Health Law 101:
Issue-Spotting In Dealing With Health-Care Providers

by William H. Hall Jr.

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Health care is among the most highly regulated industries in the United States. Understanding the regulatory framework for health care is increasingly important, whether a practitioner represents health-care providers or others who deal with health-care providers. Some clients' risks are unique to the health-care industry. This article outlines legal issues that affect health-care providers and those who interact with them.[1]

The Federal Anti-Kickback Statute

A federal anti-kickback statute[2] applies to any arrangement involving individuals or businesses that provide health care or who can influence referrals for health care. The law prohibits individuals and businesses from knowingly and willfully soliciting, receiving, offering, or paying any remuneration, in cash or in kind, directly or indirectly, in return for referring an individual to a person for furnishing or arranging for the furnishing of items or services reimbursable under federal health-care programs, or purchasing, leasing, ordering, or arranging for or recommending, purchasing, or ordering any good, facility, item or service reimbursable under a federal health-care program. Violation of the anti-kickback statute is punishable by fines of up to $25,000 and imprisonment for up to five years for each violation. In addition, if a person is convicted of violating the law, the person is subject to exclusion from federal health-care programs.

The anti-kickback statute prohibits arrangements that might be common in other industries. For example, a business might provide gifts or referral fees for others who send clients to the business. If, however, a hospital paid a referral fee to a physician, that referral fee would subject both the hospital and the physician to prosecution under the anti-kickback statute.

The anti-kickback statute is broadly drafted. To protect legitimate transactions, the Office of the Inspector General (OIG) of the Department of Health and Human Services issued safe harbors under the anti-kickback statute. An arrangement that meets the terms of a safe harbor will not be subject to prosecution. To benefit from a safe harbor, the arrangement must comply with each standard within the safe harbor. Compliance is not mandatory, and there are a number of legitimate arrangements that may not comply. But it is important to understand whether an arrangement complies with a safe harbor, and to advise clients accordingly.

There are safe harbors for space rental, equipment rental, personal-service and management contracts, bona fide employment relationships, and investments in group practices. Each safe harbor includes requirements. While the safe harbor for employment relationships does not require an employment agreement, most other safe harbors require a written agreement. The safe harbors for equipment rental and space rental each require that the lease term be at least one year and that the aggregate rental charge be set in advance. These safe harbors also require that the rental charges be consistent with

fair market value and not determined in a manner that takes into account the volume or value of referrals or other business generated between the parties for any items or services reimbursable under Medicare, Medicaid, or other federal health-care programs. The safe harbors for equipment and space leases and the safe harbor for personal-service and management contracts also require that the items and services not exceed those that are reasonably necessary to accomplish the commercially reasonable business purpose for the arrangement. For example, if a physician practice contracted with an independent referring physician to lease space from that referring physician, but had no legitimate need for the space, the arrangement would not comply with the space rental safe harbor even if the rental rate was consistent with fair market value and the arrangement met other standards of the safe harbor.

Stark II Physician Self-Referral Statute

In 1989, the OIG reported that Medicare patients of physicians who owned or invested in clinical laboratories received 45 percent more clinical laboratory services than Medicare beneficiaries in the aggregate. In response to this study and to reduce the rising costs of health care, Congress enacted a federal physician self-referral statute. That law is Stark I, named after the primary sponsor of the legislation, Rep. Fortney "Pete" Stark. Stark I applied only to physician self-referral for clinical lab services. Other studies found that physicians who maintained financial interests relating to other types of health-care goods and services also referred more patients. In response to these studies, Congress adopted the Stark II statute[3] that expanded the prior legislation to cover not only referrals of clinical laboratory services, but referrals for other services as well, including physical, radiation and occupational therapy; radiology services; durable medical equipment and supplies; parenteral and enteral nutrients, equipment and supplies; prosthetics, orthotics, and prosthetic devices and supplies; home health services; outpatient prescription drugs; and inpatient and outpatient hospital services. These services are identified under the Stark II statute as designated health services.

Under Stark II, if a physician or an immediate family member of the physician has a financial relationship with an entity, the physician may not refer Medicare or Medicaid patients to that entity for designated health services unless an exception is satisfied. The Stark II statute and regulations define financial relationship to include both direct and indirect ownership and investment interests, as well as direct and indirect compensation arrangements. An ownership or investment interest can involve directly owning an interest in the entity that furnishes designated health services, or owning an interest in another company that owns an interest in the entity that furnishes designated health services.

