

# Business Law and the Practice of Otolaryngology

**Robert S. Ivrey   Stephanie P. Ottenwess   Jessica L. Gustafson**  
**Kathryn Hickner-Cruz   David M. Ottenwess   Reginald Baugh**

With the continuing avalanche of new regulations, the ever-tightening belt of third party payor reimbursement, the increased scrutiny by federal and state enforcement authorities, the increased emphasis on cost-containment and pay-for-performance measures, and the always looming threat of medical malpractice actions, physicians find themselves having to play the role of accountant, attorney, billing consultant, business manager, financial advisor, risk manager, and, if time permits, practicing physician. Long past are the days when a physician could simply devote virtually all of his or her professional time seeing patients and providing high-quality care.

In today's environment, physicians must still focus on providing high-quality care to their patients; however, they may also need to delegate certain aspects of the business side of medicine to the right individuals in order to optimize their success. This may seem counterintuitive to some in that in order to maintain control over their practice as a whole, physicians must learn to let go of some of the pieces.

The most important first step to gaining or regaining control over one's practice is to identify key advisors and specialists. Selecting an experienced health care attorney and an accountant with significant experience in representing physicians and physician practices is crucial as they can help navigate through the often murky waters of the health care regulatory landscape. There are numerous legal and accounting aspects of starting, maintaining, expanding, merging, and even closing a medical practice that require professional advisors to guide physicians so as to avoid the myriad of serious negative consequences that can result from noncompliance with the ever-changing rules of the game. Some of these consequences include, but are not limited to, overpayment demands by third party payors, debarment or exclusion from third party payors, civil fines, and even criminal sanctions. Experienced, qualified health care attorneys, accountants, and other advisors can mitigate against the risks of facing such consequences as well as assist in crucial administrative matters for example, obtaining

and maintaining the appropriate licenses (such as one's medical license, controlled substance license, drug control license, and Drug Enforcement Administration [DEA] registration), obtaining the best financing for medical and office equipment and supplies, obtaining the appropriate insurance (e.g., professional liability, personal liability, property, workers' compensation, directors and officers liability policies, and even policies now available to insure against fines and defense costs for billing errors and omissions).

Some physicians find it helpful to consult with a business advisor as well to sit down with the other professional advisors and to help develop a business plan based upon the physician's desires and needs. Such plans may include staffing determinations, changes in physical location, adding ancillaries such as imaging and laboratories, marketing, and developing affiliations with other health care providers, entities, and organizations. Prior to implementing such plans, it is a good idea to run them past one's key advisors to assure legal compliance.

Another important step is to make sure that the physician has a good understanding of where his or her practice stands in terms of the billing of professional services rendered. Remember, a physician alone is responsible for the use of his or her provider number. Whether one chooses to do his or her own billing, to employ an in-house biller, to contract with an outside company, or to rely upon his or her employer, ultimately the physician is responsible for the claims submitted under his or her provider number. Thus, if a physician chooses to rely upon others to do his or her billing, the physician should make sure that he or she has the requisite knowledge and experience in his or her specific field of practice. Being proactive, asking the right questions, and researching the prospective biller prior to engagement are time well spent and can save the physician significant headaches in the future. While the enforcement authorities *may* find that the physician did not have the requisite intent for criminal prosecution because his

or her biller made the errors and not the physician, the physician will still incur significant costs in both time and money defending the billings, and very often, the physician is subject to significant fines and penalties on top of returning monies to which the physician believed he or she was entitled and upon which he or she relied in the operation of the practice. As such, the physician needs to be familiar with the billing rules as they pertain to his or her specific area of practice. Responsibility for this knowledge and expertise should not be delegated.

Of course, no chapter on the business of medicine would be complete without discussion of medical malpractice and the efforts to reform the system—which to many appears broken and sorely in need of repair but without a viable solution. For the past three decades, medical malpractice tort reform has remained a highly polarizing, heavily contested legal issue, which affects not only physicians and attorneys but also the great many Americans seeking health care each year. But why does this legislation inspire such fervency in those that revile it and in those that champion it? Ask its critics, which typically include much of the plaintiffs' bar, and the answer is simple: medical malpractice tort reform strips individuals of their ability to redress injuries that they have incurred and right the perceived wrongs that have been committed against them. To its advocates, the answer is equally clear: medical malpractice tort reform is the mechanism by which defensive medicine is prevented, doctors' personal and professional livelihoods are protected, and litigious plaintiffs with frivolous lawsuits are deterred from bringing suit. While both sides make frequently valid and often convincing arguments, the reality of medical malpractice tort reform lies somewhere in the middle. It is a legislatively constructed concept, which has made its impact, both positive and negative, on the American legal landscape.

The purpose of this chapter is to provide the physician with a general overview of some, but not all, topics of interest to otolaryngologists regarding the business of medicine. It is by no means an exhaustive list as health care is a broad field and highly regulated with ever-changing laws, regulations, rules, advisory opinions, guidance, and contractual provisions. The goal of this chapter is to provide the physician with a business perspective of medicine and to arm the physician with enough insight and business savvy to recognize certain risk areas so that the physician may timely seek appropriate assistance in compliance with such areas and avoid the negative consequences often associated with a lack of knowledge.

## MEDICAL LIABILITY

### Medical Liability Claims in the United States

#### Introduction

Medical malpractice, or negligence law, is just one subset of the legal behemoth that is tort law. A tort is generally defined as a civil wrong that causes an injury, for which a

victim may seek damages, typically in the form of money damages, against the alleged wrongdoer (1). Tort law is that body of law that serves as the vehicle by which tort liability can be sought in a court of law against such wrongdoers and generally serves to award damages to a victim sufficient to restore him to the position he would have been in, had the tortious conduct not occurred (1). Tort law typically governs three types of causes of action or, more simply phrased, legal theories of a lawsuit: negligence, strict liability, and intentional torts. A claim for negligence is brought when an injury results from an individual's failure to exercise the standard of care of a reasonably prudent person would have exercised in a similar situation (2). These matters involve unintentional acts that may cause harm. Actions for medical malpractice are classified under the umbrella of negligence claims. Claims for strict liability do not require an intent to harm or the presence of actual negligence but rather are based on the breach of an absolute duty to make something safe (3). Strict liability typically arises in situations that are considered inherently dangerous. For example, an individual who keeps a domesticated Siberian tiger in his home is strictly liable for any injuries that the tiger may cause, no matter the precautions the individual takes in protecting the safety of others. He need not be found to have breached the standard of care to be found strictly liable in such scenarios. Finally, intentional torts are defined as torts committed by a wrongdoer acting with intent (4). Examples of intentional torts include assault and battery, defamation, and false imprisonment.

#### Historic Analysis of Tort Law and the Evolution of Medical Malpractice Action in the United States

The modern system of American tort law and its district categories are by no means a recent construct. Tort law has existed in some form for hundreds of years, originating from English common law. Common law is defined as law that is issued from judicial decisions and not derived from legislatively enacted laws or statutes. Consequently, centuries-old decisions made by judges in England have greatly affected how the US legal system addresses actions for negligence, strict liability, and intentional tort. Taken one step further, the law that is applied in the most complex medical malpractice case can trace its ancestry to an English judge deciding whether a Welsh farmer's horse was negligently corralled during the 15th century.

The element of damages in tort law is of major significance and is integral to understanding the overall concept of medical malpractice law, mainly because the "runaway juries" have been the subject of great media attention and scrutiny. In tort law, compensatory money damages can be sought by a victim for both economic and noneconomic losses (5). Economic damages seek to compensate an individual for quantifiable economic losses, such as lost income and medical bills, while noneconomic damages are more speculative and seek to compensate an individual for noneconomic losses, such as mental distress and pain and

suffering (5). In certain rare scenarios, generally involving egregiously reckless conduct or behavior, a victim may also seek punitive damages against a wrongdoer (6).

Tort law is a function of state law, with each state providing different rules for bringing about a tort claim.<sup>1</sup> Procedurally, various states may approach tort claims differently; however, the basic premise of a tort claim and the elements that a plaintiff must prove in order to bring a successful cause of action remain consistent across all 50 states. This chapter focuses its state-specific discussion of tort law and medical malpractice tort reform on the state of Michigan and utilizes Michigan's experience with medical malpractice tort reform to illustrate how, in recent years, many states have attempted to handle the rising number of suits for medical malpractice.

The modern medical malpractice system in this country dates its origins to the 1840s, when the United States experienced a sudden surge in the number of medical malpractice actions brought in state courts (7). This boom could be attributed to the lack of a national "standard of care" for medical treatment, which often left patients seeking care from unqualified or unskilled medical practitioners (7). As the number of medical malpractice actions spiked, plaintiffs' attorneys also found a new niche in which lucrative careers could be made, primarily due to the availability of contingency fees, wherein a plaintiff's attorney receives as his fee one-third of the plaintiff's overall jury award or settlement. This time frame is typically considered the first medical malpractice "crisis," and the commencement of the long and complicated interplay between the medical community and the legal system.

The second significant medical malpractice crisis in the United States occurred in the 1970s and 1980s (7). During this time period, there was a rapid rise in the number of medical malpractice claims filed, as well as the size of awards made in medical malpractice actions. It has been estimated by the American Medical Association (AMA) that in 1975 as many as 14,000 malpractice suits were filed against physicians. The average jury award in these suits was \$171,000 (7). The influx of medical malpractice claims and their subsequent jury awards created a chain reaction that had a far-reaching effect. Many private insurance companies began withdrawing from providing insurance coverage, and the insurers that remained responded by raising

malpractice premiums. In 1975, it was documented that malpractice premiums had increased from anywhere from 100% to 750% (7). The sudden increase in insurance premiums, coupled with the loss of many private insurance companies from the market, resulted in some physicians leaving particular practice areas, or retiring from the practice of medicine altogether. It was the culmination of these factors that sparked a call for policy change at both the state and federal levels, and with that, modern medical malpractice tort reform was born.

Before addressing tort "reform" and its impact on the physician's practice, it is important to understand the anatomy of a modern medical malpractice case, as oftentimes the physician is quick to equate "reform" with the altogether elimination of medical malpractice claims from the American legal system. It is not the legal system, however, that is broken. Our civil litigation system has existed for centuries; it is only because it is so interwoven with and dependent on the human element that we see it as controversial. Consequently, a description of a malpractice action is in order that will outline the "theory" of litigation along with the "reality" of being a party defendant in a medical malpractice case.

## Medical Malpractice Litigation

### Anatomy of a Medical Malpractice Case<sup>2</sup>

#### General Legal Background

As a practicing physician with a highly advanced degree, years of sophisticated training, and a hard-earned professional license to protect, it is important to gain an understanding of the basic elements of a medical malpractice claim and the procedural aspects of bringing a lawsuit in order to best understand how to limit your exposure to claims of medical negligence. In today's legal environment, physicians often think that a lawsuit is a natural consequence of any "bad result" arising out of care provided to a patient. While a bad result should put the physician on alert that a suit may be on its way, a bad result does not, in and of itself, qualify as a legitimate malpractice claim. To bring, and sustain, an action for medical malpractice, the plaintiff bears the burden of establishing the four basic elements required of any negligence claim, with some variations. Specifically, the plaintiff must establish (a) that a physician or health care provider owed the plaintiff a duty of care, (b) that this duty of care was breached by conduct that was not in accordance with the standard of care that a reasonable physician would have employed under like circumstances, (c) that this breach was a cause of the plaintiff's injury, and (d) that the plaintiff suffered damages as a result of this breach (8).

<sup>1</sup>While tort law is primarily a function of state law, there is a Federal Tort Claims Act ("FTCA"), enacted in 1948, that provides that a private individual may sue the United States in a federal district court for most torts committed by persons acting on behalf of the United States. The FTCA imposes some limitations upon actions brought under the Act, specifically that the action must be brought in federal, rather than state court, the matter must be heard in a bench trial, presided over by a judge, and that the United States is not liable for any punitive damages sought by the plaintiff. In a medical malpractice context, claims brought pursuant to the FTCA most typically arise when an individual sues a VA or military hospital for medical negligence.

<sup>2</sup>Most of the authors' medical malpractice work arises out of claims filed in the State of Michigan. Consequently, examples and case law cited here will often involve specific Michigan rules and statutes.

In regard to the third element of causation, a physician's allegedly tortious conduct must be both the cause in fact and the proximate cause of the victim's injury. The cause in fact (or "but-for" cause) of a plaintiff's injury simply means that but for the physician's conduct, the injury would not have occurred. Proximate cause is a complex legal concept, one that is particularly vexing to first-year law students, but essentially, proximate cause can be defined as the initial conduct or act, which sets off a natural and continuous sequence of events that produces an injury.<sup>3</sup> In order for a plaintiff to successfully bring an action for medical malpractice, he or she must establish that the defendant's actions were both the cause in fact and the proximate cause of his or her injuries. Thus, because a bad result may be a natural consequence of treatment, there is no viable claim until a similarly situated physician testifies that the defendant physician breached the standard of care *and* that the breach was a cause of plaintiff's injuries.

### Presuit

In a vacuum, a patient who suspects that he or she has been the victim of medical malpractice will retain an attorney who will determine if the plaintiff has a viable claim. If the attorney believes there is evidence of a physician's negligence, the attorney will conduct an investigation, which requires having a qualified physician look at the medical records involved and offer an opinion whether proper treatment was rendered in the case in question. Once the attorney is convinced that the expert will testify adequately about the legal requirements of duty, standard of care, and proximate cause, the attorney may initiate a lawsuit by filing a complaint, almost always in state court. But, in some instances, there may be ways to avoid a lawsuit and circumvent the entire adversarial litigation process.

As a practical matter, a patient who may feel that he or she received inadequate medical treatment due to negligence knows little or nothing about the "burden of proof" or what other legal requirements are necessary to proceed in a court of law. Consequently, a patient who has a negative experience is angry and wishes some redress or, if nothing else, a bit of an explanation as to why *he* fell into that small percentage of patients that his physician quoted as being at risk of a potential complication from the medical treatment in question. As a result, a patient really may only be looking for answers, rather than an attorney.

It is during this period that, in some instances, a physician can head off a lawsuit if her office is receptive to the patient's concerns. Some physicians have gone to great lengths to avoid speaking directly to patients about the

"mechanics" of medicine when a less than optimal result has occurred. However, avoidance or vagueness almost always instills suspicion and can, by itself, be the impetus for a patient to head to the nearest attorney's office. One course of action to follow is to be as straightforward and direct with the unhappy patient as possible and to speak with them at length about their complaints if they seek out an explanation. Also, a physician should provide a patient with any requested medical records and may offer to refer a patient to another physician, if the patient so desires. While it is not in the physician's best interest to admit that anything he or she did was inappropriate (unless, of course, what he or she did *was* inappropriate, and then you must let your conscience be your guide), being empathetic to the patient's plight may even go so far as to head off a potential lawsuit.

### Suit Filed: Discovery

Assuming that the patient is neither placated nor interested in an informal discussion about the patient's medical care and an attorney is retained who has obtained a positive review from an expert, the formal action is begun in court by filing a pleading known as a complaint.<sup>4</sup> The complaint initiates a civil action and outlines with specificity the basis for the plaintiff's medical malpractice claim and the relief that the plaintiff seeks (9). The complaint is then filed upon the opposing side, who in response must file an answer, which is the defendant's first pleading that addresses the merits of the case and generally denies the plaintiff's allegations and sets forth any of the defendant's defenses and counterclaims (10).

After the complaint and answer have been filed, the pretrial process of gathering evidence to support either party's position, referred to as the discovery stage of the proceedings, begins. During discovery, interrogatories are exchanged between the parties, which are written sets of questions that are required to be answered candidly. Also during the discovery period, depositions of the relevant witnesses are taken. A deposition is a witness' out-of-court testimony, which is taken under oath and recorded for later use at trial or to further additional discovery (11). Depositions are a critical part of the discovery process, as they assist counsel for both parties to focus their discovery requests and identify important issues to be addressed at trial.

The discovery phase of the lawsuit is really the nuts and bolts of the litigation process. The physician learns exactly the nature of the charges being advanced by the patient and what steps will be necessary to defend against the claims. In Michigan, the defendant physician will get some early

<sup>3</sup>Proximate cause "normally involves examining the foreseeability of consequences, and whether a defendant should be held legally responsible for such consequences." *Skinner v Square D Co*, 445 Mich 153, 163 (1994).

<sup>4</sup>In some states, such as Michigan, a Notice of Intent to File Claim (NOI) must be served before a formal complaint may be filed with the Court. An NOI puts potential defendants on notice that a case *may* be filed. By law, a claimant must wait approximately 6 months after serving the NOI before proceeding to a court action by filing a legal complaint.



inkling of the specific claims of malpractice being brought, as the plaintiff must file an affidavit of merit with the complaint. This affidavit must be executed by a similarly trained and certified physician who is prepared to testify as an “expert” witness that the defendant physician committed professional negligence. The entire scope of the expert’s opinions, however, does not materialize until the witness is actually deposed. It is during the deposition of the expert that the attorneys are given, relatively speaking, free rein to delve into the bases of the expert’s opinions and to examine the expert’s background and training to verify whether the expert has adequate credentials and/or the adequate background to testify in the case.

