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White Collar and Government Enforcement Practice

White Collar Watch

An eye on whistleblowers, false claims and compliance

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Government demonstrates willingness to enforce Affordable Care Act provision that could cost providers millions of dollars

By Nicholas J. Nastasi and Nicholas C. Stewart

Under a little-known provision of the Patient Protection and Affordable Care Act ("ACA"), healthcare providers could face millions of dollars in liability for failing to reimburse the government for overpayments in a timely manner. Pursuant to this "reverse false claims" provision as amended by the ACA, providers now have only 60 days from the moment they identify an overpayment to reimburse the government. While much has been written about this amendment, and many concerns have been raised by providers and commentators alike, the federal government has recently demonstrated its willingness to enforce this provision and hold providers to this 60-day standard.

In June 2014, the federal government joined a whistleblower lawsuit against Continuum Health Partners, which has since merged with one of New York City's largest not-for-profit healthcare organizations, Mount Sinai Health System. In this first-of-its-kind suit, the government alleges that Continuum received approximately $1 million in overpayments for 900 claims. Because providers can face an $11,000 penalty for each claim *multiplied by three*, and because the government is seeking the maximum penalty here, Continuum could be on the hook for $30 million in damages – 30 times the amount of the alleged overpayments.

Continuum returned all of the questionable payments. However, according to the allegations in the suit, Continuum did not repay the claims for more than two years after a whistleblower "identified" them by noting his concerns in an email, and it only repaid certain claims after the government began formally investigating. Continuum has filed a motion to dismiss, countering that the 60-day time limit did not begin to run until it had completed its own substantive investigation of possible overpayments. Continuum also alleges that, even if it ought to have reimbursed the government more quickly, it did not "knowingly" conceal or "knowingly and improperly" avoid these repayments, as required by law (the federal False Claims Act in particular). Finally, Continuum contends that the government is prohibited from applying the state law equivalent of the federal reverse-false-claims provision because it was not enacted until March 2013 – after the alleged overpayments were identified.

This case demonstrates the federal government's willingness to enforce the 60-day time limit even when a provider has reimbursed it for the overpayments. The consequences can be significant. Providers should take the necessary steps to cause their internal compliance programs to work as efficiently as possible to ensure that any potential overpayments are repaid as soon as possible.

Words can come back to haunt you: Boilerplate pleading could lead to inadvertent waiver of attorney-client privilege

By Nicholas J. Nastasi and Albert F. Moran

IN BRIEF

- **Recently, a federal district court in Georgia ruled that a defendant waived the attorney-client privilege in communications with counsel about the lawfulness of its conduct under the False Claims Act simply by pleading good faith compliance in its answer to the complaint.**
- **In considering whether to plead good faith compliance or another affirmative defense that negates a statute's *mens rea* requirement, industry members should consider the possibility that a court may order disclosure of attorney-client communications.**

Attorneys often view drafting answers as a mechanical process in which they may throw any and all possible affirmative defenses. Given some recent case law, parties defending a False Claims Act case should be more cautious with an eye toward potential consequences. In August 2014, defendant Columbus Regional Healthcare System, Inc. ("Columbus Regional") was likely blindsided when a federal district court ordered the company to produce certain confidential communications with its attorneys. The court justified its decision by finding that Columbus Regional waived its attorney-client privilege when it included in its pleading a statement that it had complied with all laws in good faith in an attempt to defeat the *mens rea* requirement of the asserted claims. The court's decision in this regard exemplifies the potential fragility of the attorney-client privilege and serves as a stark reminder that pleadings can cause unexpected consequences.

In *U.S. ex rel. Barker v. Columbus Regional Healthcare System, Inc.*, a relator alleged that Columbus Regional violated the False Claims Act, the Anti-Kickback Statute, and the Stark Law through various billing and remuneration practices and a transaction in which the defendant bought real estate from a source of patient referrals for more than fair market value. Because the False Claims Act only attaches liability to defendants who knowingly submit false claims with an intent to violate the law, Columbus Regional pleaded as an affirmative defense that it did not knowingly violate the law. In support of this affirmative defense, Columbus Regional planned to offer evidence regarding the extent of its knowledge. The relator responded by moving to compel communications between Columbus Regional and its attorneys to show exactly what the company knew when it entered into the transactions.

Reciting that the attorney-client privilege is a "shield and not a sword," the court granted the relator's motion to compel. Although the court acknowledged the privilege's esteemed place in American law and its purpose of encouraging communication between clients and lawyers, it also stressed that the privilege is waivable. Columbus Regional erred in simultaneously offering to show that it lacked a culpable state of mind while arguing that documents that might show its state of mind were privileged. The defendant, the court said, could not have it both ways: by "injecting its belief as to the lawfulness of its conduct into the case," Columbus Regional waived the privilege as to communications involving the lawfulness of its conduct.

The court emphasized that the Eleventh Circuit Court of Appeals issued binding precedent in a similar case (*Cox v. Adm'r U.S. Steel & Carnegie*), and as a result quickly rejected several of Columbus Regional's defenses to waiver – including a contention that no waiver occurred because Columbus

Regional had not advanced an advice of counsel defense. The court did, however, comment on two "arguably unique" defenses. Columbus Regional first argued that it "merely denied" an essential element of the relator's claim (knowledge) and, as such, no waiver occurred. Although the court agreed that some dicta in appellate case law supported this idea, the court distinguished denying the elements of a claim from affirmatively intending to explain a state of mind. Columbus Regional, the court said, chose the latter approach – an assertion that went "beyond mere denial." The court also rejected an argument that an exception to the waiver should be recognized in the healthcare industry due to its status as a heavily regulated field and corresponding need for robust attorney-client communications. The court conceded that this argument had some appeal, but it explained that carving out such an exception was the appellate court's decision to make.

