

Academic Medical Centers

Our interdisciplinary Academic Medical Centers (AMC) team is committed to helping you navigate the most complicated health care delivery issues in the nation, complex organizational structures and your wide-ranging mission-critical activities of education, research and clinical care. Our AMC clients often face the most difficult and complicated patient care issues in our health system. Polsinelli attorneys know that the components of an academic medical center must collaborate to carry out their special missions of education, research and clinical service.

Polsinelli understands our clients' business and the operational implications of our legal advice. We leverage a national health care team of more than 200 lawyers to assist clients to stay ahead of potential issues, avoid regulatory problems, drive innovation and support execution of strategy.

Research & Discovery

- Clinical research
- Federally funded grants/contracts
- Commercially funded research
- Intellectual property
- Scientific misconduct
- Life sciences
- Animal research

Health Care Delivery

- Health care operations in all care settings
- Experience in critical health care operational issues
- GPO and supply chain, CLIA laboratories, specialty pharmacies and 340B, behavioral health, health information technology/electronic medical records; licensure and certification
- Facilities
- Unique health care regulatory frameworks
- Financial reimbursement including emerging models
- Risk management and professional liability matters
- Patient relations

Not-for-Profit Governance & Finance

- Tax-exempt issues
- Financing mechanisms
- Investments/endowments
- Board governance
- Relationships with universities

- Bankruptcy

Workforce

- Labor
- Employment relationships
- Educational programs for non-physician health care professionals
- Immigration/Visas
- Diversity and inclusion
- Employee benefits and executive compensation
- Pension plans
- OSHA
- Medical staff
- Credentialing

Lobbying & Congressional Affairs

- Advocacy at state and federal level
- Congressional affairs

Regulatory & Compliance

- Fraud and abuse compliance
- Facility and professional reimbursement compliance
- Compliance program development
- Privacy and security
- Antitrust
- EMTALA
- Export controls
- White collar criminal defense
- False Claims Act
- Regulatory audit defense

Unique Academic Issues

- Accreditation standards
- Faculty practice plans
- Residency issues
- Relationship with university
- Mission support and funds flow between components of AMCs
- Student health care centers
- FERPA

Innovative Transactions

- Strategic affiliations
- Clinical alignments
- Mergers and acquisitions
- Joint ventures
- Health system and practice plan structures
- Clinically integrated networks
- Other strategic transactions

Strategic, Contracting & Operational Support

- In-network v. out-of-network strategies

- Patient billing strategies and processes
- Payor contract strategies and legal review, including value-based arrangements
- Payor engagement audits/processes
- In-house data analytics
- Legislative strategy and implementation
- Deal support/managed care due diligence

Payor Disputes

- Out-of-network underpayments and misclassified emergency claims
- COVID-19 reimbursement
- Challenges to new payor medical/billing policies and protocols
- “Surprise Billing” arbitrations
- Payor audits, recoupments, and offsets
- General denials/other in-network disputes
- Class actions

Matters

Research and Discovery

- Advised on human subject protection, including informed consent, protocol review, data repositories and DUAs.
- Served on institutional review board.
- Advised on development of conflict of interest policies and investigations.
- Represented institution in scientific misconduct, FDA audits and CLIA audits.
- Advised on Medicare clinical trial national coverage decision and provided defense before OIG and DOJ.
- Advised on intellectual property, patents, technology transfers and commercialization strategies.
- Faculty effort reporting requirements for federal grant compliance.
- Advised on university human subject protection plan, navigating the scope of the promise to pay, Medicare secondary payer rules, and federally funded research requirements.
- Negotiated research sponsor, clinical trial site agreements and agreements for Phase III COVID-19 studies.
- Advised on tissue bank acquisition and creation of multi-AMC research networks.
- Designed and hosted a digital platform with online portal to facilitate innovation and commercialization efforts of office of technology development.
- Developed improved standards for handling patent searches, patent applications, licenses and other agreements.
- Coordinated handling of invention disclosures including assessment to identify potentially innovative features and advise on strategy for commercialization.
- Managed extensive patent portfolio including preparing patent applications directed to life science, mechanical, electrical and computer software arts such as chemical compounds, COVID-19 treatments, tumor characterization and imaging, radioprotective agents, radiation shields, shunts, assay plate design, microscopes, imaging systems, forceps, therapeutics, cancer diagnosis and treatment and treatments for Parkinson’s disease, autoimmune disorders and drug addiction.

