



Report From February 23, 2012, Pharmaceutical Compliance Roundtable

Introduction

On February 23, 2012, the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS) convened a Government-industry Pharmaceutical Compliance Roundtable. The Roundtable provided an opportunity for OIG to discuss with compliance professionals in the pharmaceutical industry their experiences under Corporate Integrity Agreements (CIAs) and with various types of compliance activities. One goal of the Roundtable was to identify compliance measures that participants find effective and share these with others within and beyond the pharmaceutical industry.

Forty-two compliance officers and other compliance professionals from 23 pharmaceutical manufacturers currently under CIAs attended the day-long event. The Roundtable consisted of large and small group sessions. During the small group sessions, industry representatives engaged in dialogue with more than 15 representatives from the Office of Counsel to the Inspector General, including several CIA monitors for the companies in attendance. While OIG gained valuable insights, the participants understood that the Roundtable was an opportunity to exchange information and that existing CIAs would not be renegotiated on the basis of their comments.

The Roundtable began with a large group session during which Inspector General Daniel Levinson and Chief Counsel Lewis Morris delivered introductory remarks. The large group then divided into smaller breakout sessions. During the day, all attendees discussed each of these five topics: (1) Challenges in Implementing CIAs; (2) Compliance Program Structure and Oversight; (3) Risk Assessment and Monitoring Activities; (4) Policies, Procedures, and Training Activities; and (5) Compliance Post-CIA.

Teams of OIG representatives functioned as moderators and scribes for each breakout session. At the end of the day, the moderators highlighted some of the issues discussed in their respective groups. A summary of those discussions is set forth below.

Topic 1: Challenges in Implementing CIAs

Participants discussed issues related to challenges in implementing CIA requirements. The primary issues were: (1) the definition of “Relevant Covered Person,” (2) the deadlines for the initial implementation of CIA requirements, (3) training requirements, (4) the health care provider (HCP) notice letter, (5) payment-posting requirements, and (6) working with Independent Review Organizations (IROs). Participants described their experiences in implementing the CIAs and recommended changes to CIAs.

Definition of “Relevant Covered Persons”: CIAs require that companies provide specified written policies and procedures and training to individuals who meet the CIA definition of “Relevant Covered Persons.” Participants reported that their companies interpret the definition broadly and that this creates challenges in correctly identifying all Relevant Covered Persons. Some participants reported that the broad definition may cause companies to train categories of employees (*e.g.*, manufacturing and research personnel) for whom the training may not be directly relevant to their daily job responsibilities. Participants expressed concern that such training may undermine compliance credibility if training does not seem meaningful.

Some participants reported that it is particularly challenging to correctly identify Relevant Covered Persons who are contractors. Participants suggested that OIG narrow the definition of “Relevant Covered Persons” so that it includes only contractors who interact directly with HCPs or consumers or who create promotional or product-related materials that could be used externally without first receiving internal company review. Another challenge identified by participants was training for contractors who provide services to more than one company. This issue is discussed below as part of Topic 4.

Deadline for initial implementation of CIA requirements: CIAs typically require companies to develop and implement codes of conduct, policies and procedures, and training within specific timeframes following the effective date of the CIAs. Participants expressed concern that the timeframes are too short to allow for effective development of company-specific policies, procedures, and training materials. Participants reported that as a result, their companies may use “generic” policies, procedures, and training materials to meet the CIA deadlines for initial implementation. Participants recommended that to allow for development of more meaningful and effective policies, procedures, and training, CIA deadlines be extended.

Training requirements: CIAs require companies to certify that they have trained all Relevant Covered Persons. Participants reported that these requirements cause companies to develop and implement computer-based training modules for which completion is easier to track. While participants believe that small group training (such as that provided during in-person sales meetings) is more effective than computer-based training, attendance at such training may be difficult (and labor-intensive) to track. Some

participants suggested that OIG modify CIA requirements to allow for less than 100-percent completion of training or to permit companies to certify that training sessions were held and that managers are responsible for ensuring attendance.

