7 Things a Non-Health Care Lawyer Should Know When Advising a Health Care Client[1]

By John A. Anderson

FAST FACTS:

The Stark Law permits unsolicited non-monetary gifts to referring physicians if the annual aggregate value is not greater than $300 and the gift is not tied to referrals.

The Beneficiary Inducement Statute prohibits remuneration that is likely to influence a beneficiary's selection of a health care provider.

A health care provider who retires or closes a practice "shall not abandon the medical records."

Health care law can be complex, dynamic, and oftentimes confusing. Many lawyers who practice health care law—as well as many who do not—would undoubtedly agree with that proposition. What's more, the recently enacted Patient Protection and Affordable Care Act has added an entirely new level of complexity to this already intricate area of law. Those complex matters, however, are largely beyond the scope of this article. This article instead offers some guidance to lawyers who practice largely outside the health care law arena but have clients who look to them for advice on a variety of legal issues regarding the daily business operations of health care providers that require careful analysis under applicable federal and state law.

Be Careful About Gifts to Physicians Who Are Referral Sources

The federal Anti-Kickback Statute (AKS) 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.[2] The term "remuneration" is construed broadly and includes the transfer of anything of value (including gifts, sports tickets, meals, or other incidental benefits), directly or indirectly, overtly or covertly, in cash or in kind. Determining whether remuneration was made "in return for" or "to induce" referrals is based on an examination of the parties' intent.[3] Additionally, whether the AKS has been violated depends on the totality of the facts and circumstances, including the value of the remuneration, the nature of the relationship, the existence of potential conflicts of interest that might diminish objectivity or professional judgment, and the potential overutilization of federal health care services.[4]

The other law that could apply to gift giving is the physician self-referral law, commonly known as the Stark Law.[5] Essentially, the Stark Law prohibits a physician from referring patients to an entity for the furnishing of a designated health service[6] if there is a financial relationship[7] between the referring physician and the entity, unless an exception applies. Making a gift to a physician creates a financial relationship. However, a specific exception in the Stark Law, the Non-Monetary Compensation Exception,[8] allows non-monetary gifts to physicians who are referral sources if the value of the gifts is below a certain annual dollar amount. Thus, compensation in the form of items or services (not including cash or cash equivalents) that does not exceed an aggregate

of $300 a year (adjusted for inflation to $359 for 2011) is permitted if other conditions enumerated in the applicable regulation are also satisfied.[9] The physician cannot solicit the compensation, and the amount of compensation may not be determined by the volume or value of referrals or other business generated.[10] Thus, on a practical level, a ticket for a sporting event may be given to a physician as long as the gift is not solicited and the annual aggregate value of such tickets does not exceed $359 for 2011.

Commission Compensation Paid to Health Care Marketers Should Be Carefully Structured

The AKS is also implicated by compensation arrangements for health care marketers. As mentioned, the AKS may prohibit the offer or receipt of remuneration in return for referring or recommending the purchase of supplies and services reimbursable under government health care programs.[11] Given that the job of a health care marketer is specifically to make such recommendations, how does that reality square with the AKS prohibitions? One safe way to structure such arrangements is reliance on the AKS Employment Safe Harbor when the health care marketer is a bona fide employee.[12] The Employment Safe Harbor provides that remuneration does not include any amount paid by an employer to an employee who has a bona fide employment relationship with the employer.[13] The term "employee" is defined as any individual who has the status of an employee "under the usual common-law rules applicable in determining the employer-employee relationship."[14] Under the safe harbor, bona fide employees may be paid a commission on sales without violating the AKS.

Compensation arrangements with independent contractors who market health care services are more problematic. The AKS Personal Services and Management Contracts Safe Harbor excludes from the scope of remuneration any payments made by a principal to an agent as compensation for the services of the agent.[15] However, the Personal Services and Management Contracts Safe Harbor specifically prohibits compensation paid to the agent that is determined "in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties…."[16] Thus, while this safe harbor would allow certain independent contractor fixed-fee arrangements (e.g., $1,000 a month), it would not permit commission arrangements for independent contractors (e.g., $100 a sale). The regulation also prescribes other specific standards that must be met to qualify for safe-harbor protection, including a written agreement signed by the parties with a term of no less than one year.[17]

Although commission payments to independent contractor health care marketers are not per se unlawful under the AKS, any such arrangement should be carefully structured on the advice of a health care lawyer experienced in this area.

Avoid Problems with Beneficiary Inducement

The Beneficiary Inducement Statute (BIS) prohibits any person or company from offering or transferring any remuneration to a Medicare or Medicaid beneficiary if the person or company knows or should know that the remuneration is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of Medicare- or Medicaid-payable items or services.[18]

Penalties for violating the BIS are severe. Violators may be subject to, among other things, a civil money penalty of not more than $10,000 for each item or service, an assessment of not more than three times the amount claimed for each such item or service, and the person or company may be excluded from participation in Medicare and Medicaid.[19] Thus, the offer of any incentives to Medicare or Medicaid beneficiaries for marketing or promotional purposes should be carefully evaluated to comply with this statute.

