ASLMS Annual Meeting Special Coverage

Legal and Compliance Issues Impacting Medical Practices Using Laser Technology

Medical practices that routinely use laser technology are subject to some of the same legal issues as other types of practices. Use of lasers creates additional compliance issues and highlights certain compliance risk areas. This special coverage issue contains articles on some of the legal issues impacting these practices.

- *Compliance Program Operation.* All medical practices should have an active compliance program effective at identifying risk areas and taking steps to ensure compliant practice. Risk areas specific to the practice should be integrated into a continuously operating compliance program.
- *Fraud and Abuse.* Fraud penalty calculations under the False Claims Act (FCA) result in exorbitant penalties, even based on otherwise reasonable overpayment amounts. There has been a steady flow of fraud and abuse cases involving practices using lasers, even where there is no actual knowledge of a non-complying practice.
- *60-Day Repayment Rules.* Federal law provides an overpayment not repaid within 60 days after discovery becoming a false claim and exposes the practice to the draconian remedies under the FCA summarized above. This requires practices to establish standard policies identifying how overpayments are handled. Mistakes made in this area can be extremely costly.
- *Whistleblower Risks.* The recent fraud cases are being used aggressively as advertising by attorneys who focus on whistleblower cases. Whistleblower lawyers take their cases on a contingency fee basis and encourage cases be brought under the Draconian damage provisions in the federal FCA.
- *Supervision of Physician Extenders.* Proper supervision of physician extenders is dictated by state law and reimbursement requirements (for example "incident to" rules under Medicare). Every medical practice using physician extenders should have written policies on supervision which clearly communicate requirements to physicians and staff. Documentation of appropriate supervision is also necessary.
- *Tele-dermatology Issues.* The use of telehealth technologies is rapidly increasing. Dermatology is one specialty area that benefits from the expansion of telehealth using both real time and "store and forward" technologies. The use of telehealth in the practice of dermatology facilitates expert consultation and long distance examination reaching into remote areas.
- *HIPAA Stage 2 Audits.* As OCR continues to move forward with its multi-stage audit program, the consequences of OCR finding a deficiency in HIPAA practices are becoming more serious. A systematic review of HIPAA policies and procedures should be conducted to ensure all required elements are covered.

Also in this issue ...

Practice Team

	John Fisher, CHC, CCEP jfisher@ruderware.com
	Bob Reinertson rreinertson@ruderware.com

The 60-Day Repayment Rule – "Innocent" False Claims

False Claims can happen to any provider. Under recently enacted federal law, a provider is obligated to return overpayments to the federal government within 60 days following identification. Failure to repay the overpayment within 60 days makes the overpayment a False Claim. False Claims Act penalties can easily turn a relatively small and manageable overpayment into a potentially business ending event. Penalties under the FCA are three times the overpayment plus up to $21,563 per claim. The per claim penalty is significant in an industry where numerous claims are made each day.

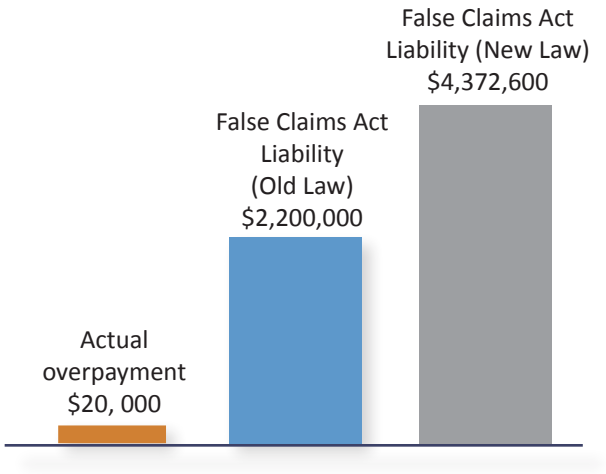
Potential FCA penalties create a strong incentive for providers to repay identified overpayments promptly. The problem is that an overpayment does not have to be "actually identified" to be considered "identified" under the "False Claims Act." Identification can be imputed to a provider if reasonable steps are not taken to discover a potential overpayment. The standard is not whether a provider actually knows about an overpayment, but whether they should know.

The government does not stop the inquiry if it is evident the provider had no knowledge the overpayment existed. Even if repayment is made within 60 days of obtaining knowledge, the government can still apply FCA penalties if they believe the provider should have known about the overpayment earlier. This is why providers need to actively look for problems as part of an ongoing compliance program.

What is the Solution to Reduce FCA Risk?

1. *Identify areas that present potential risk of overpayment.*
2. *Self audit those areas to help proactively identify overpayments.*
3. *Promptly repay identified overpayments.*
4. *Consider with legal counsel whether self disclosure is appropriate.*

False Claim Damages Over
200 Claims/Day @ $100/Claim



The False Claims Act – Application of the Lincoln Law to the Health Care Industry

When Congress originally passed the False Claims Act (31 USC §§ 3729-3733), no one had the modern health care system in mind. The FCA (commonly referred to as "Lincoln's Law") was focused on unscrupulous vendors who provided overpriced and often faulty supplies to the military during the Civil War.

The False Claims Act was strengthened in 1986 in response to some of the much publicized $1,000 toilet seats and other abuses with respect to companies supplying the United States military. The 1986 amendments to the False Claims Act provided for treble damages plus civil penalties of between $5,000 and $11,000 per claim. These legislative changes were intended to add real incentive for *qui tam* litigants to bring fraud claims.

The health care industry was never the real target of the False Claims Act. In health care, a single provider makes multiple claims to the federal government every day. False claim allegations can cover a number of years, greatly increasing the number and value of claims that may be at issue. When treble damages plus $5,000 to $11,000 per claim are applied on top of the actual amount of a "fraudulent" claim, the obligation amount can become staggering. See above graphic.

