ARTICLE 02

STATE TRANSPARENCY AND GIFT BAN STATUTES

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MEDICAL ALLEY ASSOCIATION

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While many manufacturers have policies and procedures in place to comply with the federal Sunshine Act, a surprising number have overlooked the various state transparency (reporting) laws and gift bans applicable to medical device and pharmaceutical company interactions with healthcare professionals. This can be a costly mistake, especially in light of the recent focus on the opioid crisis that is spurring a rash of new and proposed state legislation to reign in what is perceived as undue influence on prescriber behavior.

Violations of state statutes may carry fines as high as $10,000 per occurrence, and there has been enforcement activity. Also, the most recent opioid-related scrutiny of manufacturer-physician interaction may foreshadow a stricter stance against violations of the laws. The Vermont attorney general's website lists over 30 different enforcement actions that it has settled with a variety of companies since early 2015.

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Federalism at Work

The federal Sunshine Act requires reporting of various "value transfers" by device and drug manufacturers and distributors to physicians and teaching hospitals. The act contains a provision allowing states to impose requirements in addition to Sunshine, and they do. At present, at least eight states and the District of Columbia have laws requiring reporting of, or somehow limiting the context in which, gifts, payments or other transfers of value may be made by pharmaceutical and device companies to various healthcare professionals.

A number of these laws require affirmative acts (e.g., adopting and posting a compliance program and registration) of the companies. In addition, the state statutes expand the scope of covered recipients from physicians and teaching hospitals, covered under Sunshine, to, in some states, any prescriber or person who is in a position to recommend a prescribed drug or device.

Apparently in reaction to the opioid epidemic, some of the most recent legislation has been more focused on pharmaceutical manufacturers than on device manufacturers, although there are a number of states that have laws that apply to both.

The following chart summarizes the state transparency and gift ban laws applicable to some medical device and pharmaceutical manufacturers and some of the key steps required for compliance:

State	Requirement to Adopt a Compliance Program	Requirement of State Filing or Posting of Compliance Program	Restrictions on Transfers	Requirement to Report Expenditures	Devices as well as Pharma Manufacturers Covered?
California	✓	✓	✓		✓
Illinois				✓	
Connecticut	✓		✓	✓*	✓
Washington D.C.				✓	
Maine			✓		✓
Massachusetts	✓	✓	✓	✓	✓
Minnesota			✓	✓	
Nevada	✓	✓		✓	✓
Vermont		✓	✓	✓	✓
Federal Sunshine Act				✓	✓

*Only for transfers APRNs who are not practicing in collaboration with a physician.

The Challenge of Compliance Implementation

Implementing a compliance program in this patchwork of state requirements can be difficult. For instance, Vermont and Massachusetts ban life sciences manufacturers from providing meals to covered persons except in certain circumstances, but the circumstances in each state varies. Vermont and Minnesota both allow pharmaceutical companies to give only educational gifts to prescribers, but Minnesota does not include textbooks in this category while Vermont does. Some states only regulate activity within the state, while others regulate the activity of state-licensed healthcare providers even when they are outside of the state.

In this varied and complex landscape, companies who want to be compliant must decide whether to enact a policy with carve-out rules for the "special states," which could prove to be a compliance nightmare, or to impose the most restrictive prohibitions on all interactions, which can be seen as overly restrictive. Some companies might also consider pulling out of Vermont, one of the most restrictive states, but this is obviously not an option for all.

Tips to Build Your Policy and Avoid Fines

At the end of the day, the tension will likely be between a desire for flexibility (i.e., avoiding adopting the most restrictive rules) and the cost of conforming to numerous different rules. Whatever your company decides, here are some practical tips for your policies and procedures:

- Make them applicable to all employees, independent contractors and agents.
- Set concrete rules in order to prevent judgment calls in the field.
- Invest in tracking systems from the beginning (it will be costly and perhaps impossible to make the required reports or demonstrate compliance, retroactively).
- Establish mechanisms for training, audit and discipline.
- Establish mechanisms for certification of compliance on which the party signing the reports can reasonably rely.

AUTHOR CREDITS

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Contact Us

Learn more by contacting Sheva Sanders or Tricia Kaufman, attorneys who have worked with numerous life sciences companies to craft transparency and gift ban policies that comply with federal and state laws.


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