KING & SPALDING

Client Alert

Insurance Coverage & Recovery Practice Group

February 27, 2013

Insurance Coverage for Healthcare False Claims Act, Stark, and HIPAA/HITECH Government Investigations

Federal enforcement of False Claims Act (FCA), Stark anti-kickback, and HIPAA/HITECH claims against healthcare companies continues to rise rapidly. FCA recoveries by the U.S. Department of Justice (DOJ) exceeded $9.5 billion from January 2009 through the end of 2012—a record for any four-year period. Insurance can be a valuable asset to defray the costs to defend individual directors and officers and the company from a government investigation and pay any ultimate settlements and judgments.

This alert provides tips for getting the most out of your company's traditional Directors & Officers (D&O) and Errors & Omissions (E&O) policies for FCA and similar healthcare government investigations, and highlights key features of recently-developed specialty healthcare E&O policies that target coverage specifically for FCA, Stark, and HIPAA/HITECH related claims and investigations.

Don't Sleep on Your Traditional D&O and E&O Coverage

Private-company D&O and E&O policies may provide "investigations" coverage that will cover defense costs for FCA and other regulatory actions. Investigations coverage is particularly important for FCA claims, where the *qui tam* suit (the "Claim" that would otherwise give rise to potential coverage) often remains under seal for an extended time. To put your D&O and E&O coverage on good footing for a potential FCA or other regulatory claim, it is important to work with experienced coverage counsel and your broker to examine your policies at the time you learn of a potential *qui tam* suit or DOJ investigation, and also ahead of renewal. Key D&O and E&O terms for healthcare regulatory coverage include:

- "Claim" and "Civil Proceedings" Definitions: These policy definitions may limit the types of investigations that are covered. Best private-company terms provide for broad investigations coverage, including any "formal *or informal*" investigation, to encompass FCA and healthcare regulatory enforcement inquiries by the Office of the Inspector General (OIG), Department of Health and Human Services (DHHS), HIPAA enforcement units and others. Public company D&O policies typically limit investigations coverage to formal securities-related investigations initiated by the U.S. Securities Exchange Commission (SEC) or equivalent State agency.

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- "Defense Costs" Definition: Some D&O carriers offer what they refer to as an enhanced definition of covered Defense Expenses to include expenses incurred with respect to any Claim arising out of the "return or request to return funds which were received from any federal, state, or local government agency." This coverage is often sublimited to $1 million above a $1 million deductible and by accepting this coverage an insured may be limiting its recovery of Defense Expenses that may otherwise be fully covered under the D&O policy.

- Fraud / Willful Violation Exclusion: Because FCA liability can be based on "reckless disregard," the Fraud / Willful Violation exclusion can be avoided. It is critical, however, to ensure that your D&O policy contains a favorable "trigger" for this or any other "conduct" exclusion so that it does not apply unless and until there has been a final, non-appealable adjudication or judgment of deliberately dishonest conduct in an action not initiated by the insurance company. Most FCA claims end in settlement, so a final adjudication or judgment never occurs and the Fraud / Willful Violation exclusion does not provide grounds for the carrier to claw back defense costs.

- Illegal Profit or Advantage Exclusion: Like the Fraud / Willful Violation exclusion, it is critical that the "Illegal Profit or Advantage" exclusion be triggered only after a final adjudication or judgment. FCA claims alleging over-charges to the government may be susceptible to this exclusion or a more generic defense that any "restitutionary" type claims are "uninsurable as a matter of law." As to the latter, the applicable state law governs whether, if at all, any damages that are allegedly restitutionary in nature are uninsurable.

- Billing Errors Provision / Exclusion: Traditional E&O insurance for FCA investigations may be limited if the policy excludes billing related practices from the definition of "Professional Services" or contains a specific exclusion for billing practices. In some cases, traditional E&O coverage can be amended by endorsement to broaden the definition of "Professional Services" to include billing errors and HIPAA violations and to provide coverage for related government investigations.

New Specialty Healthcare E&O Coverage to Insure Government Investigations

In recent years, some E&O policies designed specifically for healthcare companies have become available that cover defense costs, fines, penalties, and other losses from regulatory proceedings arising from "billing errors proceedings," Stark, HIPAA/HITECH and EMTALA violations. Where such claims may fall through the cracks of traditional D&O or E&O coverage, the specialty E&O policies are designed to fill the gaps. Although there are several different offerings of this coverage with different terms, key features include:

- Broad Investigations Coverage: Coverage for Loss arising from civil or administrative investigations brought by the Government or any Commercial Payer alleging "Billing Errors" and Stark, HIPAA, HITECH, and EMTALA violations.

- Broad Loss Definition: Covered Loss includes Defense Expenses, Audit Expenses, and Regulatory Fines and Penalties.

