Physician Practice Compliance Reference Guide

A comprehensive resource for easy implementation of compliance activities for the physician practice

SECOND EDITION
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While federal and private payers have different objectives (such as the age of the population covered) and use different contracting practices (such as fee schedules and coverage policies), the plans and providers set similar elements of the quality in common for all patients. Nevertheless, it is important to consult with individual private payers if you have questions regarding coverage.

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# Contents

**Introduction** ........................................................................................................... 1  

**CHAPTER 1**  
**Healthcare Compliance Basics** ........................................................................... 3  
- Where Does Compliance Come From? ................................................................. 3  
- How Rules Are Enforced ....................................................................................... 4  
- 6 Compliance Must-Knows. .................................................................................. 7  
- Questions and Answers ......................................................................................... 9  

**CHAPTER 2**  
**How to Build a Culture of Compliance** ................................................................ 11  
- The 7 Elements of an Effective Compliance Program ............................................... 11  
- Follow a Compliance Calendar in Your Practice ..................................................... 15  
- Questions and Answers ......................................................................................... 16  

**CHAPTER 3**  
**The False Claims Act (FCA)** ................................................................................ 17  
- False Claims Act Basics ....................................................................................... 17  
- A False Claims Act Timeline ................................................................................ 17  
- Head Off Qui Tam Lawsuits With These 9 Steps. .................................................. 19  
- Exit Interviews and Qui Tam Problems ................................................................ 20  
- Paybacks Required .............................................................................................. 22  
- Documentation Counts ........................................................................................ 22  
- Avoid Cut-and-Paste ........................................................................................... 22  
- Questions and Answers ......................................................................................... 23  

**CHAPTER 4**  
**The Anti-Kickback Statute** .................................................................................. 25  
- The Anti-Kickback Statute (AKS) Basics ............................................................... 25  
- Fair Market Value ................................................................................................ 26  
- Safe Harbor Helps Merit-Based Incentive Payment System (MIPS) and Value-Based Reimbursement ................................................................. 27  
- Medical Director Arrangements May Violate the AKS ........................................... 29  
- Financial Relationships Between Physicians and Clinical Labs ................................ 30  
- Marketing Programs Could Be Subject to AKS and Stark ....................................... 30  
- Guidelines for Compliant Gifting ......................................................................... 31  
- Questions and Answers ......................................................................................... 32
## Contents

### CHAPTER 5
The Stark Law (Also Called the Physician Self-Referral Law) .......................................................... 35
- Stark Basics ........................................................................................................................................... 35
- Exceptions to Stark ............................................................................................................................... 36
- Modernizing and Clarifying Stark ....................................................................................................... 37
- Compliant On-Call Coverage Arrangements ....................................................................................... 38
- A Stark Example .................................................................................................................................. 40
- Case Study: How to Create a Professional Service Arrangement That Complies With Stark, AKS Regulations ........................................................................................................................................... 41
- Clean Claims ....................................................................................................................................... 42
- Filing Your Claim ................................................................................................................................. 42
- Questions and Answers ...................................................................................................................... 43

### CHAPTER 6
All About Audits ................................................................................................................................. 45
- 5 Medicare Administrative Contractor Myths That Can Hurt Your Practice's Compliance Efforts ................................................................. 45
- What to Do When You Receive an Audit Letter .................................................................................... 46
- Audit Letter Tips ................................................................................................................................. 47
- Prepare Ahead for a RAC Audit ........................................................................................................... 49
- After the Audit .................................................................................................................................... 49
- Building an Effective Self-Auditing Program ....................................................................................... 50
- Audit Hotspots ...................................................................................................................................... 52
- Medicare Billing Compliance ............................................................................................................. 59
- The 60-Day Overpayment Rule ........................................................................................................ 60
- Lookback Timeframe Shortened ......................................................................................................... 60
- OIG’s Exclusion Rules ........................................................................................................................ 61
- Exclusion Lists .................................................................................................................................... 62
- References .......................................................................................................................................... 63
- Shared Visit vs. Incident To .................................................................................................................. 63
- Advance Beneficiary Notices .............................................................................................................. 65
- What Should an ABN Contain? .......................................................................................................... 66
- ABNs Protect Patients Also ............................................................................................................... 66
- How to Move Forward — Without a Signature ...................................................................................... 67
- 2 ABN Myths ....................................................................................................................................... 68
- Request an ABN for Second Opinions ................................................................................................. 69
- Place of Service Codes ....................................................................................................................... 69
- Questions and Answers ...................................................................................................................... 70
## CHAPTER 7
### HIPAA

