

PBM Audit

Defending Pharmacies in PBM Audits

Pharmacy Benefit Manager (“PBM”) audits of pharmacies are a major profit center for PBMs. For over two decades, Frier Levitt has been fighting Pharmacy Benefit Managers (“PBMs”) on behalf of pharmacies, state and national pharmacy associations, and physician dispensers and has achieved immense success in retrieving and/or saving millions of dollars against PBM audits before all major PBM companies. We have handled a multitude of legal matters before major PBMs – including the big three (CVS Caremark, Express Scripts, and OptumRx) – during the pre-litigation dispute resolution procedure and in arbitration/litigation proceedings following the PBM audit. We have seen first-hand how onerous a PBM audit can be to you and your pharmacy.



Background

PBMs routinely conduct audits, whether it be on-site or desk-top audits, on member pharmacies. By and through such audits, PBMs are supposed to monitor pharmacies’ performance and to capture improper payments made to the pharmacies. However, PBMs often go beyond the intent of the audit and utilize audit as a source of revenue for themselves at the expense of independent pharmacies, plan sponsor, taxpayers, and most importantly, patients. PBMs clawback the entire amount of reimbursement on claims that were already dispensed by pharmacies. This not only causes significant financial harm, but also disrupts the pharmacy’s day-to-day business. PBMs have increasingly hired third party companies – such as SCIO, Xerox, Conduent or others – to conduct pharmacy audits. Many times, these companies are compensated based on the

amount of money they recoup on behalf of the PBM (thus, they are incentivized to find as many discrepancies as possible). They are given very little training and certainly are not made aware of applicable audit laws. Perhaps worst of all, these third party auditors can be exceedingly difficult to contact, creating challenges for pharmacies when responding to complex audits. Pharmacies should emphatically contest audit discrepancies and demand transparency from PBMs especially when the pharmacy provided sufficient documentation to overturn the discrepancies. We have an army of lawyers including clinician-attorneys prepared to take an aggressive approach to fight for your rights following the audit and in arbitration/litigation. Unlike other firms and consultants, Frier Levitt has absolutely zero conflicts when it comes to fighting PBM audits.

Common PBM Audit Types

Invoice Audits

When conducting invoice audits, PBMs generally examine limited types of claims submitted by a pharmacy in a particular timeframe. In an invoice audit, PBMs are looking to match purchase history of the pharmacy with the number of claims submitted by the

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Invoice Audits *Continued*

pharmacy. PBMs request the pharmacy to provide, through the wholesalers, invoices and purchase summaries. Despite the relatively uncomplicated nature of invoice audit, PBMs have used different tactics to discredit valid purchases made by pharmacies. One very worrisome tactic we recently uncovered involves “wholesaler’s license.” More specifically, one of the largest PBMs conducted a desk-top audit of an independent pharmacy and identified discrepancies, including drug invoice shortages. In response, the pharmacy provided invoices and purchase summaries that sufficiently addressed the alleged drug invoices shortages. However, in issuing final audit results, the PBM did not appear to take them into account. It was not until several further inquiries were made by this office that the PBM conceded that it needed a confirmation as to whether the wholesaler maintained a valid distributor license. Notably concerning, the PBM did not include “verification of wholesaler’s license” as the underlying basis of drug invoice shortages alleged in the audit.

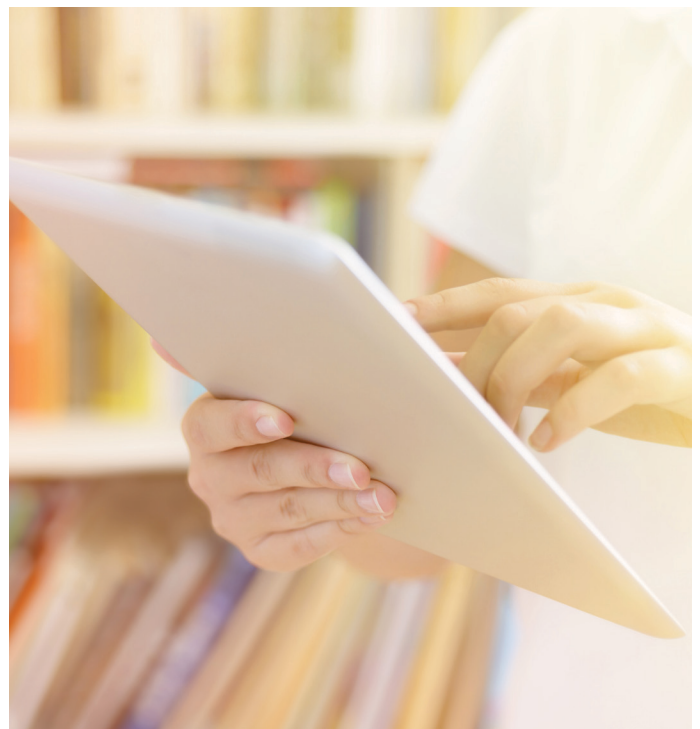
Another prominent issue that comes up during an invoice audit involves purchases for allegedly unauthorized wholesalers or distributors. PBMs have been conducting extensive purchase verifications and imposing discrepancies on all claims for products not purchased from a wholesaler listed as an “authorized distributor” on certain pharmaceutical manufacturers’ websites. Essentially, PBMs have refused to accept otherwise valid and lawful purchases from licensed wholesalers, and has instead, determined pharmacies to have insufficient inventory to support claims dispensed. PBMs have taken this draconian position even when a pharmacy maintains proper documentation to support the purchases, including invoices and proof of payment.

