RIsk Matters: New 2023 Live Risk Education Seminar

By Jeffrey A. Woods, JD

We are excited to announce the 2023 Risk Education live seminar "Challenging Relationships in Medicine". The program will take an in-depth look at professional relationships in medicine. Attendees will examine distressed behaviors, conflict management, emotional intelligence, and effective communication. We are excited to have Charlene M. Dewey, MD, MEd, MACP Assistant Dean for Educator Development Director, Center for Professional Health, Vanderbilt University Medical Center, as our speaker again this year.

For more information on schedules or the details of the course, please click here for a downloadable PDF.

To register for this very worthwhile seminar, please click here, call the Risk Education Department at 800-342-2239, or contact us via email at ContactSVMIC@svmic.com

Gratitude or Grift: The Perils of Physician Gifts to Patients and Referral Sources (Part 2 of 2)

By Mark A. Ison, J.D.

Note: *If you missed Part 1 of this article in the March 2023 Sentinel, please click here to read it.*

Ethical Obligations

Codes of professional ethics typically address (and prohibit) the payment or receipt of kickbacks, but also may address the separate and sensitive issue of whether a provider may accept a gift *from* a patient. As most providers know, accepting a gift from a patient is about much more than merely saying "thank you" or avoiding giving offense, as such a gift

can complicate the provider-patient relationship. In particular, the American Medical Association *Code of Ethics* (which has been adopted as binding on physicians in many states, including Tennessee) provides:

> Patients offer gifts to a physician for many reasons. Some gifts are offered as an expression of gratitude or a reflection of the patient's cultural tradition. Accepting gifts offered for these reasons can enhance the patient-physician relationship. Other gifts may signal psychological needs that require the physician's attention. Some patients may offer gifts or cash to secure or influence care or to secure preferential treatment. Such gifts can undermine physicians' obligation to provide services fairly to all patients; accepting them is likely to damage the patient-physician relationship. The interaction of these factors is complex and physicians should consider them sensitively before accepting or declining a gift.

AMA Code of Ethics, Op. 1.2.8.

In particular, and as the AMA *Code of Ethics* notes, providers to whom a patient offers a gift should:

- consider the gift's value relative to the patient's or provider's means and should decline gifts that are disproportionately or inappropriately large, or when the provider would be uncomfortable to have colleagues know they accepted the gift;
- not allow the gift or offer of a gift to influence the patient's medical care; and
- decline a gift if acceptance would present an emotional or financial hardship to the patient's family.

Alternatively, a provider could suggest that the patient make a charitable contribution instead of a gift to the provider. If a patient makes such a contribution, the recipient charity should be a *bona fide* tax exempt organization that is independent of, and not controlled by, the provider. Whether the provider may suggest a gift to a particular organization, and whether the patient may give a gift to an organization in which the provider participates through management (e.g., as a board member) or services (e.g., as a volunteer or staff member), would depend on the specific circumstances and whether the gift to the organization could reasonably be viewed as benefitting the provider in some way.

For example, a suggestion by a provider that a patient make a gift to the American Heart Association, even if the provider serves on the local board or provides volunteer services for the organization, would probably pose little to no risk of violating ethical standards (or applicable laws governing healthcare fraud, waste and abuse). On the other hand, a gift to a private foundation controlled by the provider or benefitting the provider or the provider's patients in some targeted way, or to an organization that materially compensates the provider for the provision of services, would likely give rise to the same concerns as a gift made directly to the provider.

Takeaways and Specific Circumstances

Often, when considering whether a proposed course of conduct would violate healthcare fraud and abuse laws, it is helpful to consider how one would explain the conduct to a cynical government regulator. Such an exercise can highlight the differences between ordinary business activities, such as marketing and showing gratitude for business relationships, and problematic behavior intended to induce or reward referrals.

