

Pharmacy Regulatory Compliance



King & Spalding has the expertise to successfully guide clients through the complex regulatory environment and the overlapping federal and state regulations that impact the pharmacy industry.

Pharmacies must comply with the pharmacy acts and board of pharmacy regulations of each state in which they operate. State requirements for the prescribing and dispensing of prescription drugs and other elements of pharmacy operations can be highly technical and may vary significantly from state to state. Moreover, state laws are frequently amended, which requires clients to stay abreast of the rapidly changing pharmacy regulatory environment.

When handling drugs that have been classified as controlled substances, another layer of regulation applies. The federal Controlled Substances Act (CSA) is implemented by the Drug Enforcement Administration (DEA) through comprehensive regulations that cover all aspects of the manufacturing, ordering, receipt, storage, distribution, prescribing, dispensing, and destruction of controlled substances. The CSA and the DEA regulations, however, do not preempt state laws relating to controlled substances. Most states have enacted their own controlled substance acts and regulations, which can also vary widely by state.

Failure to comply with pharmacy and controlled substance laws and regulations can result in civil and administrative penalties, suspension or revocation of licensure, and even criminal sanctions.

Pharmacies must also comply with HIPAA and various other state and federal privacy and security provisions. Various aspects of pharmacy practice are also impacted by the Food and Drug Administration (FDA) regulations and analogous state laws that govern pharmaceuticals and over-the-counter drugs, including laws relating to pedigree, reporting obligations, the federal Prescription Drug Marketing Act, and state laws pertaining to promotion and advertising.

Additionally, pharmacy reimbursement is subject to specific and highly technical rules and regulations. Individual state Medicaid programs, Medicare Part B and Part D, and other government programs have comprehensive regulations governing issues such as provider participation, claims submission, reimbursement limits, and overpayment disclosure and repayment. Federal and state prosecutors and individual *qui tam* plaintiffs are becoming more aggressive in bringing suits against pharmacies

King & Spalding's Healthcare Practice was one of seven finalists nationally for the *Chambers USA 2013 Award for Excellence*.



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recognized King
& Spalding's
Healthcare Practice
as "home to some of
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in the practice of
healthcare law."

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for failure to abide by these requirements. Liability under the False Claims Act, the Anti-Kickback Statute, and related state provisions can result in significant civil penalties, enhanced compliance obligations, and potential exclusion from participation in government healthcare programs.

King & Spalding has a team of professionals drawn from multiple practice areas who specialize in the regulation of the pharmacy industry. Our pharmacy team members have experience at all levels of the distribution chain, including active ingredient and pharmaceutical manufacturers and distributors; retail, mail order, specialty, long-term care and Internet pharmacies; hospitals and clinics; and physician groups. We have counseled clients on compliance, conducted internal investigations and compliance reviews, and worked with clients to modify systems, policies and procedures, and training materials to satisfy regulatory requirements. Our lawyers have handled criminal, civil, and administrative regulatory matters involving the DEA, FDA, state controlled substance agencies and boards of pharmacy, and they have litigated related proceedings in federal and state trial courts and courts of appeals.

Representative Clients and Matters

- Serving as lead trial counsel for a Fortune 100 healthcare company in administrative proceedings before the DEA as well as in related federal district and appellate court litigation.
- Serving as lead counsel in False Claims Act investigations and litigation involving alleged improper pharmacy billing to Medicare Part D, Medicaid and other healthcare programs.
- Conducting an internal investigation for a major national retail pharmacy chain related to drug substitution requirements.
- Conducting a compliance review of a Fortune 100 retail pharmacy to assess the effectiveness of the company's policies, procedures, and monitoring programs in meeting federal and state regulatory obligations.
- Conducting a compliance review of a national mail order pharmacy to assess compliance with federal and state pharmacy and controlled substance laws.
- Developing a multistate pharmacy regulatory database for use by in-house legal and operations personnel that provides a plain language summary of state and federal requirements for a range of key topics.
- Advising a Fortune 100 pharmacy retailer regarding the development of internal systems and controls relating to implementation of regulations allowing the electronic prescribing of controlled substances.
- Advising a national pharmacy chain regarding various state Medicaid agency requirements for coordination of benefits billing.
- Providing advice to a coalition of more than 50 pharmaceutical, medical device, and biotechnology companies regarding compliance with state marketing code of conduct, gift prohibition, marketing cost disclosure, drug price reporting, and prescriber data privacy laws.
- Representing an industry working group of two dozen pharmaceutical companies in the implementation of FDA-mandated Risk Evaluation and Mitigation Strategies (REMS) for long-acting opioids.
- Assisting a healthcare company with the implementation and operation of 340b drug pricing program.
- Advising pharmacy clients regarding the implementation of processes, policies, and procedures for sale of pseudoephedrine and other listed chemicals.
- Advising pharmacy and hospital clients with regard to state and federal regulations governing storage and disposal of pharmaceuticals and hazardous waste.
- Conducting internal reviews of a client's policies and procedures governing pharmacy use of social media and other patient communications.