- HIPAA Timeline ........................................................................................................... 76
- HIPAA Regulators ......................................................................................................... 76
- 12 HIPAA Myths ........................................................................................................... 80
- Business Associates ................................................................................................. 81
- Guidelines for Business Associate Agreements ......................................................... 81
- How to Protect Your Practice From Unscrupulous Vendors ........................................... 81
- Cybersecurity and Compliance Plans ............................................................................. 82
- Cyberattacks ................................................................................................................ 83
- HIPAA Breaches .......................................................................................................... 89
- Human Resources Compliance .................................................................................... 90
- OSHA Compliance ....................................................................................................... 92
- Payment Under Fee-For-Time Compensation Arrangements (formerly referred to as Locum Tenens Arrangements) ................................................................. 94
- Questions and Answers ............................................................................................. 95

### APPENDIX A

**Glossary** .................................................................................................................. 101

### APPENDIX B

**OIG Compliance Program for Individual and Small Group Physician Practices** ................................................................. 105

### APPENDIX C

**OIG Compliance Program for Hospitals** .................................................................. 125

### APPENDIX D

**OIG Supplemental Compliance Program for Hospitals** ............................................. 137

### APPENDIX E

**OIG Supplemental Compliance Program for Third-Party Medical Billing Companies** ................................................................. 157

### APPENDIX F

**Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Healthcare Programs** ................................................ 173

### APPENDIX G

**Additional Resources and References** ...................................................................... 193
Introduction

With everything else you must do to run a successful medical practice, compliance can be a big hurdle to tackle. But it’s absolutely essential to safeguarding your practice’s future.

Whether you are new to running a practice or you simply can’t remember all you need to know — and no one can — The Physician Practice Compliance Reference Guide has you covered. Safeguard against compliance liabilities with clear explanations and practical advice, including:

- Elements of an Effective Compliance Program
- Follow a Compliance Calendar in Your Practice
- Steer Clear of Upcoding to Reduce FCA Risk
- Conquer the Anti-Kickback Statute (AKS)
- What You Need to Know About Fair Market Value (FMV)
- Know the Ins and Outs of The Stark Law
- Nail Down the OIG’s Exclusion Rules
- Create a Professional Service Arrangement That Complies with Stark and AKS Regulations
- Guard Against Audit Hotspots & Build an Effective Self-Auditing Program
- Prevent Your Marketing Programs From Running Afoul of AKS and Stark
- Medicare Billing Compliance Must-Knows
- Get a Crash Course on the 60-Day Overpayment Rule
- Know When to Bill Shared Visit Versus Incident-To
- All About Advance Beneficiary Notices (ABNs)
- Meet Human Resources Compliance
- Glossary of Relevant Terms

We’d appreciate your feedback and your suggestions so we can be sure our reference guide serves your needs.
A False Claims Act Timeline

1777
Congress created the Inspector General of the Army. U.S. Army Inspector General Baron Frederick William Augustus Von Steuben is considered the first “effective” U.S. Army Inspector General. (West Point)

1778
The Founding Fathers passed the nation’s first whistleblower law. (National Whistleblower Center, 2014)

1863
Also called the Lincoln Law, the False Claims Act (31 U.S.C. §§ 3729–3733) was enacted to combat fraud by suppliers of goods to the Union Army during the U.S. Civil War.

