

OUR PRACTICE

Pharmacies

Baker Donelson advises retail, specialty, long term care (and other "closed door") pharmacy clients on a variety of business and regulatory matters. Our lawyers are familiar with the intricacies of the many laws and regulations that apply in the operation of all types of pharmacies, including those that service special populations. We offer a range of services – from assistance on transactional matters to navigating the day-to-day regulatory issues (at both the federal and state level) that affect pharmacies. At times, our role as counsel to pharmacies requires us to apply our knowledge of the industry, the law and in many cases, government enforcement representatives, to the legal and practical considerations involved in both internal and government investigations.

In addition to its pharmacy-specific experience, Baker Donelson regularly advises all types of health care providers, including physicians, hospitals, hospital systems, long term care facilities and pharmaceutical distributors. We have gained national recognition for our experience in advising on federal health care program compliance, as well as the anti-fraud and abuse laws, including the False Claims Act, the anti-kickback statute and the Stark Law. Many of our attorneys have past work experience with various government agencies, including the Office of General Counsel of the Department of Health and Human Services (HHS), the Center for Medicare and Medicaid Services, the Office of Counsel to the HHS Inspector General, multiple state Attorneys General and the Department of Justice. Our attorneys frequently lead seminars and participate in panel discussions concerning Medicare and Medicaid fraud and abuse issues.

Our experience in the pharmacy industry includes advising and representing clients in a wide range of areas, including:

- Developing and executing health care due diligence reviews for large retail chain pharmacies, specialty pharmacies and long term care pharmacies
- Advising pharmacy clients on issues relating to possible diversion and related reporting requirements
- Advising pharmacies and pharmacists regarding inquiries by the state Boards of Pharmacy
- Assisting retail and long term care pharmacy clients in the development of DEA-compliant policies for dispensing of Schedule II medications
- Advising clients on issues relating to the federal 340B Drug Discount Program, including enrollment, contracting, audits, compliance and self-disclosures
- Conducting internal investigations relating to regulatory compliance, including repackaging, drug returns and credits, compounding issues, possible diversion, the use of pharmacy technicians, and Medicaid pricing issues (e.g., "best price" and MFN)
- Responding to Medicaid and other payor audits