

Fraud and Abuse Provisions in the Patient Protection and Affordable Care Act as Amended by the Health Care and Education Reconciliation Act

by Sean A. Timmons

In all the excitement over the passage of the Patient Protection and Affordable Care Act (Pub. L. 111-148) ("PPACA") and its companion, the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152) ("HERA"), it was easy to overlook that there are several significant fraud and abuse provisions in this legislation. After all, with 961 total pages of legislative text promising an overhaul of our entire health care system, fraud and abuse seemed like a bit player on the health care reform stage. Nonetheless, many of these provisions will have significant effects on health care providers and practitioners, particularly with respect to the relationships between physicians and the entities to which they refer.

This article will provide a brief analysis of selected provisions of PPACA and HERA, and their effects on health care providers and practitioners. It will address the new disclosure requirements associated with the in-office ancillary services exception under the Stark statute; the limitation on physician ownership of hospitals to which they refer; the establishment of compliance programs as a condition of Medicare enrollment; clarification regarding the application of the False Claims Act to claims arising from violations of the federal health care program anti-kickback statute; clarification regarding the intent standard under the federal health care program anti-kickback statute; the new ability of the Centers for Medicare and Medicaid Services to suspend payments during the pendency of an investigation; and the new Stark self-disclosure protocol.

In-Office Ancillary Services Disclosure

Section 6003 of PPACA amends the Stark statute by adding a new provision to the in-office ancillary services exception.

See, 42 U.S.C. § 1395nn(b)(2). Under prior law, physicians could refer Medicare and Medicaid patients for certain designated health services within their group practice, so long as the referral (and the group practice) met certain conditions. The new provision mandates that the Secretary adopt regulations requiring that with respect to magnetic resonance imaging, computed tomography, positron emission tomography, and any other designated health services deemed appropriate by the Secretary, the referring physician must notify the patient in writing at the time of the referral of other suppliers who furnish such services in the area in which the patient resides.

This new regulation will have some interesting features. First, it will need to define the "area" within which a patient lives. It will be highly inefficient for physicians to have to develop customized lists for each patient based on the patient's home address, so we can only hope that the new regulations will define "area" in such a way as to allow the preparation of standard lists of suppliers. Second, the statute is careful to state that the list must be of "suppliers (as that term is defined in section 1861(d) [of the Social Security Act]." "Suppliers" in this context means persons or entities that offer health care items and services to patients, excluding those entities that are defined as "providers," and most notably, hospitals. Consequently, the referring physician must list competing physicians and independent diagnostic testing facilities, but is not required to list hospitals.

Third, the statute requires this disclosure for MRI, CT and PET, but offers the Secretary broad discretion to include any of the other designated health services. "Designated health services" are defined at 42 U.S.C. § 1395nn(h)(6) to include clinical laboratory services; physical therapy services; occupational therapy services;

radiology, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services; radiation therapy services and supplies; durable medical equipment and supplies; parenteral and enteral nutrients, equipment, and supplies; prosthetics, orthotics, and prosthetic devices; home health services and supplies; outpatient prescription drugs; inpatient and outpatient hospital services; and outpatient speech-language pathology services. While some of the designated health services would not be subject to, or permissible under, the in-office ancillary services exception, the rest are fair game for the new disclosure regulation, which could conceivably result in physicians' being required to identify all of the labs, physical therapy providers, imaging providers and other suppliers in each patient's local area. Physicians would not be required; however, to identify hospitals and skilled nursing facilities.

Finally, this provision of PPACA is supposed to be effective with respect to services furnished on or after Jan. 1, 2010. However, the statute was not enacted until March 23, 2010, and who knows how long it will take for CMS to implement the required regulations. Given the uncertainties, it seems reasonable to assume that CMS will not attempt to enforce this provision until after it has published the regulations, but there is no guarantee that this is the case.

Limitation on Physician Ownership of Hospitals to Which They Refer

Section 6001 of PPACA, as amended by Section 10601 of PPACA and by Section 1106 of HERA, further amends the Stark statute by modifying the rural provider exception, codified at 42 U.S.C. § 1395nn(d)(2), and the hospital ownership

(whole hospital) exception, codified at 42 U.S.C. § 1395nn(d)(3), to require that these exceptions will only apply with respect to hospitals in which the physician had an ownership or investment interest on December 31, 2010, and that the hospital has not expanded since the date of enactment of PPACA, except as expressly permitted under the statute. In addition, the hospital will be required to provide annual reports to the Secretary on various aspects of the hospital, and to impose certain limitations on the physicians' ownership interest that bear a strong resemblance to the ownership limitations included in the safe harbor under the federal health care program anti-kickback statute for physician investments in ambulatory surgical centers. *See*, 42 C.F.R. § 1001.952(r).

