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White Collar and Government Enforcement Practice

White Collar Watch

The Newsletter of the White Collar and Government Enforcement Practice

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New HIPAA "Megarule" Broadens Enforcement

By Scott D. Patterson and Patrick M. Hromisin

The U.S. Department of Health and Human Services ("HHS") has published its long-awaited Final Rule, the so-called "Megarule," to codify major changes in its health privacy and security rules. These changes fall under the Health Insurance Portability and Accountability Act ("HIPAA") and the Health Information Technology for Economic and Clinical Health Act ("HITECH"), and have been under rulemaking consideration since early 2009, when HITECH was enacted.

This update focuses on major changes to the enforcement provisions in 45 CFR Part 160. The three most substantial changes covered under the January 25, 2013 Megarule publication are:

- Extension of direct liability and civil money penalties to business associates
- Finalization of the penalty scheme previously announced by HHS in an Interim Final Rule in October 2009
- Clarification of aggravating and mitigating factors, and states of mind associated with greater or lesser degrees of culpability

These enforcement changes are only a small subset of the universe of regulatory changes affected by the Megarule. The enforcement changes discussed in this update go into effect March 26, 2013, although new substantive compliance obligations to be enforced are not effective until September 23, 2013.

Extension of Direct Liability to Business Associates

Current HIPAA rules impose direct compliance responsibility on "covered entities": health plans, health care clearinghouses and health care providers. Covered entities are required to enter into contractual agreements with their "business associates": third-party providers who create, receive, maintain or transmit protected health information ("PHI") on the covered entity's behalf. Under this structure, business associates' liability exposure has been indirect and contractual. Subcontractors of business associates have been one step further removed from the process.

Under the Megarule, business associates now take on **direct** privacy and security compliance obligations and become **directly** subject to civil money penalties. Critically, a business associate's subcontractor who creates, receives, maintains or transmits PHI is now also classified as a "business associate" with direct exposure to HIPAA penalties. As a result, service providers who were previously concerned only about their contractual responsibilities to their business partners can now be held accountable both by HHS and by state attorneys general (who were given HIPAA privacy and security enforcement powers by HITECH).

Moreover, both covered entities and business associates can be held liable when their "agents" (including subcontractors and other business associates who would be considered "agents" under the federal common law of agency) violate HIPAA regulations. HHS stated in the background document for the Megarule that its purpose in making this change was "to ensure, where a covered entity or business associate has delegated out an obligation under the HIPAA Rules, that [it] would remain liable for penalties for the failure of its business associate agent to perform the obligation on the covered entity or business associate's behalf." HHS noted that a commenter had argued that this change would impose strict liability on covered entities for the actions of third parties not under their control. HHS countered that the Megarule "does not make a covered entity or business associate liable for the acts of third parties that are not under its control because such third parties are not its agents."

Civil Money Penalties

Penalty Tiers

The Megarule finalized interim rules defining four penalty tiers for HIPAA privacy and security violations occurring on or after February 18, 2009. HITECH and the October 2009 interim final rule had already boosted civil penalties significantly above previous levels. The tiers are:

- Violations in which the covered entity or business associate did not know the violation was occurring and could claim ignorance ($100 to $50,000 per violation)
- "Reasonable cause" violations (discussed below) ($1,000 to $50,000 per violation)
- Violations involving "willful neglect," where the covered entity or business associate ultimately corrected the violation ($10,000 to $50,000 per violation)
- Violations involving willful neglect that the covered entity or business associate did not take action to correct ($50,000 per violation)

For all tiers of culpability, the maximum amount that can be imposed for violations of an identical provision within one calendar year is $1.5 million. However, HHS's ability to charge multiple violations arising from the same incident could greatly multiply the $1.5 million cap. HHS retains discretion to modify penalties to make the punishment fit the violation.

Mitigating and Aggravating Factors

In addition to finalizing the tiered penalty scheme, the Megarule adds certain factors to be considered when determining the amount of a civil money penalty:

- The nature and extent of the violation, including the number of individuals affected
- The nature and extent of the harm caused, including reputational harm
- The history of prior compliance by the covered entity or business associate, including consideration of both prior violations and "indications of noncompliance"
- The financial condition of the covered entity or business associate
- Such other matters as justice may require

The Megarule also identifies "affirmative defenses." Ignorance of a violation is no longer an excuse, but only grounds for being placed in the lowest penalty tier. Within the two lowest tiers (ignorance and "reasonable cause"), however, curing the violation within 30 days after the party knew or should have known of the violation avoids the penalty, and HHS has discretion to extend that cure period.