While no general recitation of "good" and "bad" characteristics is a substitute for expert legal advice in a given case, and no gift of any value is truly free from all compliance risk, some gifting scenarios are common enough that they can be distilled into general rules of thumb for providers to keep in mind when considering giving a gift to, or receiving a gift from, a patient or referral source. Those rules include the following:

- Develop an internal policy regarding giving and receiving gifts, ideally in consultation with an attorney. The policy should address
  - limits on the value of permissible gifts;
  - a central authority for deciding when gifts are appropriate;
  - a means of keeping timely, accurate, and complete records of gifts given and received and their value;
  - guidelines for when gifts must be considered the property of a practice as opposed to a particular provider; and
  - procedures for reporting and addressing violations of the gift policy, and training requirements for staff.
- Gifts given or received in proportion to referrals or other business generated between the giver and recipient are inherently suspect. A gift, or the value of a gift, should not be dependent upon a particular volume or value of referrals or business generated.
- Cash gifts are generally prohibited, as are cash equivalents. Avoid giving gift cards where possible, as they are typically considered cash equivalents. If a gift card is redeemable for a single item or small group of items (as opposed to a Visa gift card or big-box store gift card), there is some guidance providing that the gift card would not be considered a cash equivalent, but the line is not always clear.
- For purposes of applying the dollar limits set out in the Stark Law and CMPL, and the AKS standard of "nominal value," the value of a gift is its fair market value at the time given, not a subjective value determined by the giver or recipient.
- For purposes of applying the dollar limits set out in the Stark Law and CMPL and the AKS standard of "nominal value," the overall cost of a gift for the benefit of a group of people who share alike in the enjoyment of the gift (e.g., a meal for a group of people) is generally allocated among the participants on a per capita basis.
- Give customary gifts of nominal value wherever possible, staying within the applicable limits of the Stark Law's "de minimis" exception and the CMPL's dollar limits for gifts to patients.
- Compliance with the AKS, Stark Law, or CMPL doesn't necessarily equal

compliance with the others (or applicable state law, codes of ethics, etc.).

- Bona fide charitable contributions to tax-exempt organizations independent of the parties to a referral relationship are generally acceptable. However, beware of situations where:
  - a charitable contribution is solicited as a condition of referrals;
  - a contribution is made in a manner that takes into account the volume or value of referrals or other business generated for the contributor;
  - a contribution will inure to the benefit of targeted individuals such as patients or referral sources;
  - a contribution involves a private foundation or organization controlled by a party to a referral relationship;
  - or a contribution is otherwise intended to reward or induce referrals.
- Raffles and sweepstakes for patients may pass muster under the CMPL and AKS where the prizes are reasonable, the chance of winning nominal, and the group of participants sufficiently large (ideally including the general public). In such cases, the value of the prize could reasonably be divided per capita among participants for purposes of the CMPL dollar limits but note that there is no firm guidance on these activities. Similar events involving only existing patients are risky, and providers should avoid raffles and similar contests involving referral sources. Also, be aware of state sweepstakes, lottery, or similar laws.
- Any gift tied to the purchase of a service (e.g., a new patient gift) is suspect.
- Be reasonable and be ordinary. Valuable or extraordinary gifts carry more risk, no matter the context and mindset in which they are given.
- Do not give or accept any gift if it would be embarrassing to have the gift become known to colleagues or reported in the media.
- An alternative show of appreciation (e.g., a handwritten note) can be as meaningful or more meaningful than a gift (particularly a gift fitting within restrictive federal guidelines) without the risk of violating the law.
- Reasonable meals that stay carefully within federal guidelines generally pose a low compliance risk and, of course, offer the opportunity for face-to-face interaction with the recipient.

Ultimately, as much as a physician or other healthcare provider may appreciate his or her patients and referral sources, any expression of appreciation beyond words of thanks raises at least the potential for legal exposure. Providers considering giving or receiving gifts should do so carefully and intentionally, keeping applicable law, published guidance, and internal policies in mind and considering whether to consult with an experienced health care attorney to minimize the chances that gratitude is mistaken for a grift.

If you have questions regarding gifts, SVMIC recommends contacting your corporate attorney or our Medical Practice Services Department at ContactSVMIC@svmic.com or 800.342.2239.

APP Supervision and Diagnostic Tests: Clarification from CMS

By Elizabeth Woodcock, MBA, FACMPE, CPC

If your medical practice offers imaging services, a recent clarification from the Centers for Medicare & Medicaid Services (CMS) requires attention. The March 16 2023 memo entitled: "Supervision Requirements for Diagnostic Tests: Manual Update" outlines the circumstances for which advanced practice providers (APPs) may provide diagnostic tests. Specifically, CMS states:

> *"When NPs, CNSs, and PAs personally perform diagnostic tests … the supervision/collaboration requirements … don't apply. Rather, these practitioners are authorized to personally perform diagnostic tests under the supervision/collaboration requirements applicable to their practitioner benefit category pursuant to state scope of practice laws and under the applicable state requirements." [Accordingly], "diagnostic tests can't be billed to Medicare as incident to services."*

The topic isn't a novel one; indeed, CMS expanded the supervision requirements in 2021.

