



CIAs & IROs

HCCA Healthcare Enforcement Compliance Conference
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Background on CIAs

- Entered in connection with health care fraud settlements
- Release of OIG's 1128(b)(7) exclusion authority
- CIA has 5-year term
- IA has 3-year term
- Approximately 175 active CIAs/IAs



Purpose of CIAs/IAs

- OIG oversight of entity's operation of its compliance program
- Effective compliance program can detect and address issues that impact the Federal health care programs
- IRO reviews entity's claims submitted to Federal health care programs, arrangements with referral sources, or other activities that impact Federal health care programs



Common CIA Requirements

Maintain a Compliance Officer	Screen for Ineligible Persons	Obtain Compliance Certifications from Management as well as a Board Compliance Resolution
Maintain a Compliance Committee	Report Overpayments, Reportable Events, and Investigations and Legal Proceedings	Develop Written Standards and Policies
Maintain a Confidential Compliance Program	Conduct and Annual Risk Assessment and Develop Internal Audit Work Plans	Provide Employee and Board Training
Engage an Independent Review Organization (“IRO”) to conduct Reviews	Provide OIG with Written Reports (Implementation Report and Annual Reports)	

Other Possibilities Include: Requiring a Compliance Expert to assess the effectiveness of the compliance program; requiring a Quality monitor; establishing a DOJ-type monitorship; etc.



Recent Changes to CIA

- All defined terms move to the beginning of the document
- New Transition Plan requirement
 - Transition Plan is a plan to address whether and how the entity's compliance program will continue to include the compliance program requirements set forth in the CIA, following the end of the CIA's term
 - Transition Plan must be reviewed and approved by the Board
 - A copy of the approved Transition Plan must be included in with fourth Annual Report.



Recent Changes to CIA

- Specific responsibilities given to Compliance Committee
 - Review of policies and procedures
 - Review of training plan
 - Implementation and oversight of risk assessment process
 - Development and implementation of transition plan



Recent Changes to CIA

- Independence requirement for Board Compliance Expert
 - Compliance Expert must not be employed or engaged by Provider and must not have a current or prior relationship to Provider that would cause a reasonable person to question the Compliance Expert's objectivity in performing the review
 - Compliance Expert must provide OIG with a certification that it does not have a prohibited relationship with Provider and a summary of any current or prior relationships with Provider



Negotiating a CIA

- Consider using outside compliance counsel with significant experience negotiating CIAs
- Engage the CCO early in the process
- Review other recent CIAs with related conduct to gain an understanding of potential CIA requirements
- Evaluate whether the timelines stated in the CIA are workable



Preparing to Manage a CIA

- Ensure senior leadership is kept up-to-date on the status of the negotiations
- Calculate the potential costs to implement and maintain the CIA
 - Determine whether additional staff is needed to manage and maintain the CIA
- Inform leadership and the Board about the CIA requirements including timelines and anticipated costs



Preparing to Manage a CIA

- Initiate a CIA steering committee to identify and prioritize the work necessary to implement the CIA (think policy reviews, training program development and deployment, preemptive audits, etc.)
- Create calendar entries or other “tickler” files for required reporting (business unit changes, notice of investigations, reportable events)
- Include the risks related to the CIA in the ongoing risk assessment program and create routine auditing and monitoring to address it



Practical Tips for Working Successfully with your OIG Monitor

- Schedule a call with your OIG monitor as soon as you learn their identity to introduce yourself
- Read and be familiar with the CIA before the call
- Use the call as an opportunity to ask any questions and seek clarification
- Recognize that the OIG goal is for the company to develop a robust compliance program and culture through the CIA
- If the company is uncertain what a CIA term means or how an obligation should be performed, don't guess—ask the OIG monitor
- If the company discovers it has made a mistake in complying with a CIA obligation, be forthright and tell the monitor immediately



IRO Requirements

- Appendix A –
 - IRO Qualifications, Responsibilities, Independence/Objectivity
 - Provider Responsibilities
 - IRO Removal/Termination
- Appendix B – IRO Review Details



Focus Arrangements IRO Qualifications

- Knowledgeable in requirements of the Anti-Kickback Statute and the Stark Law, regulations and other guidance documents related to these statutes
- Possess expertise in fair market valuation issues or ability to associate a valuation firm to assist in conducting the transactions review component and
- Sufficient staff and resources to conduct the reviews required by the CIA on a timely basis



