Land Mine: Hidden Stark Law Issues Can Explode

By Theresamarie Mantese and Gregory Nowakowski

Most healthcare transactional attorneys understand that physicians work in a highly regulated environment. Almost every aspect of a physician's career is governed by healthcare laws—licensing, hospital staff privileges, third-party payer and Medicare audits, and federal and state oversight of the healthcare system.

Physicians typically retain healthcare attorneys to guide them through this regulatory system before they enter into joint ventures, mergers, or other financial relationships. Most physicians appreciate their obligations under the Stark Law[1] and the Anti-Kickback Law.[2] Physicians do not willingly invite litigation because of the expense, the toll it takes on their medical practice, and the stress it places on professional relationships. They understand that they work in a collegial environment in which they do not want be perceived as litigious or uncooperative.

Yet physicians sometimes find themselves in a position in which litigation is necessary. Unlike the transactional setting, physicians are less likely to retain a healthcare attorney to assist them in the context of litigation. Instead, they typically seek skilled litigation attorneys to advise them. Physicians often believe that a unique set of skills is needed to advocate their positions in court and in other forums—and they are not wrong. Of course, there are healthcare attorneys with strong litigation skills who are also excellent transactional lawyers.

"Trial Practice" is designed to provide advice and guidance on how to effectively prepare for and conduct trials.

Physicians, like other clients, often seek from their litigation attorneys an opinion of the chances of success or failure in proceeding with a lawsuit in court or an alternative dispute forum. Litigation attorneys should be cautious in advising physicians who are contemplating lawsuits. One serious reason for caution is the potential for Stark Law issues implicated by the dispute. Because physicians who violate Stark Law are held strictly liable for a violation, a physician litigant is potentially at risk if he or she has any involvement whatsoever in the alleged violation.

Unlike other healthcare statutes, the self-referral prohibition in the Stark Law is a strict liability offense with no scienter requirement. The Stark Law "is triggered by the mere fact that a financial relationship exists; the intention of the referring physician is not taken into consideration."[3]

Often a litigant will assert or threaten a Stark Law violation; however, it does not matter if the physician is trying to enforce the illegal transaction or defending against enforcement of the illegal transaction. The end regulatory result is the same: all physicians and parties are strictly liable for the Stark Law violation.

Stark Law's two-step analysis

To determine if a case involves Stark Law issues, attorneys should consider two questions:

(1) Is there a potential Stark Law issue?

(2) Is there an applicable exception to the Stark Law?

The first step involves analyzing whether there is a potential Stark Law issue. In general, the Stark Law prohibits physician self-referrals for certain designated health services if those services are reimbursed by Medicare or Medicaid. By definition, there is a potential Stark Law issue if the arrangement involves at least one physician and at least one referral.

A Stark Law referral is broadly defined and includes more than just a commonly understood referral. A "referral" under Stark Law might also include physician orders for physical therapy, prescriptions, and care plans. Furthermore, the general prohibition applies to specific designated health services, which include (1) clinical laboratory services; (2) physical therapy services; (3) occupational therapy services; (4) radiology services, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services; (5) radiation therapy services and supplies; (6) durable medical equipment and supplies; (7) parenteral and enteral nutrients, equipment, and supplies; (8) prosthetics, orthotics, and prosthetic devices and supplies; (9) home health services; (10) outpatient prescription drugs; (11) inpatient and outpatient hospital services; and (12) outpatient speech-language pathology services.[4]

The Stark Law's prohibition applies *only if* the physician has a "financial relationship" with the recipient of the referral.[5] A "financial relationship" can include a compensation arrangement between the physician and the entity that receives the referral.[6]

If the case appears to involve a Stark Law issue, the second step in the analysis is to determine whether there is a statutory or regulatory exception protecting the arrangement. During that analysis, it is critical to review the requirements of each particular exception—all must be met for a Stark Law exception to apply. It is beyond the scope of this article to discuss the various

exceptions and examine their applicability to a given set of facts. In general, the litigation attorney should carefully examine all the facts of a case before deciding whether the physician has exposure under Stark Law before filing a particular lawsuit.

Why inquire about Stark Law?

