



# Advice for the Non-Healthcare Lawyer

## Representing Clients in Arrangements with Hospitals and Other Healthcare Providers

By Ann T. Hollenbeck

**T**hird parties (and their lawyers) seeking to do business with healthcare providers often find themselves confused and frustrated by the complex regulatory environment in which hospitals, health systems, long-term care facilities, surgery centers, hospice, and home health providers operate. Do you represent vendors seeking to sell products or services to healthcare providers? Do you occasionally have the opportunity to represent a physician seeking to enter an employment relationship or some sort of seemingly simple business arrangement or transaction with a healthcare provider? Familiarizing yourself with the healthcare regulatory environment will aid you in effectively advising your clients in forging the business relationships they seek. This article reviews four key areas of regulation and provides additional resources for further reference.

### [The Federal Health Insurance Portability and Accountability Act of 1996 \(HIPAA\)](#)

If your client will have access to or use the healthcare provider's patient health information, HIPAA issues will arise. In

the case of a physician who will provide clinical services on behalf of the healthcare provider, it is likely he or she will be classified as a member of the healthcare provider's workforce for HIPAA purposes even if the physician is an independent contractor. As a member of the healthcare provider's workforce for HIPAA purposes, your physician-client will be subject to numerous HIPAA-related policies that address the physician's obligations to properly use, access, disclose, and safeguard patient health information.

If your client is a services or equipment vendor and will use or have access to the healthcare provider's patient health information (even if your client won't use or need it), your client will likely be treated as a "business associate" by the healthcare provider and be required to enter into a "business associate agreement." As counsel to a business associate, you should be educated on the required provisions of a business associate agreement, ensure that it does not impose additional terms that are unduly burdensome to your client, and advise your client on capabilities required to satisfy business associate requirements.

## FAST FACTS

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Physicians are routinely considered “disqualified persons” in relation to tax-exempt healthcare providers.

### Summary of HIPAA<sup>1</sup>

HIPAA and its related federal regulations seek to protect individually identifiable health information relating to an individual's past, present, or future physical or mental health, the provision of healthcare to the individual, and the payment for the provision of healthcare to the individual. HIPAA applies to “covered entities” defined as (1) healthcare providers, including hospitals, doctors, outpatient clinics, nursing homes, and pharmacies; (2) health plans; and (3) healthcare clearing-houses.<sup>2</sup> HIPAA requires covered entities to implement safeguards to protect the privacy of personal health information and limit the uses and disclosures that may be made of such information without patient authorization.<sup>3</sup> HIPAA also gives a patient rights over his or her health information, including rights to examine and obtain a copy of his or her health records and request corrections.<sup>4</sup> Failure to comply with HIPAA can result in civil and criminal penalties.<sup>5</sup>

### Business associates

A covered entity is permitted to disclose protected health information to third parties (known as “business associates”) for purposes of assisting in carrying out the covered entity's healthcare functions, but only if the covered entity obtains satisfactory assurances that the business associate will use the information only for the purposes for which it was engaged by the covered entity, safeguard the information from misuse, and help the covered entity comply with some of its duties under HIPAA.<sup>6</sup> A covered entity must have a written agreement with the business associate that contains these specified terms.<sup>7</sup> Business associate activities include billing and claims processing, utilization review, quality assurance, data analysis and operations management, legal services, and accounting and auditing services.<sup>8</sup>

## Stark Law and Anti-Kickback Statute

When representing a physician-client, issues associated with patient referrals to the healthcare provider and its affiliates will likely be of concern. In the case of physician employment, expect overall compensation to be capped and for any clinical service-based, non-fixed compensation or bonus to be limited to services personally performed by the physician. In the case of an independent contractor arrangement for medical director, teaching, research, or part-time clinical services, be ready to discuss fair market value of payments and enter into a detailed written agreement for the arrangement.

Similarly, when representing a vendor seeking to provide services or lease real estate or equipment in exchange for payments based on volume of use or a percentage of revenue or collections, be prepared for a detailed discussion as to whether this is permissible and, if so, whether the associated compliance risk is necessary or prudent. Expect a detailed written agreement seeking to meet an applicable safe harbor or exception to the prohibitions described below.

