

## Specialty Pharmacy Services



### Industry Insight

Quarles & Brady has been representing pharmacies for decades. Few law firms have the pharmacy law experience found within our firm. More importantly, we understand that specialty pharmacy is unique. The legal issues that face specialty pharmacies are different because specialty pharmacy is different. From REMS to accreditation, the Federal Anti-Kickback Statute (AKS) to adherence programs, licensing to 340B issues, and HUBs to data use agreements, our attorneys have significant experience providing practical, real-world legal advice to specialty pharmacies. Our pharmacy team has tremendous operational knowledge of the specialty pharmacy industry. We don't just represent specialty pharmacies, but also payors, prescribers, manufacturers, and pharmacists. Our team of specialty pharmacy attorneys includes a former pharmacy technician, former nurses, and two partners who started their professional careers as pharmacists, one of whom was the owner of an independent pharmacy. Further, we have cultivated meaningful relationships with regulators and are actively involved in industry organizations. Our ability to combine multiple industry perspectives with our legal expertise enables us to provide unparalleled strategic counsel to help our clients achieve their long-term objectives.

### High-Touch Legal Services

There's no shortage of challenges in running a specialty pharmacy—increased competition, narrowing of networks, negotiating reimbursement, and new regulations.

Coordinating legal services should not be one of them. At Quarles & Brady, our focus is solely on helping clients achieve their business goals on their terms. This means providing representation efficiently and cost-effectively and defining success by our clients' metrics. We strive to see goals and benchmarks through your eyes—and then use our experience and insight to best position you to exceed them. Your challenges are our challenges; your triumphs are our triumphs. With Quarles & Brady, you're not just a client—you're a partner.

### One-Stop Shopping

In addition to having one of the largest and most experienced health law groups in the country, the depth and breadth at Quarles & Brady as a whole, gives our specialty pharmacy clients access to "one-stop shopping" for the entire range of legal issues they face, including labor and employment, intellectual property, real estate, M&A, and insurance regulation, to name a few.

### Representative Services

#### Contract Drafting and Negotiation

- Drafting and negotiation of pharmacy services agreements with manufacturers, other pharmacies, and payors.
- Providing strategic advice on regulatory issues related to agreements.

## Fraud and Abuse

- Advising on compliance with federal and state laws including issues specific to rebates, coupons, PAP programs, AKS safe harbors, formularies, usual and customary price and “switching programs.”
- Providing assistance during investigations.

## Corporate Transactions

- Advising on strategic acquisition and divestiture transactions and related due diligence.
- Advising on general corporate matters, including business planning and formation of business entities.

## Licensing

- Advising on license and reporting requirements for pharmacies, pharmacist-administered vaccinations and screening tests, and pharmacy wellness centers, including clinics within pharmacies.
- Responding to individual state board queries, representing clients in administrative proceedings and advising on reporting requirements before state health care licensing and regulatory entities.

## Data Privacy and Security

- Advising on HIPAA and state privacy laws issues, including determining whether there has been a privacy or security breach and the related reporting requirements, uses of de-identified data, the refill reminder exception and contracting required of covered entities and business associates.
- Providing guidance during investigations and inquiries from regulators.
- Developing policies, procedures, and processes to mitigate risks and enhance compliance.

## Billing and Coding Practices

- Developing guidelines for avoiding unintentional mis-billing and over-utilization of pharmacy services and products.
- Advising on appropriate billing of prescription medications, including auditing of pharmacies, developing internal audit procedures, corporate compliance guidelines and compliance education.
- Assisting with obtaining reimbursement from governmental and third-party payors.

## DEA

- Advising on all aspects of compliance with the CSA and DEA regulations, including registration, recordkeeping, reporting, and proper handling of controlled substances and listed chemicals.
- Developing Standard Operating Procedures involving controlled substances and listed chemicals.
- Representing clients in administrative or other enforcement proceedings before the DEA.



For more information, please contact

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