CIA requirements also require companies to provide a specified number of hours of training annually about topics outlined in the CIAs. Some participants reported that requirements to provide a specified number of hours of training cause companies to provide repetitive training from year to year that is not focused on new developments or different topics. Participants offered several suggestions to improve training. These included: (1) permitting companies to develop more flexible training plans (especially after the initial reporting period of the CIA) that would be approved by the CIA monitor annually; (2) permitting general training requirements to be satisfied through competency testing (in such cases, employees who pass a compliance test would be exempted from additional training requirements for the year); and (3) revising CIA requirements to allow companies to satisfy CIA obligations with training tailored to identified risk areas.

Notice to health care providers: Some CIAs require companies to send to HCPs a letter briefly describing the terms of the settlement between the Government and the company and the alleged misconduct at issue. Some participants reported that sending this letter is expensive and that it is not an effective vehicle to promote awareness of compliance issues among HCPs. Some participants recommended that if CIAs continue to include this requirement, OIG permit more flexibility in how the content of the letter is delivered. Suggested alternatives were: (1) hand delivery of the letter by sales representatives; (2) posting the pertinent information on a company Web site; or (3) sending the letter by less expensive means (*e.g.*, by regular mail or email) than required by the CIA.

Payment-posting requirements: Certain CIAs require companies to track and post on company Web sites information about payments made by the companies to HCPs. The representatives of companies with these CIA requirements generally agreed that the payment-posting requirements are expensive and time consuming to implement. The physician payment “sunshine” requirements of the Affordable Care Act (ACA) obligate manufacturers to report to HHS information about payments to HCPs. The information will be posted on the HHS Web site. The ACA requirements are somewhat different from the CIA requirements. Participants expressed concern about the differences between, and possible inconsistencies in, the CIA requirements and those in the ACA. Some participants requested that OIG permit companies to satisfy CIA requirements by certifying that they complied with the ACA provisions. Others requested that OIG suspend or alter the transparency requirements in CIAs after the ACA transparency regulations are finalized.

Working with Independent Review Organizations: CIAs with pharmaceutical manufacturers require that companies annually retain outside IROs to conduct reviews of specified items and systems. Participants reported that their companies devote significant compliance resources to educating the IROs about company-specific systems and processes and supporting the IROs during CIA reviews. Some questioned the value of the findings and recommendations from the IROs, especially if identified errors are immaterial or technical in nature. Some participants suggested that a “big picture” compliance review would be more helpful than multiple transaction reviews. Others suggested that to increase the utility of the IRO reviews, CIAs permit more flexibility in IRO reviews and allow, for example, changes in the focus of the IRO reviews in the second year and later years of the CIA.

Topic 2: Compliance Program Structure and Oversight

These sessions focused on two main topics: (1) boards of directors’ oversight of, and participation in, compliance-related activities, and (2) integration of compliance activities into business functions beyond the compliance department. Participants uniformly agreed that it is critical for boards of directors to be involved in compliance oversight and that the integration of compliance efforts into business activities materially enhances compliance effectiveness.

Involvement of Boards of Directors in Compliance-Related Activities

Participants provided these examples of many ways in which boards of directors are involved in compliance: (1) review and oversight of audits and identified risks, (2) review of compliance issues pertaining to particular business initiatives, (3) periodic interaction with compliance officers and with third-party compliance experts who may assess the company’s compliance program, (4) board training and education, (5) compliance-related certifications and the passage of compliance-related resolutions, and (6) general assessments of the company’s compliance program. Participants recommended that boards of directors and company management convey messages about the value and importance of compliance (including as a competitive business advantage). Participants also observed that when compliance officers routinely make reports to their companies’ boards, this activity underscores the importance of compliance.

Board resolutions and certifications: Some CIAs require that board members annually pass and sign a resolution confirming, if they can, that the company has implemented an effective compliance program. Participants reported that these requirements lead board members to better understand compliance issues and ask more questions about compliance (and their own potential liability). Certain CIAs require that boards retain outside compliance experts to independently assess the company’s compliance program. Participants reported that board experiences with compliance experts have been positive. Some participants recommended that boards engage such

experts even if not required by a CIA. Many participants reported that their boards view compliance officers as respected, informed compliance resources. Some participants noted there is a process for gaining such respect. Participants acknowledged there are challenges in evaluating and measuring compliance. They recommended that compliance metrics be articulated in a way designed to motivate compliance and discourage noncompliance.

