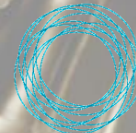


Health Care Reform: FINDING YOUR WAY

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Stark Raving Mad?

The New Stark Self-Referral Disclosure Protocol

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EXECUTIVE SUMMARY

The Patient Protection and Affordable Care Act (PPACA) creates a much-needed framework for a Self-Referral Disclosure Protocol (SRDP) for reporting potential violations of the Stark Law (Section 6409). Stark is a strict liability statute that arguably can result in disproportionate overpayment liability for violations of certain physician self-referral prohibitions, including violations that are technical and completely unintentional (42 U.S.C. 1395nn). With the passage of PPACA, within six months of the enactment date the Secretary of the Department of Health and Human Services is required to issue an SRDP pursuant to which health care service providers and suppliers can disclose actual or potential violations of Stark .. Significantly, the Secretary is given express authority to reduce amounts owed for violations of Stark laws by taking into consideration the nature and extent of the alleged misconduct, the timeliness of the disclosure, the cooperation in providing additional information related to the disclosure, and other factors the Secretary deems to be appropriate.

BACKGROUND

The Stark law was originally intended to prevent the over-utilization of certain health services by physicians who own or have other financial relationships with a provider of designated health services. The statute has been supplemented many times over the past fifteen years, including three major phases of rule making, numerous revisions, and repeated clarifications and corrections (for a comprehensive summary of the regulatory history, see 72 Fed. Reg. 51012.)

Under the statute and subsequent rules, a physician that has a “financial relationship” with a provider is prohibited from referring certain “designated health services” (DHS) that may be paid for by Medicare, to that provider unless a specific exception applies. A financial relationship can exist if the physician has an ownership or investment interest in the DHS provider or if he or she has a “compensation arrangement” with the provider. The statute also prohibits the provider of the DHS from billing Medicare for those referred services.

There are nine specific exceptions that apply to any financial relationship, five that apply to ownership or investment interests only, and 23 that apply only to compensation arrangements. These 37 exceptions break down into several categories, including a key group that exempts fair market value transactions that occur in the ordinary course of business between facilities and physicians.

Each Stark exception has multiple requirements that must all be met for that exception to apply. Some of these requirements are substantive (e.g. the compensation paid must not be more than fair market value), while many more are technical in nature (e.g. the agreement must be in writing and signed by each of the parties). If *any* requirement of an exception is lacking, then the relationship does not qualify for the exception, and that physician is prohibited from referring any DHS to that entity. The DHS provider is then obligated to repay the value of all referrals made in violation of the statute. Failing to meet a minor requirement, therefore, could have devastating financial implications.

PREVIOUS OPTIONS FOR SELF-DISCLOSURE

In 1998 the Department of Health and Human Services’ Office of the Inspector General (OIG) published its first self disclosure protocol (SDP). 63 Fed.Reg. 58,399. In it, the OIG invited providers to disclose “irregularities in their dealings with the Federal health care programs,” 63 Fed. Reg. 58400. The SDP was intended to assist in the resolution of “matters that, in the providers’ reasonable assessment, are potentially violative of Federal criminal, civil or administrative laws.” Providers were advised to consult with the appropriate carrier or intermediary, however, if a matter involved “overpayments or errors that do not suggest that violations of law have occurred.” This original SDP gave no direction regarding whether a potential violations of the Stark law would be considered “potentially violative” of federal laws, or simply an “overpayment or error.” Frankly, as a disclosure mechanism it was neither effective nor successful.

In ensuing years the OIG issued a series of “Open Letters to Health Care Providers” to provide additional guidance regarding the SDP with regard to the Stark statute. Letters on April 24, 2006, and April 15, 2008, indicated that potential Stark violations could be appropriately disclosed to the OIG under the SDP. However, in its most recent Open Letter (March 24, 2009) the OIG reversed this course. It narrowed the scope of the SDP with regard to Stark and indicated it would no longer accept disclosures of Stark violations “in the absence of a colorable AKS violation.” This left no process by which providers could raise and reasonably resolve potential Stark concerns. As with the original SDP, the clarifications provided by the Open Letters were more of academic interest than anything else as the flow of self-disclosures never increased substantially due to the risk and uncertainty. Section 6409 is an attempt, perhaps, to redress this situation.