Prescriptions and Supporting Documentation

PBMs often demand pharmacies to provide documentation demonstrating that prescriptions were prescribed to treat patients’ underlying conditions/diseases (i.e., contemporaneous medical records taken by the prescriber). It is axiomatic that in virtually all instances, the doctor’s underlying medical records are not readily available to the pharmacies. If a pharmacy is unable to produce this information (which they are not legally required to obtain and which doctors are often uneasy about providing), the PBM may take back the full reimbursement for the prescription, even when the prescription is facially valid, consistent with state and federal law, and there is no doubt that the patient received his or her medication. Moreover, PBMs demand from pharmacies clinical studies or other scientific resources (e.g., peer-reviewed scientific articles) that would support the clinical bases of the prescriptions. Critically, PBMs demand such documentation (i.e., medical records, clinical studies, peer-reviewed articles) knowing that it will be difficult for the pharmacies to obtain the documentation and that the pharmacies are not required, under Federal/State laws and board of pharmacy regulations, to maintain such documentation as part of the pharmacy’s records. We fight these audits and often win.

In a similar vein, PBMs will often attempt to collect full reimbursement on prescriptions that were written or authorized by patients’ physicians alleging that the medications were prescribed for conditions not specifically approved by the Food and Drug Administration (“FDA”). This practice of “off-label”

prescribing enables healthcare providers to prescribe and authorize medications outside of the FDA-approved label to establish optimal patient care and makes up approximately 20% of all prescriptions in the United States. Denial of payment or reimbursement for off-label use can interrupt or effectively deny access to necessary and appropriate treatment for vulnerable patient populations. Such restriction on claims associated with off-label prescribing is wholly inconsistent with the practice of medicine and practice of pharmacy and may also violate several state laws.



Prescriber-Patient Relationship

PBMs have been penalizing pharmacies for dispensing claims without verifying valid prescriber-patient relationship. What constitutes a valid prescriber-patient relationship often varies from state to state, and is very heavily dependent on fact. Several factors can be viewed as “red flags” when assessing doctor-patient relationship, including the location of the patient relevant to his or her prescriber, or that the prescriber did not submit claims for a patient visit on or around the time the prescription was written. If a pharmacy is unable to provide documentation to reach the PBM’s threshold of a valid prescriber-patient relationship, PBMs will take back the full amount of reimbursement pay to the pharmacy on the prescription-drug claim even when the prescriptions were facially-valid, consistent with state and federal law, and when the patient had already received the medication. In addition, if the PBM reaches out to a prescriber or patient to valid a prescription, but receives a denial from the prescriber or patient, the PBM will allege the pharmacy did not dispense a valid prescription with appropriate authorization from the patient.

Copayment Collection

PBMs generally require pharmacies to collect copayment from patients at the point of sale. In the event a PBM has identified copay discrepancies, a pharmacy will be tasked with providing a significant amount of documentation to prove that the pharmacy collected the correct copayment at the point of sale, and in full. Thus, copay discrepancies are sometimes the most difficult to overturn. An additional obstacle to handling these discrepancies arises when determining how the copayment was paid. Typically, a pharmacy would be required to provide point-of-sale receipts or a front and back copy of the check used as payment as well as a patient attestation confirming the copay has been remitted. However, further requirements are asked of the pharmacy when payments are made in cash. In such circumstances, pharmacies are often required to provide bank statements showing cash deposits to “adequately” prove copay collection on top of the previously stated required documents. This practice of proving copayment collection can be overwhelming for pharmacies and patients who received the prescription sometimes years earlier.

Types of Audits That We Handle

Caremark Pharmacy Audit Defense

CVS Caremark (“Caremark”) is a Pharmacy Benefit Manager (“PBM”) wholly owned by CVS Health. As a PBM, Caremark has implemented vigorous Pharmacy Audits and Investigations including on-site audits, fraud waste and abuse investigations, desktop audits, and government agency audits. Unfortunately, Audits can lead to full recoupment on claims and other adversarial actions such as Payment Suspension, Adjudication Suspension and Pharmacy Network Termination. To make matters worse, Caremark is known for its onerous and timeconsuming credentialing/recredentialing and readmission procedures. Also, Caremark charges Direct-and-Indirect Remuneration (“DIR”) Fees to pharmacies based on the performance metrics created by Caremark.

