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The Stark Reality of Being a Hospitalist: Who Knew Taking Care of Patients Would Be a Self-Referral?

The Stark Reality of Being a Hospitalist: Who Knew Taking Care of Patients Would Be a Self-Referral?

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Imagine the following hypothetical situation: Hospitalist-R-Us, P.C., ("HRUP") a professional corporation, has contracted with Big Community Hospital ("BCH") to provide inpatient care. HRUP is composed of five full-time hospitalists: Dr. A, the president of the corporation and medical director; Drs. B and C, shareholders in the corporation; and Drs. D and E, employees of the corporation. Additionally, HRUP employs moonlighters, Drs. F and G, internists in a two-physician group practice that admits to BCH. BCH is willing to offer HRUP financial incentives because of the relative low reimbursement provided by carriers in the area as well as in consideration of the financial benefits provided to the hospital by the hospitalists (e.g., shortened length of stay [LOS] and increased economies of service). These financial incentives include payment of a medical director's fee, salary guarantees to the individual physicians, and bonuses for reaching certain benchmarks, including reduced LOS and number of admissions and consults. The question presented is whether such an arrangement may run afoul of the law.

What may come as a surprise to some is that such an arrangement, if not structured carefully, may be illegal. A number of federal and state laws are implicated wherever there exists a financial relationship between a physician and an entity, such as a hospital, that provides certain medical services referred to as "Designated Health Services" ("DHS") (1). This article presents a brief overlook at the federal regulatory scheme that is implicated in the above scenario, primarily the federal prohibition against self-referral.

On March 26, 2004, the Centers for Medicare and Medicaid Services (CMS) promulgated Phase II of its Final Rule regarding the amended federal physician self-referral prohibition, otherwise known as Stark II ("Stark Law"). The new regulations became effective as of July 24, 2004 (2).

In its simplest form, the Stark Law prohibits a physician from referring a patient for DHS to an entity in which the physician has a financial relationship unless an exception applies. These exceptions are listed either in the statute itself or the accompanying regulations promulgated by CMS and consist of a checklist of conditions that must be satisfied in order to qualify for the exception. Although the federal Stark Law is applicable only to Medicare (and indirectly, Medicaid) patients, most states have their own form of self-referral law, which like New York, may be applicable to all patients (3).

The original Stark Law, which was enacted in 1992, prohibited a physician from referring a patient to a laboratory where that physician had a financial relationship. The ill Congress intended to remedy was physicians driving up health care costs and ordering unnecessary tests because the physician stood to make money from the test. A perhaps noble thought, but from this simple acorn a mighty oak tree has grown, whose convoluted roots now reach wide and far. Transgressing the Stark Law can lead to a variety of penalties, including the denial of claims, civil monetary penalties (i.e., fines), and the professional death sentence for a hospitalist: exclusion from Medicare (4). Furthermore, the Stark Law imposes strict liability. A physician is just as guilty for violating the law innocently as intentionally.

The typical hospitalist at this point may be saying "so what, I don't own a laboratory (or medical imaging center, physical therapy office, pharmacy, etc.), I work in a hospital and I am not compensated for ordering X-rays, labs or PT." Under the Stark Law, the hospitalist who orders a CBC is referring a patient to an entity (the hospital's laboratory) for DHS (the CBC, a clinical laboratory service). Stark, therefore, is implicated if the hospitalist has any form of financial

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relationship with the hospital whatsoever (5). And Stark is violated if that relationship does not satisfy an express exception.

Generally, hospitalists have one of three types of financial relationships with hospitals. On one hand is a private-practice hospitalist group, which like other private practices, has no financial relationship with the hospital. The hospitalists, like any other specialist on staff, admit to the hospital but receive no remuneration from the hospital. The Stark Law is not implicated in this situation. This arrangement, however, is the exception, not the norm because of the economic realities of hospitalist practice. On the other hand is the hospital employee, who clearly has a financial relationship with the hospital (note: the Stark Law speaks of financial relationships, not just ownership interests). Stark is implicated but a bona fide employment relationship is one of the express exceptions (6).

Increasingly more common are hybrid arrangements whereby the hospitalist group is a private entity, such as a professional corporation, but there exist contractual arrangements that include remuneration between the parties. Typical examples are those in the HRUP/BHC hypothetical: medical directors' fees, salary guarantees, and bonuses tied to certain benchmarks. Because of the complexity and ingenuity of these contractual arrangements, it is essential that hospitalists in these groups clearly know and understand (or hire a lawyer who clearly knows and understands) the Stark Law.

