From the courtroom to Compliance—
one lawyer’s journey and the lessons learned

an interview with Tracy Carlson Ivers
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Recent corporate integrity agreements: Best practices for compliance

The Office of the Inspector General (OIG) for the Department of Health and Human Services (HHS) often conditions settlement of federal healthcare program investigations arising under the civil False Claims Act (FCA) on the provider entering a corporate integrity agreement (CIA). Providers or entities agree to adhere to heightened compliance obligations outlined in a CIA, and in exchange, the OIG agrees not to seek their exclusion from participation in Medicare, Medicaid, or other federal healthcare programs. There are two types of CIAs, traditional CIAs and Quality of Care CIAs. This article is focused on the correlation between compliance programs and traditional CIAs, but providers are encouraged to also review the Quality of Care CIAs to minimize compliance and false claims risk due to patient care issues. CIAs are generally expensive to implement and require providers to complete a significant number of requirements within a short timeframe. CIAs include certain general components pertaining to the seven elements of an effective compliance program and also include additional compliance initiatives designed to help prevent against the type of activity that was the subject of the investigation. The compliance obligations outlined in CIAs can give providers insight as to what regulators view as best practices in the healthcare industry.

The OIG has defined the mission of its CIAs as follows:

CIAs have many common elements, but each one addresses the specific facts at issue and often attempts to accommodate and recognize many of the elements of preexisting compliance programs are warranted.1

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The compliance obligations outlined in corporate integrity agreements (CIAs) can give providers some insight as to what regulators view as best practices in the healthcare industry.

The standard CIA negotiated by the OIG generally includes provisions pertaining to the seven elements of an effective compliance program.

CIAs are also a resource as to what might be required of specific providers in particular industries or regarding certain compliance risks.

A review of recent CIAs for industry best practices should be included in a provider’s regular evaluation of its compliance program.

Implementation and oversight of CIAs require significant personnel and financial resources.

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voluntary compliance programs. A comprehensive CIA typically lasts five years and includes requirements to:

- 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 (someone currently ineligible to participate in the Federal healthcare programs or Federal procurement or nonprocurement programs);
- Report overpayments, reportable events, and ongoing investigations/legal proceedings; and
- Provide an implementation report and annual reports to the OIG on the status of the entity’s compliance activities.2

The rise in enforcement of the federal healthcare laws makes it more important than ever for healthcare providers to evaluate and improve their internal compliance programs. As a part of that evaluation process, providers should stay abreast of the terms of recent CIAs negotiated by the OIG.

This article highlights recent CIAs, discusses best practices that healthcare providers can glean from CIAs, and those practices which they can implement in order to ultimately avoid violations of the healthcare fraud and abuse laws.

**CIAs and best practices for compliance**

The healthcare industry’s standards for an effective compliance program are modeled on the seven elements of an effective compliance program provided in Chapter 8 of the Federal Sentencing Guidelines.3 These elements include:

1. A written code of conduct and policies and procedures
2. Organizational oversight (compliance officer and compliance committee)
3. Training and Education
4. Auditing and Monitoring
5. Consistent discipline among employees and enforcement of policies and procedures
6. Investigating systematic concerns and problems in the organization
7. Open communication and reporting concerns (i.e., anonymous hotline for complaints)

The OIG has stated that although there is no “one size fits all” compliance program, these seven elements can be customized to fit the needs and fiscal responsibilities of any given healthcare entity and that every effective compliance program begins with a formal commitment to these seven elements.

A review of the basic structure of recent CIAs provides guidance as to how OIG envisions these essential elements in practice.

**Written code of conduct and policies and procedures**

Codes of conduct and policies and procedures must contain “commitment to full compliance with all Federal healthcare program requirements,” discussion of how all relevant personnel must comply with these laws, and the requirement to report suspected violations to the compliance officer.

**Organizational oversight**

A standard CIA requires a provider’s compliance officer to report directly to the board of directors and not to the company’s general counsel, as a means of ensuring transparency and awareness throughout the corporate structure. Recent CIAs have required personal attestations of compliance by the compliance officer.
officer and other governing employees. Beyond internal oversight by the board, executives, and compliance officer, CIAs also require the engagement of an Independent Review Organization (IRO) to review the provider’s progress in implementing the requirements of the CIA and to document the provider’s overall compliance with federal healthcare laws.