Litigation attorneys understand the strategic importance of being the first party to file a lawsuit in connection with a dispute in court. They understand that time may not be on the side of their clients as they lose money, financial leverage, and bargaining position. In the rough-and-tumble world of litigation, facts and positions are often sorted out during discovery or settlement negotiations. There are also business reasons to file quickly in litigation. Many times clients may perceive that the attorney is stalling or afraid to litigate a case. They want action immediately, and if litigation is not filed quickly, the attorney may lose the case altogether to another attorney.

While these are legitimate concerns, the litigation attorney should exercise caution and circumspection. There is probably nothing more damaging to the professional career of an attorney than placing a client in a worse position than before the client sought representation. Most attorneys understand they cannot promise or guarantee a favorable result, especially in litigation. Yet litigation attorneys should and must be especially sensitive to the professional consequences to physicians if they fail to perform reasonable due diligence to Stark Law issues. Without such due diligence, litigation attorneys may find, at best, that the physician-client will be forced to confidentially settle the case for a minimal sum to avoid potential Stark Law sanctions; or, at worst, the physician-client may become entangled in a licensing complaint, third-party payer audit, and, possibly, a criminal investigation.

Conclusion

The Stark Law is a specialized area of the law with many subtleties and interpretations. Healthcare attorneys can provide a different perspective on how they view the scope of the Stark Law and its regulatory scheme. Most healthcare transactional attorneys are trying to achieve realistic goals for their physician-clients based on Stark Law requirements. Yet attorneys cannot guarantee that the U.S. government will agree with their Stark Law analysis.

With this in mind, litigation attorneys should carefully consider how they will approach disputes involving physicians. The range of directorships, shareholder disputes, productivity bonuses, leasehold arrangements, and personal services arrangements commonly found in relations between and among physicians often constitute financial relationships that pose Stark Law questions. Litigation attorneys should consider some of the following recommendations before proceeding with litigation when they represent physicians:

- Obtain *all signed* and unsigned documents related to the transaction. Each document (whether it is fully executed and when it is fully executed) may influence the Stark Law analysis.
- Take a detailed factual statement from the physician-client covering the basis of the dispute and integrate those facts into the relevant documents.
- Ask your physician-client if he or she is subject to any current or past licensing complaints, third-party payer investigations, credentialing or staff privileges hearings, or adverse reporting to the National Practitioner Data Bank.
- Ask your physician-client for all financial records including tax returns, financial statements, and records of bonuses or compensation.
- Discuss with the physician-client, financial managers, or accountant how physician compensation is computed.
- If possible, make a determination or reasonable assessment as to whether the compensation is based on fair market value or whether it could arguably be related to volume of value of patient referrals.
- Consult with an experienced healthcare transactional attorney.

While this list is not all-inclusive, it is a first step to properly representing a physician-client. No matter how much a litigation attorney (and often a physician-client) may want to circumvent this tedious process, this analysis can save the attorney from professional embarrassment and the client from costly unforeseen consequences. In the end, litigation attorneys should be prepared to confidently face the soul-searching question of whether they took appropriate steps to properly protect the career of a physician-client. ■

Theresamarie Mantese is a healthcare attorney who has represented national and statewide clients in legal matters involving noncompetes, billing, audits, licensing, and peer reviews. She has also authored many significant healthcare publications for national and peer-review journals.

Gregory Nowakowski focuses his practice on providing advice on general corporate and governance strategies. He counsels healthcare companies on risk management strategies and alternative risk financing; provides advice on areas of healthcare law, including areas relevant to regulatory compliance of healthcare captive insurance companies and their owners; and organizes and structures multispecialty physician group practice and post-payment audit defense.

ENDNOTES

1. See 42 USC 1395nn.
2. See 42 USC 1320a–7b(b).
3. *US ex rel Bartlett v Ashcroft*, ___ F Supp 2d ___ (WD Pa, 2014), citing *US ex rel Villafane v Solinger*, 543 F Supp 2d 678, 685–686 (WD Ky, 2008).
4. 42 USC 1395nn(h)(6).
5. 42 USC 1395nn(a)(1).
6. 42 USC 1395nn(a)(2)(B).