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## Health Reform Legislation Provisions Regarding Fraud and Abuse

Although most people know that the Patient Protection and Affordable Care Act ("PPACA") proposes to expand access to health insurance, lesser known provisions of PPACA will have a significant impact on the laws that prohibit "fraud and abuse" of federally funded health care programs. These provisions of PPACA make important changes to key fraud and abuse statutes, as well as increase funding for fraud and abuse enforcement.

This *GT Alert* discusses: (i) amendments to a number of provisions of the Stark anti-referral law; (ii) an amendment to the False Claims Act that will likely increase whistleblower litigation against health care entities; and (iii) the increased funding that has been appropriated to fight fraud and abuse in federally funded health care programs.

### I. Stark Law Amendments

#### *Mandatory Freedom of Choice Notifications for 'In-Office' Imaging Services*

Subject to specific exceptions, the federal "Stark Law" prohibits a physician from referring a Medicare or Medicaid beneficiary for certain designated health services to an entity with which the referring physician, or members of his or her immediate family, has a financial relationship. *See*, 42 U.S.C. § 1395nn. The Stark Law provides significant civil sanctions for referrals which do not fall within one of the many Stark exceptions.

One of the more useful Stark exceptions is the "In-Office Ancillary Services" exception (the "*IOAS Exception*"). The IOAS Exception permits physicians to make referrals of designated health services within the referring physician's own group practice. Referrals obtain IOAS status only if they meet a host of detailed rules relating to (i) who performs the service, (ii) the location of the services, and (iii) the billing of the services. PPACA adds a new "Freedom of Choice" notification requirement for certain imaging services seeking "in-office" protection.

Section 6003 of PPACA provides that referrals of magnetic resonance imaging, computed tomography, and positron emission tomography achieve IOAS protection only if, at the time of making the referral, the referring physician informs the individual in writing that the individual may obtain the referred imaging service from someone other than the referring physician or the referring physician's group practice. The written notice must provide the beneficiary with a list of other physicians, DMEPOS suppliers, IDTFs, physicians' assistants, or other applicable suppliers who furnish the imaging service in the area where the beneficiary resides.

Initially, these new Freedom of Choice rules apply only to referrals of MRI, CT, and PET scans seeking IOAS treatment. The Secretary of Health and Human Services may, by rule, impose a Freedom of Choice requirement on referrals of other designated health imaging services, such as radiology services and ultrasound. Freedom of Choice notices are not required to comply with other Stark exceptions or for IOAS services other than the imaging services designated by PPACA.

Even though Section 6003 did not become law until March 23, 2010, the Freedom of Choice notice requirement is effective as of January 1, 2010. Neither the House "Fix-It" Bill nor the Senate Bill's own internal amendments extend the start date for the Freedom of Choice requirement for in-office imaging services.

### *New Limitations on Referrals to Physician-Owned Hospitals*

Another popular Stark exception significantly affected by Health Reform is the so-called "Whole Hospital" exception. This exception allows physicians to refer designated health services for Medicare or Medicaid patients to hospitals owned, in whole or part, by the referring physician or an immediate family member of the physician. Such referrals are excepted from Stark as long as the physician's ownership is in the entire hospital and not merely a distinct part or department of the hospital.

Section 6001 of PPACA essentially prevents the formation of new physician-owned hospitals, limits service expansions at existing physician-owned hospitals, and freezes the amount of physician ownership in existing hospitals as of March 23, 2010, the date of PPACA enactment. Key changes to the Whole Hospital exception imposed by PPACA are set out below.