Training and Education
The OIG requires both general and specific training for relevant personnel under a CIA. General training relates to CIA requirements and reviews the compliance program, including the code of conduct. Specific training involves the discussion of federal healthcare program requirements and provider-specific policies and procedures that relate to federal healthcare program requirements, as well as a discussion of the personal obligations of personnel to follow federal requirements, the legal sanctions for failing to do so, and examples of non-compliance. CIAs also require board member training and certification that each relevant employee has completed their required training sessions. Careful consideration should be given in defining the term “relevant” personnel. Organizations should consider extending the training and education requirements to include all contract physicians, coders, and billers.

Auditing and Monitoring
CIAs often require companies to hire an IRO to review and report on the company’s compliance efforts and progress in implementing all facets of the CIA on an annual or more frequent basis. These reviews are typically conducted through a sampling and analysis of documentation and claims to ensure medical necessity, coding, and reimbursement accuracy. The outline of the IRO audits can provide guidance to other companies as to how they may want to consider structuring their audits in a particular risk area. CIAs also require a full systems review, related to errors that result in a net overpayment error rate of at least 5%, to determine the cause of the error and identify appropriate corrective action.

Consistent discipline and enforcement
These agreements require strict screening of employees and those it conducts business with to ensure that no “ineligible person” (i.e., an individual or entity currently excluded from participation in federal healthcare programs) is improperly engaging in an excluded activity related to federal healthcare programs. All providers, regardless of whether subject to CIA, should be conducting similar screening.

Investigating systematic concerns and problems
Many CIAs require providers to develop compliance risk evaluation and mitigation procedures that allow a provider to determine any systematic concerns in their operations before they lead to compliance violations. These procedures are meant to result in a system that collects information from internal compliance audits, items submitted to the provider’s disclosure program, and IRO reviews and then monitors for any risks and potential violations stemming from the risk areas named in those sources. This risk evaluation program is meant to be overseen by the Compliance department or an independent consultant, with the results overseen by the compliance officer.
and reviewed by the provider’s IRO. CIAs also require a full systems review related to errors resulting in a net overpayment error rate of more than 5% to determine the cause of the error and identify appropriate corrective action.

**Open communication and reporting concerns**

Providers must explicitly state in their codes of conduct that all individuals have a right to use the Compliance department’s disclosure program and that the provider is committed to non-retaliation and to maintaining confidentiality and anonymity with respect to such disclosures (non-retaliation is now often referred to as the “8th element” of an effective compliance program). The Compliance department is also required to maintain a disclosure log, which “shall include a record and summary of each disclosure received (whether anonymous or not), the status of respective internal reviews, and any corrective action taken in response to internal reviews.”

CIAs are a rich resource for providers because they demonstrate how the OIG envisions a provider should implement the seven elements into a compliance program and effectively mitigate compliance risks in day-to-day operations.

**Best practices derived from CIAs and recent enforcement**

A review of recent government enforcement activity and the CIAs negotiated by the OIG can also serve as an additional resource for best practice for compliance regarding what the OIG might require beyond the seven essential elements for a particular industry or regarding particular compliance risks. For example, recent CIAs negotiated by the OIG have included specific compliance practices for pharmaceutical companies, home health, and hospitals, as well as compliance measures related to pharmaceutical promotional practices, coding and claim processing, referrals, and physician agreements. Providers should consider implementing these specific compliance practices, in addition to the seven essential elements, to avoid criminal and civil liability under the healthcare fraud and abuse laws.

**Parkland Health and Hospital**

The Parkland system entered into a CIA on May 24, 2013 as part of its settlement to resolve allegations related to improper claims submission to both Medicare and Texas Medicaid, including upcoding of evaluation and management services (E/M), lack of medical necessity, and inadequate supervision of residents and medical students. Parkland’s CIA requires the hospital to establish a compliance committee, appoint a chief quality officer, use a patient care and quality dashboard, and engage an outside compliance expert to assist the board with their duties. The hospital was required to develop policies and procedures related to patient care, documentation, and claims submission, as well as to provide significant training to all staff and employees. The compliance and quality committees must meet with the board on a quarterly basis. The CIA also requires an
independent review of at least 100 Medicare and 100 Medicaid claims on an annual basis.