Takeaways

The lessons from *Barker* and *Cox* merit serious reflection when strategizing about pleadings. While industry members should continue to communicate freely with counsel, they should also think strategically when pleading affirmative defenses. In considering whether to plead good faith compliance or another defense that negates a statute's *mens rea* requirement, for example, industry members should consider the possibility that a court may order disclosure of certain attorney-client communications if those communications might inform the factfinder about the defendant's state of mind during the relevant time period. Additionally, although answers that incorporate a boilerplate list of affirmative defenses can be considered a conservative tactic – plead them or lose them, so the theory goes – such an approach could have negative consequences. Instead, industry members should formulate a defense strategy early in litigation, and recognize that pleading some defenses might close certain doors.

The attorney-client privilege is a valuable tool and a safe refuge from invasive discovery practices, but it is not impenetrable. Industry members should be mindful of the privilege's fragility.

Pharmaceutical manufacturers beware: HHS OIG issues warning about copay coupon programs

By Nicholas J. Nastasi and Kyle B. Nocho

IN BRIEF

- **The Office of Inspector General of the Department of Health and Human Services recently issued a warning to pharmaceutical manufacturers, reminding them that copay coupons used for drugs purchased through federal healthcare programs can constitute illegal kickbacks and a violation of the False Claims Act.**

The Office of Inspector General ("OIG") of the Department of Health and Human Services ("HHS") recently issued a warning to pharmaceutical manufacturers about allowing customers to use copay coupons on drugs purchased through federal healthcare programs like Medicare Part D. On September 19, 2014, the OIG released a Special Advisory Bulletin (http://tinyurl.com/n2mxxnk; the "bulletin") reminding manufacturers that copay coupons used for drugs purchased, either in part or in full, by federal healthcare programs can constitute illegal kickbacks under the Anti-Kickback Statute (Section 1128B(b) of the Social Security Act).

In the bulletin, the OIG noted that the Anti-Kickback Statute criminalizes "knowingly and willingly offer[ing], pay[ing], solicit[ing], or receiv[ing] any remuneration to induce or reward the referral or generation of business reimbursable by any federal healthcare program." When pharmaceutical manufacturers offer copay coupons to customers, these coupons can constitute remuneration with the purpose of inducing the purchase of certain drugs. The problem arises if the customer then uses the coupon when purchasing pharmaceutical drugs through a federal healthcare program like Medicare Part D, which may violate the Anti-Kickback Statute.

Such a claim that results in a violation of the Anti-Kickback Statue may constitute a false or fraudulent claim under the False Claims Act. Manufacturers who issue copay coupons could also face False Claims Act liability, if the coupon induces a beneficiary of a federal healthcare program to use a particular practitioner or pharmacy. The OIG explained that use of

copay coupons under these circumstances could upset the aims of cost-sharing in federal healthcare programs by: 1) encouraging physicians and patients to make prescribing decisions with the "true cost" of drugs in mind; and 2) maintaining competition among drug manufacturers for lower drug prices.

Along with the bulletin, the OIG also released a study criticizing the effectiveness of the safeguards used by manufacturers to prevent federal beneficiaries from using copay coupons. "Manufacturer Safeguards May Not Prevent Copayment Coupon Use for Part D Drugs," (OEI-05-12-00540) (http://tinyurl.com/lz5ooux ;"OEI Report"). The OEI Report focused on the flaws in the procedures used by manufacturers to prevent copay coupons from being used on drugs purchased through Medicare Part D. For example, the OEI Report noted how some manufacturers fail to include notices on their coupons alerting customers that the coupons cannot be used for the purchase of drugs through Medicare Part D.

On the other hand, manufacturers face difficult challenges in preventing use of copay coupons on drugs purchased through federal healthcare programs. The Center for Medicare & Medicaid Services ("CMS") prohibits manufacturers from accessing customers' Part D enrollment data, because that information includes private healthcare information. The manufacturers then must use different proxies like age or the insurance provider to determine whether the customer is trying to purchase drugs through Medicare Part D.

In response to this concern, the OEI Report recommends that CMS "cooperate with industry stakeholder efforts to improve reliability of mechanisms to determine when copayment coupons are used in connection with the purchase of drugs paid for, in part, by Part D." The report does not suggest that CMS should allow manufacturers to access customers' enrollment data but did generally propose improvements to the reliability of claim edits and making copayment coupons universally identifiable in pharmacy claims transactions.

Going forward, the OIG stressed that pharmaceutical manufacturers who issue copay coupons "ultimately bear the responsibility to operate these programs in compliance with Federal law." The manufacturers could face sanctions if they do not take measures to alert ineligible customers and prevent them from using these coupons on drugs purchased, either in full or in part, by federal healthcare programs like Medicare Part D. The manufacturer's "[f]ailure to take steps to prevent the use of the coupon could be evidence of intent to induce the purchase of drugs paid for by federal healthcare programs."

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