

## 2 OVERVIEW OF REGULATORY ISSUES AFFECTING PHYSICIANS

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This chapter introduces and discusses a number of federal and state statutes and regulations that govern physicians and other healthcare providers. Taken together, these laws and their implementing regulations place more restraints upon physicians than upon any other licensed profession in the United States. These regulatory compliance burdens combine with practice cost increases that exceed the rate of inflation (*e.g.*, rising malpractice premiums) and limits on reimbursement for physician services from both governmental and private third-party payer programs to increase the pressures and frustrations felt by physicians as they pursue the healing art. This chapter will facilitate the efforts of legal counsel to advise and assist their clients in meeting these serious regulatory challenges.

The first three sections of this chapter focus on three federal laws that place substantial restrictions upon the financial relationships among physicians and the various healthcare entities to which physicians make or receive referrals. These laws are the Physician Self Referral Act (commonly known as the Stark law),<sup>1</sup> the Anti-Kickback Statute,<sup>2</sup> and the Civil Monetary Penalties Law.<sup>3</sup> This chapter next turns to discussion of state licensure laws, state laws regulating fee-splitting, and the corporate practice of medicine laws active in some states. The chapter also discusses the application of federal antitrust laws to the efforts of physicians to improve their negotiating leverage with private payers. Application of Health Insurance Portability and Accountability Act (HIPAA) principles regarding privacy of patient information and security of patient information maintained by physicians will also be summarized. Finally, application of various legal principles applied in the provision of telemedicine services will be discussed.

This chapter is by no means a comprehensive discussion of the laws and regulations affecting physicians or the practice of medicine. Reference is made to chapters in this book regarding reimbursement, hospital relationships, professional liability and joint ventures for discussion of laws and regulations, with particular impact in those areas affecting physicians.

### 2.1 The Stark Law

The Stark law, Section 1877 of the Social Security Act, became effective on January 1, 1992 (Stark I).<sup>4</sup> The law gets its name from U.S. Representative Fortney (“Pete”) Stark (D-CA), the law’s primary sponsor in Congress. Stark I prohibits physicians from making referrals to an entity for clinical laboratory services if the physician (or an immediate family member of the physician) has a “financial relationship” with that entity, and it further prohibits the entity from submitting a claim for services provided pursuant to an improper referral.<sup>5</sup> The Stark law was

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<sup>1</sup> 42 U.S.C. § 1395nn.

<sup>2</sup> 42 U.S.C. § 1320a-7b(b).

<sup>3</sup> 42 U.S.C. § 1320a-7a.

<sup>4</sup> Ethics in Patient Referral Act of 1989, Omnibus Budget Reconciliation Act of 1989 (OBRA 1989), Pub. L. No. 101-239, § 6204, 103 Stat. 2106 (1989) (codified at 42 U.S.C. § 1395nn).

<sup>5</sup> *Id.*

amended by the Omnibus Reconciliation Act of 1993.<sup>6</sup> Stark II, which became effective on January 1, 1995, prohibits a physician from making referrals for any of eleven designated health services (DHS) to an entity with which the physician (or an immediate family member of the physician) has a financial relationship, unless a specific exception applies.<sup>7</sup> The Stark law prohibition on referrals is limited to referrals for any DHS that may be payable in whole or in part by Medicare or Medicaid, whether as a primary payer or secondary payer.<sup>8</sup> The list of DHS for which referrals are prohibited by the Stark law includes:

- Clinical laboratory services;
- Physical therapy services;
- Occupational therapy services;
- Radiology services, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services;
- Radiation therapy services and supplies;
- 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.<sup>9</sup>

If a referral for DHS prohibited by the Stark law, the entity may not bill the patient, the Medicare or Medicaid programs, or any other entity for such services, and the entity must refund any payments it collected for the services provided.<sup>10</sup> Although the Stark law does not impose a penalty for the referral itself, a civil monetary penalty of up to \$15,000 may be imposed for each bill submitted for services provided and/or each failure to make a required refund.<sup>11</sup> The Stark law also provides for a penalty of up to \$100,000 for any “circumvention schemes” or arrangements that the physician or the entity knows (or should know) has the principal purpose of assuring referrals by the physician to the entity that, if the physician directly made referrals to

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<sup>6</sup> Pub. L. No. 103-66, § 13562, 107 Stat. 312 (1993).

<sup>7</sup> *Id.*

<sup>8</sup> 42 U.S.C. § 1395nn(a)(1).

<sup>9</sup> *See* 42 C.F.R. § 411.351 (definition of Designated Health Services).

<sup>10</sup> 42 U.S.C. § 1395nn(g)(1)-(2).

<sup>11</sup> 42 U.S.C. § 1395nn(g)(3)-(4).

the entity, would violate the Stark law.<sup>12</sup> Further, any physician or entity that violates the Stark law may be excluded from the Medicare and Medicaid programs.

### 2.1.1 Key Stark Law Issues

In any analysis under the Stark law, there are a number of pivotal issues. The first is the “financial relationship” that triggers the anti-referral prohibition. The Stark law defines this term as any direct or indirect ownership or investment interest by a physician (or an immediate family member of the physician) in the entity providing the DHS, or any direct or indirect compensation arrangement between the physician (or an immediate family member of the physician) and the entity providing the DHS.<sup>13</sup> The entity may be any entity that receives referrals from physicians and furnishes DHS, and may include the physician’s own group practice, as well as any hospital, laboratory, diagnostic testing facility, ambulatory surgery center, medical equipment supply company, or other organization that provides DHS.<sup>14</sup> The Stark law clarifies that an ownership or investment interest may be through “equity, debt, or other means,” and may be through ownership interests in other entities that own an interest in the entity providing the DHS.<sup>15</sup> For example, if a physician is a shareholder in a professional corporation, and the professional corporation owns an equity interest in another entity that provides radiology services, then the physician will be deemed to have an indirect ownership interest in the other entity, which constitutes a financial relationship with an entity providing DHS for purposes of the Stark law. Accordingly, unless an exception applies, the physician would be prohibited from referring patients to the other entity for radiology services. The term “compensation arrangement” is further defined as one involving any “remuneration” between a physician (or an immediate family member of the physician) and an entity.<sup>16</sup> The remuneration may be any direct or indirect payment or benefit, overt or covert, in cash or in kind, with very limited exceptions.<sup>17</sup> For example, salary paid by a group practice to an employed physician and rental payments made by a physician to a hospital for office space would clearly be considered compensation arrangements that implicate the Stark law. Likewise, compensation arrangements include such benefits as malpractice insurance subsidies, loan forgiveness and even free meals received by a physician in a hospital cafeteria.

Further, an “indirect compensation arrangement,” which constitutes a financial relationship for purposes of the Stark law, may exist between a referring physician and an entity furnishing DHS if:

- (1) There is an unbroken chain of ownership, investment interests or compensation arrangements between the physician (or an immediate family member of the physician) and the entity;

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<sup>12</sup> *Id.*

<sup>13</sup> 42 C.F.R. § 411.354.

<sup>14</sup> 42 C.F.R. § 411.351.

<sup>15</sup> 42 U.S.C. § 1395nn(a)(2).

<sup>16</sup> 42 C.F.R. § 411.354(c).

<sup>17</sup> *Id.*

- (2) The physician (or immediate family member) receives aggregate compensation that varies with or otherwise reflects the volume or value of referrals or other business generated by the physician for the entity; and
- (3) The entity knows or has reason to suspect that the physician (or immediate family member) receives compensation that varies with the volume or value of referrals.<sup>18</sup>

For example, if a physician is a shareholder in a professional corporation, and the professional corporation owns an equity interest in another entity that provides hospital-based services, and if this entity is under a professional services contract with a hospital pursuant to which the hospital pays the entity a fee per procedure or a percentage fee that fluctuates based on the volume or value of services provided by the physician to the hospital's patients, then an indirect compensation arrangement may exist between the physician and the hospital that constitutes a "financial relationship" for purposes of the Stark law. The analysis of whether the Stark law even applies to a certain financial relationship can be complicated.

The next critical issue is what constitutes a "referral." The Stark law defines the term as the request by a physician for an item or service for which payment may be made under Part B of the Medicare program, including the request or establishment of a plan of care by a physician that includes a DHS and a request for a consultation with another physician.<sup>19</sup> This has been made applicable, albeit indirectly, to the Medicaid program as well. Phase II of the final Stark II rules, which became effective July 26, 2004, made the important clarification that a referral does *not* include any DHS that is personally performed by the physician.<sup>20</sup> For purposes of this new rule, in order for a DHS to be considered "personally performed" by the physician, the physician must perform the actual service.<sup>21</sup> Accordingly, any work performed by any other persons (even by physician assistants and nurse practitioners under the physician's supervision) will *not* be deemed personally performed by the physician. There is a very limited exception to this rule for (1) requests by pathologists for clinical diagnostic laboratory tests and pathological examination services, (2) requests by radiologists for diagnostic radiology services, and (3) requests by radiation oncologists for radiation therapy, provided that the "request results from a consultation initiated by another physician."<sup>22</sup> As a rule, a physician is usually deemed to have made a referral for purposes of the Stark law each time the physician orders or requests a test, procedure, device, supply or other item or service from another entity or physician (even within the physician's own practice) that falls under the category of DHS, and the test, procedure, device, supply, item or service may be payable by Medicare or Medicaid.

### 2.1.2 Stark Law Exceptions

Unlike the Anti-Kickback Statute discussed in the following section of this chapter, the intent of the parties is *not* an issue under the Stark law. Under the Anti-Kickback Statute,

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<sup>18</sup> 42 C.F.R. § 411.354(c)(2).

<sup>19</sup> 42 C.F.R. § 411.351.

<sup>20</sup> *Id.*

<sup>21</sup> *Id.*

<sup>22</sup> 42 C.F.R. § 411.351(2).

compliance with the statutory exceptions or regulatory “safe harbors” is voluntary (although recommended), and failure to fall within a safe harbor does not necessarily mean that the parties are acting illegally. Under the Stark law, however, a broad prohibition and strict liability is created. If a financial relationship exists between a physician and an entity furnishing DHS, then no referrals for DHS may be made by the physician to the entity unless the relationship meets *all* of the requirements to qualify for a specific exception. As explained, if any prohibited referrals are made, then the entity may not bill anyone for the services provided, and the entity must refund any payments collected for the services. Because the DHS covered by the Stark law include inpatient and outpatient hospital services, clinical laboratory services and radiology services, and in light of the penalties for violations of the Stark law, the amount of money at risk can be quite substantial.

Fortunately, there are numerous exceptions under the Stark law that apply to common, legitimate financial arrangements between physicians and their group practices, hospitals and other service providers. The first step in analyzing what exception(s) may be applicable to a certain financial relationship is to determine exactly what type of financial relationship exists. There are specific exceptions that apply only to ownership or investment interests, some that apply only to compensation arrangements, and some that apply to both. Although the scope of this chapter is not intended to cover all of the Stark law exceptions that may apply to physician financial relationships, this section will summarize the general requirements of several of the most important exceptions affecting physicians and their practices.

#### 2.1.2.1 *Bona Fide Employment Relationships*

The bona fide employment relationships exception applies to any amounts paid by an employer to a physician (or an immediate family member of the physician) who has a bona fide employment relationship with the employer if the following conditions are met: (a) the employment is for specific, identifiable services; (b) the amount paid is consistent with fair market value and not determined in a manner that takes into account (directly or indirectly) the volume or value of referrals made by the physician or other business generated between the parties; and (c) the compensation is provided under an agreement (written or verbal) that would be commercially reasonable even if no referrals were made by the physician to the employer.<sup>23</sup> The law clarifies that the requirement described in (b) above does *not* preclude payment of a productivity bonus to a physician based on services *personally performed* by the physician.<sup>24</sup> This exception can apply to any bona fide employment relationships that provide for direct compensation from the employer to the physician, whether the employer is the physician’s own group practice, a hospital or another service provider.

#### 2.1.2.2 *In-Office Ancillary Services*

The Stark law exception for in-office ancillary services is probably the most important exception applicable to physicians who are members of group practices. This exception allows physicians to refer DHS within the physician’s own group practice, and allows the group to bill for such services without violating the Stark law. The exception, which applies to both

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<sup>23</sup> 42 U.S.C. 1395nn(e)(2).

<sup>24</sup> *Id.*

ownership/investment interests and compensation arrangements between physicians and their group practices, specifically permits the referral of DHS (excluding certain items of durable medical equipment and all parenteral and enteral nutrients, equipment and supplies), subject to very specific conditions that are set forth in the final rules.<sup>25</sup> The following is a general summary of those specific regulatory conditions.

- The services must be personally furnished by:
  - (i) The referring physician;
  - (ii) A physician who is a member of the same group practice as the referring physician, or an individual who is supervised by the referring physician; or
  - (iii) Another physician in the group practice.
- The services must be furnished in one of the following locations:
  - (i) The same building in which the physician or the physician’s group practice has an office that is open to patients for medical services at least thirty-five hours per week, and where the physician or a member of the physician’s group regularly practices medicine and furnishes physician services to patients at least thirty hours per week (subject to very specific requirements);
  - (ii) The same building in which the patient usually receives physician services from the physician or group practice, where the physician or group practice owns or rents an office that is normally open to patients at least eight hours per week, and where the physician regularly practices medicine and furnishes physician services to patients at least six hours per week (subject to very specific requirements);
  - (iii) The same building in which the physician is present and orders the DHS or the physician or a member of the group practice is present while the DHS is furnished, where the physician or group practice owns or rents an office that is normally open to patients at least eight hours per week, and where the physician or a member of the group practice regularly practices medicine and furnishes physician services to patients at least six hours per week (subject to very specific requirements); or
  - (iv) A “centralized building” used by the group practice for the provision of some or all of the group’s clinical laboratory services or DHS other than clinical laboratory services.

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<sup>25</sup> 42 C.F.R. § 411.355(b).

- The services are billed by:
  - (i) The physician performing or supervising the service;
  - (ii) Such physician’s group practice, under a billing number assigned to the group practice;
  - (iii) An entity that is wholly owned by such physician or the physician’s group practice under the entity's own billing number or under a billing number assigned to the physician or group practice; or
  - (iv) An independent third-party billing company acting as an agent of the physician, group practice or entity, under a billing number assigned to the physician, group practice or entity.<sup>26</sup>

For purposes of this exception, a centralized building is defined as, generally, all or part of a building (or a mobile vehicle, van or trailer) that is owned or leased on a full-time basis by a group practice and that is used exclusively by the group practice. Separate, exclusively used space within the same building will meet this requirement. However, space in a building (or mobile vehicle, van or trailer) that is shared by a group practice with a third party is *not* considered a centralized building for purposes of this definition. For example, if a group practice exclusively uses its leased office space Monday through Friday, but subleases the space to a solo practitioner or to a diagnostic imaging company on the weekends, then the space could not be deemed a centralized building.

The Stark law provides a somewhat complicated definition of “group practice” for purposes of this exception that also contains very specific regulatory conditions.<sup>27</sup> The following is a general summary of those specific conditions:

- (a) The group practice must consist of a single legal entity operating as a physician group;
- (b) The group practice must have at least two physicians who are members of the group;
- (c) Each physician who is a member of the group must furnish substantially the full range of patient care services that the physician routinely furnishes through use of the group’s office space, facilities, equipment, and personnel;
- (d) Substantially all (at least 75%) of the patient care services of the physicians who are members of the group must be furnished through the group and billed under a billing number assigned to the group, and the amounts received must be treated as receipts of the group (with a specific exception for services provided in a designated Health Professional Shortage Area (HPSA));

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<sup>26</sup> *Id.*

<sup>27</sup> 42 C.F.R. § 411.352.

- (e) The overhead expenses of, and income from, the practice must be distributed according to methods that are determined before the receipt of payment for the services giving rise to the overhead expense or producing the income;
- (f) The group practice must be a unified business having centralized decision making by a body representative of the group practice that maintains effective control over the group's assets and liabilities, and having consolidated billing, accounting, and financial reporting (provided, however, that location and specialty-based compensation practices are permitted with respect to non-DHS revenues, and may be permitted with respect to revenues derived from DHS under the special rules for productivity bonuses and profit shares described in 42 C.F.R. § 411.352(i));
- (g) No physician who is a member of the group practice directly or indirectly receives compensation based on the volume or value of referrals by the physician, except as provided in the special rules for productivity bonuses and profit shares described in 42 C.F.R. § 411.352(i); and
- (h) Members of the group must personally conduct no less than 75% of the physician-patient encounters of the group practice.<sup>28</sup>

In a nutshell, the special rules for productivity bonuses and profit shares described in 42 C.F.R. § 411.352(g) provide that physicians may be paid either: (a) a productivity bonus based on services that they personally perform, including services that are “incident to” those services;<sup>29</sup> or (b) a share of the overall profits of the group; provided, however, that the productivity bonus or profit share is not determined in any manner that is directly related to the volume or value of referrals of DHS by the physicians.<sup>30</sup>

### 2.1.2.3 *Ownership of Publicly Traded Securities and Mutual Funds*

An important exception applies to the ownership of publicly traded securities that are either (i) listed for trading on the New York Stock Exchange, the American Stock Exchange, any regional exchange in which quotations are published on a daily basis, or foreign securities listed on a recognized foreign, national, or regional exchange in which quotations are published on a daily basis, or (ii) are traded under an automated interdealer quotation system operated by the National Association of Securities Dealers. Further, these investment securities must be in a corporation that had stockholder equity exceeding \$75 million at the end of the corporation's most recent fiscal year or on average during the previous three fiscal years.<sup>31</sup> A similar exception exists for ownership of shares in a regulated investment company as defined in § 851(a) of the

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<sup>28</sup> *Id.*

<sup>29</sup> 42 C.F.R. § 411.351.

<sup>30</sup> 42 C.F.R. § 411.352(i).

<sup>31</sup> 42 C.F.R. § 411.544(b).

