



Compliance 101: What you Need to Know to Protect Yourself and Your Practice

**Debra Duncan
Office of Compliance
Brody School of Medicine
ECU HIPAA Privacy Office**



Topics

- **Introduction**
- **Documentation and Billing**
- **Federal False Claims Act**
- **Federal Anti-kickback Statute**
- **Physician/Pharma Relationships**
- **Legal/Regulatory Landscape**
- **Importance of Compliance Programs**
- **BSOM Compliance Program**



Top Compliance Risk Areas

- **Documentation and Billing**
- **Federal False Claims Act**
- **Federal Anti-kickback Statute**
- **Physician/Pharma Relationships**
- **Stark Law**
- **Research**

Documentation and Billing

- **Teaching Physician Documentation Rules**
 - **Generally need evidence of physician presence during key portion of procedure or exam and review of medical management with resident.**

 - **Primary Care Exception Clinics**
 - ✓ **Family Medicine Clinic; General Internal Medicine Clinic, Geriatrics Clinic, General Pediatrics Clinic; General OB/GYN Clinic**
 - ✓ **Teaching Physician needs to document that case was reviewed and examined with resident**
 - ✓ **Teaching Physician does not have to examine patient unless billing at a higher level (level 4 or 5)**



Documentation and Billing

- **Electronic Medical Record Issues**
 - **Sharing of passwords prohibited**
 - **Cutting and pasting may be problematic (i.e. may be difficult to demonstrate medical necessity)**
 - **If you cut and paste, make sure you also review and edit**



Documentation and Billing

Billing and Reimbursement

- **Billing for services not performed (or underperformed)**
- **Ordering/billing for medically unnecessary services**
- **Improper billing and documentation for teaching physician services**
- **Double billing**
- **Upcoding/Downcoding**

Documentation and Billing

Recent OIG and DOJ Settlements related to billing:

- **\$25.1M Pediatrix Medical Group**
 - Billing for critical care services when infant's condition did not substantiate critical care
 - Occurred over 3-year time period
- **\$1.25M Carlinville Area Hospital**
 - Coded for diagnoses involving gram negative pneumonia, septicemia, and acute renal failure when documentation did not support such codes.
- **\$493K University of Rochester Strong Memorial Hosp.**
 - Teaching physician documentation problems
- **\$900M Tenet Healthcare**
 - Excessive outlier payments
 - Upcoding
 - Federal Anti-kickback Statute violations

Federal False Claims Act

Background Federal False Claims Act:

- **False Claims Act (FCA) prohibits anyone from “knowingly” submitting a false or fraudulent claim for payment**
- **“Knowingly” means (i) actual knowledge; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information.**
- **No proof of specific intent to defraud is required; liability is proven by evidence of deliberate ignorance or reckless disregard of truth of the claim**

Federal False Claims Act

Background Federal False Claims Act (Cont'd):

- **Damages: Triple damages and penalties of \$5,500 to \$11,000 per false claim for submission or causing submission of false claim.**
- **“Claim” is generally defined as a CMS 1500**
- **May result in imposition by the government of a “corporate integrity agreement”**

Federal False Claims Act

Background: Qui Tam Actions

- The FCA allows a private person (a “qui tam relator”) to bring a civil action in the name of the United States.
- Qui tam relators share in any money recovered (including settlements).
 - If government joins in action, relator is entitled to 15% to 25% of proceeds depending on relator’s contribution to case.
 - If government does not join in action, court may award relator not less than 25% and not more than 30% of proceeds.



Federal Anti-kickback Statute

- **Forbids any knowing and willful conduct involving the solicitation, receipt, offer or payment of any kind of remuneration in return for referring an individual or for recommending or arranging the purchase, lease or ordering of an item or service that may be paid for under a federal health care program.**
- **Criminal and civil liability for failure to comply.**

Federal Anti-kickback Statute

➤ Regulatory Safe Harbors

- Not a “per se” violation of law to be “outside” of a safe harbor
- Most important consideration is “fair market value”
- Affects many physician contractual relationships
- Leases with referral sources (space or equipment), employment and recruitment agreements, and joint ventures, for example, may implicate the Federal Anti-kickback Statute.