Organizational structure issues: CIAs require the appointment of compliance officers who are members of senior management and are not subordinate to the general counsel or the chief financial officer. Participants reported that they have found this structure to be beneficial. Some participants noted that some companies not under CIAs continue to make compliance officers subordinate to general counsels and suggested that OIG clarify (or reiterate) the risks associated with this type of reporting structure.

Some participants opined that the CIAs did not adequately account for differences in the organizational and oversight structures of companies. These differences may arise, in part, because of the national or international nature of the company (including whether there are national and/or international boards) and whether the company is publicly traded or privately held. Participants recommended that OIG take into account these differences and consider: (1) more flexible approaches to board training requirements and (2) flexibility in IRO and compliance expert review requirements.

Integration Into and Coordination Between Compliance and Business Operations

Participants uniformly agreed that integration of compliance into a company's broader business operations greatly enhances the effectiveness of compliance programs. Participants reported that their companies accomplish this integration by, among other things, locating compliance personnel and resources at headquarters and using training, communications, technology, and compliance personnel and field-based managers to disseminate compliance messages and activities to the field.

Examples of compliance/business integration: Reported examples of the integration of compliance and business functions include: (1) appointing deputy compliance officers within individual business units; (2) requiring business unit managers to incorporate compliance considerations in business decisionmaking; (3) increasing individual accountability by requiring compliance-related certifications from senior management in key business units; (4) imbedding compliance representatives (sometimes called liaisons, ambassadors, or champions) in individual business units; (5) including compliance-related requirements as an element in performance plans of all employees; (6) staffing compliance committees with individuals from varied business units and disciplines; and (7) fostering lines of communication between headquarters compliance staff and business unit personnel, including through monitoring of field activities by headquarters staff.

Business “ownership” of compliance: Participants recommended that to the extent possible, business units “own” compliance. Participants suggested this could be accomplished by: (1) educating business unit managers about compliance so that they understand and can identify relevant compliance risks, (2) ensuring that business unit policies and procedures incorporate compliance elements, (3) requiring business unit personnel to deliver periodic compliance training, and (4) proactively incorporating compliance considerations into business decisionmaking and business initiatives. Participants stressed the importance and efficiency of the last point and suggested that it could be accomplished, in part, by including compliance personnel as part of the business team rather than as a separate unit. Participants noted that increased coordination between compliance and business functions can lead to increased opportunities for cross-functional usage of data (*e.g.*, information available to the company through compliance assessments may be useful for business units) and underscore business benefits that can come from compliance activities.

Challenges to compliance and business integration: Participants noted several challenges to integrating compliance into business functions. Frequent changes at pharmaceutical companies are one such challenge. Companies routinely experience turnover of personnel and changes in product portfolio. Participants recommended that their companies be vigilant about compliance in the face of such changes. Increased outsourcing to third-party vendors was identified as another challenge. Participants suggested that companies establish lines of communication and appropriate verification and oversight processes with their vendors. Finally, participants identified as another challenge the development of meaningful and appropriate training. Training is discussed in more detail below, but participants generally stressed the need for personnel from compliance, human resource, information technology, and other components to understand the importance of compliance, understand their respective responsibilities, and have good working relationships in order to design and implement effective compliance programs and training initiatives.

Topic 3: Risk Identification and Monitoring Activities

These sessions focused on risk-assessment processes and methods by which companies conduct internal monitoring. While most CIAs do not explicitly require companies to engage in a specific process to identify compliance risks, most participants indicated that their companies routinely engage in a variety of risk-assessment activities. Many CIAs require companies to monitor specified types of activities during each year of the CIA (through internal programs and/or IROs). Participants commented on various types of monitoring activities and recommended that CIAs allow for increased flexibility with regard to required monitoring activities.

Risk-Assessment Practices

Participants widely reported that their companies engage in multiple types of risk-assessment activities, including those at a companywide level, on a product-specific basis, or both. Participants observed that the types of risk assessments that are effective for one company may not be effective for another company.