Internal Revenue Code of 1986, if the company had, at the end of its most recent fiscal year, or on average during the previous three fiscal years, total assets exceeding \$75 million.<sup>32</sup>

#### 2.1.2.4 *Hospital Ownership*

There is an exception to the Stark law referral prohibition related to ownership of investment interests in hospitals located in Puerto Rico, and to hospitals located outside of Puerto Rico if the following conditions are met:

- (a) The referring physician is authorized to perform services at the hospital;
- (b) The ownership or investment interest is in the entire hospital and not merely in a distinct part or department of the hospital; and
- (c) Effective for the eighteen-month period beginning on December 8, 2003 (or such other period as Congress may specify), the hospital is not a specialty hospital.<sup>33</sup>

The exclusion of specialty hospitals from this exception was a result of the 2003 Medicare Prescription Drug, Improvement, and Modernization Act of 2003, which imposed a moratorium on physician investment in specialty hospitals.<sup>34</sup> Until this moratorium ends, physicians will be prohibited from making referrals for DHS to a specialty hospital in which they have an ownership or investment interest. Watch for legislation from Congress regarding the extension of this moratorium, with heavy lobbying from hospital associations in favor of the moratorium, and heavy lobbying from medical societies and specialty hospital associations against it.

#### 2.1.2.5 *Ownership of Rural Providers*

There is another exception to the Stark law referral prohibition related to ownership of investment interests in a rural provider (*i.e.*, a provider that furnishes at least 75% of its DHS to residents of a rural area).<sup>35</sup> Under this exception, a physician may make referrals for DHS to a rural provider in which the physician has an ownership or investment interest, provided that the DHS is actually furnished in a rural area.<sup>36</sup> For purposes of this exception, a “rural area” means any area that is not an “urban area”.<sup>37</sup> An urban area means “a Metropolitan Statistical Area (MSA) or New England County Metropolitan Area, as defined by the Executive Office of Management and Budget” or certain specified counties in New England.<sup>38</sup> During the period of the moratorium on physician investment in specialty hospitals described in the section above, this exception will not apply to any rural provider that is a specialty hospital.

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<sup>32</sup> 42 C.F.R. § 411.356(b).

<sup>33</sup> 42 C.F.R. § 411.356(c).

<sup>34</sup> Pub. L. No. 108-173, § 507, 117 Stat. 2066 (2003).

<sup>35</sup> 42 C.F.R. § 411.356(c).

<sup>36</sup> *Id.*

<sup>37</sup> *Id.*

<sup>38</sup> 42 C.F.R. § 412.62(f)(1)(ii).

2.1.2.6 *Rental of Office Space and Equipment*

There are separate Stark law exceptions for the rental or leasing of office space and equipment, but they have substantially similar requirements.<sup>39</sup> These requirements are as follows:

- There is a written rental or lease agreement, signed by the parties;
- The agreement describes the specific premises or equipment rented or leased;
- The term of the agreement is at least one year in duration, and if the agreement is terminated during the term (with or without cause), the parties are restricted from entering into a new agreement during the first year of the original term of the agreement;
- The space or equipment rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease or rental arrangement;
- The space or equipment is used exclusively by the lessee when being used by the lessee (and is not shared with or used by the lessor or any person or entity related to the lessor);
- With respect to the rental of office space, the tenant may make payments for common area maintenance fees or charges only if the payments do not exceed the tenant's pro rata share of expenses for the space based upon the ratio of the space used exclusively by the tenant to the total amount of space (other than common areas) occupied by all persons using the common areas;
- The rental charges over the term of the agreement are set in advance and are consistent with fair market value;
- The rental charges are not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties; and
- The agreement would be commercially reasonable even if no referrals were made between the parties.<sup>40</sup>

A holdover month-to-month rental immediately following the end of the term of an agreement that met all of the conditions described above will be deemed to continue to satisfy the requirements of this exception for a period of up to six months, provided the holdover rental is on the same terms and conditions as the agreement.<sup>41</sup>

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<sup>39</sup> 42 C.F.R. § 411.457(a) and (b).

<sup>40</sup> 42 C.F.R. § 411.457(a) and (b).

<sup>41</sup> *Id.*

2.1.2.7 *Personal Service Arrangements*

When a physician is hired to provide services to a third party as an independent contractor rather than as an employee, the exception for personal service arrangements may be applicable. This is often the case with respect to temporary or part-time medical directorships and consulting arrangements between physicians and hospitals for which direct employment may not be appropriate. In order for this exception to apply, all of the following conditions must be satisfied:

- The arrangement is set out in writing, signed by the parties, and describes the specific services covered by the arrangement;
- The arrangement covers all of the services to be furnished by the physician (or an immediate family member of the physician) to the entity, provided that this requirement will be met if all separate arrangements between the entity and the physician (or family members) incorporate each other by reference or cross-reference a master list of contracts;
- The aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement;
- The term of the arrangement is at least one year, and if it is terminated during the term (with or without cause), the parties are restricted from entering into the same or substantially the same arrangement during the first year of the original term of the arrangement;
- The compensation is set in advance in the agreement, it does not exceed fair market value, and it is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties (except in the limited case of a physician incentive plan, as provided in the final rules); and
- The services to be furnished under the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates any state or federal law.<sup>42</sup>

For purposes of this exception, a physician (or family member) can “furnish” services personally as well as through employees they hire for the purpose of performing the services, through a wholly owned entity, or through *locum tenens* physicians.<sup>43</sup>

2.1.2.8 *Physician Recruitment*

Phase II of the final Stark law rules clarified the exception for payments or benefits provided by a hospital to recruit a physician.<sup>44</sup> There are different regulatory requirements

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<sup>42</sup> 42 C.F.R. § 411.357(c).

<sup>43</sup> *Id.*

<sup>44</sup> 42 C.F.R. § 411.357(e).

depending on whether the payments or benefits are provided directly to the physician, or indirectly through payments made to another physician or physician practice. The specific requirements of this exception are discussed in Chapter 7, *Hospital Relations*.

2.1.2.9 *Isolated Financial Transactions*

An exception applies to an isolated financial transaction, such as a one-time sale of personal or real property, or the one-time sale of a physician practice, if all of the following conditions are met:

- The amount paid is consistent with the fair market value of the transaction, and is not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the physician or other business generated between the parties;
- The remuneration is provided under an agreement that would be commercially reasonable even if the physician made no referrals to the other party; and
- There are no other transactions between the parties for at least six months after the isolated transaction, except for transactions that meet the requirements of another specific Stark law exception, provided, however, that commercially reasonable post-closing adjustments are permitted if these adjustments do not take into account the volume or value of referrals or other business generated by the referring physician.<sup>45</sup>

For example, if a physician is selling the practice to a hospital, which in turn will employ the physician or contract with the physician for professional services immediately following the sale, the exception for isolated financial transactions can apply in conjunction with the bona fide employment relationships exception or the exception for personal service arrangements described above. If the hospital holds some of the purchase price in escrow and later uses a portion of these funds to cover shortfalls in the physician's accounts receivable or other potential liabilities of the physician under the purchase agreement, these subsequent transactions may be considered permissible "commercially reasonable post-closing adjustments" under this exception, provided they are not related to the volume or value of the physician's referrals or DHS to the hospital or other any business generated by the referring physician.<sup>46</sup>

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<sup>45</sup> 42 C.F.R. § 411.357(f).

<sup>46</sup> *Id.*

2.1.2.10 *Non-Monetary Compensation Under \$300*

There is an exception that applies to compensation from an entity in the form of items or services, not including cash or cash equivalents, that does not exceed a total of \$300 per year.<sup>47</sup> The \$300 limit will be adjusted each calendar year based on increases in the Consumer Price Index.<sup>48</sup> The exception applies if all of the following conditions are satisfied:

- The compensation is not determined in any manner that takes into account the volume or value of referrals or other business generated by the physician;
- The compensation may not be solicited by the physician or the physician's practice, including employees and staff members of the practice; and
- The compensation arrangement does not violate the Anti-Kickback Statute (discussed in Section 2.2, *infra*) or any federal or state law or regulation governing billing or claims submission.<sup>49</sup>

2.1.2.11 *Fair Market Value Compensation*

A very important regulatory exception has been created to apply to compensation from an entity to a physician (or an immediate family member of the physician) or to any group of physicians for the provision of items or services to the entity.<sup>50</sup> For this exception to apply, all of the following conditions must be met:

- The arrangement is set forth in a written agreement, signed by the parties, and covers only identifiable items or services, all of which are specified in the agreement;
- The agreement has a specific term, which can be for any period of time and contain a termination clause, provided the parties enter into only one arrangement for the same items or services during the course of a year, and further provided that an arrangement made for less than one year may be renewed any number of times only if the terms of the arrangement and the compensation for the same items or services do not change;
- The specific compensation is set in advance in the agreement, 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 by the physician(s);
- The arrangement is commercially reasonable and furthers the legitimate business purposes of the parties;

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<sup>47</sup> 42 C.F.R. § 411.357(k).

<sup>48</sup> *Id.*

<sup>49</sup> *Id.*

<sup>50</sup> 42 C.F.R. § 411.357(1).

- The arrangement does not violate the Anti-Kickback Statute (discussed in Section 2.2, *infra*), or any federal or state law or regulation governing billing or claims submission; and
- The services to be performed under the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates a state or federal law.<sup>51</sup>

2.1.2.12 *Medical Staff Incidental Benefits*

There is another exception that applies to incidental benefits provided by a hospital to members of its medical staff, if all of the following conditions are met:

- The items or services provided by the hospital are only used on the hospital's campus, except with respect to Internet access, pagers, and two-way radios which may be used away from the hospital campus to obtain hospital medical records or information or to contact patients or personnel on the hospital campus;
- The benefits are offered to all members of the medical staff practicing in the same specialty without regard to the volume or value of referrals or other business generated between the parties;
- The benefits are provided only when the medical staff members are making rounds or are engaged in other services or activities that benefit the hospital or its patients, except with respect to in-hospital advertising or identification of the medical staff members on a hospital website;
- The benefits are reasonably related to the provision of, or designed to facilitate directly or indirectly, the delivery of medical services at the hospital;
- The value of the benefits provided is less than \$25 with respect to each occurrence of the benefit (the limit will be adjusted each calendar year based on increases in the Consumer Price Index);
- The benefits are not determined in any manner that takes into account the volume or value of referrals or other business generated between the parties; and
- The compensation arrangement does not violate the Anti-Kickback Statute (discussed in Section 2.2, *infra*) or any federal or state law or regulation governing billing or claims submission.<sup>52</sup>

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<sup>51</sup> *Id.*

<sup>52</sup> 42 C.F.R. § 411.357(m).

2.1.2.13 *Indirect Compensation Arrangements*

As briefly discussed earlier in Section 2.1.1, *Key Stark Law Issues*, indirect compensation arrangements between physicians and DHS entities are not considered to be “financial relationships” that implicate the Stark law, provided all of the following conditions are satisfied:

- The compensation received by the physician (or immediate family member) is fair market value for services and items actually provided and is not 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;
- The compensation arrangement is set out in writing, signed by the parties, and specifies the services covered by the arrangement, except in the case of a bona fide employment relationship between an employer and an employee (in which case the arrangement need not be set out in a written agreement, but must be for identifiable services and be commercially reasonable even if no referrals are made to the employer); and
- The compensation arrangement does not violate the Anti-Kickback Statute (discussed in Section 2.2, *infra*) or any federal or state law or regulation governing billing or claims submission.<sup>53</sup>

2.1.2.14 *Professional Courtesy*

Professional courtesy offered by a DHS entity to a physician or to a physician’s immediate family member or office staff might also fall under a specific exception.<sup>54</sup> Professional courtesy means the provision of free or discounted healthcare items or services.<sup>55</sup> For this exception to apply, all of the following conditions must be satisfied:

- The professional courtesy is offered to all physicians on the entity’s medical staff or in the entity’s local community or service area without regard to the volume or value of referrals or other business generated between the parties;
- The healthcare items and services provided are of a type routinely provided by the entity;
- The professional courtesy policy of the DHS entity is set out in writing and approved in advance by the entity’s governing body;
- The professional courtesy is not offered to a physician or immediate family member of the physician who is a federal healthcare program beneficiary, unless there is a good faith showing of financial need;

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<sup>53</sup> 42 C.F.R. § 411.357(p).

<sup>54</sup> 42 C.F.R. § 411.357(s).

<sup>55</sup> 42 C.F.R. § 411.351.

- If the professional courtesy involves any whole or partial reduction of any coinsurance obligation, the insurer is informed in writing of the reduction; and
- The arrangement does not violate the Anti-Kickback Statute (discussed in Section 2.2, *infra*), or any federal or state law or regulation governing billing or claims submission.<sup>56</sup>

### 2.1.3 Compliance

Compliance with the Stark law may require arduous and painstaking analysis, even with respect to seemingly minor financial transactions or benefits involving physicians and providers of DHS. This is especially true in light of the complexity of the Stark law regulations, the strict liability nature of the law and the potentially crippling financial sanctions for violations. Attorneys who represent physicians should always consider the potential Stark law issues arising from any and all contracts, transactions or arrangements entered into or contemplated by their clients.

In light of the relatively recent issuance of the final rules, there is fairly limited guidance on the Stark law outside of the regulations themselves. Although the Centers for Medicare & Medicaid Services (CMS) is authorized to issue advisory opinions interpreting the Stark law on a case-by-case basis,<sup>57</sup> to date there have been only three such advisory opinions issued. The first two opinions were both issued in 1998: one regarding a proposed ambulatory surgical treatment center,<sup>58</sup> and the other concerning the in-office ancillary services exception and referrals for eyeglass prescriptions filled subsequent to cataract surgery with the insertion of an intraocular lens.<sup>59</sup> The third CMS Stark law Advisory Opinion, regarding specialty hospitals, was issued in 2004.<sup>60</sup> These advisory opinions, however, offer only limited guidance regarding the specific factual situations, and are only binding on CMS and the requesting party.<sup>61</sup> Further, significant case law interpretations of the Stark law requirements are essentially nonexistent at this point.

One of the best resources for Stark law compliance is the regulatory preambles and commentary to the Phase I and Phase II final rules. These preambles offer excellent insight into CMS's rationale for the various rules, and provide detailed explanations as to the intended scope of the various exceptions. Before advising clients on the technical requirements of specific Stark law exceptions, healthcare attorneys would be well advised to review the applicable commentary by CMS in the preambles regarding those specific rules.

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<sup>56</sup> 42 C.F.R. § 411.357(s).

<sup>57</sup> 42 U.S.C 1395nn(g)(6).

<sup>58</sup> Advisory Opinion No. CMS-AO-98-001.

<sup>59</sup> Advisory Opinion No. CMS-AO-98-002.

<sup>60</sup> Advisory Opinion No. AO-SH-2004-06-01, June 8, 2004.

<sup>61</sup> See 63 Fed. Reg. 1653 (1998).

## 2.2 Anti-Kickback Statute and Related Safe-Harbor Regulations

### 2.2.1 Introduction and Comparison to Stark Law

The Anti-Kickback Statute overlaps with the Stark law and actually precedes the Stark law in history.<sup>62</sup> Both laws regulate the financial relationships that exist between physicians and individuals or entities to which physicians make referrals or from which physicians receive referrals. There are a number of differences between the Anti-Kickback Statute and the Stark law.

- The Anti-Kickback Statute is both a civil and a criminal statute that offers enforcement authorities a choice of seeking civil or criminal enforcement remedies; the Stark law is a civil statute that imposes civil enforcement remedies.
- A violation of the Anti-Kickback Statute requires proof of unlawful intent. Although meeting all the requirements of a statutory exception or regulatory safe harbor exempts a physician's financial relationship with a third party from the reach of the Anti-Kickback Statute, failure to meet such requirements does *not* mean the Anti-Kickback Statute has been violated. By contrast, the Stark law is a strict liability statute – if there is a financial relationship between a physician and another person or entity, then referral of Medicare or Medicaid patients by that physician to the person or entity is prohibited unless the financial relationship meets all the criteria of a statutory or regulatory exception.
- The Anti-Kickback Statute more broadly reaches other governmental program patients such as TriCare, the Black Lung program, and the Indian Health Service, in addition to those covered by Medicare, Medicaid and other state healthcare programs; the Stark law applies directly only to Medicare patients and indirectly to Medicaid patients.
- The Anti-Kickback Statute more broadly applies to financial relationships with any person or entity that is a source of patient referrals to the other party to the financial relationship; the Stark law applies only to financial relationships involving physicians or members of their families.
- The antikickback statute extends to “recommending” as well as referring and no statutory or regulatory definition of the term referral is provided. By contrast, the Stark law specifically defines a referral as the physician's order or request for a service, product or item or the physician's establishment of a plan of care. Further, the Stark law contains certain exceptions for follow-up tests or procedures ordered by a pathologist, radiologist or radiation oncologist pursuant to a consultation requested by another physician.

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<sup>62</sup> The Anti-Kickback Statute was originally enacted in 1972 and subsequently amended several times, most recently in 1997. The Stark law was enacted in 1989 and subsequently amended several times, most recently in 2003.

### 2.2.2 Prohibited Conduct; Civil and Criminal Remedies

The Anti-Kickback Statute specifically prohibits anyone from knowingly and willfully offering or paying on the one hand or soliciting or receiving on the other hand any remuneration to induce or in return for: (1) referring an individual to a person for the furnishing or arranging for the furnishing of any item or service payable in whole or in part by a federal healthcare program, or (2) purchasing, leasing ordering or arranging for, or recommending purchasing, leasing or ordering any good, facility, service or item payable under a federal healthcare program. The statute broadly defines remuneration as the transfer of anything of value, in cash or in kind, directly or indirectly, overtly or covertly.<sup>63</sup>

Violation of the Anti-Kickback Statute is a felony that may be punished by a fine of up to \$25,000, a jail term of up to five years, or both. A conviction will also result in automatic exclusion from participation in federally funded healthcare programs. Further, the U.S. Department of Health and Human Services (DHHS) may seek exclusion from these programs through administrative action, regardless of whether criminal charges are brought. Violations of the Anti-Kickback Statute are also subject to civil monetary penalties of up to \$50,000 and damages of up to three times the amount of the illegal kickback.

### 2.2.3 Case Law Interpretation

The courts have broadly interpreted the Anti-Kickback Statute. Beginning with the Third Circuit opinion in *United States v. Greber*,<sup>64</sup> the courts have followed the so-called “one-purpose” test, holding that the Anti-Kickback Statute is violated where one purpose of a questioned payment is to induce referrals, even if there are other lawful purposes for the payment. In addition to the breadth of the one-purpose test, the First Circuit in *United States v. Bay State Ambulance & Hospital Rental Service*<sup>65</sup> illustrated the breadth of the concept of remuneration by holding that the mere opportunity to earn money may be considered remuneration to induce a person to channel referrals to the provider or arranger of the opportunity.

