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# Pharmaceutical Executive



## Five things you can do to prepare for compliance in all 50 states—starting today

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**O**ver the last three years, the federal government has increasingly regulated, investigated, and fined the pharmaceutical industry. Now, the states are taking their turn. Amidst rising state Medicaid costs, constituent concern over DTC advertising, and public scrutiny of industry motives, individual states are enacting their own legislation regulating industry behavior. However, while OIG guidelines focused on providing companies a broad ethical-operating framework, the states have enacted laws requiring more specific actions.

For pharma, the problem lies not with the act of complying with this or that particular law. Instead, the inconsistent standard of legislation across the states poses the greatest challenge to compliance for the industry. The state laws that have passed generally fall into one of four broad categories. (See “Looking at the Laws,” page 66.) But each state’s requirements differ, with some calling for broad disclosures and others requiring detailed reporting of every promotional line item given to

healthcare providers. Therefore, operational implementation of policies that respond to these compliance standards poses a considerable burden for companies in terms of time and expense, and is set to worsen unless the industry changes the way it responds to state laws.

In the past, companies would develop local responses when a state passed legislation regulating industry practices. When Minnesota created its law limiting gifts to healthcare providers in 1993, most pharma companies developed policies and training programs only for sales reps in that state. When Vermont enacted its marketing-cost disclosure law in 2002, companies again used a localized approach to frame their responses. Only in 2004, when California enacted its law requiring companies to establish a comprehensive compliance program that included an annual spend limit on healthcare professionals, did some firms begin to consider the impact of the new law on the overall business approach—as opposed to just the business in one particular state.



# Looking at the Law

To help industry better understand the impact of state laws, it is helpful to group legislation into four broad categories.

**Spending limits** These requirements set maximum annual thresholds—established in some states by pharma companies, and in others, by the state itself—for categories of spend, such as gifts or meals.

“Each pharmaceutical company shall establish explicitly in its Comprehensive Compliance Program a specific annual dollar limit on gifts, promotional materials, or items or activities that the pharmaceutical company may give or otherwise provide to an individual medical or health care professional in accordance with the ‘Compliance Program Guidance for Pharmaceutical Manufacturers’ and with the ‘Code on Interactions with Health Care Professionals.’” (CALIFORNIA LAW SB 1765, CHAPTER 8, DRUG MARKETING PRACTICES)

“It is unlawful for any manufacturer or wholesale drug distributor, or any agent thereof, to offer or give any gift of value to a practitioner. . . . As used in this section, ‘gift’ does not include: . . . (2) items with a total combined retail value, in any calendar year, of not more than \$50.” (MINNESOTA LAW 151.461, GIFTS TO PRACTITIONERS PROHIBITED)

**Cost disclosures** These laws require pharma companies to disclose aggregate and/or per-individual healthcare provider expenditures of various sales, marketing, and advertising components.

“Annually on or before December 1 of each year, every pharmaceutical manufacturing company shall disclose to the office of the attorney general the value, nature, and purpose of any gift, fee, payment, subsidy, or other economic benefit provided in connection with detailing, promotional, or other marketing activities by the company, directly or through its pharmaceutical marketers, to any physician, hospital, nursing home, pharmacist, health benefit plan administrator, or any other person in Vermont authorized to prescribe, dispense, or purchase prescription drugs in this state. Disclosure shall include the name of the recipient.” (VERMONT LAW § 2005 (A) (1) PHARMACEUTICAL MARKETERS)

“Advertising costs for prescription drugs, based on aggregate national data, must be reported to the state council by all manufacturers and labelers of prescription drugs dispensed in this state that employs, directs or utilizes marketing representatives. . . . the reporting requirements of information by labelers and manufacturers shall include all national aggregate expenses associated with advertising and direct promotion of prescription drugs through radio, television, magazines, newspapers, direct mail and telephone communications as they pertain to residents of this state.” (WEST VIRGINIA LAW §5A-3C-13(A), ADVERTISING COSTS; REPORTING OF SAME)

**Price disclosures** Requires companies to disclose elements of federal pricing. For example, in Vermont, reps must disclose the AWP of their product and all AWPs of their competitors during any mailing, telephone call, e-mail, face-to-face meeting, or detail with providers by distributing a form showing the requisite information.

“When a pharmaceutical marketer engages in any form of prescription drug marketing directly to a physician or other person authorized to prescribe drugs, the marketer shall disclose to the physician or other prescriber the average wholesale price (AWP) of the drugs being marketed. Disclosure shall include the AWP per pill and the price relationship between the drug being marketed and other drugs within the same therapeutic class.” (VERMONT LAW 33 V.S.A. § 2005A, PHARMACEUTICAL MARKETER PRICE DISCLOSURE LAW)

**Declaration of compliance** This legislation requires companies to attest to compliance with OIG Guidelines and the PhRMA Code through a “Declaration of Compliance” on their corporate Web site, while also disclosing their “Comprehensive Compliance Program,” for which they must provide a toll-free number.

