



Ad Hoc Sunshine and State Law Compliance Group

King & Spalding's Ad Hoc Sunshine and State Law Compliance Group is a subscription service that offers life sciences companies comprehensive federal and state law guidance in an efficient, practical and cost-effective manner. Membership in the coalition of over 65 pharmaceutical, biotechnology and medical device companies provides access to a comprehensive suite of federal and state law resources and services.

King & Spalding established the Group in November 2004 to provide guidance to companies on the California Compliance Program Law. The scope of the coalition has since grown substantially, as states continue to enact laws and regulations targeting the life sciences industry.

The Group also focuses on the Federal Physician Payments Sunshine Act, enacted as part of the Affordable Care Act, which imposes broad payment disclosure obligations on the industry.

We currently provide guidance to the Ad Hoc Group on the following wide range of federal and state laws and regulations:

- **Federal Physician Payments Sunshine Act** (aka Open Payments)
- **Federal prescription drug sample transparency requirements**
- **State drug price transparency laws** (including laws in CA, NV, OR and VT among others)
- **State marketing code of conduct laws** (including laws in CA, CT, MA and NV)
- **State disclosure and aggregate spend laws** (including laws in CT, DC, MA, MN and VT)
- **State gift prohibition laws** (including laws in ME, MN, NJ and VT)
- **State drug price reporting laws** (including laws in LA, NM and TX)
- **State prescription drug coupon bans** (including laws in CA and MA)
- **State and local pharmaceutical representative licensing and registration laws** (including laws in Chicago, DC and NV).

We have a team of seven King & Spalding life sciences professionals that focus on counseling companies on Sunshine and state law compliance issues.

AD HOC SUNSHINE AND STATE LAW COMPLIANCE GROUP MEMBER BENEFITS (CONT'D)

King & Spalding provides a number of resources to members of the Group, including:

- **Regular email updates on developments.** Email updates notify members of various federal and state law developments, including legislative activity, regulatory activity, changes in reporting forms or certifications, and updates to guidance documents.
- **Frequent conference calls on the issues.** Conference calls provide overview and analysis of new federal and state requirements, analysis of implementation of enacted laws, and discussion of relevant pending legislation. Calls provide an opportunity for Q-&-A/information sharing. In addition, all calls are recorded for replay by members who may be unable to dial in for scheduled calls. King & Spalding antitrust counsel are present on all conference calls and monitor email communications.
- **PowerPoint slide presentations summarizing new requirements.** These presentations detail new federal and state requirements in an accessible and user-friendly format. Many in-house attorneys and compliance professionals use these presentations to educate and/or train internal clients.
- **Compliance toolkit items.** Toolkit items assist compliance professionals with their compliance efforts. Toolkit items include comparison charts, an annually updated compliance calendar, quick reference tools, and summaries of laws and regulations.
- **Members-only website.** The members-only website is an abundant repository of resources. The website contains downloadable copies of laws and regulations, regulatory guidance, reporting forms, certifications, a comprehensive listing of pending legislation, toolkit items, links to important websites, and archived copies of emails and conference call slide presentations.
- **Key pending legislation tracking (federal and state).** We track all key pending federal and state legislation and report significant developments to members.
- **Access to King & Spalding professionals.** A team of seven attorneys, consultants, and paralegals in King & Spalding's 40-member FDA & Life Sciences Practice Group focuses on these issues. We are available to assist Ad Hoc Sunshine and State Law Compliance Group members with any general Sunshine or state law inquiries, as well as with questions about member resources.

Member companies may authorize access to these resources to as many in-house attorneys and in-house compliance professionals as they wish.

COMPANY-SPECIFIC COUNSELING WHEN YOU NEED IT

In addition to the subscription service we provide through the Ad Hoc Sunshine and State Law Compliance Group, King & Spalding provides company-specific Sunshine and 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. We are able to leverage our knowledge and experience in supporting the Group to provide company-specific services in a prompt and cost-efficient manner.

RELATIONSHIPS THAT MATTER

We maintain relationships with various government agencies, including state boards of pharmacy, departments of health, and offices of attorneys general, as well as the federal Centers for Medicare and Medicaid Services and Department of Health and Human Services Office of Inspector General. Through these relationships, we are able to develop an understanding of the issues from the unique perspective of government administrators and enforcers. In addition, although we do not directly engage in legislative and regulatory advocacy on behalf of the Ad Hoc Sunshine and State Law Compliance Group, we regularly communicate with key trade associations and lobbying organizations, such as PhRMA and AdvaMed, and stay abreast of their efforts in that regard.

We possess a depth of experience that helps companies understand their Sunshine and state law obligations and take the necessary steps to ensure compliance

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