AstraZeneca's Recent Round of Letters to Pharmacies Expands Farxiga Dispensing and Billing Review — What Pharmacies Need to Know Now

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Earlier this year, biopharmaceutical company AstraZeneca issued notices to pharmacies regarding data discrepancies concerning Farxiga. AstraZeneca's notices requested pharmacies to provide detailed documentation and information relating to their dispensing and purchasing of Farxiga during 2024. Notably, on January 3, 2024, the generic dapagliflozin was introduced to the market. Now, with generic versions available, it is clear from AstraZeneca's request that there is increased scrutiny and concern regarding pharmacies' dispensing and purchasing practices of Farxiga, including questions about whether such pharmacies dispensed Farxiga or its generic equivalent, dapagliflozin. Pharmacies that receive these communications from AstraZeneca should understand their obligations to respond and should seek legal counsel with experience handling these and similar notices from manufacturers.

Pharmacies across the country continue to receive correspondence from AstraZeneca and its representatives regarding alleged dispensing and billing discrepancies related to Farxiga. In successive rounds, these letters have asked pharmacies to explain perceived mismatches between what was billed and what was dispensed and to produce supporting documentation on short timelines. The latest wave indicates that AstraZeneca is extending its review window into 2025 and will be seeking additional detail to reconcile those purported mismatches. This development raises renewed operational, financial, and compliance considerations for pharmacy owners.

Background and What's New

In prior rounds, AstraZeneca notified pharmacies that it identified potential "dispensing discrepancies" on Farxiga claims after comparing claims-level data to purchase histories. The letters generally assert that certain claims may reflect inconsistencies in strength, quantity, days' supply, or NDC usage, and request an explanation supported by records. Pharmacies were asked to respond with clarifying documentation, and to address specific claims or date ranges identified by the manufacturer.

What the letters typically request:

- Purchase documentation sufficient to reconcile dispensing to wholesaler invoices for the relevant period.
- Dispensed quantities of Farxiga during the relevant period

While framed as fact-finding, these requests have practical implications. Whereas the previous letters issued in July 2025 focused only on a review of claims submitted and purchases made in 2024, the newest communications broaden the review period into 2025 and, in some instances, ask for more granular proof, including the identification of certain claims that were "affected" by any purported misbilling.

Pharmacies should treat these letters as formal inquiries requiring careful consideration of whether and how to respond.

Key Risk Areas Emerging from Recent Letters

Recent letters and pharmacy experiences reveal recurring pressure points that can drive "discrepancy" findings:

- **NDC selection and product interchangeability.** Even when therapeutically equivalent, claim-level NDCs must reflect the actual product dispensed. Mismatches between NDCs on a pharmacy's inventory and NDCs billed and submitted—often arising from software defaults or product unavailability—are frequent triggers. This is particularly concerning when a pharmacy dispenses a generic medication but bills the brand name medication, which could result in higher reimbursement or could circumvent plan limitations.
- **Prior authorization, step therapy, and DUR overrides.** Where clinical or payor exceptions are used, missing pharmacist notes, prescriber confirmations, or DUR documentation can create the appearance of noncompliant

dispensing or billing.
- **Purchase-to-dispense reconciliation.** Disparities between wholesaler purchase histories and patient-level dispensing records—especially in periods of backorders, substitutions, or inventory transfers—invite deeper inquiry.

Immediate Actions for Pharmacies Receiving Letters

Pharmacies that receive an AstraZeneca letter should move quickly and methodically. First, pharmacies should calendar all response deadlines and confirm the date of receipt. Second, they should carefully parse the scope of the request, including the claim date ranges, specific patients or prescriptions at issue, and any itemized data fields sought. Third, pharmacies should assemble a clean documentation package tied to each queried claim, including the original prescription image, e-prescription data, pharmacist verification records, label copy, fill logs, patient counseling notes, DUR override justifications, signatures (where applicable), and any communications with the prescriber. Fourth, pharmacies should verify that the NDC on the patient label and fill record matches the NDC billed; if a different but therapeutically equivalent NDC was used at the time of claim submission due to availability or other reason, understand why that might have occurred. Finally, pharmacies should reconcile wholesaler purchase reports with the dispensing history for the period in question, addressing any backorders, substitutions, or transfers to explain gaps.

As it relates to a response to AstraZeneca, pharmacies should understand their obligations to respond, particularly where there is no contractual relationship with AstraZeneca, but they should also consider the practical considerations in not providing a response.

Understanding the Obligation to Respond

There may be several reasons why AstraZeneca is issuing this request to pharmacies—it may relate concerns about lost rebates, policing of the market, prevention of potential fraud, waste, or abuse related to the medication at issue, etc. While there may be several areas of concern, pharmacies should be aware of their obligation to respond to AstraZeneca and importantly, the potential consequences of providing information to AstraZeneca. Not only could pharmacies experience an adverse action from AstraZeneca, but also from PBMs and government agencies. It is clear that this request could impact a pharmacy's relationship with third-parties, including PBMs and regulatory agencies, such as a State Board of Pharmacy, CMS, etc.

With the review horizon now extending into 2025, pharmacies should treat each letter as part of a broader risk-management program. If a manufacturer's characterization of a discrepancy appears to misinterpret payor rules, plan overrides, or clinical justifications, and result in higher reimbursements, suggesting financial incentives, then pharmacies should be especially cautious in crafting their response and how they engage with AstraZeneca.

Minimizing Disruption and Financial Exposure

These inquiries can consume staff time and introduce cash-flow pressure if they lead to clawbacks or payment holds by stakeholders who later rely on manufacturer findings. Pharmacies that receive multiple letters or requests where their review now extends to 2025 may face additional exposure. Pharmacies that have implemented corrective action measures upon receipt of the July 2025 notices have faced less risk where AstraZeneca has otherwise confirmed the pharmacy's compliance and resolution. Nevertheless, pharmacies receiving these notices are being asked to identify affected claims and resolve them directly with PBMs, an extremely difficult, if not impossible, task without likely escalating the matter.

Outlook

AstraZeneca's communications to pharmacies demonstrate a pattern of manufacturers conducting their own reviews into pharmacies' compliance with billing and purchasing requirements. Pharmacies should ensure they are submitting accurate drug product information, including name and NDC at the time of claims submission, and should ensure they maintain sufficient purchases to support claims billed. Pharmacies that receive inquiries should have a prompt, thoughtful strategy at the outset, as it can materially affect the trajectory and outcome of the review.

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