At the time, however, stakeholders were left confused by the language of the rulemaking. The 2021 Final Rule stated that a *physician* may offer general supervision of diagnostic tests, with no mention of nurse practitioners, certified nurse specialists, or physician assistants. Further, the tests that require personal supervision dictate that a *physician* must be in attendance, according to the then-published text.

Although it took two years, the recent memo provides clarity to the supervision requirements. Advanced practice providers may supervise diagnostic tests. CMS edited the language in the Medicare Benefit Policy Manual to read:

> *"Direct Supervision - in the office setting means the physician (**or other supervising practitioner**) must be present in the office suite and immediately available to furnish assistance and direction…"*

This new language was accompanied by additional clarifications and can be reviewed at this link.

To determine the application of this newly clarified rule for your practice, the supervision requirements for the imaging test(s) being performed must be understood. The manufacturer of the equipment may be a resource; however, the rules change, and it's better to go directly to the source of the regulations – the federal government. To query CMS' requirements, look up the CPT code under the Physician Fee Schedule.

There is a column titled "**Phys Supv**" that reveals the level of required supervision. (See this manual for instructions about the tool, as well as descriptions of the supervision levels. Note that this guide has not yet been updated with the newly released requirements, as of the time of the publication of this article.)

The clarification from CMS is welcome as it helps sift through the once muddy water. Despite the changes in federal rulemaking, however, remember that APPs must act within their scope of practice under state licensing laws. Therefore, state regulations must be reviewed (and followed) as well.

If you have questions about this recent clarification, or other practice management issues, please contact SVMIC's Medical Practice Services department at 800.342.2239 or ContactSVMIC@svmic.com

The Hazards of Using Foreign Medical Scribes

By Stephen A. Dickens, JD, FACMPE

Scribes have long been employed in medical practices as a tool to increase the productivity of physicians and practitioners by lessening the demand on their time for documentation in an electronic health record (EHR). A well trained and competent scribe does exactly that. Given the staffing challenges of recent years, practices are struggling to hire staff for all positions. One of the emerging trends to combat staff shortages is the use of foreign virtual scribes who “observe” the physician and participate in the patient encounter remotely. These services are generally available at a lower cost than a full-time, in-house staff member. While this may seem like the solution to a problem, practices should be aware of the risks associated with this type of relationship.

While the potential for an incorrect entry exists with all scribes, it is heightened in this scenario. English may not always be the first language of a foreign scribe. Even if it is, American colloquialisms vary by region and can be confusing for those not familiar with them. This presents a serious risk to patient safety. Physicians and practitioners are responsible to review and validate the scribe’s documentation. Failure to catch and correct

a mistranslation could result in irrevocable patient harm.

One of the greatest risks is the potential HIPAA threat arising from access to the electronic health record. Practices are responsible for ensuring the safety and security of patients' electronic Protected Health Information (ePHI). That can be difficult to do when all employees are under one roof. Granting access remotely around the globe, given the increasing cybersecurity incidents, requires an even higher level of due diligence. Speaking of cybersecurity, another consideration is the threat to the service provider which may be greater based on their location. The practice must take the relationship and potential threats to the service provider into consideration when conducting the practice's security risk analysis. Health and Human Services specifically addresses the need for this when utilizing a foreign communication service provider (CSP) and the risk to ePHI in a FAQ found here.

A virtual medical scribe and the company for which they work are considered a business associate to the practice's role as a covered entity. This means they too have an obligation to safeguard ePHI. Should they fail to implement adequate administrative, physical, and technical safeguards as required by the HIPAA Security Rule, they could face penalties. While they may willingly sign a business associate agreement, the issue becomes one of enforcement of penalties should they fail to meet their obligations. At this point, guidance is not available from the Office of Civil Rights (OCR) regarding how they will manage a foreign actor for violating HIPAA. The OCR's authority does not extend beyond the United States, and it seems unlikely they would pursue these organizations. The practice, however, is within the OCR's authority making it much easier to seek recovery from them. Unless the business associate voluntarily pays any imposed fines, the practice may be left responsible even if it was compliant.

