Roundtable Takes on Compliance Challenges

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by Sue Prophet, RRA, CCS

The Office of Inspector General (OIG) of the Department of Health and Human Services (HHS) and the Health Care Compliance Association conducted a one-day joint roundtable on healthcare compliance to gain new insights into the challenges of creating effective compliance programs. The roundtable, "Building a Partnership for Effective Compliance," took place in March. Its objectives were two-fold:

- to provide an opportunity for the healthcare industry to inform the OIG of issues surrounding the implementation and maintenance of a compliance program
- to give the OIG the opportunity to further present the policy objectives underlying its corporate integrity initiatives and compliance program guidance

The OIG wanted to engage in constructive discussions with the healthcare compliance industry about various practices and policies related to compliance programs, including how to deal with compliance recommendations advanced by the OIG.

Roundtable participants were selected through an application process, which looked at criteria such as compliance experience, expertise, leadership, and contributions the candidate felt he or she could make to the roundtable discussions. More than 125 compliance officers, healthcare compliance consultants, and government representatives attended the event. Sue Prophet represented AHIMA.

Getting Down to Business

After opening remarks, the day was spent discussing a series of compliance-related topics. These topics, proposed in advance by the participants, were organized into 10 discussion groups led by a team of two moderators. Each team had one representative from the government and one from the healthcare industry. Sessions were held concurrently, so moderators presented a summary of the various discussion groups at the end of the day. Each group was given specific issues to discuss within four main topic areas.

Developing a Compliance Program

- How can a compliance program be designed to focus on risk areas associated with an industry, company, or the government?
- What should be the scope of compliance programs (e.g., billing fraud and OIG issues, healthcare in general, full range of compliance and ethics issues)?
- How are compliance efforts coordinated for subsidiaries, affiliates, or departments of an organization?
- How is the growth and strength of compliance programs promoted within an organization?
- How is the momentum of a compliance program continued long after the initial years of implementation?
- How is effective communication between employees and compliance staff ensured?
- How are hot line calls followed up?
- What outreach efforts can a compliance officer utilize?
- When a compliance officer function has been added to a key management position with other duties (e.g., chief financial officer, general counsel), what conflicts with compliance objectives can arise?
- How can several compliance issues, all in need of attention at the same time, be prioritized and handled?
- What can a compliance officer do if he or she cannot adequately address compliance issues in a reasonable amount of time?
- What are the potential benefits of outsourcing compliance efforts?
- What are the potential pitfalls of outsourcing compliance efforts?
- How to create a compliance committee with objective and qualified members?

- How to develop effective and creative oversight mechanisms for billing?
- How can overpayments be properly returned to carriers?
- What processes can be developed to ensure proper implementation and monitoring of arrangements with referral sources?
- How can a provider make its contractors and agents adhere to the policies and practices of the organization's compliance program(s)?

Evaluating a Compliance Program's Effectiveness

- How should a provider assess the effectiveness of its compliance program?
- How can a provider establish baselines and trend analysis?
- How should a provider demonstrate the effectiveness of its compliance program?
- What should a provider document?
- How does the government determine the effectiveness of a compliance program?
- What is the benefit of having a compliance program, should a provider be subject to a government investigation, audit, or *qui tam* suit?
- How does an organization determine the extent, frequency, and parameters of an internal review?
- Are auditing techniques valid and conducted by objective reviewers?
- How should billing claims be reviewed? Retrospectively? Prospectively? Statistically random sample?
- Are the elements of a compliance program monitored?
- Does an audit ensure compliance with all applicable laws and federal healthcare program requirements?
- What is the role of legal counsel in an internal investigation?
- Are results of past audits, pre-established baselines, or prior deficiencies reevaluated?

Conducting Internal Investigations and Self-disclosures

- How should the parameters of an internal investigation be defined?
- What circumstances prompt retrospective review and how far back should you look?
- What are the pros and cons of retrospective versus prospective review?
- How can compliance officers effectively respond to identified issues?
- How can corrective action that is creative, proactive, and preventive be actualized?
- How can identified overpayments be returned to carriers?
- What parts of an internal investigation are not subject to the attorney-client privilege?
- When is it necessary to self-disclose?
- What are timing issues associated with self-disclosure?
- How does a provider evaluate circumstances to determine materiality?
- What is the process for self-disclosure?
- What are the practical implications of self-disclosure?
- What are the different roles of the compliance officer and general counsel when it comes to self-disclosure?

