



**OBERHEIDEN, P.C.**

# TOP 5 THINGS TO KNOW ABOUT HEALTH CARE COMPLIANCE



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# INTRODUCTION

Whether you are a physician, pharmacist, facility administrator, or company executive, if you are directly or indirectly responsible for billing the federal government for medical equipment, prescription medications, or patient services, you need to be focused on compliance. Lacking an effective compliance program is among the most-common issues that trigger liability in federal health care fraud audits and investigations, and the costs of non-compliance can be substantial.

# ABOUT THE AUTHOR

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Dr. Nick Oberheiden is a federal health care fraud defense lawyer who has more than a decade of experience representing providers, durable medical equipment (DME) companies, and other health care entities in more than 40 states across the country. He has earned a nationwide representation for effective advocacy and representation in all matters pertaining to Medicare, Medicaid, Tricare, and Department of Labor (DOL) compliance and enforcement. Dr. Oberheiden's experience includes assisting numerous clients with the development and implementation of comprehensive compliance programs, and helping his clients use these programs to avoid charges when faced with audits and federal investigations.

# 5 KEY FACTS ABOUT FEDERAL HEALTH CARE COMPLIANCE

## 1 HEALTH CARE COMPLIANCE MEANS MUCH MORE THAN HIPAA COMPLIANCE

Most health care providers are familiar with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and its stringent requirements for protecting patient privacy. However, what most health care providers do not realize is that HIPAA compliance is just one relatively small component of a comprehensive health care compliance program. In fact, HIPAA's requirements are so standardized that "off-the-shelf" compliance programs are available; and, in many (though not all) cases, adopting one of these programs will be sufficient to insulate providers from potential liability under HIPAA.

Federal program billing compliance, on the other hand, is a different story entirely. Medicare, Medicaid, Tricare, and the DOL's health care benefit program all have differing billing rules and regulations. From allowable expenses to what qualifies as a "medically-necessary" treatment or medication for program billing purposes, each program's standards are different. The billing rules and regulations are also constantly changing; and, in areas such as telemedicine and the prescription of opioid medications, federal law enforcement mandates mean that providers are subject to constant and intense scrutiny.

So, if your practice's or business's compliance efforts only focus on HIPAA, they are not enough. If you have not updated your compliance program recently, it is almost certainly out of date. In order to protect yourself (and your business, your employees, and maybe even the colleagues you work with on a regular basis), it will be important to reinforce your compliance program as soon as possible.

## A COMPREHENSIVE COMPLIANCE PROGRAM WILL TOUCH ALL ASPECTS OF A BUSINESS OR PRACTICE

Just as a health care compliance program must not focus solely on HIPAA, it also must not focus solely on patient care. From billing policies and procedures to contracts with suppliers and other third parties, all aspects of your business or practice can potentially have federal compliance implications.

As a baseline, a federal health care compliance program should minimally address:

- **Billing policies and procedures**
- **Employment policies and procedures**
- **Employee education and training**
- **Ongoing documentation to ensure and demonstrate compliance**
- **Compliance standards and requirements for third-party contracts**
- **Appointment of a compliance officer (or other comparable designee(s))**
- **Compliance implementation and monitoring**
- **Lines of communication and chain of command for reporting potential compliance issues**
- **Rapid response protocols for compliance violations**
- **Disciplinary standards for employees who commit compliance violations**
- **Emergency response protocols in the event of an audit or federal investigation**

Each component of a compliance program should be carefully tailored to the unique needs and risks of the particular practice or business for which it is prepared. What works for one physician group, clinic, or DME company is highly unlikely to work for another. But, by working with experienced legal counsel to develop a fully-customized compliance program, you can feel confident knowing that your compliance program will withstand federal scrutiny and serve as a strong line of defense in the event that your practice or business faces accusations of intentional or unintentional health care fraud.

## LACK OF DOCUMENTATION IS THE NUMBER ONE CAUSE OF FEDERAL SCRUTINY

Among all of the various issues that can lead to allegations of health care fraud, the number one cause of federal scrutiny is lack of documentation. This applies across the board, from lacking a documented compliance program to failing to maintain adequate patient records, and from failing to substantiate program billings to failing to enter into compliant contracts with third-party suppliers. In fact, even if your practice or business is fully-compliant, if you cannot prove it with adequate documentation, overcoming allegations of health care fraud during an audit or investigation is going to be a challenge.