Before depositions of experts can be completed, the defendant physician must undergo his or her own deposition. Short of trial, this is typically the most difficult part of the litigation process for a physician. A physician must be very well prepared for his or her deposition testimony, as such testimony usually only can “lose” a case and rarely ever results in one getting dismissed. It is therefore imperative that the pertinent medical records are reviewed in great detail prior to the physician’s deposition and that the physician meet with the attorney well in advance of the deposition to ensure a comfort level for both the physician and the attorney. With the expense involved in litigating medical malpractice actions, the defendant physician can fully expect the plaintiff’s attorney to be well prepared for the deposition, which makes it crucial that the physician not take the procedure lightly. While the actual process one must undertake to get ready for a deposition could fill another chapter, suffice it to say, the more prepared one is for grueling questioning, the better off the defense of the case will be. Remember, the plaintiff’s attorney is not only listening to your every answer; she is also sizing you up to determine just how well you will present before a jury and exactly how you will handle yourself under difficult circumstances.

Having survived the deposition process, it may appear that your case has suddenly disappeared; do not be misled. The lull in the action is only due to the fact that your attorneys are now turning their sights toward taking the discovery of either other defendants or the plaintiff’s expert witnesses. This process can usually take several months and only makes it *appear* as if nothing is moving.

### Expert Witnesses

In a medical malpractice action in Michigan, as is true in virtually every state, the plaintiff *must* secure medical expert testimony in order to advance the case before a jury.<sup>5</sup> That

is to say, before a jury can actually decide the merits of the case, the plaintiff must present expert testimony that the defendant physician breached the standard of care during the treatment of the patient and that that breach was a cause of injury to the plaintiff. This testimony is required because the typical jury does not, as a whole, have the requisite knowledge to decide intricate questions of medical treatment without the assistance of a qualified expert witness. Just what constitutes a qualified expert witness is a matter of discretion for the trial judge and is one of the “human elements” that make litigating a case more difficult. For instance, the judge may have a more liberal interpretation of what the expert needs to be “qualified,” which can be frustrating to the defendant.

Because there are no standard rules regarding what is “proper” expert testimony, the use of expert witnesses in medical malpractice cases has become a main source of contention for many advocates of medical malpractice tort reform. As filings of medical malpractice lawsuits have increased throughout the country, the provision of expert witness testimony has become very lucrative for physicians across all medical disciplines. As a result, proponents of tort reform argue that because of the ease at which an expert can be retained to offer expert testimony on a medical malpractice claim, it is increasingly easier for plaintiffs to bring such claims, exacerbating the medical malpractice crisis in the United States. Thus, while theoretically the parties should get well-trained, credible, and reliable experts to testify, this is not always the case.

As a practical matter, proposed expert witnesses are not always bound by their ethical and moral obligations. Because the standard of care is, in most circumstances, neither codified nor objective in nature, there may be wide disagreement as to what really constitutes the “standard of care.”<sup>6</sup> For the most part, experts, while genuine in their opinions, will oftentimes confuse their own practice, or what they believe the practice should be, with a national standard of care. For instance, while it is inappropriate for a physician in Michigan to testify about the standard of care in relation to what he or she does or does not do in their practice personally, many experts do just that. Because it is difficult to verify oft-stated, sweeping generalizations made by an expert that their opinions “are common knowledge,” “may be heard at any meeting,” or “can be readily found in the literature,” the defendant physician may risk that a jury will simply accept unsupported statements as true because they do not possess the requisite knowledge of the subject matter. While steps can be taken to hold an expert’s feet to the fire on certain medical issues, a liberal judge or

<sup>5</sup>In most states, the defendant physician is not necessarily *required* to secure an independent expert to testify on her behalf at trial as the defendant physician is considered an expert in her own right. As a practical matter, however, defense counsel almost always retains an independent, similarly situated physician to assist in the defense of the claim.

<sup>6</sup>In Michigan, the standard of care is defined as what an ordinary board certified physician would do or not do under like or similar circumstances. *Patelczyk v Olson*, 95 Mich App 281, 283; 289 NW2d 910 (1980).

sympathetic jury may be persuaded by an expert who does little else but sit in an office and testify against physicians.

Indeed, there are a few physicians who rely heavily on the income derived from testifying against physicians. It is highly lucrative, and the physician is at little risk for repercussions. Experts on behalf of the plaintiff will typically testify against physicians outside of their state, which gives them a comfort level that they would not ordinarily enjoy if they were testifying against a local colleague.

Progress has been made to limit and correct some of these problems. Various medical organizations have established their own ethical guidelines for expert witness conduct. For example, the American Academy of Otolaryngology–Head and Neck Surgery sets forth that an expert witness to a medical malpractice action should not adopt a position as an advocate or partisan in the legal proceedings; should review all the appropriate medical information in the case and testify to its content fairly, truthfully, and objectively; should review and be thoroughly familiar with the relevant standards of practice and medical literature prevailing at the time of the occurrence and limit their testimony to their areas of expertise; should be prepared to state the basis of the testimony presented and whether it is based on personal experience, specific clinical references, or a generally accepted opinion in the specialty field; should be compensated at a rate that is reasonable and commensurate with the time and effort given in preparation for testifying and should not link their compensation to the outcome of the case; and should be aware that transcripts of their deposition and courtroom testimony are public records, subject to independent peer review (12).

Stringent ethical guidelines, such as the ones imposed by the American Academy of Otolaryngology–Head and Neck Surgery, help ensure that expert witness testimony offered in medical malpractice actions is scientifically truthful and founded in reliable and universally recognized methodologies. These guidelines protect the equitable nature of the civil litigation process and hold accountable expert witnesses who proffer less than truthful medical opinions under oath.

While individual societies are trying to take steps to reign in unreliable testimony, it is not likely to vanish entirely. What constitutes the standard of care is simply too subjective in many instances, and the lines of what constitutes an exercise of judgment and what constitutes medical negligence are often blurred. The important thing to note is that the defendant physician should try to avoid taking any such criticisms personally and should consider the source of those opinions when applicable.

### The End Game: Settle or Not to Settle

Once discovery has been completed in a particular case, counsel will begin the process of a cost–benefit analysis of whether a case should, or even can, proceed to trial. This is usually the most difficult part of the case for the defendant physician. The defendant is faced with a Hobson's choice

of either grinding it out in trial, with no guarantee of success, or suffer the ignominy of “caving in” to the plaintiff's demands. While those views represent opposite ends of the emotional continuum, the defendant physician experiences these pangs of emotion when deciding what to do.

Before the physician arrives at a decision about settlement versus trial, counsel must first do a complete analysis of the case to determine whether from a factual and legal standpoint, there is a good chance of prevailing at trial. To that end, counsel will analyze all of the opinions of the defendant physicians, the subsequent treating physicians, and the expert witnesses. Counsel will take into account the jurisdiction (where the case is located), the judge involved in the matter, the attorney who is representing the plaintiff, and, perhaps most importantly, the presentation of the client himself. While having excellent experts and a great judge on a case is extraordinarily helpful, those factors may pale in the face of a tentative witness, who also happens to be the defendant. Juries often look to the parties, that is, the plaintiff and the defendant physicians, in order to formulate a decision about the case as, oftentimes, they have heard polar opposite testimony from the experts on the question of whether the defendant breached the standard of care. So, while a case may be extraordinarily “defensible,” it may be impossible to move forward with trial because of the personality or fortitude of the defendant physician.

Similarly, many physicians simply cannot afford to be out of the office for several days or several weeks while a trial is being conducted. Trials are typically a session of consecutive days until completion and often take all day to attend. It is easy to “fight to the death” on a case when your physical presence is not needed leading up to trial and your own time and assets are not at risk because your insurance dollars are paying all of the discovery costs and expenses. But when trial is imminent, hard decisions need to be made. It is only when the defendant traverses the “courthouse steps” that either backbones stiffen or knees buckle. Consequently, settlements may be made strictly from a convenience or emotional standpoint, as opposed to on the merits of a case.

Another major reason why cases typically will not proceed to trial is that the defendant physician simply cannot stand the process emotionally. Indeed, it is very difficult to sit through days, if not weeks, watching a parade of witnesses criticizing your every action. Further, the inability to understand the procedural machinations of the court can sometimes make matters extraordinarily frustrating. As a result, it is the rare physician who will take that trip to trial on more than one occasion.

Once it is determined that you want to move forward with trial, new anxieties arise. The question of “How can a jury of lay people possibly understand the medicine and decide in my favor?” is a common concern. Indeed, this fear is often the major reason to settle a case. It is here that counsel must ensure that the issues presented in the case are concise, relevant, and put into language that the jury

can understand. For the most part, juries can be trusted to understand the issues presented in a medical malpractice action and with the proper preparation on the part of defense counsel, a jury will typically make an informed decision.

If a defendant physician does in fact decide to go to trial, he must be prepared to enter an entirely different world and face a process that can be potentially grueling and involves going to court on consecutive days until the case is complete. One of the first steps of trial that a physician will witness is jury selection. Initially, a group of individuals, called the venire, are brought into the courtroom and prospective jurors are selected randomly to hear the case. Before the jury is sworn in, the attorneys and the judge will ask questions to determine whether any of the potential jurors have any biases or prejudices that would render them incapable of arriving at a fair verdict. This process is known as *voir dire*. Once the jury is impaneled, the parties proceed to opening statements and then evidence is produced, hopefully, in a reasonable fashion. Once all of the evidence has been heard, both sides have rested, and plaintiff has met his burden of proof to present a *prima facie* case of negligence, the jury is charged by the court to decide the case. The jury then deliberates in private and renders a verdict.

This brief overview of the trial process encapsulates what can amount of many weeks worth of events and also is based on the assumption that all the parties involved in the process will be reasonable. More often than not, that is not the case, as in the adversarial setting of a courtroom it is the opponent's job to be unreasonable. Furthermore, some judges, possessing little more than a rudimentary understanding of the medical issues involved, sit and decide important evidentiary issues. Fortunately, the jury decides "guilt" or "innocent"; however, this may provide little comfort to the physician in the hot seat.

As if 2 years of litigation culminating in a long drawn-out trial were not enough, if the physician prevails, the plaintiff has the option to appeal. Depending on the state in which the case sits, the appellate process may take another additional 1 to 4 years. After sweating it out for this period, the appellate court could overturn your hard-fought win and require you to relitigate your case. Thus, given the many unknowns that are associated with trial, physicians and their insurance carriers will look closely at each of the factors involved with a case to determine the best course.

On the other hand, the consequences of settling the case are a bit clearer. First, the case has ended completely with no chance of it hanging over the defendant's head *ad infinitum*. A release and settlement agreement is entered into, which, in some cases, allows for a confidentiality agreement; that is, the terms of the case cannot be discussed by any of the parties. Also, the physician is not admitting negligence by entering into a settlement agreement, only resolving a "disputed" claim. The only real cost with this course of action is a mandatory report to the National Practitioner Data Bank and perhaps a wounded ego. While

this is not necessarily desirable, settlement at least allows the physician to move forward without protracted litigation hanging over her head.

### Medical Malpractice Insurance

Because of the risks associated with litigation noted above, along with the sheer number of malpractice claims filed annually in the United States, it is not surprising that professional liability insurance has, and should, become a high priority for most practicing physicians and health care professionals. Professional liability insurance can serve a number of goals, the most important of which is the protection of a physician's personal and professional assets and the provision of legal support if a lawsuit is initiated. While most states legally require a physician to purchase a minimum amount of professional liability insurance, there are various other components to consider when deciding what type of coverage best fits a physician's specific needs.

Certain elements affect how much professional liability insurance a physician requires, including the physician's practice area, whether his state requires a minimum level of coverage and whether the physician is willing to jeopardize his personal assets if his level of coverage is insufficient. Once it has been determined exactly what a physician's unique needs are, it is then important to evaluate potential professional liability insurance carriers based upon the levels of protection that they offer against lawsuits, their financial solvency, their process for handling specific medical malpractice claims, and the type of coverage they offer.

Professional liability insurance carriers often offer one of two types of coverage: an occurrence policy or a claims-made policy. An occurrence policy offers protection from losses, which occurred while the policy was in effect, or during the policy term. Furthermore, an occurrence policy will continue to cover those losses any number of years in the future, even if the policy has since expired. For example, if a physician buys an occurrence policy in 1999 and terminates the policy in 2009, he will be covered for any incident of alleged malpractice that occurred in that period of 10 years, even if he is sued for such an incident in 2012, well after the occurrence policy has expired. Essentially, with an occurrence policy, a physician is covered for any incident that occurred during his or her policy term, no matter when he or she is sued. Occurrence policies are especially attractive to physicians because often evidence of alleged medical malpractice is not discovered until many years in the future and occurrence policies allow physicians to remain protected from any potential undetected exposure. Occurrence policies are, however, typically more expensive than a traditional claims-made policy, due to their permanence.

A claims-made policy is also another viable option for professional liability insurance coverage. Claims-made policies differ from occurrence policies in that they offer protection from claims made during a specific time period. A claims-made policy must continually be renewed from the time of the alleged incident to the time the claim is

filed, and when a claims-made policy expires, a physician no longer has coverage in the future for alleged incidents of malpractice that occurred in the past. For example, if a physician purchases a claims-made policy in 1999 and renews it until 2009, at which point the physician allows it to expire, the physician will not be covered from a potential claim that is brought in 2011, even if the alleged act of malpractice occurred in 2006, when he or she had claims-made coverage.

In order to reduce their risk of liability exposure, physicians with claims-made policies will often purchase what is called tail coverage. Tail coverage serves to cover losses that occur after a claims-made policy has expired. Functioning much like an occurrence policy, tail coverage protects a physician from claims made after the expiration of the claims-made policy, but which occurred while the policy was effective. For example, a physician purchases a claims-made policy in 2002, which he renews until 2004, at which point he allows it to expire. He then purchases a tail policy in 2004, which protects him from any claims brought against him during the 2002–2004 time frame during which the physician was insured.

The primary difference between tail coverage and an occurrence policy is that when an occurrence policy expires or is terminated, the physician is no longer required to pay premiums on the policy and yet, will continue to have coverage for any losses that occurred during his or her policy term. With tail coverage, the physician must continue to pay premiums until he or she no longer wishes to have protection from incidents that may have occurred during the time the physician's claims-made policy was in effect.

The decision whether to purchase claims-made or tail insurance is a complicated one, which should take into account your particular needs and exposure risks. Claims-made policies offer physicians great flexibility because they are renewed annually, allowing an individual to revise or change his insurance coverage. Furthermore, claims-made policies are portable and may be transferred between insurance carriers, while occurrence policies remain with their original carriers, as they are permanent. Occurrence policies, however, are not without their advantages. An occurrence policy offers protection *ad infinitum*, is not required to be renewed, and does not require the additional purchase of supplemental or tail coverage.

Finally, it is important to consider that in the context of medical malpractice professional liability insurance, a physician's insurance premiums may be covered by the hospital or practice group that employs him. Typically, in such instances, this coverage is made on a claims-made basis. Therefore, if the physician is then to leave the hospital or practice group for other employment, it is critical that he purchases tail coverage to protect against any potential liability that may have occurred while working for his former employer.

No matter the type of insurance coverage a physician chooses to purchase, a physician's protection of his personal assets must be a top priority, particularly in light of

the fact that a physician may be personally liable for any portion of a judgment or settlement in excess of his professional liability insurance coverage. After the lengthy and expensive process of obtaining a medical license, a physician must utilize every asset protection strategy available to him to protect his livelihood, including sound tax and estate planning and low-risk financial investments.

Asset protection strategies can be easily implemented by a physician with little expenditure of time or effort. For example, a physician can maximize his contributions to his IRA or other qualified employee benefit plan, which are typically shielded from claims of creditors. Various life insurance arrangements may also be considered, as many jurisdictions exempt all or part of the cash value of a life insurance policy from creditor claims. It is also critical to hire an experienced estate planner, who can suggest trust arrangements that offer significant asset protection and may provide some protection from the claims of creditors, and a knowledgeable accountant or tax expert, who will suggest methods by which to protect assets from various taxing authorities.

While maintaining insurance to protect personal assets is the overarching goal to the insured, there are other avenues of insurance coverage, which, if appropriately managed, provide security and could ultimately produce income. Offshore captive insurance groups have become very popular with large health systems and large physician groups. Essentially, offshore captives are developed and owned off of the US borders by the insured parties. The captives are subject to the insurance laws of the country of domicile and are not formally required to adhere to US insurance regulations, like a typical domestic or US-domiciled company.

The upside for ownership interest in a captive is a potential return on your premium dollars. Instead of paying a local insurance company tens of thousands of dollars in premiums—money that will never be recouped—these insurance dollars may be placed in a captive, where theoretically, those dollars will grow, ultimately leading to distributions or, at least, a tangible asset. It is important to understand, however, that in order for these entities to become viable and, later, profitable, they must be well capitalized and very well managed—usually with outside underwriters, actuaries, and financial advisers. A well-run offshore captive can turn a liability, insurance premiums, into an asset.

