HOOPER LUNDY BOOKMAN

Compliance

Given the disruptive and costly fallout from government investigations and enforcement actions, the challenges and complexities of regulatory compliance are often top of mind for health care providers. These concerns make the development and maintenance of effective compliance programs imperative. With an exclusive focus on the health care industry and a multidisciplinary roster of attorneys who know the legal, operational, and practical nuances of compliance, Hooper, Lundy & Bookman provides proactive and responsive counsel that helps mitigate risk and counter threats.

Comprehensive Compliance Capabilities

At HLB, we recognize that every aspect of patient care, governance, billing, reimbursement, operations, or transactions in the health care industry has a regulatory compliance component. Navigating these compliance requirements can be a complex endeavor, given that in many cases, multiple federal and state laws and regulations apply and can be enforced by multiple authorities. Evolving areas of health care can involve unsettled and novel issues that also evolve in real-time, and enforcement approaches and priorities can rapidly shift with the political winds. In this sense, health care "compliance" involves scores of separate legal disciplines that require deep and specialized knowledge, experience, and insights.

Hooper, Lundy & Bookman has proven leadership and a wealth of experience in the broad range of compliance issues that our clients face, including hospitals and hospital systems, physicians and physician groups, long-term care providers, skilled nursing facilities, hospices, behavioral health providers, clinically integrated networks, suppliers, pharmacies, academic medical centers, drug and medical device companies, and health care technology companies.

We understand how the law intersects with the practical realities of how our clients function. This leads to pragmatic, functional compliance strategies as well as effective approaches to government investigations, audits, and enforcement actions. We work closely with clients on their development and implementation of proactive compliance efforts, drafting policies and procedures, assessing the effectiveness of a program based on OIG guidance, and providing compliance training sessions for providers and staff. If a potential compliance issue arises, we can assist with assessing the exposure or conducting an internal investigation. Our compliance counseling is tailored to each client's needs, whether it is helping a small start-up develop an initial compliance program or acting as an outside resource to a large health system's compliance department.

Industry-Leading Counsel

Our attorneys include some of the nation's most impactful and respected practitioners on compliance matters. HLB lawyers have written definitive compliance treatises and texts, including the American Health Lawyers Association treatise on Stark Law, the comprehensive <u>Hospital Compliance Manual</u> produced by the California Hospital Association, and BNA treatises on third-party reimbursement issues, among other publications.

HLB's interactions with regulators, investigators, and prosecutors are led by attorneys who formerly held positions in the U.S. Department of Justice, the Centers for Medicare & Medicaid Services, the California Attorney General's Office, and state Medicaid agencies. We have fostered positive working relationships with authorities across the regulatory landscape who know and respect our attorneys for their knowledge, advocacy, and integrity. Our lawyers know how regulators think, what investigators look for, and why prosecutors pursue cases. This lays the foundation for both favorable negotiated resolutions and effective defense strategies.

HLB has defended health care facilities, organizations, and individuals across the country in many landmark fraud and abuse cases and has been instrumental in many precedent-setting decisions favorable to the health care industry.

A Full Suite of Compliance Representation

HLB's health care compliance capabilities extend to every regulatory touchpoint, concern, need, and issue, including:

- Accreditation
- Antitrust
- Anti-kickback counseling and defense
- Billing and coding
- Corporate integrity agreement negotiations
- Compliance program preparation, development, and implementation
- Corporate compliance/governance
- Corporate practice of medicine
- Cost reporting
- Criminal and civil investigations and prosecutions
- False Claims Act defense
- FTC Regulations and Red Flag Rules
- Federal and state fraud and abuse allegations
- Hospital operations
- Internal investigations and audits
- Licensing
- Medical staff
- Medicare and Medicaid coverage and reimbursement
- Non-profit and tax-exempt entity compliance
- Physician dispensing of drugs
- Pharmacy regulation
- Privacy and security (HIPAA, CA privacy and security law, CAN-SPAM Act, COPPA)
- Risk contracting, business of insurance, and IPA/ACO/MCO license issues
- Sarbanes-Oxley
- Scope of practice
- Securities law, state and federal
- Self-referral analysis
- Self-reporting strategies
- Stark and PORA compliance
- Trade secrets
- Voluntary disclosures to governmental agencies
- Whistleblower claims
- Workplace discrimination