Arrangements Systems Review

Appendix B, §§ A & B
1st and 4th Reporting Periods

Review of compliance systems & processes, including:

- Focus Arrangements Tracking System
- Documenting individuals involved in negotiation, review & approval
- Compliance with financial terms and terms are commercially reasonable
- FMV documentation (who conducted, who received, range and corresponding time periods)
- Monitoring use of space, supplies, equipment, etc.
- Tracking service & activity logs
- Initiating arrangements (authority) and specifying business need/rationale
- Review & approval process (legal, other internal, business need, FMV)
- Compliance Officer's annual review
- Responses to problems
- Ensuring compliance with Focus Arrangements Requirements



Arrangements Transactions Review

Appendix B, §§ C & D
1st through 5th Reporting Periods

Review of a random sample of Focus Arrangements to confirm:

- Maintained in FATS (parties, persons involved in negotiating, review & approval, relevant terms, performance)
- Subject to internal review & approval (including legal & business reviews)
- FMV documentation obtained & remuneration tracked to confirm adherence to contract terms
- Business need/rationale was specified
- Service & activity logs completed & reviewed
- Use of space, supplies, equipment monitored
- CIA Focus Arrangements Requirements met (in writing, signed, contract language incl.)



Claims Review IRO Qualifications

- Expertise in the Medicare and state Medicaid program requirements applicable to the claims being reviewed
- Knowledgeable about appropriate statistical sampling techniques
- Nationally recognized coding certifications
- Licensed nurses or physicians (or other licensed health care professionals acting within their scope of practice) to make medical necessity determinations
- Sufficient staff and resources to conduct the reviews required by the CIA



Recent Changes to Claims Review

- IA – Annual claims review instead of quarterly
- Default for both IA and CIA is sample of 100 Medicare paid claims (additional 100 claim samples may be required for other payors)
- All provider types will have the option to submit proposals each year to focus the scope of the claims review on certain types of claims/risk areas
- Specific Appendix B for the following provider types:
Ambulance, Skilled Nursing Facility, Hospice, and Pharmacy



Recent Changes to Claims Review

- Both IA and CIA require provider to repay the extrapolated overpayment amount based on the findings of the IRO's claims review (IRO must determine estimate of actual overpayment in population)
- The “netting” of underpayments is allowed
- Repayment of the extrapolated overpayment at the lower bound/lower limit



IRO Claims Review

- Review of sample to confirm:
 - Medically necessary
 - Appropriately documented
 - Correctly coded, submitted, and reimbursed
 - May be additional/specific review requirements related to the reasons for the settlement
- Quantitative results and IRO recommendations



Evaluating Results Claims Review

- Addressing Findings
 - Payment Impact vs. Procedural Findings
 - Significant error rate?
- What if there are NO findings?
- Will the review be worthwhile?
 - Improved processes or clean audit?
 - Is the claims population still significant?




Evaluating Results: IRO Review Process and Report

- Interim Check-Ins with IRO
- Discussion of Draft Reports & IRO Obligation
- Supplemental Materials
- Final Report and Management Response



Managing the IRO Review

- Annual Report due 60 days after Reporting Period end
 - Identify your stakeholders early
 - Set expectations and timeframes
 - There are 3 rounds with the IRO
 - Set a daily check-in meeting until complete

A close-up photograph of a silver stethoscope resting on a light-colored grid pattern, possibly a medical chart or desk mat. The stethoscope's chest piece and tubing are visible.

Practical Tips for Working Successfully with an IRO



- Start your search for an IRO early & interview several candidates
- Ensure the organization and the selected IRO are in agreement with the interpretation of the CIA Appendix B requirements
- Assign a team/point person to work with the IRO
- Define required data set/sample frame in advance and test data acquisition processes
- Work with the IRO to establish detailed review procedures & present to OIG for comment in advance of initiating review
- Define documents required for review and test ability to access documents in advance of review period



CIA Resources

- OIG website - <https://oig.hhs.gov/compliance/corporate-integrity-agreements/>
 - Current CIAs/IAs
 - Closed CIAs/IAs
 - CIA Frequently Asked Questions
 - CIA Compliance Resources
 - CIA Enforcement Actions (Reportable Events/Stipulated Penalties/Material Breach/Exclusions)



Questions & Discussion





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