

MASTER GUIDE TO CLINICAL LAB COMPLIANCE

Navigating Stepped-Up Investigations,
Audits, & Enforcement Actions





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Master Guide to Clinical Lab Compliance 2023 Edition Navigating Stepped-Up Investigations, Audits, & Enforcement Actions

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ISBN: 978-1-58673-437-4

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CHAPTER 1:

INTRODUCTION

Clinical laboratories are the eyes and ears of the healthcare system. Over 70 percent of all treatment decisions are guided by the findings of laboratory tests. Labs furnish the data that make it possible to personalize treatment, contain costs, and prevent unnecessary surgical procedures and other medical interventions.

However, as with medical decision-making, many of the most widespread and pernicious forms of healthcare fraud and abuse run through the clinical lab. Consequently, labs have been a primary target for government enforcement action from the moment enforcement and Medicare, Medicaid, and other federal healthcare program integrity became a policy priority. After focusing on illegal drugs in the 1980s, federal enforcement agencies pivoted to broader healthcare fraud in the 1990s. Not coincidentally, it was a clinical lab scandal, the notorious Operation LabScam \$800 million unbundling scheme, that kicked off the new era in enforcement. And while the dragnet has broadened considerably over the decades, labs are on the receiving end of a disproportionate number of compliance investigations, audits, reviews, prosecutions, and lawsuits.

The Centers for Medicare and Medicaid Services (CMS); the U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG); the U.S. Department of Justice (DOJ). These are only a few of the sets of suspicious eyes gazing over the shoulders of labs as they conduct their federal healthcare regulated operations. Other nemeses include state fraud investigators and private whistleblowers, as well as private health insurance companies, consumers, and even corporate lab companies' own shareholders. Nor is there any shortage of laws that can be used to hold labs accountable for false billing and other acts of fraud and abuse.

The 3 Key Laws

In the healthcare context, the term "fraud and abuse" generally refers to improprieties in the procurement, delivery, and billing of medical services provided to patients or "beneficiaries" of federal health programs like Medicare, Medicaid, CHAMPUS, and other federal health programs. There are three main federal laws that generate the lion's share of the enforcement activity: The False Claims Act, Anti-Kickback Statute, and the Stark Law.

Compliance During the Public Health Emergency

In 2020, after nearly three decades of continuous and mounting pressure, labs finally got something of a reprieve from an unexpected source: the novel coronavirus. While the COVID-19 pandemic burdened labs with unprecedented demand for tests, exacerbated by accompanying shortages of testing supplies, personal protective equipment, and staff, it also brought a degree of relief on the compliance front.

It began in January 2020, when the HHS Secretary declared a public health emergency (PHE) giving it the right to exercise its authority to take emergency actions under Section 319 of the Public Health Service Act, including measures directly affecting COVID-19 lab testing, coverage, and reimbursement.

Return to Regulatory Normalcy

For purposes of this introduction, the key point is that the COVID-19 PHE is winding down. Although HHS has committed to keeping it in place through the early months of 2023, the consensus is that the end will come some time during the first half of the year.

The end of the PHE may not necessarily spell the immediate end of the temporary legal changes made to clear the way for COVID-19 testing and care. Thus, for example, the expansion of Medicare telehealth coverage rules will likely remain in place, perhaps via the enactment of new federal legislation, long after the PHE ends.

More significantly, the PHE has actually done very little to slow either the pace or volume of federal enforcement activity. As this Guide will explain, it has pretty much been business as usual insofar as enforcement is concerned.

The PAMA Factor

In 2016, Congress adopted a law called the Protecting Access to Medicare Act (PAMA) that was designed to cut what Medicare Part B spends on lab tests. The unspoken assumption was that labs were charging Medicare more than private payors for equivalent services. PAMA mandated the use of market-based pricing to eliminate those disparities and reduce Medicare spending without affecting test utilization.