The Federal government is quite content to leave these disproportionate penalties in place as part of its effort to reduce the cost of health care and to generate additional revenues. The government is taking a "return on investment" approach to health care fraud enforcement and makes at least eight dollars for every dollar it spends pursuing health care fraud cases. Many cases involve people who intentionally try to defraud the system. A good number are based on imputed knowledge; things the government believe a provider "should know" through operation of an effective compliance program.

Clarification of Medicare Rules for Billing Physician Extenders

It is increasingly common for physician practices to utilize nonphysician personnel. ASLMS has been in the forefront of developing guidelines for use of lasers by nonphysician staff. Guidelines assure proper training and licensure of staff and establish supervisor requirements for delegating physicians.

Issues relating to supervisor requirements and licensing requirements are generally covered under state law. Medicare has separate standards that must be observed when the services of physician extenders are billed “incident to” the services of a physician.

The "incident to" rules permit services or supplies furnished as an integral, although incidental, part of the physician's personal professional services in the course of diagnosis or treatment of an injury or illness be reimbursed at 100% of the physician fee schedule, even if the service is not directly furnished by the billing physician.

The “incident to” rules require direct personal supervision by the physician. The supervising physician does not necessarily need to be present in the room where the procedure is being performed. The “direct supervision” standard requires the supervising physician to be “physically present in the office suite and immediately available to furnish assistance and direction” during the time the auxiliary personnel is providing the service.

The 2016 Medicare physician payment rule provided some clarification on how the direct supervision requirement under the “incident to” billing rules operates. The new rule clarifies the physician who directly supervises the applicable auxiliary personnel is the only party who can bill the service of the auxiliary personnel as “incident to” his or her service. CMS considers this a clarification of its long-standing policy, but many providers will see this as a new restriction on the application of the “incident to” rules.

Prior to this “clarification,” the physician who originally ordered the service might have billed the service as “incident to” even though another physician actually supervised the performance of the service. The revised regulatory language clarified that only the physician actually present in the office suite who supervises the service can bill for the service as “incident to” their service. When making a claim for services billed “incident to” a physician’s services, the billing number of the physician that actually supervises the performance of the service must be used rather than that of the ordering physician.

Creating Effective Physician Compliance Programs

In today's environment of complex regulations, aggressive prosecution, exorbitant penalties, and hungry whistleblower attorneys, it is necessary for medical practices to maintain effective compliance programs. Failure to do so puts the practice at a great deal of unnecessary risk. Most practices will eventually make errors in their billing and collections or other regulatory areas. Self-discovery of these issues is unpleasant but manageable. Discovery by a government enforcement agency or a whistleblower can be personally and financially devastating.

> *A laser technology program should address the seven core elements of an effective compliance program and practice-specific risk areas.*

A compliance program creates a systematic process proactively operating to discover potential regulatory risks, to audit and monitor identified risk areas, and to take action to correct discovered deficiencies. A compliance program contains seven core elements without which a program will not be effective. The seven core elements include: compliance oversight, policies and procedures, compliance reporting system, training and education, discipline and enforcement, risk identification, and a corrective action process. Having an active compliance process in place will help identify and correct issues before they are the subject of enforcement or legal action.

A typical compliance program will also include policies and standards covering the primary risk areas specific to the practice. For example, a health care provider is exposed to potential risk in billing and coding and will need to have policies and procedures covering general billing practices supplemented with specific billing requirements pertaining to their specific practice area. Risk area policies and procedures establish requirements and communicate them to staff. They also establish a baseline against which auditing and monitoring activities can be measured.

Three Recent Fraud Cases Involving Dermatologists Illustrate Primary Compliance Risks in Dermatology Practices

Three relatively recent cases involving dermatology billing practices illustrate some of the main compliance risks faced by dermatology practices. These risk areas include: improper use of multiple removal CPT codes; billing for "impossibly long days;" and, failure to follow supervision rules required to permit "incident to" billing.

Improper Supervision of Physician Extenders. An allegation from a competing dermatologist resulted in accusations that a Florida dermatologist charged the Medicare program for approximately $49 million in unnecessary biopsies and radiation treatments that were not rendered, not properly supervised, or were given by unqualified physician assistants.

There was evidence the doctor was not in the country while some of the services were performed. The doctor alleged he was available by phone while the procedures at issue were being performed. The Medicare "incident to" billing rules require the physician to be in the same office suite while the service is being performed.

Excessive Use of Multiple Removal Codes. A dermatologist was convicted of Medicare fraud for submitting false claims for more than 800 patients that led to payment of reimbursement of approximately $2.6 million. One of the primary allegations involved falsely documenting hundreds of cases of medically unnecessary cosmetic treatments that he reported as involving the removal of lesions (CPT 17004). The physician allegedly billed under the CPT code applicable to the removal of 15 or more lesions on a more or less routine basis. This was allegedly done on hundreds of repeat patients over a number of years. Patients received this treatment during 10 or more visits.

Impossibly Long Days. In a third case, a dermatologist paid a hefty penalty for submitting bills that reflected impossibly long work days using the time value assigned to the applicable RVU.

These cases involve extreme situations but hold lessons for providers in more ordinary circumstances. For example:

- Care should be taken when using multiple removal codes such as 17004. These types of codes should not be used systematically. Over time the numbers of removals add up to indicate potential fraud.
- The record should be accurately and completely documented to support the use of multiple removal codes.
- Care should be taken not to bill codes relating to time increments or work units that, in the aggregate, result in an unrealistic amount of time in any given day.