The Stark Law does not prohibit physicians from self-referral. It merely requires that an exception exist. This requires certain terms be included (or excluded) in the contracts contemplated above in order to satisfy an exception. These rules are both complex and ambiguous. Considerable commentary and uncertainty have been generated about the Stark Law, and the discussion below is meant only to give the reader a brief exposure to these rules.

The relationship in the HRUP/BCH hypothetical is an "indirect compensation arrangement" ("ICA"). That is because Dr. B, who refers the patient to the entity (BCH) for DHS (the CBC), does not receive remuneration directly from the entity. Rather, there is an "unbroken chain" from BCH (which pays the salary guarantees, medical director fees, and bonuses) to HRUP (which pays his salary) to Dr. B. CMS will consider the arrangement an ICA if Dr. B's aggregate compensation "varies with, or otherwise reflects, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS" (7). Since Dr. B's entire income "reflects," albeit indirectly, the volume of referrals to the hospital, an ICA will exist if Dr. B's total income varies year to year (which is usually the case with the owners of a practice). Therefore, so as to not violate Stark, the contract between HRUP and BCH must fit into the ICA exception.

The ICA exception consists of four conditions, all of which must be satisfied: 1) the arrangement must be a fair market value; 2) the amount of remuneration cannot be determined in any manner that takes into account the value or volume of referrals or other business generated by the referring physician for the entity furnishing DHS; 3) the arrangement must be set out in writing, signed by the parties, and specify the services; and 4) the arrangement must not violate the anti-kickback statute or any federal or state law or regulation governing billing or claims submission (8).

The fourth condition requires that the arrangement not violate the federal Anti-Kickback Statute ("AKS"). The AKS prohibits anyone from paying or receiving any remuneration in any form, either directly or indirectly, in return for referring a Medicare or Medicaid beneficiary for any item or service (9). The AKS is potentially implicated for all the physicians employed by HRUP because all the physicians are indirectly receiving remuneration from the entity to which they refer Medicare and Medicaid patients. Unlike Stark, the AKS is only violated if a party's intent is to induce further referrals. CMS has promulgated a safe harbor for personal services and management contracts (applicable in the HRUP/BCH scenario) that is very similar to the Stark Law exception (10).

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The Stark Law must be taken into account when structuring any of the contracts in the above hypothetical. Take, for example, Dr. A's medical director fee. As a shareholder in the P.C., her compensation will vary based upon the profits of the corporation. If BCH pays the fee directly into the coffers of HRUP, there is an ICA. On the other hand, if BCH pays Dr. A directly there is a personal service arrangement, which must satisfy either the personal service exception or fair market value exception (11).

An interesting, and often overlooked, aspect of the Stark Law involves the moonlighters, Dr. F and G. Assume, as part of their group practice, that they refer patients to themselves for DHS (e.g., they have an in-office laboratory). This is permitted under the in-office ancillary services exception (12). But to qualify at least 75% of the medical services provided by the physicians in the group must be provided through the group (13). If Drs. F and G moonlight often, such that they bill over 25% of their services through HRUP, their "group practice" would be disqualified and they would violate the Stark Law when referring patients to their in-office laboratory.

A fifth issue implicated by the above hypothetical is the Medicare Gainsharing prohibition. Section 1128A(b)(1) of the Social Security Act prevents hospitals from making payments, either directly or indirectly, to induce a physician to reduce or limit services to Medicare or Medicaid beneficiaries (14). This prohibition is implicated by the bonuses based on reduced LOS. Such arrangements should always be avoided, and HRUP and BCH should look to other benchmarks in determining bonuses.

A final (for the purposes of this article, anyway) Stark Law issue involves the recruitment of new physicians. Assume that as a condition of the exclusive contract with BCH there is a "sweeps clause" whereby, upon termination, a physician employed by HRUP must resign his/her privileges at BCH. HRUP wants to hire a sixth full-time physician because Drs. F and G are discontinuing moonlighting (their lawyer told them about the Stark Law and the 75% rule for the in-office ancillary services exception). BCH, which had been paying HRUP $100,000 annually, agrees to increase this compensation to $120,000. Due to the sweeps clause, the arrangement would not qualify under the new physician-recruitment exception because the practice is imposing "additional practice restrictions on the recruited physician" (15).