**Best practice takeaway:** The Parkland CIA supports the need to develop strong policies and procedures related to patient care, documentation, coding, and billing. It emphasizes the importance of education and training on code of conduct, policies and procedures, and proper patient care to all levels of administrative and clinical staff. It also stresses the need for effective auditing and monitoring of clinical documentation as well as claims accuracy. The Parkland CIA requirement to appoint an outside compliance expert to assist the hospital and board in its duties is unique and suggests that if providers do not have in-house healthcare compliance experts, partnering with outside experts is advised.

**Johnson & Johnson**

Johnson & Johnson entered into a CIA on October 31, 2013 as part of its settlement to resolve allegations related to its prescription drugs Risperdal, Invega, and Natrecor. Johnson & Johnson was accused of promoting these drugs for uses unapproved by the Food and Drug Administration (FDA) and of paying kickbacks to physicians and the nation’s largest pharmacy specializing in dispensing prescription drugs to nursing home patients. Johnson & Johnson’s CIA requires the company to “change its executive compensation program to permit the company to recoup annual bonuses and other long-term incentives from covered executives if they, or their subordinates, engage in significant misconduct”, which includes both currently employed executives and executives who have left the company. The CIA also requires Johnson & Johnson to modify its policies and procedures to discuss appropriate ways to conduct promotional and product-related functions with third parties to maintain compliance, including a discussion of the types of materials and information that may be distributed by Johnson & Johnson sales representatives and how those representatives can and cannot discuss non-FDA approved (“off-label”) uses of Johnson & Johnson products. The CIA requires Johnson & Johnson sales representatives to refer questions about off-label uses of government-reimbursed products to the “relevant medical affairs” or “medical information & services department” rather than fielding the questions themselves.

**Best practice takeaway:** The Johnson & Johnson CIA suggests that pharmaceutical policies and procedures should include instruction to sales personnel on the appropriate ways to conduct promotional and product-related functions with third parties to maintain compliance. OIG has indicated that policies and procedures should feature a discussion of the types of materials and information that may be distributed by sales representatives and how those representatives can and cannot discuss off-label uses. The Johnson & Johnson CIA also indicates that industry best practice is to have sales representatives refer all questions they receive about off-label uses of government-reimbursed products to their company’s Medical Affairs or Medical Information & Services departments, rather than fielding the questions themselves.

**Endo Health Solutions Inc. and Endo Pharmaceuticals Inc.**

Endo entered into a CIA on February 21, 2014 to resolve allegations that it marketed the prescription drug Lidoderm for uses unapproved by the FDA. Endo’s CIA includes compliance measures such as “making publicly available the results of certain clinical trials and requiring an annual review and certification of its compliance efforts by the Chief Executive Officer of its parent company, Endo Health Solutions.” The CIA also places significant restrictions and disclosure requirements on “third-party educational activity,” which are defined in the CIA as “professional education...
for [healthcare providers] intended to be independent of Endo’s control or influence and that are conducted by a third party and supported by Endo including continuing medical education (CME), disease awareness, or sponsorship of symposia at medical conferences.”

Endo is required to post summary information on its company website about medical education grants and charitable contributions made by Endo—including the number and total value of those grants and contributions in each calendar year. Endo is also required to ensure that all of its consultants are contractually obligated to fully comply with the disclosure requirements of the CIA. Finally, the CIA requires that Endo contractually obligate all authors of biomedical manuscripts affiliated with Endo to fully comply with the International Committee of Medical Journal Editors criteria regarding authorship and disclosure of their relationship with Endo and to disclose any potential conflict of interests that may bias their work.

**Best practice takeaway:** As discussed in the Endo CIAs, it is important for pharmaceutical companies to closely monitor the provider education programs that they sponsor. OIG has sent the message that pharmaceutical companies should be reviewing, tracking, and evaluating their funding of third-party educational activities to ensure that funding decisions are “based on objective criteria such as qualifications of the requestor, the quality of the Third Party Educational Activity program, and pre-established educational goals” of the company. Integrating this kind of funding review and tracking system into a corporate compliance program can help mitigate overall risk.