SVMIC recommends extreme caution before entering into any agreement that places a practice's system and information at risk. The agreement should clearly outline the responsibilities and obligations of both parties. For those groups considering a foreign CSP, practices should at least consider the following:

- Determine what the service has done to become HIPAA compliant and how they monitor compliance of their employees. They should be able and eager to provide details.
- Secure a signed Business Associate Agreement (BAA). This is a HIPAA requirement for all covered entities. The BAA must be signed by either the service provider or the individual scribes. Health and Human Services (HHS) requires a BAA to contain the following:
    - A description of the permitted and required uses of ePHI;
    - A provision that the business associate will not use or further disclose the ePHI other than as permitted or required by the contract or as required by law; and
    - A requirement that the business associate use appropriate safeguards to prevent the use or disclosure of ePHI other than as provided for by the

contract.

- Conduct and document your own HIPAA training for the virtual scribe(s). Even if the service provides its own staff education, this ensures the appropriate information is conveyed and adds a level of documentation for your records.
- Limit access to the ePHI. Scribes should be able to access only what is absolutely necessary to perform their function. Assign unique usernames and passwords. If possible, control access from the practice's end to allow EHR system access only when you are actively engaging the scribes. Routinely monitor system access and be prepared to suspend it if anything seems amiss. Prohibit any download of data from your system.

Beyond the risk issues outlined, all scribes, whether in person or virtual, must be qualified and properly trained to perform the job. The American Health Information Management Association (AHIMA) provides excellent guidance on those requirements and best practices here. Regardless of the situation, practices should ensure they are using scribes appropriately which requires review and authentication of the information.

Practices must weigh the perceived benefit of these arrangements against the significant risks associated with these services, understanding they will almost certainly be held responsible for any breaches and penalties arising from these relationships. Given the uncertainty of how a breach, or any legal issue for that matter, might be handled given the lack of US jurisdiction over a foreign actor, SVMIC cannot recommend or suggest the use of a foreign based entity.

Grace Under Fire

By William "Mike" J. Johnson, JD

"You're a LIAR!" The plaintiff's attorney passed close to the defendant physician as he leveled the accusation in front of the jury. The physician handled this charge as he did the entire trial: with grace and composure. The trial showcased two very different trial practice styles. The plaintiff team: aggressive, histrionic, emotional, "over the top" and overreaching. The defense team: well-reasoned, calm, thorough, well prepared and thoughtful. Who would the jury believe?

Years before, the family practice physician had ordered an echocardiogram (ECHO) to assess a heart murmur that he heard during an exam. The report indicated moderate mitral valve regurgitation. The plaintiff was asymptomatic. Several months after the echocardiogram, the plaintiff suffered a ruptured chordae and flail leaflet which resulted in acute congestive heart failure and left the plaintiff in very critical condition and at risk of death. Mitral valve replacement via open heart surgery was required. The surgery appeared to have been a success, however, the plaintiff claimed a multitude of injuries some of which included, brain injury, and a long list of associated cognitive impairments, respiratory failure, renal failure, and atrial fibrillation.

There were several issues presented in this case: Was the plaintiff properly advised by the

physician of the electrocardiogram findings and their implications, such that the plaintiff could have chosen to undergo preemptive treatment for mitral valve regurgitation? Should the plaintiff have been referred to a cardiologist, which possibly would have resulted in a less invasive repair that may have avoided the trauma and cognitive impairments that he claimed? Did the plaintiff actually suffer the damages he claimed?

The plaintiff alleged that he was told the ECHO findings were normal. The defendant physician maintained that the patient was not told that the test results were "normal." Instead, the physician contended that he discussed the report with the plaintiff and explained that the report showed moderate mitral regurgitation, but that absent symptoms, no intervention was needed and that he should return in one-year unless symptoms developed earlier.

The plaintiff's out-of-state family practice expert witness opined that moderate regurgitation was abnormal and required referral to a cardiologist. However, his credibility was substantially damaged by defense counsel's rigorous cross- examination. Moreover, the defense had a very strong local family physician expert to support the insured physician's judgment that, based on no symptoms and an ECHO showing moderate mitral regurgitation, the advice to return in one year for an annual physical and repeat ECHO was appropriate.