Manipulating Physician Prescribing Practices: A Drug Rep's "Tell All" Article

**Fugh-Berman, Adriane and Ahari, Shahram.
"Following the Script: How Drug Reps Make
Friends and Influence Doctors," PLoS
Medicine: 2007, Vol. 4, Issue 4, 0621-0625.**

- **Former drug rep "tells all" about
pharma marketing practices towards
physicians**
- **Trained to assess physicians'
personalities, practice styles, and
preferences**
- **Tactics for manipulating physicians
based on physician's personality**

Manipulating Physician Prescribing Practices: A Drug Rep's "Tell All" Article (cont'd)

Methods used in "detailing" depends on physician personality:

- **"Friendly and engaging" – every rep's favorite; cultivating "friendship" is goal**
- **"Aloof and skeptical" – reps are armed with journal articles and other evidence-based documentation for the physician**
- **"Mercenary" – applies to docs that reps want to "buy out" – closely associate gift with prescribing expectation**
- **"High prescribers" – receive better gifts; those gifts are used to induce guilt and social pressure to prescribe drug**
- **"Hard to see docs" – reps provide food to office staff – they become advocate for drug rep**
- **"Thought leaders" – provide lectures; reps look for allegiance by prescribing practices**

Manipulating Physician Prescribing Practices: A Drug Rep's "Tell All" Article (cont'd)

Prescription Tracking

- **Pharmacies sell prescription records to pharma**
- **Patient names not provided; physicians only identified by number**
- **AMA maintains database linking numbers to names; obtained \$44 million in 2005 from sales of database information**
- **Pharma tracks scripts and physicians are rated on a scale of 1 to 10 based on being a "low" or "high" prescriber**
- **Pharma also tracks to see effects of gifts, promotions, etc.; identify docs who are most susceptible to marketing efforts.**



Manipulating Physician Prescribing Practices: A Drug Rep's "Tell All" Article (cont'd)

Value of Samples

- **Samples make both physicians and patients happy; allows reps to gain entry into office**
- **Article noted that studies “consistently show that samples influence prescribing choices.”**
- **Patients given a sample for a portion of a course of treatment are usually prescribed the same drug for the remaining treatment course.**

Legal/Regulatory Landscape

Settlements under False Claims Act

- **Serono (\$567M):** Admitted to providing physicians trips to France in exchange for certain number of prescriptions for new drug

- **TAP (\$875M) and AstraZeneca (\$355 M):** Federal anti-kickback statute implicated for marketing practices
 - “educational grants” to encourage use of product
 - Free trips, funding office holiday parties, lavish meals
 - Payment for inconsequential drug studies
 - Cash payments for small record-keeping tasks

Legal/Regulatory Landscape

Settlements under False Claims Act

- **Bristol-Myers Squibb (\$328M):** BMS paid kickbacks to doctors in the form of bogus consulting fees to induce them to purchase BMS's drugs; off-label marketing of its drug, Abilify; kickbacks to wholesalers and retail pharmacies to induce purchases of generic products.
- **Zimmer, Inc.; Depuy Orthopaedics, Inc.; Biomet Inc., and Smith & Nephew, Inc. (\$311M):** Companies used consulting agreements with orthopaedic surgeons to induce the purchase of their devices. Firms paid surgeons hundreds of thousands of dollars a year for consulting contracts and provided lavish trips and other expensive perks in exchange for using the companies' products exclusively.



Legal/Regulatory Landscape

FDA Prohibition on Marketing Off-Label Use of Drug

- **Once a drug is approved, the drug may not be legally marketed or promoted for any use not specified in the new drug application (and which was approved by the FDA).**
- **In 2004, Pfizer paid \$430 million to settle allegations it marketed the epilepsy drug Neurontin for pain and psychiatric illnesses (some say this was a mere “slap on the wrist” since sales of the drug reached \$2.7 billion in 2003).**
- **Schering was ordered to pay \$435 million to settle allegations related to illegal promotion of Temodar and Intron A for the treatment of certain cancers without approval.**

PhRMA Guidelines on Interactions with Healthcare Professionals

Effective July 1, 2002; updated 2004

Newest version effective January, 2009 and may have significant impact on pharma marketing practices

- **Informational Sessions and Meals to Physicians and Staff**
 - **Occasional meals are acceptable provided they are (i) modest value; (ii) are not part of an entertainment or recreational event; and (ii) provided in a manner conducive to informational communication**
 - **Cannot include spouses or other guests; take out meals not appropriate**
 - **As of January, 2009, meals associated with informational sessions must only be provided in the office or hospital settings; no longer allowed to provide meals at outside restaurants.**
- **Company speaker programs may be conducted outside the office or hospital setting provided that the venue is conducive to informational communication and the meal is modest as judged by local standards**

What To Do?