This provision is the culmination of a long effort by Congress and CMS to do away with the ability of physicians to invest in hospitals in which they have an ownership interest. The expressed concern has been that physicians "cherry-pick" the higher-paying cases to send to the hospital in which they have an ownership interest, while sending lower pay patients to the local community hospital. Based on this provision, it seems likely that the number of physician-owned hospitals is likely to decline fairly sharply after Dec. 31, 2010.

Compliance Program Requirement

Section 6401(a) of PPACA, as amended by Section 10603 of PPACA and by Section 1304 of HERA imposes a number of new requirements related to the enrollment of providers and suppliers. The most significant requirement is that all providers and suppliers must adopt compliance plans as a condition of enrollment. The statute requires the Secretary to adopt core elements of compliance plans for each type of provider or supplier, and each industry segment.

It seems likely that the core elements to be established by the Secretary will be based on the various "Compliance Guidance" documents published by the Office of Inspector General and available on their website at <http://oig.bhs.gov/>. If so, this requirement could be a significant burden on smaller entities that lack the workforce to address compliance issues as suggested in the OIG's documents.

Anti-Kickback Violations as False Claims

Section 6402(f)(1) of PPACA establishes conclusively that claims arising out of violations of the federal health care program anti-kickback statute (42 U.S.C. § 1320a-7b(b)) are false claims for purposes of the federal False Claims Act. *See* 31 U.S.C. §§ 3729 et seq. In the past, prosecutors and whistleblowers have argued, with success, that because of the so-called "implied certification" theory, any claim that was the result of a referral tainted by prohibited remuneration is necessarily a false claim. In other words, there was no way that a tainted referral could allow a claim to be submitted, and the service performed, in compliance with applicable laws.

Prior to the passage of PPACA, defense attorneys had the opportunity to argue that even if there was prohibited remuneration, the claim itself was not false, and the anti-kickback statute contained its own punishment for the conduct in question. Now, that argument has been removed.

Anti-Kickback Intent Standard

Section 6402(f)(2) of PPACA amends the federal health care program anti-kickback statute by adding a provision to clarify that "a person need not have actual knowledge of this section or specific intent to commit a violation of this section." This provision appears to be designed to address the holding in *Hanlester Network v. Shalala*, 51 F.3d 1390 (9th Cir. 1995). In that case, the court held that in order for a defendant to have violated the statute, the defendant must have knowledge of the statute being violated, and specific intent to violate the law. This holding was in sharp contrast to many other circuits, which generally hold that if even "one purpose" of the remuneration at issue is to induce or reward referrals, the statute has been violated, regardless of the defendant's knowledge of the applicable law. *See, e.g., U.S. v. Greber*, 760 F.2d 68 (3d Cir.), cert. denied, 474 U.S. 988 (1985). Now, it seems likely that all circuits will fall back on the "one purpose" test, so California providers should consider reevaluating their relationships with referral sources.

Payment Suspension

Section 6402(h)(1) of PPACA permits the Secretary to suspend payments to a sup-

plier or provider pending an investigation of a "credible allegation" of fraud. The statute requires the Secretary to adopt regulations implementing this provision. It seems almost too much to hope that the regulations will define "credible" in this context. Given the dependence of many providers and suppliers on the income stream from Medicare, there is a significant risk that an indefinite suspension pending an investigation could force providers and suppliers out of business. It is therefore of critical importance to all Medicare beneficiaries that the definition of "credible" be as narrowly drawn as possible.

Stark Self-Disclosure Protocol

Finally, Section 6409 of PPACA requires the Secretary to implement regulations establishing a self-disclosure protocol for violations of the Stark statute. This is a welcome development, as the OIG has ceased accepting self-disclosures of Stark violations under its self-disclosure protocol. In a perfect world, the self-disclosure protocol would allow the Secretary some leniency to address "technical" violations of the Stark statute, which is a strict liability statute.

But Wait, There's More...

Unfortunately, this has been a survey of the highlights of the statute. There are also provisions specifically directed at nursing homes, pharmaceutical manufacturers, durable medical equipment providers and others. Adding to the complexity is that Title X of PPACA amends many of the previous sections of the legislation, while HERA amends them further still. Until the kinks have been worked out of properly codifying all of the new and amended provisions, it would be wise to take great care in reviewing all of the possible locations for changes in the fraud and abuse laws. ■

Sean Timmons practices in the area of health care and regulatory law. His experience includes Certificate of Need issues, joint ventures between physicians and institutional providers, Medicare and Medicaid fraud and abuse, North Carolina anti-referral laws, Medicare and Medicaid reimbursement, and acquisition and other transactions involving health care entities. Mr. Timmons has advised numerous health care clients on the formation of business entities and physician buy-ins and buy-outs.