On the other hand, an undercapitalized or poorly managed captive can be a physician's worst nightmare. Poor planning, reckless underwriting, or fraud can spell doom for the captive and could result in zero insurance protection to the participating physician for a period of time. Just to litigate a medical malpractice case up to the time of trial can cost upward of \$200,000.00. This figure does not include trial costs, appeals, or a possible verdict, which can be staggeringly expensive. Stated simply, a lack of insurance could result in bankruptcy, humiliation, and a possible legal investigation.

The physician just beginning practice should ask many questions if his or her new group owns its own insurance



company and obtain counsel if necessary—as this could make the difference between entering into a practice with a viable, sound captive and entering into a practice with a poorly managed captive destined for failure and economic ruin.

## Tort Reform

### Theory

In response to the above-mentioned criticisms of medical malpractice litigation and the medical malpractice crisis of the 1970s and 1980s, physicians and malpractice insurance carriers began to lobby heavily for changes to reduce medical malpractice tort liability. Proponents of medical malpractice tort reform argued that as a result of changes to laws governing medical malpractice claims and their associated awards, malpractice insurance premiums would decrease. They further argued that lower insurance premiums for health care providers would increase the number of practicing physicians, lower the costs of health care for consumers, and result in an overall improvement in available medical care. These arguments obviously struck a chord in state legislatures throughout the country because by the mid-1980s, medical malpractice tort reforms had been widely adopted. It is important to note that while medical malpractice reform legislation was introduced at both the state and federal levels, as will be discussed below, attempts to pass real reform have taken hold on the state level, while attempts at passing federal legislation have been unsuccessful.

Typically, medical malpractice tort reform at the state level has focused on legislative reforms to the general doctrines of tort law, such as rules governing punitive damages, noneconomic damages, collateral sources, and joint and several liability (13). These doctrinal reforms have had varying degrees of success throughout the nation, with some reforms being widely adopted across all jurisdictions, and others being less enthusiastically received.

State laws capping noneconomic damages have been just one of the legislatively implicated medical malpractice tort reforms. Advocates of tort reform argue that noneconomic damages are arbitrary and unpredictable and, as such, complicate the settlement process. Further, it is argued that losses for emotional distress and pain and suffering are intangible and exceedingly difficult to assign a dollar value. Currently, over 30 states have caps on noneconomic damages as applied to medical malpractice actions.<sup>7</sup> These limitations on noneconomic damages

vary across jurisdictions: some states employ caps on both economic and noneconomic damages in medical malpractice awards; some states apply noneconomic damage caps only to certain types of malpractice claims, such as obstetrics; and other states allow for increased recovery in particular scenarios, such as where the patient has died or has substantial physical injury (14).<sup>8</sup> Typically, the limit on noneconomic damages varies on a state by state basis, with caps on damages ranging from \$250,000 to \$500,000 (14).

The tort law concept of joint and several liability has also undergone significant tort reforms in the context of medical malpractice claims. Traditionally, joint and several liability allows a plaintiff, who has been injured by two or more wrongdoers, to recover the full amount of his damages from any one of the defendants that may have been involved in the tortious conduct. This has historically resulted in an injured party seeking damages against the defendant with the most financial resources. A party sued under a theory of joint and several liability may then seek contribution from the additional parties at fault, so that the other defendants have to share in the payment of damages. Oftentimes, however, contribution cannot be achieved because the additional at-fault parties lack the financial means to contribute. As a result, proponents of tort reform argue that joint and several liability is an inequitable concept because one defendant, generally the defendant with the most financial resources, is required to pay damages in an amount considerably more than his share of the total liability. This criticism has caused over 40 states to enact tort reforms to the joint and several liability system, either outright abolishing joint and several liability or requiring an individual defendant to pay an amount of damages proportionate to his share of the overall fault (15).<sup>9</sup>

### States Where Tort Reform Has Been Enacted

Michigan serves as an illustrative example of how the specific states have addressed medical malpractice tort reform in an attempt to deal with the modern medical malpractice crisis. In recent years, Michigan has passed sweeping legislation curtailing frivolous litigation in the context of medical malpractice. For example, in 1986 the state passed a rule allowing a court to assess attorneys'

<sup>7</sup>States with noneconomic damages caps include Alabama, Alaska, California, Colorado, Florida, Georgia, Hawaii, Idaho, Illinois, Kansas, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nevada, New Hampshire, North Dakota, Ohio, Oklahoma, Oregon, South Carolina, South Dakota, Texas, Utah, Washington, West Virginia, and Wisconsin. American Tort Reform Association, <http://atra.org/issues/index.php?issue=7338> (Last visited Dec. 6, 2010).

<sup>8</sup>Compare MONT. CODE ANN. § 25-9-411 (2005) (cap of \$250,000), with N.D. CENT. CODE § 32-42-02 (1996) (cap of \$500,000).

<sup>9</sup>States with such reforms include Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, and Wyoming. American Tort Reform Association, <http://atra.org/issues/index.php?issue=7345> (Last visited Dec. 6, 2010).

fees and costs for filed actions that are perceived as frivolous (16). In 1993, Michigan also enacted noneconomic damages caps in medical malpractice actions, limiting the award of noneconomic damages in medical liability cases to \$280,000 for ordinary occurrences and \$500,000 in cases where the plaintiff has suffered serious damage to the brain, spinal cord, or reproductive organs (16). In 1995, the state passed a reform to the rule of joint and several liability, barring the application of joint and several liability in the recovery of all damages, except in cases of medical malpractice where the plaintiff is determined to have no allocation of fault (16). The Michigan state legislature additionally passed reforms to the collateral source rule in the context of medical malpractice litigation (16). Prior to passage, the collateral source rule prohibited the presentation of evidence at trial that an injured party has received compensation for his losses from another source, such as an insurance policy. The collateral source rule reform passed by the state of Michigan as part of the overall medical liability reform package now provides that medical malpractice awards be offset by the amount of collateral source payments received by the plaintiff (16).

Through the adoption of comprehensive medical malpractice tort reform, Michigan has done what many other states have wished to achieve: the near-total elimination of all medical malpractice litigation. Indeed, reform began to gain traction in Michigan in the early 2000s following a series of conservative holdings by the State's Supreme Court strictly interpreting the key medical malpractice reform statutory provisions. Reports from the State of Michigan Office of Financial and Insurance Regulation (OFIR) demonstrate that reported claims<sup>10</sup> for the period 2000–2007 show a 77% decrease in court filings (1,142 in 2000 to 263 in 2007). This is a significant drop in cases, which has resulted in a modest drop in insurance premiums. Nonetheless, as will be discussed in the "Compliance and Regulatory Issues" section of this article, health care costs have not declined. Contrary to assertions that less litigation will protect physicians from the constant threat of second-guessing from their patients who have obtained a less than optimal result, health care costs and unnecessary testing has continued to rise.<sup>11</sup>

<sup>10</sup>STATE OF MICHIGAN OFFICE OF FINANCIAL AND INSURANCE REGULATION, EVALUATION OF THE MICHIGAN MEDICAL PROFESSIONAL LIABILITY INSURANCE MARKET (October 2009). Although the OFIR report includes only those entities that filed a "Form A" notice and does not include many filings against self-insured captives insuring many hospitals and physicians in Michigan, the study is still a good indication of the percentage decline throughout the entire state.

<sup>11</sup>Interestingly, although the American Medical Association and other physician organizations wanted substantive medical malpractice reform to avoid "defensive medicine," no such reforms were seriously considered in the recent health reform debate—a debate where rising health care costs was the impetus for the resultant enacted legislation.

Despite the adoption of the above-mentioned tort reform measures throughout a variety of US jurisdictions, tort reform has yet to gain momentum on a federal level. Attempts at passing federal legislation restricting medical malpractice liability have failed since the 1970s, when federal tort reform was proposed in response to the first modern medical malpractice crisis. While contemporary presidents and politicians have campaigned for the adoption of far-reaching federal tort reform, all have failed in their efforts. In 2004, President George W. Bush proposed tort reforms affecting the liability exposure of physicians and drug and medical equipment manufacturers; however, opposition in the U.S. Senate prevented the enactment of this federal legislation (17). Additional proposals made in 2005 sought to cap noneconomic damages in medical malpractice actions, restrict the availability of punitive damages, restrict the statute of limitations for medical malpractice suits, and limit contingency fees collected by plaintiffs' attorneys in jury awards (18). Again, this federal legislation failed to get out of Congress.

With efforts at federal tort reform legislation stalled, it is impossible to determine the effect federally implicated restrictions on medical malpractice liability would have on overall national health care costs. It is, therefore, critical to consider whether medical malpractice tort reform at the state level has achieved the movement's stated goal: to reduce health care expenditures.

## Relationships between Medical Malpractice Litigation and Health Care Costs

### Impact on Rising Health Care Costs

One of the greatest criticisms leveled at the medical malpractice tort system is that the defense of medical malpractice actions needlessly increases the costs of health care in the United States. Medical malpractice tort reform advocates have long argued that the ever-present threat of litigation forces health care providers to charge higher rates to offset the costs of rising malpractice insurance premiums as well as promotes the practice of defensive medicine, which is defined as the overuse of diagnostic testing and health services in order to minimize a physician's liability exposure. The contention that medical malpractice tort reform is the soundest means by which to stabilize malpractice insurance premiums and generally lower health care costs, however, remains a controversial stance among both the legal and medical communities.

Much of the research conducted on the medical liability system suggests that in actuality, costs surrounding medical malpractice litigation are a small fraction of overall health care spending in the United States. Per the National Association of Insurance Commissioners, the overall cost of defending medical malpractice claims and compensating victims of medical malpractice in 2007 was estimated at \$7.1 billion, a mere 0.3% of the annual health care costs for that year (19). Even when these figures account for the

use of defensive medicine, as well as the expense of defending medical malpractice claims and compensating plaintiffs, the total costs associated with medical malpractice litigation are modest relative to overall health care spending. In 2008, the annual medical malpractice tort system costs, which included the costs of defensive medicine, were estimated to be \$55.6 billion, or 2.4% of the total health care costs for the year (20).

If recent statistics appear to reflect that the cost of medical malpractice litigation does not have an overwhelming effect on the overall cost of health care spending, then why have rising health care costs been routinely evoked to demand the adoption of medical malpractice tort reform? The answer may lie with the perception perpetuated by insurance and health care provider lobbyists alike: that the practice of defensive medicine, as well as increased malpractice insurance premiums, is the direct result of increased medical malpractice litigation. Empirical evidence has shown, however, that malpractice insurance premiums are much less affected by medical malpractice litigation than commonly believed and that the costs of defensive medicine are often exaggerated.

### Insurance Premiums

During the previously mentioned cycles of medical malpractice crises in the United States, malpractice insurance premiums have generally risen dramatically. Advocates of medical malpractice tort reform point to these premium increases as evidence that medical malpractice claims drive the rising cost of health care. While there is no question that rising insurance premiums place an additional financial burden on physicians seeking malpractice coverage, premium rates are not based solely, or even in large part, upon medical malpractice claim or settlement payouts (21). This is because most insurance companies' profits are not generated from the premiums they receive from their insured physicians (21). Most malpractice insurance carriers face a delay between the time they receive premium payments from their insured physicians and the time they have to pay out medical malpractice claims. Due to this delay, many insurance companies invest the premiums they receive in bonds or other financial securities (21). It is the return on these investments, not malpractice insurance premiums, that generates an insurance company's profits. Therefore, even if the number of malpractice claim payouts an insurance company makes is stable, the company may still be forced to raise premiums if their investments fail to yield adequate returns (21).

In addition, premiums do not only represent a malpractice insurer's indemnification costs. Malpractice insurance premiums represent a variety of costs assumed by an insurance company and passed on to their insured physicians. These costs may include a company's estimated indemnification costs, defense costs, operating fees, reinsurance costs, and profit or surplus building (22). Tort reform opponents argue that even with legislature in place to limit

jury awards or settlements in medical malpractice actions, rising insurance premiums would still be a financial hardship faced by the medical community, as the underwriting cycle and malpractice premiums are affected by much more than the threat of medical malpractice litigation.

Research performed in states that have enacted tort reform in the context of medical malpractice litigation also indicates that rising malpractice premiums are not tied to an influx of medical malpractice filings. In 1986, the state of Florida enacted medical malpractice tort reforms; however, despite this legislation, malpractice premiums in the state have increased on average from 30% to 50% since 2000 (23). In 2003, Florida, after a second bout of tort reform measures, experienced an increase in insurance premium rates by as much as 45% (23).

This empirical evidence challenging the connection between tort reform and malpractice premiums is not just limited to the state of Florida. In 1995, the state of Texas passed legislation limiting the amount of punitive damages available in jury awards (24). Despite this measure, insurance premiums in the state continued to increase. These statistics cast doubts on the claim that tort reform is the most effective way to manage skyrocketing malpractice premium rates and reduce overall health care costs.

### Defensive Medicine: Real or Imagined?

Tort reform proponents also typically cite the rise of defensive medicine as the other major negative residual effect of medical malpractice litigation. Those favoring medical malpractice tort reform argue that litigation-weary physicians order unnecessary and exhaustive tests on their patients, which, in turn, drives up the cost of health care. Empirical evidence appears to suggest, however, that both the impact and the prevalence of defensive medicine have been overstated.

Much of the support for the proposition that the practice of defensive medicine is the costly offshoot of medical malpractice litigation comes from a controversial 1996 study conducted by two Stanford University economists, Daniel Kessler and Mark McClellan. In this study, the economists analyzed the costs of care for hospitalized elderly Medicare patients with heart disease in states both with and without medical malpractice tort reforms (25). Based on their findings, Kessler and McClellan concluded that tort reforms resulted in hospital costs savings of 5% to 9% (25). The economists then applied these findings to the entire health care system, hypothesizing that tort reform could lead to a reduction of over \$50 billion annually in health care expenditures (25). Tort reform supporters used this study to buttress their claim that without the ever-looming fear of litigation, physicians are freer to order fewer diagnostic tests, which, in fact, reduces their medical spending and lowers overall health care costs.

While Kessler and McClellan's findings became vindication for advocates of medical malpractice tort reform, subsequent research has criticized many of the hypotheses

contained within the study. In 2003, the U.S. Government Accountability Office (GAO) issued a statement questioning the applicability of Kessler and McClellan's findings to the entire health care system (26). The GAO's report argued that due to the limited scope of the study and its examination of patient behavior in the specific clinical situation of elderly patients with cardiac issues, "the study results cannot be generalized to estimate the extent and cost of defensive medicine practices across the health care system." (27) The report also concluded that while members of the medical community admitted that defensive medicine exists to some degree, the instance of its actual practice is extremely difficult to measure (27). This difficulty in quantifying the prevalence of defensive medicine in turn makes it more onerous to hypothesize any sort of costs savings for its reduction in practice.

More recent studies performed by the US government also reflect the tenuous connection between tort reform and its impact on the practice of defensive medicine. A 2004 study performed by the Congressional Budget Office (CBO) applied the methods employed by Kessler and McClellan's study to a wider set of medical ailments (26). It was concluded by the agency that there is no evidence linking restrictions on tort liability to reduced medical spending. A second analysis of the link between defensive medicine and health care costs performed by the CBO additionally confirmed no significant statistical difference in medical spending between states with and without medical malpractice tort limits (26).

One of the major reasons that medical malpractice tort reform has not definitively been found to effectively manage the practice of defensive medicine is because defensive medicine has been shown to be motivated by more than just a fear of litigation on physicians' parts. Some behavior that could be characterized as defensive medicine may be motivated more by the increased income additional diagnostic testing can generate for physicians, or the benefits a patient receives from additional testing, and less by fears of liability exposure (26). Additionally, it is unclear exactly how strongly concerns over medical malpractice liability actually affect a physician's treatment decisions. Physicians are highly educated professionals, who have to treat a patient's ailment based on myriad factors and considerations. To assume that all physicians require additional testing merely due to fears of liability exposure is unfounded.

Medical malpractice tort reform may also do little to curtail the practice of defensive medicine because empirical evidence seems to suggest that physicians typically have high levels of malpractice concern, in states both with, and without, tort reform. Research has shown that physicians in states with high malpractice risks have reported nearly the same level of concern over liability exposure as physicians in states with the low malpractice risks due to heightened medical malpractice tort reform (28). These results appear to be further evidence suggesting that tort reform in

the context of medical malpractice may do little to assuage physicians' fears of liability or impact their diagnostic behavior in regard to the practice defensive medicine.

