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Your settlement with the government requires an Independent Review Organization: Now what?

» Begin searching for and interviewing Independent Review Organization (IRO) candidates as soon as it becomes apparent that the settlement agreement will require one.

» Choose your IRO carefully to ensure that it has the credentials, experience, and independence necessary to accomplish the tasks outlined in the settlement agreement.

» Begin preparing the information that the IRO will need to perform its assigned tasks so that it can be completed within the normal 60-day reporting timeframe.

» Ensure that claims and compliance process maps, policies, and procedures are prepared, because the IRO will likely be required to review them as part of their work.

» Be prepared to respond quickly to questions and requests from the IRO, and agree on a timeframe to review its findings and respond, if necessary.

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The Health and Human Services Office of Inspector General (OIG) has accused your company of improprieties, and after careful negotiation by your counsel, there is an agreement to settle under the auspices of a Corporate Integrity Agreement (CIA). Now that your company has entered into a CIA, it can get back to business as usual, right? Not so fast. As part of the CIA, the OIG has required that the company engage (at its expense) an Independent Review Organization (IRO). Let's explore what an IRO is and what this might mean for your company.

IRO history

According to the OIG publication, "Protecting Public Health and Human Services Programs: A 30-Year Retrospective," the first CIAs were signed in 1994. CIAs were originally constructed around the core elements of the Federal Sentencing Guidelines as follows:

- Implementation of compliance measures
- Appointment of a compliance officer
- Developing compliance-specific policies and procedures
- Developing and delivering compliance-related training programs

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- Developing and implementing compliance-related reporting mechanisms

The first CIAs did not include the requirement for a company to engage an IRO, and it is not clear when the first CIAs contained that requirement. Nevertheless, the concept of an IRO emerged due to an ever-increasing number of settlements calling for oversight to ensure that the settling company did not violate the auspices of their CIA. The OIG found that this stretched their resources, causing the OIG to create an alternative means to monitor each company who entered into a CIA. The IRO concept was born with the IRO acting on behalf of the OIG to ensure that the settling company adhered to the CIA settlement terms.

IRO qualifications

The selection of the IRO is left up to the settling company. It is advisable for a company to begin identifying and interviewing IRO candidates as it negotiates its CIA and becomes aware that one will be required. This is important, because the CIA will likely allow for a 90-day timeframe after the CIA is executed to engage an IRO without incurring agreed-upon daily monetary penalties as stipulated in the CIA. Although the company has responsibility for selecting the IRO, within 30 days of selection, the OIG has the opportunity to block the selection based upon the IRO's qualifications (or lack thereof) or the belief that the IRO cannot carry out the duties as outlined in the CIA (more on those duties later).

Typically, an IRO must possess the technical capability to conduct the required review (usually a detailed claims analysis), must demonstrate their independence (as defined by Government Auditing Standards issued by the Government Accountability Office), and should have a history of being an IRO or performing in a similar function. Once the company selects an IRO, an engagement letter that details the IRO's activities, responsibilities, and fees should be executed. Additionally, the IRO should sign a business associate agreement, which details the IRO's responsibilities regarding protection of personally identifiable information (PII) and other information protected under the Health Insurance Portability Accountability Act (HIPAA).

What does an IRO do?

The IRO's duties are specified in the CIA and are usually detailed in appendices to the formal agreement. Typically, the IRO is required to:

- Obtain a basic understanding of the company's business;
- Select a sample of claims submitted to and paid by a federally funded program (i.e., Medicare, Medicaid, Champus, CHIP). The size of the sample and whether it is to be selected randomly or based on a statistical formula is detailed in the CIA;
- Review the selected sample of submitted and paid claims, in accordance with applicable federal and state healthcare program rules and reimbursement guidelines, to determine whether the items and services furnished were medically necessary and appropriately documented and whether the claim was correctly coded, submitted, and reimbursed. If the IRO determines through its review that an overpayment has occurred, the IRO will be required to review the system(s) and process(es) that generated the paid claim and identify any problems or weaknesses that may have resulted in the identified overpayments;
- Provide its observations and recommendations on suggested improvements to the system(s) and the process(es) that generated the paid claim in its report; and
- Perform—depending on the language contained in the CIA—an extrapolation

to calculate an overpayment amount for the entire population if an overpayment is identified during the review of the claims sample selected.

The IRO will also prepare a claims review report that typically provides the following information.

Claims review methodology

- A description of the population subject to the claims review;
- A statement of the objective intended to be achieved by the claims review;
- A description of the process used to identify paid claims in the population and the specific documentation relied upon when performing the claims review (e.g., medical records, physician orders, CMS program memoranda, Medicare carrier, or intermediary manual or bulletins);
- A narrative description of how the claims review was conducted and what was evaluated; and
- A description of any supplemental materials the IRO relied on that were not contained in the claims files.

Statistical sampling documentation

- A copy of the printout of the random numbers generated by the statistical sampling software used by the IRO; and
- A description of the statistical sampling software used by the IRO (e.g., RAT-STATS, Excel).

