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Client Alert: Pharmacies Receiving Manufacturer Document Requests

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Pharmacies operate in regulatory minefields, subject to various federal and state laws, with additional responsibilities imposed via PBM provider manuals. And it is no secret that audits play a key role in assuring a pharmacy's compliance. While the typical audit is performed by a federal payor (Medicare or Medicaid) or a PBM, manufacturers have recently entered the audit arena, requesting documents from pharmacies to assure proper billing and dispensing of that manufacturer's brand name drug.

Brand name drugs that become generically available are ripe for these types of audits. Regardless of *why* the manufacturers are conducting these audits, and not the PBMs (rebates), the implications are concerning for pharmacies. First, it is one more quasi-regulatory entity to comply with. Second, it has become clear that pharmacy data is being shared both horizontally (to other payors) and vertically upstream (to manufacturers).

Pharmacies found to be improperly billing and dispensing can face several consequences. Manufacturers can terminate the pharmacy if enrolled in a co-pay assistance program. With this data in hand, manufacturers could report any discrepancies to enforcement agencies if a state or federal network is implicated.

With that being said, best practices for a pharmacy continue to be to self-audit. Whether the plan only covers brand or requires the newly available generic, pharmacies must continue to bill and fill the correct NDC and substantiate purchasing inventory for the brand name drugs across all payors.

If your pharmacy has been contacted by a manufacturer seeking information from the pharmacy, you should speak with legal counsel immediately. Contact Angelo Cifaldi and Joseph Carlo regarding possible legal representation.

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Practice
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