### Risk Management

Although attempts to curtail medical malpractice litigation have been undertaken by many states with varying degrees of success, it is undisputed that this litigation has decreased over the last two decades. No matter the level of success in your state at instituting tort reform, however, medical malpractice litigation will never disappear entirely. As such, every solo practitioner or ENT practice group must focus its efforts at reducing risk by establishing a comprehensive risk management and compliance program to improve the safety and quality of the care that its physicians and employees provide. A key component of any program is the continuous assessment of quality management processes with a focus on implementing changes where necessary to ensure patient safety and the provision of high-quality and accurate medical care.

While specific areas of risk for otolaryngologists and how such risks can be minimized will be addressed later within this chapter, the structure of any risk management/quality and performance improvement program will certainly vary depending on the size of your particular practice group. It is widely accepted that with varying degrees of focus, depending on the size and structure of the practice or group, any risk management program must include the implementation of processes to monitor performance, implement change, and meet regulatory requirements in the areas of patient safety, process improvement, quality, and professional staff education and assessment.

Importantly, although voluntarily implementing these quality-related programs in order to reduce exposure to allegations of medical malpractice is necessary for any ENT practice or group to succeed, many of these processes are required by the very organizations that regulate the otolaryngology profession—thus making such implementation of these programs mandatory.

For example, the American Board of Otolaryngology Maintenance of Certification (MOC) program is for diplomats who are working in their ten (10)-year cycle of maintaining their certification. Although the specific requirements of the competencies and components of each MOC program will depend on an ENT's particular practice area, the MOC program generally evaluates four (4) essential competencies on a continuous basis including (a) professional standing, (b) continuing education/self-assessment, (c) cognitive examination, and (d) performance in practice (29). Evaluation of these competencies seeks to ensure that high standards of health care quality are maintained throughout the ENT practice as a whole, and these exacting quality requirements serve to minimize exposure to individual physicians from the overall risk of medical negligence claims. Other organizations with compliance and regulatory quality requirements include



the Joint Commission on Accreditation of Healthcare Organizations and the Accreditation Council for Graduate Medical Education.

Thus, it is clear that every otolaryngology practice, department, or group must focus considerable effort and time in the development and maintenance of a comprehensive quality, risk management, and compliance program to improve patient safety and quality of care not only for the welfare of patients and to maintain a competitive edge but to reduce the ever-present risk of and exposure related to medical malpractice.

## COMPLIANCE AND REGULATORY ISSUES

### Introduction to Federal Health Care Fraud and Abuse Laws

It is unquestionable that billing and reimbursement have become integral parts of the practice of medicine. It is also unquestionable that few people would devote at least 9 years of their lives to become an otolaryngologist with the intent to cheat the federal government in their billing of medical claims. Various factors, such as greed or carelessness, may contribute to improper behavior by physicians during their careers, but ignorance of the law need not be one of those factors.

Although maintaining proper financial dealings with federal health care programs in the current health care environment is part of being a physician, medical schools and residency programs do not uniformly teach trainees about fraud and abuse. Indeed, in 2010, the Office of the Inspector General (OIG) surveyed all medical school deans and designated officials for institutions that sponsor residency and fellowship programs to determine whether their institutions provide education about fraud, waste, and abuse; to identify knowledge gaps; and to determine how the OIG could best promote education about compliance with the relevant laws. The survey revealed that less than half of the nation's medical schools provide instruction on fraud and abuse (30).

Violating the fraud and abuse laws can result in criminal penalties; civil fines; exclusion from the federal health care programs, which include Medicare and Medicaid; and even loss of your medical license by your State Medical Board. Thus, a good understanding of the five most important federal fraud and abuse laws that apply to physicians is essential.

### Enforcement

Three federal government agencies are charged with enforcing the fraud and abuse laws: the Department of Justice, the Department of Health & Human Services Office of the Inspector General (OIG), and the Centers for Medicare & Medicaid Services (CMS). The five laws include

the Physician Self-Referral Law (Stark Law), Antikickback Statute (AKS), the False Claims Act, the Exclusion Authorities, and the Civil Monetary Penalties Law.

### Physician Self-Referral Law (Stark Law)

The Physician Self-Referral Law,<sup>12</sup> commonly referred to as the Stark Law, (a) prohibits a physician from making referrals of certain designated health services (DHS) payable by Medicare or Medicaid to an entity with which he or she (or an immediate family member) has a financial relationship (ownership or compensation) unless an exception applies<sup>13</sup> and (b) prohibits the entity from filing claims with Medicare or Medicaid (or billing another individual, entity, or third party payor) for those referred services, unless an exception applies. When originally enacted in 1989, the law applied only to physician referrals for clinical laboratory services. In 1993 and 1994, Congress expanded the prohibition to include additional DHS.

DHS now include (a) clinical laboratory services; (b) physical therapy, occupational therapy, and speech-language pathology services; (c) radiology and certain other imaging services; (d) radiation therapy services and supplies; (e) durable medical equipment and supplies; (f) parenteral and enteral nutrients, equipment, and supplies; (g) prosthetics, orthotics, and prosthetic devices and supplies; (h) home health services; (i) outpatient prescription drugs; and (j) inpatient and outpatient hospital services.

Significantly, the Stark Law is a strict liability law, which means that proof of specific intent to violate the law is not required. If Stark is triggered, and an exception is not met, a health care provider will be subject to severe sanctions, including denial of filing claims for those referred services, civil monetary penalties, exclusion from Medicare and Medicaid, and potential False Claims Act liability.

### Antikickback Statute

The AKS<sup>14</sup> makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a federal health care program. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a federal health care program, the AKS is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible "kickback"

<sup>12</sup>42 U.S.C. §1395nn.

<sup>13</sup>Stark Law contains approximately 35 exceptions that describe acceptable financial relationships that allow a physician to refer to an entity for the provision of designated health services (42 CFR Part 411, Subpart J). Some commonly applied exceptions to the Stark Law include the exceptions for personal services, bona fide employment relationships, physician recruitment, and physicians practicing in rural areas and locations designated as Health Professional Shortage Areas. Each of the exceptions to the Stark Law has numerous elements that must be met in order to qualify for the exception, and care should be taken to assure compliance with each of these elements.

<sup>14</sup>42 U.S.C. §1320a-7b(b).

transaction. For purposes of the AKS, “remuneration” includes the transfer of anything of value directly or indirectly, overtly or covertly, in cash or in kind.

The AKS has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals (31). With the passing of the Patient Protection and Affordable Care Act (PPACA)<sup>15</sup> on March 23, 2010, the AKS “intent” element was revised to remove any specific intent or actual knowledge of an AKS violation. Thus, one does not have to have “knowingly” and “willfully” violated the AKS to make the kickback actionable. Violation of the AKS constitutes a felony punishable by a maximum fine of \$25,000, imprisonment up to 5 years, or both. Conviction will also lead to mandatory exclusion from federal health care programs, including Medicare and Medicaid. PPACA<sup>16</sup> also expanded the punishment for violation of the AKS Statute adding that any AKS violation is now a false claim under the False Claims Act, subjecting the provider to civil penalties.

Due to the breadth of the potential application of the AKS, the OIG was required to develop “safe harbor” regulations designed to protect various payment and business practices because such practices would be unlikely to result in fraud or abuse.<sup>17</sup> If an arrangement falls outside of the safe harbor, it is not *per se* illegal, but the facts and circumstances behind the arrangement must be carefully reviewed. The safe harbors set forth specific conditions that, if met, assure entities involved that they will not be prosecuted or sanctioned for the arrangement qualifying for the safe harbor. However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor.

### False Claims Act

False Claims Act violations occur when claims are submitted for payment to Medicare or Medicaid that are false or fraudulent. No specific intent to defraud is required. Filing false claims may result in civil penalties of not less than \$5,500 and not more than \$11,000 for each claim plus three times the programs’ loss. Significantly, each instance of an item or a service billed to Medicare or Medicaid counts as a claim; thus, the potential fines can add up quickly. Moreover, a claim that results from a kickback or is made in violation of the Stark Law may also render it false or fraudulent, creating liability under the False Claims Act in addition to the AKS and the Stark Law.

The OIG may initiate administrative proceedings to impose civil monetary penalties and may also initiate administrative proceedings to exclude a party that files a

false claim from the federal health care programs. There is also a criminal False Claims Act,<sup>18</sup> which imposes criminal penalties for submitting false claims including imprisonment and criminal fines.

### Exclusion Statute<sup>19</sup>

The OIG is required to exclude from participation in all federal health care programs individuals and entities convicted of criminal offenses including (a) Medicare or Medicaid fraud, (b) patient abuse or neglect, and (c) felony convictions for health care–related fraud, theft, financial misconduct, unlawful manufacture, distribution, prescription, or dispensing of controlled substances. The OIG has discretion to exclude individuals and entities on several other grounds. In recent years, the OIG has been exercising its permissive exclusion power with much more frequency in order to combat health care fraud. As of January 2011, more than 5,000 physicians were excluded from participation in the federal health care programs because of these types of violations and cannot treat any of the approximately 100 million Medicare and Medicaid beneficiaries.<sup>20</sup>

Exclusion from participation in the federal health care programs is devastating to any career. The federal programs will not pay the provider for items or services furnished, ordered, or prescribed. As a result, providers may not bill Medicare or Medicaid directly for treating patients nor may their services be billed indirectly through their group practice. Moreover, once excluded from the federal health care programs, it is likely that other third party payors will follow suit, disallowing the excluded provider from submitting claims for reimbursement. As such, an excluded provider will be unemployable as the provider will be unable to receive payment for services rendered from the federal health programs. Unfortunately for such providers, it is impossible to hide from the reality of being excluded as the OIG maintains a List of Excluded Individuals and Entities on its Web site, which can be found at <http://oig.hhs.gov/fraud/exclusions.asp>.

### Civil Monetary Penalties Law<sup>21</sup>

The Civil Monetary Penalties Law grants the OIG the authority to seek civil monetary penalties and, in some instances, exclusion, for a wide variety of conduct. Violations of the law includes violating AKS, presenting claims that the persons knows or should have known is for an item or service that was not provided as claimed or is false or fraudulent or for which payment may not be made. Penalties range from \$10,000 to \$50,000 per violation and, possibly, exclusion from the federal health programs.

<sup>15</sup>Section 6402(f)(2).

<sup>16</sup>Section 6402(f)(1).

<sup>17</sup>See 42 C.F.R. § 1001.952. Some safe harbors address personal services and rental agreements, investments in ambulatory surgical centers, and payments to *bona fide* employees.

<sup>18</sup>18 U.S.C. §287.

<sup>19</sup>42 U.S.C. §1320a-7.

<sup>20</sup><http://healthpolicyandreform.nejm.org/?p=13576>.

<sup>21</sup>42 U.S.C. §1320a-7a.

## Application of the Laws

Given that the health care environment has drastically changed over the years, physicians of all experience levels must understand the fraud and abuse laws and how they influence the way medicine is practiced. This is particularly true since physicians must understand that they are personally liable for claims submitted under their national provider identifiers regardless of whether or not they personally code or bill the services. Although a physician can certainly delegate such tasks from a business and administrative perspective, the physician continues to have a significant stake in ensuring compliance. Some physicians are surprised to learn that every CMS 1500 form that is submitted contains a certification statement wherein the physician personally attests that the services were medically necessary and that (absent an exception permitted under the regulations) he or she personally furnished the service.

The key to avoiding violations of the fraud and abuse laws is to have a clear understanding of how they shape and control the three “most common” relationships that physicians encounter in their careers: relationships with payors (like the Medicare and Medicaid programs), relationships with vendors (like drug, biologic, and medical device companies), and relationships with fellow providers (like hospitals, nursing homes, and physician colleagues).

### Physician Relationships with Payors

Physicians need to develop and maintain systems in their practice to oversee that they are accurately coding and billing for services rendered to patients and diligently maintaining accurate and complete medical records and documentation to support the fact that the services billed for were necessary and have actually been provided. Physicians must also avoid the misuse of their physician and prescription provider numbers and understand the strict requirements of the Medicare reimbursement rules as a participating or nonparticipating provider. In addition to the fraud and abuse implications resulting from poor documentation practices, physicians should keep in mind that the primary reason for denial in postpayment audit cases (e.g., Medicare audits requesting refunds of alleged overpayments) typically relates to documentation deficiencies. Enhancement of documentation practices in any physician practice should unquestionably be a top priority.

### Physician Relationships with Fellow Providers: Physicians, Hospitals, Nursing Homes, Etc.

Within these relationships, physicians must steer clear of any situation in which their decision-making with respect to patient referrals or use of products or services is based on anything other than what is medically necessary and appropriate for the patient. As most physicians have figured out by now, the fraud and abuse laws are complicated; however, physicians are held accountable for ensuring that relationships are structured in a compliant manner. Physicians

can avoid the pitfalls of improper arrangements by making sure that they appropriately consult with experts prior to entering into the relationship. Unfortunately, the fact that a physician was unaware of the implications of the fraud and abuse laws to the relationship is not a legitimate defense.

### Physician Relationships with Vendors

A particular area of vulnerability for physicians involves relationships with pharmaceutical and medical device industries. Like physician relationships with fellow providers, physicians must steer clear of allowing the pharmaceutical or medical device industries from buying their loyalty or otherwise inducing them to prescribe or use products based on anything other than what is a medical necessity. The OIG offers some practical questions a physician should self-inquire to test the propriety of any proposed compensation relationship with these entities:

- Does the company really need my particular expertise or input?
- Does the amount of money the company is offering seem fair, appropriate, and commercially reasonable for what it is asking me to do?
- Is it possible the company is paying me for my loyalty so that I will prescribe its drugs or use its devices? (32).

Physicians can also review the OIG’s Compliance Program Guidance for Pharmaceutical Manufacturers available at [www.oig.hhs.gov/authorities/docs/03/050503FRCPGPharmac.pdf](http://www.oig.hhs.gov/authorities/docs/03/050503FRCPGPharmac.pdf). Moreover, in protecting oneself in these relationships, one must keep in mind that under the PPACA,<sup>22</sup> transparency is coming in the form of requiring drug, device, and biologic companies to publicly report nearly all gifts or payments they make to physicians beginning in 2013.

## Compliance Programs

Prior to PPACA, health care providers were encouraged but not required to maintain compliance programs to help ensure their compliance with fraud and abuse laws and federal health program requirements. Under PPACA, if you treat Medicare and Medicaid beneficiaries, you are required to establish a compliance program.<sup>23</sup> Seven

<sup>22</sup>Pub. L. 111-148 was signed into law on March 23, 2010.

<sup>23</sup>Section 6401(a). On February 2, 2011, the Centers for Medicare and Medicaid Services (“CMS”) published its final rule for establishing new screening requirements for enrollees in Medicare, Medicaid, and the Children’s Health Insurance Program (“CHIP”) pursuant to Section 6401(a) of PPACA (the “Final Rule”) (76 FR 5941). The Final Rule also addressed the compliance program requirement as set forth in Section 6401 of PPACA, which prescribes that, as a condition of enrolling in Medicare, Medicaid, or CHIP, providers and suppliers must establish compliance programs that meet certain “core elements.” Notably, however, CMS did not finalize any rules related to mandatory compliance. Instead, CMS noted in the Final Rule that it would continue to do further rule making and would “advance specific proposals at some time in the future.”



components to establishing a “solid” compliance program include (a) conducting internal monitoring and auditing, (b) implementing compliance and practice standards, (c) designating a compliance officer or contact, (d) conducting appropriate training and education, (e) responding appropriately to detected offenses and developing corrective action, (f) developing open lines of communication with employees, and (g) enforcing disciplinary standards through well-publicized guidelines.

Notwithstanding the PPACA mandates, in recognition of the increase in enforcement and audit activity, now, more than ever, it is imperative that every physician have in place an effective compliance program that is tailored to his/her particular practice and specialty.

## THIRD PARTY PAYOR AUDITS

### Third Party Payor Audit(s) Overview

Physicians submitting claims to all third party payors (i.e., Medicare, Medicaid, and private payors) must be cognizant that all claims are under unprecedented payor scrutiny. In an effort to protect the integrity of the Medicare and Medicaid Trust Funds, as well as the bottom line of private insurers, all payors are actively auditing claims. Health care providers must be mindful of this increased claims scrutiny and conduct themselves accordingly.

With respect to claims submitted to Medicare, not only do Medicare Administrative Contractors (MACs) (and/or Medicare Carriers and Intermediaries) conduct their own audits, but also the CMS contracts with various other entities to perform Medicare auditing functions. For example, Medicare’s Recovery Audit Contractor (RAC) program is now operational nationwide (and has been expanded to include Part C and Part D claims). RAC auditors are tasked to identify and correct all types of improper Medicare payments and are compensated on a contingency fee basis. In addition, Zone Program Integrity Contractors (ZPICs) (or Program Safeguard Contractors [“PSCs”]) are actively conducting benefit integrity audits nationwide.

With respect to Medicaid claims, in addition to each state conducting their own Medicaid audits, there also exist federal Medicaid auditing programs. Under the Medicaid Integrity Program, Audit Medicaid Integrity Contractors (MICs) are auditing Medicaid claims in every state. The focus of the Audit MICs is on providers with “truly aberrant” claim submissions. In addition, the nationwide RAC program has been expanded to also include Medicaid claims.

