

Compliance program development

Compliance Program Improvements for Reducing Risks: Beginning with the Fundamentals

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Pharmaceutical companies have been working to implement the recommendations included in the OIG's voluntary compliance guidance for nearly seven years, including policies and procedures, training, and internal monitoring. Yet, these efforts have not prevented violations and prosecutions in many companies.

A picture of what is missing from these compliance efforts emerges from recent statements from Department of Justice prosecutors, the revised U.S. Sentencing Guidelines, and the ever-increasing requirements of corporate integrity agreements.

Specific issues include:

- 1. A gap between written compliance policies and compliance conduct.** Companies have had difficulty translating their policy changes into behavioral change in the field and within the organization.
- 2. Inadequate monitoring of field conduct for potential violations.** Recent corporate integrity agreements have required companies to institute internal field-based monitoring of sales representatives' conduct. In many companies, sales managers and compliance departments are not aware of actual field conduct because audits are conducted by external groups or because information is not shared. Inadequate monitoring also leaves companies open to future violations because they cannot monitor risk.
- 3. An inability to respond quickly or adequately to allegations or evidence of compliance violations.** Companies have lacked appropriate procedures for following up on allegations or reports, as demonstrated by the fact that many *qui tam* claims were reported internally and not resolved before they were reported externally. Companies are not informed of *qui tam* investigations until long after they have begun, so they cannot institute corrective changes to avoid prosecution.

4. A lack of a compliance culture or organizational commitment to compliance efforts. Recent CIAs have called for Senior Manager and Board Member involvement in compliance efforts, including signing a "certification" that compliance efforts are effective. This is also evidenced by the findings of the Compliance and Leadership Ethics Council report that compliance failures were due to conduct throughout the organization, and not just at the field level.

To summarize, many existing compliance programs are: 1) missing critical elements, such as an effective method for responding to reports of violations, and 2) ineffective at implementing compliance policies, as demonstrated by the gap between policy and conduct and by their failure to change behavior across the organization.

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Improving Compliance Programs

To reduce the risk of future compliance violations and prosecutions, companies need adequate, written compliance policies and procedures for ensuring these policies result in compliant behavior. In order to change the culture of compliance and behavior across the organization, improvements to compliance program implementation procedures are required.

These should include the following:

- 1. Determine what sales professionals can and cannot say.** In many companies, compliance and sales training are conducted separately. Compliance tells sales representatives what they cannot do and Sales provides them with sales knowledge and tools. Representatives are left to connect the two on their own. Instead, compliance and sales should coordinate training efforts by jointly determining

what sales professionals can and cannot say. This would set clear compliant behavior standards for the company and better equip sales professionals to handle all questions or situations without going “off-script.”

2. Effectively train sales professionals to produce behavior change. Another advantage of combining compliance and sales training is that it can shift the focus of compliance training from knowledge of rules and regulations to training in behavior skills. Knowledge training results in a minimum of behavior change because it does not teach learners how to transfer their learning to real-life situations. Behavior-based compliance training is required to change compliance behavior. The chances of causing lasting behavior change also increase when training includes components such as opportunities for practice, feedback, and coaching.

3. Institute a field-based behavioral monitoring program. Several guidances call for the monitoring of compliance efforts including the OIG’s compliance guidance for pharmaceutical manufacturers and the revised PhRMA Code. Capturing actual behavior in the field fulfills these requirements, plus it reveals whether compliance training is changing behavior in the field and enables appropriate corrective action if standards are not being met. When this monitoring involves both field managers and district managers, it also reinforces compliance training efforts. Specific examples of field behavior can be used by field managers for coaching and developing sales professionals, and by district managers for developing field managers.

4. Create a reporting system that enables responsiveness to behavior in the field. Ongoing real time reporting on field behaviors provides accurate data that can be used by the organization in several ways. It enables senior managers and board members to certify with confidence that compliance efforts are effective. It also enables the organization to proactively identify behavioral trends, potential compliance issues, and areas of risk. When this data is combined with a procedure for effectively investigating and acting on all external and internal reports of potential compliance issues, the organization can reduce their risk of external compliance investigations.

5. Involve all senior management and board members in compliance efforts. To create a culture of compliance throughout the organization, compliance efforts need to involve more than the field sales professionals and their immediate managers. As a first step, reports containing timely data on compliance behavior in the field can be distributed to keep the entire organization aware of compliance efforts. More direct involvement includes cascading compliance behavioral training throughout the organization and involving senior management in the training of field managers. This would publically demonstrate organizational commitment and help address compliance violations occurring at different levels of the organization.

6. Create a match between the desired results of compliance programs and incentive programs. Incentives for behavior throughout the organization should drive compliant behavior. For example, field force incentive compensation programs need to remove any possible motivators for inappropriate promotion and reward compliant selling excellence.

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These additional changes to compliance programs and procedures are part of a systematic approach to compliance implementation that companies should follow. Companies need to focus on the training, monitoring, and reporting of compliance behavior to ensure that compliance policies are effective. Compliance efforts should also be ongoing and interconnected, with a cycle between policy, training, monitoring, and reporting that demonstrates an organizational commitment to effective implementation. ■

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