

HEALTH CARE

ATTORNEY ADVERTISING

Ballard Spahr

HEALTH CARE

Ballard Spahr represents clients across the industry, from hospitals and long-term care facilities to insurance companies and pharmaceutical manufacturers. We advise on regulatory, compliance, transactional, financing, labor and benefits issues, as well as litigation matters.

OUR CLIENTS:

- Hospitals
- Medical schools
- Physician and dental practices/ surgery centers
- Nonprofit organizations
- Self-funded and administered medical plans
- Third-party payers
- · Health care coalitions
- · Hospice and home care providers
- Post-acute and long-term care providers, including senior and assisted living facilities
- Health plans
- Investors in health care, including private equity funds

INTELLECTUAL PROPERTY

Ballard Spahr is home to a tier-one, nationally ranked Intellectual Property team. We work with universities, hospitals, and biotech companies in the development, protection, and marketing of all forms of intellectual property. Ballard Spahr has more than 60 intellectual property attorneys and professionals, including more than 20 registered patent practitioners with extensive legal experience and deep technical knowledge in fields from chemistry to bioinformatics.

We draft and negotiate agreements covering patented technology, trademarks, copyrights, and trade secrets. We help development-stage businesses in license technology from university technology commercialization offices, founders, developers, and strategic partners. Our IP litigators try complex, high-stakes cases involving cutting-edge technologies in jurisdictions nationwide and before the Patent and Trademark Trial and Appeal Boards.

HEALTH LAW REGULATORY AND TRANSACTIONAL

Our health care lawyers have closed M&A, joint venture, licensing, and other transactions in virtually every segment of the health care market and across the country. Our hallmark has been to find solutions for our clients that facilitate their business and clinical objectives without engendering legal and regulatory exposure.

We advise on issues related to federal and state health care laws and regulations, including the CARES Act, Paycheck Protection Program (PPP), ACA, Medicare and Medicaid false claims, Stark and anti-kickback prohibitions, HIPAA/HITECH, antitrust, value-based purchasing, and other reform initiatives.

Our work includes advising on requirements, compliance, conditions of participation, reimbursements, licensure, accreditation, and counseling related to government stimulus programs.

FINANCING

Our public finance attorneys have participated in billions of dollars of tax-exempt financings in all 50 states and three territories. We have served as bond counsel, health system counsel, and underwriter's counsel to many of the nation's leading health care systems. We also handle financings for community hospitals, specialty hospitals, medical schools, and academic medical centers and their affiliates.

Our finance team has helped health care clients secure funding to build, expand their facilities, and purchase goods and equipment. We also advise on the restructuring of financing and supply chain arrangements and help clients manage issues related to the CARES Act and loan forgiveness.

GOVERNMENT ENFORCEMENT, INTERNAL INVESTIGATIONS, AND LITIGATION

We handle internal and government investigations, civil and administrative litigation, and the defense of criminal matters. We also advise on litigation avoidance through the development and implementation of internal compliance and ethics standards. Our attorneys represent clients facing actual or threatened enforcement.

We represent clients during all stages of health care fraud proceedings, from responding to government inquiries, subpoenas, and investigations through trial, if necessary. We have been involved in significant health care antitrust litigation and other health care litigation, including class actions.

LABOR AND EMPLOYMENT

We serve as labor counsel for health care organizations with organized labor campaigns and collective bargaining negotiations involving nurses, residents, and other staff, ERISA litigation, and the day-to-day employment and medical staff issues that arise in the health care industry. Our attorneys conduct on-site training programs for managers on labor and employment law topics.

EMPLOYEE BENEFITS AND EXECUTIVE COMPENSATION

Our practice—one of the largest in the country—advises employers on matters involving qualified and non-qualified retirement plans, health and welfare benefit programs, and a wide variety of executive compensation arrangements.

We have a particular focus on employers in the health care industry. Our attorneys have significant prior work experience with the IRS, U.S. Department of Labor, and Pension Benefit Guaranty Corporation. We advise on statewide unemployment compensation requirements, as well as matters related to the PPP and other CARES Act provisions.



LIFE SCIENCES

In addition to representing health care providers, our practice serves entities engaged in the development and application of new life science technologies. Our clients include public and private biotechnology and pharmaceutical companies as well as many venture capital organizations investing in the life sciences. We typically advise and represent clients on:

- Formation, financing, and structuring of corporations and other entities
- Licensing, distribution, and marketing agreements
- Joint ventures
- Strategic alliances
- Sponsored research and collaboration agreements
- Intellectual property protection
- Regulatory compliance
- Technology transfer

TELEMEDICINE, REMOTE CARE, AND DIGITAL SOLUTIONS

Our attorneys help entrepreneurs develop and bring products to market, guide health care providers and businesses in implementation, and assist in the formation of partnerships that will bring about new levels of patient care. We advise on:

- Corporate formation, operation, and governance
- Fraud and abuse
- Coverage, payments, and coronavirus-related reimbursements
- · Licensure, credentialing, and privilege
- Online prescribing of medicines and lab tests
- Intellectual property issues
- Malpractice, professional liability, and insurance issues
- Reimbursement and other regulatory issues
- Data security and privacy

REAL ESTATE

We have represented numerous universities and teaching hospitals through all stages of development and expansion. We draft and negotiate construction contracts, obtain zoning and land use approvals and permitting, and handle eminent domain matters. Our national real estate team handles financing, leasing, and construction matters and, together with our health care attorneys, addresses issues such as certificates of need, licensure, and reimbursement.