### Which Physicians Are Likely to Be Audited?

All auditors (Medicare, Medicaid, and private payors) use proprietary “data mining” techniques to determine claims likely to constitute overpayments and to identify providers with utilization patterns that may suggest overpayments

to be occurring. Therefore, physicians providing a high volume of higher-cost procedures, or physicians with a noticeable volume of high-level office visits (e.g., a high volume or level 4 or level 5 office visits), may find themselves under increased claims scrutiny. As noted elsewhere herein, through various guidance documents (e.g., the RAC-approved issues lists), CMS indicates claims likely to be subject to increased scrutiny under the Medicare and Medicaid programs. Physicians submitting these types of claims may see more auditing activity. Moreover, physicians should identify risk areas specific to his or her field of practice. These areas are often identified in specialty publications and can be found in third party payor guidances, local medical review policies, OIG guidances, fraud alerts, and the annual OIG work plan. One such area that has been a significant focus of the enforcement authorities and third party payors is E & M (or Evaluation and Management) services. In addition, physicians can discover their own personal practice risk areas by conducting self-audits focusing on, for example, the ten (10) most-often billed procedures and/or the ten (10) procedures yielding the highest practice revenue, looking at published policies and guidelines for these procedures, meeting with other providers in the physician’s office and the billing staff, and discussing the documentation and billing of these procedures.

When conducting such audits, there are a number of significant items to consider. For example, (a) whether the audit should be prospective as opposed to retrospective, (b) whether the audit should be conducted for general educational purposes or for specific reasons (e.g., to quantify a suspected error), (c) whether one should use external auditors or internal auditors, (d) the sample size of the audit, (e) which documents to review, and (f) how often to perform the audit. Importantly, it is highly recommended that any self-audit be done at the direction of legal counsel—not only to help one decide the best manner in which to conduct the audit and to address the aforementioned items, but also to avoid providing a “road map” of any problems revealed by the audit to the enforcement authorities. Self-audits that are not directed by legal counsel are not protected by the attorney work product doctrine and/or attorney–client privilege and thus are discoverable by the enforcement authorities who can use the findings against the physician.

### Typical Audit Processes for Medicare

Generally speaking, Medicare audits are conducted to determine whether claims are or were properly submitted to Medicare. When Medicare audits are conducted for medical review purposes, the contractor’s focus is to determine whether services are covered, are reasonable and necessary, and are correctly coded. When Medicare audits are conducted for benefit integrity purposes, the focus is different (e.g., looking for possible falsification). Medicare audits may be conducted on either a prepayment or postpayment



basis and may be conducted either on-site or via “desk audit.”

When initiating either a prepayment review or postpayment audit for medical review purposes, a Medicare contractor is required to issue a written notification to the physician, which includes the following elements:

1. That the physician has been selected for prepayment review or postpayment audit and the reason for the selection. If the reason the physician was selected for audit was comparative data, then the Medicare contractor should provide the comparative data to the physician as part of this notification.
2. Whether the review will be conducted on a prepayment or postpayment basis
3. If postpayment audit, a list of claims requiring medical records to be produced (including the time frames for returning additional documentation—typically 30 to 45 days)

Note: It is essential that physicians adhere to the time frames for submitting requested documentation. If the time frames are not met, the Medicare contractor will deny the subject claims. The contractor thereafter may, but is not required to, reopen the claims upon appeal.

Generally speaking, prepayment review(s) or postpayment audit(s) is conducted within 60 days from receipt of requested medical records.<sup>24</sup> When reviewing claims, the Medicare contractor will use both published Medicare guidance (e.g., National Coverage Decisions (NCDs), Local Coverage Decisions (LCDs), CMS Manuals, CMS Coding Articles, etc.), and internal review guidelines. In a postpayment audit, following the review, the Medicare contractor will prepare a letter to notify the physician regarding the results of the audit, including the rationales for denials and information regarding the statistical extrapolation performed, if applicable. The physician also will receive a demand letter, which triggers relevant appeal deadlines. Prepayment review results will be communicated via Remittance Advice.<sup>25</sup>

### The Medicare Appeals Process

Part A and Part B Medicare claim denials arising from Medicare audits are subject to the five-stage appeals process set forth at 42 C.F.R. Part 405, Subpart I. It is essential from a business perspective that physicians understand this appeals process and appeal claim denials as they occur. Denials may be successfully overturned in the Medicare appeals process, resulting in monies returned to the physician. The five-stage appeals process is as follows:

1. *Stage 1: Redetermination.* The first level in the appeals process is redetermination. There is no amount in controversy requirement. Providers must submit redetermination requests in writing within 120 calendar days of receiving notice of initial determination.

Significantly, federal law prohibits Medicare from recouping an alleged overpayment during the first two stages of the appeals process (i.e., during the redetermination and reconsideration stages of appeal). Although federal regulations grant physicians 120 calendar days to file a request for redetermination, Medicare will begin recouping the alleged overpayment arising from a Medicare audit prior to the expiration of the 120-day appeals time frame if a valid request for redetermination is not first received. Specifically, recoupment will begin on the 41st day from the date of the notice of initial determination, unless a valid request for redetermination is received 30 days following the date of notice of initial determination. If this time frame is not met, Medicare will stop recoupment at whatever point an appeal is received, but it will not refund any amounts withheld prior to that time.

2. *Stage 2: Reconsideration.* Physicians dissatisfied with a redetermination decision may file a request for reconsideration to be conducted by a Qualified Independent Contractor (QIC). A QIC is a Medicare contractor tasked to complete this second level of appeal (reconsideration level of appeal). There is no amount in controversy requirement. This second level of appeal must be filed within 180 calendar days of receiving notice of the redetermination decision.

Although federal regulations grant physicians 180 calendar days to file a request for reconsideration, Medicare will again begin recouping its alleged overpayment following the redetermination stage prior to the expiration of the 180-day appeals time frame if a valid request for reconsideration is not first received. Specifically, recoupment may begin on the 61st day from the date of redetermination decision, unless a valid request for reconsideration is received. If this time frame is not met, Medicare will stop recoupment at whatever point an appeal is received.

Significantly, physicians must submit a “full and early presentation of evidence” in the reconsideration stage. When filing a reconsideration request, a physician must present evidence and allegations related to the dispute and explain the reasons for the disagreement with the initial determination and redetermination. Absent good cause, failure of a physician to submit evidence prior to the issuance of the notice of reconsideration precludes subsequent consideration of the evidence. Accordingly, physicians may be prohibited from introducing evidence in later stages of the appeals process if such evidence is not presented at the reconsideration stage.

<sup>24</sup>This 60-day time period does not apply to reviews for benefit integrity purposes (PSC or ZPIC audits).

<sup>25</sup>See generally, Medicare Program Integrity Manual (CMS Pub. 100-08), Chapter 3, Section 30.4 *et seq.*

3. *Stage 3: Administrative Law Judge (ALJ) Hearing.* A provider dissatisfied with a reconsideration decision may request an ALJ hearing. The request must be filed within 60 days following receipt of the QIC's decision and must meet an amount in controversy requirement. ALJ hearings can be conducted by video teleconference (VTC), in person, or by telephone. The regulations require the hearing to be conducted by VTC if the technology is available; however, if VTC is unavailable or in other extraordinary circumstances, the ALJ may hold an in-person hearing. Additionally, the ALJ may offer a telephone hearing.
4. *Stage 4: Medicare Appeals Council (MAC) Review.* The fourth level of appeal is the Medicare Appeals Council (MAC) Review. The MAC is within the Departmental Appeals Board of HHS. A MAC Review request must be filed within 60 days following receipt of the ALJ's decision. Among other requirements, a request for MAC Review must identify and explain the parts of the ALJ action with which the party disagrees. Unless the request is from an unrepresented beneficiary, the MAC will limit its review to the issues raised in the written request for review.
5. *Stage 5: Federal District Court.* The final step in the appeals process is judicial review in federal district court. A request for review in district court must be filed within 60 days of receipt of the MAC's decision and meet an amount in controversy requirement.

### Audit Defenses

In preparing a Medicare appeal, physicians should both challenge the merits of the claim denials and employ applicable legal defenses. In arguing the merits, physicians should prepare a position paper and/or a summary of the documentation relevant to the claims at issue, setting forth the justification for the services as billed. Attached to the position paper should be all records supporting the claims at issue, organized in a user-friendly manner. Note that this likely will involve more records than just the records for the specific dates of service denied. For example, if a procedure is denied, the submitted documentation should include any office visit preceding the procedure supporting the medical necessity for the procedure. In arguing the merits of the claim, physicians should engage the services of a qualified medical/coding/statistical expert, as applicable. In addition to arguing the merits, physicians may choose to employ the following legal defenses, as applicable:

1. *Provider without Fault:* As a general rule, a provider will be considered without fault if it exercised reasonable care in billing for and accepting payment (i.e., it complied with all pertinent regulations, made full disclosure of material facts, and, on the basis of the information available, had a reasonable basis for assuming

that the payment was correct). A provider or supplier will be presumed to be without fault if an overpayment is discovered subsequent to the third year following initial determination.<sup>26</sup>

2. *Waiver of Liability:* In the event a Medicare contractor denies a service as not medically reasonable and/or necessary, the denial constitutes a denial under Section 1862 (a) of the Social Security Act, subjecting the claims to waiver of liability consideration. The statutory authority for the application of Waiver of Liability is set forth in Section 1879 (a) of the Social Security Act. Generally speaking, once waiver of liability applies, the relevant inquiry focuses on whether the provider or supplier knew or could have reasonably been expected to know that payment would not have been made for the services.
3. *Treating Physician's Rule:* The legal theory of the Treating Physician's Rule provides that the treating physician's determination that a service is medically necessary and appropriate should predominate over a reviewer's determination.
4. *Challenges to Statistics:* Providers may also legally challenge the statistics in connection with extrapolated audits. This will involve the retention of a qualified statistical expert to review the statistical sample and extrapolation performed for compliance with Medicare guidelines. Challenging the statistical extrapolation performed (which, if successful, would bring the overpayment demand to the "actual" overpayment, rather than the projected overpayment) should be a key focus of any appeal where a statistical extrapolation is performed.<sup>27</sup>

### Compliance Tips

Although physicians may not be able to prevent a Medicare audit from occurring, physicians should prepare for increased claims scrutiny and audit activity by dedicating resources to the following:

1. Regularly *monitoring* guidance documents educating physicians regarding the types of claims subject to increased Medicare claims scrutiny, including historical audit data (such as the review results arising from the RAC Demonstration Program), the RACs' Web sites identifying approved audit issues (links available from [www.cms.hhs.gov/RAC](http://www.cms.hhs.gov/RAC)), the OIG Work Plan, etc.

Note that the RAC demonstration program did not focus on ENT physicians specifically; thus, a review of the RAC demonstration results is not particularly helpful for ENT physicians with the exception of vestibular

<sup>26</sup>Section 1870 of the Social Security Act. See also Medicare Financial Management Manual, CMS 100-06, Chapter 3, Section 70 *et seq.*

<sup>27</sup>See Section 1893 of the Social Security Act and Medicare Program Integrity Manual, CMS Pub. 100-08, Chapter 3, Section 3.10 *et seq.*

function testing.<sup>28</sup> As of the date of publication of this chapter, the RACs' Web sites did include certain ENT physician-specific issues presently under RAC review (e.g., the RACs are presently reviewing certain E & M issues). These Web sites should be continuously monitored as Medicare approves additional areas for RAC review. A review of other guidance documents, such as the OIG Work Plan, will be helpful to identify areas that may be subject to scrutiny. For example, the 2011 OIG Work Plan states that payments for E & M services will be subject to scrutiny in 2011.

2. *Reviewing* and educating physicians regarding any Medicare NCDs and LCDs applicable to claims submitted by the physicians
3. *Designating* an audit "point person" responsible to monitor communications from Medicare and its contractors, which will include monitoring records requests and ensuring that such requests are responded to within the requisite time frames
4. *Implementing* compliance efforts, including but not limited to (a) educating staff members regarding the potential business impact of Medicare audits and the corresponding importance of compliance and appropriate response to records requests and claim determinations and (b) performing documentation and coding education. Documentation and coding education may entail engaging a qualified health care legal professional and coding professional to conduct a formal compliance audit of high-risk claims.
5. *Tracking* claim denials, monitoring and abiding by appeal deadlines, and properly working up appeals to challenge denials in the appeals process

## PHYSICIAN LICENSING ACTIONS AND THEIR COLLATERAL EFFECTS

### Introduction

Whether an otolaryngologist is a medical doctor or an osteopath, his or her ability to practice in any given state within the United States (other than at a federal institution such as a VA hospital) is governed by the laws of that state. While some states allow a physician who is not licensed in their particular state, but who is licensed in another state in good standing, to practice in their state under certain special circumstances (e.g., in an educational setting or in emergency circumstances), the far majority of the time a physician must be compliant with the laws, rules, and regulations of each state in which the physician practices.

<sup>28</sup>The majority of physician claim denials made during the RAC demonstration program involved pharmaceutical injectables, Neulasta (incorrect coding), Vestibular function testing, and duplicate claims. See "The Medicare Recovery Audit Contractor (RAC) Program: An Evaluation of the 3-Year Demonstration," available at <http://www.cms.gov/RAC/Downloads/RACEvaluationReport.pdf>.

Physicians will be deemed to have constructive knowledge of such laws, rules, and regulations regardless of whether he or she has actual knowledge thereof. As such, it is imperative for a physician seeking licensure in a given state to become familiar with that state's governing laws, rules, and regulations, especially since there are some significant differences (e.g., in some states there are express prohibitions against prescribing medication to family members regardless of the circumstances, whereas in other states, such prescribing is allowed as long as the physician determines that he or she can maintain objectivity when treating the patient). Typically, states have boards of medicine that promulgate administrative rules and guidance to which physicians should adhere, in addition to public health codes and other statutory and case law, in order to avoid disciplinary action taken against a physician's license. Some states have one board of medicine that governs both medical doctors and osteopaths while other states have separate boards for each—although the rules and guidance for medical doctors often mirror those for osteopaths. These medical boards are administrative agencies often composed of not just physicians but other health care providers and members of the public appointed by state executive officials (such as the governor) and serve to govern the medical profession and help to protect the health, safety, and welfare of the public.

The bases for disciplinary action are often codified by statutory law in each state and are enforced by the state's medical board. Some bases may be very specific (e.g., violation of a particular state statute regarding prescribing a medication for an illegitimate, nontherapeutic purpose), while other bases are rather broad (e.g., acting outside the applicable standard of practice). An important distinction for physicians to keep in mind is the difference between a licensing action and a medical malpractice action. In a medical malpractice action, the physician's actions or omissions must cause damages for liability to arise. In a licensing action, causing damages is not a requisite element. As such, a physician may find himself/herself subject to a licensing action for failing to document information where the applicable standard of practice requires such documentation in the medical record even though the lack of documentation did not result in any harm to a patient.

### How Licensure Actions Arise

An action against a physician's license typically arises from a complaint filed with the state medical board by a person or entity with firsthand knowledge of alleged wrongdoing by the physician (e.g., a patient, employee, or employer of the physician). Some states allow for completely anonymous complaints while others require the complainant to identify himself or herself in order to commence an investigation. In some scenarios, the complainant is the court clerk who under legal authority is required to report to the medical board when a physician is convicted of a crime



or an alcohol- or drug-related offense. In some states, the complainant may be the physician's medical malpractice defense attorney who is required to report to the medical board a verdict or settlement against the physician in a medical malpractice action. The complainant may be a hospital where the physician had his or her medical staff privileges reduced, limited, suspended, or revoked or employment terminated. The physician himself or herself may even be the complainant as, in nearly every state, the physician has a duty to self-report a disciplinary action or criminal conviction against the physician in another state within a certain prescribed time frame (e.g., 30 days from the date of the final order or conviction).

Typical allegations asserted against a physician are for quality of care concerns, a scope-of-practice concern issue or the conduct of the physician—which may include potential criminal conduct (e.g., a patient who is billed for services that he or she never received may submit a written allegation against the physician to the applicable state medical board). After receiving an allegation, the medical board typically reviews it and determines whether the alleged facts, if true, could be deemed a violation of the state's public health code or other statutory laws or case law and thereby warrant an investigation.

An investigation into an allegation usually involves interviewing the person filing the allegation, interviewing the physician, identifying and interviewing other persons such as coworkers or employers who may provide relevant information, and collecting other evidence.

### Administrative Complaint and Hearing

If the medical board determines that there is sufficient evidence to demonstrate a violation of the applicable public health code or law, a formal administrative complaint is typically filed by the state against the physician (often called the "licensee" in such matters) charging the physician with specific statutory violations or other violations of the law.

Nearly every state also provides the medical board with grounds for the issuance of an administrative complaint for numerous preceding criminal violations. For example, a conviction of any criminal sexual conduct; reckless or intentional inappropriate destruction or alteration of medical records; a misdemeanor or felony involving fraud to obtain professional fees; a misdemeanor related to the ability to practice safely/competently; and practicing under the influence of alcohol or drugs in many states provides a basis for a licensing action against the convicted physician.