“Every pharmaceutical company shall adopt a Comprehensive Compliance Program that is in accordance with the April 2003 publication ‘Compliance Program Guidance for Pharmaceutical Manufacturers,’ which was developed by the United States Department of Health and Human Services Office of Inspector General (OIG). . . . Every pharmaceutical company shall include in its Comprehensive Compliance Program policies for compliance with the Pharmaceutical Research and Manufacturers of America (PhRMA) ‘Code on Interactions with Health Care Professionals,’ dated July 1, 2002. . . . The pharmaceutical company shall annually declare, in writing, that it is in compliance with both its Comprehensive Compliance Program and this chapter.” (CALIFORNIA LAW SB 1765, CHAPTER 8, DRUG MARKETING PRACTICES)

### 3 Short-Term Policies, Long-Term Strategies

For pharma, the backbone to state-level compliance is robust reporting systems. But building new or enhancing existing infrastructure often requires substantial amounts of time and investment. Companies often must make do with existing technology and rely on developing new policies to safeguard against compliance issues, as they look more long-term to improve their technology capabilities.

For instance, systems may not be in place to trace actual gift spending to a specific physician. As a result, in the short-term, companies may find themselves developing a corporate policy that limits frequency and types of gifts in lieu of recording and tracking all gifts to all physicians. However, over time, that dynamic will switch to a greater reliance on leveraging technology to track actual expenses.

To see where they are on that path, companies must first conduct a technology gap-assessment of their existing infrastructure for capturing the required data. For instance, using the prior example of a promotional speaking program, a company should ask questions such as if it has a technology system in place capable of tracking attendees by their unique ID numbers. After completing this, companies will then be able to identify in which areas to develop new policies in the short-term and know which systems will need to be developed or further enhanced over time.

As companies develop these IT systems, executives will be better able to address reporting shortfalls. Eventually, the new systems can be created and integrated with third-party vendors, greatly improving the accuracy of per-physician reporting.

### 4 Communicate and Train

Companies must develop new policies and pathways that address the organizational response to new state laws. However, it is often more difficult for companies to enforce their policies. Therefore, executives should consider the following steps to communicate with and train employees on their new protocols:

- » Dispatch general communication—through an Intranet or newsletter—to inform the entire organization, explaining the new state laws and their impact on the organization.
- » After informing employees, educate them on new policies and organizational changes using either online or live modules.
- » Update vendor contracts to include required data reporting and the desired format of the data. For instance, ad agencies will need to breakdown national DTC spending on a per state basis, and medical education and communication companies will need to capture and record spending to specific attendees.
- » Conduct state-specific training for employees in affected states, describing the specific requirements and definitions

used in the applicable law. Training programs can be rolled out in live or e-learning-based modules.

Executives should record and document their communication and training efforts to gain credit for implementing two of the OIG's seven elements of effective compliance programs—namely, education and training and lines of communication—as well as the requirement for attestation in California. (See “Fair Market Value,” September supplement to *Pharm Exec*, page 10.)

### 5 Audit Against Adherence

Management guru Peter Drucker once said, “If you can't measure it, you can't manage it.” But when it comes to state-level compliance, who should do the measuring?

Some companies are proposing a new operating group whose operational responsibility will be to manage, monitor, and report state-law compliance. Others are expanding the responsibilities of existing operational groups, such as business services, business analysis, public affairs, or finance. In any case, the group responsible for ensuring state-level compliance should be unique from legal or compliance, which should focus on interpreting and setting policies around these laws, respectively.

In order to ensure compliance, companies will need to audit against new operational policies. Companies must ensure that the auditors understand the compliance concerns and operational processes involved with the various state laws. This will involve auditing third-party vendors, internal sales staff, and contract sales organizations, as well as marketing activities such as promotional speaking programs and conventions.

### Here to Stay

Operations and compliance departments are likely to continue to face burdens as pending legislation develops into new law. And the six states with existing laws are still moving targets—they may decide to expand or revise their requirements in the future. But companies that set up a holistic

national plan to address state-law compliance will be better positioned to respond to any new regulatory requirement.

In addition to internal compliance and operational efforts, industry should consider lobbying for a common standard of legislation, to preempt further disparity in reporting requirements. Similarly, industry could look to develop a common standard of data exchange with vendors, to improve compliance with state laws. This combination of internal operational enhancements and external industry-wide efforts will best prepare companies for responding to existing and pending state laws. ☐

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Implementation of policies that respond to industry compliance standards poses a considerable burden for companies in terms of time and expense. Unless industry changes its response to state laws, the condition will worsen.

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