The Tenth Circuit added its own clarification to the one-purpose test when it approved the District Court’s instruction, which stated that the defendants could not be convicted “merely because they hoped or expected or believed that referrals may ensue from remuneration that was designed wholly for other purposes.”<sup>66</sup> The approved instruction further indicated that “[t]o offer or pay remuneration to induce referrals means to offer or pay remuneration with intent to gain influence over the reason or judgment of a person making referral decisions. The intent to gain such influence must, at least in part, have been the reason the remuneration was offered or paid.”<sup>67</sup> As a practical matter, no jury can be expected to distinguish between “hope” or “expectation” on the one hand and “design” or “reason” on the other. Thus, the Tenth Circuit’s approved instruction requires a conviction when the jury concludes that a design or reason for

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<sup>63</sup> 42 U.S.C. §§ 1320a-7(b) (1), (2).

<sup>64</sup> *United States v. Greber*, 760 F.2d 68 (3d Cir. 1985).

<sup>65</sup> *United States v. Bay State Ambulance & Hospital Rental Service*, 874 F.2d 20 (1st Cir. 1989).

<sup>66</sup> *United States v. McClatchey*, 277 F.3d 823 (10th Cir.), *cert denied*, 531 U.S. 1015, 121 S. Ct. 574 (2000).

<sup>67</sup> *Id.*

the remuneration was “in part” to induce referrals. In effect, this is another way of stating the one-purpose test with respect to the element of inducement in the Anti-Kickback Statute.

Case law has been less consistent in interpreting the *scienter*, or criminal intent, necessary to prove a violation of the Anti-Kickback Statute. For example, in the now famous *Hanlester Network v. Shalala* decision,<sup>68</sup> which examined a laboratory joint venture among physicians and a major laboratory company, the Ninth Circuit concluded that the defendants must have violated a known legal duty to have acted willfully. In *Hanlester*, lack of knowledge of the specific requirements of the Anti-Kickback Statute was a defense. Other courts have adopted less exacting definitions of *scienter*, preferring instead to define “willfully” to mean “unjustifiably and wrongfully, known to be such by the defendant.”<sup>69</sup> Such a standard does not require knowledge of the specific conduct prohibited by the Anti-Kickback Statute and invites a facts and circumstances analysis. On appeal, a good prosecutor can introduce sufficient facts and circumstances into evidence to support the willfulness or *scienter* element of most jury determinations of guilt.

#### 2.2.4 Statutory Exceptions and Regulatory Safe Harbors

The broad reach of the Anti-Kickback Statute as interpreted by the courts led healthcare providers to lobby Congress for exceptions to protect and distinguish legitimate business relationships from those that are illegal. The result is five statutory exceptions and delegated authority to the DHHS to create regulatory safe harbors.<sup>70</sup> Through its Office of Inspector General (OIG), the DHHS has created a number of regulatory safe harbors. Rather than listing all the statutory and regulatory exceptions, this chapter will summarize some common themes found among them and discuss those specific safe harbors that apply most often to physicians and the various financial relationships between them and third parties.

Perhaps the most pervasive theme of the safe harbor regulations and the OIG commentary that precedes them is the intent to protect arrangements in which fair market value consideration is paid for provision of commercially reasonable items or services. Many of the safe harbors require a signed written agreement for a minimum term of one year. Some of the safe harbors focus upon financial arrangements designed to facilitate delivery of medical care in medically underserved areas or to medically underserved populations. The specific criteria vary with the particular safe harbors that address these goals. A number of the safe harbors require that the *aggregate* compensation for the term of the arrangement be set in advance. This contrasts with similar exceptions in the Stark law merely requiring that the method of determining the compensation be set in advance and that it not vary with the volume or value of referrals.

Safe harbor protection is available only if an arrangement satisfies all the requirements of one of the safe harbors. If all safe harbor criteria are met by an arrangement, then the physician and other parties to it will be assured that they will not be prosecuted for the arrangement. By

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<sup>68</sup> *Hanlester Network v. Shalala*, 51 F.3d 1390 (9th Cir. 1995)

<sup>69</sup> *United States v. Jain*, 93 F. 3d 436 (8th Cir. 1996).

<sup>70</sup> 42 U.S.C. § 1320a-7b(b)(3).

contrast to the Stark law, failure to meet all of the criteria of any safe harbor does not mean that the arrangement is illegal.<sup>71</sup>

Even when an arrangement cannot meet all of the requirements of a potentially applicable safe harbor, it is advisable to try to meet as many of them as feasible under the circumstances and to take steps to advise all parties to the arrangement to enter into it only for legitimate purposes and not to have as even one purpose the prohibited intent to induce referrals. The OIG has provided and continues to provide guidance to healthcare providers through commentary to the safe harbor regulations, advisory opinions, Special Fraud Alerts, and other means.<sup>72</sup> This guidance should be carefully considered when advising physicians regarding arrangements that do not meet all of the criteria of the potentially applicable safe harbor(s). Before discussing these sources of guidance, the safe harbors most frequently applicable to physician financial relationships are discussed in this section.

### 2.2.4.1 *The Employment Exception and Safe Harbor*

The Anti-Kickback Statute provides a specific exception to its application for “any amount paid by an employer to an employee (who has a bona fide employment relationship with such employer) for employment in the provision of covered items and services.”<sup>73</sup> The OIG also promulgated a safe harbor regulation which 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, for employment in the furnishing of any item or service for which payment may be made in whole or in part under Medicare or a state healthcare program.”<sup>74</sup> The regulation then defers to the Internal Revenue Code (IRC) for the meaning of the term “employee.”<sup>75</sup>

The statutory exception and the safe harbor regulation are similar but not identical and each forms an independent basis for protection from the reach of the Anti-Kickback Statute. In advising physicians regarding planning employment relationships, it is better to rely upon the narrower and specifically drawn safe harbor because meeting the safe harbor requirements will prevent any disagreements with enforcement agencies over whether the employment relationship is bona fide or the payments made are for the provision of covered items and services.

The employment exception and safe harbor are the broadest exceptions with the fewest requirements and are, therefore, the easiest and most certain exceptions for planning financial relationships that do not violate the Anti-Kickback Statute. The regulations and case law under the IRC definition of an employee are well developed and provide substantial, easy to follow guidance for establishing a bona fide employment relationship. Generally, these factors focus upon the employer’s authority with respect to every aspect of the physician’s services (except the

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<sup>71</sup> See Office of Inspector General, commentary to 1991 and 1999 safe harbor regulations, at 56 Fed. Reg. 35,955 (July 29, 1991); 64 Fed. Reg. 63,520, 63,521, 63,545 (Nov. 19, 1999).

<sup>72</sup> OIG Advisory Opinions, many of which relate to the Anti-Kickback Statute, are *available online at* [www.hhs.gov/progorg/oig/advopn/](http://www.hhs.gov/progorg/oig/advopn/). New OIG Advisory Opinions and Fraud Alerts are *available online at* [www.hhs.gov/progorg/oig/frdalrt/index.htm](http://www.hhs.gov/progorg/oig/frdalrt/index.htm).

<sup>73</sup> 42 U.S.C. § 1320a-7b(b)(3)(B).

<sup>74</sup> 42 C.F.R. § 1001.952(i).

<sup>75</sup> See 26 U.S.C. § 3121(d)(2) and the regulations in that statute.

exercise of medical judgment), responsibility of the employer for the place of work and the tools and supplies used to perform the physician's duties, and participation by the physician in the full range of employee benefits offered by the employer to its employees generally. If the duties in the employment relationship involve the furnishing of items or services payable under Medicare or a state healthcare program, then the parties to it have met all of the safe harbor requirements and the employment relationship will not violate the Anti-Kickback Statute.

Because of the certainty of compliance that can be achieved through an employment relationship, the employment exception and safe harbor are relied upon by medical practices to dovetail with the in-office ancillary services exception to the Stark law for protection of payments made by the practice to physicians who work in the practice. It is also relied upon by hospitals and other providers who hire physicians to practice medicine in clinical settings owned or operated by those providers. The ease of compliance with the employment exception and safe harbor makes it the first choice when considering potential financial relationships involving physicians. However, the employment exception and safe harbor do not fit a number of financial arrangements between physicians and third parties. In those circumstances, one or more of the following safe harbors may apply.

#### 2.2.4.2 *Personal Services and Management Contracts Safe Harbor*

When a physician is retained to provide services to a third party, for example, a medical director contract for supervision of a facility's clinical aspects or hospital department's services, and the nature of the relationship precludes employment, then the personal services safe harbor offers protection from violating the Anti-Kickback Statute. This safe harbor provides that remuneration does not include payments by a principal to an agent for the agent's services if the following seven requirements are met:

- The agreement is in writing and signed by the parties;
- The agreement specifies the services to be provided, which are all the services to be provided during the agreement's term;
- If services are periodic, sporadic or part-time, the agreement specifies the schedule of service intervals, their precise length and the exact charge per interval;
- The agreement is for a term of at least one year;
- The aggregate compensation paid to the agent is set in advance, consistent with fair market value in arm's length transactions and not determined in a manner that takes into account the volume or value of referrals between the parties of business payable under Medicare or a state healthcare program;
- The services do not involve the counseling or promotion of a business arrangement or other activity that violates any state or federal law; and

- The aggregate services do not exceed those reasonably necessary to accomplish the commercially reasonable business purpose of the service.<sup>76</sup>

This safe harbor is narrower than the similar Stark law exception primarily because it requires that the *aggregate* compensation for the entire term of the relationship be set in advance. Many service arrangements cannot meet this requirement because the amount of time involved in performing the service varies from week to week, month to month, year to year. To fix an aggregate fee for a contract term when the amount of service rendered varies invites a dispute with enforcement agencies over whether the fee represents fair market value for the service. Therefore, prudent planning for personal services agreements requires strict compliance with the Stark law exception, meeting as many of the seven requirements of the Anti-Kickback Statute safe harbor as possible and establishing proper intent of the parties for entry into the arrangement. In addition to contract clauses that disavow any improper intent and documenting the need for the services to be provided by the physician, clients should be advised that they must not intend that the payments or even the opportunity to provide the service be a reward for past or expected referrals of federal or state healthcare program patients between the parties.

#### 2.2.4.3 *Space and Equipment Rental Safe Harbors*

There are separate safe harbors for leasing space and equipment, but they have similar requirements. These are as follows:

- (1) The lease is in writing and signed by the parties;
- (2) It describes the specific equipment or premises, which is all of the equipment or premises leased between the parties;
- (3) If the lease provides access for periodic intervals rather than full time, the schedule of intervals, their precise length and the exact rent per interval are specified in the lease;
- (4) There must be a minimum lease term of one year;
- (5) Aggregate rental charged for the lease term is set in advance, consistent with fair market value and does not take into account the volume or value of referrals between the parties of business payable under Medicare or a state healthcare program; and
- (6) The aggregate space rented or equipment rental does not exceed that which is reasonably necessary to accomplish the commercially reasonable business purpose of the rental.<sup>77</sup>

Each of these safe harbors specifically defines fair market value for purposes of that safe harbor. For space, fair market value means the value of the rental property for general commercial purposes, but not adjusted to reflect the value that either party would attribute to the

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<sup>76</sup> 42 C.F.R. § 1001.952(d).

<sup>77</sup> 42 C.F.R. §§ 1001.952(b), (c).

space because of its proximity or convenience to sources of referrals of business payable under Medicare or a state healthcare program.<sup>78</sup> Similarly, for equipment, fair market value means the value of the equipment when obtained from a manufacturer or professional distributor without adjustment for the additional value either party would attribute to it as a result of its proximity or convenience to sources of referrals of business payable under Medicare or a state healthcare program.<sup>79</sup>

Once again the requirement that the aggregate rental for the lease term be set in advance may be a difficult requirement to meet. However, if the amount of space or equipment leased for the lease term remains constant and the lease is for full-time use, the potential for compliance with the aggregate requirement in this context is much better than it is for personal service contracts. The fair market value definitions require the parties to ignore considerations that a lessor and lessee in a commercial transaction would ordinarily consider relevant (*i.e.*, proximity to sources of business). The best protection is to obtain independent evidence of a range of market values and establish a rental rate that fits within the range of market values shown by the independent evidence.

#### 2.2.4.4 *Investments in Group Practices*

This safe harbor protects payments that are a return on an investment interest, such as a dividend or interest income, made to solo or group practitioners investing in their own practice or group practice if the following four standards are met:

- The equity interests in the practice or group must be held by licensed healthcare professionals who practice in the practice or group;
- The equity interests must be in the practice or group itself and not in a subdivision of it;
- Group practices must (a) meet the Stark law definition of a group practice and (b) be a unified business with centralized decision-making, pooling of expenses and revenues, and a compensation/profit system that is not based on satellite offices operating substantially as if they were separate enterprises or profit centers; and
- Revenues from ancillary services must meet the Stark law definition of in-office ancillary services.<sup>80</sup>

This safe harbor exception is not often relied upon because most remuneration paid out of a physician practice is paid as compensation to employees or, in some cases, fees for independent contractor services. On some occasions, however, it may be necessary or desirable for one or more physicians to loan funds to their practice and receive interest income for making such loans. This safe harbor provides the strict guidelines that must be met to exempt such payments from the Anti-Kickback Statute. Two of the four requirements are dependent on

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<sup>78</sup> 42 C.F.R. § 1001.952(b).

<sup>79</sup> 42 C.F.R. § 1001.952(c).

<sup>80</sup> 42 C.F.R. § 1001.952(p).

satisfying the Stark law requirements for in-office ancillary services in solo and/or group practices. The other requirements are designed to limit the protection to practices and groups owned solely by the licensed professionals who work for it (no outside influence owners such as hospitals) and to deny protection for organizations that are group practices in name only but function substantively as a collection of independent physician practices.

### 2.2.4.5 *Safe Harbors for Sale of Practice*

There are two safe harbors for sale of a physician's practice, one for sale to other practitioners and one for sale to hospitals or other entities in health professional shortage areas.<sup>81</sup>

The first safe harbor protects any payment made by purchasing practitioners to a selling practitioner for their practice if:

- The time between signing of the initial agreement and completion of the sale is not more than one year, and
- The selling practitioner will not be in a professional position to refer to or generate business payable by Medicare or a state healthcare program for the purchaser after one year from the date the initial sale agreement is signed.<sup>82</sup>

This safe harbor is commonly relied on in the sale of practices owned by solo practitioners to younger physicians who initially work in the seller's practice. It is a flexible safe harbor, which, unlike many safe harbors, does not require that the payment be fair market value. Its primary focus is on limiting the time period during which selling physicians may actively transition their patients to the purchasing physician.

The second sale of practice safe harbor introduces the concept of medically underserved areas or populations as a reason for extending safe harbor protection. This one protects any payment made to a practitioner by a hospital or other entity for purchase of the practitioner's practice if: (1) the time from the initial agreement to completion of the sale is not more than three years; (2) the seller is not in a position after completion of the sale to make or influence referrals to the purchaser of business payable by Medicare or a state healthcare program; (3) the purchased practice is located in a HPSA as defined by regulations; and (4) beginning with signing of the initial sale agreement, the purchaser must diligently and in good faith engage in commercially reasonable recruitment activities that: (a) may reasonably be expected to result in recruitment of a new practitioner to take over the acquired practice within a one-year period and (b) will meet the requirements of the practitioner recruitment safe harbor.<sup>83</sup>

Generally, HPSAs may be found by contacting the appropriate state agency that administers healthcare entity licensing and state health law regulation, such as the department of health. There are also excellent online databases that can be used to find HPSAs.<sup>84</sup> Most HPSAs

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<sup>81</sup> 42 C.F.R. §§ 1001.952(e)(1), (2).

<sup>82</sup> 42 C.F.R. § 1001.952(e)(1).

<sup>83</sup> 42 C.F.R. § 1001.952(e)(2).

<sup>84</sup> One example is the HPSA Query Selection, *available online at* [belize.hrsa.gov/newhpsa/newhpsa.cfm](http://belize.hrsa.gov/newhpsa/newhpsa.cfm).

are located in rural areas or urban core areas. This safe harbor offers an opportunity for physicians practicing in HPSAs and approaching retirement age to sell their practice to a hospital or other entity that realizes the need to maintain the physician services in the community and will to recruit another physician to take over the practice. Because the OIG believes that sale of medical practices to hospitals and other entities to which they refer patients is subject to the potential for abuse, it was only willing to provide a safe harbor in these limited circumstances where a shortage is clear and without sale of the practice, a further reduction in available physician services would likely occur.

#### 2.2.4.6 *Other Safe Harbors to Address Medically Underserved Needs*

The OIG has established safe harbors for (a) practitioner recruitment to underserved areas,<sup>85</sup> (b) investments in entities in underserved areas,<sup>86</sup> and (c) obstetrical malpractice insurance subsidies in underserved areas.<sup>87</sup>

The first of these is usable with the sale of practice safe harbor for underserved areas to facilitate hospital participation in and financial support for transitioning the practice of a retiring physician to a newly recruited physician. It is also used on its own to protect payments for recruiting a physician to a new practice within a HPSA. This safe harbor includes nine requirements designed principally to ensure that recruitment is to a practice that truly serves patients who reside in a HPSA or who are within a medically underserved area (MUA) or are part of a medically underserved population (MUP). The arrangement must not compromise the freedom of physicians to choose among available hospitals and entities for referral of their patients.<sup>88</sup> Because this safe harbor applies only to payments for relocation of physicians into a HPSA for their specialty, this safe harbor does not fit most of the available recruitment opportunities. Whenever dealing with recruitment to rural areas or the urban core, however, this safe harbor should be considered.

The second of these safe harbors applies to investments in entities located in rural areas, which is discussed in Chapter 9, *Physician Joint Ventures*. The safe harbor for obstetrical malpractice insurance subsidies protects hospital subsidies of all, or a portion of, malpractice insurance premiums for practitioners in primary care HPSAs if seven standards are met that ensure: at least 75% of the practitioner's patients reside in a HPSA or MUA or are part of a MUP; the practitioner provides care to patients covered by Medicare and state healthcare programs; the premiums are based on a bona fide risk assessment; and the physician's judgment regarding referral of patients is not compromised.<sup>89</sup> Although of limited application, when an obstetrician/gynecologist practices in the urban core or a rural area and faces prohibitive increases in malpractice insurance costs, it is possible this safe harbor may be available to shelter a hospital subsidy of malpractice premium costs so the physician will not have to relocate his or her practice.