Since the state medical board is charged with protecting the health, safety, and welfare of its citizens, if the medical board believes that there could be an immediate risk to the public health, safety, or welfare, it may order a summary suspension of the physician's license until an administrative hearing is held. Under such circumstances, the physician must immediately cease practicing medicine

even before he or she is given an opportunity to defend his or her actions and cannot practice medicine until otherwise authorized to do so by the medical board. Summary suspension typically occurs where the physician is convicted of a felony or a misdemeanor involving the illegal delivery, possession, or use of a controlled substance.

The procedures to be followed after the issuance of an administrative complaint differ from state to state; however, they typically require the physician to file an answer to the administrative complaint and provide the licensee an opportunity to meet with members of the medical board to attempt to reach a resolution of the administrative complaint short of attending a formal administrative hearing. These procedures usually have specific deadlines associated with answering the administrative complaints, requesting and attending settlement conferences and other procedures for which failure to comply can have severe adverse consequence for the physician (e.g., failing to timely answer an administrative complaint in some states results in all of the allegations being deemed admitted and the matter goes straight to the medical board for imposition of sanctions against the physician). Proposed settlements usually require formal approval by the medical board and are typically available to the public.

If a settlement cannot be reached, the matter proceeds to an administrative hearing to be conducted in accordance with established state administrative procedures and rules governing the conduct of the hearing, introduction of evidence, and the examination of witnesses. The purpose of the hearing is to determine the facts of the case and the laws and rules that should be applied to the case. Should the physician be found to have violated the applicable state laws, sanctions will be imposed upon the physician and/or his or her license, which can include a monetary fine, probation, reprimand, restriction on the license, additional medical education beyond the standard requirements for continuing medical education, community service, and/or suspension or revocation of the license.

### Licensing Actions May Lead to Criminal Prosecution

While state public health codes have numerous grounds upon which the medical boards may rely for the issuance of an administrative complaint, some provisions are more apt to lead to criminal prosecution, for example, allegations of an inappropriate sexual relationship with a patient, a pattern of providing controlled substances without medical necessity, a pattern of fraudulent billing, and a pattern of performing medically unnecessary procedures for personal financial gain. All of these offenses typically fall within express provisions of state public health codes giving rise to a licensing action and also fall within the ambit of numerous state and federal criminal statutes, thereby leaving the physician exposed to potential criminal prosecution.



Furthermore, it is important to understand that some actions by physicians subsequent to being served with an Administrative Complaint may also lead to criminal prosecution. One common allegation contained within an administrative complaint is that the physician violated his or her general duty due to inadequate, insufficient and/or missing documentation. Such an allegation can lead a concerned physician to attempt to “correct” the situation by creating records where none existed or supplementing the records to address the alleged inadequacy or insufficiency without including sufficient information to make it clear when these new records were added. Such action by a physician is typically a felony under state statutory law.

When defending a health care licensing matter, it is important to always consider the possibility of criminal exposure for the subject physician. Such consideration is integral to the decision of whether to have the physician testify at an administrative hearing. Physicians have to weigh the risk of asserting their Fifth Amendment rights against self-incrimination in order to avoid having admissions made during administrative proceedings that could be used against them in a criminal matter.

A physician facing a health care investigation or an administrative action by a state medical board cannot afford to take a myopic view of his or her predicament. Due to the criminal implications and the domino effect that often accompanies the imposition of state-imposed sanctions, such physician are well advised to obtain experienced health care counsel as early as possible in the process who will take an expansive view of the matter in order to assess the collateral damage that could result from a proposed settlement of a state action. Although most attorneys are knowledgeable enough to inform their clients of their Fifth Amendment rights against self-incrimination in order to avoid having their clients make any admissions during the administrative proceedings, which could lead to criminal charges, many attorneys are unaware of the effects that collateral sanctions may have on their clients. Any settlement strategy should take into consideration all of the collateral sanctions and enforcement actions that could arise as a result of a settlement.

### Collateral Effects of a Licensing Action Other Than Criminal Prosecution

In addition to the aforementioned potential for criminal prosecution, there are numerous consequences and collateral effects that a licensing action may have on a physician. Any sanctions imposed upon the physician are typically published online and in the state’s disciplinary action report, and notice of the sanctions is sent to numerous state and federal authorities (which, for physicians, may include the National Practitioner Data Bank), along with applicable professional associations, and various national and local news associations (e.g., the Associated Press and the United Press International). The severity of the sanction imposed by the state medical board will determine the extent of the

collateral damage to the physician. The following is a list of some, but not all, of the repercussions that a sanctioned physician may encounter: loss of hospital privileges, loss of participation and enrollment with state professional associations, loss of participation in preferred provider organizations (PPOs), loss of enrollment with third party payors, loss of DEA registration, loss of board certification, and exclusion from participation with Medicare, Medicaid, and other federal and state government programs.

As noted above, nearly every state requires a physician who is disciplined in another state to report such discipline to their state. Thereafter, such state has the right to file its own disciplinary action against the physician even though all of the facts and circumstances that gave rise to the original disciplinary action took place in the other state. As a result, the derivative state may impose even a harsher sanction against the physician than the sanction imposed by the originating state depending upon the laws, policies, politics, and mind-set of the derivative state.

### Conclusion

Unfortunately, some physicians fail to appreciate the serious magnitude of an allegation filed against them with their state licensing body. Whether a physician is contacted directly by an investigator or whether he or she hears from a patient or an employee that an investigator has been asking questions regarding the professional behavior/conduct of the physician, the physician should immediately contact an experienced and knowledgeable health care attorney to provide assistance and guidance at the earliest possible stage. All too often, physicians believe that they can explain away or justify the alleged inappropriate behavior/conduct only to learn later on that such admissions are used as direct evidence against them to support a sanction against his or her health care license. Moreover, depending on the severity of the sanction imposed, there are numerous collateral effects that a state licensing action may have on the physician, including, but not limited to

1. Loss of hospital privileges and/or employment
2. Loss of enrollment with state professional associations and their associated benefits (e.g., health, disability, and life insurance)
3. Loss of participation in PPOs and other third party payors
4. Loss of DEA registration, state-controlled substance licenses, and other health care licenses/registrations
5. Loss of board certification
6. Exclusion from participation with Medicare, Medicaid, and other federal and state governmental programs
7. Commencement of other judicial or administrative proceedings (e.g., criminal proceedings, civil monetary proceedings, malpractice actions, and other state licensing actions)
8. Permanent reports to the National Practitioner Data Bank and state licensing data banks

Prior to the commencement of a formal hearing, there is often a window of opportunity in which an experienced and knowledgeable health care attorney can help the physician to develop and implement prophylactic measures and to take certain actions that may convince the licensing authorities not to proceed with disciplinary action or to accept a sanction less severe than originally recommended. Due to this relatively small time frame, it is imperative that the physician contact an attorney at the earliest recognizable stage of a potential licensing matter. As Benjamin Franklin once said: “an ounce of prevention is worth a pound of cure”—a physician that retains an experienced and knowledgeable health care attorney early in the process can often avoid the increased time and financial resources involved in trying to win a licensure case at an administrative hearing, when compared to resources needed to implement reasonable measures to rectify the alleged inappropriate behavior/conduct.

## SETTING UP A PHYSICIAN PRACTICE

### Introduction

Physicians very rarely graduate from medical school knowing how to successfully run a business. And a physician practice is just that: a business. Fortunately, physicians are often successful in organizing and operating their own medical practices, especially when they rely upon a team of qualified and experienced professionals, such as accountants, financial advisors, attorneys, billing companies, and third party payor enrollment consultants.

As discussed further below, from a corporate perspective, organization of a new business generally involves several steps, including each of the following:

- Establishing the business entity (typically through a state-level filing of Articles of Incorporation, Certificates of Incorporation, Articles of Organization, or other equivalent document, as appropriate)
- Applying to the Internal Revenue Service (IRS) for a federal tax identification number (EIN)
- Protecting the name and other intellectual property of the practice, as appropriate
- Negotiating and adopting governing documents (Bylaws, Shareholders' Agreement, Operating Agreement, Buy-Sell Agreement, etc.)
- Adopting initial corporate resolutions to ratify the organization of the entity; adopting the governing documents; electing directors, managers, and officers, as the case may be; authorizing the establishment of a bank account; etc.
- Enrolling in Medicare and other third party payors
- Opening bank accounts and obtaining necessary insurance

Physicians who refrain from obtaining the valuable guidance of legal, financial, and reimbursement professionals in order to limit the associated costs often eventually

incur unnecessary (and sometimes substantial) expenses to correct problems that would have been avoidable had the practice adopted a more conscientious approach to its organization. Examples of the unfortunate circumstances that sometimes face practices that have acted in an uninformed and/or careless manner include the following:

- Failure to officially organize the business entity or provision of incorrect information when applying for an EIN, resulting in delay in receiving Medicare billing numbers and lost revenue
- Disregard for corporate practice of medicine doctrines, if applicable, eventually requiring the practice to restructure
- Misunderstanding of the nature of, and the benefits offered by, the form of business entity resulting in the physician entering agreements with hospitals and others in the physician's individual capacity instead of through the business, which can lead to unanticipated adverse tax consequences
- Lack of appreciation for the importance of maintaining corporate formalities (such as holding annual meetings, adopting corporate resolutions, maintaining corporate records and minutes, etc.), which makes it more likely that creditors will attempt to impose personal liability upon the owners of an entity who otherwise have the protection of limited liability (often referred to as “piercing the corporate veil”)

The purpose of this section is to provide a broad overview of certain considerations with respect to the organization of a new physician practice. As discussed above, it is highly advisable for physicians to engage professional advisors who are able to position the new practice for success. Nothing set forth below is a substitute for such guidance.

### Choice and Formation of Business Entity

The form of a business entity, the relationship of such business entity to its owner(s) and creditors, and its operations are governed, at least in part, by the state in which the business is organized and the states in which the business operates.

Each state has its own specific statutes, regulations, and other guidance with respect to the various corporate forms recognized by such state. Most states publish an abundance of helpful information on their Web sites that explain the pros and cons of choosing one form of entity over another and the process for organizing such entity. State publications on these topics are often geared toward small businesses and include references to other related legal requirements, including those pertaining to taxes, licenses, and securities requirements. Although it is common for business entities to organize themselves in states other than those in which they operate (e.g., in the State of Delaware because of the favorable and well-developed corporate laws in such jurisdiction), physician practices are generally organized in the same state in which they operate

due to their relatively limited size and their heavily regulated nature.

A brief overview of certain common forms of business entities follow below. Although such descriptions are generally true, each state has its own unique requirements, and physicians should work with their legal and financial advisors with state-specific knowledge when making a final determination regarding choice of entity.

### **Sole Proprietorship**

A sole proprietorship is a form of entity that is owned by one person who generally owns all of the assets of the business and is personally liable for the debts of the business. Because a sole proprietorship is not a business entity that is distinct from its owner, a sole proprietorship cannot continue beyond the life of the owner. Sole proprietorships generally do not need to file documents at the state level to form their business; however, they sometimes need to file their name and other information in the counties in which they operate. For the reasons just stated and others, it is rarely advisable for a physician to form a physician practice as a sole proprietorship.

### **Partnerships**

Many states recognize at least two types of partnerships: (a) general partnerships and (b) limited partnerships.

#### **General Partnerships**

A general partnership is a form of entity that is owned by at least two people. All of the owners are personally liable for the debts of the business. All profits and losses of a partnership generally flow through to the partners for tax purposes. Partners often enter into a written partnership agreement to govern their relations. Typically no state-level filing is required to form a partnership, but partnerships sometimes need to file their name and other information in the counties in which they operate. Similar to sole proprietorships, it is typically inadvisable for a physician to form a physician practice as a partnership.

#### **Limited Partnerships**

A limited partnership is a form of entity that is owned by at least two people, at least one of which is a general partner who has personal liability for partnership debts and has the majority of management rights. Limited partnerships are typically distinct from general partnerships in that limited partnerships are generally created by filing documents at the state level and offer limited liability to some of its investors. Today, it is not common for physician practices to be formed as limited partnerships because of the lack of flexibility offered by most state limited partnership laws.

### **Nonprofit Corporation**

Although rare, physician practices can be formed as nonprofit corporations, which are formed through state-level filings typically referred to as Articles of Incorporation. Depending upon the specific state law, nonprofit corporations may be

formed on a stock, membership, or directorship basis for any lawful purpose not involving pecuniary gain or profit for its officers, directors, shareholders, or members. It is important to note that not all nonprofit corporations are federally tax-exempt organizations. Although many health care organizations are exempt from federal income tax under 501(a) of the Internal Revenue Code, such tax-exempt status is generally only available when all applicable requirements are satisfied and the entity submits an Application for Recognition of Exemption to the IRS.

### **Corporations**

Profit corporations are generally formed by submitting a state-level filing for the purpose of generating profit for their owners, who are referred to as shareholders. The internal affairs of a corporation and the relationships among the shareholders are often governed by the corporation's Bylaws, Shareholders' Agreement, and Buy-Sell Agreement, as applicable. Such document filed with the state is usually referred to as the corporation's Articles of Incorporation or Certificate of Incorporation. Most corporations are governed by three layers of management: shareholders, directors, and officers. Shareholders, directors, and officers are generally not liable for the corporation's obligations unless they sign a personal guarantee or enter a contract in their individual capacity on behalf of the corporation. A corporation can exist indefinitely and its existence is not affected by the death of a shareholder. Except in the case of an S Corporation as described below, a corporation is taxed separate from its owners.

#### **S Corporation**

An S Corporation is a profit corporation that elects "S Corporation" status for federal tax purposes by filing Form 2553 (Election by a Small Business Corporation) with the IRS. S Corporations are distinct from other general profit corporations in that the profits and losses of the S Corporation flow through to the shareholders, who report the S Corporation's income and losses on their personal tax returns. There are several requirements that a corporation must satisfy in order to be eligible for S Corporation status, including, without limitation, the following: (a) be organized as a domestic corporation, (b) have only allowable shareholders (i.e., no partnerships, corporations, or nonresident alien shareholders as shareholders), (c) have no more than one hundred shareholders, and (d) have only one class of stock.

#### **Limited Liability Company**

Limited liability companies (LLCs) are created through state-level filings, which are generally referred to as an LLC's Articles of Organization. LLCs are sometimes managed by their owners, referred to as members. In other cases, LLCs are managed by a manager or group of managers (i.e., a Board of Managers), but the members continue to have ultimate authority over certain major decisions pertaining to the LLC. In addition to the Articles of Organization

or equivalent document, the internal affairs of a company and the relationships among the members are often governed by the company's Operating Agreement, as applicable. Members are generally not liable for the obligations of their LLC unless they sign a personal guarantee or enter a contract in their individual capacity on behalf of the company. For purposes of federal income tax, LLCs are taxed as sole proprietorships, partnerships, corporations, or S Corporations depending upon the number of members and the elections made by the LLC. An LLC can exist indefinitely and its existence is not affected by the death of a member.

### Professional Service Entities

Many states either require or permit business entities that provide professional services such as medicine to be organized as a professional corporation, professional limited liability company, or other professional entity and be owned exclusively by licensed professionals who are legally authorized to provide such professional service. These requirements are typically set forth in the corporate statutory laws of such states.

### Corporate Practice of Medicine

Many states prohibit a business entity from practicing medicine or employing a physician to provide medical services (often referred to as the "corporate practice of medicine") unless an exception applies. The state corporate practice of medicine prohibitions and exceptions is set forth in state statutes, regulations, case law, and attorney general opinions. Such prohibitions are intended to protect physician decision making and prevent a physician's loyalty from being divided between the needs of a corporation and the needs of the patient. States generally limit application of the corporate practice of medicine doctrine through certain exceptions, including those created for hospitals and other licensed health care facilities and also professional business entities such as professional corporations and professional LLCs. States often adopt these exceptions because the entities covered by the exception are either licensed themselves or owned by licensed physicians, and therefore, applying the corporate practice of medicine to such businesses is not necessary to advance the underlying purpose of the doctrine.

### Name Protection

Physician practices, like most businesses, have an interest in protecting their identity and reputation. For those business entities that are formed through state-level filings, the applicable state will generally only accept the filing if the name of the business entity is distinguishable from other active names on the business records of the state. For many small physician practices, the level of protection offered by state corporate laws with respect to a corporate name is sufficient. However, business entity's that are more concerned about protecting their corporate names can register their

name as a trade mark or service mark. Additional information regarding this process can be found at <http://www.uspto.gov/smallbusiness/trademarks/>.

