Ad Hoc Sunshine and State Law Compliance Group

In November 2004, King & Spalding established the Ad Hoc Sunshine and State Law Compliance Group 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 like the federal Physician Payments Sunshine Act and the growing number of state drug price transparency laws.

Our work includes, among other things: monitoring and analyzing key legal developments in the federal Physician Payments Sunshine Act, as well as state transparency, compliance, gift ban, and drug price transparency laws; developing compliance “toolkit” items; regularly presenting on new issues and their practical implications; and drafting and submitting comments on behalf of the Group to CMS and state regulators on regulatory proposals and related implementation efforts.

The Ad Hoc Sunshine and State Law Compliance Group is a subscription service that offers life sciences companies a comprehensive suite of federal and state law guidance in an efficient, practical and cost-effective manner.

AREAS OF FOCUS

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)

65+ coalition comprised of pharmaceutical, biotechnology and medical device companies.

800+ participants who benefit from the coalition’s practical and real-time advice.
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KEY CONTACTS

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GROUP MEMBER BENEFITS

- 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.
- Overview and analysis of new federal and state requirements, discussion regarding implementation of enacted laws, and identification of relevant pending legislation.
- Opportunity for Q&A and benchmarking.
- Calls are recorded for replay by members who may be unable to join scheduled calls.
- Access to K&S-developed toolkit items, including a compliance calendar with key reporting dates; comparison charts and quick-reference tools summarizing laws covered by the Ad Hoc Group; transparency heat maps; and benchmarking surveys of member company activities.
- Access to members-only website with an abundant repository of resources (e.g., copies of state laws and guidance, toolkit items, links to important websites, and archived copies of emails and conference call slide presentations).
- Timely email updates on new developments.
- Frequent conference calls on new issues.
- PowerPoint presentations accompany each conference call that detail new federal and state requirements in an accessible and user-friendly format.

COMPANY-SPECIFIC COUNSELING WHEN YOU NEED IT

In a prompt and cost-efficient manner, we provide company-specific Sunshine and state law counseling for dozens of companies (many of which are also members of the Group) that engage us on an individual client basis.

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 developed an understanding of these issues from the unique perspective of government administrators and enforcers.

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.