The BIS defines remuneration as including, without limitation, the waiver of co-insurance and deductible amounts and "transfers of items or services for free or for other than fair market value."[20] Significantly, however, the Office of Inspector General—the agency responsible for protecting the integrity of federal health care programs—permits incentives that are of "nominal value," i.e., with a retail value of no more than $10 an item or no more than $50 in the aggregate to any one beneficiary annually.[21]

The BIS and its implementing regulations contain a limited number of exceptions. One exception allows the waiver of insurance copayments and deductible amounts; however, a provider or supplier may not routinely waive copayments and deductibles and may not advertise that it will waive these payments.[22] In addition, the provider or supplier may waive copayments or deductibles only after determining in good faith that the beneficiary is in financial need.[23] Finally, copayments and deductibles may be written off after a provider or supplier makes reasonable collection efforts.[24]

Another exception to the BIS allows incentives given to beneficiaries to promote the delivery of preventive care, provided the delivery of such services is not tied, directly or indirectly, to the provision of other services reimbursed by Medicare or Medicaid.[25] Preventive-care incentives may not include cash or instruments convertible to cash or any incentives with a value disproportionate to the value of the preventive-care service.[26]

Significant questions, such as whether and when an "investigation" begins, can be critical to protecting the health care professional's rights.

Resigning to Avoid Investigation May Trigger an Adverse Report

Both the Michigan Public Health Code[27] and the Release of Information for Medical Research and Education Act[28] require hospitals and other "entities" such as health facilities, health plans, and health agencies[29] to submit reports to the Michigan Department of Community Health about certain events relating to health professionals who are licensed or registered under Article 15 of the Public Health Code. (When the reorganization created by Executive Order 2011-4 is completed, the reports will be submitted to the Department of Licensing and Regulatory Affairs.) Reportable events include disciplinary action by the entity against the health professional on the basis of the professional's competence that results in a change in the health professional's employment status or that adversely affects the health professional's clinical privileges for more than 15 days.[30] The term "adversely affects" is broadly defined in the statutes.[31]

A reportable event occurs if the entity restricts or accepts the voluntary surrender of a health professional's clinical privileges while the health professional is under investigation by the entity or if the entity agrees not to conduct an investigation into the health professional's competence or conduct.[32] Significantly, it is also a reportable event when the health professional resigns from employment or terminates a contract with a health facility or agency, or when the contract is not renewed, instead of the entity taking disciplinary action.[33]

Reports to the Department of Community Health in these situations can jeopardize a health care professional's livelihood. Therefore, a health care professional should engage legal counsel at the first sign of any problem rather than waiting until later in the process. Significant questions, such as whether and when an "investigation" begins, can be critical to protecting the health care professional's rights.

The importance of these issues is magnified because similar matters must be reported on a national level to the National Provider Data Bank (NPDB). The NPDB was established by the federal Health Care Quality and Improvement Act of 1986. The act and implementing regulations generally require hospitals and state licensing authorities to report information about health care practitioners whose privileges have been restricted or revoked because of competence issues or professional misconduct.[34] A report must be made to the NPDB if the health care practitioner resigns or surrenders privileges while under investigation or after being notified that an investigation will be conducted but before the investigation begins.

Physicians May Provide Administrative Services for Entities to Which They Refer

The Stark Law permits physicians and their immediate family members to provide administrative services to an entity to which the physician refers patients. For example, a physician or an immediate family member may serve as a medical director to a home health agency, skilled nursing facility, or hospital. This must be done, however, pursuant to either the Stark Law's Bona Fide Employment Exception[35] or Personal Services Arrangements Exception.[36]

To satisfy the Bona Fide Employment Exception, the following requirements must be met: (1) the employment is for identifiable services, (2) the payment is consistent with fair market value and does not take into account the volume or value of referrals, and (3) the arrangement is established in a contract that would be commercially reasonable even if no referrals were made to the employer.[37]

The Personal Services Arrangements Exception allows the physician or immediate family member to be employed as an independent contractor to the entity to which the physician refers if the following requirements are met: (1) each arrangement must be in writing, signed by the parties, and specify the services covered by the arrangement; (2) the services must not exceed those that are commercially reasonable and necessary; (3) the contract must have a term of at least one year; (4) the compensation must be set in advance, not exceed fair market value, and not be determined in a manner that takes into account the volume or value of referrals or other business generated between the parties; and (5) the services must not involve the counseling or promotion of a business arrangement or other activity that violates any federal or state law.[38]

Medical Records Must Be Retained for at Least Seven Years

The Public Health Code imposes specific requirements for the retention of medical records by licensed individuals[39] and health facilities or agencies.[40] The code provides that health care providers "shall keep and retain [the records] for a minimum of 7 years from the date of service to which the record pertains" unless a longer retention period is otherwise required under federal or state laws or regulations or by generally accepted standards of medical practice.[41] There are circumstances in which a longer retention period is required. For example, under the federal Mammography Quality Standards Act, mammography films and records must be retained for not less than 10 years if no additional mammograms of the patient are performed.[42]