Not only can lacking documentation be an issue, but maintaining inadequate documentation can be an issue as well. In fact, if your patient records are unclear, or if a contract with a third-party does not clearly meet the requirements for an Anti-Kickback Statute safe harbor, your practice's or business's documentation could potentially be used as evidence against you in a civil or criminal health care fraud prosecution. In other words, simply having documentation is not enough. Having the right documentation is what really matters.

# 4 COMPLIANCE IS AN ONGOING PROCESS

If it is not already abundantly clear, federal health care compliance is an ongoing process. Compliance policies and procedures must be enforced and re-assessed on an ongoing basis, and all necessary forms of documentation must be continuously generated and stored. When an employee reports a potential compliance issue, or when you receive contact from an auditor or federal agency, efforts must be undertaken immediately to assess the allegation and commence any remedial action necessary.

Changes in program billing regulations, new federal court decisions, and changes within your practice or business can all necessitate updates to your compliance program. Once changes become necessary, adhering to an outdated compliance program can create exposure to civil, or even criminal, liability. Federal authorities take Medicare, Medicaid, Tricare, and DOL compliance extremely seriously, and they expect health care providers and other program participants to take it seriously as well.

# 5 THE CONSEQUENCES OF NON-COMPLIANCE CAN BE SEVERE

In order to understand the importance of compliance, it is necessary to understand what is at stake if your practice or business is deemed non-compliant. Depending upon the specific issue involved, compliance issues can trigger civil or criminal penalties under statutes including:

- **Anti-Kickback Statute**
- **Controlled Substances Act**
- **False Claims Act**
- **Health Care Fraud Statute**
- **Internal Revenue Code**
- **Stark Law**
- **18 U.S.C. § 371 (the federal “conspiracy” statute)**
- **Various criminal statutes of general applicability (such as those outlawing mail fraud, money laundering, and wire fraud)**

In civil cases (involving unintentional billing violations), potential penalties include fines, treble (triple) damages, attorneys’ fees and costs, and loss of federal program eligibility. In criminal cases (involving intentional fraudulent conduct), in addition to financial penalties and loss of program eligibility, licensed providers, business owners, and company personnel can also face long-term federal imprisonment. In cases under False Claims Act (which are most common, as any inaccurate billing request can be prosecuted as a “false claim”), individuals’ and organizations’ aggregate liability can easily reach into the hundreds of thousands, if not millions, of dollars. While this may sound severe, the risks are very real. The U.S. Department of Justice (DOJ) routinely issues press releases touting its “takedowns” of health care providers and other businesses in the medical field, and agencies ranging from the Federal Bureau of Investigation (FBI) to the U.S. Department of Health and Human Services’ Office of Inspector General (OIG) routinely prosecute federal health care fraud cases as well. Licensed health care professionals can also risk losing their licenses (and their professional reputations) – all due to compliance issues that can (and should) be avoided.

# HOW OUR EXPERIENCED LAWYERS CAN HELP YOU

With centuries of combined experience prosecuting health care fraud cases on behalf of the DOJ and representing private health care entities in federal matters, our attorneys can help you develop and implement a compliance program focused on the issues that matter most to the federal government. Our attorneys will work with you directly to understand your practice's or business's needs, and we will guide you every step of the way on the road to becoming fully compliant.

## HOW WE CAN HELP

### **1. Development a Custom-Tailored Health Care Compliance Program**

We will sit down with you to understand your practice's or business's needs and offer customized compliance recommendations based upon our attorneys' centuries of combined experience in federal health care matters.

### **2. Multi-Phased Implementation of Your New Compliance Program**

From drafting policies, procedures, and contracts to training your employees on all relevant aspects of federal health care compliance, we can execute a multi-phased implementation strategy to ensure that your new compliance program reaches all facets of your business or practice.

### **3. Representation in Matters Involving Auditors and Federal Authorities**

If you are contacted by auditors or federal authorities regarding your practice's or business's program billings, our attorneys can promptly intervene in the audit or investigation and interface with the auditors or federal agents on your behalf.



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