Participants reported that compliance training for management and field representatives is essential to an effective risk-identification program because it enables individuals “in the business” to better identify compliance risks and take appropriate mitigation steps. In addition, participants reported that if compliance personnel have “a seat at the table” when sales and marketing activities are planned or discussed, they can help ensure that risks are preemptively identified and addressed.

Monitoring Activities

Many CIAs require companies to annually monitor a specified set of activities. Required monitoring activities include reviews of: (1) sales representative call notes; (2) the activities of the medical information department (including responses to inquiries about off-label uses of drugs); and/or (3) speaker program activities. Several CIAs also require that compliance personnel “ride along” with field representatives on sales calls to HCPs. In addition, several CIAs require key managers to certify that the business units for which they are responsible are compliant with legal, CIA, and company standards.

Flexibility in monitoring: As a general comment, many participants requested that OIG permit greater flexibility under CIAs to monitor new or different activities in later years of a CIA. Participants asserted that the monitoring obligations of CIAs can be focused on past conduct and that by the time a CIA is implemented, the company has likely identified new risk areas (*e.g.*, as a result of risk-assessment or auditing practices) to which oversight resources would be better deployed. In addition, the risks for a company evolve during the term of the CIA. Some participants also suggested that companies be relieved of certain obligations in the later years of the CIA if they are able to demonstrate compliance with CIA requirements and positive results through auditing and monitoring.

Identity of monitors: Some CIAs require that certain monitoring activities be undertaken by compliance department personnel only. Participants requested that CIAs permit more extensive use of outside consultants or company employees from outside the compliance department in conducting auditing and monitoring activities. This would allow companies to deploy their limited compliance resources for collaborative and educational purposes. To address concerns about the qualifications of noncompliance personnel to conduct such monitoring, participants suggested that consultants and internal

staff be extensively trained and that their work be subject to oversight by compliance personnel.

Compliance messaging: Participants stressed the importance of ongoing messaging and communication about compliance as a way to enhance risk-assessment and monitoring activities. Participants recommended that companies disseminate compliance messages from a variety of sources. For example, participants suggested that compliance messages be delivered by senior, district, and regional managers; during in-person meetings with sales representatives; during various auditing and training interactions; at business unit meetings; and through bulletins from the human resources department.

Call note review: Participants reported that their companies consistently review call notes as a means to monitor activities of sales representatives. Participants noted the variability among the call note systems. Some companies use a free-text call note system (which essentially permits representatives to record their notes without limitations in a “free text” system), while other companies use a system of drop-down menus containing preset descriptors with which sales representatives may populate their call notes. Some participants noted that the drop-down systems permit a relatively simple categorization of information from call notes that may be used for multiple compliance and business-related purposes. Other participants noted that the free text systems may allow for more accurate and clear descriptions of the interactions with HCPs.

Monitoring of medical information: Some participants reported that ongoing reviews of medical information department activities yielded diminishing compliance returns in the later years of a CIA. Many participants reported that their medical information functions had strong control systems in place prior to the CIAs and that their systems do not benefit materially from additional CIA oversight.

Speaker programs: CIAs require compliance or other personnel to attend speaker programs in order to conduct “live” monitoring of the programs. Some participants recommended that the CIAs permit the monitoring of speaker programs or other events via teleconference or videoconference. This would reduce costs associated with deploying headquarters-based compliance personnel to attend programs throughout the country.

Ride-along activities: Participants reported mixed results from compliance personnel ride-alongs with sales representatives. Many participants reported that such ride-alongs do not generally lead to the identification of specific noncompliant conduct by sales representatives. However, participants widely agreed that these activities are beneficial because they establish a line of communication between field and compliance personnel and enable the development of relationships between the two groups. Some participants recommended that CIAs allow more flexibility in how companies engage in

these sorts of beneficial “relationship-building” activities (*e.g.*, through compliance personnel participation in regional sales meetings or trainings).

Most CIAs do not require that district managers (or other supervisors in a sales representative's chain of command) conduct ride-alongs. However, participants reported that such activities are common and effective and consistently yield information useful to both compliance and the business units. Participants believe that these ride-alongs are effective because the managers work closely with field personnel on a regular basis and understand issues faced by sales representatives. According to some participants, their companies incorporate compliance metrics into supervisory ride-alongs and district managers are expected and required to report on, and educate their subordinates about, noncompliant behavior. Finally, some participants reported that senior management and members of their boards of directors have sought opportunities to conduct field visits or attend national sales meetings to enhance their understanding of the day-to-day work of field representatives.