1943
FCA amended to eliminate jurisdiction over qui tam actions based on evidence or information in the government’s possession and permit the Department of Justice to intervene. In addition, the financial rewards to whistleblowers were reduced. (Finch McCranie, LLP, 2007)

1976
The Office of Inspector General (OIG) is established (now HHS-OIG). (U.S. Department of Health and Human Services Office of Inspector General)

1978
The Inspector General (IG) Act established 12 Federal Offices of Inspector General. President Carter charges the IGs to always remember that their ultimate responsibility is not to any individual, but to the public interest. (Council of the Inspectors General)

1986
FCA amended to increase financial and other incentives for qui tam relators to bring suits on behalf of the government. The FCA Amendments reactivate whistleblower activity and federal enforcement against fraudulent government contractors. (Finch McCranie, LLP, 2007)

1990s
FCA started being applied to healthcare fraud. Recovery of fraud against Medicare and Medicaid increased. (Lawsuit Legal)

2009
The government amended the FCA with the Fraud Enforcement and Recovery Act (FERA). This change affected healthcare providers particularly. Under this change, the reverse false claims provision was extended. (Lawsuit Legal)

2013
On July 30, 2013, the U.S. Senate enacted their joint resolution recognizing National Whistleblower Appreciation Day. The date was chosen to signify the nation’s first whistleblower law passed on July 30, 1778. (National Whistleblower Center, 2014)

2015
The Department of Justice publishes the Yates Memo, which makes clear that individuals — not just companies — should be held accountable for corporate wrongdoing. The Yates Memo raised the stakes for healthcare employees involved in schemes violating FCA, and more executives are held accountable individually after the Yates Memo is published. The memo is named for its author, Deputy Attorney General Sally Quillian Yates. (Sally Quillian Yates, 2015)

2016
The Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (the 2015 Act) (Public Law 114-74, Sec. 701), which further amended the Federal Civil Penalties Inflation Adjustment Act of 1990 (the Inflation Adjustment Act) (Public Law 101-410), was enacted on November 2, 2015. This act doubled the FCA penalties and requires an annual increase.

2017
President Donald Trump fires Sally Yates from her Acting Attorney General post when she refuses to enforce his immigration ban. She leaves the Yates Memo — and its implications — behind, and it continues to influence healthcare compliance.
CHAPTER 4

The Anti-Kickback Statute (AKS) Basics

Statute: 42 U.S.C. § 1320a–7b(b)

Safe Harbor Regulations: 42 C.F.R. § 1001.952

Originally passed in 1972, the AKS aims to protect Medicare and other federally funded healthcare programs from fraud and abuse. It “is a criminal statute that prohibits the exchange (or offer to exchange), of anything of value, in an effort to induce (or reward) the referral of federal healthcare program business,” explains a brief from the American Health Lawyers Association.

Example: If the owner of the lab you utilize offers your physicians “incentives” for referring your patients to them, this is considered a kickback. In this kind of situation, cash rewards, gifts, vacations, and even discounted services or supplies are considered kickbacks. Money does not have to change hands to implicate AKS. It can be anything of value.

The biggest culprits trying to lure physicians are pharmaceutical companies, labs, hospitals, nursing homes, home health groups, portable X-ray companies, and manufacturers of devices and supplies. Penalties for engaging in kickback fraud vary depending on the level of severity but can include fines, incarceration, and exclusion from the Medicare and Medicaid programs.

Here are some examples of business arrangements involving physicians that can fall under Anti-Kickback and Stark regulations:

- Physician ownership or partial ownership of ambulatory surgery centers (ASCs), clinical labs, and DME suppliers
- Physician employment arrangements outside the practice
- Independent contractor arrangements
- Leases and rentals of equipment or space

Just as the Stark Law has exceptions that enable business arrangements that would otherwise violate the law, so does the AKS. In the AKS context, they’re called “safe harbors.” The arrangements above are not automatically illegal, but must be structured to fall within AKS safe harbors and Stark exceptions to reduce risk.

When practices are evaluating a potential business arrangement involving one of their physicians, the attorney involved typically does an analysis that considers both the relevant Stark exceptions and the AKS safe harbors.