WHAT THIS MEANS FOR HEALTH CARE PROVIDERS

Section 6409 includes and/or requires the following:

- Development of an SRDP within six months;
- Identification of a specific “person, official, or office” to whom disclosures are to be made;
- Instruction on the impact of the SRDP on corporate integrity and compliance agreements;
- Publication on the web of instructions on how to make disclosures; and
- Express criteria for the Secretary to consider in negotiating reductions for Stark Law violations. As noted above these criteria include:
 - the nature and extent of the alleged misconduct,
 - the timeliness of the disclosure,
 - the cooperation in providing additional information related to the disclosure, and
 - other factors the Secretary deems to be appropriate.

An intelligent and reasonable Stark self-disclosure protocol is long overdue. Fear of strict overpayment liability under Stark, coupled with heavy-handed application of the law by regulators, has had a quantifiable chilling effect on disclosures by health care providers. The proposed SRDP, and the factors required to be considered by the Secretary in reducing potential Stark liability, should ultimately provide a reliable road map for providers who would like to address historical violations of the Stark law. The proposed SRDP is also consistent with the kinds of consideration the government has routinely given to self disclosers in other areas of criminal and regulatory law.

The answers to some provider questions, however, remain very unclear. For example, may disclosures of Stark violations only be made to an as of yet to be designated “person, official, or office” within CMS, or can disclosure still be made to a local U.S. Attorney’s office? Will these disclosures obviate the threat of lawsuits by qui tam relators? The very nature of Stark’s strict liability financial provisions makes the potential recovery in almost every technical Stark case grossly disproportionate – will the Secretary be reasonable in negotiating reductions in appropriate cases?

TAKEAWAY TIPS

Self disclosure is a sensitive and complex issue, and a step not to be taken lightly. If regulators and prosecutors truly desire self disclosure, and believe it to be a commendable course of action, they need to recognize that there must be some benefit to the discloser – a benefit, frankly, that the discloser has a right to expect. Although in the abstract, a proposed SRDP is a positive development, it remains to be seen how well it will work in practice. It may be slow going because of the institutional need for regulators to appear strong on fraud and abuse, particularly in light of FERA and the amendments to the False Claims Act. There are also practical problems of logistics. How much due diligence will regulators perform when they receive a self disclosure? Will there be random audits? Will self disclosers be required to certify their submissions?

The amount of federal money spent on health care is significant. At a time of ballooning federal deficits, the political imperative to recover misspent health care funds is at fever pitch and shows no signs of abating. At the same time, however, providers have a strong need for a place to disclose Stark concerns and be treated fairly in the process. Providers and their counsel will be anxiously waiting to see the results of the interaction between these two significant forces.

LATE BREAKING NEWS

As this alert was going to distribution, anecdotal data suggests that since the passage of PPACA, providers have indeed been approaching CMS with technical Stark disclosures, even in the absence of an official protocol. However, it is premature to discern any patterns on how those disclosures are being received or resolved.

FOR MORE INFORMATION, CONTACT A MEMBER OF OUR HEALTH CARE GROUP

This Client Alert is the third in the “Finding Your Way” advisory series, designed to assist our clients and other health care providers as they prepare to respond to health care reform. Future articles will include discussions regarding PPACA’s criminal enforcement, employment, civil fraud and abuse, accountable health organization, and health information technology provisions.

For questions about the information contained in this Alert, or any of the fraud and abuse provisions in the health care reform law, please contact James Belanger at 602.381.5485 or jbelanger@csblaw.com, or any member of the CSB Health Care Law Group:

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If you do not wish to receive future advisories, please contact Carol Keesee at 602-381-5469 or ckeesee@csblaw.com.