**Halifax Hospital Medical Center and Halifax Staffing Inc.**

Halifax entered into a CIA on March 10, 2014 and agreed to pay an $85 million settlement to resolve allegations that it violated the FCA by submitting Medicare claims that violated the Stark Law. Specifically, it was alleged that Halifax executed contracts with oncologists that provided an incentive bonus for the value of the prescription drugs and tests that the oncologists ordered and were later billed to Medicare. Halifax’s CIA requires it to “undertake substantial internal compliance reforms and to submit its federal healthcare program claims to independent review for the next five years.”

The CIA also contains a discussion of how to conduct “arrangements training” to instruct personnel on how to conduct themselves in arrangements that potentially implicate the Stark Law or the Anti-Kickback Statute (AKS). Halifax was instructed to discuss the Stark Law and the AKS; review Halifax’s policies regarding referrals and the tracking of referrals; review the personal obligations of each individual involved in the “development, approval, management or review” of the company’s physician and contract agreements; and review the legal sanctions and examples of violations of the AKS and Stark Law. The arrangements training is required under the CIA to occur for at least two hours annually and must be given to new hires before they are involved with any physician agreement or contract.

**Best practice takeaway:** The CIA entered into by Halifax contains helpful guidance related to agreements with physicians who may be potential sources for referrals.
Providers should train personnel to understand the relevant federal healthcare statutes implicated by physician agreements and other contract arrangements (Stark and AKS), review the company policies regarding physician agreements and contract arrangements, implement a system for tracking such arrangements, and discuss the personal obligations of each individual involved in the “development, approval, management or review” of the provider’s contract agreements. Providers should consider implementing or enhancing their training on the legal sanctions related to federal healthcare fraud and abuse laws, give examples of violations of the AKS and Stark Law, and ensure this training is given to new hires before they are involved in negotiating or approving arrangements with potential referral sources. Mirroring these training practices would be a strong step toward maintaining Stark and AKS compliance.

**Amedisys Inc.**
Amedisys entered into a CIA\(^\text{11}\) on April 22, 2014 as part of a settlement to resolve allegations that it violated the FCA by submitting false home healthcare billings to Medicare for ineligible patients and nursing and therapy services. Amedisys was also accused of maintaining improper financial relationships with referring physicians in violation of the AKS and Stark Law.\(^\text{12}\) The company’s CIA requires the implementation of an Internal Risk Evaluation and Mitigation Program (REM Program) that identifies the material Medicare risk areas for Amedisys’ home health services, outlines all “risk mitigation activities” that Amedisys will engage in, and requires Amedisys to create a system that monitors and tracks these mitigation activities that it implements to avoid Medicare compliance issues. The REM Program also requires the filing of an annual REM Program Review, which is conducted by an IRO.

The Amedisys CIA also outlines important training requirements for any “relevant covered person” under the agreement. Beyond general compliance training, the CIA also includes specific training requirements related to coding, reimbursement, and billing for services related to federal healthcare programs. The provisions of the CIA mandate that relevant personnel receive training in federal healthcare program requirements regarding the accurate coding and submission of home health claims; the personal obligation of each individual involved in the claims submission process to ensure that such claims are accurate; the legal sanctions for violations of these federal programs; a review of all applicable policies, procedures, statutes, and regulations; and examples of proper and improper claims submission practices. The mandates of the Amedisys CIA require this specific training of relevant personnel to occur annually for an additional hour per session.

**Best practice takeaway:** As seen in the Amedisys CIA, OIG has placed an emphasis on the training of personnel who are involved with coding and claim processing. Healthcare providers should review their orientation and training materials to ensure that they address these issues and that this training is reaching all personnel involved with coding and claims processing.

**DaVita Healthcare Partners, Inc.**
DaVita entered into a CIA\(^\text{13}\) in October of 2014 as part of a settlement to resolve allegations that it violated the FCA by paying kickbacks to induce the referral of patients to its dialysis clinics across the country. DaVita’s CIA requires it to “unwind some of its business arrangements and restructure others, and includes the appointment of an Independent Monitor to prospectively review DaVita’s arrangements with nephrologists and other healthcare providers for compliance with the Anti-Kickback Statute.”\(^\text{14}\) Under the CIA, DaVita must develop
a process for documenting the selection of healthcare providers with whom it enters into joint venture arrangements and other covered business arrangements. This process must include selection criteria that relate to the providers’ ability to perform the functions of the arrangement and not on the providers’ ability to provide referrals to DaVita.