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<sup>85</sup> 42 C.F.R. § 1001.952(n).

<sup>86</sup> 42 C.F.R. § 1001.952(a)(3).

<sup>87</sup> 42 C.F.R. § 1001.952(o).

<sup>88</sup> 42 C.F.R. § 1001.952(n).

<sup>89</sup> 42 C.F.R. § 1001.952(o).

2.2.4.7 *Other Safe Harbors of Interest to Counsel for Physicians*

Other Anti-Kickback Statute safe harbors of interest to counsel for physicians include those for investments in large or small entities<sup>90</sup> and ambulatory surgical centers<sup>91</sup> (both discussed in Chapter 9, *Physician Joint Ventures*), one for participation in referral services (e.g., Ask-a-Nurse),<sup>92</sup> one for price reductions offered to health plans,<sup>93</sup> one for referral agreements for specialty services,<sup>94</sup> and a couple that deal with specialized arrangements with managed care organizations.<sup>95</sup> (The managed care arrangements safe harbors are beyond the scope of this chapter.)

The referral services safe harbor protects any exchange of value between a participant in a referral service and the referral service if:

- (1) The referral service includes all who meet its qualifications for participation;
- (2) Any payment by participants to the referral service is assessed and collected equally from all participants, is based on operation costs and is not tied to volume or value of referrals or business between the parties for which Medicare or a state healthcare program may be responsible;
- (3) The referral service imposes no requirements on the manner in which participants provide services to a referred person (except that the referral service may require nondiscriminatory pricing or free or reduced charge services); and
- (4) The referral service makes five required disclosures to each person seeking a referral.<sup>96</sup>

The referral agreements for specialty services safe harbor protects any exchange of value between parties where one agrees to refer a patient to the other for a specialty service payable under Medicare or a state healthcare program in return for agreement of the other party to refer the patient back at a mutually agreed upon time or circumstance if four standards are met. These standards are the following:

- (1) The mutually agreed upon time or circumstance must be clinically appropriate;
- (2) The service is not within the expertise of the referring party but is within the expertise of the receiving party;

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<sup>90</sup> 42 C.F.R. § 1001.952(a)(1), (a)(2).

<sup>91</sup> 42 C.F.R. § 1001.952(r).

<sup>92</sup> 42 C.F.R. § 1001.952(f).

<sup>93</sup> 42 C.F.R. § 1001.952(m).

<sup>94</sup> 42 C.F.R. § 1001.952(s).

<sup>95</sup> 42 C.F.R. §§ 1001.952(t), (u).

<sup>96</sup> 42 C.F.R. § 1001.952(f).

- (3) The parties receive no payment from each other for the referral and do not share or split a global fee from any federal healthcare program in connection with the referred patient; and
- (4) Unless both parties are part of the same group practice, the only exchange of value is the remuneration each party receives directly from third-party payers or the patient.<sup>97</sup>

In the author's experience, this safe harbor rarely is used in a planning context because physicians usually seek legitimate ways to receive payments or remuneration from other physicians, hospitals and facilities to which they refer rather than just ways to ensure return of patients referred.

However, one example where this arrangement often is used is when an optometrist has an agreement with an ophthalmologist to refer the optometrist's patients to the ophthalmologist for lasik or surgical procedures. In exchange, the ophthalmologist's agrees to refer such patients back to the optometrist for follow-up care when the surgical procedure has been completed.

### 2.2.5 OIG Advisory Opinions

From time to time, OIG advisory opinions are published regarding specific written requests from the public, usually counsel for one or more providers to an arrangement that does not fit into any safe harbor. The OIG's regulations, which implement congressional directives that OIG offer such guidance, indicate that advisory opinions may address: (1) what constitutes prohibited remuneration; (2) whether an arrangement fits an exception or safe harbor; (3) what constitutes inducement to reduce or limit services; and (4) whether the activity would constitute grounds for the imposition of sanctions.<sup>98</sup> The OIG will not address in an advisory opinion what constitutes fair market value or whether a person is a bona fide employee.<sup>99</sup> Any request for an OIG advisory opinion must certify that the requestor intends, in good faith, to undertake the arrangement or that it will undertake the arrangement if a favorable advisory opinion is issued.<sup>100</sup> Advisory opinions are only legally binding upon the OIG for the parties that requested the opinion. Nevertheless, the reasoning behind each opinion provides insight into the OIG's likely approach to similar arrangements. Therefore, in considering any financial arrangement involving a physician to whom the Anti-Kickback Statute may apply, if a safe harbor does not apply or cannot be fully met, then OIG advisory opinions should be reviewed to see if one addressing a similar situation exists. If so, it will provide useful guidance to lawyers when advising their physician client.

The advantage of seeking and obtaining an OIG advisory opinion for an arrangement is the certainty of compliance for the parties who request the opinion. Disadvantages include the cost and delay associated with obtaining the OIG advisory opinion and the possibility of getting a negative opinion that the requestor must accept. Besides paying counsel to prepare, submit and

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<sup>97</sup> 42 C.F.R. § 1001.952(s).

<sup>98</sup> 42 C.F.R. § 1008.5(a).

<sup>99</sup> 42 C.F.R. § 1008.5(b).

<sup>100</sup> 42 C.F.R. § 1008.38(b).

discuss with OIG staff the opinion request, the regulations establish fees and expenses, including counsel fees, payable to the OIG by the requesting parties for the OIG's service in evaluating submitted requests.<sup>101</sup> Further, the minimum time to respond after OIG determines that it has received all relevant information is sixty days.<sup>102</sup>

One way the OIG can extend this time is to ask for additional information. Because of these cost and time factors, physicians and medical groups rarely feel that the advisory opinion process is cost-effective for them. Consequently, most opinions requested and issued so far do not deal with arrangements involving physicians. Some OIG advisory opinions, however, have been issued that deal with (1) physician percentage compensation arrangements;<sup>103</sup> (2) joint ventures involving physicians;<sup>104</sup> (3) malpractice insurance subsidies for physicians;<sup>105</sup> (4) physician recruitment arrangements;<sup>106</sup> and (5) leases, agreements, or other arrangements involving physicians.<sup>107</sup>

### 2.2.6 Other Guidance

OIG sometimes alerts the healthcare industry of arrangements that it believes are suspect and could potentially violate the Anti-Kickback Statute by issuing a Special Fraud Alert. Special Fraud Alerts usually describe specific features of arrangements that the OIG considers "suspect" or "questionable." These alerts are not law, but they do provide insight into arrangements that are more likely to receive careful government scrutiny and thus bear a high risk of investigation and potential criminal charges or civil proceedings. Special Fraud Alerts of particular interest to counsel for physicians include those dealing with:

- (1) Rental of space in physician offices by persons or entities to which physicians refer;<sup>108</sup>
- (2) Physician liability for certifications in the provision of medical equipment and supplies and home health services;<sup>109</sup>
- (3) Joint venture arrangements;<sup>110</sup>
- (4) Routine waiver of Medicare Part B co-payments and deductibles;<sup>111</sup>

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<sup>101</sup> 42 C.F.R. § 1008.31.

<sup>102</sup> 42 C.F.R. § 1008.43.

<sup>103</sup> See, e.g., Office of Inspector Gen., U.S. Dep't of Health & Human Servs., Adv. Op. Nos. 98-4, 01-1.

<sup>104</sup> See, e.g., Office of Inspector Gen., U.S. Dep't of Health & Human Servs., Adv. Op. Nos. 97-5, 98-12, 98-19, 01-17, 01-21, 02-9, 03-2, 03-5, 03-12, 03-13, 04-08 and 04-17.

<sup>105</sup> See, e.g., Office of Inspector Gen., U.S. Dep't of Health & Human Servs., Adv. Op. Nos. 04-11 and 04-19.

<sup>106</sup> See, e.g., Office of Inspector Gen., U.S. Dep't of Health & Human Servs., Adv. Op. No. 01-4.

<sup>107</sup> See, e.g., Office of Inspector Gen., U.S. Dep't of Health & Human Servs., Adv. Op. Nos. 98-18, 99-13, 02-5, 03-15 and 04-9. Advisory opinions are *available online at* [www.oig.hhs.gov](http://www.oig.hhs.gov).

<sup>108</sup> See 65 Fed. Reg. 9274 (Feb. 24, 2000).

<sup>109</sup> See 64 Fed. Reg. 1813 (Jan. 12, 1999).

<sup>110</sup> See 59 Fed. Reg. 65, 372 (Dec. 19, 1994).

- (5) Hospital incentives to referring physicians;<sup>112</sup>
- (6) Prescription drug marketing practices;<sup>113</sup> and
- (7) Arrangements for the provision of clinical laboratory services.<sup>114</sup>

Other guidance available from the OIG to counsel for physicians includes Special Advisory Bulletins, Medicare Advisory Bulletins, Medicare Fraud Alerts, informal advisory letters, and management advisories. Another advisory guide that deserves special mention in this chapter is an OIG Management Advisory Report on Financial Arrangements between Hospitals and Hospital-Based Physicians, which identified a number of practices it considered potential remuneration from the hospital-based physicians to the hospital for its referrals to the groups.<sup>115</sup> Examples included requiring hospital-based groups such as radiologists, anesthesiologists, pathologists, or radiation oncologists to make donations to the hospital's foundation or to purchase and lease to the applicable hospital department, free of charge, diagnostic or therapeutic equipment. This advisory has generated little follow-up enforcement activity but has not been retracted and has provided fuel for professional associations and lawyers who represent hospital-based physicians to resist the items cited in the advisory in their dealings with hospitals. Therefore, it is a document well worth review by counsel for hospital-based physicians.

## 2.3 Civil Monetary Penalties

### 2.3.1 OIG Authority and Range of Penalties

Congress authorized the OIG to impose civil monetary penalties (CMPs) on any person, organization or entity (except a beneficiary of the applicable federal or state program) who knowingly presents or causes to be presented to a state or federal government employee or agent, certain defined false or improper claims.<sup>116</sup> The range of CMPs that the OIG may impose begins at \$10,000 per item or service in most cases, and in some cases up to \$50,000 per act. There is also authority to recover treble damages.<sup>117</sup> Refer to the subsections of 42 U.S.C. §1320a-7a(a) and its implementing regulations to determine the particular penalty applicable to a particular item of prohibited conduct.

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<sup>111</sup> *Id.*

<sup>112</sup> *Id.*

<sup>113</sup> *Id.*

<sup>114</sup> *Id.*

<sup>115</sup> OIG, MANAGEMENT ADVISORY REPORT ON FINANCIAL ARRANGEMENTS BETWEEN HOSPITALS AND HOSPITAL-BASED PHYSICIANS, OE1-09-00330 (Jan. 1991).

<sup>116</sup> 42 U.S.C. § 1320a-7a(a).

<sup>117</sup> *Id.*

2.3.2 Conduct Applicable to CMPs

2.3.2.1 *Claims-Related Conduct*

The CMP statute prohibits knowingly filing claims for:

- (1) Services that were not provided as claimed (*e.g.*, upcoding);
- (2) Medical or other items or services for which the claim is false or fraudulent (*e.g.*, services not actually rendered);
- (3) Services of a physician or services provided incident to a physician's service if the physician
  - (a) Was not licensed as a physician,
  - (b) Obtained his or her license through misrepresentation, or
  - (c) Falsely represented to the patient at the time the service was provided that he or she was certified by a medical specialty board;
- (4) Medical or other items or services furnished during a time in which the provider was excluded from participation in the program under which the claim is made; or
- (5) A pattern of providing medical or other items or services that the provider knows or should know are not medically necessary.<sup>118</sup>

Intent is an important element of an activity for which a CMP may be imposed. The statute creates liability where actions are taken “knowingly” and in some cases where the individual “should know” of the falsity of the claim. Should know means that the individual acts with deliberate ignorance or reckless disregard of the truth or falsity of the information. A specific intent to defraud need not be proved.<sup>119</sup> Further, principals may incur CMP liability because of the actions of their agents.<sup>120</sup> The economic pressure upon physician practices from limits on reimbursements and rising costs, combined with sometimes aggressive advice from consultants regarding coding and billing practices, can tempt physicians to upcode or to bill for services where medical necessity is questionable. The authority of the OIG to impose CMPs for these activities should serve as a strong deterrent to physicians and other healthcare providers who are tempted.

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<sup>118</sup> 42 U.S.C. § 1320a-7a(a)(1).

<sup>119</sup> 42 U.S.C. § 1320a-7a(i)(7).

<sup>120</sup> 42 U.S.C. § 1320a-7a(l).

2.3.2.2 *Other Statutory CMPs*

The OIG also has grounds to impose CMPs to curb the following behaviors, among others:

- (1) Knowingly presenting or causing to be presented claims that violate certain Medicare assignment agreements or participating provider agreements;<sup>121</sup>
- (2) Knowingly giving, or causing to be given, false or misleading information about Medicare coverage of inpatient hospital services that could reasonably be expected to influence a decision on when to discharge a patient;<sup>122</sup>
- (3) Offering to transfer or transferring remuneration to beneficiaries to influence them to choose a particular provider or supplier, items or services that are reimbursable, at least in part, under Medicare or Medicaid;<sup>123</sup>
- (4) Direct or indirect payment as an inducement by hospitals to physicians to limit or reduce services to Medicare or Medicaid beneficiaries who are under the direct care of the physicians;<sup>124</sup>
- (5) False certifications by physicians of a patient's eligibility for home health services;<sup>125</sup>
- (6) Anti-kickback statute violations;<sup>126</sup> and
- (7) Stark law violations.<sup>127</sup>

Two of these activities have received significant attention from and guidance by the OIG. These are beneficiary inducements to choose a particular provider, item or service and hospital inducements to physicians to limit care.

Items of nominal value are not prohibited by this CMP because their nominal value makes it unlikely they will influence a beneficiary's choice of provider. The OIG interprets nominal to mean no more than \$10 per item or \$50 in the aggregate per year.<sup>128</sup> Further, if an incentive is not advertised or disclosed to a beneficiary until after the selection of provider has been made, then it falls outside the reach of this CMP because the beneficiary's choice of provider is not being influenced.

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<sup>121</sup> 42 U.S.C. § 1320a-7a(a)(2).

<sup>122</sup> 42 U.S.C. § 1320a-7a(a)(3).

<sup>123</sup> 42 U.S.C. § 1320a-7a(a)(5).

<sup>124</sup> 42 U.S.C. § 1320a-7a(b)(1).

<sup>125</sup> 42 U.S.C. §1320a-7a(b)(3).

<sup>126</sup> 42 U.S.C. §1320a-7a(a)(7).

<sup>127</sup> 42 U.S.C. §1320a-7a(a)(5).

<sup>128</sup> 65 Fed. Reg. 24,411 (Apr. 26, 2000).

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Remuneration to a beneficiary of the Medicare or Medicaid programs includes free or below market value items or services and waiver of coinsurance and deductible amounts except in limited, specifically defined situations. A copayment or deductible waiver is not remuneration if:

- (a) It is not offered as part of any advertisement or solicitation;
- (b) The person does not routinely waive coinsurance and deductible amounts; and
- (c) The waiver is based upon either
  - (i) A good-faith determination that the beneficiary is in financial need or
  - (ii) Failure of reasonable collection efforts.<sup>129</sup>

This CMP, therefore, should cause physicians and medical groups to adopt specific policies regarding incentives to patients and circumstances under which coinsurance and deductibles may be waived. Otherwise, the physician or group risks incurring significant CMP cost.

Other statutory exceptions to the definition of remuneration describe limited circumstances where an incentive to a beneficiary may be appropriate<sup>130</sup> (e.g., incentives to promote the delivery of preventive care under certain circumstances). The statute and regulations should be consulted for the specific parameters of these further exceptions.

Hospitals experience similar downward pressure on the growth of their revenues as costs continue to rise. Most decisions regarding use of hospitals are made by physicians who have no economic stake in those decisions (unless the hospital is physician owned). Consequently, in the 1990's, hospital consultants and executives began to design gainsharing programs to provide incentives to physicians to make less expensive or costly choices regarding use of hospital resources.

In 1999, the OIG issued a Special Advisory Bulletin that concluded that gainsharing arrangements violated the CMP prohibition on payments to physicians as inducements to reduce or limit services to Medicare or Medicaid beneficiaries under physicians' care. This Special Advisory Bulletin put a stop to what hospitals and physicians had hoped would be an effective approach to controlling hospital costs by providing physicians with an economic stake in the outcome. Absent a Congressional action to change the CMP law, it is unlikely that arrangements of this type will be developed or offered in the future.

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<sup>129</sup> 42 U.S.C. § 1320a-7a(i)(6)(A).

<sup>130</sup> 42 U.S.C. § 1320a-7a(i)(6)(B)-(D).

2.3.2.3 *Other Conduct Punishable by CMPs*

By regulation, the OIG has extended its CMP authority to other conduct such as:

- (a) Certain reporting failures about malpractice judgment or settlement payments and adverse actions required to be reported to the Healthcare Integrity and Protection Data Bank;<sup>131</sup>
- (b) Improper use of, or reporting to, the National Practitioner Data Bank;<sup>132</sup>
- (c) Improper association of advertisements or solicitations with symbols of DHHS or CMS used that could indicate their approval;<sup>133</sup> and
- (d) Certain Emergency Medical Treatment and Active Labor Act violations.<sup>134</sup>

2.3.3 *CMP Guidance*

Besides the statute and regulations, the OIG will use the advisory opinion process to respond to questions regarding arrangements that may constitute grounds for CMP sanctions.<sup>135</sup> A number of questions have addressed the CMP prohibiting the transfer of remuneration to beneficiaries as an inducement to them to choose a particular provider.<sup>136</sup> Also, as illustrated above with gainsharing, the OIG is more than willing to issue Special Advisories and similar bulletins to advise healthcare providers of conduct it considers likely to violate a CMP provision. Again, the OIG website is the best source of information for all guidance regarding CMPs.