### Stark Law<sup>9</sup>

The federal Stark Law prohibits (1) a physician from making a referral for any “designated health service” to an entity with which the physician has a “financial relationship” and (2) an entity from billing Medicare for any “designated health service” ordered by a physician (or immediate family member of the physician) with whom the entity has a “financial relationship,”<sup>10</sup> unless the relationship fits within a specific exception.<sup>11</sup> Financial relationships include both ownership/investment and compensation arrangements.<sup>12</sup> Designated health services include inpatient and outpatient hospital services but do not include most non-hospital services that are reimbursed by Medicare as part of a composite rate (for example, certain medical and surgical supplies included in ambulatory surgery center bundled payments).<sup>13</sup>

There are a number of exceptions to the referral prohibition, which are set forth in the Stark Law and related regulations. If an arrangement falls within one of these exceptions, it will be deemed not in violation of the Stark Law. On the other hand, if an arrangement fails to meet all of the requirements of at least one Stark Law exception, the referrals will be prohibited. The Stark Law imposes penalties for violations, including Medicare payment denial, recoupment of payments resulting from prohibited claims, civil monetary penalties, assessments of up to three times the prohibited claim, and Medicare program exclusion.<sup>14</sup>

### Anti-Kickback Statute<sup>15</sup>

The federal Anti-Kickback Statute is a criminal statute that prohibits the knowing and willful offer, payment, solicitation, or receipt of any remuneration to induce or reward the referral of items or services reimbursable by a federal healthcare

program.<sup>16</sup> In addition to criminal penalties,<sup>17</sup> when a party commits an act described in the Anti-Kickback Statute, the Office of Inspector General of the Department of Health and Human Services—the government agency charged with enforcing many of the federal government’s healthcare fraud and abuse laws, including the Anti-Kickback Statute—will likely initiate administrative proceedings to impose civil monetary penalties and exclude the party from participation in federal healthcare programs.<sup>18</sup>

The Department of Health and Human Services has promulgated safe-harbor regulations that define certain types of arrangements deemed to not violate the Anti-Kickback Statute because such practices would be unlikely to result in fraudulent or abusive practices. An arrangement will qualify for safe-harbor protection only if it precisely meets all the conditions set forth in the safe harbor; however, failure to satisfy a safe harbor does not mean the arrangement necessarily violates the Anti-Kickback Statute. Rather, the analysis of the arrangement is a facts-and-circumstances inquiry focused on whether an enforcement agency could potentially infer that the parties to the transaction had the requisite intent to violate the Anti-Kickback Statute. Further, while an arrangement failing to satisfy every condition of a safe harbor will not be afforded protection, in defending the arrangement it is nonetheless constructive to establish that its structure substantially conforms to the safe harbor’s requirements.

Commonly used exceptions to the Stark Law and Anti-Kickback Statute apply to personal services and management contracts,<sup>19</sup> space and equipment leases,<sup>20</sup> and employment relationships.<sup>21</sup> Advisory opinions have been issued by the Centers for Medicare & Medicaid Services and the Office of Inspector General on a variety of arrangements that provide helpful guidance.<sup>22</sup>

### False Claims Act

Note also that the federal False Claims Act is one of the primary vehicles currently used to enforce healthcare fraud and abuse laws. The act punishes the knowing and willful submission of fraudulent claims to the federal government with civil monetary penalties and treble damages.<sup>23</sup>

### Michigan law

Michigan law also prohibits illegal patient referrals and penalizes kickback arrangements through, among others, the Medicaid False Claims Act,<sup>24</sup> the Health Care False Claims Act,<sup>25</sup> a statute prohibiting the division of fees in certain contexts,<sup>26</sup> and a statute prohibiting the payment of fees in exchange for clinical laboratory referrals.<sup>27</sup>

### Tax-exempt parameters

If your client seeks to do business with a tax-exempt healthcare provider, be mindful that federal and state tax laws and

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regulations present a host of parameters on the operations and financial relationships of the tax-exempt healthcare provider.<sup>28</sup> These include making payments of no more than reasonable compensation and ensuring fair market value payments in exchange for goods and services, prohibitions on insider transactions that fail to meet specific criteria, and adherence to conflict-of-interest procedures.

Tax-exempt healthcare providers routinely seek independent third-party reviews of physician compensation to ensure compliance; thus, be prepared to submit information about your client’s credentials, historical practice, and intended services to the healthcare provider. A similar review may be pursued if your client seeks to provide management or operational services to a business line or unit that result in your client’s having significant influence over that area of the healthcare provider’s business. Cooperating with this process is recommended despite the delay that will likely result, as a favorable third-party review will help your client.