Resources


To read brief in full, go to www.americanhealthlaw.org.
Questions and Answers

**Question:** Could you provide a brief explanation of what incident-to billing is, and how it benefits billing reimbursement?

**Answer:** Incident-to billing, in the simplest of terms, is a Medicare benefit that allows a physician practice to bill for services personally provided by ancillary staff under the name and NPI of the supervising physician or NPP. Done correctly, it can add 15 percent to a practice’s bottom line when services are performed by a nurse practitioner, physician assistant, or clinical nurse specialist — an NPP.

**Question:** Can an NPP only bill incident to a physician if they are following an established plan of care?

**Answer:** Yes. The NPP must following the established plan of care of the physician. If it is an established patient with a new problem, the NPP can still see the patient, but must bill under their NPI and receive 85 percent of the physician fee schedule amount.

Incident-to guidelines do not allow an NPP to bill incident to a physician’s services (ie, under the physician’s PIN) when a new problem is addressed. This could happen in a situation when the patient was scheduled to be seen for an established problem but brings up a new problem during the course of the visit. Once a new problem is introduced, the visit would need to be billed under the NPP’s NPI, not the physician’s.

**Question:** What does Medicare mean when it says the NPP must be working under “direct supervision” of a physician to bill incident-to?

**Answer:** Direct supervision in the office setting means that the physician is in the office suite. The physician must be present in the office suite and immediately available to provide assistance and direction throughout the time the aide is performing services.

This is an area that often causes confusion, especially since an NPP does not need a doctor in the office to be able to treat and care for a patient in most cases. And, Medicare would agree. Only they would say just bill the services directly under the NPP and accept the 85 percent reimbursement if the physician is not in the office suite.

However, if you want to bill under the supervising physician and be paid at 100 percent of the allowable, a doctor with the practice must be in the office suite. For example, the physician cannot be across the street, three blocks away, or available via cell phone (but not in person).

The issue of “immediate availability” is one of patient safety; for example, if the patient has an adverse reaction to an injection, or passes out during a routine venipuncture, the physician must be immediately available to provide care to the patient.

**Question:** I have a physician (cardiologist) that was in a cardiology practice; he left the practice and opened his own practice with a new practice NPI. Would the patients that he saw in the previous practice be considered new patients to the new practice?
When the Health Information Portability and Accountability Act (HIPAA) first hit back in the late 1990s, it was pretty easy to deal with once we learned the basics.

It was mostly about healthcare privacy back then, so as long as we trained staffers not to holler patients’ names in the hallways and leave medical records lying around, we’d pretty much covered HIPAA Privacy Rule compliance.

The brutal fact is that HIPAA has become a lot more difficult to comply with now that most of us use health information technology like EHR, electronic claims submission, and patient portals.

When these tools are used, HIPAA security guidelines come into play. You should already have HIPAA privacy considerations built into your practice’s compliance plan, but you may not know all you need to know about HIPAA security compliance. The following information will help you establish technical safeguards, business associate agreements (BAAs), employee training programs, and other measures to protect your practice.

The HIPAA Security Rule is intended to guard protected health information (PHI) that is input, stored, and transferred electronically, while allowing providers to implement new technologies to improve the quality and efficiency of patient care, such as EHR systems, billing software, etc. All healthcare providers/health plans/clearinghouses that transmit PHI electronically are obligated to follow this rule.

We can’t cover everything you need to know about cybersecurity within this short chapter, but we can hit the highlights and point you toward resources to help you learn more. Most experts say that HIPAA security is the biggest compliance issue most physician practices face these days, so if you have the opportunity to read HIPAA security books or attend classes about HIPAA security, we urge you to do so as part of your career development.

Learning more about health information technology and HIPAA security can only help you protect your practice and help it thrive in the future. And if you haven’t already, make sure that your compliance plan addresses HIPAA security risks.