2.3.4 *Exclusion Authority*

Counsel for physicians must also be aware that Congress has authorized the OIG to exclude physicians and other healthcare providers from participation in Medicare and other federal healthcare programs for lengthy periods of time. For some offenses, this exclusion authority is mandatory<sup>137</sup> and for others it is permissive.<sup>138</sup> Because Medicare, Medicaid and other government programs pay for much of healthcare, this exclusionary authority, if exercised, is considered to be an economic death sentence for most physicians. Therefore, these exclusion authorities provide the OIG with powerful leverage in settlement negotiations with providers as an investigation nears conclusion and potential sanctions are discussed. Often, counsel for physicians and other providers are forced by the exclusion authority of the OIG to recommend settlement even where there may be significant weaknesses in the OIG's case. For a complete

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<sup>131</sup> 42 C.F.R. § 1003.102(b)(5).

<sup>132</sup> 42 C.F.R. § 1003.102(b)(6).

<sup>133</sup> 42 C.F.R. § 1003.102(b)(7).

<sup>134</sup> The preceding list is illustrative and not exhaustive. For a complete description of all OIG's CMP authority, *see* 42 C.F.R. §§ 1003.102(b)(1) through (14).

<sup>135</sup> *See* 42 C.F.R. § 1008.5(a).

<sup>136</sup> *See, e.g.*, Office of Inspector Gen., U.S. Dep't of Health & Human Servs., Adv. Op. Nos. 97-4, 98-9, 99-9, 99-11, 00-3, 00-5, 00-7, 00-10, 01-7, 01-14, 02-1, 02-6, 02-7, 02-14, 02-16, 03-4, 04-1 and 04-15.

<sup>137</sup> 42 U.S.C. § 1320a-7(a).

<sup>138</sup> 42 U.S.C. § 1320a-7(b).

listing of the OIG's exclusion authorities and the effect of exclusion upon subsequent relationships, go to the OIG website.<sup>139</sup> When at the site, review not only the statute and implementing regulations, but also the Special Advisory Bulletin titled "The Effect of Exclusion from Participation in Federal Health Care Programs."

## **2.4 State Licensure Laws, Fee-Splitting Statutes, and Restrictions on the Corporate Practice of Medicine**

Besides the federal laws preceding this section of Chapter 2, and those that follow, there are also a number of state laws that place restrictions on the method, manner and ability of a physician to practice medicine. Legal counsel for physicians must be aware of and able to navigate these restrictions, which are consistently implicated in a physician's day-to-day practice, as well as the various unique relationships and transactions physicians enter into today. The first and most important state law restriction on physicians discussed in this section is found in state licensure laws. Following the description of licensure laws is a discussion on fee-splitting statutes and restrictions imposed by the corporate practice of medicine doctrine.

### **2.4.1 State Licensure Laws**

State licensure laws are perhaps the most basic and fundamental restriction on a physician's practice. There are fifty-four licensing jurisdictions in the United States, including the District of Columbia, Guam, Puerto Rico, and the Virgin Islands.<sup>140</sup> Each jurisdiction has minimum requirements for education, training and proficiency in licensing physicians to practice medicine, and each jurisdiction place varying restrictions on the physician's ability to practice. Despite the variation that exists, each licensing jurisdiction shares common themes of regulation such as:

- (i) Administration and oversight by a professional board or agency (referred to as a "Medical Board");
- (ii) Definitions and exceptions about what does and does not constitute the practice of medicine or the "healing arts;" and
- (iii) Standards of conduct and behavior for which physicians may be subject to disciplinary action.<sup>141</sup>

This subsection will discuss these common themes of regulation and how they impact the role of legal counsel for physicians. The specific statutes, regulations and medical boards should be consulted for a detailed description of licensing in each jurisdiction.<sup>142</sup>

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<sup>139</sup> The OIG website is [www.oig.hhs.gov](http://www.oig.hhs.gov).

<sup>140</sup> American Medical Association, Physician Education, Licensure and Certification (2004), *available online at* [www.ama-assn.org/aps/physcred.html](http://www.ama-assn.org/aps/physcred.html).

<sup>141</sup> MICHAEL F. SCHAFF, THE BASICS OF REPRESENTING PHYSICIANS § 3.1 (American Health Lawyers Association 2004).

<sup>142</sup> *See infra* note 132 and accompanying text.

#### 2.4.1.1 *Medical Boards*

State licensure laws are administered by one or more medical boards<sup>143</sup> that direct the licensure process and possess continued oversight of the practice of medicine. Typically, medical boards are administrative agencies that are composed of physicians, other healthcare professionals and members of the public, who are appointed by executive officials of the state.<sup>144</sup> Medical boards are an excellent resource for legal counsel to physicians and should be consulted directly for specific interpretations of restrictions and duties placed upon physicians by state statutes and regulations. Medical boards, specifically their general counsel, are also helpful in talking through the appropriate structure of new and innovative joint ventures and physician relationships.<sup>145</sup> The website of each medical board will usually provide descriptions, summaries, and links to the statutes and regulations it administers, directories of its officials, and other helpful publications and resources.

#### 2.4.1.2 *The Practice of Medicine*

Each medical board derives its authority in licensing and regulating physicians from the state medical practice act, which defines what constitutes or is deemed to constitute the practice of medicine or the healing arts.<sup>146</sup> As an example, the state of Kansas defines the healing arts as:

any system, treatment, operation, diagnosis, prescription, or practice for the ascertainment, cure, relief, palliation, adjustment, or correction of any human disease, ailment, deformity, or injury, and includes specifically but not by way of limitation the practice of medicine and surgery; the practice of osteopathic medicine and surgery; and the practice of chiropractic.<sup>147</sup>

The advent of telemedicine, which will be described in Section 2.7 of this chapter, has put increased scrutiny on the definitions of the practice of medicine and the healing arts. This is crucial for legal counsel in advising physicians because it describes specifically and by implication what a physician can and cannot do across state lines without having a license to practice medicine in that jurisdiction.<sup>148</sup> Besides the strict practice definitions and telemedicine implications, legal counsel should also be aware of actions that are excepted from the practice of medicine. Typically, state laws provide that individuals acting in emergencies or providing

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<sup>143</sup> In addition to the typical Medical Board of each licensing jurisdiction, there are thirteen state boards of osteopathic medicine. Federation of State Medical Boards, *FSMB Facts – Membership* (2005), available online at [www.fsmb.org/aboutus.htm](http://www.fsmb.org/aboutus.htm).

<sup>144</sup> Federation of State Medical Boards, *State Medical Board Information* (2005), available online at [www.fsmb.org/consumer.htm](http://www.fsmb.org/consumer.htm).

<sup>145</sup> Contact information and links to the respective websites of medical boards are available through the Federation of State Medical Boards (FSMB), available online at [www.fsmb.org/members.htm](http://www.fsmb.org/members.htm), and by the American Medical Association (AMA), available online at [www.ama-assn.org/ama/pub/category/2645.html](http://www.ama-assn.org/ama/pub/category/2645.html). Organizations that govern or regulate the practice of medicine are available online at [www.fsmb.org/links2.htm](http://www.fsmb.org/links2.htm); [www.ama-assn.org/ama/pub/category/13365.html](http://www.ama-assn.org/ama/pub/category/13365.html); [www.ama-assn.org/ama/pub/category/2642.html](http://www.ama-assn.org/ama/pub/category/2642.html).

<sup>146</sup> For example, see KAN. STAT. ANN. §§ 65-2802, 65-2869–65-2872; MO. REV. STAT. § 334.010.

<sup>147</sup> KAN. STAT. ANN. § 65-2802(a).

<sup>148</sup> SCHAFF, *supra* note 141, at § 3.1.

limited gratuitous services and students providing services under the supervision of a licensed practitioner are not practicing medicine.<sup>149</sup>

2.4.1.3 *Standards of Conduct*

Physicians are subject to a number of standards of conduct and professional restrictions with their treatment of patients, personal behavior and business transactions. These standards and restrictions are imposed on physicians by:

- (i) A physician's membership in a hospital's medical staff (*i.e.*, medical staff bylaws);
- (ii) Board certification in a particular specialty;
- (iii) Participation in Medicare or other federal healthcare programs;
- (iv) Private agreements with group practices (*i.e.*, corporate bylaws and shareholder agreements);
- (v) Contractual obligations; and
- (vi) Membership in associations such as the AMA.

The purpose of this subsection, however, is to describe the standards and restrictions imposed on physicians by state licensing laws and medical practice acts. Besides general licensing requirements, state medical practice acts will specify conduct or behavior of a physician or licensee that constitutes professional incompetence, unprofessional conduct or professional misconduct.<sup>150</sup> The type and number of standards and restrictions will vary with each licensing jurisdiction. Violation or noncompliance with these standards may result in suspension, revocation, nonrenewal, limitation or censure of a physician's license and may also trigger violations of other standards and restrictions imposed by the authorities described above. The FSMB provides the following list as common examples of unprofessional conduct:

- Physical abuse of a patient;
- Inadequate recordkeeping;
- Not recognizing or acting on common symptoms;
- Prescribing drugs in excessive amounts without legitimate reasons;
- Impaired ability to practice because of addiction, or due to physical or mental illness;
- Failing to meet continuing medical education requirements;

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<sup>149</sup> KAN. STAT. ANN. § 65-2872.

<sup>150</sup> KAN. STAT. ANN. §§ 65-2836–65-2837; MO. REV. STAT. § 334.100.

- Performing duties beyond the scope of a license;
- Dishonesty;
- Conviction of a felony; and
- Delegating the practice of medicine to an unlicensed individual.<sup>151</sup>

Once again it is worth noting that this subsection describes general licensing issues facing physicians and is not a comprehensive survey of the various state laws associated with physician licensure. For a more detailed description, legal counsel should consult the specific state statutes and regulations for the state or states where the physician client practices, and if necessary, directly contact the appropriate medical board.

#### 2.4.2 Fee-Splitting Statutes and Restrictions on the Corporate Practice of Medicine

In addition to the restrictions described, state licensing laws, either specifically or by implication, are responsible for establishing prohibitions on fee-splitting and the corporate practice of medicine. Fee-splitting refers to state law restrictions that either generally prohibit physicians from sharing professional fees with others, or more specifically, prohibit physicians from sharing professional fees in exchange for, or as an inducement to, the referral of patients.<sup>152</sup> The corporate practice of medicine is based on the proposition that corporations are “unfit vehicles” for the practice of medicine, because (i) corporations are incapable of physician licensure and (ii) laypersons and the general profit motives of corporations should not be allowed to interfere with a physician’s professional and ethical obligations to patients.<sup>153</sup> Therefore, under the corporate practice of medicine doctrine, general corporations are prohibited from operating medical practices, employing physicians or sharing professional fees with physicians.<sup>154</sup> Fee-splitting and corporate practice of medicine restrictions not only place practice restrictions on physicians, they also create additional complications for legal counsel in structuring the multitude of new physician ventures and transactions. Counsel must be keenly familiar with these restrictions to ensure compliance under both circumstances.

##### 2.4.2.1 *Fee-Splitting*

Prohibitions on fee-splitting are commonly found in state medical practice acts, as direct prohibitions or within definitions of unprofessional conduct or professional misconduct. Also, the prohibition on fee-splitting is recognized in the AMA’s Code of Medical Ethics and other

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<sup>151</sup> Federation of State Medical Boards, *State Medical Board Information* (2005), available online at [www.fsmb.org/consumer.htm](http://www.fsmb.org/consumer.htm).

<sup>152</sup> Francis J. Serbaroli, *The Corporate Practice of Medicine Prohibition in the Modern Era of Health Care*, BNA HEALTH LAW & BUSINESS SERIES, No. 2800: Working Papers, Document 54 (2004); Carrie Valiant & David E. Matyas, *Fraud and Abuse in Payment Programs*, in HEALTH LAW PRACTICE GUIDE § 24:63 (American Health Lawyers Association 2004 ed.).

<sup>153</sup> Serbaroli, *supra* note 152, § 2800.02; HEALTH LAW HANDBOOK § 11:51 (Alice G. Gosfield ed., 2001).

<sup>154</sup> Serbaroli, *supra* note 152, § 2800.02; SCHAFF, *supra* note 141, at § 2.1.2.

physician organizations.<sup>155</sup> The reason for the prohibition is to prevent compromised patient care in situations where: (a) a physician may fail to provide services, knowing another physician will benefit; or (b) a physician may provide unnecessary treatment or services to generate higher fees that must be shared by multiple parties.<sup>156</sup> Most states have laws that specifically prohibit fee-splitting, but the manner of the prohibition varies from state to state and across medical professionals.<sup>157</sup> The level of prohibition ranges from completely prohibiting fee-splitting arrangements, to prohibiting such arrangements only when done in consideration of, or as an inducement for, referrals, and in some instances there is no specific prohibition at all.<sup>158</sup> A majority of states, however, prohibit fee-splitting when fee sharing is tied to patient referrals.<sup>159</sup>

Arrangements that commonly violate fee-splitting prohibitions include the following situations:

- (i) Where a nonphysician has an equity interest in a physician's medical practice;
- (ii) Where physicians share professional fees, other than pursuant to lawful professional corporations, associations, or partnerships; or
- (iii) Any agreement that provides payment based on, or calculated according to, a physician's revenue.<sup>160</sup>

Violation of state fee-splitting prohibitions usually means a physician's license may be subject to disciplinary action. But in some instances, criminal penalties may result, and if federal healthcare program patients are involved, violation of the federal Anti-Kickback Statute, which is described in Section II of this chapter may be triggered.<sup>161</sup>

#### 2.4.2.2 *Corporate Practice of Medicine*

Generally, state corporate practice of medicine laws prevent corporations and other business organizations that are not owned entirely by licensed physicians from employing or otherwise using licensed physicians or unlicensed individuals to provide professional medical services for which a physician's license is required. The particulars of this prohibition and any exceptions to it vary from state to state. Laws that prohibit the corporate practice of medicine and fee-splitting statutes must be read in conjunction with each other, since one practice, under certain circumstances, tends to implicate the other. For example, if a physician enters a relationship in which a portion of the physician's professional fees is paid to a general corporate

<sup>155</sup> AMERICAN MEDICAL ASSOCIATION, CODE OF MEDICAL ETHICS § 6.02, *available online at* [www.ama-assn.org/ama/pub/category/2498.html](http://www.ama-assn.org/ama/pub/category/2498.html); Serbaroli, *supra* note 152, § 2800.05.

<sup>156</sup> Serbaroli, *supra* note 152, § 2800.05 (*citing E&B Mktg. Enters., Inc. v. Ryan*, 568 N.E.2d 339 (Ill. Ct. App. 1991)).

<sup>157</sup> *Id.* at Working Papers, Document 54.

<sup>158</sup> *Id.* The editor's note to this publication warns the reader that even if the statute does not specifically prohibit fee-splitting, the prohibition may be implied as unprofessional conduct. All states allow disciplinary action against physicians for unprofessional conduct.

<sup>159</sup> *Id.*

<sup>160</sup> *Id.* at 2800.05.

<sup>161</sup> *Id.*

entity, the fee-splitting prohibition, in most cases, has been violated. Also, the corporate practice of medicine doctrine has been violated because the general corporate entity is deemed to be engaging in the unlicensed practice of medicine.

Contrary to fee-splitting prohibitions, the corporate practice of medicine doctrine is rarely found explicitly in state statutes or regulations.<sup>162</sup> Usually, it has evolved over time and is based on (a) common law interpretations of licensing statutes that specify only individuals may be licensed to practice medicine and (b) public policy concerns regarding the commercial exploitation of the medical profession if laypersons or general corporations are allowed to interfere with or control a physician's professional judgment and/or practice.<sup>163</sup>

The AMA Code of Medical Ethics does not specifically address the corporate practice of medicine doctrine. Portions of the Code, however, reinforce the doctrine by advising physician's to comply with state laws that prohibit physicians from assisting unlicensed individuals in the practice of medicine,<sup>164</sup> and by declarations that a physician's medical judgment should be free of interference.<sup>165</sup>

Most states currently have laws that prohibit the corporate practice of medicine.<sup>166</sup> But the prohibition level varies across states because the doctrine has eroded from numerous exceptions that have evolved over time.<sup>167</sup> The following entities and organizations represent common exceptions to the corporate practice of medicine doctrine:

- Professional corporations, professional associations, partnerships, and group practices owned and operated by licensed professionals;
- Health maintenance organizations and medical indemnity companies;
- Licensed medical schools that contract with hospitals to staff the hospital with physicians employed by the medical school;
- Medical school faculty practice plans;
- Medical support service corporations;
- Nonprofit corporations (*e.g.*, medical foundations, hospital service corporations);
- Fraternal, religious, labor, and educational organizations;

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<sup>162</sup> *Id.* § 2800.04.

<sup>163</sup> *Id.* §§ 2800.03, 2800.04.

<sup>164</sup> AMERICAN MEDICAL ASSOCIATION, CODE OF MEDICAL ETHICS § 3.01, *available online at* [www.ama-assn.org/ama/pub/category/2498.html](http://www.ama-assn.org/ama/pub/category/2498.html).

<sup>165</sup> *Id.* § 8.05; *see also* Serbaroli, *supra* note 152, § 2800.03.

<sup>166</sup> Serbaroli, *supra* note 152, § 2800.03, note 1 and accompanying text. For a more detailed discussion of a particular state's prohibition on the corporate practice of medicine, *see id.* at Working Papers, Document 2-53 (describing each state's prohibition on the corporate practice of medicine).

<sup>167</sup> *Id.* § 2800.06.

- Hospitals (voluntary, public, proprietary, and publicly traded), clinics, and other licensed healthcare institutions that employ physicians, interns, and residents to provide services;
- Municipalities providing healthcare services to their employees;
- Private employers providing on-site healthcare services for their employees; and
- Private businesses (*e.g.*, malls or large department stores) that maintain a limited on-site medical service for customers or employees who become ill.<sup>168</sup>

Violation of corporate practice of medicine restrictions can result in a variety of penalties and sanctions, including civil and criminal penalties for the unlicensed practice of medicine, disciplinary action against physicians if fee-splitting is involved and a number of potential federal causes of action.<sup>169</sup> Because of the variety of regulation across jurisdictions, the constant erosion described above and the potentially damaging consequences, many commentators have argued for abolishing the prohibition of corporate practice of medicine.<sup>170</sup> But unless federal legislation is created that would preempt the varying state laws that currently exist, or until each individual state abolishes or eliminates the doctrine, the prohibition of the corporate practice of medicine will continue to add complexity to the myriad of regulations, restrictions and standards that overshadow the practice of medicine.