- **Prohibition on New Physician-Owned Hospitals.** The whole-hospital exception will no longer be available for any newly formed physician-owned hospitals after this year. PPACA grants whole hospital treatment only if the physician's investment is made by December 31, 2010 in a hospital having a Medicare provider agreement in effect by that date. While this provision prohibits future expansion of the exception, it effectively grandfathers the exception for most physician-owned hospitals existing as of December 31, 2010.
- **Freeze on Additional Aggregate Physician Investments in Hospitals.** PPACA caps the aggregate percentage physician ownership in physician-owned hospitals to the percentage existing as of the law's enactment date. For example, if, on March 23, 2010, physicians owned 35 percent of the total ownership interest in a hospital (or in an entity whose assets include the hospital), then the total amount of physician ownership going forward may not exceed 35 percent. CMS will likely need to address how the March 23, 2010, effective date for this provision squares with the ability of doctors to invest in newly-formed physician-owned hospitals through December 31, 2010.
- **Restriction on Hospital Service Expansions.** Except for increases specifically permitted by the Secretary of the Department of Health and Human Services, grandfathered hospitals may not add operating rooms, procedure rooms, or beds after March 23, 2010 for purposes of compliance with Stark's Whole Hospital exception. PPACA requires the Secretary to implement, by February 1, 2012, a process for grandfathered hospitals to apply for exceptions to the service freeze.

- **Conversion From Ambulatory Surgery Centers Prohibited.** Physicians and hospitals are permitted under current law to form joint ventures to own and operate outpatient surgical centers under certain circumstances. PPACA makes clear that the Whole Hospital exception will not be available after March 23, 2010, to referrals made to any hospital that has converted from an ambulatory surgical center.
- **Physician Disclosure to Patients.** PPACA requires grandfathered hospitals to have procedures in place which require referring or treating physician-owners to disclose their hospital ownership interests to their patients by a time permitting the patient to make a meaningful decision regarding his or her receipt of care. Future regulations will likely flesh out how much time will be required in order to permit the patient to make a meaningful choice.
- **Hospital's Public Disclosure of Physician Ownership.** PPACA requires grandfathered hospitals to disclose the fact that the hospital is partially physician-owned. Such disclosures must appear on any public website of the hospital and in any of the hospital's public advertising.
- **Reporting.** Finally, PPACA requires the hospital to submit an annual report to the Secretary containing a detailed description of the identity of all physician and non-physician owners of the hospital and the nature and extent of such person's interests. Such information will be available on the CMS website.

#### *Physician-Owned Hospitals in Rural Areas*

Stark also permits physician referrals to "rural" entities, or entities where substantially all of the designated health services furnished by such entity are furnished to individuals residing in a rural area. A rural area for Stark law purposes is any area outside of a recognized Metropolitan Statistical Area.

Section 6001 of PPACA limits the broad physician ownership exception in rural entities by grafting all of the new "whole hospital" rules onto physician ownership in rural hospitals. In other words, beginning 18 months following enactment, a physician-investor's referral to a rural hospital will not obtain the protection of the rural entity exception unless the rural hospital meets all of the disclosure, reporting, ownership percentage and service expansion limitations applicable to all other referrals of designated health services to hospitals in which the referring physician has any ownership interest.

#### *Self-Disclosure Protocol for Stark Law Violations*

Last year, the Office of Inspector General announced that its Self-Disclosure Protocol for use by health care providers to disclose technical (and perhaps unintentional) violations of federal fraud and abuse laws was unavailable for disclosures of Stark violations. As such, health care providers had no clear path regarding how to self-report Stark violations or what to expect as punishment for coming forward on their own initiative.

Congress heeded provider concerns and added Section 6409 of PPACA. This section obligates the Secretary to develop and implement a disclosure protocol for actual and potential Stark violations within six months from the date of enactment. The protocol must specify the person, officer, or office to whom such a disclosure is to be made and the effect of such disclosure on corporate integrity agreements and corporate compliance agreements.