- Narrow Fraud / Illegal Gains Exclusion: Carve-backs to (i) provide coverage specifically for FCA claims, (ii) provide that the exclusion does not bar coverage for claims expenses incurred in defending a claim alleging willful, deliberate, malicious, fraudulent, dishonest or criminal acts, or gaining of any profit or advantage to which the insured is not legally entitled, and/or (iii) provide that the exclusions shall not apply to any damages,

regulatory fines and penalties that the insured might become legally obligated to pay. Similar to the "final judgment" trigger available in D&O and E&O policies, the insurer may only recover later those claims expenses incurred from any parties "found to have committed criminal dishonest, fraudulent, or malicious acts, errors or omissions by a court, jury or arbitrator," which would limit this exclusion if the claim is resolved through settlement.

- "Claim" Definition Tailored to Regulatory Investigations: Broad "Claim" definition that includes any written demand brought by or on behalf of an Government Entity or a Commercial Payer against an Insured (i) seeking Loss for a Wrongful Act, (ii) commencing an audit or investigation of a Wrongful Act, or (iii) seeking injunctive relief on account of a Wrongful Act. One issue to watch regarding this coverage is that "routine" audits may not be included in the Claim definition, and the status of inquiries initiated by private entities such as Routine Audit Contractors (RACs) or Zone Program Integrity Contractors (ZPICs) may be considered routine or not depending on the circumstances.

Consider Cyber Liability Coverage for HIPAA Risks

HIPAA violations also may be insured through Cyber Liability policies that insure liability for data security breaches causing disclosure of private information, including but not limited to information protected under HIPAA. Some policies combine Medical E&O with Cyber coverages encompassing HIPAA data breaches. Traditional General Liability policies typically do not cover such losses, in part because electronic data is not included in the definition of covered "Property." The main Cyber Liability coverages are:

- Third Party Privacy Liability: covers sums the insured is legally obligated to pay as damages and claims expenses as a result of a privacy breach or breach of privacy regulations, such as HIPAA;

- Security Liability: covers sums the insured is legally obligated to pay as damages and claims expenses arising out of computer attacks caused by failures of security including theft of client information and identity theft;

- Crisis Management / Customer Notification Expenses: covers public relations services to protect brand/image related to a claim, penalty, or sanction, as well as notification expenses to warn customers of security breaches as required by many state laws.

If You Have a Claim…

Both the new and traditional policies may contain coverage-defeating pitfalls for the unwary insured facing a regulatory investigation. Key practical tips to pursue claims and maximize coverage include:

- Review All Potentially Applicable Policies: As noted above, there may be full or limited coverage for regulatory claims, billing practices, and/or similar government investigations under D&O, E&O, Cyber / Privacy, or other specialty products. Consult with your broker and coverage counsel to ensure that coverage is not overlooked in a policy that might otherwise not appear to provide FCA claim related coverage.

- Notice of Claim: Notice of a Claim is typically required "as soon as practicable" within the policy period or 60 days thereafter. Failure to give timely notice can negate coverage. Work with your coverage counsel as soon as you receive notice of a subpoena or notice of investigation in order to properly notify the carrier. For an

FCA claim where investigations coverage may be narrow or limited under a traditional E&O or D&O policy, consult with coverage counsel *before* major investigation costs are incurred in the event that a *qui tam* is later filed so that all such costs relate to the *qui tam* suit as a "Claim." Furthermore, for FCA claims and investigations that remain under seal, consider working with coverage counsel and the government to lift the seal for the limited purpose of allowing notice to insurers.

- Notice of Circumstances: Most D&O and E&O policies allow (but do not require) insureds to give notice of circumstances that *could reasonably give rise to a potential future claim* during the policy period. When to give notice is a strategic decision that should be discussed with your coverage counsel. Giving notice of the circumstance of the investigation before the *qui tam* suit is served and becomes a "Claim" stakes the claim under the limits of the current policy period (and preserves future limits) even if the claim ultimately is made after the policy period.

- Consent For Defense Costs: Prior carrier approval to incur defense and other costs of investigation and claims is virtually always required under any liability policy. Failure to secure timely carrier consent may provide grounds for denial of coverage for all pre-consent costs.

- Consent For Settlement: Similarly, most policies require the insured to get the carrier's prior consent to any settlement that may involve the carrier's funds. Failure to secure carrier consent may negate coverage for the settlement, although some policies require that the carrier's consent "may not unreasonably be withheld." It is important to follow the policy's consent-to-settlement requirement to avoid a potential technical defense to coverage and to engage the carrier early enough before settlement so that the insured has a record of cooperation if the carrier later unreasonably withholds consent.

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Given the extreme cost of government regulatory investigations, most healthcare companies will benefit from having insurance assets in place if the government comes calling. Healthcare companies should work with experienced coverage counsel to assist with key insurance due diligence so that their coverage is ready to meet their regulatory investigations risks, and to pursue any claims to maximize coverage.

King & Spalding lawyers work closely with our healthcare clients and their risk managers to address risks arising out of regulatory investigations and related claims, ensure their insurance affords adequate protection in the event of claims, and assist in recovering from their insurers for any losses.

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This alert provides a general summary of recent legal developments. It is not intended to be and should not be relied upon as legal advice.