## 2.5 Antitrust Law Applicable to Medical Society Activities and Physician-Controlled Provider Networks

Federal and state antitrust laws apply to many different activities in the healthcare field. Other chapters deal with their application to credentialing decisions (Chapter 7, *Hospital Relations*), exclusive contracting relationships (Chapter 11, *Hospital-Based Physician Representation*), and physician attempts at unionization (Chapter 13, *Unionization*). This chapter, however, focuses specifically on antitrust laws that apply to the efforts of physicians, acting either through medical societies or physician controlled provider networks, to improve their leverage in dealings with commercial health plans. Physicians have long felt at the mercy of government reimbursement programs, which determine the rates they pay to physicians through regulatory fiat, and of commercial health plans that have significant negotiating leverage because they represent large numbers of consumers. Also, because physicians tend to practice in

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<sup>168</sup> *Id.* Please note that while these exceptions to the corporate practice of medicine doctrine are common, they do not exist in every jurisdiction and vary in degree and interpretation. For specific answers regarding the doctrine in any particular jurisdiction, consultation with that state's laws should be made. *See id.* at Working Papers, Document 2-53 (describing each state's prohibition on the corporate practice of medicine).

<sup>169</sup> *See id.* § 2800.07 (discussing potential remedies under fraud and abuse for federal healthcare programs, wire and mail fraud and honest services fraud)

<sup>170</sup> *See* Nicole Huberfeld, *Be Not Afraid of Change: Time to Eliminate the Corporate Practice of Medicine Doctrine*, 14 HEALTH MATRIX: J. OF L.-MED. 243, 245 (Summer, 2004) (arguing for the elimination of the corporate practice of medicine doctrine based on the evolution of healthcare into integrated systems, acceptance of the influence of financial gain in healthcare and policy concerns that the doctrine does not advance but may inhibit improvements in healthcare quality).

individual or small group practice settings, they are left with relatively little bargaining power in negotiating price or other terms.

### 2.5.1 Applicable Federal Laws

The principal federal statutes that apply to medical society activities and to physician controlled provider networks are the Sherman Act §§ 1 and 2,<sup>171</sup> the Clayton Act § 7,<sup>172</sup> and the Federal Trade Commission Act § 5.<sup>173</sup> Section 1 of the Sherman Act prohibits contracts, combinations, and conspiracies in restraint of trade.<sup>174</sup> Examples of conduct that could violate Sherman §1 are:

- (1) Agreements to fix prices;
- (2) Agreements to allocate markets or customers;
- (3) Agreements to engage in group boycotts; and
- (4) Refusals to deal.

Section 2 of the Sherman Act prohibits

- (1) Monopolization;
- (2) Attempts to monopolize; and
- (3) Conspiracies to monopolize.<sup>175</sup>

Section 7 of the Clayton Act prohibits mergers, joint ventures, consolidations, or acquisitions of stock or assets, the effect of which may be to substantially lessen competition or tend to create a monopoly.<sup>176</sup> Section 5 of the Federal Trade Commission Act prohibits unfair methods of competition.<sup>177</sup> This chapter will focus principally upon Sherman Act §1 because the activities it prohibits are those most frequently associated with physicians acting in groups to improve their bargaining position with respect to commercial health plans.

### 2.5.2 Enforcement and Penalties for Violations of Federal Antitrust Laws

Federal antitrust statutes may be enforced by the Antitrust Division of the U.S. Department of Justice (DOJ), by the Federal Trade Commission (FTC) and by suits brought by private third parties. Under the Sherman Act, the DOJ can bring criminal or civil actions and recover damages suffered by the U.S. government. Under the Clayton Act, it can obtain civil

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<sup>171</sup> 15 U.S.C. §§ 1, 2.

<sup>172</sup> 15 U.S.C. § 18.

<sup>173</sup> 15 U.S.C. § 45.

<sup>174</sup> 15 U.S.C. § 1.

<sup>175</sup> 15 U.S.C. § 2.

<sup>176</sup> 15 U.S.C. § 18.

<sup>177</sup> 15 U.S.C. § 45.

injunctions and recover damages suffered by the U.S. government. Criminal violations of the Sherman Act are felonies punishable by jail terms of up to three years and/or fines of up to \$350,000 for individuals and \$10,000,000 for corporations.<sup>178</sup> The FTC shares responsibility with the DOJ for enforcing the Sherman and Clayton Acts and has sole authority for enforcement of the Federal Trade Commission Act. The FTC may seek an injunction in federal district court or bring enforcement proceedings before an administrative law judge.<sup>179</sup> The administrative law judge's decision is appealable to the five commissioners of the FTC and their decision is appealable to a federal appeals court.<sup>180</sup> With private rights of action, the federal antitrust law permit suits in federal district court to recover three times the damage suffered<sup>181</sup> and/or to enjoin a violation of the antitrust laws.<sup>182</sup> These three potential enforcers and the potential for criminal penalties, substantial fines and treble damages mean that physicians must be careful to avoid violating antitrust laws when seeking to “level the playing field” in their dealings with commercial health plans.

### 2.5.3 Sources of Guidance to Counsel for Physicians

Case law and FTC decisions, which apply the antitrust laws to physician action through medical societies and physician controlled provider networks, are relatively few and recent because antitrust laws were not applied to law and medicine (the so-called learned professions exception) until the mid-1970s.<sup>183</sup> Also, federal enforcement agencies have chosen a number of nonlitigation alternatives to try to shape antitrust policy. Among these are policy statements, consent decrees and business review/advisory opinions. Although these agency approaches to enforcement policy represent the views of the DOJ and FTC, they do not represent the extent to which the courts may apply the federal antitrust laws to physician activities through medical societies and physician controlled provider networks. Because investigations are fact intensive and the consequences of a violation severe, the costs of responding to an investigation, even if the end result is a settlement or a successful defense, can be huge. Therefore, following the guidance provided by the DOJ and FTC is a prudent course to take to minimize the risk of investigation by either agency.

#### 2.5.3.1 *1996 Joint Policy Statements*

Perhaps the most important guidance in this area is the joint DOJ and FTC Statements of Antitrust Enforcement Policy in Health Care (the “Policy Statements”)<sup>184</sup> that contain nine policy statements that outline the framework under which the agencies will analyze particular transactions or issues and define safety zones within which transactions or activities will not be challenged by the agencies. A primary goal of counsel for medical societies and for physician

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<sup>178</sup> 15 U.S.C. § 1.

<sup>179</sup> 15 U.S.C. § 53.

<sup>180</sup> *Id.*

<sup>181</sup> 15 U.S.C. § 15.

<sup>182</sup> 15 U.S.C. § 26.

<sup>183</sup> See *Goldfarb v. Virginia State Bar*, 421 U.S. 773 (1975), for the Supreme Court opinion rejecting the learned profession exemption.

<sup>184</sup> U.S. DEPARTMENT OF JUSTICE & FEDERAL TRADE COMMISSION, STATEMENTS OF ANTITRUST ENFORCEMENT POLICY IN HEALTH CARE (Aug. 1996).

controlled provider networks should be to advise them to seek to fit their conduct within one or more of the safety zones established by the Policy Statements.

The agencies will also provide antitrust guidance regarding specific proposed conduct through the DOJ business review procedure<sup>185</sup> or the FTC's advisory opinion process.<sup>186</sup> A business review letter or advisory opinion is prospective, applying only to proposed conduct, not to existing behavior. Thus, the time to ask for one is before engaging in proposed conduct. Either agency may decline to give an opinion and may rescind or revoke an opinion already given. However, if an issued opinion remains in effect, the agencies will not take action against conduct that conforms to the opinion. In the Policy Statements, the agencies commit to responding to requests for business review or advisory opinions within ninety days from receipt of all information regarding formation of physician joint venture networks (120 days for multi-provider networks). Receipt of one of these opinions provides assurance that a proposed course of conduct will not be challenged. This assurance is particularly valuable if the proposed activity does not clearly fit within one of the Policy Statement's safe zones. Since a March 2002 agreement between the FTC and DOJ, the FTC has the primary responsibility for such healthcare guidance, except for health insurance and where the FTC decides it lacks jurisdiction.<sup>187</sup>

### 2.5.3.2 *Agency Consent Decrees*

Guidance also results when either agency concludes an investigation by entering into a consent decree with the subject(s) of the investigation. The procedures for entry into and final approval of consent decrees include publication for public comment before court approval for the DOJ settlements and commission approval for FTC settlements.<sup>188</sup> Although each consent decree is specific to the facts uncovered during the course of a particular investigation, the agencies usually seek terms that end the challenged conduct, require periodic reports to the agencies of compliance efforts to prevent a reoccurrence, and seek permission to inspect the records of the other party to the consent decree. Nearly all consent decrees contain a statement expressly disavowing any liability on the part of the party settling with one of the agencies. This avoids an admission that could be used in a private lawsuit to recover damages because of the challenged conduct. Because the relief sought is usually an end to challenged conduct and because the risks and costs of litigating an enforcement action brought by one of the agencies are serious, entry into a consent decree is usually an attractive alternative for subjects of an agency investigation. Consent decrees are published so their provisions provide insight into enforcement agency application of antitrust laws regarding the activities of physician controlled provider networks.

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<sup>185</sup> 28 C.F.R. § 50.6. DOJ business review letters are *available online at* [www.us-doj.gov/atr/busreview/letters.htm](http://www.us-doj.gov/atr/busreview/letters.htm).

<sup>186</sup> 16 C.F.R. §§ 1.1–1.4. FTC advisory opinions are *available online at* [www.ftc.gov/bc/advisory.htm](http://www.ftc.gov/bc/advisory.htm).

<sup>187</sup> Memorandum of Agreement between the Federal Trade Commission and the Antitrust Division of the U.S. Department of Justice concerning Clearance Procedures for Investigations (March 5, 2002).

<sup>188</sup> *See* 15 U.S.C. § 16(b)(h) for procedures applicable to DOJ consent decrees; 16 C.F.R. §§2.31, 2.32, 3.25 for procedures applicable to FTC consent decrees.

2.5.4 Sherman Act Section 1 Substantive Analysis

2.5.4.1 *Concerted Action*

To establish a Sherman Act Section 1 violation, a plaintiff must show a “contract, combination . . . or conspiracy” in unreasonable restraint of trade.<sup>189</sup> Most issues arise in the context of what constitutes an unreasonable restraint of trade. However, sometimes questions arise regarding whether there is a contract, combination or conspiracy, particularly about the components of a single enterprise. In *Copperweld Corp. v. Independence Tube Corp.*, the U.S. Supreme Court held that a parent corporation and its wholly owned subsidiary are incapable of conspiring in violation of §1 as a matter of law.<sup>190</sup> The Supreme Court’s analysis focused on the unity of interests and common economic incentives of a parent and its wholly owned subsidiary. U.S. Courts of Appeal have split on the question of whether the *Copperweld* analysis exempts activities of a hospital and its medical staff, especially for credentialing decisions.<sup>191</sup> With physician controlled provider networks, the Second Circuit Court of Appeals ruled that participants in an individual practice association (IPA) were capable of conspiring among themselves if they had some control over the IPA and operated independent private practices.<sup>192</sup> Finally, for concerted activity a plaintiff must show an actual agreement or conspiracy as opposed to independent but similar behavior. Usually circumstantial evidence that creates a reasonable inference of a conscious commitment to a common scheme to achieve an unlawful objective will be enough to establish an agreement or conspiracy.<sup>193</sup>

2.5.4.2 *Unreasonable Restraint of Trade*

There are two basic standards applied to conduct when determining if the conduct unreasonably restrains trade in violation of Sherman Act § 1—the per se rule and the rule of reason. Courts have found concerted action to be unreasonable per se if it involves:

- (a) Horizontal price fixing<sup>194</sup> (*i.e.*, an agreement among competitors regarding the prices they will charge for their products or services);
- (b) Market division or customer allocation<sup>195</sup> (*i.e.*, an agreement among competitors to allocate among them the geographic or demographic markets in which they will sell their products and services); or

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<sup>189</sup> 15 U.S.C. § 1.

<sup>190</sup> 467 U.S. 752 (1984).

<sup>191</sup> See *Weiss v. York Hospital*, 745 F. 2d 786 (3rd Cir., 1984), *cert. denied*, 470 U.S. 1060 (1985), for a decision holding that a hospital cannot conspire with its medical staff, *but see Bolt v. Halifax Hospital Medical Center*, 891 F. 2d 810 (11th Cir., 1990), *cert. denied*, 495 U.S. 924 (1990), for a decision holding that a hospital could conspire with its medical staff.

<sup>192</sup> *Capital Imaging P.C. v. Mohawk Valley Medical Associates*, 996 F. 2d 537 (2d Cir., 1993), *cert. denied*, 510 U.S. 947 (1993).

<sup>193</sup> *Monsanto Co. v. Spray-Rite Service Corp.* 465 U.S. 752 (1984).

<sup>194</sup> See, e.g., *Arizona v. Maricopa County Medical Society*, 457 U.S. 332 (1982).

<sup>195</sup> See, e.g., *United States v. Topco Assocs.*, 405 U.S. 596 (1972).

- (c) Group boycotts (*i.e.*, an agreement among competitors not to deal with certain customers or potential customers for the products or services they offer).

An example of the last item would be a situation in which all the doctors in a community refuse to sign contracts with a particular commercial health insurance plan.<sup>196</sup> Conduct that does not fall within a category considered per se unlawful is analyzed under the rule of reason, which requires a balancing of the reduction in competition from the challenged conduct with the competitive benefits flowing from it. Often, this requires a lengthy analysis of the relevant product or service and geographic markets to determine the pro- and anti-competitive effects of a particular conduct.

## 2.5.5 Application of Sherman Act Section 1 Analysis to Medical Society Activities and Physician-Controlled Provider Networks

### 2.5.5.1 *Medical Society Activities*

The temptation of physicians to reduce the imbalance in bargaining power between them and commercial health plans has led to discussions at medical society meetings and, in some cases, official medical society actions that can risk violating Sherman Act §1. Among these have been discussions regarding:

- (a) The maximum prices the physicians will charge;
- (b) The copayment amounts they will charge;
- (c) Whether to grant discounts;
- (d) Whether to participate in a health plan if its physician fee schedule is not increased;
- (e) Whether to adopt and issue to medical society members an advisory fee schedule;
- (f) Whether to formulate and distribute to medical society members a relative value scale and/or a conversion factor or factors to convert the scale to a fee schedule; and
- (g) Whether to appoint an agent to negotiate with commercial health plans on behalf of medical society members.

The question for enforcement agencies and courts is when do such activities become unlawful price fixing, market allocation or group boycott activities, which are per se unlawful. First, if the conduct amounts to a “naked” agreement to fix prices, allocate markets, or boycott a payer or payers, then it is per se unlawful. Such an agreement is naked if it is unrelated to the parties economically integrating their business functions to achieve efficiencies in the joint marketing of their services, but instead was created to affect the prices that the physicians

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<sup>196</sup> See, e.g., *United States v. General Motors Corp.*, 384 U.S. 127 (1966).

charge.<sup>197</sup> The U.S. Supreme Court employed this analysis to conclude that the Maricopa County Medical Society suggested maximum prices was a per se price fixing arrangement in violation of Sherman Act §1.<sup>198</sup> Advisory fee schedules have been upheld by some courts absent a showing of an understanding among competing providers to use them,<sup>199</sup> but stricken as per se violations in other cases that concluded that the understanding to use them may be inferred from the circumstances.<sup>200</sup> Both the FTC and the DOJ have challenged the formulation and dissemination of relative-value scales by physician groups.<sup>201</sup> The agencies' concern is that publication of the relative-value scales by provider groups to their members would facilitate price fixing agreements among members of the groups.

Where discussions among medical society members have led to refusals to participate in or decisions to withdraw from participation in commercial health plans unless reimbursement demands or goals of the physicians are met, courts have found per se unlawful group boycotts.<sup>202</sup> It is unclear, however, where courts will draw the line when a medical society or group of physicians provides information to a commercial health plan about fees or other matters, but the element of an obvious refusal to deal except on those terms is absent. If the facts and circumstances of the situation show the payer was coerced or pressured into pricing decisions it would not otherwise make, then the finding of a Sherman Act Section 1 violation is much more likely. By contrast, medical society advice or information provided to a payer, which is acted upon unilaterally by the payer, will likely not result in an antitrust violation.<sup>203</sup>

Three of the nine 1996 Policy Statements focus on the agencies' views of when provider information sharing is "safe" and when it risks violating the antitrust laws. Statement 4 discusses Providers' Collective Provision of Non-Fee-Related Information to Purchasers of Health Care Services; Statement 5 discusses Providers' Collective Provision of Fee-Related Information to Purchasers of Health Care Services; and Statement 6 discusses Provider Participation in Exchanges of Price and Cost Information. The safety zone for non-fee-related information is fairly broad and protects collective provision of underlying medical data that may improve a health plan's resolution of issues about the mode, quality or efficiency of treatment. One example is outcome data provided by network physicians that are used by the medical society to recommend that a health plan cover a particular procedure. The Policy Statement warns, however, against attempts to coerce health plan decision-making on these non-fee-related terms through implied threats of group boycotts.<sup>204</sup>

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<sup>197</sup> *Arizona v. Maricopa County Medical Soc'y*, 457 U.S. 332 (1982).

<sup>198</sup> *Id.*

<sup>199</sup> *United States v. Am. Soc'y of Anesthesiologists*, 473 F. Supp. 147 (S.D.N.Y. 1979).

<sup>200</sup> *United States v. A. Lanoy Alston, D.M.D., P.C.*, 974 F. 2d 1206 (9th Cir. 1992).

<sup>201</sup> *Am. Coll. of Obstetricians & Gynecologists*, 88 F.T.C. 955 (1976), *modified* 104 F.T.C. 524 (1984) (consent order); and *United States v. Ill. Podiatry Soc'y*, 1977-1 Trade Cas. (CCH) ¶ 61,767 (N.D. Ill. 1977) (consent decree).

<sup>202</sup> *See, e.g., Pa. Dental Ass'n v. Medical Services Ass'n*, 815 F. 2d 270 (3rd Cir. 1987), *cert. denied*, 484 U.S. 851 (1987).