Even if a physician does not receive payments directly from an entity that furnishes designated health services, Stark II affects the arrangement, and the physician may be treated as having a financial relationship. In the absence of an exception, the referring physician can be treated as having an indirect compensation arrangement when there is an unbroken chain of financial relationships between the referring physician (or a member of his or her immediate family) and the entity furnishing designated health services. While the language relating to indirect compensation arrangements is broadly drafted, the referring physician (or an immediate family member) does not have an indirect compensation arrangement unless the physician (or a family member) receives aggregate compensation from the person or entity in the chain with which the physician or immediate family member has a direct financial relationship that varies with or takes into account the volume or value of referrals or other business generated for the entity; and the entity furnishing designated health services has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician or immediate family member receives aggregate compensation that varies with or takes into account the volume or value of referrals or other business generated by the referring physician for the entity furnishing the designated health services.

Referral also is important. The term includes any request by a physician for, ordering of, or certifying or recertifying the need for any designated health service, or the establishment of a care plan by a physician that includes a designated health service. Under these standards, a physician need not direct a patient to a particular provider in order to be considered to have made a referral.

Stark II is sometimes characterized as a strict-liability statute because the referral prohibition applies even if the service is medically necessary and there is no inappropriate intent to direct referrals. Unless an exception applies, a physician may not refer a Medicare beneficiary for designated health services to an entity with which the

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physician has a financial relationship, even if the services are medically necessary. The statute imposes substantial civil monetary penalties upon any person who presents or causes to be presented a bill or a claim for a service involving a prohibited referral. If a physician or entity enters into an arrangement that the physician or entity knows or should know has a principal purpose of ensuring referrals by the physician to a particular entity, and that would otherwise violate Stark II, the statute provides for civil monetary penalties of up to $100,000 for the physician and the entity. This penalty is a penalty on circumvention schemes.

The Stark II statute and regulations include a number of other exceptions that permit some common relationships. Exceptions apply to compensation arrangements and ownership/investment interests. One that is most commonly used is for in-office ancillary services. This exception is available for both ownership/investment interests and compensation arrangements. The in-office ancillary services exception is only available for services furnished through certain referral structures, in certain locations, and billed by the physician performing or supervising services.

The Stark II statute and regulations also include exceptions for compensation arrangements relating to office space and equipment rentals, bona fide employment relationships, personal service arrangements, physician recruitment, and an exception for certain fair-market-value compensation arrangements. While the exception for bona fide employment relationships does not require a written agreement, most other exceptions under Stark are only available where the parties have signed a written agreement. The exceptions typically will not allow physicians to be paid in a manner that varies with the value or volume of referrals, but in some circumstances the regulations allow compensation based upon a fair-market-value per-unit fee. The requirements of each exception are detailed, and it is imperative to assess the terms of each exception before relying on any exception.

Virginia Practitioner Self-Referral Act

While the Stark II statute applies only to designated health services for beneficiaries of governmental health-care programs, the Virginia Practitioner Self-Referral Act[4] includes restrictions applicable to all health-care services and all patients, regardless of whether a governmental payor is involved. Under the statute, absent an exception, the practitioner may not refer a patient to an entity outside the practitioner's office if the practitioner or any immediate family member is an investor in the entity. The statute covers physicians and other individuals licensed or certified by any of the health regulatory boards within the Virginia Department of Health Professions.

However, the prohibition does not apply if the practitioner directly provides health services within the entity and is personally involved with the provision of care to the patient. The prohibition likewise does not apply to services provided within the practitioner's office or group practice as defined under the act. Under § 54.1-2413.E, if a referring practitioner has a financial arrangement that would quality for an exception under Stark II standards for ownership or investment interest, the referral will not be treated as violating Virginia law.

The Virginia statute also provides the Virginia Department of Health Professions with authority to issue advisory opinions relating to proposed arrangements. The opinions apply only to the individuals and entities involved but can provide insight regarding application of the Virginia statute. The advisory opinions are available on the Web site of the Virginia Department of Health Professions at **www.dhp.state.va.us**.