Additionally, if the arrangement involves your client’s use of the healthcare provider’s tax-exempt, bond-financed facility, expect additional discussion about your client’s use, potential limitations, and the necessary terms and conditions that must be set forth in the related written agreement.<sup>29</sup>

### Taxpayer Bill of Rights 2 (TBOR2)

In 1996, Congress enacted TBOR2, which added Section 4958 to the Internal Revenue Code of 1986 providing for intermediate sanctions on individuals participating in prohibited private inurement. Section 4958 provides that any transaction or contract entered into by a tax-exempt organization (1) that gives rise to an economic benefit directly or indirectly to (2) any “disqualified person,” i.e., an individual in a position (currently or within the five prior years) to exercise substantial influence over the affairs of the tax-exempt organization (even if that power is not actually used) when (3) the fair market value of that benefit exceeds the consideration paid in return is considered an “excess benefit transaction,” subjecting the individual receiving the excess benefit and any officer or director (or person vested with similar powers) of the tax-exempt organization who approved the transaction to taxes

and fines of up to 225 percent and 10 percent of the excess benefit, respectively.<sup>30</sup> If the IRS views the excess benefit to be significant or ongoing, the tax-exempt status of the organization could also be revoked.<sup>31</sup>

An excess benefit transaction is any transaction by which an applicable tax-exempt organization provides an economic benefit—virtually anything of value, including compensation, loans, guaranties, property, use of property, gifts, payment of personal expenses, free or discounted benefits, etc.—directly or indirectly (such as through an affiliate) to or for the use of any disqualified person, and the fair market value of that benefit exceeds the consideration paid in return, whether in cash or in kind such as services. The amount of the excess benefit is the differential from fair market value.<sup>32</sup>

Under Code Section 4958(a)(1), a disqualified person is any person or entity in a position (at the time of or within five years before the transaction) to exercise substantial influence over the affairs of the tax-exempt organization, even if that power is not actually used. Certain individuals are deemed to be disqualified persons, such as CEOs, COOs, CFOs/treasurers, and voting members of the board. The term “disqualified person” also includes any such individual’s family members and their 35 percent-controlled entities.<sup>33</sup> Collectively, these are “deemed disqualified persons” regardless of other factors as to actual influence.

For anyone other than deemed disqualified persons, various factors apply in determining whether someone is a disqualified person.<sup>34</sup> No one factor is determinative, nor is more than one necessarily required. Physicians are routinely considered disqualified persons under a facts-and-circumstances analysis that examines whether they have the ability to exercise substantial influence over the affairs of the tax-exempt organization.

To avoid excess benefit transactions, tax-exempt organizations typically undertake the following actions:

- Maintain a conflict-of-interest policy requiring disqualified persons to submit disclosure statements annually, and
- Follow the “rebuttal presumption procedure” in advance of any transaction or contract with a disqualified person.

The rebuttal presumption procedure is a three-step procedure requiring (1) any transaction or contract between the tax-exempt organization and a disqualified person to be reviewed and approved in advance by independent members of the tax-exempt organization’s board of directors who have relied on (2) appropriate fair market value data in determining that the transaction or contract does not result in any excess benefit and (3) the determination be thoroughly documented concurrent with the determination.<sup>35</sup>

## Certificate of Need

The State of Michigan Certificate of Need (CON) program is a state regulatory program enacted in 1972 which seeks



to ensure that only needed healthcare services and expenditures are pursued in Michigan. If your client’s relationship with a healthcare provider involves CON (for example, sale of equipment or construction services to a health facility), be prepared for additional project planning and cost analysis as well as a possible delay while CON reviews take place.

Any entity (including a health facility, physician, group practice, etc.) proposing any of the following types of projects must obtain a CON, regardless of the capital expenditure proposed:

- Increase in the number of licensed beds or the relocation of licensed beds from one site to another
- Acquisition of an existing health facility
- Operation of a new health facility
- Initiation, replacement, or expansion of numerous covered clinical services (including cardiac catheterization services; CT, MRI, MRT, and PET scanner services; surgical services; and lithotripter services)
- Short-term nursing care program

Additionally, capital expenditure projects (whether new construction or renovation of an existing facility) that involve a health facility—defined to include a hospital, nursing home, and freestanding surgical outpatient facility, among others—require a CON. The capital expenditure threshold is indexed annually by the State of Michigan Department of Health and Human Services based on the Consumer Price Index. Effective January 1, 2017, the threshold is \$3,187,500. Determinations of the application of CON standards and CON approval must be obtained in writing and are subject to a detailed process of review.<sup>36</sup>

The CON program is administered by the Department of Health and Human Services, which undertakes various reviews, each of which has specific deadlines and requirements:

- A substantive review is used for projects requiring a full review and is performed on an individual project basis; examples include the initiation of an MRI service or a new ambulatory surgery center.
- A nonsubstantive review is used for non-full review projects. These require less information and are processed more quickly; examples include equipment replacements and the addition of mobile host sites for clinical services.
- A comparative review is used for competing project types for which the need is limited; examples include hospital beds and transplantation services.

