

Lab Operations & Compliance

Focused on Clients | Driven by Data |
Measured on Outcomes

We assist some of the nation's largest laboratories in addressing a variety of operational and compliance concerns.

LAB SERVICES

We have helped our laboratory clients with:

- Investigations and reviews into billing for laboratory services under the Medicare and Medicaid programs
- Due diligence reviews related to potential transactions
- Financial performance improvement, including operational and revenue cycle reviews
- Corporate Integrity Agreements resulting from issues related to the settlement of allegations involving federal healthcare programs
- Commercialization of laboratory-developed tests
- Sales and marketing concerns involving, for example, the Anti-Kickback Statute and the Stark Law

Our Approach

While we have strong laboratory services and credentials, our client base spans the entire health care spectrum, including providers, payers, life sciences, and commercial/private-equity entities. Maintaining such a broad array of clients provides us with an in-depth understanding of the regulatory requirements affecting the entire industry and the impact those requirements can have on financial, operational, clinical and compliance performance at all points in the healthcare industry.

Notably, our work product is regularly scrutinized and relied upon by regulatory agencies and enforcement bodies including OIG, DOJ, CMS, state Attorneys General, state Medicaid agencies and various accreditation bodies such as the Joint Commission and NCQA. We regularly present to and meet with such bodies during the course of our engagements; our practice leadership and work product are known and respected in these circles.

Representative Experience



Corporate Integrity Agreement

FTI Consulting served as Independent Review Organization (“IRO”) for a Urine Drug Testing (“UDT”) Lab under their Corporate Integrity Agreement (“CIA”) with the OIG. As the IRO, FTI Consulting conducted an annual review of the lab’s systems, processes, policies, and procedures related to Focus Arrangements for the five-year term of the CIA.



Board Compliance Expert

FTI Consulting serves as the Board Compliance Expert (“BCE”) for a Drug Testing Lab under their CIA. In our function as BCE, we evaluated the overall effectiveness of the organization’s compliance program relative to prevailing OIG and CMS guidance and regulatory requirements and common industry practices.



Billing and Coding Investigation

FTI Consulting assisted a diagnostic laboratory company that was the subject of an investigation into claims submitted to Medicare for diagnostic tests using a product that was alleged not to be effective. This involved analyzing billing data and sales data to develop models of test usage and Medicare billing. We worked with counsel to analyze and rebut damage claims and prepare alternative damage models.



Diagnostic Testing Pricing and Contracting Practices

FTI Consulting assisted a laboratory company that was the subject of both Medicare and Medicaid investigations into diagnostic testing pricing and contracting practices. FTI Consulting utilized the company's data and data from outside sources to analyze fee schedules and pricing and billing from various physician groups, hospital and payer populations as well as cost information related to a number of testing centers. We also analyzed trends of Medicare, Medicaid and private payer test requisitions. This work culminated in a detailed response to the government's restitution demands and the development of alternative approaches to framing potential damages.



Evaluating Business Projections

FTI Consulting assisted a committee of lenders in evaluating business projections related to UDT and other laboratory testing revenue for an entity that was the subject of a DOJ and CMS investigation into billing practices. The review also involved assessing the relevant billing guidelines for Medicare, Medicaid and Commercial payers along with the company's billing practices.



Billing and Compliance Program Review

FTI Consulting assisted a molecular lab company with service offerings in reproductive health, women's medicine and oncology in examining their current billing operations and performing a compliance program review. FTI Consulting reviewed testing and billing practices, including the identification of certain billings that resulted in potential overpayments from both government and commercial payers.



Physician-Referrals Investigation

FTI Consulting assisted a major pathology laboratory that was the subject of an investigation into whether donations of electronic health record technology were used as an incentive to increase physician referrals. FTI Consulting performed analyses of claims data and referral data from various physician practices and created benchmarks for evaluating different populations of provider groups based upon specialty and region.

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