If the health care provider is unable to comply with the seven-year requirement, the provider must arrange with a third party to protect and maintain the medical records so they remain accessible to the patient or the patient's authorized representative.[43]

Specific Requirements Apply to Medical Records of Providers Who Retire or Close a Practice

If a provider sells or closes a practice, retires from practice, or otherwise ceases to practice, the provider or the personal representative of a deceased provider "shall not abandon the medical records."[44] The Public Health Code requires written notice to the Department of Community Health, specifying who will have custody of the medical records and how a patient may request copies or gain access to them.[45] Additionally, the code requires that either one of the following be done:

> (1) transfer the records to (a) a successor health care provider; (b) the patient, the patient's authorized representative, or a licensed provider of the patient's choosing; or (c) a health care provider, health facility or agency, or medical records company pursuant to an agreement to protect, maintain, and provide access to the records; or
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> (2) destroy the records, provided that written notice has been sent and written authorization to destroy has been received from the patient or the patient's representative.[46]

Alternatively, the patient may request a copy of the records or request transfer of the records. If the patient fails to request a copy or transfer of the medical records or fails to provide written authorization for destruction, then the provider may destroy records that are at least seven years old, but must retain records that are less than seven years old.[47]

Conclusion

The list of topics contained in this article is certainly not exhaustive, but it should equip the non-health care lawyer with a few practical pointers when counseling clients that provide health care services. Just as importantly, it should alert lawyers about common practices and circumstances in the health care business that may require assistance from health care practitioners. ■

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FOOTNOTES

1. The material in this article offers general guidance to the reader based on laws, regulations, court decisions, and administrative rulings and is not intended to provide legal advice or legal opinions on specific facts.
2. 42 USC 1320a-7b(b).
3. See, e.g., *United States v Greber*, 760 F2d 68, 71–72 (CA 3, 1985); accord *United States v Katz*, 871 F2d 105 (CA 9, 1989).
4. See Office of Inspector General (OIG) Supplemental Compliance Program Guidance for Hospitals, 70 Fed Reg 4858, 4863 (January 31, 2005).
5. 42 USC 1395nn.
6. See 42 CFR 411.351. "Designated health services" include, among other services, inpatient and outpatient services, physical therapy, certain imaging services, home health services, durable medical equipment, and clinical laboratory services. See the regulation for a complete list.
7. See 42 CFR 411.354.
8. 42 CFR 411.357(k).
9. See *id.;* U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS), Physician Self Referral, *CPI-U Updates* <http://www.cms.gov/PhysicianSelfReferral/50_CPI-U_Updates.asp#TopOfPage>. All websites cited in this article were accessed May 3, 2011.
10. OIG Special Fraud Alert <http://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html>.
11. 42 USC 1320a-7b.
12. 42 CFR 1001.952(i).
13. *Id.*
14. 26 USC 3121(d)(2).
15. 42 CFR 1001.952(d).
16. 42 CFR 1001.952(d)(5).
17. 42 CFR 1001.952(d)(4).
18. 42 USC 1320a-7a(a).
19. 42 USC 1320a-7a (a)(7).
20. 42 CFR 1003.101.
21. 65 Fed Reg 24400, 24410–24411 (April 26, 2000).
22. 42 USC 1320a-7a(i)(6)(A); 42 CFR 1003.101.
23. 42 USC 1320a-7a(i)(6)(A); 42 CFR 1003.101.
24. 42 USC 1320a-7a(i)(6)(A); 42 CFR 1003.101.
25. 42 CFR 1003.101.
26. 42 USC 1320a-7a(i)(6)(D); 42 CFR 1003.101.
27. MCL 333.20175(5).
28. MCL 331.531.
29. See MCL 331.531(2)(iii).
30. MCL 333.20175(5)(a).
31. See MCL 331.531(5)(a) and MCL 333.20175(5)(a).
32. See MCL 331.531(5)(b) and MCL 333.20175(5)(b).
33. See MCL 331.531(5)(c) and MCL 333.20175(5)(c).
34. The NPDB main website can be accessed at <http://www.npdb-hipdb.hrsa.gov/>.
35. 42 CFR 411.357(c).
36. 42 CFR 411.357(d).
37. 42 CFR 411.357(c).
38. 42 CFR 411.357(d).
39. MCL 333.16213.
40. MCL 333.20175.
41. MCL 333.16213(1) as to licensed individuals; MCL 333.20175(1) as to a health facility or agency.
42. 21 CFR 900.12(c)(4)(i) and (ii).
43. MCL 333.16213(2).
44. MCL 333.16213(3).
45. *Id.*
46. MCL 333.16213(3)(a).
47. MCL 333.16213(3)(b).