Management certifications: Participants favor the inclusion of certification requirements for board members and managers in CIAs because they lead to deeper levels of involvement in compliance activities. Participants uniformly found that such certifications cause board members and managers to ask questions about compliance and take ownership of compliance.

Topic 4: Policies, Procedures, and Training Activities

CIAs require that companies establish written policies and procedures related to the business operations of the company (*e.g.*, sales, marketing, and interactions between companies and HCPs). CIAs also require companies to provide general training and job-function-specific training to persons covered by the CIA. Participants offered insights about the development and dissemination of policies and procedures and training activities at their companies.

Policies and Procedures

Development and revision of policies and procedures: Participants uniformly recommended that to generate the most effective policies and procedures, business unit personnel and other affected stakeholders participate in the development and revision process. In most companies, participants noted that compliance officers or other compliance personnel collaborate with business unit personnel to draft and revise policies and procedures. Participants recommended that policies be straightforward and relatively simple to maximize compliance and facilitate the identification of noncompliance. One participant reported that the company's compliance department tested policies by having compliance staff observe policies being implemented in the field and by having field-based employees explain the policies to the compliance staff.

A variety of methods may be used to identify areas for which new or revised policies are appropriate. Some participants reported that companies create or update policies in response to changes in applicable legal requirements or on the basis of newly identified risk areas (such as those identified through an internal investigation). Other participants suggested that issues identified through disclosure programs or raised to compliance personnel may signal a need for policy clarification or revision. According to participants, companies may also periodically review their policies to determine whether each policy is still necessary and appropriately written.

Accessibility and format: Participants agreed widely that policies must be accessible to employees and be provided in a useful format. Different methods may be used to achieve this goal, including technology-based initiatives. Some participants reported that their companies post compliance policies and the code of conduct on an Intranet Web page and provide prominent links between business unit Web pages and the compliance department's Web page. Other companies have reportedly developed specific compliance Web pages for individual business units (*e.g.*, a marketing compliance page) or written compliance products tailored to individual business units (*e.g.*, a compliance guide for the marketing department).

Participants also emphasized the need to make compliance information available in different formats and to permit questions to be asked through various mechanisms. In addition to reporting a compliance department Intranet site and a hotline, some participants reported that their companies established electronic search capabilities that enable employees to search for particular topics within compliance-related documents. Participants reported that some companies have also established electronic mechanisms through which employees may send text or email queries directly to the compliance department and/or legal departments.

Training

Many themes discussed in connection with the implementation of CIAs (summarized above for Topic 1) were repeated during this session. For instance, participants reiterated the challenges in identifying Relevant Covered Persons and meeting CIA deadlines. Participants also raised the concept of competency-based training and requested more flexibility in developing and implementing training.

Effective training: Participants stressed the need for effective training and agreed widely that in-person training tailored to the specific job functions of employees is particularly effective. Participants found the inclusion of specific relevant examples in training (*e.g.*, those based on real-world conduct) to be meaningful. Participants also reported good results from training business unit supervisors and, in turn, having the supervisors provide the training within the business units. Other productive training

activities reported by participants included role-playing activities, competitive games, and the use of a virtual classroom for training staff dispersed across a large area.

Training of contractors: Participants identified unique challenges in training employees of contractors engaged in functions covered under CIAs. Participants reported that they spend a significant amount of time determining which contractors must receive training under the CIAs. Some contractors provide services to one or more companies operating under CIAs and, as a result, have multiple training obligations. Participants suggested that OIG and/or companies under CIAs create baseline training for Relevant Covered Person contractors and permit the completion of the baseline training to satisfy CIA training requirements for all companies. Another variation on the theme was a suggestion that CIAs permit contractors to use certificate-based training. Participants suggested that, under this proposal, a contractor would take OIG-approved training annually. The company under the CIA would then obtain a certification from the contractor confirming the completion of OIG approved-training within the past year, and the company could rely on this certification to fulfill its CIA obligations. However, participants also suggested that if a contractor operates in an area of high compliance risk, the manufacturer under the CIA might nonetheless decide to provide direct training to that contractor to reduce compliance risk.

