Corporate Integrity Agreements

Corporate Integrity Agreements (CIA) are an important element for any Compliance Officer to be aware of. No organization wants to be under any type of a CIA. Having a CIA means the organization has in some way violated state or federal health laws. If an organization has to move into a CIA, the agreement will always require that the organization has a designated Compliance Officer.

The Centers for Medicare and Medicaid (CMS) provide some of the best information about CIAs and what this process means. From CMS: A CIA is a document outlining the obligations a corporate provider agrees to as part of a civil settlement. This means a lawsuit occurred or an investigation was completed where there was wrong doing found on the part of the health care provider. CIAs are seen as an enforcement tool used by the U.S. Department of Health and Human Services (DHHS), Office of Inspector General (HHS-OIG), and the Department of Justice (DOJ) to fight health care fraud, waste, and abuse.

While often coming from some type of a civil settlement involving a corporate health care provider, the state or federal government can also use CIAs to address quality of care and program integrity issues. For example, wounds and pressure injuries are tracked in skilled nursing facilities (SNF) and must be reported upon within 24 hours of discovery. If a SNF demonstrates that the number of acquired wounds far exceeds what would be expected in any facility, an investigation may find poor quality of nursing care, poor positioning, or poor pressure management of mattresses. The result for the SNF is to pay a civil find and move into a CIA that defines what the SNF agrees to do to remedy the situation. This could include staff education and ongoing training; could require regulatory oversight frequently; could require new equipment or mattresses; and usually requires more frequent reporting.

CIAs promote compliance with federal health care program requirements. They create a framework a corporate provider and its officers, directors, employees, and contractors must operate within to avoid exclusion from participation in federal health care programs. Violations to federal law for organizations could result in Medicare being withdrawn or facilities not allowed to admit any new patients with Medicare.

States also use CIAs as part of their anti-fraud efforts. State-based CIAs generally deal with Medicaid fraud or licensing issues. For example, a physical therapy clinic that hires aides to provide physical therapy services and then bills for those serves as if a physical therapist or physical therapist assistant provided the services would be in violation of state law. A state CIA would be required. The clinic would also be required to pay back all funds to Medicaid and any state health plans that were billed for services that were not provided by the PT or PTA. This effectively would close most clinics that tried to operate in this type of fraudulent manner.

CIAs generally last 5 years. During this time the provider is usually required to implement or expand a comprehensive employee training program, a confidential disclosure program, written standards and policies, and designate a compliance officer and committee. Compliance officer and committee requirements will be discussed in the next lesson.

CIAs also mandate establishing processes for managing and reporting “reportable events.” Reportable events include overpayments, ongoing investigations or legal proceedings, potential violation of criminal, civil, or administrative laws applicable to the organization. All of the laws discussed in this lesson and previous lessons all fall under the umbrella of possible inclusion in a CIA.

Some CIAs require an Independent Review Organization to review and monitor compliance with the terms and conditions of the CIA. Most CIAs require claims reviews to identify errors and their underlying causes. These types of claims reviews are known as audits.

Case Study: DaVita to Pay $350 Million to Resolve Allegations of Illegal Kickbacks

This case provides an excellent example of a combination of Safe Harbors violations; fraud issues; and kickback schemes all resulting in large fines along with a CIA for an aggressive provider of dialysis services.

DaVita Healthcare Partners, Inc., one of the leading providers of dialysis services in the United States, agreed to pay $350 million to resolve claims that it violated the False Claims Act by paying kickbacks to induce the referral of patients to its dialysis clinics. DaVita is headquartered in Denver, Colorado and has dialysis clinics in 46 states and the District of Columbia.

The government alleged that DaVita used a three-part joint venture business model to induce patient referrals. First, using information gathered from numerous sources, DaVita identified physicians or physician groups that had significant patient populations suffering renal disease within a specific geographic area. DaVita would then gather specific information about the physicians or physician group to determine if they would be a “winning practice.” In one transaction, a physician’s group was considered a “winning practice” because the physicians were “young and in debt.” Based on this careful vetting process, DaVita knew and expected that many, if not most, of the physicians’ patients would be referred to the joint venture dialysis clinics.

Next, DaVita would offer the targeted physician or physician group a lucrative opportunity to enter into a joint venture involving DaVita's acquisition of an interest in dialysis clinics owned by the physicians, and/or DaVita's sale of an interest in its dialysis clinics to the physicians. To make the transaction financially attractive to potential physician partners, DaVita would manipulate the financial models used to value the transaction.

Last, DaVita ensured future patient referrals through a series of secondary agreements with their physician partners. These included paying the physicians to serve as medical directors of the joint venture clinics, and entering into agreements in which the physicians agreed not to compete with the clinic.

All three of these pieces are clear violations of state law. Some would argue that the physicians should have known better. However, it was not the physician groups who were found liable. It was DaVita.

As part of the settlement, DaVita agreed to a Civil Forfeiture in the amount of $39 million based upon conduct related to two specific joint venture transactions entered into in Denver, Colorado. Additionally, DaVita entered into a Corporate Integrity Agreement with the Office of Counsel to the Inspector General of the Department of Health and Human Services which required DaVita to unwind some of its business arrangements and restructure others, and included the appointment of an Independent Monitor to prospectively review DaVita's arrangements with nephrologists and other health care providers for compliance with the Anti-Kickback Statute.

Corporate Integrity Agreements indicate that an organization has been involved in some type of violation of law. One way most organizations have moved to prevent violations of law is to have a Compliance Officer and compliance committee. You may wonder what would have happened if any of the involved physician groups had consulted a compliance officer before entering into contracts with a firm like DaVita.

DaVita remains a strong operator in the area of renal dialysis. As an independent group, many DaVita centers are found in strip malls of shopping centers. Dialysis has a strong profit motive for any provider. Medicare pays well for end stage renal dialysis (ESRD) that includes dialysis. Let DaVita be an example of what not to do on all business fronts.