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Issues in Corporate Integrity Agreements in Health Care Fraud and Abuse

In the first 24 days of May, the Office of Inspector General (OIG) of the Department of Health and Human Services announced 35 criminal and civil fraud settlements with Medicare and Medicaid providers.

By **David H. Glusman** | June 20, 2019 at 12:19 PM



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In the first 24 days of May, the Office of Inspector General (OIG) of the Department of Health and Human Services announced 35 criminal and civil fraud settlements with Medicare and Medicaid providers. That rate of almost 1.5 cases per day demonstrates the aggressive stand the federal government is taking against health care fraud and abuse.

Billing fraud and financial dealings that violate the Stark Law or Anti-Kickback Statute (AKS) are the two most common categories of OIG or Department of Justice (DOJ) enforcement actions. Billing fraud includes unnecessary services or overutilization, services never delivered, duplicate services and upcoding of services. Stark Law and AKS cases commonly include excessive physician compensation arrangements, equipment and office lease arrangements, and a wide range of crafty financial inducements for physicians to refer patients to home health, hospice, inpatient and outpatient services or for physicians to provide high-cost drugs.

The federal enforcement actions result in many providers being excluded from the Medicare and Medicaid programs but many cases are resolved with fines or restitution plus a corporate integrity agreement (CIA) that allows the provider to continue to participate in Medicare or Medicaid. Legal counsel often plays a key role in cases that are settled with a fine or restitution and a CIA. .

When a client is approached in an OIG or DOJ investigation the attorney needs to quickly understand the underlying issues and the scope of the circumstances being investigated. Before a CIA will be considered, either OIG or DOJ investigators will gain significant understanding of the operation of the health care entity and any relationships that exist between the client (target) and other health care entities.

DHHS and DOJ investigators have considerable expertise, but they also have heavy caseloads and are busy. Their investigations can pursue physician practices, hospitals, nursing homes, continuing care communities, pharmaceutical manufacturers, diagnostic facilities and home health agencies. It is difficult for investigators to have detailed knowledge across different provider sectors. Therefore, their work is not infallible and it is important for legal counsel to monitor governmental investigations from the outset and conduct their own investigations.

OIG and DOJ investigations involving billing fraud are subject to the complexities that have been introduced by electronic health records and the myriad of procedure and diagnosis coding in terms of documentation of services, audit trails for transactions, and inadequate reporting. Counsel needs to be sure that their client's billing and clinical staff have true expertise in the system they are using. An outside billing and EHR expert is often needed.

OIG and DOJ investigations involving the Stark Law and Anti-Kickback Statute will center on contracts and financial terms. In addition to fully understanding all the economic arrangements underlying the client's operation, gaining a full understanding of the definition and terminology for fair market value and commercially reasonable, specifically in the health care environment, will be part and parcel of the representation. Utilizing specialized expertise, whether in the form of client personnel or outside experts, usually retained under a Kovel agreement—named for the case law under *United States v. Kovel*, 296 F.2d 918 (2d. Cir. 1961)—legal counsel will look for all the attributes of an arm's length, fair market value arrangement. Simply by way of example, the physician practice that receives gratis services from a home health agency that is receiving referrals from the physician practice,

would likely be the subject of an investigation and potentially a subsequent CIA. Each of the different types of healthcare clients is likely to lead to different aspects of investigation of the underlying arrangements.

Even once the economics appeared to be gaining clarity, understanding the dollar impact is an important part of coming to an understanding with the government prior to the government deciding whether to either prosecute criminally, seek significant civil penalties and fines, or take no action. The forensic expert often plays a significant role, as legal counsel may not have the wherewithal to put a dollar value on the allegations by the government.

Legal counsel plays an important role in negotiating settlements through a CIA. The CIA will require the target company to hire an independent review organization (IRO). Internally the client will routinely need to create an office of compliance, policies and procedures that the government agrees are adequate as well as the hiring IRO. These agreements routinely run for three to five years, and often have very specific procedures for testing compliance, and often on a quarterly or even monthly basis, with the filing of a report the government by the IRS. These can be somewhat exhaustive with regard to the client adhering to the new operational policies and procedures, as well as providing information the IRO needs to complete its quarterly monitoring reports.

CIAs have many common elements but each is also specifically designed to address the facts at issue in the action brought by the OIG. The OIG website lists the following as likely steps and processes in a CIA:

- Hire a compliance officer/appoint a compliance committee;
- Develop written standards and policies;
- Implement a comprehensive employee training program;
- Retain an independent review organization to conduct annual reviews;
- Establish a confidential disclosure program;

- Restrict employment of ineligible persons;
- Report overpayments, reportable events, and ongoing investigations/legal proceedings; and
- Provide an implementation report and annual reports to OIG on the status of the entity's compliance activities.

With CIAs covering billing fraud the IRO will be required to formally audit billing and reimbursement activities. In situations with Stark law violations the monitoring will cover, for example, physician compensation arrangements, space or equipment leasing activities and other financial dealings considering fair market value and commercial reasonableness standards. The Stark Law and Anti-kickback Statutes have unique definitions, guidance and regulations covering fair market value and commercial reasonableness.

Medicare and Medicaid fraud settlements involving CIA's present obvious need for forensic expertise, auditing expertise, health care operational expertise and client management skills.

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