

OUR PRACTICE

Health Care Regulatory

The health care regulatory landscape is in constant flux, driven by rapid advancements in medical technology, evolving policy priorities, and shifting political climates. We recognize that navigating this dynamic environment requires more than just a solid understanding of existing laws – it demands agility and foresight. Our Health Care Regulatory team is dedicated to helping clients adapt to these changes with confidence, ensuring compliance, and mitigating risks in an industry where precision and adaptability are paramount.

At Baker Donelson, our Health Care Regulatory team is dedicated to guiding clients through the complex and ever-evolving landscape of regulations. With a deep understanding of the intricate legal and regulatory frameworks that govern the health care industry, we offer comprehensive legal services tailored to the needs of health care providers, organizations, and entities. From the initial development of compliance policies and programs and licensing to complex transactions and policy advocacy, our team provides end-to-end support tailored to the unique needs of each client. We leverage our in-depth industry knowledge and regulatory experience to offer strategic advice, proactive risk management, and effective representation across various aspects of health care law. Whether you're navigating new regulatory requirements, involved in significant transactions, seeking to influence health care policy, or attempting to ensure regulatory compliance related to day-to-day operations, we are equipped to deliver insightful, practical solutions that drive your success.

Our capabilities include:

- **Regulatory Compliance.** Navigating health care regulations requires extensive knowledge of the law and current enforcement priorities and guidance. We help our clients comply with federal and state regulations, including those set by the Centers for Medicare & Medicaid Services (CMS), the Food and Drug Administration (FDA), and the Department of Health and Human Services (HHS). Our team provides strategic advice on compliance with virtually all health care laws, including the Anti-Kickback Statute (AKS), Stark Law, and the Health Insurance Portability and Accountability Act (HIPAA).
- **Medicare and Medicaid.** We assist with reimbursement and enrollment processes that govern billing and payment for health care services; handle audits, appeals, payor disputes, and post-payment reviews; manage voluntary repayments; structure arrangements to meet Medicare and Medicaid reimbursement requirements, Conditions of Participation, and Conditions of Payment; and develop sound policies and procedures so providers consistently meet the requirements of Medicare, Medicaid, Tricare, Veterans Administration health programs, and private payers. Our team regularly advises providers regarding relevant reimbursement laws to allow them to structure arrangements to comply with those requirements and be paid for their services. We advise on federal, state, and commercial reimbursement issues, including disputes with payors.
- **Corporate Practice of Medicine.** Our team offers legal counsel on the corporate practice of medicine, including issues related to fee-splitting and compliance with state professional practice regulations. We help health care organizations navigate complex legal frameworks to ensure they operate within the bounds of the law while maintaining ethical and financial integrity.
- **Operational Advice.** We provide guidance on day-to-day operational issues, peer review processes, corporate governance, clinical privileges, and medical staff matters. We ensure compliance with

industry regulations. We help health care organizations navigate credentialing, mitigate risks, and implement legally sound practices to support high-quality patient care.

- **Care Coordination.** We develop and implement value-based and care coordination arrangements. We are structuring and negotiating managed care arrangements, clinical integration transactions, and service agreements.
- **Compliance Programs and Reviews.** We are adept at developing and implementing programs to ensure adherence to state and federal regulations. Our team also has extensive experience conducting reviews to assess and improve compliance program effectiveness.
- **Fraud and Abuse Counseling.** We advise on laws and regulations related to fraud and abuse.
- **Privacy and Security.** Assisting with patient privacy, data security, subpoenas, and HIPAA compliance.
- **Investigations and Disclosures.** Our team regularly defends clients against federal and state audits and investigations and manages voluntary self-disclosures under CMS and Office of Inspector General (OIG) protocols. We are also experienced with internal investigations, disciplinary proceedings, and peer review processes.
- **Licensing and Accreditation.** Obtaining and maintaining the necessary licenses and accreditations is crucial for health care organizations. We assist with applications, renewals, change of ownership transfers, and compliance issues related to licensure and accreditation from bodies such as The Joint Commission, the National Committee for Quality Assurance (NCQA), and state health departments.
- **Health Care Transactions.** We support clients through the regulatory aspects of health care transactions, including mergers, acquisitions, joint ventures, and affiliations. Our team conducts due diligence, drafts and negotiates transaction documents, and ensures compliance with regulatory requirements.
- **Policy and Advocacy.** Our Firm is engaged in shaping health care policy and advocating for clients' interests at both state and federal levels. We monitor legislative and regulatory developments, advise on policy implications, and represent clients in discussions with policymakers.

Our team of seasoned attorneys and advisors brings a wealth of experience in health care law and regulatory matters. We are committed to providing tailored, practical solutions that address the specific needs of each client. By staying abreast of regulatory changes and industry trends, we ensure that our clients are well-positioned to navigate the complexities of the health care environment.