### Securing a Business Loan

Newly formed physician practices require capital to procure the resources required to commence operations (e.g., office space, office and medical equipment, IT/EHR software and hardware, furnishings, supplies, payroll, insurance premiums, legal and other professional expenses, etc.), and such capital may be obtained in several different ways. First, practice owners (usually referred to as the partners, members, or shareholders depending upon the form of business entity selected) often contribute capital or loan money to the business. Yet most physicians are unable to independently provide all of the necessary financing. Second, the initial financial burden of commencing the practice operations can be mitigated if the practice leases the items, or obtains financing from the vendor, instead of purchasing the items immediately in cash. Third, it is also important to note that federal law, including the federal Stark Law and Antikickback Law, permits hospitals to provide certain financial support and income guarantees to physicians that relocate and establish a practice within the geographic area served by a hospital when certain requirements are satisfied. Such support is most prevalent in underserved areas. Fourth, in the event that the options just described are insufficient, traditional third party financing is an attractive option. The legal and financial advisors to the practice often have strong relationships with banks and finance companies and can therefore recommend those that provide competitive interest rates on fair terms. However, it is important to understand that most lenders will require personal guarantees or other security interests necessary to sufficiently protect them if the practice defaults on the loan.

### Securing Insurance

It is highly advisable for physician practices to acquire insurance coverage that is appropriate for the size and nature of the practice's business. Such insurance policies may include, without limitation, the following:

- a. Commercial liability
- b. Auto
- c. Employment practices
- d. Professional liability
- e. Errors and omissions
- f. Directors and officers
- g. Premises liability
- h. Personal property
- i. Workers' compensation
- j. Key-Man life
- k. Health, disability, long-term care, etc.



Before contacting insurance agents to obtain information and quotes for coverage, physician practices should understand their insurance needs. For example, the practice should consider the following terms: coverage limits, naming additional insureds, whether the insurance should be on a claims-made or occurrence basis, who needs to be covered (i.e., employees, volunteers, etc.), etc. Practices also need to be cognizant of those insurance requirements imposed upon the practice by applicable state law (e.g., pertaining to workers' compensation insurance and often professional liability insurance) and those insurance requirements imposed upon the practice by contract (e.g., office space and equipment leases, employment and independent contractor agreements, agreements with hospitals, third party payors, etc.).

### Obtaining a Federal Tax Identification Number

After a new business entity is officially organized (through the filing of Articles of Incorporation, Certificate of Incorporation, Articles of Organization, or otherwise), the next priority is generally to file for a federal employer identification number (often referred to as a TIN or an EIN). Additional information regarding federal tax identification numbers and the process for applying for such number can be found at <http://www.irs.gov/businesses/small/>. Irrespective of whether the application is submitted online, by telephone, by fax, or by mail, applicants must be very careful to complete the forms in a diligent manner to ensure that all information provided is complete and correct to avoid subsequent problems from arising. Physician practices should maintain a copy of the application and all related documentation, including IRS Form CP575 (which provides verification of the EIN), as it will often be required to open a bank account and apply for a Medicare provider number. Further, it is advisable for physician practices to work closely with their financial advisors in this regard to ensure that the S election, if applicable, and other related filings are timely filed.

### Enrolling with Third Party Payors

In order for a physician practice to operate and thrive, it will be necessary for the practice to effectively and efficiently obtain reimbursement for its services. Therefore, enrollment with Medicare and other third party payors is an important part of organizing a physician practice. Today, Medicare enrollment can be accomplished electronically through CMS' Internet-based Provider Enrollment, Chain, and Ownership System established by the CMS, which is the branch of the U.S. Department of Health & Human Services (HHS) that administers the Medicare program. CMS Form 855B is the enrollment application used by clinics and group practices, and CMS Form 855I is the enrollment application used by physicians. Such

applications require the submission of an abundance of information and documentation in a complete and accurate manner. Additional information pertaining to Medicare provider enrollment is available at <http://www.cms.gov/MedicareProviderSupEnroll/>. Each third party payor also has its own unique provider enrollment policies and procedures although many such payors utilize a universal credentialing application called Universal Provider Datasource, which is described at <http://www.caqh.org/ucd.php>.

## IMPLEMENTING HIPAA PRIVACY AND SECURITY IN A PHYSICIAN'S OFFICE

### Introduction

HIPAA, the Health Insurance Portability and Accountability Act,<sup>29</sup> was passed by Congress in 1996 and was designed to improve the efficiency and effectiveness of the health care system. Although the primary purpose of HIPAA is to protect health care coverage for individuals who lose or change their jobs, it also includes Title II, better known as the Administrative Simplification Act. Title II requires the U.S. Department of HHS to adopt national standards for electronic health care transactions in order for the health care industry to become more efficient. Congress also recognized, however, that advances in electronic technology could erode the privacy and security of health information. Consequently, Congress incorporated into HIPAA provisions that mandate the adoption of federal privacy and security protections for individually identifiable health information.

### HIPAA Privacy Rule

The HIPAA Privacy Rule pertains to three categories of "covered entities"—health care providers, health plans,<sup>30</sup> and health care clearinghouses.<sup>31</sup> Health care providers are covered if they transmit health information electronically. Even a doctor in a small practice who keeps only paper records will almost certainly use a billing service that transmits information electronically. In short, it is nearly impossible to provide health care today without using electronic means in some way and therefore fall under the purview of the HIPAA Privacy Rule.

<sup>29</sup>Pub. L. 104–191.

<sup>30</sup>Health plan means almost anyone that pays for the cost of medical care. This includes health insurance companies, HMOs (health maintenance organizations), group health plans sponsored by an employer, Medicare and Medicaid, and virtually any other company or arrangement that pays for your health care.

<sup>31</sup>Health care clearinghouses can be any number of organizations that work as a go-between for health care providers and health plans. An example of this would be a billing service that takes information from a doctor and puts it into a standard coded format. Patients rarely deal directly with clearinghouses.

The HIPAA Privacy Rule generally safeguards the confidentiality of protected health information (PHI), which is defined as “individually identifiable health information” that is transmitted electronically, maintained electronically, or transmitted or maintained in any other form or medium.<sup>32</sup> It includes not only paper and electronic records but oral statements as well. Common documents that would be considered to contain PHI would include (a) all components of the medical record, (b) information contained on billing cards or superbills, (c) information contained on hospital face sheets, and (d) information contained on other forms such as the financial consent, informed consent, and patient information sheets.

The HIPAA Privacy Rule places restrictions on how a physician group can use PHI within the practice and how and when PHI can be disclosed to entities outside the practice. In general (with exceptions for emergencies), the privacy rule prohibits health care providers from using or disclosing PHI without first obtaining the patient’s HIPAA consent. The HIPAA consent is different from informed and financial consents in that the HIPAA consent is for “use” and “disclosure” of PHI. However, HIPAA consent is not required to use and disclose PHI for treatment, payment, and operations.<sup>33</sup> If the physician group uses or discloses information for other purposes such as for certain research or marketing activities, a HIPAA authorization would have to be signed by the patient.

Another important document that must be provided to the patient at the time of the HIPAA consent is the group’s HIPAA Notice of Privacy Practices.<sup>34</sup> This document is separate and apart from the HIPAA consent and must be posted in a conspicuous place in the physician’s office. The HIPAA notice is a document that must set forth a number of items including, but not limited to, (a) all of the different uses and disclosures of PHI that the physician group is permitted to make under the privacy rule, (b) how the patients can get access to their information, (c) the manner in which patients can complain to the group with regard to potential breaches of privacy, (d) a statement that the patient has the right under HIPAA to request certain restrictions on their PHI (note that the group is not required to agree to all restrictions), and (e) an explanation of the privacy policies and procedures that the practice has put in place.

In addition to the HIPAA consent and notice requirements, physician groups are also required under the privacy rule to implement privacy policies, establish formal safeguards, and train the practice’s staff to ensure the privacy of PHI. In order to meet these administrative requirements,

organizations must first formally designate an individual within the organization as the “Privacy Officer.” The Privacy Officer will be responsible for the “development and implementation” of the policies and procedures necessary for compliance under the HIPAA privacy rule.<sup>35</sup> These administrative requirements impose a focus on privacy that may have previously taken a back seat in the hectic, business-like atmosphere that often characterizes modern-day health care.

In order to effectuate the required training, physician practices should have compliance programs in place, which should include HIPAA education as part of an annual compliance education in service. The education should focus on providing employees with a general understanding of HIPAA as well as explaining the policies and forms that will be put in place. Education should also include practical tips to make certain that a patient’s privacy is not breached, such as the following:

1. Following phone protocols. A medical office must have specific guidelines for what information is given over the phone. Certain individuals like health insurance representatives or family members might have clearance to be told patient information, but other callers should be given only basic information that does not violate HIPAA.
2. Protect workstations. A computer that has access to PHI, should always be locked when the person who uses it is away from the desk to prevent unauthorized use.
3. Protect papers. Documents like medical claims and bills should be turned face down when the person who is responsible for them is away from the desk. The files must be kept in secure containers where they cannot be read by someone passing by.
4. Use HIPAA-compliant waste baskets and shredders. Some offices have color-coded trash bins, one set for regular trash like apple cores and gum wrappers and another covered set of bins for documents. The documents that go in the secure bins get shredded every day. The other trash bins get emptied by cleaning people at night.

In addition to training its employees, practice groups must enter into agreements with each of their business associates (BAs) wherein the BAs agree to safeguard PHI provided by the group or PHI that the BAs access via permission of the group.<sup>36</sup> In general, BAs are independent entities that provide services on behalf of the group that involve PHI. A list of common BAs for a practice may include the following:

1. Billing companies
2. Practice management companies
3. Collection agencies
4. CPA firms and law firms

<sup>32</sup>45 C.F.R. §160.103.

<sup>33</sup>The privacy rule incorporates what it calls a “minimum necessary” standard when it comes to how much information should be disclosed. Covered entities are required to limit the amount of information disclosed to others to the minimum necessary to accomplish the intended purpose. 45 CFR §§164.502(b), 164.514(d).

<sup>34</sup>45 CFR §164.520(a) and (b).

<sup>35</sup>45 CFR §164.530(a)(1).

<sup>36</sup>45 CFR §§164.502(e) & 164.504(e).

5. Independent compliance auditors
6. Record storage companies
7. Software vendors
8. Cleaning services

### The HIPAA Security Rule

Privacy and data security go hand in hand. The security rule, like the privacy rule, creates a national standard. This means that all health care providers, health plans, and health care clearinghouses that transmit information electronically must adopt a data security plan.

Only PHI maintained or transmitted in electronic format (E PHI) is covered by the security rule.<sup>37</sup> For example, E PHI would include billing information contained on a computer system, electronic medical records, and computerized patient scheduling systems in an ENT practice. Although nonelectronic PHI (e.g., hardcopy medical charts) is not covered by the HIPAA security rules, this information is still protected by the HIPAA privacy rules.

The security rule, according to the HHS, was designed to be flexible, establishing a security framework for small practices as well as large institutions. All covered entities must have a written security plan.<sup>38</sup>

The general requirements of the HIPAA Security Rule mandate that covered entities do all of the following:

1. Ensure the confidentiality, integrity, and availability of all E PHI that the entity creates, receives, maintains, or transmits
2. Protect against any reasonably anticipated threats or hazards to the security or integrity of such information
3. Protect against any reasonably anticipated uses or disclosures of such information that are not permitted or required by the HIPAA Privacy Rule
4. Ensure workforce compliance<sup>39</sup>

To achieve compliance with the general HIPAA Security Rule requirements set forth above, covered entities are required to meet 18 standards. In order to meet each of these standards, the HIPAA Security Rule sets forth implementation specifications that serve as the instructions for compliance with each standard. There are two types of implementation specifications, "required" and "addressable."

Required implementation specifications must be implemented as set forth in the HIPAA Security Rule. Addressable implementation specifications allow covered entities to implement alternative specifications instead of, or in combination with, the implementation specification set forth in the HIPAA Security Rule. If an alternative approach is taken, the entity must document its decision

not to implement the HIPAA Security Rule's implementation specification, the rationale behind its decision, and the alternative approach that it has chosen. The standards and their related implementation specifications are broken down into three broad categories: (a) administrative safeguards,<sup>40</sup> (b) physical safeguards,<sup>41</sup> and (c) technical safeguards.<sup>42</sup> The administrative safeguard standards require entities to analyze the risks of unauthorized disclosure of E PHI within the entity, implement a number of required policies and procedures, and maintain certain documentation to manage and minimize risk. Physical safeguard standards deal with the security measures taken to protect buildings and equipment, which house E PHI, from natural and environmental hazards and unauthorized intrusion. The policies and procedures required under this standard include policies to protect the physical locations that house electronic equipment, as well as to protect the equipment itself. Technical safeguard standards deal with the technology measures to safeguard and control access to E PHI as well as the development and implementation of policies and procedures dealing with the use of technology.

To address HIPAA security, the following action plan should be implemented:

1. Appoint a Security Officer (this is required under the rule<sup>43</sup>) who must review and understand the requirements of the rule. The Security Officer may need to seek outside assistance from attorneys or consultants versed in the HIPAA Security Rule.
2. Identify BAs that are creating, receiving, or transmitting E PHI for the practice and include HIPAA security language in the BA agreement.
3. Inventory E PHI and electronic systems within the practice and begin working on the required policies and procedures.
4. Conduct required security training with all workforce members.

### Why Physician Offices Must Be HIPAA Compliant

HIPAA sets a national standard for accessing and handling medical information. Before HIPAA, the right to privacy of health information varied from state to state. Now, health care providers, health plans, and other health care services that operate in all states have to abide by the minimum standards set by HIPAA. Any state is free to adopt laws that give patients more privacy, but it cannot take away the basic rights given by HIPAA.<sup>44</sup> Compliance with HIPAA's privacy and security requirements is mandatory, and failure to

<sup>37</sup>45 CFR §160.103.

<sup>38</sup>45 CFR §§164.306(b)(2) and (e).

<sup>39</sup>45 CFR §164.306(a).

<sup>40</sup>45 CFR §164.308(a).

<sup>41</sup>45 CFR §164.301(a) to (d).

<sup>42</sup>45 CFR §164.312(a), (b), (c), and (e).

<sup>43</sup>45 CFR §164.308(a)(2).

<sup>44</sup>45 CFR §§164.202, 164.203.

comply could lead to civil and criminal penalties. In 2009, the Health Information Technology for Economic and Clinical Health (HITECH) Act was passed, which, in part, strengthens HIPAA's privacy and security protections and, notably, increases its enforcement rules.

The HHS Office of Civil Rights (OCR), which in addition to its responsibility for enforcing the HIPAA Privacy Rule was given responsibility in July 2010 for security rule enforcement too, has implemented a stronger enforcement program in the form of HIPAA privacy and security audits. The OCR's implementation of proactive HIPAA compliance audits, required under the provisions of the HITECH Act, marked a shift from the largely reactive approach to compliance and enforcement seen since the HIPAA Privacy and Security Rules went into effect in 2003 and 2005, respectively. The audits will focus on how covered entities are meeting specific HIPAA requirements such as implementation of appropriate safeguards and seek evidence that risk analysis, contingency planning, and other key activities are in fact being carried out. In concert with stronger procedural methods for enforcement, the HITECH Act also increased the civil and criminal penalties for noncompliance, gave state attorneys general the right to sue covered entities for violations on behalf of state residents, and mandated formal investigations for any cases of HIPAA violations involving willful neglect. Collectively, all of these measures must make compliance a bigger priority for HIPAA-covered entities (and BAs too, since HITECH extended most HIPAA requirements to apply directly to them as well).

## OPERATIONAL ISSUES

### Office Electronic Medical Records

Electronic medical records lie at the center of any computerized health information system. However, there is no law that requires medical practices to adopt electronic records. Nonetheless, the HITECH stimulus act does threaten nonadopters with cuts in their Medicare reimbursements. The cuts begin in 2015 and increase to a maximum of 5% of the reimbursements. As such, while not a mandate or law requiring the adoption of electronic medical records, the HITECH Act strongly encourages physicians to do so.

One of the primary purposes of the HITECH Act and the regulations promulgated under HITECH is to promote use of electronic health records (EHRs) in a manner that advances quality, safety, and efficiency of patient care. To that end, the HITECH Act not only includes provisions to protect the privacy and security of patient health information contained within EHRs but also provides for significant financial incentives under Medicare and Medicaid to eligible health providers who demonstrate meaningful use of EHRs. HITECH specifically authorizes the CMS to provide reimbursement incentives for eligible professionals and eligible hospitals who are successful in becoming "meaningful users" of EHRs.

On July 13, 2010, CMS issued the Final Rule<sup>45</sup> titled "Medicare and Medicaid Programs; Electronic Health Record Incentive Program" (the "Final Rule"), which sets forth the criteria that eligible health providers must satisfy to demonstrate meaningful use of EHRs sufficient to receive incentive payments from the federal government.

### Meaningful Use Criteria

Under the Final Rule, achieving meaningful use requires using certified EHR technology to achieve improvements in quality, safety, and efficiency in health care (i.e., physicians will not be able to achieve meaningful use through the adoption of EHRs alone). The Final Rule divides the meaningful use criteria into a "core" group of required objectives and a "menu set" of procedures from which providers can choose. This "two-track" approach ensures that the most basic elements of meaningful EHR use will be met by all providers qualifying for incentive payments while also allowing latitude in other areas to reflect the varying needs of providers pursuing full EHR use.