Topic 5: Compliance Post-CIA

In these sessions, participants were asked to identify which CIA-required compliance measures they would recommend their companies continue after the conclusion of the CIAs. Participants were also asked to predict the biggest compliance risks likely to face their companies and the industry in the next 5 years.

Compliance Measures After the Term of the CIA

Most participants expect that their companies will continue a number of compliance activities following the conclusion of the CIA. However, participants predict that their companies would tailor these measures to the companies' risks and priorities. Specific types of compliance measures likely to be retained included the following:

Certifications and board involvement: Participants expressed wide agreement that management certifications are valuable and would likely be continued. As discussed above, participants find that the certification process promotes compliance throughout the company and generates personal accountability for compliance. Some participants proposed that following the CIA, companies make truthful certifications a condition of employment or a requirement in order to receive a bonus. Participants also predicted that boards would continue to be substantively involved in post-CIA compliance programs and that such involvement would be vital.

Training and disclosure programs: Participants indicated that their companies would continue training efforts but would make the training more flexible and tailor it to their companies' current risks and values. Participants expect that post-CIA training will emphasize quality of training over the number of hours of training. In addition, participants recommended that disclosure programs be continued because they permit employees to raise compliance issues and underscore that every employee has a role in ensuring compliance.

Field monitoring: Participants expect their companies to continue to monitor field-based activities after their CIAs ended. However, participants also suggested that the monitoring likely would become more flexible to focus on current risk areas (which change over time). In light of the widely recognized benefits of relationship-building activities, most participants indicated that their companies would continue to engage in ride-along activities with sales representatives. However, participants also expect their companies to conduct fewer such activities and use other means to monitor the field sales force.

IRO-type reviews: Participants anticipate that their companies will continue to rely on external parties (such as IROs) to conduct reviews, but would do so on a limited basis. Participants predicted that the scope of the reviews would be special projects and work related to current risks. Participants find IROs to be expensive. Some participants believe that internal audits would be equally beneficial.

Predicted Future Compliance Challenges

Participants also identified areas that are expected to present the biggest compliance challenges in the near future. Anticipated challenges include the following:

Changing regulatory and other requirements: Across the board, participants identified their biggest compliance challenge as staying abreast of changing requirements and regulatory complexities, especially in the area of transparency. Many participants cited as an example the requirements relating to the ACA sunshine provisions and the analogous (but different) State reporting requirements. Other participants identified compliance with expanding global requirements (including those in the area of transparency) as a challenge. Finally, participants noted that their companies also face challenges associated with new Government requirements, including those relating to accountable care organizations.

Social media and technology: Participants also identified growing future challenges associated with information about products found on the Internet, including on social media Web sites. This would include information posted by manufacturers as well as other information found on the Internet. Participants voiced a consensus that there is a

lack of clarity and guidance in these areas. They expressed a desire for additional guidance from the Government.

Changing business models: Participants also noted that they face challenges associated with adapting to future changes in their companies and the pharmaceutical industry. Some participants acknowledged ongoing changes in the interactions between their industry and HCPs and expect increased outsourcing of certain functions (such as promotion and research and development). They also emphasized continuing challenges associated with finding qualified staff to undertake compliance activities. Participants underscored the need to maintain flexibility in the face of these changes.

Conclusion

One objective of the Roundtable was to learn more about compliance measures that industry compliance professionals find to be effective. Many of those insights and experiences are reflected in this report. We hope this report will be useful to providers outside the pharmaceutical industry as they seek to enhance their own compliance programs.

OIG received very positive feedback about the Roundtable from participants during the day and following the event. OIG also was pleased with the open and collaborative nature of the dialogue between OIG and industry representatives. While noting that they did not always share OIG's view about certain aspects of CIAs, participants offered valuable feedback about specific CIA provisions and, more generally, about compliance activities. Participants' comments were informative, and OIG will consider them as OIG evaluates provisions for future CIAs. OIG also looks forward to continued positive dialogue with the industry to promote compliance.