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Keeping organizations compliant, secure, and safe

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CIAs: Roadmap to a compliance officer's annual work plan?

» Compliance officers should inform their boards of essential expectations in corporate integrity agreements (CIAs).
» CIAs can facilitate a roadmap to compliance by providing suggestions for better controls and improving the business/corporate culture.
» The financial error rate (FER) and the arrangements tracking system are useful audit tools.
» Independent quarterly or annual claims audits are advisable for work plans.
» Transactions and systems reviews should be part of annual work plans.

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Corporate Integrity Agreements (CIAs), which certain healthcare organizations enter into with the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS), are typically part and parcel of a settlement agreement with government agencies to resolve allegations of wrongdoing or violations of law and to avoid exclusion from federal healthcare programs. Currently there are several hundred CIAs, including several "Quality CIAs" listed on the HHS OIG website.[1] Managing a compliance program under a CIA is one of the most significant challenges that a compliance officer can face. However, aside from the stresses and additional workload that CIAs typically trigger, CIAs can also serve as a catalyst for business improvements, provide suggestions for better controls, and bring positive changes to the corporate culture.


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In fact, any compliance officer, manager, or board member can and should learn from the various CIA agreements made available to the public. The CIAs for organizations that are of a similar type as their own organization are especially important. The *Practical Guidance for Health Care Governing Boards on Compliance Oversight* (*Practical Guidance*)[2] provides guidance to boards regarding oversight of the Compliance, Internal Audit, Legal, and Quality Improvement functions. The *Practical Guidance* stresses the importance of taking cues from CIAs and states that:

> Boards are encouraged to use widely recognized public compliance resources as benchmarks for their organizations. The Federal Sentencing Guidelines (Guidelines), OIG's voluntary compliance program guidance documents, and OIG Corporate Integrity Agreements (CIAs) can be used as baseline assessment tools for Boards and management in determining what specific functions may be necessary to meet the requirements of an effective compliance program.
>
> …CIAs impose specific structural and reporting requirements to promote compliance with Federal health care program standards at entities that have resolved

> fraud allegations. ...Basic CIA elements mirror those in the Guidelines, but a CIA also includes obligations tailored to the organization and its compliance risks.

The *Practical Guidance* promotes the idea that CIAs are not only there for organizations that have entered them, but can be considered tools to assess and baseline any similar type entity's compliance program. In other words, boards, management, and compliance officers are encouraged to integrate the information and expectations raised in CIAs into their own compliance and oversight efforts.

The *Practical Guidance* further emphasizes the importance of board duties relating to CIAs, when it states that "[existing] CIAs may be helpful resources for boards seeking to evaluate their organizations' compliance programs." It is further suggested in the context of board responsibilities that: "Although compliance program design is not a "one size fits all" issue, Boards are expected to put forth a meaningful effort to review the adequacy of existing compliance systems and functions. Ensuring that management is aware of the Guidelines, compliance program guidance, and relevant CIAs is a good first step."[3]

In other words, boards, management, and compliance officers are encouraged to integrate the information and expectations raised in CIAs into their own compliance and oversight efforts.

So what is typically to be found in CIAs that is so useful?

CIAs on compliance program elements

The typical requirements in CIAs listed under "Corporate Integrity Obligations" involve aspects related to the commonly known seven elements of an effective compliance program, as set forth in the various HHS OIG Compliance Program Guidances (CPGs). For example, as far as the assignment of compliance responsibility is concerned, a certain infrastructure (such as having a Compliance Committee and a compliance officer who must not be subordinate to legal counsel or CFO) are typically mandated in CIAs. To strengthen board oversight, sometimes independent compliance experts to advise the board are also mandated. Regarding written standards, typically a code of conduct and policies and procedures must be developed and disseminated to covered persons under the CIA.

As far as training and education requirements go, both general and specific compliance training are standard requirements, with a minimum of one hour of general and 2–3 hours of specific training per year. Specific training may, for instance, include arrangements training or billing and coding training. All covered persons are expected to complete the training (i.e., compliance rates are practically 100%), including a disclosure program that involves mechanisms for confidential reporting to the compliance officer (hotline) and non-retaliation policies. Mandatory sanction screening of employees, vendors, and providers is also a typical corporate integrity obligation.

As far as auditing and monitoring are concerned, numerous CIAs require mandatory, internal, comprehensive risk assessment programs. In addition, most CIAs require the entity to engage an Independent Review Organization (IRO) that conducts various

audits or reviews, either quarterly or annually. The most typical reviews are claims reviews and arrangements reviews. IROs in essence serve an external surveillance function, must be independent and objective, and follow Yellow Book standards for auditing. In particular, these claims and arrangement reviews can be emulated by any Compliance Office and made part of the annual work plan in some form. They can be taken as a best practice and proactive step to avoid CIAs in the first place.

Transaction reviews, such as retrospective audits of a set of paid claims, should not be the end.

