

Morgan Lewis

Minimizing FCA Liability Attaching to Price Reporting when Making Reasonable Assumptions

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FCA

- A. Purpose – to attach civil monetary penalties to actions resulting in overpayments by the Federal government, or actions aimed at improperly reducing payments owed to the Federal government.

FCA (Cont.)

B. Elements

1. Scierter (includes reckless disregard)
2. Falsity
3. Existence of a claim, or omitted information
4. Materiality

FCA Implications for Price Reporting

A. Reductions in liability and increases in overpayments

1. Medicaid Drug Rebate

- a. Potential to minimize rebate liability through improperly small URA
- b. Potential to have Federal upper limit improperly high

2. ASP – potential for improperly high reimbursement rate

3. 340B not an issue because not the government's money

How can price reporting implicate the FCA? *(cont.)*

B. Cases

1. *Streck*. Allegations that fees paid to distributors, such as distribution services, data reporting services, and inventory management, were treated as discounts, rather than as bona fide service fees. The purported false claim arises from the reduction in the URA. Lawsuit is ongoing.
2. *Sanofi*. Samples given in lieu of reductions in price, so as to maintain ASP pricing for Hyalgan. Settlement is \$109 million.
3. *Amgen*. Claims of free Aranesp given as “overfills” that distorted ASP. Settlement for \$760 million for multiple issues.

FCA Implications for Price Reporting (*cont'd.*)

B. Cases (cont.)

4. *Schering*. Offer to buy “data” from payers regarding Claritin, rather than give deeper rebates, to protect best price. \$345.5 million settlement. [not under the FCA]
5. *Merck*. Allegations of mistreatment of deep discounts as “nominal pricing” excluded from best price considerations for sales of Pepcid to hospitals. Settlement was for \$250 million.
6. *Dava*. Purported mistreatment of cefdinir, clarithromycin, and methotrexate as generic drugs, rather than as branded drugs, so as to reduce MDRP rebate liability. \$11 million settlement.

FCA Implications for Price Reporting (*cont.*)

B. Cases (*cont.*)

7. *Aventis*. Purported misconduct entailed not paying rebates on Azmacort and Nasacort that were sold under a private label to Kaiser. \$95.5 million settlement.
8. *GSK*. Purported failure to properly account for nominal pricing. \$300 million settlement.

Due inquiry

A. Triggers

1. Unique transaction that has not been encountered previously or memorialized in policy or SOP, and for which there is no agency guidance
2. Discovery of inconsistent treatment of similar transactions
3. Evidence of technical errors, rather than just lagged pricing information
4. Indications that legal authorities have been misinterpreted or omitted from consideration
5. Unsatisfactory audit report
6. Any allegations of intentional misconduct

Due inquiry (*cont.*)

B. Manner of conduct

1. Factual inquiry (documents and interviews)
2. Review of legal authorities
 - a. Statute
 - b. Regulations
 - c. Federal Register
 - d. Medicaid Drug Rebate Agreement
 - e. Medicaid Drug Rebate Releases
3. May be prudent to protect under attorney-client privilege

Due inquiry (*cont.*)

C. Possible follow-up actions

1. Nothing

- a. No action would be necessary if it is concluded that neither the letter nor the spirit of the law has been violated
- b. May still choose to write a memorandum to the file to be kept with the other price reporting materials

2. Reasonable assumptions letter

- a. If the law is silent, but subject to multiple reasonable interpretations, especially if there are conflicting policy concerns
- b. If there are conflicts in the law, but the support for the company's position is derived from the higher level of authority

Due inquiry (*cont.*)

C. Possible follow-up actions (*cont.*)

3. Refile data

- a. If there is a clear error
- b. If there is a reasonable argument that there was an error, and it resulted in a reduction in the company's liability

4. Make a disclosure

- a. Appropriate when there appears to be evidence of either willful action or gross negligence
- b. Should be accompanied with a recalculation, if appropriate

“Reasonable Assumption” Letter

A. Guidance

1. It is a letter that explains why the manufacturer’s treatment of its price reporting data is consistent with the law, regulations, and customary business practices “in the absence of specific guidance”
2. Note that CMS has expressly stated that manufacturers are not to rely on the withdrawn AMP rule
3. Assumptions letters “should” be submitted for ASP
4. In a proposed rule, CMS stated that manufacturers “must” maintain a written or electronic record of their assumptions

“Reasonable Assumptions” Letter (*cont.*)

B. Protection Offered

1. If complete, the letter would defuse any argument that the company “concealed” its liability
2. To be effective, assumptions must be reasonable

“Reasonable Assumptions” Letter (*cont.*)

B. Contents

1. Key facts

- a. Nature of the product (unit, method of dispensing, distribution chain)
- b. Nature of the transactions at issue
- c. Any prior communications with the agency regarding the product

2. Applicable law, including any conflicting guidance

3. Company’s interpretation of law

Disclosure Letters

- A. A disclosure letter differs from a reasonable assumptions letter, in that it explains facts that could point to a violation of law
- B. Protection offered
 - A. As with a reasonable assumption letter, it provides some insulation for the company against claims of concealment

Disclosure Letters *(cont.)*

B. Protection offered *(cont.)*

2. The strength of the protection will vary based on:
 - a. The thoroughness of the internal investigation
 - b. Extent to which the conduct at issue reached to the highest levels
 - c. The effectiveness of the compliance program to detect the conduct early on
 - d. The extent to which the company had proper policies in place, such that it is apparent that the conduct was the result of a “rogue” employee
 - e. The extent to which the company rectifies the matter both retrospectively and prospectively

Disclosure Letters *(cont.)*

C. Contents of the disclosure letter

1. Description of how the matter was uncovered
2. Description of the steps taken to quantify the error
3. Description of the steps taken to rectify the matter
4. Undertakings to avoid a repeat of the error
5. Need to draft the letter carefully, so as to avoid the waiver of attorney client privilege for the internal investigation