraudulent claims for Targretin Gel 1%. To conceal over \$18 million of their criminal proceeds they funneled money through several shell companies, including sham pharmacy wholesale companies designed to look like legitimate wholesalers.
2022	New York	A pharmacy owner was sentenced to 78 months in prison for submitting claims to Medicare and Medicaid for prescription drugs that were not dispensed, not prescribed as claimed, not medically necessary, or that were purportedly dispensed during a time when the pharmacy was no longer registered with the State of New York. The fraudulent claims included claims for expensive prescription drugs for the treatment of the human immunodeficiency virus (HIV).
2019	New York	The Attorney General announced the arrests of a New York City pharmacy owner and three managers for participating in a \$10+ million-dollar Medicaid fraud scheme involving kickbacks and HIV drugs.

YEAR	CASE IN STATE	CASE SUMMARY
2019	New York	New York announced that the owner and pharmacist-in-charge of Nassau Pharmacy, Inc., will pay \$100,000 to resolve allegations of billing the federal and state governments for prescription drugs that were never dispensed.
2022	North Carolina	Federal court entered a consent decree that a pharmacy violated the Controlled Substances Act by dispensing opioids while disregarding numerous "red flags"—that is, obvious indications of drug abuse, drug diversion and drug-seeking behavior. For example, according to the complaint, the defendants filled prescriptions for dangerous combinations of drugs known to be sought by drug abusers and which significantly increase the risk of overdose; filled high-dose opioid prescriptions on a long-term basis; and filled prescriptions for patients who appeared to have "shopped" for doctors willing to prescribe controlled substances.
2021	Ohio	A federal court ordered a Toledo pharmacy and two of its pharmacists to pay a \$375,000 civil penalty and imposed restrictions related to the dispensing of opioids and other controlled substances. The complaint alleged that the defendants repeatedly dispensed opioids and other controlled substances in violation of the Controlled Substances Act by ignoring "red flags"—that is, obvious indications of drug diversion and drug-seeking behavior.
2019	Oklahoma	A federal judge has sentenced a pharmacy owner to over three years in prison and ordered payment of nearly \$1.1 million in restitution for a false claims scheme in 2019. The pharmacy owner falsified prescription information within the pharmacy's software program, then submitted those false claims to SoonerCare and Medicare Part D for drugs that were never prescribed or dispensed to patients.
2022	Pennsylvania	Owner of a Philadelphia pharmacy was charged for inappropriately dispensing oxycodone and other dangerous and addictive opioid drugs. In addition, the pharmacy submitted entirely fraudulent claims to health care benefit programs for prescription drugs not dispensed. These drugs were designated in patient profiles as "BBDF" which was an acronym for "Bill But Don't Fill." From 2013 through 2019, Medicare and other insurers paid over \$450,000 for these bogus claims.
2022	Tennessee	Two Florida pharmacy owners were convicted by a federal jury in Tennessee of conspiracy to commit health care fraud, 22 counts of mail fraud and introduction of a misbranded drug into interstate commerce. U.S. District Judge J. Ronnie Greer sentenced Bolos to 14 years in prison and ordered him to pay more than \$24.6 million in restitution and \$2.5 million in forfeiture in a case involving millions of dollars' worth of claims from private insurers such as Blue Cross Blue Shield of Tennessee, and public insurers such as Medicaid and TRICARE.
2021	Tennessee	Federal indictment alleges that a podiatrist and multiple in-house pharmacies prescribed and dispensed antibiotic and antifungal drugs to be mixed into a tub of warm water for patients to soak their feet that were not medically necessary. From in or around October 2018 to the present, Lucas allegedly caused his pharmacies to submit nearly \$4 million in claims to Medicare and TennCare for dispensing expensive foot bath medications that were not medically necessary and would not have been eligible for reimbursement.
2022	Texas	A pharmacy owner was charged in a federal indictment for a scheme that generated millions of dollars in payments for unnecessary, expensive prescriptions through bribes paid to prescribing physicians. During the time of the conspiracy, the indictment alleges that the pharmacy and its co-conspirators paid more than \$1 million in kickbacks and bribes and received more than \$10 million in reimbursements from insurance programs, including Medicare and Tricare.
2021	Texas	Indictment alleges call center's employees offered patients medically unnecessary diabetic supplies and topical creams although many refused the solicitations. However, a group of pharmacies allegedly billed the patients' insurance plan anyway. The indictment alleges that from Dec. 13, 2013 through March 3, 2020, the pharmacies collectively received over \$134 million in payments from Medicare and other health care benefit programs based on fraudulent claims.

YEAR	CASE IN STATE	CASE SUMMARY
2021	Texas	Three Houston-area pharmacists, a doctor, and a pharmacy technician were arrested for allegedly running three pharmacies and two clinics as "pill mills" distributing hydrocodone, oxycodone, and other controlled drugs without a legitimate medical purpose. They are alleged to have illegally sold around 2.25 million of the highest-strength short-acting hydrocodone and oxycodone pills commercially available.