Implementing a Corporate Integrity Agreement

- How are corporate integrity agreements (CIAs) negotiated and implemented?
- How are CIAs adapted to a voluntary compliance program that is already in place?
- How does the OIG monitor CIAs?
- How does the OIG assess the effectiveness of a compliance program developed pursuant to a CIA?
- How does a provider operate under a CIA?
- What is the role of the independent review organization in the CIA process?
- When should a provider subject to a CIA notify the OIG about identified overpayments?
- How comprehensive should compliance training be after the first year of a CIA?
- What parts of a CIA annual report are not subject to the Freedom of Information Act?

Roundtable Discussion Highlights

Following is a summary of the biggest issues discussed at the roundtable.

Developing a Compliance Program

Scope of compliance program: In discussing the scope of a compliance program, general support was offered for the inclusion of ethics and values. Concern was expressed that the OIG's compliance program guidance may appear to focus on compliance to the exclusion of ethics, which may discourage providers from adopting an ethics-based approach.

Identifying risk areas: During discussion on how an organization determines the risk areas to focus upon for purposes of crafting a compliance program, participants indicated they mostly focus on the areas highlighted by the government, as identified through OIG compliance program guidances, special fraud alerts, OIG work plans, and fraud settlements. Participants also receive input on possible risk areas from provider associations, peer groups, clients, and employees.

The group observed that, in addition to externally identified risk areas, risk assessments of a particular organization may reveal multiple compliance weaknesses that are specific to that provider and require corrective action and/or implementation of preventive measures. A provider's prior history of noncompliance with applicable laws or healthcare program requirements may indicate types of risk areas where the provider may be vulnerable and require necessary policy measures to be taken to prevent avoidable recurrence. Additional risk areas are often incorporated into the written policies, procedures, and training elements that are developed as part of a provider's compliance program. Ultimately, providers find it essential to document the rationale for the choices made in prioritizing and addressing competing compliance issues, including the factors considered in making those choices.

Coordinating compliance program among departments or subsidiaries: Participants generally felt that healthcare organizations need to coordinate a single compliance program among individual departments and subsidiaries. Good communication among the different divisions on compliance issues was viewed as critical. A suggestion for large companies is to make sure different units are represented on the compliance committee, with a compliance person in each major business unit. Smaller providers who may not have a designated compliance committee could establish a task force to address compliance concerns as they arise.

Human resource and compliance issues: Participants noted that there are overlaps in the responsibilities of human resources and compliance. Close collaboration between these two functions exists. However, compliance officers cannot merely be reactive. They also need to reach out to employees, using methods such as field visits to work locations and employee polls about compliance and work issues. If employees know the compliance officer, they may be more likely to talk freely with that person. Participants suggested that more information might be obtained through interviews and one-on-one communication with employees than through the hot line, because many employees may not feel comfortable reporting concerns to a hot line or they may not perceive an issue as being significant enough to report to the hot line. E-mail was another suggested communication mechanism, but some participants commented that employees may not feel comfortable reporting compliance issues via e-mail due to the perception that there is no anonymity (the e-mail message could be traced back to the individual). Employee communication can be enhanced further by creating a nurturing environment, having a strong policy against retaliation, the use of newsletters, exit interviews, and the application of technology such as e-mail and Web sites.

Outsourcing: Participants from both large and small healthcare providers indicated that, with the exception of the adoption of codes of conduct, there is little that cannot be outsourced to consultants or other compliance experts. Benefits of outsourcing compliance activities include gaining access to compliance "best practices" by virtue of the consultant's broader exposure to the industry, verifying internal compliance processes, and supplementing scarce internal resources. However, there are some drawbacks, such as the potential for lack of institutional "ownership" of the compliance program and the failure to develop internal expertise that could lead to long-term cost and operational efficiencies. Hot lines were frequently cited as a compliance function that can be outsourced. Participants suggested that a healthcare provider interested in using an outside hot line vendor should look for one with prior healthcare industry experience. Price and the vendor's references are two variables to consider during the selection of a vendor. The cost of hiring an outside vendor to operate the hot line was considered a drawback, particularly since participants claimed about 75 percent of the hot line calls are related to human resource issues.

Training: Participants agreed that training should cover topics such as code of conduct, ethics, compliance requirements, and corporate policies and procedures. Some participants indicated that they provide "cascade" training, which permits the training to evolve from general to specific. Comprehensive training in the areas of billing and coding was felt to be imperative. No standard was set to determine how often compliance training should be conducted, but generally, participants decided that some form of compliance education should take place once a year. However, for large providers with many regional or state

offices, this could be very costly and time consuming. It was noted that acquiring a training budget for compliance training was easier when the government requires it through a settlement and corporate integrity agreement. Participants also noted that getting physicians to attend educational programs pertaining to compliance issues is particularly challenging.

