

Health Care Regulatory and Compliance

Understanding Complex Health Care Regulations

The health care industry is highly regulated and as a result, hospitals and other health care companies cannot freely enter into contracts and arrangements like businesses in some other industries. In order to advise health care facilities and businesses on day-to-day issues, contracts and joint ventures, it is imperative for health care attorneys to have an in-depth understanding of applicable federal and state laws and regulations.

Our attorneys are intimately familiar with the federal and state regulations applicable to hospitals, long-term care facilities and other health care companies. For example, we frequently advise our hospital clients about certificate of need and licensure regulations, and other federal and state laws and regulations that impact health care operations and reimbursement (e.g., prompt payment rules, Health Care Quality Act, Medicaid regulations, HMO regulations, CHAPA law, etc.).

Further, we advise health care clients on a daily basis regarding the federal Anti-kickback law and regulations, the federal Stark law and regulations, and IRS rules and regulations that restrict the activities of tax-exempt organizations. Almost every agreement, arrangement and transaction involving health care facilities, physicians and other third parties must be carefully structured so as to comply with the broad prohibitions set forth in these federal (and state) laws and regulations.

We keep abreast of court cases, advisory opinions and other rulings interpreting these regulations, we write periodic "health care law updates" and articles regarding new developments in this area, and we speak at seminars, both locally and nationally, about these issues.

For several of our clients, we have conducted "Stark audits" to assess the compliance of their various arrangements with physicians and physician affiliates, including (without limitation), medical director agreements, lease arrangements, services agreements and any other arrangement pursuant to which hospitals and physicians provide one another with payment, services, space, staff, items or anything else of value. Potentially problematic arrangements include those which are not reflected in writing, have expired, are not (or no longer) "fair market value," or for which the level of services has changed but compensation remains the same. We work with our clients on options for remedying arrangements that arguably may be noncompliant, and practical recommendations to avoid future noncompliance.

We also have audited the "effectiveness" of several of our client's corporate compliance programs, and provided detailed reports containing recommendations to improve such programs. The OIG expects that hospitals audit the effectiveness of their compliance programs on a regular basis. Enhancements to compliance programs also have the benefit of preventing future regulatory violations.

Sills Cummis & Gross P.C.

Regulatory Agencies

The Sills Cummis & Gross Health Care Practice Group attorneys are frequently called upon to provide legal advice about the rules and regulations of various regulatory agencies. Over the years, we have helped our clients navigate through the demands of the regulatory agencies that affect both the national and local health care industry. We have worked with the following agencies:

- The Centers for Medicare and Medicaid Services (“CMS”), regarding conditions of participation, federal survey issues, reimbursement and billing issues, EMTALA issues, the federal Stark law, and various other matters. We frequently consult with CMS officials about these issues.
- The Office of Inspector General (“OIG”), regarding the federal Fraud and Abuse law, safe harbor regulations, and advisory opinions. We have regular contact with OIG officials, including lawyers in the OIG’s Office of Legal Counsel.
- The New Jersey Department of Health and Senior Services (all divisions) (“DHSS”), regarding certificate of need matters, licensure issues and state surveys. We frequently speak and meet with DHSS officials regarding regulatory issues on behalf of our hospital clients.
- The New Jersey Department of Human Services, Division of Mental Health Services (“DMHS”), regarding requirements in connection with the treatment of psychiatric patients.
- The New Jersey Department of Human Services, Division of Medical Assistance and Health Services (“DMAHS”), regarding issues under the state Medicaid program.
- The Joint Commission regarding compliance with relevant accreditation standards.
- The New Jersey Department of Banking and Insurance (“DOBI”), regarding HMO/managed care issues and insurance fraud issues (e.g., the Insurance Fraud Prevention Act).
- The New Jersey Attorney General (“AG”) regarding approvals under CHAPA, letters confirming the inapplicability of CHAPA and no-action letters under the AG’s common law jurisdiction over the disposition of charitable assets.

Further, we have submitted comments on behalf of our health care clients in response to proposed federal and state regulations, which comments were adopted by the agencies and benefitted our clients. In one case, our comments were adopted and resulted in a savings of over \$3.5 million per year for our client.

Strong Relationships with State and Federal Officials

In addition to having working relationships with many senior officials in the agencies described above, our many years both in the state and this industry have enabled us to establish and maintain close relationships with not only top officials in the Governor’s office, but also with many state and federal legislators.

Regulatory Appeals and Litigation

Our health care lawyers have represented hospitals and other health care facilities in connection with various regulatory appeals and litigation involving health care regulatory agencies.

Representative Matters

- The representation of several hospitals and nursing homes in administrative hearings and appeals challenging civil monetary penalties and other remedies imposed in connection with negative survey findings.
- The representation of several health care clients in the administrative appeal of Medicare reimbursement determinations, many of which were successful or resulted in favorable settlements.
- The defense of various health care providers in both civil and criminal Medicare and Medicaid fraud trials and proceedings.
- The representation of hospitals in administrative litigation regarding certificate of need and related regulatory issues.