Importantly, Section 6409 authorizes the Secretary to reduce the amount due and owing for all Stark violations disclosed to an amount less than otherwise provided in the Stark law. To determine the decreased penalty, the

Secretary may consider (i) the nature and extent of the improper or illegal practice, (ii) the timeliness of the self-disclosure, (iii) the provider's cooperation in providing additional information related to the self-disclosure, and (iv) such other factors the Secretary considers appropriate. The new self-disclosure protocol is to appear on CMS' website within six months of the enactment date.

Interestingly, the new protocol does not refer to other federal law requiring health care providers to refund, within 60 days, all governmental health care payments which are identified as overpayments. It is possible that the new protocol, once announced, will address whether the act of filing a self-disclosure will toll the 60 day overpayment period.

## II. False Claims Act Amendments

The Fraud Enforcement and Recovery Act of 2009, which accompanied federal economic stimulus legislation, made significant amendments to the federal False Claims Act (31 U.S.C. § 3729, *et seq.*) (the FCA) and broadened the basis for FCA liability. Less than a year later, PPACA has further altered key provisions of the FCA in a manner calculated to increase whistleblower litigation.

PPACA dramatically alters the "public disclosure" and "original source" provisions of the FCA. These provisions were designed to prevent whistleblower actions brought by private citizens based on material already within the public domain, unless the whistleblower had obtained his or her knowledge in some manner other than trolling through public information.

Specifically, the public disclosure provision of the FCA, *pre*-PPACA, deprived a federal court of jurisdiction over an FCA whistleblower action where that action was "based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or [GAO] report, hearing, audit or investigation, or from the news media." 31 U.S.C. § 3730(4)(A) (*pre*-PPACA). The *pre*-PPACA provided an exception to the public disclosure bar for a claim brought by "an original source of the information," which was defined as "an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing" an FCA complaint based on the information. 31 U.S.C. § 3730(4)(A), (B) (*pre*-PPACA).

In an effort to increase the incentive for whistleblowers to file FCA claims, the public disclosure rule is likely no longer jurisdictional under PPACA. Rather, this provision, as amended, removes the phrase "[n]o court shall have jurisdiction," and instead states only that an action subject to the public disclosure shall be dismissed "unless opposed by the Government." 31 U.S.C. § 3730(4)(A) (*post*-PPACA). This new language vests in the Government substantial input into determining whether to permit the whistleblower to proceed.

While it remains to be seen how this discretion will be exercised, the amendment to the public disclosure rule may well have been intended to curtail the United States Supreme Court's ruling in *Rockwell Int'l Corp. v. U.S.*, 549 U.S. 547 (2007), in which the Court applied the jurisdictional language of the former public disclosure rule in dismissing an FCA case that was litigated to a successful plaintiff's verdict. The new public disclosure rule reigns in the powerful disincentive that the *Rockwell* case had set up for would-be whistleblowers.

PPACA also amended the public disclosure rule by restraining the circumstances in which the rule even applies. While the bar previously applied where the public disclosure was made in a "criminal, civil, or administrative hearing" (31 U.S.C. § 3730(4)(A) (*pre*-PPACA)), this language now reads as follows: "*Federal* criminal, civil, or

administrative hearing *in which the Government or its agent is a party*" (31 U.S.C. § 3730(4)(A) (*post*-PPACA) (emphasis added)). Accordingly, by narrowing this language, a wide swath of whistleblower claims that would be prohibited by the former public disclosure rule may now be permitted to proceed.

In addition to modifying key portions of the public disclosure rule, PPACA has also significantly modified the original source exception to that rule. As noted, under the *pre*-PPACA standard, the original source exception required a showing that the whistleblower had "direct and independent knowledge of the information on which the allegations are based", and required that such information be shared with the Government prior to the filing of the whistleblower action. 31 U.S.C. § 3730(4)(B) (*pre*-PPACA).

