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Client Alert

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First Circuit Reverses District Court Dismissal of False Claims Case against Device Maker

On June 1, 2011, the First Circuit reversed a district court dismissal of a False Claims Act (FCA) action against a medical device manufacturer that had allegedly paid kickbacks to physicians inducing the use of its products.[1]

The Relator's Allegations

The Relator alleged that the device manufacturer paid kickbacks to doctors so they would use its products in certain spinal surgeries in violation of the Anti-Kickback Statute (AKS). The Relator alleged that as a result of the kickbacks, doctors performed spinal surgeries on Medicare and Medicaid patients using the manufacturer's devices. The Relator argued "that through its kickback scheme, the [device manufacturer] 'knowingly cause[d]' healthcare providers to present 'false or fraudulent' claims for payment to federal healthcare programs."[2]

The First Circuit Decision

A. A claim may be false or fraudulent due to an implied representation of compliance with a precondition of payment that is not expressly stated in a statute or regulation.

The relator claimed that the device manufacturer caused the submission of claims by physicians and hospitals that were false or fraudulent because these claims certified compliance with the AKS. The device manufacturer argued, and the district court held, "that implied conditions of payment can only be found in statutes and regulations, and that these sources must expressly state the obligation."[3] The First Circuit rejected both requirements.[4] The First Circuit held that the position "that only express statements in statutes and regulations can establish preconditions of payment is not set forth in the text of the FCA."[5] In response to the argument that its holding would extend too far the breadth of the FCA, the Court noted that "[t]he text of the FCA and our case law make clear that liability cannot arise under the FCA unless a defendant acted knowingly and the claim's defect is material."[6]

1 *United States ex rel. Hutcheson v. Blackstone Medical Inc.*, No. 10-1505 (1st Cir. June 1, 2011).
2 *Hutcheson* at 7.
3 *Id.* at 20.
4 *Id.*
5 *Id.* at 23.
6 *Id.* at 24.

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B. Liability under the FCA may exist for causing the submission of false or fraudulent claims even though the submitting entity does not know of the underlying falsehood or fraudulence.

The Relator alleged that the claims submitted by the hospital were false because the device manufacturer's violation of the AKS rendered the hospital's implicit certification of compliance with the AKS false. The device manufacturer argued that a hospital's truthful certification of its own legal compliance is not "rendered false 'by the acts of an unrelated third party somewhere in the supply chain.'"[7] Rejecting this argument, the First Circuit stated:

> *The categorical limitation [the device manufacturer] advances does not appear in the text of the statute and is inconsistent with both the statutory text and binding case law. The FCA imposes liability on any person who "knowingly presents, or causes to be presented" to the government "a false or fraudulent claim for payment or approval," 31 U.S.C. § 3729(a)(1) [emphasis added], or "knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government,"* id. *3729(a)(2) [emphasis added]. When the defendant in an FCA action is a non-submitting entity, the question is whether that entity knowingly caused the submission of either a false or fraudulent claim or false records or statements to get such a claim paid. The statute makes no distinction between how non-submitting and submitting entities may render the underlying claim or statements false or fraudulent.*[8]

The First Circuit added that "[t]he Supreme Court has long held that a non-submitting entity may be liable under the FCA for knowingly causing a submitting entity to submit a false or fraudulent claim, and it has not conditioned this liability on whether the submitting entity knew or should have known about a non-submitting entity's unlawful conduct."[9]

Rejecting the device manufacturer's concerns that such a holding would unduly expand the reach of the FCA, the Court held:

> *First, we cannot rewrite statutes. Second, the policy concerns are overblown. Only persons who knowingly submit or cause the submission of a false or fraudulent claim can be held liable for violating the FCA. The term "causes" is hardly boundless; it has been richly developed as a constraint in various areas of the law.* See, e.g., *W. Page Keeton et al.,* Prosser and Keeton on Torts *§ 41-44 (5th ed. 1984) (discussing causation in tort law).*[10]

7 *Id.* at 26.
8 *Id.* at 27.
9 *Id.* at 28.
10 *Hutcheson* at 32.

C. *The Provider Agreements and Hospital Cost Report forms sufficiently identified AKS compliance as a precondition to payment.*

The device manufacturer argued that, with respect to hospital claims, the Provider Agreement and Hospital Cost Report forms did not identify the precondition of compliance with the AKS with sufficient specificity to render the claims at issue false or fraudulent. With respect to the physician claims, the device manufacturer argued that while the Provider Agreement represented physician compliance with the AKS, this representation extended only to claims actually induced by kickbacks.

The First Circuit held that the language of the Provider Agreement "makes clear that the federal Medicare program will not pay claims if the underlying transaction that gave rise to the claim violated the AKS."[11] According to the Court, this prohibition against payment applies when the "'underlying transaction' violated the AKS because of the actions of a third party like [the device manufacturer]."[12] The First Circuit further found that the language of the Hospital Cost Report "makes it abundantly clear that AKS compliance is a precondition of Medicare payment and makes no exceptions for violations caused by third parties like [the device manufacturer]."[13] Accordingly, the First Circuit held that the Provider Agreement and Hospital Cost Report "are more than specific enough to make clear that the claims submitted by hospitals represented that any underlying transactions had not involved third party kickbacks prohibited by the AKS."[14] Similarly, the First Circuit held that the "Provider Agreement is also sufficiently clear to establish that the claims submitted by physicians represented that the underlying transactions did not involve kickbacks to physicians prohibited by the AKS."[15]

D. *The alleged hospital and physician misrepresentations regarding AKS compliance were sufficiently material to support the FCA claim.*

The device manufacturer argued that the payment mechanism for hospitals rendered any AKS non-compliance irrelevant to the payment of hospital claims. The device manufacturer noted that hospitals "classify patients within 'diagnostic-related groups' (DRGs) and receive a set payment for treating patients in a group regardless of the particular services provided."[16] With respect to physician claims, the device manufacturer noted that "physicians submitted claims for their services conducting medically necessary surgeries, not for the devices allegedly used because of [its] kickbacks."[17]

In response, the First Circuit stated:

> *If kickbacks affected the transaction underlying a claim, as [Relator] alleges, the claim failed to meet a condition of payment. [The device manufacturer's] argument that Medicare would excuse these violations because of a bureaucratic mechanism or because of an implicit medical necessity requirement*

11 *Id.* at 35.
12 *Id.*
13 *Id.* at 35-36.
14 *Id.* at 36 (emphasis in original).
15 *Id.* (emphasis in original).
16 *Id.* at 38.
17 *Id.*

> *impermissibly cabins what the government may consider material. Neither the Provider Agreement nor the Hospital Cost Report forms speak of such exceptions recognized by Medicare. We find [Relator's] allegations sufficient to show, for purposes of this motion to dismiss, that the kickbacks were capable of influencing Medicare's decision as to whether to pay the hospital and physician claims.*[18]

Therefore, the Court concluded that it could not conclude as a matter of law that the alleged misrepresentations were immaterial to the payment of claims.

For a copy of the First Circuit decision, please click here.[19]

18 *Id.* at 39.
19 http://www.agg.com/media/interior/publications/Rissler-First-Circuit-Reverses-District-Court-Dismissal-link-hutcheson-case.pdf