For a summary of the HIPAA Security Rule, go to:

https://www.hhs.gov/hipaa/for-professionals/security/laws-regulations/

https://www.law.cornell.edu/cfr/text/45/part-160

https://www.law.cornell.edu/cfr/text/45/part-164

   Enforced by the agency that bears the same name, these regulations apply to all workplaces. Penalties can be up to $63,000 per instance.

   **The good news:** The guidelines available on OSHA’s website are admirably clear and easy to follow, especially if you’ve become accustomed to sweating through confusing compliance guidance from CMS.

   **Tip:** If you run across a compliance consultant who wants to sell you "an OSHA training program" for your practice, don’t shell out any coin until you check out what’s available on OSHA’s website for free. It’s highly likely the site has all the resources and training materials you need, so save your outsourcing budget for other kinds of compliance help.

   **The OSHA standards most relevant to physician practices are:**
   - Bloodborne pathogens
   - Hazardous chemicals
   - Exit routes
   - Electrical
   - Reporting occupational injuries and illness (state law)
   - OSHA poster
   - Ionizing radiation (if you have machines like X-ray)

   **Resources**

   - **Handy, Free OSHA References**
     - Compliance Assistance Quick Start for Healthcare: [https://www.osha.gov/dcsp/compliance_assistance/quickstarts/health_care/](https://www.osha.gov/dcsp/compliance_assistance/quickstarts/health_care/)
     - OSHA Guidelines about standards most relevant to physician practices: [https://www.osha.gov/Publications/osha3187.pdf](https://www.osha.gov/Publications/osha3187.pdf)
     - To obtain a poster for your breakroom: [https://www.osha.gov/Publications/poster.html](https://www.osha.gov/Publications/poster.html)

   **OSHA Compliance**

   Is your binder of OSHA guidelines collecting dust? Do you even have a binder of OSHA guidelines in your clinic?

   If an accident or injury occurs, you don’t want to get slammed with OSHA fines — or in the worst-case scenario, a lawsuit.