This Final Rule (Stage 1 of 3) will apply only to the first two (2) years of the federal meaningful use incentive programs. Stages 2 and 3 will include more stringent requirements for achieving meaningful use of EHRs in the future.<sup>46</sup>

### Physician Eligibility

Eligible physicians, who for purposes of Medicare generally include doctors of medicine or osteopathy, dentists or dental surgeons, podiatrists, optometrists, and chiropractors, began registering for the EHR meaningful use Medicare/Medicaid incentive program in January 2011. Payments under the incentive program began in May 2011. Importantly, hospital-based physicians are not eligible for the Medicare incentive payments and, subject to certain limited exceptions, are also not eligible for the Medicaid incentive payments. Under the Final Rule, CMS defines hospital-based physicians as those who furnish at least 90% of their professional services within an inpatient hospital or an emergency room hospital. Typical examples of hospital-based physicians include pathologists, anesthesiologists, hospitalists, or emergency physicians. CMS will determine noneligibility based upon site of service codes. In other words, physicians providing services in outpatient settings, including ambulatory clinics, are eligible for incentives.

Some physicians believe that being exempt from eligibility for the Medicare/Medicaid EHR incentives is a desirable result. This is due to the fact that hospital-based physicians who are exempt from otherwise available incentives

<sup>45</sup>75 FR 44590.

<sup>46</sup>The requirements contained within each of the three stages have been hotly debated, most notably by the physician specialists. These specialists have repeatedly complained that the requirements are only realistically attainable by the primary care physicians, and as a result, they will face financial sanctions for being unable to meet unattainable goals in the meaningful use of EHR.



will also be exempt from the penalties that will begin in 2015 if a provider fails to meet the meaningful use requirements. According to many specialty groups, this is particularly significant since they will find it difficult to meet the meaningful use requirements because the measures either do not apply to their specialty or they are not reportable through their specific practice's information management systems.

### Understanding Your Electronic Medical Record

As noted earlier in this chapter, physicians are facing unprecedented scrutiny in the submission of claims. For example, with respect to Medicare claims, not only do Medicare Affiliated Contractors (MACs), Medicare Carriers, and Intermediaries conduct their own audits, but also Medicare's RAC program is operational nationwide and has been expanded to include Part C and Part D claims, and Zone Program Integrity Auditors (ZPICs) and PSCs are conducting nationwide benefit integrity audits. With respect to Medicaid claims, MICs are actively auditing claims, and the RAC program is expanding to Medicaid claims as well. Physicians must be cognizant of this increased claims scrutiny and conduct themselves accordingly, with an increased focus on compliance.

Certain compliance issues are heightened with the use of electronic medical records. Auditors and medical reviewers routinely deny claims because an item or service is found not to be medically necessary. As such, it is essential that when a physician documents a service performed, such documentation must establish for the reviewer the medical necessity of the service rendered. There are special compliance issues that arise with respect to the use of electronic medical records, particularly with respect to issues of medical necessity. For example, many electronic medical records have built in "time savers," such as self-populating fields that insert a patient's medical history or procedural history into each record. These time-saving devices ultimately may hurt a provider if not used correctly, should the provider be subject to an audit. Auditors and claim reviewers may deny claims for medical necessity if it appears that the documentation is not tailored to the service performed but is merely a template. Each record should be distinct from the next. Additionally, auditors and claim reviewers may deny claims if they find that the medical records associated with the service or procedure are internally inconsistent. For example, claims have been denied because the medical record states in one area: "patient has no complaints of pain," but in another area states: "patient presents with severe pain." Providers using electronic medical records must ensure that they understand the capabilities of the software, have knowledge regarding which fields self-populate, and tailor each record to the patient's condition at the time of assessment.

With the coming of quality assessment programs from the government or commercial payers, the need exists for the inexpensive collection of quality data through

a limited series of questions, typically less than 10. Independent of any externally mandated data collection effort you need to understand your practice and how you can better serve your patients. Several kinds of systems are available for use including the manual review of paper or electronic medical records, paper forms completed by the patient or staff, interactive voice response systems, local electronic data capture systems, or central web-based systems. The advantages and disadvantages of each system are beyond the scope of this chapter. Your chosen system should permit you to capture information easily into a readily accessible format (usually electronic) easily manipulated by you or your staff. Careful consideration should be given to the capacity of a practice through its EMR or other systems to acquire information in a cost-effective timely manner.

Use of the Shewhart cycle or PDCA (Plan, Do, Check, Act—repeat) has proven to be a useful tool for process improvement. Focus on the correction of issues preventable by process improvement. Identify the root cause (people, processes, tools, materials) of issues. The purpose of data acquisition is not to improve the outcome by measuring it, but to improve its production process. However, if the outcome is unknown or variable in its outcome, document the processes that produce the desired outcome. If the process is variable, the process must first be stabilized, and then measured against stakeholder expectations. As long as the process is unstable, it will be impossible to make systematic changes to the process and get uniform results. A stable production process will prevent errors and assure ongoing consistent quality outcomes. Often true medical outcomes are often too costly in time, effort, or money to measure, and interim process measures must be utilized. Picking an interim process step or outcome that has face validity maybe acceptable alternative. Whenever possible, identify and use standardized data definitions to facilitate comparisons with surrogate data.

### Social Media and E-mail Communication

As with all businesses, medical practices face competition from other offices in their area and must differentiate themselves by portraying value and quality to their prospective clients. The use of social media outlets like Facebook, or collaboration tools like blogs or wikis, has provided a place for patients to learn about a physician's practice and decide on the value and quality of the practice before they become a patient. As a result, health care providers are more frequently utilizing social media to market their practices and to dispense health information. In doing so, however, it is critical for any provider or practice to ensure that their use of social media outlets does not inappropriately invade the physician–patient relationship or erode a continued positive Internet presence for health care providers.

With these goals in mind, the AMA adopted recommendations for physician use of social media.<sup>47</sup> The guidelines recommend that physicians utilize privacy settings on social media Web sites and develop appropriate mechanisms to monitor their Internet presence for accuracy and appropriateness. The AMA also suggests that health care providers maintain proper boundaries when interacting with patients on the Internet and exercise good faith efforts to protect their clients' privacy and confidentiality. Finally, the AMA cautions physicians to be mindful of the potential negative implications arising from the use of social media on their reputations and professional careers.

E-mail communication between physicians and patients within a professional relationship, in which the physician has taken responsibility for the patient's care, is also on the rise. Although the use of e-mail communication within this professional relationship can certainly be useful and effective, caution must be exercised when used for urgent matters or when relaying confidential information in that privacy and security measures are in place. Those patients who a provider communicates with via e-mail must have an understanding of the need to call the provider's office directly if the matter is urgent (requiring a response on the same day) and have a clear understanding of the expected response time on nonurgent e-mails. This can best be accomplished by written statements on all e-mail communications with patients that clearly states the relevant expectations and understandings.

The AMA has also issued guidelines governing the use of e-mail within the physician-patient relationship.<sup>48</sup> Within these guidelines, the AMA urges against the use of e-mail communications as replacing "the crucial interpersonal contacts that are the very basis of the patient-physician relationship" but that it only be used to enhance such contacts.

## Hospital Call

A physician's duty to undertake hospital emergency department call and whether or not the hospital is required to pay for such call coverage (and if so, how much) is a complicated and evolving matter with vast ethical, legal, and medical implications. Typically, hospitals require physicians within certain specialties to share in some minimal amount of emergency department call coverage in order for the hospitals to meet certain federal and state quality of care requirements (e.g., EMTALA) and therefore mandate that these physicians provide some minimal call coverage in order to obtain and maintain medical staff privileges at the hospitals. However, over the years, in certain geographic areas, there has been a

reduction in the willingness of physicians to provide such coverage, in part, due to an increase in the number of uninsured patients receiving their only care in emergency rooms, a shortage of certain specialty physicians, falling reimbursement for certain specialty physician services, and a perceived increase in the risk of lawsuits to the physician if the physician provides such coverage. In August 1992, the OIG published a report on Specialty Coverage in Hospital Emergency Departments, which found that "sixty-seven percent of hospitals report that they encounter difficulty ensuring coverage for at least one specialty service they offer in their emergency departments." The report also indicated that only about 10% of the hospitals encouraged specialty physicians to provide emergency care by offering them direct compensation for being on the on-call list. At the time, the OIG strongly encouraged physicians, hospital administrators and boards, consumers and advocacy groups, health insurers, and government officials to get together and address the issue immediately. Unfortunately, approximately 20 years later, we are still faced with the same issues.

When physicians request compensation for providing the additional emergency department call coverage requested by the hospital in order to offset the physicians' aforementioned financial concerns, legal issues arise. Such compensation may run afoul of numerous federal and state laws governing hospital-physician relationships including, but not limited to, the federal AKS and Stark regulations. Moreover, nonprofit hospitals also need to be aware of IRS regulations pertaining to private inurement and benefit issues to maintain their nonprofit status. The remainder of this article focuses on how such compensation may run afoul of the federal AKS.

The OIG has expressed concern that payments by hospitals for ER call coverage could be easily misused to entice physicians to join or remain on the hospital's staff or to generate additional business for the hospital in violation of the AKS. While the AKS bars the parties from making unlawful kickback payments in any form, it does not compel physicians to provide on-call services for free. As with any compensation relationship between a hospital and a physician, compensation for ER call coverage must be at fair market value for actual and necessary services rendered based upon an arm's length transaction and cannot take into account, directly or indirectly, the value or volume of any past or future referrals or other business between the parties. On-call compensation will be scrutinized to ensure that it is not a vehicle to disguise improper payments for referrals. Although the OIG does not opine on whether a certain dollar amount is or is not at fair market value *per se*, it has published two instructive advisory opinions that should guide physicians and hospitals when deciding an appropriate on-call compensation arrangement.

On September 20, 2007, the OIG issued Advisory Opinion 07-10, which provides some guidance as to how

<sup>47</sup>AMA Policy: Professionalism in the Use of Social Media. [www.ama-assn.org/ama/pub/meeting/professionalism-social-media\\_print.html](http://www.ama-assn.org/ama/pub/meeting/professionalism-social-media_print.html)

<sup>48</sup>AMA H-478.997 Guidelines for Patient-Physician Electronic Mail

to structure such compensation arrangements to avoid AKS violations. Included in the Advisory Opinion were statements by the OIG that warned against on-call compensation arrangements: (a) based upon lost opportunity (i.e., payments that do not reflect bona fide/actual lost income to the physician), (b) where physicians are compensated and there are no identifiable services provided, (c) involving aggregate payments that are disproportionately high compared to the physician's regular practice income, and (d) wherein the physician receives separate reimbursement from insurers or patients in addition to the hospital's on-call payment resulting in the physician being paid twice for the same services. The OIG approved the per diem payment arrangement to physicians who were willing to (a) participate in an equal prorated share of on-call coverage, (b) provide follow-up inpatient care, (c) timely respond to calls, (d) appropriately document the services provided, (e) participate in quality programs, and (f) provide 1.5 days of uncompensated on-call coverage per month. The per diem rate was based upon (a) the physician's specialty, (b) the severity of the illness typically seen by that specialty, (c) the likelihood of having to respond to call or provide follow-up care, and (d) whether the coverage was on a weekday or weekend (which resulted in a slightly higher fee).

On May 14, 2009, the OIG issued Advisory Opinion 09-05, which provided some additional guidance on how to structure an AKS-compliant on-call compensation arrangement. The OIG approved an alleged FMV flat fee-for-service arrangement where, in order to be reimbursed for claims provided to indigent and uninsured patients treated at the hospital's ER, the physicians were required to (a) participate in an on-call rotation, (b) provide follow-up inpatient care, (c) timely respond to calls, and (d) evaluate the patient in person. The flat fee schedule was determined based upon patient acuity levels, average length of stay, physician time commitment for each kind of service, and consideration of the fees paid by public, private, and self-payers for such services.

On October 23, 2012, the OIG issued Advisory Opinion 12-15, to address an inquiry regarding a hospital's payment of per diem fees to physicians for providing on-call coverage for unassigned patients presenting to the hospital's ER. The hospital's arrangement involved 130 specialist physicians who provide unrestricted call coverage for the ER per written agreement whereby they agree to respond within a required time frame, provide inpatient care and follow-up care in their office practices for ER patients whom they admit, timely prepare medical records, and participate in medical staff committee appointments—all regardless of an ER patient's insurance status or ability to pay. The hospital created a uniform per diem fee to be paid to the physicians providing such call in each specialty based upon numerous factors associated with each specialty's call burden including the number of days per month that a specialist would likely be called, the number

of patients likely to be seen per call day, and the number of patients likely to require inpatient and follow-up care. The hospital retained an independent consultant who opined that the per diem rate was consistent with fair market value without regard to the volume or value of referrals or any individual physician's referral pattern. The OIG warned against arrangements that pay for "lost opportunity" (as opposed to true lost income), which pay more than FMV, or which pay physicians for services for which they already receive separate reimbursement. Nonetheless, the OIG approved the arrangement based upon similar factors set forth within Advisory Opinions 07-10 and 09-05 including that the per diem payments: (a) were consistent with fair market value and tailored to reflect the call coverage burden applicable to each specialty; (b) were calculated and allocated in advance each year without regard to physician referral patterns; (c) were the only payment available to the physicians for a significant amount of care provided; (d) were offered to all specialists in staff required to provide unrestricted call coverage under the hospital's bylaws; and (e) did not result in any additional costs to the federal health healthcare programs.

With the increasing desire to have specialists on call at hospitals, there will likely be more guidance issued in the future to address such matters.

## HIGHLIGHTS

- The business of medicine is complex. Obtain key advisors and specialists to assist you in the management of your practice.
- Ultimately, you, the physician, are responsible for your provider number. You need to be familiar with the billing rules.
- Bad results do not in and of themselves result in a potential malpractice risk. Communication breakdowns are often at the heart of many malpractice actions.
- Malpractice claims require four basic elements: establishing the medical provider had a duty of care, that the duty was breached by conduct not in accordance with a standard of care, that the breach was the cause of the injury, and the plaintiff suffered damages.
- The discovery phase is the nuts and bolts of the litigation process. In it the physician learns the exact nature of the charges being advanced and the steps necessary to defend the claim. Preparation is paramount as few cases are won during the discovery but many more are lost.
- Settlement of a malpractice action may be the best course of action based upon the jurisdiction, judge, attorney, physician factors, convenience, merit, or an emotional standpoint.



- Two professional liability insurance policies are available: occurrence and claims made. The former offers protection from losses that occur while the policy is in effect. Claims-made policies offer protection from claims made during a specific time period. Upon termination, tail coverage is often necessary with a claims-made policy.
- Protection of your personal assets is a top priority. Professional liability insurance, the use of IRAs or employee benefit plans, life insurance, and the services of an experienced estate planner, accountant, or tax expert may be a few of the strategies used to protect personal assets.
- Empiric evidence tying malpractice and tort reform to medical malpractice litigation is limited and provides little support for the contention that it is the most effective means of managing skyrocketing malpractice premium rates or reducing health care costs. Further defensive medicine is motivated by more than fear of litigation.
- The Physician Self-Referral Law, commonly referred to as the Stark Law, prohibits a physician (or immediate family member) from making referrals of DHS such as laboratory services, DME, home health, hospital services, radiology and other imaging services, PT, OT and speech services, and radiation therapy for Medicaid or Medicare patients to an entity they have a financial relationship with without an exception. Proof of specific intent to violate the law is not required.
- The Antikickback Statute makes it a crime to knowingly and willfully offer, pay, solicit, or receive any remuneration (anything of value) for referral of items or services reimbursable by a federal health care program.
- Physicians need to develop and maintain systems in their practice to oversee coding, billing, and documentation for services rendered. Physicians should steer clear of any situation in which their decision making with respect of patient referrals or use of products is based upon anything other than what is medically necessary and appropriate.
- The seven components of a compliance program include conducting internal monitoring and auditing, implementing compliance standards, having a compliance officer or designate, conducting education and training, responding in a timely and appropriate fashion to detached offenses and developing corrective action plans, keeping communication avenues open with patients and staff, and enforcing disciplinary standards.
- Licensure actions arise out of complaints and should prompt appropriate counsel and response at the earliest possible stage.
- Organizing a practice has seven basic steps: establishing the business entity, obtaining an IRS federal

tax identification number, protecting the name and any intellectual property, developing the governing documents of the business, adopting the necessary corporate resolutions to ratify the business entity, enrolling in third party insurance plans, and opening business accounts and obtaining the necessary insurance.

- The HIPAA safeguards the confidentiality of PHI that is transmitted electronically. Virtually every practice is covered by this act even if you chose not to use an electronic medical record.
- Compliance issues related to medical necessity are highlighted when documentation in the electronic medical records is not tailored to the service performed but is merely a template.

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