The "direct and independent" showing, as applied by the courts, was a fairly high standard. That standard is no longer the law, as the term original source is now defined as "an individual who *either* (i) prior to a public disclosure . . . has voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based, or [ii] who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action." 31 U.S.C. § 3730(4)(B) (*pre*-PPACA) (emphasis added). In replacing the rigorous "direct and independent" standard with these two alternative showings, PPACA arguably creates a more functional analysis that essentially asks whether the whistleblower was either an original source of information (as that term would be understood in plain English), or otherwise brought material information to the Government that it otherwise might not have obtained.

There is no question that PPACA's modifications to the language of the FCA's public disclosure and original source provisions are substantial. What remains to be seen is how these provisions will be interpreted and applied by the courts in litigated proceedings.

### III. Increased Funding to Fight Fraud and Abuse

In its haste to get the Reconciliation Bill to the president for his signature, Congress appears to have inadvertently included two separate measures significantly increasing the funding for anti-fraud efforts. PPACA provides \$100 million in additional funds at the rate of \$10 million per year for fiscal years 2010 through 2020 to the Health Care Fraud and Abuse Account (HCFAC) to fight fraud, waste and abuse in the Medicare and Medicaid programs. However, Section 1304 of the Reconciliation Bill also supplements anti-fraud funding, allocating \$250 million to HCFAC as follows:

FY 2011	\$95,000,000
FY 2012	\$55,000,000
FY 2013	\$30,000,000
FY 2014	\$30,000,000
FY 2015	\$20,000,000
FY 2016	\$20,000,000

The FY 2010 funding for HCFAC *before* the new law was passed was \$1.172 billion in mandatory base funding, and \$311 million in proposed discretionary funding. Thus, unless one of these is subsequently rescinded, HCFAC will have a total of \$350 million in additional funding in the coming years.

PPACA also extends the indexing of funds for HCFAC and the Medicare Integrity Program to the Consumer Price Index for urban consumers (CPI-U) beyond 2010. The Reconciliation Bill indexes the funds for the Medicaid Integrity Program to CPI-U for FY 2011 and forward.

This *GT Alert* was prepared by Daniel Brown, Matthew Fenster and Francis Serbaroli. Questions about this information can be directed to:

- [Daniel Brown](mailto:brownd@gtlaw.com) — 678.553.2650 | [brownd@gtlaw.com](mailto:brownd@gtlaw.com)
- [Matthew Fenster](mailto:fensterm@gtlaw.com) — 212.801.2155 | [fensterm@gtlaw.com](mailto:fensterm@gtlaw.com)
- [Francis Serbaroli](mailto:serbarolif@gtlaw.com) — 212.801.2212 | [serbarolif@gtlaw.com](mailto:serbarolif@gtlaw.com)
- Or your [Greenberg Traurig](#) attorney

**Albany**  
518.689.1400

**Amsterdam**  
+31 20 301 7300

**Atlanta**  
678.553.2100

**Austin**  
512.320.7200

**Boston**  
617.310.6000

**Chicago**  
312.456.8400

**Dallas**  
214.665.3600

**Delaware**  
302.661.7000

**Denver**  
303.572.6500

**Fort Lauderdale**  
954.765.0500

**Houston**  
713.374.3500

**Las Vegas**  
702.792.3773

**Los Angeles**  
310.586.7700

**London\***  
+44 (0) 203 349 8700

**Miami**  
305.579.0500

**New Jersey**  
973.360.7900

**New York**  
212.801.9200

**Orange County**  
949.732.6500

**Orlando**  
407.420.1000

**Palm Beach County North**  
561.650.7900

**Palm Beach County South**  
561.955.7600

**Philadelphia**  
215.988.7800

**Phoenix**  
602.445.8000

**Sacramento**  
916.442.1111

**San Francisco**  
415.655.1300

**Shanghai**  
+86 21 6391 6633

**Silicon Valley**  
650.328.8500

**Tallahassee**  
850.222.6891

**Tampa**  
813.318.5700

**Tysons Corner**  
703.749.1300

**Washington, D.C.**  
202.331.3100

**White Plains**  
914.286.2900

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