

# Life Sciences State Law Compliance

## Helping Companies Manage Compliance in an Ever-Evolving Environment



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Pharmaceutical, medical device, and biotechnology manufacturers must comply with an increasing number of state laws that regulate the industry, including:

- Anti-kickback laws
- Marketing code of conduct laws
- Prescription drug pedigree laws
- Gift prohibition laws
- Distributor laws
- Drug price reporting laws
- Marketing cost disclosure laws
- Prescriber data privacy laws
- Maine's clinical trial disclosure law
- District of Columbia's pharmaceutical detailer licensure law

These laws demand an ongoing vigilant compliance effort. The penalties for non-compliance are increasing, as are the number of state enforcement actions. The laws sometimes implicate common business practices and many require companies to submit annual (or quarterly) reports and certifications to state administrative and enforcement agencies. Furthermore, industry legal and compliance professionals often struggle to stay current on state law issues as state agencies continuously issue and update guidance documents, reporting forms, certifications, and other compliance resources. No two state laws are exactly alike.

A team of eight professionals in King & Spalding's approximately 40-member FDA & Life Sciences Practice Group specialize in state law compliance issues. We can help ease the ongoing burden of complying with state laws. We are also there to help investigate and defend potential violations.

### Ad Hoc State Law Compliance Group

King & Spalding offers membership in a coalition of over 50 pharmaceutical, medical device, and biotechnology companies, to which we provide guidance on a majority of the state laws mentioned above. Currently, we provide members of the coalition, known as the *Ad Hoc State Law Compliance Group*, guidance on state marketing code of conduct laws, gift prohibition laws, marketing costs disclosure laws, drug price reporting laws, prescriber data privacy laws, the Maine clinical trials disclosure law, and the District of Columbia pharmaceutical detailer licensure law.

We have extensive experience in working with companies' legal and compliance departments to achieve state law compliance that is practical and enduring.



## Ad Hoc State Law Compliance Group (cont'd)

For a flat quarterly rate, we provide *Ad Hoc State Law Compliance Group* members a comprehensive suite of state law resources and services, including: regular email updates on state law developments; conference calls on state law issues; various compliance toolkit items (e.g., compliance calendar); access to a members-only website that contains an abundance of state law resources; tracking of key pending state and federal legislation; and access to King & Spalding professionals.

## Comprehensive Company-Specific State Law Counseling

In addition to the subscription service we provide through the *Ad Hoc State Law Compliance Group*, King & Spalding provides company-specific state law counseling for dozens of companies (many of which are also members of the *Group*) that engage King & Spalding on an individual client basis. For individual clients, we provide comprehensive counseling on state laws, including laws within the purview of services we provide to the *Group*, as well as state anti-kickback laws, prescription drug pedigree laws, and pharmaceutical and medical device distributor laws.

### **For individual clients, we provide a wide range of services, including:**

- interpreting state wholesale distributor and controlled substance licensing laws and their implications for in- and out-of-state manufacturers, distributors, and service providers
- advice on the implementation of state-level pedigree laws and their intersection with the federal Prescription Drug Marketing Act (PDMA)
- counseling on compliance with state anti-kickback laws, compliance program laws, and marketing laws
- preparing and reviewing agreements to ensure state law compliance
- analysis on whether specific programs/payments may be appropriate and/or reportable under state laws
- assisting with the preparation of required state law reports
- assisting in development of aggregate spend policies and tracking systems
- preparing communications to field sales personnel and other internal clients
- preparing risk assessments on state law compliance
- conducting independent investigations of potential violations and defending government investigations
- representation in certain enforcement actions by state boards of pharmacy
- working anonymously with various state agencies on behalf of clients

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