Health Care Delivery

- Leveraging largest health care legal department in nation to meet full scope of AMC health care delivery needs and patient relation activities.
- Served as sole outside general counsel in creative fixed fee arrangement.

- Provided 340B audit readiness; regulatory advice to successfully provide access to 340B pricing and defend against refund requests.
- Creation of specialty pharmacy programs and group purchasing organizations.
- Significant representation of NCI-designated cancer centers to obtain and maintain NCI status; creation of cancer treatment telemedicine platforms.
- Coordinating risk and claims management among various pools of internal AMC components and categories of workforce.
- Responded to CMS' statements of deficiencies.
- Advised on supply chain contracts including tracking obligations for medical device credits.
- Advised on requirements for obtaining and maintaining CMS approval of adult heart transplant operation.

Not-for-Profit Governance and Finance

- Advised university boards on comprehensive governance and oversight objectives and instituted major governance reforms.
- Created integrated governance and management structures among components of an AMC.
- Structured research consortium of nonprofits and governmental organizations utilizing a supporting organization structure and a for-profit technology transfer subsidiary; obtained a favorable private letter ruling to support structure.
- Regularly advise on unrelated business income consequences of clinical research; establish protocols for documenting file to obtain favorable IRS rulings.
- Negotiated with CMS on multiple intergovernmental transfers (IGTs) issues.

Workforce

- Routinely provide employment and labor advice, conducting investigations, bargaining discussions, and litigation services; OSHA and employee safety; staff compensation and benefits; and visa and immigration matters.
- Advised on medical staff matters in academic environments, including faculty code matters, privileging and credentialing, peer review and national practitioner data bank reporting.
- Represented institutions in lawsuits by tenured faculty members, including procedural and substantive due process issues, defamation, and discrimination.
- Negotiated professional services and medical director agreements; non-solicitation and non-compete arrangements.
- Developed physician recruitment arrangements, balancing teaching, research and education.

Lobbying and Congressional Affairs

- Assist clients to obtain approval for new medications and medical devices for federal reimbursement.
- Guiding or reshaping federal regulations.

Regulatory and Compliance

- Assuring regulatory compliance with off-label use of drugs and devices, antitrust, Stark law, anti-kickback statute, and state and federal fraud and abuse laws.
- Advised on GDPR compliance, cyber security, HIPAA Privacy and security advice, response to investigations and litigation in government enforcement actions. Represented whether Medicare billing requirements for overlapping surgeries were met, and whether residents and fellows were adequately supervised when performing or assisting with cardiothoracic surgeries.
- Coordinated the investigation of and led community notification and patient response process for major privacy breach.

Unique Academic Issues

- Advised on physician compensation design, incentives, and benchmarking faculty physicians, including fee-for-service and valued-based reimbursement.
- Negotiating complex funds flow arrangements between components of AMCs, including obtaining successful OIG Advisory Opinion of benefit to all AMCs.
- Creation of new faculty practice plans and integration of community physicians.
- Negotiated accreditation of affiliated non-ACGME training programs.
- Negotiation of health sciences student and resident rotation agreements.
- Negotiating of complex GME structures, including hospital funding of residents and other GME costs, accreditation matters, and new program issues.
- Negotiation of affiliation agreements between and among school of medicines, teaching hospitals and universities.

Innovative Transactions

- Developed strategies for initiating a "Hospital Without Walls" program.
- Represented AMCs entering clinically integrated networks as equity owners.
- Developed strategies for launching a nationwide "Second Opinion" program.
- Negotiated numerous material transfer agreements, collaborative research agreements, sponsored research agreements, inter-institutional agreements and licenses.
- Advised on various asset acquisition, member substitution, joint ventures and ownership strategies, including in oncology, radiology, cardiology, primary care and whole hospitals.
- Represented a client to form an innovative nonprofit/for-profit joint venture to own and operate hospitals and health systems.
- Advised on valuation issues associated with use of brand for equity ownership.
- Creating coordinated service line co-management arrangements, managing and responding to the competing concerns between hospital executives, physician leaders and academic department chairs.
- Negotiated \$100M+ technology contract between and AMC and one of the world's largest software companies.
- Represented new AMC, including consolidation of 18 independent practice groups into one multi-specialty faculty practice plan.