The plaintiff's out- of- state expert cardiologist witness was polished and made a good witness for the plaintiff. However, his testimony was based on multiple hypotheticals stacked on top of each other. His position was that **if only** the insured physician had referred the plaintiff to a cardiologist, the cardiologist **would have** interpreted the ECHO as showing severe regurgitation which **would have** made the plaintiff a surgical candidate and **therefore avoided** the life-threatening situation that developed later. During cross examination, defense counsel got the expert to admit that the report itself showed Stage B -moderate regurgitation—and further admitted that under the guidelines, a patient with this level of regurgitation could participate in competitive sports. By contrast, support for the insured physician's care came from an impressive in-state cardiologist. Furthermore, the treating cardiac surgeon's video deposition was played for the jury, and he stated multiple times that the plaintiff was not a surgical candidate based upon the ECHO report.

The plaintiff's experienced and polished out-of-state expert psychiatrist also made a good presentation, but his testimony was largely neutralized by defense counsel's cross examination that challenged the lack of specific evidence to support the claim that there was an extended period of hypoxia sufficient to cause brain injury. Defense counsel observed that the deposition of the plaintiff's out of state neuropsychologist was read to the jury without really capturing the jury's interest. The defense, on the other hand, offered live testimony from a local neuropsychologist and in-state neurologist to challenge the lack of objective proof of plaintiff's cognitive impairment claim.

Plaintiff's claims of brain damage were particularly concerning for the defense. However, given that the plaintiff was employed in a very intellectually demanding career before and after the event at issue, his claim of brain damage and cognitive difficulties was a "hard

sell." He did not further his position when he testified extensively and performed so well on the stand that it was difficult to believe that he had any type of brain injury. For example, he testified extensively about his thorough medical research regarding his condition and damages, including reading medical journal articles and white papers. In his testimony, the plaintiff discussed the research as if he was a physician. Showing how quick he was on his feet and his grasp on the details, he even corrected defense counsel for leaving something out of the discussion of his record. Ironically, his testimony compellingly demonstrated not that he had cognitive defects, but that he did not have them.

The jury returned a verdict for the defense in approximately 30 minutes.

Takeaways

- Keeping Cool

  Despite the plaintiff attorney's harsh and aggressive tactics, the defendant physician never gave up the high ground. While medical malpractice trials are heavy with medical information and analysis, they are as personal as the people in them. Trials are adversarial, emotionally charged, and often bruising events. If the plaintiff's attorney controls your emotions, he controls you. There will be an opportunity to respond to personal attacks in a measured, careful, and thoughtful way. Such a response allows you to keep your grace under fire and shows the jury that you are a calm and composed, professional—traits the jury appreciates in a physician.

- Credibility, Reputation, and Relationships

  A trial takes place in front of members of your community. The reputation that you develop in that community cannot be totally separated from you for purposes of trial. Thus, being a well-liked, respected and credible member of your community can be a substantial asset. In this case, the defendant physician is sincere and likeable. Moreover, he grew up in his community and was active in it.

- Instincts, Strategy and Strong Bonds

  The defense counsel who tried this case has exceptional instincts in reading people and strategy. For example, he knows how far to go in "playing his hand," but, not "overplay it." He can sense when a jury has heard enough, and he has the confidence to remain quiet when the plaintiff's proof is actually helping the defense's case. In this case, the attorney relied on his instincts and sense of strategy in choosing not to call one of the defense experts. He reasoned that the point had already been made very well with the first expert, the jury was eager to begin deliberations, and putting on another expert could risk a change in the jury's composition due to scheduling constraints of some members of the jury. These strategy decisions must be made amid the trial,

but it turned out to be the right call in this case.

The lengthy challenge of litigation often forges a strong bond between the defendant physician and their defense attorney which, over time, is welded into a strong and zealous defense. The defense attorney and the physician take the process and its outcome very personally. Comments after the trial from the defense attorney about his client underscore this bond:
"He is a really good man and I think the jury sensed that."
"Thank you again for allowing me to represent Dr. _________. He is truly a good man and we have become brothers in arms during a trial".
"They are such great people [the physician and his wife]. I could not ask for better and more loving clients. This is really what it is all about in my mind."

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