

## COMPLIANCE COUNSEL

Health care providers of all types function in a high-risk regulatory environment. This includes, but is not limited to, hospitals, skilled nursing facilities, inpatient rehabilitation facilities, large multi-specialty physician groups, ambulatory surgery centers, laboratories, home health agencies and hospices, all of which have become common targets of governmental investigations as regulators and legislators continue to prioritize enforcement actions against perceived provider fraud and abuse. Whistleblowers also are incentivized to file cases as they seek to benefit personally from provider activity that may not fully conform to regulatory expectations. No provider is immune, no matter how effective its corporate responsibility program. For these reasons, all providers need experienced Compliance Counsel to assist them in trying to prevent regulatory violations, to determine the scope of and assist with correcting identified compliance issues and to defend them in the event they do become a target of government investigative activities.

The compliance team at Hall Render is composed of a large, diverse group of attorneys across all of our offices. These team members provide counsel on the full spectrum of regulatory compliance matters, from the initial regulatory assessment through the investigation defense and settlement process and beyond.

### **Government Investigations and Whistleblowers**

Despite best efforts with their own corporate responsibility efforts, some providers will still become the subject of a government inquiry. Every day, our compliance team works with providers on properly responding to governmental audits, civil investigative demands, subpoenas and other formal investigations. We are involved in defending providers in a number of national enforcement initiatives often involving whistleblowers, directed by the U.S. Department of Justice, Office of Inspector General, Federal Bureau of Investigation, State Attorney General Offices, Medicaid Fraud Control Units and other health care enforcement agencies. Past experience with both the type of issue under investigation and, in some cases, the same individuals coordinating the government investigation can be very helpful in developing the best defense approach to these cases. We believe that our vast experience in these investigations provides significant benefit to our clients.

### **Self-Disclosures and Voluntary Refunds**

## AREAS OF FOCUS

- Anti-Kickback Statute
- Compliance Audits
- Compliance Education & Training
- Compliance Plans
- Compliance Risk Assessment
- EMTALA
- Excluded Providers
- False Claims Act
- Fraud & Abuse Issues
- Government Investigations
- Licensure & Accreditation
- Stark Law
- Survey & Certification
- The Joint Commission (TJC)

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We routinely interact with compliance officers and general counsel regarding matters that have been reported through their compliance programs and advise them regarding how best to implement any necessary corrective action. Based on our extensive experience, we advise these providers on the most appropriate manner for self-disclosing or voluntarily refunding any past conduct that requires such an approach. We further coordinate with providers to gather necessary information, assist with calculating potential overpayments, prepare self-disclosure or refund materials for submission and represent the provider throughout the self-disclosure settlement process. The most important consideration is for providers to efficiently and effectively address the non-compliant activity to minimize future regulatory risk to the organization.

### **Internal Compliance Audits Under the Attorney-Client Privilege/Work Product Doctrine**

We regularly work through the attorney-client privilege and work product doctrine, as necessary, to internally investigate compliance issues with the provider. We have relationships with a wide range of external consultants that we may engage to perform medical necessity, coding and billing, fair market value or other technical reviews. These external reviews assist us in rendering advice to providers regarding appropriate corrective actions and the potential need to self-disclose prohibited conduct or refund identified overpayments and are often a key factor used in developing a defense strategy during a government investigation.

### **Corporate Integrity Agreements**

Our knowledge and experience extend beyond the end of a government investigation. Some providers may be required under the terms of a settlement to enter into a Corporate Integrity Agreement with the Office of Inspector General. These Corporate Integrity Agreements often impose significant compliance obligations on the provider, including but not limited to, establishing new compliance programs, providing annual compliance training to staff, performing annual reviews and reporting to the Office of Inspector General any further suspected compliance issues the provider discovers. Our team members can assist providers in meeting the full range of their compliance obligations under a Corporate Integrity Agreement. In certain circumstances, our attorneys have also served in the role of an Independent Review Organization to perform compliance reviews as necessary to meet the provider's Corporate Integrity Agreement obligations.

### **Compliance Program Development and Assessment**

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Our regulatory compliance practice would not be complete without team members who regularly assist our provider clients to improve their own internal compliance program practices. Maintaining effective compliance programs for providers in the health care industry has never been more important than it is now, and it is the best "preventative medicine" for keeping a government investigation from the provider's doorstep. Hall Render attorneys can conduct a formal compliance program assessment and make recommendations to ensure the provider has a fully comprehensive and active corporate compliance program, as well as develop a process to keep the current compliance policies up to date and support the provider in maintaining the program's effectiveness. We work directly with client compliance officers and general counsel to advise them on the latest legal and Office of Inspector General requirements and standards. Through our focused assistance, a provider's compliance program will operate more efficiently and effectively while meeting organizational needs.

### **Compliance Education and Other Proactive Compliance Initiatives**

To assist with ensuring compliant activities throughout an organization, our compliance team members are available to provide compliance training and education to not only an organization's compliance officer but to all other stakeholders, such as compliance committee members, physicians and medical staff professionals, managers and employees and Boards of Trustees/Directors. We also work with providers to perform proactive compliance risk assessments to help them identify problem areas before they escalate further.

### **General Compliance Counsel Services**

In addition to our specialized compliance services, our compliance team has extensive experience regarding particular compliance issues arising under the False Claims Act, Civil Monetary Penalties Law, Stark Law and Anti-Kickback Statute. On a day-to-day basis, we counsel providers on compliance questions that arise regarding particular coding and billing practices and relationships with physicians.

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Beyond the false claim and fraud and abuse inquiries, our compliance team also routinely handles a number of other regulatory compliance matters, including but not limited to, those involving EMTALA, licensure/certification, CLIA and Sarbanes-Oxley. Our experiences in these areas include not only providing general compliance advice but also assisting clients who receive negative survey findings or who are at risk of termination from participation in any federal health care programs. It is also important for our client base to maintain knowledge of these related regulatory issues in case compliance investigations expand into other areas. For example, even though the Sarbanes-Oxley Act directly applies only to publicly traded providers, it also provides some helpful guidance to our nonprofit clients as it shifted the playing field for corporate boards and officers, making them much more accountable for the organization's financial and accounting compliance. This attitude has been extended to the governance of many nonprofit providers as well, making their organizational compliance efforts more effective. Our compliance team attorneys have worked with publicly traded companies, as well as nonprofit hospitals, to perform independent board investigations and reviews to ensure compliance with all applicable requirements.

In short, our compliance practice is uniquely positioned to meet all of a provider's health care compliance needs, no matter how challenging.

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