Ensuring compliance by contractors: Participants discussed how to ensure that a provider's contractors and other agents adhere to the policies and practices of the provider's compliance program. It was suggested that more favorable contract terms be offered to contractors if they have a compliance program in place and agree to abide by the provisions of the provider's compliance program.

Evaluating Compliance Program Effectiveness

Assessing effectiveness: Participants agreed that assessing the effectiveness of a compliance program was an ongoing effort, requiring a continuous review of the program to verify that each of the seven core elements of the federal sentencing guidelines is met. Communication with employees, department managers, and the board of directors was considered a key element in determining the effectiveness of a provider's compliance program. This communication could include interviews with employees, and hot line reports could be used to assess the effectiveness of the compliance program. Claims denials and overpayments should be analyzed to identify any patterns or trends.

Three types of audits were recommended: baseline, proactive (could be based on the risk areas identified in the OIG's compliance program guidances, special fraud alerts, or OIG Work Plan), and issue-based (when the provider knows there is a problem and is trying to ascertain its depth). The question of who should conduct the audits also was discussed. Participants agreed that individuals who audit should have expertise in the area that is under review. It was suggested that functional groups could perform audits within their functional area and submit their findings to the compliance officer. For example, a group composed of HIM professionals and physicians could conduct audits of coding and documentation. Annually, the auditing process for each functional group could be validated by an external entity, and the auditors in the compliance department could focus their efforts on auditing the compliance program itself. Some participants developed auditing teams comprising nurses to review claims both on a pre- and post-claim basis. Compliance officers for small providers recommended assembling the proper people together to discuss billing changes described in the contractor's bulletins. This team can then assign responsibility to a selected individual to ensure that the change is implemented.

In order to establish compliance baselines and develop a trend analysis, the participants recommended an annual forensic review of major areas that have risk exposure linked to prior audit results. It was also suggested that providers develop benchmarks through routine audits, as well as the use of Medicare contractor statistics. Since it is difficult to decide where to direct limited compliance resources, participants suggested that proactive audits could focus on the highest percentage of the provider's revenue, such as the top five services or top 10 DRGs. Participants recommended that all payer classes, not just Medicare, should be audited. Many of the participants noted that one of the largest impediments that they encounter is finding qualified personnel to conduct the audits. Several participants indicated that they had previously received improper advice from consultants who had conducted risk assessments and evaluations of their respective organizations. It was recommended that thorough interviews of consultants be conducted prior to contracting with them.

Also brought up for discussion was the fact that audits tend to be more reactive than proactive. Most of them had relied heavily on the OIG's work plan and past investigations by the OIG and the Department of Justice as a basis for establishing their audit work plans. Many of the participants expressed frustration that they were unable to take more proactive measures in their auditing and monitoring. One explanation for the reactive approach to audits was that compliance personnel expend most of their audit resources in response to internal investigations. And many compliance officers noted the chilling effect that audits tend to have on individual physicians. As a result, the compliance officers noted a trend toward "downcoding" and have focused their auditing and training efforts on promoting proper documentation, as opposed to detecting fraud and abuse concerns.

Another issue raised regarding the design of the audit plan was the use of retrospective reviews versus prospective reviews. In general, the participants viewed prospective reviews as the more favorable method. If a problem was identified during a prospective review, then a decision could be made, based on the specific issue, as to whether there was a need to conduct a retrospective review. Of course, at this point it would be an internal investigation rather than an audit. Prospective reviews tend to be less costly and less time consuming and they allow identified problems to be fixed up front. However, it was noted that there are situations in which retrospective reviews are necessary (e.g., in response to an investigation).

The participants had differing views on the size of the sample they deemed necessary to substantiate the validity of audit results. The OIG's "Provider Self-Disclosure Protocol" represents the OIG's view that an initial sample should consist of 30 units, at a minimum. By contrast, the *Medicare Carriers Manual* requires a sample of 10 units. The participants believed that defining the sample size depends largely on the nature and objective of the review.

The issue of how much auditing is necessary to satisfy the requirements of an effective compliance program was discussed. Participants agreed that no amount of auditing is ever enough. To assess the effectiveness of training, participants recommended that pre- and post-training audits be conducted.

Long-term effectiveness of compliance program: Participants discussed the challenge of continuing a compliance program's momentum after the initial implementation period. Senior management "buy-in" and ongoing commitment to the compliance program were considered critical. It was also suggested that emphasizing the positive aspects of a compliance program (such as improved quality of patient care, improved operational efficiency, and early detection and resolution of problems) is important.

