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Will Usual and Customary Price be the Next False Claims Act Battleground?

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Recently, a federal judge held that a *qui tam* relator's allegations that a pharmacy routinely reported falsely inflated "usual and customary" prices for generic medications in claims submitted to federally funded health care programs, was sufficient to state a cause of action under the federal and certain state false claims acts. In an order denying the pharmacy's Motion to Dismiss, the Court found that while the relator had not proven his allegations, he had plead with sufficient particularity the who, what, when and why of the alleged fraud.

Pharmacy claim forms contain a field for the pharmacy to submit its "usual and customary" price for the medication at issue. That price may be taken into consideration by federally funded health programs in processing and paying claims for the medication. The Court found that because that price appears on the face of the claim, the assertion of falsity was not based on any implied certification theory. Further, the relator provided enough details regarding the structure of the Medicaid, Medicare and Tricare systems and the impact that the alleged falsity had on the processing of claims, to pass muster under Rules 9(b) and 12(b)(6).

While practitioners may leap to the conclusion that allegations of false usual and customary charges make *per se* FCA cases, the issue of usual and customary charges presents challenges in false claims enforcement. Why?

- Not all government programs use "usual and customary" prices as a factor in processing and paying pharmacy claims in the same way.
- The definition of what actually constitutes a "usual and customary" price may vary significantly from program to program, or from program contractor to program contractor.
- When it comes to Medicaid, the applicable definition of what actually constitutes a usual and customary price may vary significantly from state to state.

Practitioners are advised to carefully examine the applicable regulations in all programs and all states at issue when confronting alleged false claims based on usual and customary prices.

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Theresa advises clients on all aspects of the pharmaceutical supply chain, including counseling industry stakeholders on a range of business, legal, transactional, and compliance matters. She provides clients with strategic counseling and creative business modeling that considers legal restrictions and regulatory risk in light of innovation and business goals.