   **Make sure you’re up to speed in the following safety areas, or risk paying for it later:**

   1. **Personal Protective Equipment**

      You may not think you need an impervious gown on hand, but you’d be surprised. The maintenance of personal protective equipment (PPE) is an area that is deficient in some practice settings. Your practice should have basic protection such as gloves, eye shields, and impervious gowns readily available. At a minimum, you should have gloves available in each major treatment area. Items, such as gowns and eyewear, could be stored in a supply closet, depending on your facility’s need.
<table>
<thead>
<tr>
<th>Acronym/Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Authentication</td>
<td>The act of confirming the validity of a single piece of data or entity. While identification refers to the act of stating a person or thing's identity, authentication is the process of actually confirming that identity.</td>
</tr>
<tr>
<td>Business Associate (BA)</td>
<td>HIPAA’s term for a person or organization that has access to PHI in order to perform functions on a CE’s behalf, but is not part of the CE’s work force. Examples of business associates that may have access to PHI at your practice include answering service, medical billing company, EHR and other software vendors, IT contractor, cloud vendor, your janitorial service, and many more.</td>
</tr>
<tr>
<td>Business Associate Agreement (BAA)</td>
<td>A written contract between a CE and BA that establishes how PHI will be disclosed and used in the arrangement, as well as the HIPAA compliance obligations of both parties.</td>
</tr>
<tr>
<td>Breach</td>
<td>Under the HIPAA Privacy Rule, a breach is an impermissible use or disclosure that compromises the privacy or security of PHI.</td>
</tr>
<tr>
<td>Cloud</td>
<td>A network of computers and servers that stores data, allowing you to access that data from anywhere on almost any device. Cloud storage is often used instead of a hard drive, which stores data on one machine and only allows you to access your data on that machine.</td>
</tr>
<tr>
<td>Client Server</td>
<td>An in-house computer system that services computers and hardware within your office.</td>
</tr>
<tr>
<td>Cloud Server</td>
<td>An external server hosted by an outside source that you can easily access from your computer, tablet, or smartphone — as long as you have an internet connection.</td>
</tr>
<tr>
<td>Confidentiality</td>
<td>One of the three core concepts of information security (confidentiality, integrity, availability), confidentiality refers to restricting access to information to only authorized persons.</td>
</tr>
<tr>
<td>Covered Entity (CE)</td>
<td>HIPAA’s term for any health plan, clearinghouse, or healthcare provider that transmits PHI. Your practice is a covered entity.</td>
</tr>
<tr>
<td>Cyberattack</td>
<td>Any kind of malicious activity that attempts to collect, disrupt, deny, degrade, or destroy information systems or the data itself. Cyberattacks against healthcare systems have increased dramatically in recent years.</td>
</tr>
<tr>
<td>Cybersecurity/data security</td>
<td>Interchangeable terms that refer to the practices and mindset a person or company adopts to protect sensitive electronic data from being accessed, viewed, or transmitted by unauthorized users.</td>
</tr>
<tr>
<td>Data Breach</td>
<td>Incident in which sensitive, protected, or confidential data, such as PHI has potentially been viewed, stolen, or used by unauthorized individuals.</td>
</tr>
<tr>
<td>Data for Ransom, Ransomware</td>
<td>A type of malware (malicious software) or virus that restricts access to a computer system and demands that the user pay a ransom to the hackers. Ransomware typically encrypts data on the computer’s hard drive until the ransom is paid.</td>
</tr>
<tr>
<td>Data Use Agreement</td>
<td>An agreement that sets forth the permitted uses and disclosures of limited data sets, including who may use or receive the data and limitations on the receiving party’s ability to re-identify or contact the individuals who are subjects of the limited data sets.</td>
</tr>
<tr>
<td>Department of Justice (DOJ)</td>
<td>Executive-level department of the U.S. Federal Government that collaborates with OIG and CMS to handle cases of Medicare/Medicaid fraud.</td>
</tr>
<tr>
<td>Disclosure</td>
<td>Release or divulgence of information by an entity to persons or organizations outside of that entity.</td>
</tr>
<tr>
<td>Disclosure History</td>
<td>Under HIPAA, this is a list of any entities that have received personally identifiable healthcare information for uses unrelated to treatment and payment.</td>
</tr>
</tbody>
</table>
To enhance OIG’s ability to protect the Medicare and Medicaid programs and beneficiaries, the Medicare and Medicaid Patient and Program Protection Act of 1987, Public Law 100-93, expanded and revised OIG’s administrative sanction authorities by, among other things, establishing certain additional mandatory and discretionary exclusions for various types of misconduct.

The enactment of the Health Insurance Portability and Accountability Act (HIPAA), Public Law 104-191, in 1996 and the Balanced Budget Act (BBA) of 1997, Public Law 105-33, further expanded OIG’s sanction authorities. These statutes extended the application and scope of the current CMP and exclusion authorities beyond programs funded by the Department to all “Federal health care programs.” BBA also authorized a new CMP authority to be imposed against health care providers or entities that employ or enter into contracts with an excluded person to provide items or services for which payment may be made under a Federal health care program.

Since the publication of the 1999 Bulletin, various statutory amendments have strengthened and expanded OIG’s authority to exclude individuals and entities from the Federal health care programs. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care Education Reconciliation Act of 2010 (ACA), expanded OIG’s exclusion waiver authority. The ACA also modified and expanded OIG’s permissive exclusion authorities and amended the CMPL by adding a new provision that subjects an excluded person to liability if the person orders or prescribes an item or a service while excluded and knows or should know that a claim for the item or service may be made to a Federal health care program.
APPENDIX G

Additional Resources and References


Comparative Billing Reports, https://cbr.cbrpepper.org/home


The Business of Healthcare at Your Fingertips

Get all of your professional resources at aapc.com

- Get the latest healthcare news in our Knowledge Center
- Order tools and resources to help you navigate through your career
- Learn from industry pros in our virtual webinars and workshops
- Find free tools, including the E/M Analyzer, CPT® RVU Calculator, and more
- Discover new products and the latest deals on existing products

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