Demonstrating effectiveness: Participants believed that documentation is the key to demonstrating the effectiveness of a provider's compliance program. Documentation of the following should be maintained:

- audit results
- logs of hot line calls and their resolutions
- corrective action plans
- due diligence efforts regarding business transactions
- disciplinary action
- modification and distribution of policies and procedures

Since the OIG is encouraging self-disclosure of overpayments and billing irregularities, maintaining a record of disclosures and refunds to the healthcare programs was strongly endorsed. Records of employee education, including the number of training hours, the courses offered, and the identities of the attendees are valuable. Maintaining such records demonstrates to both employees and external entities that the provider is committed to its compliance program. Participants noted that a comprehensive training and education program is the key to an effective compliance program. It was also noted that annual reports and Web sites are other ways to showcase a compliance program.

Contractor advice: Many participants expressed frustration with reconciling the views of different individuals employed by Health Care Financing Administration (HCFA) contractors (i.e., fiscal intermediaries and carriers) and how to respond to conflicting advice received from them. The participants indicated that a provider receiving advice from a contractor should document all communications with HCFA and its contractors, attempt to seek clarification from the HCFA regional office, and, if necessary, contact HCFA headquarters regarding any unresolved issues. Participants expressed a need for advice on how to address the varying documentation requirements and issues among payers. They agreed that they would like to see HCFA develop a better system through which providers could ask questions and obtain guidance on all billing and coding issues.

Government's assessment of effectiveness of compliance program: Government participants cited a number of factors to consider in evaluating the effectiveness of a provider's compliance efforts, including management's commitment and good faith efforts to implement a program. The effectiveness of a compliance program may be measured by the funding and legitimate support provided to the function, as well as the background of the individual designated as the compliance officer. The government looks for evidence that the key elements of a compliance program have actually been implemented.

Whether or not there is "buy-in" by the provider's employees and contractors can be influenced by the sufficiency of training and the availability of guidance on policies and procedures. Evidence of open lines of communication and the appropriate use of information lines to address employee concerns and questions are also important. A documented practice of refunding overpayments and self-disclosing incidents of non-compliance with program requirements were also cited as evidence of meaningful compliance efforts by a provider.

In general, government participants emphasized that the OIG considers the attributes of each individual element of a provider's compliance program to assess its "effectiveness" as a whole. Examining the comprehensiveness of policies and procedures implemented to satisfy these elements is merely the first step. Evaluating how a compliance program performs during a provider's day-to-day operations is critical to the process. In order to assess effectiveness, the OIG attempts to look beyond

the "paper" representations regarding a program and assess how it is actually working in practice. A training program that appears appropriate on paper would not be effective if none of the trainees retained the important information imparted during the training. Providers can assess the effectiveness of their programs by testing compliance goals against benchmarks. Both proactive and preventive measures are essential. The OIG does not believe that a compliance program can be expected to prevent any problems from arising.

Internal Investigations and Self-disclosures

Determining the parameters of an internal investigation: The participants identified a series of questions that will guide the scope of an internal investigation:

- What is the origin of the issue to be investigated? A billing concern may be the result of a systematic practice, a third-party inquiry, or misconduct by certain individuals. A systematic, non-compliant billing practice may have been tied to a new system implementation or initiated based upon faulty advice received from a consultant or Medicare contractor. A third-party inquiry may have been prompted by a whistleblower or an improper claim submitted.
- When did the issue under investigation originate? A systematic billing practice may warrant an internal inquiry into the origin of the practice and the extent of its impact upon an organization. Improper billing by certain individuals may require scrutiny of their entire employment history, an analysis of their effect upon other employees, and a review of the directions they may have received from superiors.
- How far back should the investigation go? The participants agreed that a provider should establish reasonable and calculated benchmarks to assist in determining the parameters of an internal investigation. Investigation standards for one organization may not be applicable to another organization. Some providers may always commence their internal investigations by reviewing a year of previous billing, while other providers may start with a month of prior billing. Some providers designate a specific number of claims to review. Others may review a percentage of claims.
- The parameters of an internal investigation can also depend on the specific issue being investigated. Consider the duration and extent of the practice in question before establishing parameters. Regardless of the investigative protocol used, the participants believed a provider should determine the parameters of its investigation based upon a reasonable approach that is justified under the circumstances. For example, regardless of the initial period of time reviewed or the number of clinical services analyzed, the inquiry should be expanded if the results of an initial review suggest a broader problem. Billing misconduct by one employee may prompt scrutiny of the conduct of other employees. Problems with one facility in a large healthcare organization may warrant review of other facilities. In any case, providers need to document the investigative methods used and the reasons for their decisions.
- Can extrapolation of a statistical sample be used? Some participants indicated that they rely on statistical samples and extrapolation to rectify reimbursement problems when it is too difficult or costly to ascertain the exact cause of improper billing. Others indicated that they do not rely on extrapolation because the identified samples of improper billing may not accurately represent an organization's entire billing practices (e.g., sample of deficient billing may be the product of certain individuals, specific sites of operation, or particular billing procedures).