<sup>203</sup> *Barry v. Cross*, 805 F. 2d 866 (9th Cir. 1986).

<sup>204</sup> U.S. JUSTICE DEPARTMENT AND FEDERAL TRADE COMMISSION, STATEMENTS OF ANTITRUST ENFORCEMENT POLICY IN HEALTH CARE, Statement No. 4 (August 1996).

The safety zones for fee-related information sharing with purchasers of healthcare services and for physician participation in price and cost surveys that are shared among survey participants require the following three standards be met: (a) the collection of the information should be managed by a third party; (b) any information available to the physician members of the medical society or group must be more than three months old; and (c) there must be at least five providers reporting data for each statistic that is published to the membership, no more than 25% of any statistic may be represented by a single provider's data, and the data published to the physician members must be aggregated to prevent participants from identifying the prices charged by any individual physician or medical group.<sup>205</sup>

#### 2.5.5.2 *Physician-Controlled Provider Networks*

Physician controlled provider networks seek to aggregate or integrate the provision by independent physicians and medical groups of their professional services to individuals who are covered by commercial health plans. Generally, physician controlled provider networks are owned by the independent physicians and practice groups that organize them. Some are owned solely by physicians and are frequently referred to as IPAs. Others may be co-owned with hospitals or other providers and are known as physician hospital organizations, management service organizations, etc. Usually, these networks have agreements with the physicians and other providers who own the network to obtain physician and other providers' participation in commercial health plans contracts. How these physician controlled provider networks obtain such agreements for the physicians and other providers who participate in them is a primary focus of the DOJ and FTC in enforcing Sherman Act § 1.

For example, some networks have been investigated as shams, triggering per se rule violations of Sherman Act Section 1 because they operated simply to keep prices high.<sup>206</sup> But, if a network is economically or clinically integrated, its agreements on price and other significant terms for participating physicians will be analyzed under the rule of reason.<sup>207</sup> If a network is not economically or clinically integrated, then it must use a messenger as a conduit between the physicians and the health plans to discuss price and other competitively significant terms.<sup>208</sup>

#### *Economic Integration*

Economic integration is found where physicians and other providers participating in the network share the risk of costs from overuse of network services by individuals who are covered by the health plans with which the network contracts. The Policy Statements describe the following five types of procompetitive risk sharing:

- (1) Capitated contracts between the network and the health plans;

<sup>205</sup> *Id.*, Statements No. 5 and No. 6.

<sup>206</sup> *See, e.g., In re Physicians Group, Inc.*, No. C-3610 (FTC August 11, 1995) (complaint and consent order); *United States v. Mountain Healthcare, P.A.*, Civil No. 1:02 CV 288T (W.D.N.C. Dec. 13, 2002) (proposed final judgment). In each case the consent order required the group to dissolve.

<sup>207</sup> *See, e.g., U.S. DEPARTMENT OF JUSTICE AND FEDERAL TRADE COMMISSION STATEMENT OF ANTITRUST ENFORCEMENT POLICY IN HEALTH CARE*, Statement No. 8 and Statement No. 9 (August, 1996).

<sup>208</sup> *Id.*

- (2) Where the network creates significant financial incentives for its providers to meet cost containment goals;
- (3) Where provider reimbursement is based on a percentage of health plan premiums or revenues;
- (4) Where overall cost or utilization goals are established and subsequent financial rewards or penalties apply to those goals; and
- (5) Where the network has global or all inclusive case rates.<sup>209</sup>

*Substantial Clinical Integration*

The Policy Statements indicate that substantial clinical integration consists of an ongoing program to evaluate and modify the practice patterns of network participants to create a high degree of interdependence and cooperation among them.<sup>210</sup> According to the Policy Statements, such a program may include:

- (i) Establishing mechanisms to manage utilization and to control costs and ensure quality;
- (ii) Selectively choosing network participants who are likely to further efficiency objectives; and
- (iii) Investments in resources needed to realize the network's efficiencies.<sup>211</sup>

Substantial clinical integration permits networks to negotiate fee-for-service reimbursement and other nonrisk-sharing pricing arrangements without fear of a per se violation of Sherman Act Section 1.

This is a new and welcome development for physician networks that often had difficulty negotiating and successfully operating under contracts with health plans under which the physicians shared the financial risk of overutilization. It also appears that the FTC will give a new network the benefit of the doubt rather than to require a track record showing substantial clinical integration.<sup>212</sup> But, the FTC will not hesitate to challenge a network's joint pricing activities if it believes that the clinical integration is insufficient.<sup>213</sup> It is the author's belief that to date, physician networks have yet to use clinical integration in a meaningful way for participating in joint pricing activities.

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<sup>209</sup> *Id.*

<sup>210</sup> *Id.*

<sup>211</sup> *Id.*

<sup>212</sup> See, e.g., MedSouth FTC Staff Advisory Opinion, Feb. 19, 2002, available online at [www.ftc.gov/bc/adops/medsouth.htm](http://www.ftc.gov/bc/adops/medsouth.htm).

<sup>213</sup> See, e.g., *In re California Pacific Medical Group, No. 9306* (FTC July 9, 2003) (complaint); No. 9306 (FTC Feb. 9, 2003) (proposed consent order).

*Messenger Model Operations*

Another alternative to financial and clinical integration is for a physician controlled provider network to use a messenger model approach to contracts with health plans. The Policy Statements specifically recommend use of this approach and have established guidelines for its implementation.<sup>214</sup> In the messenger model approach, an independent third party “messenger” serves as a conduit for communications between the network physicians and the health plans with whom they wish to contract. To avoid price fixing concerns, the messenger must not communicate information among the physicians in the network. The messenger’s role is strictly limited to communications between the payers and individual physicians who participate in the network. Further, the messenger must refrain from negotiating on behalf of the network physicians. Each physician or medical group must decide on their own whether or not to agree to the health plan terms and conditions communicated by the messenger.

An example in the Policy Statements describes the leeway that a messenger may have when serving as a conduit between health plans and network physicians. It specifically permits a messenger to obtain from each network participant a schedule of minimum acceptable fees and to contract on their behalf with any payers that offer prices that equal or exceed the minimum levels. Also, for a limited time period, the messenger may be authorized to bind a network physician to any contract offer with prices equaling or exceeding those in a contract that the physician previously accepted. Lastly, the messenger may take the minimum fee schedules from each of the network participants and develop a schedule that shows health plans the percentages of network participants that have authorized contracts at differing price levels. However, under the example, the messenger may not take matters one step further and negotiate with payers to obtain the most favorable pricing possible and then ask each network provider to accept or reject it.<sup>215</sup>

Since 2002, the FTC has aggressively pursued price-fixing cases, challenging the use of messengers in negotiations by physician networks that also lacked financial and clinical integration sufficient to permit joint negotiations regarding price and other competitive terms. From 2002 until the present time, there have been more than a dozen consent decrees. A number of common elements appear in most of the consent agreements such as:

- (i) Little clinical or financial integration among the physicians;
- (ii) The messenger’s refusal to communicate to the physicians offers deemed insufficient;
- (iii) The messenger’s substantive involvement in evaluating the offers;

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<sup>214</sup> U.S. DEPARTMENT OF JUSTICE AND FEDERAL TRADE COMMISSION STATEMENTS OF ANTITRUST ENFORCEMENT POLICY IN HEALTHCARE, Statement No. 9 (August 1996).

<sup>215</sup> United States Department of Justice and Federal Trade Commission Statement of Antitrust Enforcement Policy on Health Care, Statement No. 9 (August 1996).

- (iv) A pattern of offering participating physicians an opportunity to “opt in or out” of the agreement once it was negotiated; and
- (v) Participating physician ownership or control of the network that retained the messenger.<sup>216</sup>

No case law exists regarding the agencies’ guidelines for the messenger model approach to network contracting. Given the clarity of the guidelines and the consequences of losing a litigated case, it is unlikely that a network challenged by either agency will seek to litigate the outcome. Therefore, it is not likely that case law will soon develop to accept or modify the agency views regarding the permissible scope of messenger activity on behalf of physician networks.

### *Spillover Collusion*

Another concern with physician controlled provider networks is that their operations may facilitate spillover collusion. Examples of this include network providers applying the network’s jointly negotiated prices to patient services from outside the network contracts, or where providers who accept limits on territories or services for network contracts agree among themselves to allocate territories or services outside the context of the network.

There are two main strategies that physician networks use to reduce the risk of spillover collusion. First, they limit the information shared among network participants to information directly related to the network’s operations. Sometimes third parties are used to develop and retain the network’s fee structure so individual physicians don’t know each other’s rates. Second, networks remind their participants that agreements among them for network activities must not be used outside the network and they must behave as competitors making independent decisions about competitive activities.

#### 2.5.6 The Sherman Act Section 1 “Straightjacket” and the Future

Many physicians and counsel for physicians come to the conclusion that the federal antitrust laws, and Sherman Act, § 1 in particular, place physicians “in straightjackets” concerning their efforts to equalize bargaining power when negotiating with commercial health plans. The most promising development for physicians has been the recent agency recognition that substantial clinical integration may provide a legitimate basis for joint price negotiations by physicians with commercial health plans. It is unknown what specific efforts toward clinical integration will be sufficient. Future enforcement actions and advisory opinions will, hopefully, yield more guidance for all involved parties. Currently, the most recent guidance can be found in a July 2004 DOJ and FTC joint report, which was followed by extensive hearings on competition law and policy affecting the healthcare market.<sup>217</sup>

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<sup>216</sup> See, e.g., *In re Physician Consulting Network, LLC*, File No. 021-0178 (FTC July 22, 2003) (proposed consent order); *In re Aurora Associated Primary Care Physicians, LLC*, File No. 011-0174 (FTC May 13, 2002) (proposed consent order).

<sup>217</sup> *Improving Health Care: A Dose of Competition—A Report by the Federal Trade Commission and the Department of Justice* (July 2004).

Two key observations regarding physician network operations were included in the DOJ and FTC report. Concerning clinical integration, the report directed networks to answer a series of questions to determine whether they would be sufficiently clinically integrated for joint price negotiations. Key among these questions is whether joint contracting with payers contributes to the program's clinical goals and what basis there is for the belief that individual physicians will try to accomplish the clinical goals of the network?

A second key observation regarding physician networks is that payment for performance arrangements among a group of physicians may constitute a form of financial risk sharing. Look for future developments on this subject as the agencies try to define the extent to which a payment for performance arrangement constitutes financial risk sharing related to the pricing agreement between network physicians and commercial health plans.

## **2.6 HIPAA Provisions Regarding Privacy of Patient Information**

Prior to the adoption of HIPAA,<sup>218</sup> the government and private organizations recognized that much of the healthcare costs in the United States were from administrative and financial transaction expenses. Many of the expenses were caused by a lack of standardized forms and methods for processing these transactions. Recognizing the cost benefits from creating national standards for healthcare transactions, HIPAA was developed to reduce costs by standardizing the processing of healthcare transactions, improve the portability of health coverage, increase the security and privacy of healthcare information and make other changes to the healthcare delivery system.

Currently included in HIPAA are the following four major health information standards:

- (1) Transaction and code set standards;
- (2) Privacy standards;
- (3) Security standards; and
- (4) National identifier standards.

The privacy and security standards are designed to protect the confidentiality, integrity and availability of people's healthcare information. These two standards usually present the most problems for attorneys representing healthcare providers and will therefore be the focus of this chapter.

This section identifies who must comply with HIPAA Privacy and Security Rules, summarizes compliance requirements and patient rights concerning their protected healthcare information, examines uses and disclosures of protected healthcare information, and explains the penalties for failing to comply with HIPAA's Privacy and Security Rules. This chapter is a cursory summary of some of the key elements of HIPAA's Privacy and Security Rules and is not a complete or comprehensive guide.

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<sup>218</sup> Health Insurance Portability and Accountability Act, Pub. L. No. 104-191 (Aug. 21, 1996).

### 2.6.1 Definitions

A working knowledge of the following definitions is required to understand the application of HIPAA's Privacy and Security Rules.

- *Covered Entity*—A health plan, healthcare clearinghouse, or healthcare provider that transmits any health information in electronic form in connection with a transaction covered by HIPAA.<sup>219</sup>
- *Business Associate*—Persons that perform, or assist in the performance of, a service or function on behalf of a Covered Entity when the function or activity involves the use or disclosure of protected health information, including but not limited to: claims processing or administration, data analysis, processing, or administration; utilization review; quality assurance; billing; benefit management; or practice management. A Business Associate also includes any person to whom protected health information is disclosed by a Covered Entity and who provides any of the following types of professional services to or for the Covered Entity: legal, actuarial, accounting, consulting, data aggregation, management, administration, accreditation or financial services. The definition of Business Associate excludes the performance of functions or activities in the capacity of a member of a Covered Entity's workforce.<sup>220</sup>
- *Healthcare Provider*—Means a provider of services, a provider of medical or health services, and any other person or organization who furnishes, bills, or is paid for healthcare in the normal course of business.<sup>221</sup>
- *Individually Identifiable Health Information*—Information, including demographic data, that is created or received by a healthcare provider, healthcare plan, employer, or healthcare clearinghouse, and that relates to: the individual's past, present, or future physical or mental health or condition; the provision of healthcare to the individual; or the past, present or future payment for the provision of healthcare to the individual; and that identifies the individual or for which there is a reasonable basis to believe the information can be used to identify the individual.<sup>222</sup>
- *Protected Health Information (PHI)*—Individually identifiable health information that is maintained or transmitted in any form or medium by a Covered Entity or its Business Associate.<sup>223</sup>
- *Workforce*—Employees, volunteers, trainees and other persons whose conduct, in the performance of work for a Covered Entity, is under the direct control of such entity, whether or not they are paid by the Covered Entity.<sup>224</sup>

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<sup>219</sup> 45 C.F.R. § 164.103.

<sup>220</sup> 45 C.F.R. § 164.103.

<sup>221</sup> 45 C.F.R. § 164.103. A “provider” of services is defined in section 1861(u) of HIPAA, 42 U.S.C. 1395x(u), and “provider of medical or health services” is defined in section 1861(s) of HIPAA, 42 U.S.C. 1395x(s).

<sup>222</sup> 45 C.F.R. § 164.103.

<sup>223</sup> 45 C.F.R. § 164.501.

Clearly, the definitions of “Covered Entity” and “healthcare provider” include physicians, medical groups, and many of the facilities (*e.g.*, hospitals, surgery centers, diagnostic testing facilities) where physicians provide care and treatment to patients. For convenience, this section will use the statutory term “Covered Entities” when referring to the physicians and other healthcare providers to whom the privacy rules apply.

### 2.6.2 The Privacy Rule

The Privacy Rule sets a national minimum of basic protections for individuals’ PHI that Covered Entities were required to comply with by April 14, 2003. The Privacy Rule addresses uses and disclosures of PHI by Covered Entities, grants new rights to patients to gain access to, and more control over, the use and disclosure of their PHI, and sets new obligations for Covered Entities to respect these rights. The Privacy Rule is designed to be flexible and comprehensive while limiting how and when an individual’s PHI can be used or disclosed. The information in Part C identifies:

- (a) The permitted, authorized, and restricted uses and disclosures of PHI;
- (b) A Covered Entity’s administrative requirements; and
- (c) An individual’s new rights of access to, and control over the use and disclosure of, their PHI.

#### 2.6.2.1 *Use and Disclosure*

The main purpose of the Privacy Rule is to define and limit the circumstances in which an individual’s PHI may be used or disclosed by Covered Entities. A Covered Entity may not use or disclose PHI, except as the Privacy Rule permits or requires, or as the individual who is the subject of the information (or the individual’s personal representative) authorizes in writing.<sup>225</sup>

A Covered Entity is only required to disclose PHI in two situations: (1) to individuals (or their personal representatives) specifically when they request access to, or an accounting of disclosures of, their PHI; and (2) to the DHHS when it is undertaking a compliance investigation or review or enforcement action.<sup>226</sup> As will be discussed, there are several purposes and instances under which a Covered Entity is permitted, but not required, to use and disclose an individual’s PHI, without their authorization. For any use or disclosure of PHI that is not permitted under the Privacy Rule, a Covered Entity must obtain a written authorization from the individual who is the subject of the information. A Covered Entity can avoid HIPAA regulation by de-identifying healthcare information before its use or disclosure.<sup>227</sup> De-identified health information neither identifies nor provides a reasonable basis to identify an individual.

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<sup>224</sup> 45 C.F.R. § 164.103.

<sup>225</sup> 45 C.F.R. § 164.502(a).

<sup>226</sup> 45 C.F.R. § 164.502(a)(2).

<sup>227</sup> 45 C.F.R. §§ 164.502(d)(2), 164.514(a), (b).

*Permitted Uses and Disclosures*

A Covered Entity is permitted, but not required, to use and disclose PHI without an individual's authorization, for the following purposes or situations:

- (a) To the individual (unless required for access or accounting of disclosures);
- (b) For treatment, payment, and healthcare operations (TPO) purposes (except for psychotherapy notes);
- (c) After providing the individual an opportunity to agree or object;
- (d) When it is incidental to an otherwise permitted use and disclosure;
- (e) For public interest and benefit activities; and
- (f) In a limited data set (as will be defined) for research, public health or healthcare operations purposes.<sup>228</sup>

These permitted uses and disclosures are discussed in this subsection.

- *Individual.* A Covered Entity may disclose PHI to the individual who is the subject of the information.
- *TPO Purposes.* Uses and disclosures of PHI are broadly permitted under the Privacy Rule for a Covered Entity's own activities related to TPO and are almost as broadly permitted for treatment and payment purposes of a third party.<sup>229</sup> This permission narrows though when the disclosure is for a third party's healthcare operations purposes. Specifically, a Covered Entity may disclose PHI for the treatment activities of any healthcare provider, the payment activities of another Covered Entity and of any healthcare provider, or the healthcare activities or fraud and abuse detection and compliance activities, if both the Covered Entities have or had a relationship with the individual and the PHI pertains to the relationship. Although the use and disclosure of PHI for treatment and payment purposes may be easily identified, it is harder to recognize what constitutes healthcare operations without reviewing its definition. The HIPAA definition of healthcare operations includes, but is not limited to:
  - (a) Conducting quality assessment and improvement activities;
  - (b) Reviewing the competence or qualifications of healthcare professions and conducting training programs;
  - (c) Underwriting, premium rating, and other activities relating to the creation, renewal, or replacement of a contract of health insurance or benefits;

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<sup>228</sup> 45 C.F.R. § 164.502(a)(1).