Standards for Tax-Exempt Organizations

Because a number of health-care providers (especially hospitals and health systems) are exempt from federal income tax under § 501(c)(3) of the Internal Revenue Code, it can be important to assess these special standards in providing guidance to health-care providers. An organization can jeopardize its tax-exempt status if it enters into arrangements involving private inurement, by paying an insider more than a fair-market-value share of the profits. The Internal Revenue Service has defined "insider" to include officers, directors, and others in a position to exert substantial influence over a tax-exempt organization. In representing a tax-exempt organization or others dealing with tax-exempt organizations, it is important to ensure that any payments to insiders are consistent with the fair market value of any items or services provided.

In addition to the prohibitions against private inurement, it is important to assess tax-exempt financing. The applicable standards typically prohibit tax-exempt organizations from dedicating the proceeds of tax-exempt bond financing to private business use. For example, if a tax-exempt entity were to use the proceeds of a tax-exempt bond issuance for construction of an office building that was leased entirely to private for-profit businesses, the underlying bonds could lose their tax-exempt status. The IRS says that management agreements also can create risks of private business use. For example, if a tax-exempt health system financed a clinic with the proceeds of tax-exempt bonds and entered into a management agreement for the clinic, the management agreement could implicate the standard that prohibits private business use of tax-exempt bond financing. In Revenue Procedure 97-13, the IRS issued guidance for determining whether a management agreement will be considered to result in private business use; the determination of whether a management agreement may jeopardize the tax-exempt status of bonds depends upon the term of the agreement and the compensation structure.

In addition to legal standards for the tax-exempt entities, there also are legal standards that apply to individuals participating in transactions with tax-exempt entities. The Internal Revenue Code establishes excise taxes on disqualified persons who enter into excess benefit transactions with tax-exempt organizations.[5] Disqualified persons include offi-

cers, directors, and trustees of a tax-exempt organization, others who exert substantial influence over the affairs of the organization, and individuals who have held such a position within five years prior to the excess benefit transaction. Excess benefit transactions include arrangements in which a disqualified person receives above fair market value for items or services provided by the individual to the tax-exempt organization. If a physician served as a director on the board of a tax-exempt hospital and, one year after leaving the board, leased space to the hospital at a rental rate more than fair market value, the arrangement would constitute an excess benefit transaction. Under the excise tax provisions, a disqualified person may be subject to excise taxes of up to 200 percent of the amount of the excess benefit, and organization managers (defined to include officers and directors of the tax-exempt organization) who approve of the transaction knowing that it is an excess benefit transaction also may be subject to significant excise taxes. Given these standards, it is important to ensure that arrangements are consistent with fair market value and that appropriate documentation is maintained to demonstrate that terms of arrangements are reasonable.

Protections to Prevent Patient Dumping

The Emergency Medical Treatment and Active Labor Act (EMTALA)[6] was enacted in 1985 to address congressional concerns regarding patient dumping by hospital emergency departments. EMTALA imposes standards relating to hospitals that participate in the Medicare program. The hospital must conduct a medical screening examination for any patient who requests one, or who is deemed to have requested one. A medical screening examination is a medical exam conducted to determine whether a patient is suffering from an emergency medical condition. Under EMTALA, emergency medical conditions include conditions that, if not treated immediately, could place the individual's health in serious jeopardy, or result in serious impairment to bodily function or serious dysfunction of any bodily organ or part. This definition of emergency medical condition encompasses many conditions beyond what one might typically view as an emergency.

Another standard under EMTALA relates to providing care for any emergency medical condition. If the patient has an emergency medical condition, the hospital must either provide necessary stabilizing treatment, or, if the hospital cannot provide necessary treatment, the hospital must transfer the patient.

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While many issues under the EMTALA statute and regulations affect hospitals, physicians also are affected by EMTALA. The third primary standard under EMTALA requires hospitals to make arrangements for physician call coverage for medical specialties that members of the hospital's community may reasonably expect to be available on an emergency basis. While the EMTALA regulations and guidance provide hospitals with some flexibility in establishing call coverage rosters for physicians, if a physician on the hospital's call roster fails to respond or refuses to provide care, both the hospital and the physician involved are subject to civil monetary penalties of up to $50,000 for each violation. Both the hospital and the physician may be subject to exclusion from participation in Medicare and Medicaid.