"Reasonable Cause" Tier

The modifications also change the definition of "reasonable cause," the level of culpability required to impose a penalty in the second tier of the penalty scheme. HHS stated that it amended the definition in order to "clarify the *mens rea* (state of mind) associated with the reasonable cause category of violations and to clarify the full scope of violations that will come within the category."

The current HIPAA regulations defined "reasonable cause" as "circumstances that would make it unreasonable for the covered entity, despite the exercise of ordinary business care and prudence, to comply with the … provision violated." Under the Megarule, "reasonable care" is redefined to mean "an act or omission in which a covered entity or business associate knew, or by exercising reasonable diligence would have known, that the act or omission violated [a] provision, but in which the covered entity or business associate did not act with willful neglect." HHS noted in the background document for the Megarule that the modified definition "would now include violations due both to circumstances that would make it unreasonable for the covered entity or business associate, despite the exercise of ordinary business care and prudence, to comply with the…provision violated, as well as to other circumstances in which a covered entity or business associate has knowledge of a violation but lacks the conscious intent or reckless indifference associated with" violations that would fall into a higher penalty tier.

Conclusion

The expansion of direct HIPAA liability to business associates and their subcontractors, with potential liability for acts and omissions of agents down the disclosure chain, dramatically changes the overall HIPAA compliance landscape. Service providers handling PHI must now pay attention for the first time not only to their contracts, but to the direct compliance obligations they now face, with the possibility of costly enforcement actions outside the control of friendly business partners. In turn, covered entities must be more vigilant than ever about how their business associates and their subcontractors are handling the entity's PHI.

The modifications to penalty tiers and culpability standards help to tailor penalties more closely to circumstances, but also create additional potential for health care organizations and their service providers to be held liable for violations that would previously have been excused, with potentially significant economic consequences. For significant breaches affecting multiple individuals and categorizable as multiple violations, the true exposure may be many millions of dollars.

Government Declines to Seek Rehearing of Landmark Off-Label Speech Decision

By Gregory G. Schwab

The government will not ask the United States Court of Appeals for the Second Circuit to revisit a ruling in which it held that the federal Food, Drug, and Cosmetic Act could not prohibit pharmaceutical manufacturers or their marketing representatives from making truthful statements promoting the off-label use of approved drugs.

As we wrote previously here (http://www.saul.com/publications-alerts-985), the case before the Second Circuit involved an appeal of a "misbranding" conviction of a pharmaceutical sales representative, Alfred Caronia. *United States v. Caronia*, 703 F.3d 149 (2d Cir. 2012).

The Second Circuit concluded in December that the government's closing argument and the trial judge's jury instructions showed that Caronia's conviction was based on a theory that the defendant's speech promoting the drug for off-label uses was itself the illegal conduct. That interpretation, the Appeals Court ruled, violated the First Amendment. The court concluded "that the government cannot prosecute pharmaceutical manufacturers and their representatives under the FDCA for speech promoting the lawful, off-label use of an FDA-approved drug."

January 16, 2013 was the deadline for the government to file a motion for rehearing in the case, and it did not. Instead, the agency issued a statement, saying, "FDA does not believe that the *Caronia* decision will significantly affect the agency's enforcement of the drug-misbranding provisions of the Food, Drug and Cosmetic Act. The decision does not strike down any provision of the . . . act or its implementing regulations, nor does it find a conflict between the act's misbranding provisions and the First Amendment or call into question the validity of the act's drug approval framework." While FDA has until March 4, 2013 to ask the United States Supreme Court to review the case, the Agency's failure to seek a rehearing in the Second Circuit and its public statement strongly indicate that it will not escalate the issue for further review.

At least one DOJ official recently has stated that the *Caronia* decision will not affect enforcement actions outside the Second Circuit. U.S. Attorney Zane Memeger of the Eastern District of Pennsylvania said that prosecutors in his office will continue to focus on finding evidence of misbranding in the form of misleading promotional statements as part of the overall effort to combat health care fraud. Memeger did acknowledge, however, that *Caronia* can be "relied upon for guidance" outside of the Second Circuit.