- **Be aware of industry guidelines**
- **Notify sales reps when those are violated**
- **Establish policies in your office regarding vendor/physician interactions**
 - **Meals**
 - **Education**
 - **Access of reps to physicians**
- **Educate your fellow physicians about exposure for being on receiving end of non-compliant marketing practices**
 - **Civil/Criminal fines and potential jail time**



Federal Prohibition on Physician Self-Referral (Stark Law)

➤ History:

- **Physician ownership in labs; saw marked increase in ordering of lab tests**
- **Original Stark law only applied to lab services; now much broader including, but not limited to, all inpatient and outpatient services**
- **Must satisfy regulatory “safe harbor” otherwise per se violation of rule; no intent necessary to violate law**



Federal Prohibition on Physician Self-Referral (Stark Law)

- **Governs most financial relationships between physicians and referral sources (even members of same group practice)**
- **Space and equipment leases, any type of ownership or compensation relationship, employment arrangements, independent contractor arrangements between an entity and a referral source**
- **Examples of requirements:**
 - **Written agreements**
 - **Term of one year**
 - **Compensation “set in advance”**
 - **Compensation cannot vary with volume or value of referrals**
 - **Fair market value for services/equipment**

Research

➤ **Clinical Trial Billing**

- **Cannot bill third party payor for items or services being provided “free” in trial or being paid for by the sponsor**
- **As PI, must be sure to notify institution’s finance department of billing status**
- **Medicare now pays for certain “routine costs” for patients involved in a Medicare “qualifying clinical trial,” provided that services associated with those costs are not promised “free” or being paid for by the sponsor**
- **Must perform coverage analysis looking at all services that will be provided as part of the protocol.**
- **Helps with negotiating study budgets with sponsor.**



Importance of Compliance Programs

- **Required by law as of January 1, 2007**
- **Maintain institutional reputation, credibility**
 - **Public confidence**
 - **Ability to attract and maintain top-level physicians and scientists**
- **Possible reduction in fines if found to have an “effective compliance program”**
- **Avoidance of a “corporate integrity agreement” (government-mandated compliance program)**
- **Expect Administration and physicians to set the “tone” for organizational compliance and ethics; other staff look to them for leadership and direction**



BSOM Compliance Program

- **Wide range of activities to help prevent, detect, and avoid fraud and abuse**
- **BSOM Compliance officer, BSOM compliance committee, risk assessment, monitoring, education, recommendation of disciplinary action, reporting system for potential incidents of non-compliance.**
- **BSOM contracts review process to help maintain compliance with Stark law and Federal Anti-kickback law, among others**
- **Monitoring program for provider documentation**
 - **Random and targeted reviews**
 - **Always provide follow-up review and education for provider**



BSOM Compliance Program (cont'd)

➤ BSOM Conflict of Interest

- **All EPA Faculty disclose COI annually**
- **Research Investigators – prior to submission of proposals**
- **COI Management Plan**



BSOM Compliance Program (cont'd)

➤ BSOM Code of Conduct

- **All employees required to sign**
- **Carefully read and understand terms**
- **Condition of employment**
- **Annual attestation required**



Reporting Incidents of Potential Non-compliance at BSOM

- Encouraged to use supervisors, administrators as the first line of reporting of any known incidents of noncompliance.
- **BSOM Compliance Hotline**
 - Available 24 hours a day, 7 days a week
 - Can be anonymous
 - Toll free 1-866-515-4587
 - E-mail bsomcompliance@ecu.edu
- No retaliation for good faith reporting of incidents of noncompliance.
- All good faith reports will be fully investigated.
- Confidentiality maintained to the fullest extent possible.
- Physicians and staff have a professional duty to report potential problems.



Office of Compliance at BSOM

- **Serves as a resource to all faculty, learners, and staff**
- **Contact information:**
 - **Micki Jernigan, JD, MPH**
Chief Compliance Officer
 - **jerniganm@ecu.edu**
 - **744-5200**