2021	Texas	Thirteen defendants, including three compounding pharmacy owners, three physicians, two pharmacists, and three patient recruiters, pleaded guilty to a years-long, multi-state scheme to defraud the U.S. Department of Labor's Office of Workers' Compensation Programs (OWCP), and TRICARE. The defendants submitted false and fraudulent claims to the OWCP and TRICARE for prescriptions for compounded and other drugs prescribed to injured federal workers and members of the armed forces. The defendants also paid kickbacks to patient recruiters and to physicians to induce them to prescribe these drugs. The defendants chose the particular compounds and other drugs based not on the patients' medical needs but in light of the amount of reimbursement for the drugs. The drugs were then mailed to patients, even though the patients often never requested, wanted, or needed them.
2022	Wisconsin	Wisconsin announced a \$2,050,000 agreement with Milwaukee based Hayat Pharmacy to resolve allegations that a pharmacy submitted claims to Medicaid for iodoquinol-hydrocortisone-aloë, topical cream, that was not medically necessary and/or dispensed without a valid prescription. On average, the pharmacy was reimbursed over \$6,000 per tube of the topical cream.

ENDNOTES AND REFERENCES

- 1 Katherine Keisler-Starkey and Lisa N. Bunch, [Health Insurance Coverage in the United States: 2021](#), Census Bureau, September 2022
- 2 Grabowski, H., & Mullins, C. D. (1997). [Pharmacy benefit management, cost-effectiveness analysis and drug formulary decisions](#). *Social science & medicine*, 45(4), 535-544.
- 3 CVS Health, [Pharmacy benefits management](#); Greg O. Callahan, Marc Guieb, and Dustin Pollastro, [PBM Best Practices Series: Clinical programs and value-based decision-making](#), Milliman, May 2021
- 4 American Pharmacy Cooperative, "Audit Information," 2022; Tracie Acosta, [Pharmacy Audits What You Need to Know & How to Prepare](#), June 7, 2018
- 5 PBA Health, [8 Common Pharmacy Audit Issues](#), June 2021
- 6 Baranek, Devon, and Maria H. Sanchez. [The Tricare Fraud: A Case Study in Data Analytics for Healthcare Fraud Detection](#). *Journal of Accounting & Finance* (2158-3625) 18.8 (2018); Department of Justice, [The Health Care Fraud and Abuse Control Program Protects Consumers and Taxpayers by Combating Health Care Fraud](#), February 26, 2016; Miranda Hester, [Tips for Tackling PBM Audits With Your Staff](#), *Drug Topics*, November 8, 2022; Texas Health and Human Services Inspector General, [Data increases efficiency in the detection of fraud, waste and abuse](#), October 11, 2022; and Caryl Brzymialkiewicz, [What Role Does Data Play in Fighting Healthcare Fraud, Waste and Abuse?](#), HHS OIG, June 7, 2016
- 7 Loren Bonner, [Fighting for fair PBM auditing practices, state by state](#), *Pharmacy Today*, March 2015
- 8 Tracie Acosta, [Five Common Mistakes Made on Pharmacy Claims—And How to Avoid Them](#), October 10, 2019
- 9 CMS, [Control Practices to Improve Medicaid Program Integrity and Quality Patient Care—Booklet 4: Billing Practices](#)
- 10 Humana Pharmacy Solutions Audit and Claim Review Guide, December 2022; and Prime Therapeutics Provider Manual for Pharmacy Providers, Effective January 1, 2023
- 11 Notes: 1) Only a couple of States have a system in place to do this and this would only be in markets where the State has jurisdiction; and 2) Article 56A of Chapter 58 of the North Carolina General Statutes as amended by Session Law 2021-161 established a pharmacy compliant process, but to date no reports nor data have been publicly released.
- 12 Florida Agency for Health Care Administration, [Statewide Provider and Health Plan Claim Dispute Resolution Program](#), 2022
- 13 [Florida Statewide Provider and Health Plan Claim Dispute Resolution Program Annual 2021 Report](#); [Florida Statewide Provider and Health Plan Claim Dispute Resolution Program Annual 2020 Report](#); [Florida Statewide Provider and Health Plan Claim Dispute Resolution Program Annual 2019 Report](#); and [Florida Statewide Provider and Health Plan Claim Dispute Resolution Program Annual 2018 Report](#)
- 14 See case FL20-000022, available online at https://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Commercial_Managed_Care/docs/SPHPClaimDRP/AnnualReportJan-2020.pdf
- 15 A small pharmacy is defined for this purpose as one with no more than fourteen (14) retail outlets.
- 16 Washington State Office of the Insurance Commissioner, [Small Pharmacy Reimbursement Appeals information](#), 2022
- 17 Analysis of case files in 2021 for "Small Pharmacy Appeal" available online at <https://fortress.wa.gov/oic/consumertoolkit/search.aspx?searchtype=ord>
- 18 Timofeyev, Y., Hayes, S. A., & Jakovljevic, M. B. (2022). Predictors of loss due to pharmaceutical fraud: evidence from the US. *Cost Effectiveness and Resource Allocation*, 20(1), 1-11.