While the controversy over the system CMS uses to implement the market-based pricing provisions of the statute are beyond the scope of this Guide, the key point is that PAMA isn't saving Medicare money on lab testing. In FY 2018 and 2019, the first two years under the PAMA system, Medicare payments under the Clinical Laboratory Fee Schedule (CLFS) actually increased. The same thing happened in FY 2020, but with a difference: this time the fly in the ointment was the \$1.5 billion spent on COVID-19 testing; spending on non-COVID-19 tests actually did decline a bit since new payment rates took effect in 2018.

The Bottom Line: The OIG still thinks Medicare is paying too much for lab tests and is pressuring CMS to do something about it. Meanwhile, the agency has started to crack down on providers that fail to report their PAMA price data to CMS on time.

Inside the Beltway: OIG Turns Up the Enforcement Pressure on CMS

With all these forces coming down on them, it's not hard to understand why compliance managers are under so much stress. Regrettably, if the OIG had its way, compliance personnel would have to dedicate even more of their personal budgets to Tums, Roloids, and other antacid tablets. In fall 2022, the agency issued a report criticizing CMS for not doing enough to recover the Medicare overpayments that OIG auditors are uncovering. CMS recovered only \$272 million of the \$498 million (55%) of overpayments identified over a review period running from October 1, 2014, to December 31, 2016, according to the report. And since CMS didn't provide adequate documentation, there's no telling how much of the unaccounted for \$226 million was left on the table.

The real takeaway of the report comes from the OIG's recommendations, more precisely, CMS' response to them. In a rare public display of disharmony between federal agencies, CMS indicated its non-concurrence with seven of the nine measures the OIG called on it to do to improve collections of overpayments uncovered by OIG audits. The response suggests significant philosophical differences about the adequacy of current overpayment recovery systems, policies, and procedures, with CMS poo-hooing many of OIG's recommended measures as either unnecessary, redundant, or unrealistic. Even the two recommendations that CMS did accept came with grumbles.

The Changing Face of Enforcement

Enforcement is not only intensifying, but becoming more sophisticated and efficient. CMS, the OIG, and DOJ are getting much better at detecting healthcare fraud and abuse via the use of powerful new detection methods like data mining, and high-tech systems like the CMS's Fraud Prevention System (FPS) which uses advanced analytics to uncover improper payments. Moreover, once the agencies do detect fraud, they are using more sophisticated investigation and prosecution techniques to bring providers to justice.

New Enforcement Targets

While enforcement against testing labs remains a constant, the patterns of targeted conduct continue to evolve. Genetic testing, toxicology testing & urine drug tests, telehealth cancer genetic tests, and Silicon Valley test scams are some of the most recent targets.

Privatization of Enforcement Activity

Another reason that the COVID-19 PHE hasn't eased the pressure on labs is that the government has gained a powerful new ally in its war on healthcare fraud and abuse: the private sector. This includes not only whistleblowers who file qui tam lawsuits on the government's behalf but also a host of new players bringing civil claims against labs that do them wrong.

(See Chapter 3 for a detailed discussion of private sector enforcement.)

The Silver Lining

While it feels scary, the fact that healthcare fraud and abuse enforcement is getting bigger, smarter, and more effective is in many ways a positive development. For one thing, it means enforcement is now targeted and less random. Targeted enforcement is big trouble for the cheaters and inveterate offenders but good news for the vast majority of labs that make the effort to comply and play by the rules.

How This Guide Will Help You

This Guide was written to help lab managers—whether in hospital, physician practice, independent labs, or other settings—recognize and manage the compliance risks they face. Although the substance is legal, the presentation and language are meant to be colloquial, straightforward, and user-friendly. **Our objective:** Explain legal complexity for the non-attorney.

The Guide is also intended to break down the legal issues from a practical, operational perspective so that you understand not only what the law says, but what you must do to comply with it.

Also included as appendices in this Guide are the “Model Compliance Program Guidance for Clinical Laboratories,” special fraud alerts related to clinical lab services, helpful compliance tips from the HHS Office of Inspector General, and a list of key compliance resources.

We are confident that you'll find this Guide an invaluable resource that you can use to keep your lab in compliance as you navigate the complex regulatory requirements governing federal payment of diagnostic services.

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