CIAs on systems and transactions reviews—claims

CIAs typically require the review of a statistical discovery sample (e.g., 50-100 paid claims) annually, or a statistical probe sample (30 paid claims or items) quarterly, from a total population of claims. Paid claims audits are transaction reviews. The sample is reviewed for reimbursement accuracy and the calculation of a financial error rate (FER) is required. The FER is calculated by dividing the net overpayment identified in the sample by the total dollar amount associated with the paid claims in the sample. If the FER is 5% or more, the review has to be expanded to a larger sample (typical in annual reviews) or is directly extrapolated to the population (typical in quarterly reviews). In any case, unless the sample results indicate that less than 5% of the monies were reimbursed inappropriately, reporting and refunding on an extrapolated overpayment basis is required. In addition, FERs equal to and above 5% also can trigger other types of reviews, such as the systems reviews of claims processes. These reviews are business process reviews of the revenue cycle that examine policies, procedures, and internal controls to determine the root cause of detected errors and internal control weaknesses.

The lesson learned from these mandated CIA reviews is that organizations may want to conduct routine claims audits on their own, using statistical samples and developing trigger or threshold rates similar to the 5% FER metric. These thresholds can be used to decide whether to escalate concerns and justify deepening probes/audits. They also establish a metric that can be reported to the board, tracked, and trended as audits are repeated. Transaction reviews, such as retrospective audits of a set of paid claims, should not be the end. Rather, root causes and systemic issues must also be pursued through systems reviews and weeded out if error rates are significant.

CIAs on systems and transactions reviews—arrangements

CIAs often also require the review of so-called "focus arrangements." The particular focus is determined in the CIA. The arrangements are typically contracts with providers and involve (directly or indirectly) the offer, payment, solicitation, or receipt of anything of value where any actual source of healthcare business or referrals is at issue. The arrangements must be checked for certain types of contract content and criteria, as well as compliance with Stark and anti-kickback laws. Similar to the claims reviews, arrangements reviews can be arrangement transaction reviews or arrangement systems reviews.

Arrangement systems reviews are business process reviews of an organization's systems, policies, processes, and procedures relating to the initiation, review, approval, and tracking of arrangements, and require a tracking system.

They also require a review of internal controls designed to ensure that all required approvals for entering arrangements are obtained. They further require a review of the processes for ensuring that all focus arrangements are subject to a legal review by counsel with expertise in the Anti-Kickback Statute and Stark Law. In addition, the compliance officer must conduct an annual review of arrangements and report to the Compliance Committee and board on the focus arrangements tracking system; internal review and approval processes; and other arrangements systems, policies, processes, and procedures.

To complement systems reviews, arrangement transactions reviews must be conducted annually and verify compliance with a list of certain criteria. Verification steps include checking a variety of issues, including but not limited to checking that:

- Internal review and approval procedures were followed;
- A valid and properly documented business need or business rationale exists;
- A sound fair market valuation methodology was applied;
- Service and activity logs are properly completed;
- The agreement is set forth in writing and signed by both parties; and
- The agreement includes in the written agreement a certification by the parties that they will not violate the Anti-Kickback Statute and the Stark Law.

The arrangements transactions review typically consists of a sample review by the IRO (e.g., 25–75 focus arrangements) that were entered into or renewed by the entity during the particular 12-month period under review. As mentioned already, these reviews are conducted annually and retrospectively.

The lesson learned from these arrangement reviews is that it would be prudent to develop a contracting process similar to those mandated in CIAs, with a similar formality, a tracking system, and logs. It would also be wise to perform periodic reviews of contract content and whether contract implementation is consistent with contract language. Lastly, annual reports of findings of the arrangements or contracting review should be presented to management and the board. Not having adequate safeguards through a well-monitored contracting process can create enormous risk exposure. Providers' claims billed to federal healthcare programs may be at great risk of being deemed false claims if they are based on contracts that violate the Stark Law or Anti-kickback Statute.

Conclusion

Compliance officers should facilitate their management's and board's understanding of typical CIA requirements, and then implement, as appropriate, routine transactions and systems reviews of claims and arrangements. They should also integrate these reviews into their own annual compliance program work plans. In my experience, the content of the HHS OIG's Annual Work Plan is studied by many compliance officers when they develop their annual compliance program work plan. However, CIAs are not typically considered when making these work plans, but they should be. Once boards and management better understand the complexity of the government's expectations related to arrangements and claims processing, and what can be taken as a best practice according to CIAs, they may also likely be more supportive when it comes to funding and approving budgets for these types of proactive reviews undertaken by or initiated by the Compliance Office.

1. HHS OIG Website: Corporate Integrity Agreements. Available at http://1.usa.gov/1VgdHIu
2. HHS OIG, joint release with the Internal Healthcare Auditing Professionals (AHIA), American Health Lawyers Association (AHLA), and HCCA: Practical Guidance for Health Care Governing Boards on Compliance Oversight. April 2015. Available at http://1.usa.gov/1J5dqmf
3. Idem, p.3