- 19 Analysis of HHS Office of Inspector General, September 2022 [Updated LEIE Database](#)
- 20 DOJ, [Two Pharmacy Owners Plead Guilty in COVID-19 Money Laundering and Health Care Fraud Case](#), November 2022
- 21 See, for example, [US v. Samuel Khaimov](#) et al and [US v. Marion Shun Lund](#) cases
- 22 [US v. Samuel Khaimov Indictment](#)
- 23 U.S. Attorney's Office, District of New Jersey, [Pharmacy Owner Sentenced to 41 Months in Prison for Role in Multimillion-Dollar Illegal Kickback Scheme and Evading Taxes on Over \\$33 Million of Income](#), November 3, 2021
- 24 [Grand Jury Charges in US v. Marriion Shaun Lund](#)
- 25 Maryland Attorney General, Attorney General Frosh Charges Prince George's County Pharmacist for Allegedly Operating a Pill Mill, May 2021
- 26 American Society of Health-System Pharmacists, [Alprazolam](#), 2022
- 27 State of Tennessee Department of Finance and Administration Request for Proposals for Pharmacy Benefits Management [RFP # 31786-00151](#)
- 28 California Medi-Cal Exhibit A, Attachment II—Scope of Work Operations—Quality Management & Program Integrity Rx [RFP 19-g6125](#); Request for Proposals for Pharmacy Benefit Management Services for Louisiana Medicaid Managed Care Organizations RFP #:3000018331, January 2022; New Jersey T2679 Employee Benefits: Pharmacy Benefit Management Bid Solicitation [Bid #19DPP00348](#); State of Wisconsin Pharmacy Benefit Program Agreement Issued by the Department of Employee Trust Funds On behalf of the Group Insurance Board, RFP Release Date: November 18, 2016
- 29 [42 CFR 423.504\(b\)\(4\)\(vi\)\(G\)](#)
- 30 [Prescription Drug Benefit Manual Chapter 9](#), Compliance Program Guidelines and Medicare Managed Care Manual Chapter 21—Compliance Program Guidelines
- 31 Executive Office of the President of the United States, Office of Management and Budget (OMB) [CIRCULAR A-136](#); Executive Order 13520 ([codified in 31 USC 3321](#))
- 32 [FY 2022 HHS Agency Financial Report](#)
- 33 Analysis of CMS data available online at <https://www.cms.gov/research-statistics-data-and-systems/monitoring-programs/medicare-ffs-compliance-programs/cert/additionaldata> and <https://www.cms.gov/research-statistics-data-and-systems/improper-payment-measurement-programs/medicare-part-d>
- 34 See, for example, [Medicare Advantage and Part D Program Audits](#); and the [Medicare Fee for Service Recovery Audit Program](#)
- 35 [FY2023 CMS Congressional Justification of Estimates for Appropriations Committees](#)
- 36 Illinois, Ohio, North Carolina, Florida, and Texas. See CMS, [Prior Authorization and Pre-Claim Review Initiatives](#) for more information. All other home health agencies are subject to audits from the CMS Unified Program Integrity Contractor (UPIC).
- 37 [CMS, Review Choice Demonstration for Home Health Services](#), Special Open Door Forum: November 27, 2018
- 38 CMS, [Review Choice Demonstration for Home Health Services Operational Guide](#), Updated May 25, 2022
- 39 See CMS, [Supporting Statement Part A Medicare Parts C and D Program Audit Protocols and Data Requests](#) (CMS-10191, OMB 0938-1000); CMS [2020 Timeliness Monitoring Project \(TMP\)](#) October 8, 2019 memorandum; CMS, [Continuation of the Prescription Drug Event \(PDE\) Reports and PDE Analysis Reporting Initiatives for the 2022 Benefit Year](#), April 29, 2022 memorandum; and CMS, [One-Third Financial Audits Overview](#)
- 40 CMS, [Supporting Statement Part A Medicare Parts C and D Program Audit Protocols and Data Requests](#) (CMS-10191, OMB 0938-1000)
- 41 Harini M. Bupathi, Esq., Dae Y. Lee, Pharm.D., Esq., CPBS, Jesse C. Dresser, Esq., [How Pharmacies Can Prepare for PBM Audits and Challenge Audit Results](#), *Drug Topics*, June 1, 2021
- 42 PAAS National, [Pharmacy Benefit Manager Audit Practices During a Public Health Emergency](#), March 26, 2021
- 43 IQVIA, [The Use of Medicines in the U.S.](#) 2022, April 2022
- 44 [Surescripts 2021 National Progress Report](#); and [Surescripts 2013 National Progress Report and Safe-Rx Rankings](#)
- 45 See, for example, Cardinal Health's [Prescription Editing Solution](#) and McKesson's [RelayRx Audit Intervention Service](#)
- 46 This is not a comprehensive list, but an illustrative set of recent cases.