Prioritizing issues that warrant an internal investigation: When trying to prioritize several compliance issues--all of which develop at the same time--participants suggested that the legal and financial implications and level of regulatory exposure for each issue be considered. The following points were raised for the compliance officer to consider when prioritizing issues that may need further investigation:

- Does a corporate integrity agreement with the OIG require the compliance officer to focus on certain issues?
- Does the problem pertain to a discontinued practice or a current practice with prospective exposure?
- Can certain billing software be used to perform a prompt preliminary review?
- Can deficient billing be suspended or stopped until a review can be completed?
- Could the issue under investigation have a significant impact on the provider's Medicare cost report and interim payments?
- Does an issue present credible evidence of ongoing misconduct that may violate criminal, civil, or administrative law and should be immediately reported to a government authority?
- Has the organization established its own standards for the amount of time allotted to address incoming compliance concerns?

Reporting evidence of noncompliance to the government: Participants spent considerable time discussing the circumstances under which the findings of an internal investigation should be reported and where to submit such a report. Participants believed that when billing errors, honest mistakes, or simple negligence result in improper claims, the provider should return the funds to the affected healthcare program. Providers should consult with their Medicare contractor for guidance in processing Medicare repayments and establishing the information that would be needed to quantify the amount of the overpayment. Once the problem has been rectified, the provider should add the issue to its list of topics to be reviewed during internal monitoring and auditing efforts.

Participants also had difficulty defining what constitutes a "simple billing mistake." The size of an overpayment would be one of the determining factors when deciding whether to refund an overpayment to a carrier or intermediary or to proceed through the OIG's Provider Self-Disclosure Protocol. It was also suggested that the compliance officer determine if there was a pattern to the errors. Problems showing a clear pattern may be a candidate for disclosure to the government, whereas an isolated incident with no clear pattern would be less likely to be a candidate. Participants agreed that it is difficult to determine whether a matter is an "overpayment" that should be brought to the attention of a Medicare contractor, or whether it rises to the level of being "potentially violative of a federal criminal, civil, or administrative law" and should be disclosed to the OIG pursuant to the Self-Disclosure Protocol. All participants believed that matters resulting in improper payments must be resolved and refunds issued. The payment of refunds was viewed by some participants as a fundamental and routine part of doing business.

Participants' biggest concern focused on what to do about compliance issues that fell into "gray" areas. This decision must be made carefully, as the repercussions can be damaging either way. Labeling a finding as fraudulent without a proper inquiry could have irreparable consequences. On the other hand, the careless or deliberate portrayal of a matter as less serious than it actually is could have enormous punitive results. Participants identified a few questions to assist a provider in deciding whether to disclose a matter to the OIG or simply refund the overpayment to the Medicare contractor:

- What is the applicable standard?
- Did the provider have actual or constructive notice of the standard?
- Was it the result of intentional conduct or gross negligence?
- Would a reasonable provider operating in a highly regulated environment have an obligation to inquire?
- How substantial is the material that is discovered?
- Is it a purely financial matter or is quality of care also implicated?
- What is the loss to the federal healthcare programs?

Participants generally agreed that the best time to disclose a problem is after it has been identified, but before someone files a *qui tam* suit.

Participants from the compliance industry were concerned with the government's potential treatment of a disclosure (e.g., they felt that a disclosure pursuant to the Self-Disclosure Protocol should not automatically result in multiple damages and penalties or necessarily result in a settlement with the government). Such matters are evaluated by the OIG in close coordination with the disclosing provider. The OIG will make the initial determination regarding matters brought forward under the Self-Disclosure Protocol as to whether they warrant a referral to the Department of Justice for further inquiry and potential prosecution or whether they merit a referral to the Medicare contractor for collection of an overpayment.

Conclusion

Roundtable participants gained new insights into the challenges of creating effective compliance programs with the opportunity to hear different perspectives on compliance from both federal government and healthcare industry representatives. More important, it resulted in a greater understanding on the part of both sides of how the government and provider community can work together to protect the integrity of the healthcare system.

References

"Building a Partnership for Effective Compliance: A Report on the Government-Industry Roundtable." Available at the HHS Office of Inspector General Web site at http://www.hhs.gov/progorg/oig.

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