Claims review findings

- A description of the company's billing and coding systems, including the identification by position description of the personnel involved in coding and billing;
- A description of the company's controls in place to ensure that all items and services billed to federal healthcare programs are medically necessary and appropriately documented;
- An explanation of the IRO's findings and supporting rationale regarding the claims review, including reasons for errors, patterns, etc. and the results of the claims review samples;
- Total number and percentage of instances in which the IRO determined that the coding of the paid claims submitted by the company differed from what should have been the correct coding and in which such difference resulted in an overpayment to the company;
- Total number and percentage of instances in which the IRO determined that a paid claim was not appropriately documented and in which such documentation errors resulted in an overpayment to the company;
- Total number and percentage of instances in which the IRO determined that a paid claim was for items or services that were not medically necessary and resulted in an overpayment to the company;
- Total dollar amount of all overpayments in the claims review samples;
- Total dollar amount of paid claims included in the claims review samples;

The IRO's report is typically required to include any recommendations for improvements to the company's billing and coding system.

- Error rate in the claims review samples (the error rate is calculated by dividing the overpayment in the claims review samples by the total dollar amount associated with the paid claims in the claims review samples); and
- An extrapolation to determine the estimate of the actual overpayment in the population at the mean point estimate or other statistical method as called for in the CIA.

A spreadsheet of the claims review results should be created that includes the following information for each paid claim: Federal health care program billed, beneficiary name and health insurance claim number, date of service, code submitted (e.g., DRG, CPT code), code reimbursed, allowed amount reimbursed by payor, correct code (as determined by the IRO), correct allowed amount (as determined by the IRO), and the dollar difference between allowed amount reimbursed by payor and the correct allowed amount.

The IRO's report is typically required to include any recommendations for improvements to the company's billing and coding system or to the company's controls for ensuring that all items and services billed to any federal healthcare program are medically necessary and appropriately documented.

The IRO's report would also include the names and credentials of the individuals who: (1) designed the statistical sampling procedures and the review methodology used for the claims review; and (2) performed the claims review.

Upon conclusion of the IRO's work and submission of its report, the IRO may be required to meet with representatives from the OIG to review the report and findings. This requirement is normally detailed in the CIA, and the obligation to cooperate with the OIG's requests should be clearly stated in the engagement letter between the company and the IRO.

How does the IRO interact with the company?

The IRO will request a meeting with the company to begin the process of identifying and selecting claims for their review. Company attendees at the meeting would likely include the company general counsel, chief compliance officer, and head of Information Technology. During that meeting the following should be discussed:

- **Who the primary contact point will be** for the IRO at the company;
- **Claims identification process**, including a description of how the claims are processed and housed, and any software programs used by the company to adjudicate and/or process and submit claims;
- **Description of compliance-related activities** undertaken by the company in connection with claims processing, submission, and handling of overpayments identified as part of the compliance function;
- **Process and timing** for the company to make the claims population available to the IRO for claims selection;
- **Process for the IRO to provide the claims selection to the company** so that the appropriate claim files and documentation can be provided to the IRO through a secure site to address requirements under HIPAA;
- **Timing and process** for the company to provide the selected claims and supporting documentation to the IRO. This is particularly important because most CIAs require the company to file a report that includes the IRO's findings within 60 days of their required reporting period. Particular care should be taken to understand what specific software, if any, may be necessary to allow the IRO to read the

supporting documentation. For example, certain "readers" may be required to view radiographs.

- **Process to discuss and address issues identified by the IRO** during its claims review to include any overpayments identified and potential for extrapolation of those overpayments to the entire population as called for in the CIA.

Can the IRO be removed/terminated?

The short answer is yes; however, there are requirements that must be followed.

If the company terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, the company is required to submit a notice explaining: (1) the reasons for termination of the IRO or (2) the IRO's reasons for its withdrawal to the OIG, normally no later than 30 days after termination or withdrawal. Additionally, within a given timeframe (typically 60 days) of termination or withdrawal of the IRO, the company will be required to identify a new IRO and provide the OIG with the proposed IRO's credentials for approval. If the OIG does not object within 30 days of submission of the information regarding the proposed IRO, the company may proceed to engage the new IRO in accordance with the terms of the CIA.

In the event the OIG has reason to believe that the IRO does not possess the requisite qualifications as described in the CIA, is not independent and objective, or has failed to carry out its responsibilities as described in the CIA, the OIG can notify the company in writing regarding the OIG's basis for determining that the IRO has not met the requirements of the CIA.

The company will be given a timeframe (usually 30 days) from the date of the OIG's written notice to provide information regarding the IRO's qualifications, independence, or performance of its responsibilities in order to resolve the concerns identified by the OIG. If, following the OIG's review of information provided by the company regarding the IRO, the OIG determines that the IRO has not met the requirements as described in the CIA, the OIG will notify the company in writing that the company will be required to engage a new IRO in accordance with the terms of the CIA. The company will be given a timeframe to engage a new IRO, which is typically within 60 days of its receipt of the OIG's written notice. As previously stated, agreed-upon monetary penalties may be incurred if a new IRO is not engaged within the timeframe stated in the CIA. The final determination as to whether or not to require the company to engage a new IRO is normally made at the sole discretion of the OIG.

Conclusion

Because selection of an IRO is a time-consuming process, care should be taken to identify and engage an IRO with the requisite qualifications and experience to avoid the headache of having to identify and engage a new one. Additionally, since most CIAs are for a five-year term, the IRO and company will "have to live with each other" for that time period. To avoid disagreements that could lead to IRO resignation or removal, we recommend that the company and the IRO meet after the conclusion of the initial review (and subsequent reviews) to discuss any issues encountered during the review process. This interaction will go a long way to ensure that subsequent reviews go smoothly. ✳

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