OptumRx Pharmacy Audit Defense

OptumRx is a Pharmacy Benefit Manager (“PBM”) wholly owned by UnitedHealth Group. As a PBM, OptumRx maintains a network of pharmacy providers who service OptumRx’s patients. OptumRx monitors performance of their network pharmacies through various means including, without limitation, routine on-site and desktop audits. The Audit Findings may result in significant chargeback on prescription claims that were already dispensed by the pharmacies. Audit Findings can lead to Payment/Adjudication Suspension as well as Pharmacy Network Termination. It is also worth noting that OptumRx is well known for its enhanced credentialing/credentialing and readmission procedures. Therefore, it is imperative that pharmacies receive requisite counseling and assistance from Pharmacy Attorneys.



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Types of Audits That We Handle *Continued*

PBM Qui Tam Lawsuits

Pharmacy Benefit Managers (“PBMs”) have positioned themselves as the “middlemen” in the healthcare industry and have exerted significant influence over how Americans receive their prescription medications. Yet at the same time, PBMs have extraordinarily complex and mercurial business models, with multiple revenue streams, that often create conflicts with one another, and with their stated goal of saving the healthcare system money. By owning their own pharmacies (including chain pharmacies, mail-order pharmacies, and specialty pharmacies), PBMs often have perverse financial incentives when it comes to drug prices and billing to governmental healthcare payors, such as Medicare and Medicaid. As direct competitors of the pharmacies in their networks, PBMs routinely treat their pharmacies different than non- PBM owned/affiliated pharmacies, but not always in a way that benefits the ultimate payors. Finally, as middlemen, PBMs have become increasingly scrutinized in how they “pass along” to the government, the claims that are submitted by independent providers, and the representations made in the process.

Express Scripts Pharmacy Audit/FWA Defense

Express Scripts, Inc. and Medco (collectively “ESI”) operate one of the largest Pharmacy Benefit Managers (“PBM”) in the country. ESI monitors their network pharmacies’ performance mainly through Fraud, Waste and Abuse (“FWA”) investigations on behalf of its Plan Sponsor/Plan clients, one of which includes its parent company, Cigna. Many states have enacted Pharmacy Audit Laws that provide substantial protection to pharmacies from abusive PBM audit practices. However, by necessity, many of these State Pharmacy Audit Laws contain exceptions permitting more aggressive PBM action where the PBM is investigating FWA. We have spotted a trend whereby nearly all PBM audits are “in the name of FWA” investigations. Pharmacies must understand their rights to challenge FWA investigative findings.



Implications Outside of PBM Audit

Network Termination

Often, many pharmacies allow PBM audit findings to go uncontested due to smaller claw back amounts. Even if a PBM audit does not result in adverse action beyond the recoupment of monies from the pharmacy, PBMs keep track of their network pharmacies’ audit histories. Increasingly, PBMs are using prior audit results as justification to terminate the pharmacy years later after the pharmacy has another adverse audit finding. Though the smaller amounts may not seem “worth” disputing, failure to do so may serve as the basis for network termination by a PBM somewhere down the road.

Cross-Termination

There is a growing trend of pharmacies that are being terminated from pharmacy networks by PBMs due to the pharmacy’s affiliation with providers who have been previously terminated from the PBM’s pharmacy network in connection with unrelated pharmacies. PBMs are targeting pharmacies that have relationships with terminated individuals or pharmacies. This means that your pharmacy could be subject to termination if it has common ownership, hired employees, or maintains officers, directors, or even family members who have all been terminated from the PBM’s pharmacy network in an unrelated matter.

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Implications Outside of BPM Audit *Continued*

Reporting of Audit Findings to Government Agencies

PBMs have previously reported findings, often those associated with suspected fraud, waste, or abuse to state and federal agencies. PBMs also make complaints or refer a pharmacy to a state or federal Agency for reasons that are more closely associated with contractual violations than any violation of state and/or federal rules and regulations that might otherwise justify a complaint. For example, recently, a PBM filed a complaint against a pharmacy with the pharmacy's State Board of Pharmacy for reasons largely associated with contractual violations, such as relatively minor audit discrepancies based on the PBM's own terms and conditions, mailing claims to patients under a retail contract, and alleged failures to disclose common ownership.

Frier Levitt's Results Against PBMs

Frier Levitt has, on numerous occasions, obtained injunctive relief against PBMs prohibiting the PBM from retracting monies from pharmacies, and/or terminating pharmacies from PBM networks. The unchecked, unregulated and abusive audit practices by PBMs must be contested and placed under scrutiny within the boundaries of the law such as fair audit laws that are meant to provide certain levels of protection against abusive audit practices. Meanwhile, the pharmacies should implement policies and procedure, which Frier Levitt can tailor for each pharmacy, in anticipation of the PBM audits. Otherwise, independent pharmacies will continue to dwindle, and the patient care will be dictated by PBMs.

Regardless of the size of your pharmacy or the amount at stake, Frier Levitt is ready to assist you in successfully challenging the audit. If you have questions or need help with a PBM Audit, contact Frier Levitt to speak to an attorney.