## Conclusion

Complexities abound for hospitals, health systems, long-term care facilities, and home healthcare providers. Representing individuals and entities that do business with healthcare providers requires an anticipation and understanding of the key regulatory issues to guide clients through these important relationships. Delving into the issues and confirming your client is properly classified (whether as a business associate, an insider, or referral source) and the project involved is properly managed (whether through CON or the rebuttable presumption process) is an essential and important role you will serve for your clients as they navigate relationships with healthcare providers. ■



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## ENDNOTES

1. A user-friendly resource can be found at US Dept of Health and Human Services, *HIPAA for Professionals* <<http://www.hhs.gov/hipaa/for-professionals>>. All websites cited in this article were accessed January 10, 2017.
2. 45 CFR 160.103.
3. 45 CFR 164.502.
4. 45 CFR 164.520.
5. 42 USC 1320d-5; 45 CFR 160.400 *et seq.* For more information on these penalties, visit US Dept of Health and Human Services, *HIPAA Enforcement* <<https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/>>.
6. 45 CFR 164.504(e).
7. *Id.*
8. 45 CFR 160.103. For a sample business associate agreement, visit US Dept of Health and Human Services, *Business Associate Contracts* <<http://www.hhs.gov/hipaa/for-professionals/covered-entities/sample-business-associate-agreement-provisions/index.html>>.
9. See generally Centers for Medicare & Medicaid Services, *Physician Self Referral* <<https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/index.html?redirect=/physicianselfreferral>>.
10. 42 USC 1395nn.
11. 42 CFR 411.351.
12. 42 USC 1395nn(a)(2).
13. 42 CFR 411.351.
14. 42 USC 1395nn(g).
15. A user-friendly resource can be found at Office of Inspector General, *A Roadmap for New Physicians* <<https://oig.hhs.gov/compliance/physician-education/01laws.asp>>.
16. 42 USC 1320a-7b(b) (Section 1128B(b) of the Social Security Act).
17. There are additional statutory provisions relating to criminal penalties of up to \$250,000 for each offense for individuals, and up to \$500,000 for each offense for a corporation. 18 USC 3571.
18. See 42 USC 1320a-7b(b)(1), (2); see also 42 USC 1320a-7(b)(7); 42 USC 1320a-7a(a)(7).
19. 42 CFR 411.357(d) (Stark); 42 CFR 1001.952(d) (Anti-Kickback).
20. 42 CFR 411.357(b) (Stark); 42 CFR 1001.952(b) and (c) (Anti-Kickback).
21. 42 CFR 411.357(c) (Stark); 42 CFR 1001.952(i) (Anti-Kickback).
22. For information about Stark Law advisory opinions, visit Centers for Medicare & Medicaid Services, *Advisory Opinions* <[https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/advisory\\_opinions.html](https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/advisory_opinions.html)>. For information about Anti-Kickback Statute advisory opinions, visit Office of Inspector General, *Advisory Opinions* <<https://oig.hhs.gov/compliance/advisory-opinions/>>.
23. 31 USC 3729.
24. MCL 400.604.
25. MCL 752.1004.
26. MCL 333.16221(d)(ii); MCL 750.428.
27. MCL 445.162.
28. For tax-exempt laws and regulations, visit IRS, *Charities & Non-Profits* <<https://www.irs.gov/charities-non-profits>>.
29. Rev Proc 97-13, 1997-1 CB 632 (October 1, 1997); Rev Proc 2016-44, 2016-36 IRB 316 (August 22, 2016).
30. IRC Code 4958(a) and (b).
31. The final regulations provide that prior inurement law and private benefit rules continue in force. 26 CFR 53.4958-8(a).
32. 26 CFR 53.4958-1(b); 26 CFR 53.4958-4(a)(1) and (2).
33. 26 CFR 53.4958-3.
34. 26 CFR 53.4958-3.
35. 26 CFR 53.4958-1(d)(4)(iv); 26 CFR 53.4958-6(b).
36. See Michigan Dept of Health and Human Services, *Michigan's Certificate of Need Program 2017* <[http://www.michigan.gov/documents/mdch/2015\\_CONb\\_Brochure\\_488915\\_7.pdf](http://www.michigan.gov/documents/mdch/2015_CONb_Brochure_488915_7.pdf)>.