CLIENT ALERTS & INSIGHTS

Seventh Circuit Holds Drug Manufacturer's AMP Reporting Violated False Claims Act by Excluding Post-Sale Price Increases

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What Happened:

- Relator Ronald Streck filed suit under the False Claims Act (FCA) asserting that Eli Lilly falsely under-reported its Average Manufacturer Price (AMP) for Medicaid by excluding "price increase values" (sometimes called "clawbacks") that wholesalers were required to remit back to Lilly when Lilly raised drug prices after initial wholesale sales but before those wholesalers sold to pharmacies.
- Between 2005-2017, Lilly's practice was to report only the initial price paid by wholesalers, not the subsequent "price increase value" that wholesalers handed back to Lilly. This had the effect of lowering Lilly's AMP and thereby reducing its Medicaid rebate obligations.
- A jury found in favor of Streck, awarding substantial damages, which were trebled under the FCA. Lilly appealed.

What the Seventh Circuit Held:

- **AMP Calculation Must Include Price Adjustments That Manufacturers Actually Realize**
  The court concluded that Lilly's exclusion of the price-increase values from its AMP was not permissible. The statute, regulatory history, and Lilly's agreement with Medicaid made clear that adjustments to prices "actually realized" must be included in AMP, even if those adjustments occur after initial sale to wholesalers.
- **"Bona Fide Service Fee" Exclusion Did Not Cover the Clawbacks**
  Lilly attempted to classify the price increase values as part of a "bona fide service fee" under the statute, which might justify excluding them. But the court found that they did not satisfy the statutory test: among other things, the price increases were passed through to retail pharmacies, and the mechanism was not equivalent to a service fee paid by Lilly to wholesalers under the statute.

- **Falsity, Materiality, and Scienter Were Supported**
  - **Falsity**: Lilly's AMP certifications were objectively false as a matter of law because its exclusion practice was contrary to the plain statutory requirements.
  - **Scienter**: The jury reasonably found that Lilly knew (or was recklessly ignorant of) the falsity. Lilly had engaged in practices (e.g. submitting explanations, internal modeling, changing its methodology in 2016) that the court determined supported a finding of "knowingly" under FCA standards.
  - **Materiality**: The misreported AMPs had a significant monetary effect in reducing rebate obligations-over $60 million-while Lilly derived hundreds of millions in revenue from the excluded values during the relevant period. The court upheld the materiality finding.

Why It Matters:

- **Precedent on AMP Reporting**: This decision clarifies that manufacturers under Medicaid cannot exclude post-sale price adjustments (which they in fact receive) from AMP merely by treating them as fees or adjustments outside the "price actually realized" calculation.

- **Limits on "Reasonable Assumptions" Defense**: While regulations and prior agreement permitted "reasonable assumptions" in ambiguous areas, the court held Lilly's assumptions here were not reasonable because the law was sufficiently clear in the relevant respects.
- **Compliance Implications**: For manufacturers and others subject to reporting obligations under federal healthcare reimbursement programs, this decision underscores risks of aggressive interpretations of exclusions. Practices that reduce reported rebates or obligations-if not squarely supported by statute/regulation/agreement-can lead to substantial FCA liability.

Benesch is here to assist your organization in assessing FCA risk and navigating proactive compliance strategies, including the regulations and enforcement policies that come with it. If you have questions regarding the FCA and government investigations related thereto, or enforcement actions more generally, the White Collar and Healthcare+ Practice Groups at Benesch are here to help.