The Health Insurance Portability and Accountability Act (HIPAA)

Health-care providers are subject to patient privacy and security regulations. In Virginia, the primary medical record privacy standards are the Health Insurance Portability and Accountability Act (HIPPA) privacy standards (codified in 45 CFR Parts 160 and 164) and the standards under Virginia Code § 32.1-127.1:03. The HIPAA privacy standards apply to health-care providers who transmit health information in electronic form in connection with certain transactions, including electronic billing. Because most providers bill electronically, most health-care providers are subject to the HIPAA privacy standards.

The HIPAA privacy standards draw a significant distinction between use of patient information (typically referring to use and dissemination of patient information within an organization) and disclosure of information (typically referring to dissemination of patient information to others outside of the organization). Under the HIPAA privacy standards, health-care providers are permitted to use patient information for treatment purposes, payment activities, and health-care operations. Health-care providers are allowed to disclose patient information to other health-care providers for treatment purposes, for payment activities, and for certain limited health-care operations by other providers. HIPAA privacy standards include other exceptions to allow uses and disclosures of health information, but the requirements of each exception are detailed. Providers must ensure each use and disclosure of information complies with an exception under HIPAA privacy standards. HIPAA privacy and security standards require covered entities to maintain policies and procedures addressing patient privacy and security of patient information. Covered entities must provide training for their employees and volunteers on the standards for privacy and security of patient information.

Where a health-care provider wishes to share patient information with counsel or others (such as billing companies, accountants, or others providing services to the

health-care provider), the provider must sign a business-associate agreement before sharing information. HIPAA regulations include standards addressing specific provisions that must be included in agreements with business associates. Attorneys should note also that, under the regulations, even if a patient's name is omitted from a record, the record may still be subject to the HIPAA regulations if the record includes other information that could be used to identify the patient. For example, if a record includes a patient's Social Security number, address, date of birth, or other similar information, the HIPAA regulations will still have an impact on use and disclosure of the record.

Virginia Code § 32.1-127.1:03 includes standards similar to those within portions of the HIPAA privacy standards, but there are differences. While the HIPAA privacy standards include default provisions that give providers thirty days to give a patient access to records, the Virginia statute typically requires that patients be given access within fifteen days. Virginia law includes specific provisions relating to subpoenas for medical records, and those provisions include some specific requirements beyond those mandated under HIPAA privacy standards.

In addition to the requirement under the HIPAA regulations and Virginia Code § 32.1-127.1:03, other standards can affect the use and disclosure of patient information. Federally assisted drug and alcohol programs are subject to more stringent restrictions on uses and disclosures of patient information.[7] Records containing human immunodeficiency virus information are subject to additional restrictions under Virginia Code § 32.1-36.1, and Virginia Code § 20-124.3:1 includes certain special restrictions relating to mental health providers in cases in which the custody or visitation of a minor child is at issue.

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Certificate of Public Need

Under Virginia Code § 32.1-102.3, before beginning any project, individuals and businesses must obtain a certificate of public need (COPN). Projects include the establishment of a medical care facility, such as hospitals, nursing homes, specialty clinics, and portions of a physician's office developed for the provision of outpatient surgery, cardiac catheterization, computed tomographic scanning, gamma knife surgery, lithotripsy, magnetic resonance imaging, magnetic source imaging, positron emission tomographic scanning, radiation therapy, and nuclear medicine imaging. Physicians and others who wish to provide these specialty services in Virginia are subject to the Virginia COPN requirements.

Conclusion

Health-care providers are subject to a multitude of regulatory requirements that often are complex. Compliance can hinge upon details, facts, and circumstances that might appear minor in other industries. When assessing health-care providers' business arrangements, attorneys must determine whether the parties comply with those requirements. ⚖

Endnotes:

1 Medical malpractice risks and other professional liability risks are always important factors in assessing transactions involving health-care providers, but a detailed discussion of those issues is beyond the scope of this article.

2 42 U.S.C. § 1320a-7b

3 42 U.S.C. § 1395nn

4 Chapter 24.1 of Title 54.1 of the Code of Virginia

5 26 U.S.C. § 4958

6 42 U.S.C. § 1395dd

7 42 C.F.R. Part 2