A regulatory inspection by the Drug Enforcement Administration or a state board of pharmacy can be a high stakes event. Penalties for violations of the federal Controlled Substances Act may include criminal penalties, significant civil monetary fines and administrative action up to and including a “show cause” proceeding to suspend or revoke a pharmacy’s controlled substance registration. Violations of state law similarly can result in a wide range of criminal and civil penalties or administrative actions, including the suspension or revocation of a pharmacy’s license.

The consequences can be even more significant for a chain pharmacy, because the identification of a regulatory issue at one store can cause an agency to take a close look at other stores, triggering a domino effect of violations.

Additionally, violation of some pharmacy regulations can impact the validity of claims for prescription reimbursement submitted to government health programs, which are subject to overpayment disclosure and repayment obligations. Federal and state prosecutors and individual qui tam plaintiffs also are becoming increasingly aggressive in bringing False Claims Act suits against pharmacies based on such violations.

To minimize these risks, pharmacy chains should take a proactive approach to regulatory compliance by conducting periodic regulatory compliance reviews. The purpose of a compliance review is to identify and address potential regulatory compliance issues before they result in violations.

Compliance reviews can be conducted by corporate personnel (e.g., internal audit or compliance) or with the assistance of outside resources such as law firms and/or consultants. Depending on the scope of the project and the surrounding circumstances, it may be appropriate to conduct a compliance review under the protection of the attorney-client privilege.

**Identification of regulatory issues to be evaluated**

Because of the broad range of highly specific requirements imposed on pharmacy operations by federal and state law, it is not practical to evaluate every potential regulatory issue in a single compliance review.

Instead, the focus should be on developing a list of key regulatory issues covering the following
categories:

• The basics — Fundamental regulatory issues that are evaluated by inspectors on a consistent basis.

• Past problems — Issues that frequently have been the source of regulatory violations for the chain in the past.

• Hot topics — Issues that are likely to be the subject of heightened regulatory scrutiny because of current events.

A checklist of pharmacy regulatory issues should always include controlled substance recordkeeping. DEA diversion investigators typically conduct an accountability audit with regard to several controlled substances during a pharmacy inspection, so the biennial controlled substance inventory, DEA 222 forms, and other documentation required for an accountability audit should be reviewed to be sure that they have been accurately completed and are readily accessible. Controlled substance theft/loss reporting and security measures are also regular DEA audit issues that should be included.

Issues that are regularly addressed in state pharmacy board inspections include employee licensure and continuing education documentation; pharmacy technician ratios, supervision and training; patient counseling; generic substitution; compliance with prescription requirements; and drug stock issues such as temperature controls and out-of-date stock. Some state pharmacy boards use a standard inspection form, which can provide a useful starting point for identifying issues. Pharmacy chains should have systems in place to internally track regulatory visits and any resulting violations, and this system should be used to identify frequently cited regulatory issues.

These issues should be included in a compliance review because sanctions can be more severe for repeat violations and also because repeat violations may be indicative of a problem that requires corporate action. For example, a pattern of citations for the same issue at multiple stores could indicate a companywide system weakness or could reveal a deficiency in controls within a particular region or district.

Additionally, a compliance review should prioritize issues relating to current industry hot topics because of the increased likelihood that regulators will be focused on these issues. For example, in recent years, in response to alarming trends in prescription drug abuse and overdose deaths, federal and state legislators have enacted a number of new laws designed to prevent the diversion and abuse of controlled substances, and state and federal regulatory agencies have increased their enforcement activity with regard to diversion-related issues.

As a result, regulatory requirements relating to the security and proper dispensing of controlled substances should be addressed in any pharmacy compliance review. These issues include security measures to prevent employee diversion, theft/loss reporting and a pharmacist’s corresponding responsibility to only dispense controlled substances pursuant to a prescription written for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. Similarly, in the wake of a high-profile situation involving contaminated sterile compounded products, many states amended their compounding regulations and regulators increased their scrutiny of compounding operations. If a pharmacy is engaged in
compounding, these regulations should be included in a compliance review.

**Assessment of operational compliance**

Once the list of issues to be addressed in the compliance review is finalized, corporate policies, procedures and training materials should be evaluated to ensure that they accurately reflect the current regulatory requirements and provide clear guidance to field-level personnel.

Having strong corporate policies, procedures and training materials is important not only because they help prevent regulatory violations, but also because, when violations occur, these materials provide evidence that the company was actively taking steps to ensure that individual stores and employees followed the applicable regulations.

Regardless of how well a company’s policies and procedures reflect the regulatory requirements, it is of critical importance that store-level compliance be evaluated. A store-level evaluation will reveal how well corporate policies are implemented and how consistently they are followed. A store-level evaluation can also identify whether pharmacy systems or work flow create any barriers or disincentives to regulatory compliance.

Quite often, regulatory violations result from field personnel implementing a well-intentioned shortcut or attempting to work around a perceived problem. Store evaluations can also reveal areas in which additional substantive regulatory training is needed. In addition to weaknesses, a store-level compliance review can also identify best practices that have been implemented in certain stores or areas that can be expanded to other pharmacies.

There are a variety of methods that can be used to assess store-level compliance, including store reviews by company compliance personnel, internal audits and full-blown mock inspections. Because of time and resource constraints, these methods are typically implemented at a limited number of pharmacies.

However, there are methods, such as pharmacy supervisor store checks and pharmacist-in-charge (PIC) self-checks that can be implemented chainwide using a standardized checklist. For chains operating pharmacies in multiple states, supervisor or PIC regulatory checks can be an efficient way to address state-specific requirements, because the regulatory compliance checklist can easily be modified on a state-by-state basis.

**Importance of prompt remedial action**

Any areas of noncompliance or system weaknesses that are identified in a compliance review must be addressed promptly through the development and implementation of an action plan. Specific action items will depend on the scope of the review and the nature of the problems identified, but they may include policy changes, system updates, additional training for store personnel on certain topics or appropriate disciplinary measures.

Prompt corrective action is necessary to minimize the potential for future violations, and it will also bolster the company’s position when violations do occur. Having an internal compliance review process that proactively identifies and addresses potential regulatory issues shows that the company is committed to compliance and is actively working to
maintain a high level of compliance across its stores.

On the other hand, failing to address problems identified in a compliance review can have negative consequences, particularly if a compliance review indicates a system weakness or other issue that can have widespread impact. Regulators are more likely to take a hard line in an enforcement action if there is evidence that corporate management had been made aware of an issue but did not take steps to address it.

Catherine O'Neil (coneil@kslaw.com) is a partner and Shannon Cox (scox@kslaw.com) is a counsel at the law firm King & Spalding.

This article originally appeared on Page 24 of the October 24, 2016 issue of the periodical Chain Drug Review