

# HEALTH LAW & LIFE SCIENCES

Health care is undergoing dramatic transformations and facing unprecedented challenges as competition increases to deliver quality, cost-efficient health care to a growing and aging population. Providers and health related businesses need to create and implement solutions that meet the demands of advancing technology, complex regulations, higher penalties for noncompliance and increased government enforcement efforts.

Our attorneys understand these challenges and offer a wealth of legal and business experience insight into the regulatory and business environment in which our health care clients operate. One of our group members is the former general counsel to the Florida Department of Health. Another holds a master's degree in public health, worked in the pharmaceutical industry and provided business operations counsel to a private medical practice. They collaborate with colleagues across our other practice areas, such as corporate, government and administrative law, labor and employment, tax, insurance, intellectual property, and others, to offer clients a comprehensive approach to their matters.

Several of our attorneys hold the highest ratings from Martindale-Hubbell, are Florida Bar Board Certified in Health Law and have been honored by *Chambers USA* as leading health care lawyers, *Best Lawyers in America*® in health law, and *Florida Super Lawyers*. They have held leadership positions in professional organizations, including the American Health Lawyers Association, its Health Law Certification and Executive Council Committees, and the Health Law Section of the Florida Bar and American Bar Association. They also frequently speak and write on the latest legal issues in the industry, including changes to hospital client compliance, the regulatory impact on providers of new laws, and other topics.

## Experience

With this insight and experience, our attorneys offer business and legal counsel to the following health care clients:

- Adult living facilities;
- Home health agencies;
- Hospitals and multi-hospital systems;
- Medical device companies;
- Medical equipment suppliers;
- Nursing homes and facilities;
- Surgery centers;

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- Pharmaceutical companies and pharmacies;
- Physicians and physician groups;
- Physical therapy and rehabilitation centers; and,
- Other health care providers and suppliers.

Our team has been retained to handle Medicare audits, licensure issues, disciplinary actions, insurance, peer reviews, and other matters before the following agencies:

- Agency for Health Care Administration;
- Department of Business and Professional Regulation;
- Florida Department of Health;
- Department of Insurance;
- Intervention Project for Nurses; and,
- Professionals Resource Network.

Our attorneys also deliver counsel on corporate, regulatory, compliance, tax, labor and employment and insurance matters, including:

- Corporate development, from formation through exit strategies, including mergers, acquisitions, divestiture, management of internal structure and growth, and capital formation
- Regulatory and legislative activity relating to health care entities
- Fraud and abuse, Stark Law and anti-kickback compliance, HIPAA and HITECH compliance, and regulatory compliance
- Strategic tax planning advice and expertise particularly in controversial areas
- Credentialing, contracting, peer review, bylaws, PHOs, medical staff privileges and discipline
- Labor contract negotiations and arbitration, and strategy in employee relations, including EEOC, Title VII, OSHA, ADA, unemployment compensation, and wage and hour matters
- Insurance claims work, antitrust and medical staff disputes
- Patient care issues, including risk management, and claims defense, policies for treating patients with AIDS and other diseases, and conditions requiring sensitive and unique care and treatment

### Fraud and Abuse

Our attorneys counsel clients on issues that involve state and federal fraud and abuse matters and self-referral prohibitions and restrictions. They help clients plan and structure transactions so they are transparent, which minimizes unwanted governmental scrutiny. They handle complex issues stemming from such situations as hospital-physician joint marketing agreements, upcoding, global

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billing, fraud, and billing for services provided by physician assistants and nurse practitioners.

Our attorneys have developed working relationships with the Federal Bureau of Investigation, Department of Justice, Office of the Inspector General, and other state and federal agencies. We draft and help implement corporate compliance policies and programs, and we counsel health care providers to assess and react to alleged violations of federal and state law.

Our team also reviews and analyzes contracts, joint ventures, and other agreements. They show clients how to properly document services to avoid billing issues with state and federal health care payors, and conduct internal investigations and employee compliance training. In addition, our attorneys help clients restructure non-compliant relationships to avoid potential civil and criminal penalties.

### Health Care Entity Operations

Our team can guide health care providers through the myriad of legal issues which arise from day-to-day operations. With experience in licensure, clinical trials and human research, peer review, internal and external audits, compliance planning and training, HIPAA, patient consent, medical records, general contracting and other areas, our attorneys work to become valued members of your team.

Our attorneys help clients handle medical staff and governance issues and advise clients on executive employee compensation and its tax implications. They perform internal and outside audits and counsel on general contracting matters. They develop programs for clinical trials to protect human research subjects. They also advise clients on licensure, state and federal regulatory compliance and end of life issues. They also serve as outside general counsel to in-house counsel.

### Life Sciences

Our attorneys are proud to help our clients who are working on cutting-edge technology leading to medical advancements, product development and medical research and discovery. They serve pharmaceutical and medical device companies, hospitals, physicians, physician groups, and health systems that participate in all types of clinical research. By offering a thorough review of their policies and procedures, our attorneys ensure clients comply with regulations and protect their interests so they can concentrate on developing medical innovations. We negotiate and draft agreements involving confidential disclosure, clinical trials and budgets, strategic alliances and joint ventures, contract research organizations, sponsored research, research consortia, and material transfers.

We counsel clients on subjects such as the following:

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- Medicare reimbursement for clinical trials
- Fraud and abuse issues in research programs
- Research issues and tax-exempt status
- Protection of human and animal subjects in research
- HIPAA privacy and research
- FDA regulation and compliance

When it comes to protecting intellectual property, our attorneys prepare and prosecute patent and trademark applications; license patents, trademarks and technology; analyze trademarks and copyright infringements; and conduct intellectual property audits and due diligence reviews.

### HIPAA

With a wide range of experience in HIPAA, our attorneys can help clients with compliance and operational concerns. They write policies, forms, and communications for virtually all health care entities. They educate and counsel governing boards, management, and medical staffs of hospitals, multi-state health care providers, long-term care facilities, and physician practices on HIPAA requirements. Additionally, they advise and defend our clients in the broader areas of health information management and patient confidentiality, and work regularly with clients who are implementing electronic health record systems.

### Management Services Organizations (MSOs)

Our team also has experience in representing Management Services Organizations (MSOs) within the healthcare industry. We advise MSOs on a wide array of issues, including regulatory compliance, business operations, and strategic growth initiatives. We pride ourselves on delivering comprehensive legal services that address the unique needs of MSOs. Our team is skilled in negotiating contracts that protect our clients' interests and mitigate potential risks. In the event of disputes, we provide effective resolution strategies to safeguard our clients' business objectives.

By leveraging our experience and understanding of the health care sector, we empower MSOs to thrive in a competitive and regulated environment. Our dedication to client success is reflected in the long-standing relationships we maintain with our MSO clients.

### Regulatory Compliance

Navigating the intricate landscape of health care regulations is a cornerstone of our practice. Our attorneys are adept at guiding MSOs through the complexities of both state and federal laws to assist them in remaining compliant with applicable regulations. We provide tailored advice on structuring management agreements that align with legal requirements and industry standards.

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### **Business Operations and Strategic Growth**

Our firm supports MSOs in optimizing their healthcare clients' operations as well as pursuing strategic growth. Our attorneys work closely with MSOs to develop strategies that enhance operational efficiency and expansion, giving providers the peace of mind to focus on their patients' care.

### **Professionals**

Rikki Lober Bagatell

Steven K. Barber

Joseph M. Goldstein

Timothy E. Monaghan

Jennifer J. Perez

Michael E. Siegel

Jamie B. Wasserman

### **Related Industries**

Health Care