OUR PRACTICE

Compliance Counseling

For health care providers large and small, ensuring compliance with federal regulations has become a critical task. Using sophisticated analytical and predictive tools such as data mining, the Centers for Medicare and Medicaid Services (CMS) and private auditors search vast amounts of information to identify irregular billing patterns and suspicious activity. The goal is to uncover fraud and abuse, but many become caught in the web of suspicion. No one is safe from scrutiny. Errors – even inadvertent errors – are likely to cost money.

At the same time, the U.S. Department of Health & Human Services Office of Inspector General (OIG) has increased pressure on health care providers to reveal overbillings and other mistakes that might constitute fraud. In April 2013, the OIG released a new Provider Self-Disclosure Protocol outlining procedures "to voluntarily identify, disclose, and resolve instances of potential fraud" involving federal health care programs such as Medicare and Medicaid. In addition, federal law requires providers to report and repay Medicare and Medicaid overpayments within the later of 60 days of the date an overpayment is identified or the date any corresponding cost report is due, and providers are penalized if they don't make a timely disclosure.

No health care provider can afford *not* to have an effective compliance program.

What distinguishes Baker Donelson's Health Law Department and Health Care Regulatory Task Force is our deep knowledge both of health care law and our clients' businesses – whether that client is a large hospital or a small physicians' group, a chain of urgent care clinics or a university academic center.

With many clients, our attorneys work closely with compliance officers on diverse matters such as the investigation of complaints received through the compliance communications process; internal reviews of billing and coding questions; and compliance with corporate integrity agreements, including the preparation of annual reports. When self-disclosure is necessary, we facilitate the repayment of federal and state funds (including discussions with federal intermediaries, carriers and, where appropriate, U.S. Attorneys and State Attorneys General).

With others, Baker Donelson helps assess and strengthen compliance programs from top to bottom: advising officers and directors on corporate responsibility and compliance; conducting annual compliance reviews and updating compliance documents; and directing base-line and periodic compliance audits, as well as charge master audits.

With clients who are contemplating or engaged in an acquisition, joint venture or other transaction, we serve as an integral part of the business transaction team to assure compliance with federal and state laws *before* the transaction takes place.

Non-compliance is expensive – even with self-disclosure, the OIG's general practice is to require, at a minimum, penalties of 1.5 times the amount of claims at issue. Comprehensive Error Rate Testing (CERT) and Recovery Audit Contractor (RAC) audits can be even more costly. Helping clients develop and implement what the OIG calls a "robust and effective compliance program" can be one of the most critical and cost-effective services Baker Donelson provides.

Representative Matters

- Implemented Corporate Compliance and Ethics Plans and HIPAA Compliance Plans for health care organizations including hospitals, nursing home chains, hospice providers, physician practices, DME suppliers, and pharmaceutical manufacturers.
- Conducted audits and due diligence reviews for a broad array of clients with regard to compliance with Medicare standards, HIPAA, fraud and abuse, and 340B Drug Pricing Program compliance.
- Advised suppliers on fraud and abuse anti-kickback statute and physician self referral (STARK) law compliance.
- Drafted PCI Compliance programs for merchants.
- Conducted risk assessments of major health systems to develop work plans to address and reduce legal liabilities associated with data security.
- Counseled numerous providers through drug theft and diversion and corresponding reporting and risk management issues.
- Served as regulatory counsel in numerous fraud and abuse internal and governmental investigations.
- Authored fraud and abuse compliance plans/programs, codes of conduct and employee manuals for various types of health care entities; served as regulatory counsel to clients and the litigation teams in fraud and abuse government investigations.
- Analyzed and structured numerous business, marketing and regulatory scenarios to assist hospitals (and other health care entities) and device/pharmaceutical manufacturers in complying with the fraud and abuse laws.
- Represented a Florida client subject to Medicaid fraud investigation. Presented detailed evidence demonstrating fundamental errors in case which was subsequently withdrawn.
- Represented a home health agency in a fraud exclusion before the Office of Inspector General.
- Conducted an internal audit of Stark Law compliance in physician hospital contracts for a major academic medical center.
- Gave compliance advice to providers on fraud and abuse anti-kickback statute and physician self referral (Stark) law compliance.
- Represented three hospitals and two medical practices regarding self-disclosure of Stark law violations under the Stark Self-Referral Disclosure Protocol.
- Defended a hospital in four-year parallel criminal and civil FCA/AKS investigation in which USAO for the Eastern District of Louisiana alleged kickbacks were made to a medical doctor resulting in millions in alleged damages. Criminal cases against the hospital and management were declined without action, and a successful $1.75 million civil settlement with no remedial measures was achieved. Non-client medical doctor was sentenced to seven and a half years.