ENVIRONMENTAL ISSUES AND MEDICAL WASTE MANAGEMENT

We counsel on all medical and non-medical waste management issues, including regulatory compliance and enforcement actions. We assist in the siting of both captive and commercial medical waste incinerators and other waste processing facilities, and advise on the management of low-level radioactive waste.

In the compliance area, we are experienced with underground tank, asbestos, hazardous materials management, PCBs, and off-site waste disposal issues.

BANKRUPTCY, CREDITORS' RIGHTS, AND RESTRUCTURING

We represent creditors and debtors with asset recoveries and financial restructuring issues. Our attorneys advise on the transfer of licenses, certification for Medicare and Medicaid preparation, changes in management, foreclosures, and the purchase of bankrupt health care facilities. We have handled major hospital bankruptcies and asset sales and regularly advise on workouts, financings, and defaults involving Continuing Care Retirement Centers.

TAX

We are experienced in international, federal, state, and local tax matters and advise tax-exempt hospitals and health care institutions on tax-exempt bonds, joint ventures with for-profit entities, Form 990 reporting requirements, unrelated business income tax reporting, real estate tax exemption, employment taxes, and mergers and acquisitions. We practice before the IRS and in the courts.

We have been engaged by health care clients to advise on matters related to PPP terms and loan forgiveness, CARES Act tax issues, paid leave tax credits, and matters involving state tax relief.

PRIVACY AND DATA SECURITY

Our Privacy and Data Security team advises on information technology contracting, contracting with electronic medical record vendors, health information exchanges, and other health information technology (HITECH) projects and ventures.

Our HIPAA/HITECH team represents health care providers, health plans, and business associates in implementing HIPAA/HITECH compliance programs, undertaking data security assessments, preparing breach response plans, conducting breach assessments and notifications, and advising on the use of data for research, marketing, and other purposes.

SENIOR LIVING AND LONG-TERM CARE

Ballard Spahr is nationally recognized for its work representing senior housing and long-term care clients in regulatory, compliance, licensing, transactional, risk management, employment, privacy and security, legislative support and advocacy, and litigation matters. We have one of the few dedicated Senior Living and Long-Term Care practices in the country—offering a full suite of services to owners, operators, managers, developers, and investors in the senior living and long-term care industry.

HEALTH CARE REPRESENTATIVE EXPERIENCE

- Chart review and in-home assessment program compliance and related enforcement issues at national Medicare Advantage Organizations (MAOs)
- Representation of a high level executive in the long term care industry accused of health care fraud, resulting in full acquittal after a five-week trial
- Representation of specialty pharmacies against accusations of fraud involving prior authorizations
- Medicare risk adjustment (MRA) coding data integrity and submission practices
- RADV audits by the Centers for Medicare and Medicaid Services (CMS) and the Department of Health and Human Services Office of Inspector General (HHS-OIG)
- Medicare Advantage bid strategy in light of government audit and enforcement initiatives
- Medicare Advantage and Commercial Insurance
 Medical Loss Ratio compliance issues
- Theft of trade secrets by employees and joint venture partners at MAO-owned entities
- Regulatory comment on proposed rules (including the recent RADV rule) and related management of actuarial and statistical experts
- Physician incentive plans in compliance with updates to federal Stark and Anti-Kickback laws (and state law equivalents)
- Provider and device manufacturer arrangements implicating various federal Anti-Kickback safe harbors
- Academic affiliations between universities' schools of medicine and medical centers. Specific issues included the Stark Law exception related to academic health centers
- Various joint venture arrangements between large specialty physician practice groups, hospitals, and other physician practice groups. Regulatory advice included issues relating to outpatient provider-based status, Stark, and Anti-Kickback matters

- Establishment and expansion of multistate telehealth platforms for primary care, specialty care, urgent, and behavioral health
- Acquisitions, affiliations, and compensation arrangements related to provider groups and facilities (including assistance with related government approval processes)
- Concierge medical service contracting with private employers to provide concierge primary care services and onsite clinics for employees
- Various provider administrative and management services agreements, including for purposes of legal compliance and obtaining additional investment
- Provider agreements and related compliance infrastructure for purposes of compliant participation (including appropriate billing practices) in evolving accountable care organizations, other collaborative care models, and capitated Medicare and Medicaid arrangements
- Arrangements for clinical rotations for graduate and undergraduate medical education (and related physician supervision)
- Agreements for compliant referrals and sharing of health information



CONTACTS

For more information, please visit us at www.ballardspahr.com/ healthcare or contact:

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