



**November 2, 2010**

## Compliance *Matters* ...

As we move forward in this new era of health care reform, the importance of a strong compliance program is ever apparent. In fact, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care Education Reconciliation Act of 2010 (the Health Care Reform Law), grants the Secretary of Health and Human Services the authority to require mandatory compliance and ethics programs for a broad range of providers and suppliers. While it is not yet clear how that authority will be exercised, it is clear that the bar has effectively been raised with respect to compliance and ethics programs.

Many providers struggle with the tension between an effective and robust compliance program and how to resolve identified issues – especially potential Stark law violations that carry significant penalties. While the OIG has offered providers a mechanism to voluntarily disclose potential fraud, waste, or abuse to the OIG through its self-disclosure protocol, the OIG's protocol has not been available for Stark-only disclosures. The Health Care Reform Law obligated the Centers for Medicare and Medicaid Services to establish a voluntary self-referral disclosure protocol (SRDP) applicable to all providers and suppliers for resolution of potential or actual violations of the Stark law and granted the Secretary of HHS the authority to compromise the amount due and owing for Stark violations. The CMS SRDP, which closely resembles the OIG self-disclosure protocol, is available to providers on the CMS website ([https://www.cms.gov/PhysicianSelfReferral/Downloads/6409\\_SRDP\\_Protocol.pdf](https://www.cms.gov/PhysicianSelfReferral/Downloads/6409_SRDP_Protocol.pdf)). Many questions remain surrounding the SRDP that will hopefully be resolved or clarified with time but having a SRDP from CMS should help compliance programs more effectively address self-referral issues that are identified.

Identifying compliance problems and taking the initiative to correct the problem is proving to be extremely economical. We often talk about compliance enforcement in terms of government initiatives but overlook the most likely initiator of a compliance action, your staff. We continue to see a number of enforcement actions initiated by whistleblowers who are often motivated by the opportunity for substantial payouts. An effective compliance and ethics program can help alleviate the risk of a whistleblower by identifying compliance issues early and allowing the provider the opportunity to evaluate the identified compliance issues and whether disclosure to the government is necessary. As illustrated below, providers continue to utilize the OIG self-disclosure protocol to resolve potential and/or actual violations of the fraud and abuse laws for modest amounts as compared to litigated settlements.

### ***Noteworthy Settlements***

#### ***Southern California Medical Center (Imperial County, California) – September 2010***

The El Centro Regional Medical Center is a 165 bed acute care hospital. A former employee filed a qui tam action against the Hospital for allegedly inflating charges to Medicare patient to obtain large



reimbursements. The Hospital was allegedly billing for short inpatient admissions when in reality they should have been billed as outpatient “observation” services or emergency room visits. The Federal Government intervened in the lawsuit and a \$2.2 million settlement was entered into by the parties. As part of the settlement, the qui tam relator (the whistleblower) received \$375,000. Glenn R. Ferry, the special agent in charge for the Los Angeles Region of the OIG-HHS, commented “Whistleblowers are critical to ensuring that Medicare dollars are not siphoned off, but find their way to those who most need them. Office of Inspector General special agents and our law enforcement partners have forged a powerful team that will work with private citizens who come forward to protect the Medicare Trust Fund and defend it from fraud and abuse.”

***United Shockwaves Services, United Urology Centers and United Prostate Centers (Chicago, Illinois) – July 2010***

The United States filed suit against United Shockwaves Services, United Urology Centers and United Prostate Centers alleging that the defendants solicited and received payments from hospitals in exchange for patient referrals, violating the Federal anti-kickback laws. Physicians had investment interests in the defendant companies. The defendant companies would solicit contracts from the hospital in return for the physician investors referring patients to the hospitals. The OIG’s press release alleges that the physicians would threaten to divert referrals to other hospitals if the hospital did not enter into contracts with the defendants. The total settlement amount was \$7,359,500 and the defendants entered into a five year Corporate Integrity Agreement. The OIG Press Release includes a statement by the IG that “companies, including those with physician-owners cannot use Federal health care beneficiary referrals to line their pockets by securing business from hospitals or other providers.”

***Azmat and Satilla Regional Medical Center (Waycross, Georgia) – July 2010***

The United States has intervened into a qui tam action filed by a nurse alleging violations of the False Claims Act by Dr. Azmat and Satilla Regional Medical Center. While the case is still pending, the intervention by the government and the allegations in the government’s complaint are extremely telling. The government alleges that Dr. Azmat was not qualified to perform endovascular procedures, and therefore the services rendered and billed were worthless services. Billing for worthless services may be considered a false claim. Because Satilla was aware of Dr. Azmat’s lack of qualifications to perform endovascular procedures, Satilla is also liable for submitting false claims for the service it rendered in association with Dr. Azmat’s services. This case is unique in that it highlights the possibility of linking poor medical staff credentialing to false claims.

***Self-Disclosure Settlements***

There have been two recent self-disclosure settlements that are noteworthy. First, the OIG entered into a settlement agreement with St. John’s Regional Medical Center (located in Missouri) after the Medical Center made a self-disclosure of potential stark and anti-kickback issues. There were two primary issues identified: (1) the Medical Center allowed a physician to be delinquent in paying rent pursuant to a lease agreement over a substantial period of time, and (2) the Medical Center paid physicians for reading electrocardiograms over several different periods of time without a written agreement. The OIG believes



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this case is significant because it highlights the need to have written agreements for services and to ensure that the parties abide by the terms of the written agreement. The total settlement value was \$274,815.

In another settlement, two physician groups and Mercy Medical Center (located in Maryland) entered into a settlement agreement with the OIG for \$195,000 after a self-disclosure of a number of arrangements that potentially violated Stark and the anti-kickback laws. Some of the arrangements at issue included lease agreements, professional billing services agreements, and on-call physician arrangements.

Both of these settlements include modest numbers compared to the settlement numbers for cases arising out of litigation. While discovering these issues and self-disclosing them may seem painful, it is a lot less painful than having a qui tam action or government initiated action.

## ***The Government does want to help!***

CMS is launching a new publication *Medicare Quarterly Provider Compliance Newsletter* which is “intended to help physicians, providers, and suppliers and their billing staffs understand how to avoid certain billing errors and other improper activities (such as failure to submit medical record documentation timely) when dealing with the Medicare Fee-For-Service (FFS) program.” The first edition of this newsletter was published for October 2010 and can be seen at:

[http://www.cms.gov/MLNProducts/downloads/MedQtrlyComp\\_Newsletter\\_ICN904943.pdf](http://www.cms.gov/MLNProducts/downloads/MedQtrlyComp_Newsletter_ICN904943.pdf).

The newsletter uses information from the OIG and General Accountability Office, Recovery Audit Contractors (RAC), Program Safeguard Contractors, Zone Program Integrity Contractors and Medicare Administrative Contractors. Through an analysis of this data, CMS provides recommendations to avoid billing errors and other compliance issues. For example, the first issue addresses inpatient hospital and skilled nursing facilities’ failure to submit requested documentation, services with excessive units – units billed exceeded the number approved per CPT/HCPCS code descriptions, e.g. cardiac pacemaker implantation – not medically necessary to receive care in inpatient setting, and more. This newsletter will provide some insight into the routine problems that are on the mind of CMS.

*For more information about this update or any other compliance related matters, please feel free to contact us at 410.224.3000 or visit our website at [www.hospitallaw.com](http://www.hospitallaw.com).*

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