Seizure of Rothstein Ponzi Assets Highlights Tension Between Forfeiture Statutes and Bankruptcy Code

By Adam H. Isenberg and Justin B. Ettelson

On December 1, 2009, the United States government charged Scott Rothstein with money laundering and mail and wire fraud pertaining to his operation of a $1 billion Ponzi scheme. In connection with these charges, the government filed a Bill of Particulars identifying certain properties subject to criminal forfeiture upon conviction. These properties included bank accounts titled in the name of Rothstein's law firm (Rothstein Rosenfeldt Adler, P.A.) ("RRA"), real estate, vehicles, jewelry and various business interests purchased by Rothstein with funds obtained from RRA, all of which were forfeited to the United States government. Significantly, at the time the government filed its Bill of Particulars, RRA was in bankruptcy; creditors had filed an involuntary Chapter 11 petition against the firm on November 10, 2009 and the petition was granted on November 25, 2009.

On June 9, 2010, Rothstein was sentenced and forfeiture was imposed as part of the sentence. The bankruptcy Trustee appealed the forfeiture with respect to, among other things, the RRA bank accounts. Consistent with criminal forfeiture statutes, an ancillary forfeiture hearing was held before the United States District Court for the Southern District of Florida. At the hearing, the Trustee proved by a preponderance of the evidence that he had a superior interest to Mr. Rothstein in several RRA bank accounts totaling approximately $1.9 million, including two operating accounts, a payroll account, a merchant account and several interest on trust accounts ("IOTA"). The District Court also ruled adversely to the Trustee with respect to several other IOTAs totaling approximately $500,000. The government filed a motion for reconsideration and the District Court reversed its earlier ruling in favor of the Trustee with respect to two of the law firm's IOTAs.

Not surprisingly, the Trustee appealed the District Court's ruling to the United States Court of Appeals for the Eleventh Circuit. The Court of Appeals recently heard oral argument. It was, reportedly, a hot bench. The Trustee asserted that the forfeiture resulted in the erroneous taking of property that did not belong to Rothstein but instead belonged to RRA which, before its bankruptcy, had been an active law firm with 70 lawyers and allegedly "significant independent existence beyond Mr. Rothstein." More fundamentally, the Trustee asserted that "the government supplanted the congressionally mandated and time-tested system of equitable distribution of an insolvent estate . . . with criminal statutes that were never intended to address the disposition of any property other than those assets owned by the criminal defendant." The government countered that "these are proceeds of Rothstein's criminal offenses," and "the fact that he deposited them into someone else's account is of no consequence."

In 1986, Congress extended criminal forfeiture to money laundering crimes and, over the years, has amended forfeiture statutes to include a panoply of financial crimes including fraud, false statements and mail and wire fraud. Under Section 982 of Title 18 of the United States Code, a defendant must be convicted of a substantive underlying crime for the government to seize his property. Moreover, section 853(a) of Title 21 of the United States Code provides that the defendant shall forfeit:

> (1) any property constituting, or derived from, any proceeds the person obtained, directly or indirectly, as the result of such violation; (2) any of the person's property used, or intended to be used, in any manner or part, to commit, or to facilitate the commission of, such violation; and (3) in the case of a person convicted of engaging in a continuing criminal enterprise [] any property described in paragraph (1) or (2), any of his interest in, claims against, and property or contractual rights affording a source of control over, the continuing criminal enterprise.

Generally speaking, all of the proceeds of a crime and the property used or involved in the commission of a crime may be subject to forfeiture. However, the government must prove that the defendant has an interest in the forfeited property. As noted in the Trustee's brief, "[c]riminal forfeiture is an *in personam* proceeding. The purpose of criminal forfeiture is to punish the criminal defendant by requiring him to relinquish any ill-gotten gains or any of his property used to commit the offense." The issue raised by the Trustee in the Rothstein case is the extent to which a forfeiture action can reach property in which a third party may have an interest – such as RRA's bank accounts.

For property to be subject to criminal forfeiture, there must be some nexus between the property and the crime. Pursuant to the relation back doctrine under section 853(c) of the Code, "[a]ll right, title, and interest in property" with a nexus to the criminal action vests in the government at the time the crime is committed or at the time the property is used to commit the crime. These theories provide the government with significant power to seek criminal forfeiture.

Given the extent of this power, how does a third party, such as a bankruptcy trustee, challenge a criminal forfeiture? The criminal forfeiture statute provides two defenses that a third party may claim in asserting its interest in forfeited property, which interest must be asserted within 30 days of the final publication of notice of the forfeiture. Under section 853(n) of the Code, a court is required to amend a forfeiture order if the petitioner proves by a preponderance of the evidence that:

> (A) the petitioner has a legal right, title, or interest in the property [which] renders the order of forfeiture invalid . . .; or (B) the petitioner is a bona fide purchaser for value of the right, title, or interest in the property and was at the time of purchase reasonably without cause to believe that the property was subject to forfeiture… .