The above analysis is overly simplistic and is only meant to give the reader an idea of the legal constraints on contracting with an entity that provides DHS to its patients. In conclusion, any form of financial relationship between a hospital and a hospitalist is a financial arrangement made between a referring physician and an entity that provides DHS. Careless contracting, even innocently, could result in a violation of the Stark Law and potentially dire consequences. Hospitalists, and their legal representatives, must be familiar with the Stark Law, as well as other applicable federal and state law, and draft contracts that comply with the appropriate statutory or regulatory exceptions.

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Endnotes

1. Federal law defines DHS to include: (1) clinical laboratory, (2) physical therapy, (3) occupational therapy, (4) medical imaging, (5) radiation therapy, (6) durable medical equipment, (7) parenteral and enteral nutrients, (8) prosthetics and orthotics, (9) home health care, (10) pharmacy and (11) inpatient and outpatient hospital services. 42 U.S.C. § 1395nn(h)(6).
2. See 69 Fed. Reg. 16054 (2004). The Stark Law is codified at 42 U.S.C. § 1395nn.
3. See N.Y. Public Health Law § 238-a. New York limits DHS to only laboratory, pharmacy, radiation therapy, physical therapy, and medical imaging services but makes the prohibition applicable to all patients. PHL § 238-a(1).
4. 42 U.S.C. § 1395nn(g)(3).
5. The Stark Law imputes the financial relationship to the physician's spouse and other "immediate family members." 42 U.S.C. § 1395nn(a)(1). When I was an employed hospitalist, my wife was a pediatrician in private practice who would send patients to a laboratory owned by my hospital. The Stark Law was implicated but not violated with respect to her because my employment satisfied the bona fide employment exception.
6. 42 U.S.C. § 1395nn(e)(2) provides the employment exception so long as the

employment is for identifiable services, payment reflects fair market value and is commercially reasonable in the absence of referrals to the employer, and the employment does not otherwise violate federal or state law. Furthermore, the amount of payment cannot take into account (directly or indirectly) the volume or value of referrals. Because of this latter element, even a bona fide employment relationship could violate Stark if the physician receives a sliding-scale bonus based on the number of admissions (e.g., X dollars at 1000 admissions, Y dollars at 1500 admissions, etc.).

7. 42 C.F.R. § 411.354(c)(2)(ii). There is a third element, which will always be present in a hospitalist/hospital financial arrangements, the hospital must have actual knowledge or act in reckless disregard of the fact that such a financial arrangement exists. § 411.354 (c)(2)(iii).
8. 42 C.F.R. § 411.357(p).
9. 42 U.S.C. § 1320a-7b(b)(1).
10. 42 C.F.R. § 1001.952(d). The necessary conditions to satisfy the safe harbor are: (1) the agreement is in writing and signed by the parties; (2) covers and specifies the services provided by the physician to the hospital; (3) if not full-time, specifies the schedule; (4) the term is not less than one year; (5) the aggregate compensation is set in advance, fair market value and does not vary with the volume or value of referrals or business otherwise generated; (6) does not violate federal or state law; and (7) the services are reasonably necessary and commercially reasonable. Note how conditions (3) and (4) could easily and unknowingly be violated by the arrangement with Drs. F and G, the moonlighters, unless the contract specifically included these provisions.
11. 42 C.F.R. § 411.357(d) and (l), respectively. The conditions are very similar and are essentially the same as the AKS safe harbor in footnote 10, above. One minor difference is the FMV exception permits the term to be less than one year so long as the compensation does not change if renewed within a twelve month period. § 411.354(l)(2).
12. 42 C.F.R. § 411.355(b).
13. 42 C.F.R. § 411.352(d).
14. 42 U.S.C. § 1320a-7a(b)(1). This prohibition exists despite the fact the Office of Inspector General for CMS recognizes that appropriately structured gainsharing arrangements offer significant benefits to society. See 64 Fed. Reg. 37985, 37985 (1999).
15. 42 C.F.R. § 411.357(e)(4)(vi). Admittedly, it is uncertain whether the additional $20,000 is truly "recruitment" or merely additional indirect compensation. It is this type of ambiguity that makes Stark Law analysis so difficult.