DaVita must also create a centralized tracking system for all existing or new covered business arrangements with healthcare providers that tracks: remuneration between parties, investments made by parties, and estimated return of investment for parties for all partial acquisitions and partial divestiture arrangements. The system must also track the services provided under these arrangements; the use of leased spaces and medical equipment; and establish a system of review, approval, and enforcement that ensures compliance with the CIA and the AKS in all covered business arrangements. Finally, DaVita’s CIA also requires it to send notice to all joint venture partners and medical directors notifying them that they (and their colleagues) are free to refer patients to non-joint venture facilities, that DaVita will not enforce any “patient-related non-disparagement or non-solicitation clauses,” and that DaVita will not enforce the investment non-compete provisions found in its joint venture clinics formed by partial divestitures.

**Best practice takeaway:** Joint ventures and other agreements between a healthcare provider and physicians who refer patients to that provider create potential compliance issues. The DaVita CIA offers guidance on how to avoid these issues. As suggested by the Halifax CIA, providers should consider creating (or enhancing) a system that documents the selection of healthcare providers with whom it enters into joint venture arrangements and other business arrangements. Selection criteria for these business arrangements should relate to the providers’ ability to perform the functions of the arrangement and not on the providers’ ability to provide referrals. Providers should also track all existing or new business arrangements with healthcare providers, investments made by parties, and estimated return of investment for parties for all partial acquisitions and partial divestiture arrangements. It is also important to track the services provided under these arrangements and the use of leased spaces and medical equipment.

**Dignity Health**

Dignity Health entered into a CIA\(^5\) in October of 2014 as part of a settlement to resolve allegations that it improperly overcharged the Medicare and Tricare programs for inpatient services that could have been rendered on an outpatient basis. The CIA designates a significant number of roles as “certifying employees” and requires that each member in one of the designated roles certify on an annual basis that they have received training and understand the compliance requirements that pertain to them, and that the department is in compliance with federal healthcare program requirements and the terms of the CIA. Employees required to provide this annual certification include the president, chief financial officer, chief executive officer, chief operating officer, and chief medical officer. The CIA also requires the performance of a system-wide, annual risk assessment, as well as an annual review conducted by an IRO of at least 100 claims.

**Best practice takeaway:** The Dignity Health CIA reinforces the importance of a commitment to compliance by all employees at every level within the organization. Compliance education and training should be provided to all employees and employees should be required to demonstrate an understanding of the compliance requirements and how those requirements apply to them on a day-to-day basis.
Conclusion
The risks of criminal and civil liability are significant for healthcare providers who fail to regularly evaluate their compliance program. Additionally, the cost of implementing a CIA and engaging an IRO are significant financial expenses. As a part of any provider’s regular compliance evaluation, in addition to reviewing the federal healthcare laws and regulations for changes or updates, providers should also review the terms of recent CIAs negotiated by the OIG in order to ascertain the OIG’s perspective of current industry best practices for an effective compliance program and their ability to meet the government’s expectations.

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2. Health & Human Services: Office of Inspector General: Corporate Integrity Agreements. Available at http://1.usa.gov/1s8XTP
4. Health & Human Services: Office of Inspector General: Corporate Integrity Agreement between OIG and Dallas County Hospital District (Parkland). Available at http://1.usa.gov/1SyEFY
6. Department of Justice, Office of Public Affairs, press release: “Johnson & Johnson to pay more than $2.2 billion to resolve criminal and civil investigations.” November 4, 2013. Available at http://1.usa.gov/1s8PZh
9. Health & Human Services: Office of Inspector General: Corporate Integrity Agreement between OIG and Halifax Hospital Medical Center and Halifax Staffing, Inc. Available at http://1.usa.gov/1Cg6Lu
11. Health & Human Services: Office of Inspector General: Corporate Integrity Agreement between OIG and Amединsys, Inc. and Amedinys Holding, LLC. Available at http://1.usa.gov/1Jxw7Jy

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