These defenses highlight the Trustee's main argument – "that a criminal defendant must have some interest in the property to be forfeited . . . before a criminal forfeiture can take place" and that a petitioner necessarily should prevail if he can show that the criminal defendant never had any interest in the forfeited property. In asserting that Rothstein had no interest in the RRA bank account, the Trustee relied upon evidence that over $5 million of non-Ponzi scheme funds had been deposited in the forfeited RRA accounts, "totaling more than the amount of funds on deposit in the aggregate at the time the accounts were seized."

Whatever the Eleventh Circuit rules, the tension between forfeiture law and the bankruptcy code will remain, as few cases address ancillary proceedings between the government and third parties. Cases that traverse both bodies of law necessarily affect competing rights: on the one hand, the right of the government to seek criminal forfeiture of a defendant's property to provide restitution to victims and, on the other, the rights of a bankruptcy trustee to gather the assets of a debtor to which the debtor has legal or equitable title for the benefit of all creditors. Trustees and other third parties should be mindful that title to forfeitable assets vests in the government as soon as the crime is committed. This disposition to the government will not be disturbed absent a statutory defense, which must be asserted in an ancillary proceeding within 30 days of the final forfeiture notice. As a consequence, it likely is best for any bankruptcy trustee to seek an agreement with the government as to how seized assets will be disposed. As for the Rothstein case, victims and creditors alike continue to wait for their distributions pending ultimate resolution of the case.

How Will Mary Jo White's Nomination to the SEC Affect Market Recovery?

By Nicholas C. Stewart

Tough, tenacious, aggressive – these are some of the most common adjectives used by news outlets when describing Mary Jo White, President Obama's nominee for chairwoman of the Securities and Exchange Commission (SEC). These traits, which effective prosecutors often possess, have served Ms. White well in the past and no doubt will continue to do so in the future. However, just how Ms. White's unique constitution will affect the market and financial industry in coming years is a matter of great interest and speculation.

After all, the SEC's mission is not only to "protect investors," but also to "maintain fair, orderly, and efficient markets" and to "facilitate capital formation." In order to make progress on all these fronts, Ms. White will have to safeguard investors, while also promoting an environment of regulatory certainty and reliability that encourages investment and risk taking.

This will not be an easy task. Ms. White will face pressure from many sources to quickly establish her toughness, tenacity and aggressiveness. First, as the former U.S. Attorney for the Southern District of New York, Ms. White will be expected to assert her prosecutorial credentials in her new position as head of the nation's financial watchdog; however, the law-and-order approach of a prosecutor may lead to punitive, rather than thoughtful and well-reasoned, policymaking. This tendency may be exacerbated by the pent-up frustration of those who believe that financial institutions escaped punishment for their role in the Great Recession.

Further adding to the pressure, Ms. White has spent many years in the private sector at major law firms, defending financial clients against the kind of enforcement she would now be in charge of spearheading. To shake off the image of closeness with Wall Street, Ms. White may be inclined to take swift, aggressive action, which may do a lot to protect investors but not as much to promote an environment of stability necessary for investment. At her disposal, Ms. White will have the Dodd-Frank law, an expansive effort to reform Wall Street that augments the SEC's regulatory authority. Under Dodd-Frank, the SEC is expected to promulgate numerous rules, which are already overdue and which could meaningfully affect the way the market operates in the near future.

Despite these understandable pressures, Ms. White has a tremendous opportunity to make progress on all fronts of the SEC's mission and to advance the nation's most important economic objective – market recovery. By enforcing existing regulations in a consistent and fair way, and by promulgating new regulations that are needed and digestible, Ms. White's SEC can help create an environment of sustained, sizable growth. Practically speaking, such a balanced approach would empower businesses and those thinking about starting a business to: (1) change their conduct without substantial compliance costs; (2) make more accurate and confident decisions regarding investing in new jobs and new construction; (3) gain access to capital more easily at lower interest rates; and (4) expand in to new markets while avoiding overly costly barriers to entry, among other things.

In the final analysis, if Ms. White is able to simultaneously leverage her tools as a prosecutor and her understanding of the private sector, she may be able to help improve the public's confidence in the marketplace while also contributing to America's road to recovery.

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