

# Under Scrutiny:

## SHB's Government Enforcement & Compliance Update

DECEMBER 19, 2008



### COURT ISSUES BLOW TO "INFLATIONARY IMPACT" THEORY IN FCA MEDICARE CASE

The U.S. District Court for the Northern District of Illinois joined a growing consensus of courts in applying a materiality requirement in a False Claims Act (FCA) case involving Medicare claims. *U.S. ex. rel. Kennedy v. Aventis Pharm.*, 2008 U.S. Dist. LEXIS 100444, Dec. 10, 2008.

Judge Matthew Kennelly held that individual charges submitted on a particular Medicare claim are not material to the government's decision to pay, when payment is based on a diagnosis related group (DRG). The court also dealt a major blow to the relators' inflationary impact theory, a new theory advanced by the government in similar cases, holding that false statements on cost reports must be tied to particular claims to be actionable. So ruling, the court granted the defendant's motion to dismiss.

The relators in *Kennedy* alleged that Aventis Pharmaceuticals violated the FCA by marketing off-label uses of the drug Lovenox, thus causing hospitals to submit false claims to Medicare for reimbursement. Relators also alleged that Aventis caused hospitals to submit false cost reports, when those cost reports itemized an off-label use of Lovenox. According to relators, the cost reports are used to calculate DRG payments for future years; therefore Aventis was allegedly causing future DRG payments to be inflated.

Aventis argued in its motion to dismiss that even if the claims filed for individual patients did include a charge for Lovenox for an off-label use, such charge was not material to the government's decision to pay the claim. Aventis also argued that any falsity in a cost report would only affect outlier payments, as the cost reports were used only to calculate cost-to-charge ratios in outlier payments.

#### GOVERNMENT ENFORCEMENT & COMPLIANCE

Our clients face unprecedented enforcement scrutiny and novel legal theories. Today, government enforcement actions can include civil as well as criminal investigations and litigation. They can involve a host of independent actors including federal and state prosecutors, regulators, whistleblowers and their counsel, and class-action attorneys. These cases must be defended under the watchful eye of investors and the public.

Our Government Enforcement & Compliance Practice consists of former prosecutors -- including a former U.S. Attorney, former Justice Department officials and even former corporate executives -- who counsel and defend companies, their executives and employees in the full range of criminal, civil and regulatory government enforcement actions at the state and federal level. We counsel clients on how to avoid enforcement scrutiny. When investigations do arise, however, we work with our clients to resolve it as efficiently, cost-effectively and quietly as possible.

### ***Kennelly Agrees with Other Courts that Apply a Materiality Requirement***

Several circuits, including the Seventh, have incorporated a materiality requirement into the FCA, requiring that the false claim, statement or record must be material to the government's decision to pay. Accordingly, some courts applying the materiality requirement to Medicare claims under prospective payment systems have found that an individual charge on a claim for payment is not material to the government's decision to pay.

Judge Kennelly, agreeing with these courts, found that the off-label uses of Lovenox included on a patient's "bill" to Medicare did not cause the government to pay any more than it would have had the charges not been included. Because payment was based on a DRG, there was no causal relationship between the alleged falsehood and the amount the government paid. Thus, relators could not prove an essential element of their claim.

### ***When Cost Reports Are Deemed False Claims, Records and Statements***

Cost reports have been held to be false claims when payment is conditioned on a cost report. In this case, however, relators alleged that cost reports were instead false records or statements made to get false claims paid because they included items that would cause future DRG rates to be inflated. The court flatly rejected this theory.

Although the parties disputed whether cost reports were used to calculate DRGs, even assuming cost reports are used to set DRGs, the court found that the connection between any allegedly false statements on a cost report and the government's decision to pay (an increased DRG) was too attenuated to be material. The court reasoned that because a DRG is a prospective rate—an estimate of treatment costs for the following year—the cost report can only affect future DRGs.

Furthermore, the calculation of DRGs is so complex and includes so much data that a single hospital's cost report, or even those of several hospitals, comprises a very small portion of the data used in the decision to increase or decrease a particular DRG. Finally, as the FCA imposes liability only when a false statement or record is used "to get" a false claim paid, relators needed to connect the allegedly false cost reports with particular claims. As relators were unable to show that the cost reports were false records or statements used to support any particular claim, they failed to allege that an individual cost report was material to the payment of any given claim.

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The *Kennedy* case, when read in conjunction with the U.S. Supreme Court's decision earlier this year in *Allison Engine Co., Inc. v. U.S. ex. rel. Sanders*, emphasizes the increasing vulnerability of FCA cases where the plaintiffs cannot establish that a false claim is material to government's decision to pay and that any false record or statement was made with the intent "to get" a false claim paid.

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