<sup>229</sup> 45 C.F.R. § 164.506(c).

- (d) Conducting or arranging for medical review, legal services, or auditing functions;
  - (e) Business planning and development, such as conducting cost-management and planning-related analysis related to managing and operating the entity; and
  - (f) Business management and general administrative activities.<sup>230</sup>
- *Opportunity to Agree or Object.* There are three types of uses and disclosures of PHI that are permitted if the individual is informed in advance and given the opportunity to agree, to object, or to restrict the use or disclosure. These three situations involve: (1) family and friends directly involved with the individual’s care or payment for care, (2) healthcare facility directories, and (3) disaster relief situations.<sup>231</sup> Where the individual is incapacitated, or in an emergency situation, or not available, Covered Entities may generally make such uses and disclosures, if in their professional judgment, the use or disclosure is determined to be in the best interest of the individual.
  - *Incidental Uses and Disclosures.* Secondary uses or disclosures that cannot reasonably be prevented, that are limited in nature, and that occur as a by-product of an otherwise permitted use or disclosure under the Privacy Rule are permitted. As a practical matter, this “incidental” permission means that generally where a practice has been duly careful limiting the PHI it shares to the minimum necessary, and has adopted reasonable safeguards, then the fact that some PHI may be overheard will not constitute a violation of HIPAA.<sup>232</sup>
  - *Public Interest and Benefit Activities.* The Privacy Rule permits, but does not require, a Covered Entity to use or disclose PHI for a broad variety of public-good activities without first obtaining an individual’s authorization or giving the individual an opportunity to agree or object to the use or disclosure. Special requirements apply to each of these public-good permissions and the Privacy Rule does not permit these uses or disclosures if another federal or state law prohibits or restricts them. Examples include PHI disclosures made to report victims of abuse, neglect or domestic violence or to avert a serious and imminent threat to the health and safety of persons or the public.<sup>233</sup>
  - *Limited Data Set.* A limited data set is PHI from which certain specified direct identifiers of individuals, and their relatives, household members, and employers have been removed.<sup>234</sup> A limited data set may be used and disclosed for research,

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<sup>230</sup> 45 C.F.R. § 164.501.

<sup>231</sup> 45 C.F.R. § 164.510.

<sup>232</sup> 45 C.F.R. § 164.502(a)(1)(iii).

<sup>233</sup> For a complete description of the fifteen types of public-good disclosures and the specific requirements for each of them, *see* 45 C.F.R. § 164.512.

<sup>234</sup> 45 C.F.R. § 164.514(e).

healthcare operations, and public health purposes, provided the recipient enters into a data use agreement promising specified safeguards for the PHI within the limited data set.

### *Authorized Uses and Disclosures*

For any use or disclosure of PHI that is not otherwise permitted under the Privacy Rule, a Covered Entity must obtain a HIPAA authorization from the individual that is the subject of the information. A HIPAA authorization is a detailed document that gives Covered Entities permission to use or disclose PHI for a specified purpose. An authorization must be written in plain language and specify a number of elements, including a description of the PHI to be used and disclosed, the person authorized to make the use or disclosure, the person to whom the Covered Entity may make the disclosure, the purpose for which the information may be used or disclosed, an expiration date, and the patient's signature. There are also specific statements that must be included in the authorization regarding the individual's rights to revoke it and the security of the PHI from redisclosure. With limited exceptions, Covered Entities may not condition treatment or coverage on the individual providing an authorization.<sup>235</sup>

Two specific uses and disclosures requiring an authorization that warrant special attention are those for psychotherapy notes and marketing purposes. The Privacy Rule provides greater protections to psychotherapy notes because of their sensitive nature and has specific requirements on any use and disclosure of PHI for marketing purposes. Counsel for physicians or other Covered Entities should conduct a detailed review of the applicable provisions of the Privacy Rule when advising clients on these types of disclosures.

#### 2.6.2.2 *Minimum Necessary Rule*

The Privacy Rule requires a Covered Entity to make reasonable efforts to limit the use, disclosure of, and requests for PHI to the minimum amount necessary to accomplish the intended purpose of the use, disclosure or request.<sup>236</sup> To allow Covered Entities the flexibility to address their unique circumstances, the rule requires Covered Entities to make their own assessment of what PHI is the minimum amount reasonably necessary for a particular purpose. This standard calls for an approach consistent with best practices to limit the unnecessary dissemination of medical information. Be aware that the minimum necessary rule applies when a Covered Entity receives a request for PHI. A request for the entire medical record absent documented justification for such request is a presumptive violation of the Privacy Rule.<sup>237</sup> The Privacy Rule provides the following six exceptions to the minimum necessary rule:

- (1) Disclosures to or requests by a healthcare provider for treatment;
- (2) Uses or disclosures of PHI made to the individual;
- (3) Disclosures made following an authorization;

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<sup>235</sup> 45 C.F.R. § 164.508.

<sup>236</sup> 45 C.F.R. §§ 164.502(b), 164.514(d).

<sup>237</sup> 45 C.F.R. § 164.514(d)(5).

- (4) Disclosures made to the secretary of the DHHS for purposes of compliance and enforcement related to HIPAA;
- (5) Uses or disclosures that are required by law; and
- (6) Uses or disclosures that are required for compliance with applicable requirements of HIPAA.

Although a Covered Entity usually must determine the minimum necessary information to use or disclose in a given situation, the Privacy Rule permits (but does not require) a Covered Entity to rely on requests from the following people or organizations as being the minimum necessary PHI: (1) public officials; (2) another Covered Entity; (3) a professional who is a Business Associate of the Covered Entity, and the information is requested to provide professional services to the Covered Entity; and (4) a researcher that provides documentation or representations that comply with the requirements for public-good disclosures for research purposes.<sup>238</sup>

### 2.6.2.3 *Administrative Requirements*

The Privacy Rule requires Covered Entities to develop and implement written privacy policies and procedures reasonably designed to ensure compliance with the rule. These policies and procedures will vary depending on the size, available resources and risks to the PHI undertaken by the Covered Entity. To properly develop these policies and procedures, Covered Entities need a thorough understanding of how PHI flows into, within, and out of their offices and who within their business practice requires access to it. A documented and comprehensive risk analysis (HIPAA audit) of the Covered Entity is required to achieve a detailed understanding of how PHI is collected, stored, transmitted or disposed of during routine and nonroutine practice operations. Once the HIPAA audit is completed, the Covered Entity should perform a “gap” analysis to identify where the flow of PHI is not properly protected as required by the Privacy Rule. After completing these risk management activities, the Covered Entity can draft appropriate privacy policies and procedures. Note that Covered Entities must also comply with stricter state laws concerning PHI privacy and this compliance must be reflected in their privacy policies and procedures. Outlined below are some key administrative requirements of the Privacy Rule.

#### *Notice of Privacy Practices*

The Privacy Rule requires Covered Entities to develop and distribute a notice of their privacy practices. The notice of privacy practices (NPP) should be one of the first documents addressed by a Covered Entity. The NPP has many required provisions, including:

- (a) Permitted uses and disclosures of PHI;
- (b) An explanation of individual’s privacy rights;
- (c) The Covered Entity’s privacy responsibilities;

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<sup>238</sup> 45 C.F.R. § 164.514(d)(3)(iii).

- (d) The patient's right to file a complaint;
- (e) The contact information for the Covered Entity's designated privacy official; and
- (f) A statement that the Covered Entity must abide by the terms of the notice.

The Privacy Rule also contains specific distribution requirements for the NPP. Covered healthcare providers with direct treatment relationships must deliver the notice to every patient no later than the first service encounter by personal delivery (for patient visits), by automatic and contemporaneous electronic response (for electronic service delivery), and by prompt mailing (for telephonic service delivery). Indirect-treatment physicians are only required to provide the NPP upon request and are not required to obtain the acknowledgements that are discussed below.<sup>239</sup>

After properly distributing the NPP, a Covered Entity is required to make a good faith effort to get the individual's written acknowledgment that he or she has received the NPP. The Covered Entity must document the acknowledgment by getting the individual's signature or document the failure to get the signature. Covered Entities that maintain an office or other physical site where they provide healthcare directly to individuals are required to post their entire NPP at their facility in a clear and prominent location and the NPP should include the same information that is distributed directly to the patients. The NPP must be available upon request and in a form that patients can take with them. Covered Entities must also make their NPP electronically available on any website they maintain for customer services or benefits information.<sup>240</sup>

#### *Personnel Designations*

Covered Entities must designate a privacy official who is responsible for the development and implementation of their privacy policies and procedures. They must also designate a contact person or office that is responsible for receiving privacy complaints. The privacy official should be able to provide further information about the NPP. Covered Entities should draft a job description for the privacy official and update it as needed or at least once a year.<sup>241</sup>

#### *Complaints*

Covered Entities must provide individuals with a process for making complaints about the Covered Entity's privacy policies and procedures or the Covered Entity's compliance with those policies and procedures or the Privacy Rule.<sup>242</sup>

#### *Training*

Covered Entities must train all members of their workforce on their privacy policies and procedures within a reasonable period of time from the date of hiring. Training must be updated

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<sup>239</sup> 45 C.F.R. § 164.520(b).

<sup>240</sup> 45 C.F.R. §§ 164.502(i), 164.520.

<sup>241</sup> 45 C.F.R. §§ 164.530(a)(i), 164.530(a)(ii).

<sup>242</sup> 45 C.F.R. § 164.530(d).

within a reasonable period of time after any material change in the Covered Entity's privacy policies or procedures.<sup>243</sup>

### *Sanctions*

Covered Entities must have appropriate sanctions in place against members of their workforce who fail to comply with their privacy policies and procedures.<sup>244</sup>

### *Mitigation*

Covered Entities must mitigate, to the extent practicable, any known harmful effect because of a use or disclosure of PHI in violation of their policies and procedures or the requirements of the Privacy Rule.<sup>245</sup>

### *No Retaliation or Waiver of Rights*

A Covered Entity may not intimidate, threaten, coerce, discriminate against, or take other retaliatory action against a person exercising rights provided by the Privacy Rule, assisting in an investigation by the DHHS or another appropriate authority, or for opposing an act or practice that the person believes in good faith violates the Privacy Rule. Covered Entities cannot require individuals to waive any of their rights under the Privacy Rule as a condition of the provision of treatment, payment and enrollment in a health plan, or eligibility for benefits.<sup>246</sup>

### *Data Safeguards*

Covered Entities must maintain reasonable and appropriate administrative, technical and physical safeguards to prevent intentional or unintentional use or disclosure of PHI in violation of the Privacy Rule and to limit their incidental uses and disclosures of PHI.<sup>247</sup>

### *Documentation*

The Privacy Rule contains specific requirements for creating and maintaining documents about privacy compliance. A Covered Entity must maintain, in written or electronic form, its privacy policies and procedures, its privacy practices notices, disposition of complaints, and other actions, activities, and designations required under the Privacy Rule. The documents and information must be maintained for a period of six years from the later of, the date created or the date last in effect.<sup>248</sup>

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<sup>243</sup> 45 C.F.R. § 164.530(b).

<sup>244</sup> 45 C.F.R. § 164.530(e).

<sup>245</sup> 45 C.F.R. § 164.530(f).

<sup>246</sup> 45 C.F.R. §§ 164.530(g), 164.530(h).

<sup>247</sup> 45 C.F.R. § 164.530(c).

<sup>248</sup> 45 C.F.R. § 164.530(j).

*Business Associates*

The Privacy Rule requires that Covered Entities obtain assurances from their Business Associates that the Business Associates will appropriately safeguard the PHI they receive or create on behalf of the Covered Entity. The satisfactory assurances must be in writing between the Covered Entities and the Business Associates, whether in the form of a contract or other agreement, and containing a number of required provisions.<sup>249</sup> Because the Privacy Rule compliance date has passed, one of the major considerations for any attorney representing physicians and medical groups will be identifying Business Associates and developing Business Associate Contracts for those relationships.

Covered Entities are not required to monitor or oversee the way their Business Associates carry out privacy safeguards or the extent to which their Business Associates abide by the contract privacy requirements. Nor are Covered Entities responsible or liable for the actions of their Business Associates. But if a Covered Entity knows about a material breach or violation of the contract by the Business Associate, it must take reasonable steps to cure the breach or end the violation, and, if unsuccessful, terminate the contract with the Business Associate.<sup>250</sup>

2.6.2.4 *Patient Rights*

One of the most significant aspects of the Privacy Rule is the creation of new patient rights to access and gain more control over the use and disclosure of their PHI. Covered Entities must have written policies and procedures to facilitate these rights, which are summarized below.

*Access to Information*

The Privacy Rule grants patients new rights to inspect and obtain copies of their PHI maintained in “designated record sets.” Designated record sets are clinical, billing, and other records about a patient used in whole or in part to make decisions about that patient. The right to request access does not apply to: (1) psychotherapy notes; (2) PHI compiled in reasonable anticipation of or for use in civil, criminal, or administrative actions or proceedings; and (3) certain types of PHI maintained by the Covered Entity that are subject to or exempt from the Clinical Laboratory Improvements Act of 1988. A Covered Entity must permit an individual to request access to inspect or obtain a copy of PHI about the individual in a designated record set but may require such request to be in writing, provided that the entity informs the individual of that requirement. Attorneys who represent physicians and medical groups are encouraged to review 45 C.F.R. 164.524 to determine the reviewable and nonreviewable grounds for denying a patient’s request to access their PHI and the time limits within which a Covered Entity must respond to the patient’s request (between thirty and ninety days, depending upon the circumstances).<sup>251</sup>

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<sup>249</sup> 45 C.F.R. § 164.502(e). DHHS has published proposed model Business Associate Contract provisions, *available online at* [www.hhs.gov/ocr/hipaa/propmods.pdf](http://www.hhs.gov/ocr/hipaa/propmods.pdf).

<sup>250</sup> 45 C.F.R. § 164.504(e)(1).

<sup>251</sup> 45 C.F.R. § 164.524.

*Amendments*

The Privacy Rule grants patients the right to request an amendment of the PHI contained in designated record sets. Covered Entities may deny a request to amend if they determine that the PHI: (1) was not created by the Covered Entity unless the individual provides a reasonable basis to believe that the originator of the PHI is no longer able to act on the requested amendment; (2) is not part of a designated record set; (3) would not be available for inspection under the individual's right to inspection; or (4) is accurate and complete. A Covered Entity has between thirty and ninety days to respond to a patient's request for an amendment depending upon the circumstances. If a Covered Entity accepts an amendment request, it must make reasonable efforts to provide the amendment to persons that the individual identifies as needing it, as well as to persons that the Covered Entity knows might rely on the information to the patient's detriment. If the request is denied, Covered Entities must provide the individual with a written denial and allow the individual to submit a statement of disagreement for inclusion into the record. A Covered Entity must amend PHI in its designated record set upon receipt of notice to amend from another Covered Entity. The Covered Entity also must notify the patient of the amendment.<sup>252</sup>

*Accounting of Disclosures*

An individual has a right to receive a summary of all PHI disclosures made by a Covered Entity in the six-year period preceding the date on which the accounting is requested (the six-year period does not include information before April 14, 2003), except for disclosures:

- (a) To carry out TPO;
- (b) To the individual or the individual's personal representative;
- (c) For a HIPAA-compliant authorization;
- (d) For notification of or to persons involved in an individual's healthcare or payment for healthcare, for disaster relief, or for facility directories;
- (e) Of a limited data set;
- (f) For a national security or intelligence purpose;
- (g) To correctional institutions or law enforcement officials having lawful custody of an individual;
- (h) To otherwise permitted or required uses or disclosures; or
- (i) That occurred before April 14, 2003.

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<sup>252</sup> 45 C.F.R. § 164.526.

There are specific content requirements for the accounting of disclosures, and a Covered Entity must respond to a request for an accounting within sixty or ninety days, depending on the circumstances.<sup>253</sup>

### *Further Restrictions*

The Privacy Rule provides individuals with the right to make a request to further restrict the uses and disclosure of their PHI for: (a) TPO purposes; (b) disclosure to persons involved in the individual's healthcare or payment for healthcare; or (c) disclosure to notify family members or others about the individual's general condition, location, or death. A Covered Entity is not required to agree with these requests, but if it does, then it must document the agreement and comply with the further restrictions. Even if a Covered Entity agrees to additional restrictions, that agreement is not effective under the Privacy Rule to prevent uses or disclosures:

- (1) To the individual,
- (2) For facility directories,
- (3) For any of the public-good disclosures, or
- (4) To treat the individual in an emergency.<sup>254</sup>

### *Alternative Communications*

The Privacy Rule allows individuals to request alternative means or locations than those typically provided by the Covered Entity to receive communications about their PHI. If an individual's request is reasonable, then the Covered Entity must comply with that request. A Covered Entity can require an individual to make a written request when the individual desires alternative communications. A Covered Entity also may require information on the following: how payment will be handled, a new or alternative address, and any additional method of contacting the individual before accommodating the individual's request.<sup>255</sup>

### 2.6.3 The Security Rule

The Security Rule applies to Covered Entities that transmit electronic PHI (ePHI) and establishes minimum standards for protecting ePHI. Unlike the Privacy Rule, the Security Rule does not include standards for PHI in nonelectronic forms. Covered Entities should have had Security Rule compliance plans well established to meet the April 20, 2005, deadline. Compliance with the Security Rule required Covered Entities to begin the following procedures:

- (1) Assess current security, risks and gaps;
- (2) Develop security policies and procedures;

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<sup>253</sup> 45 C.F.R. § 164.528.

<sup>254</sup> 45 C.F.R. § 164.522(a).

<sup>255</sup> 45 C.F.R. § 164.522(b).

- (3) Implement security measures and solutions;
- (4) Document its analysis, decisions and rationale for its decisions; and
- (5) Periodically review and update security measures and documentation.

The substantive sections of the Security Rule that require these procedures can be categorized as follows:

- (a) Security standards;
- (b) Administrative safeguards;
- (c) Physical safeguards;
- (d) Technical safeguards;
- (e) Organizational requirements;
- (f) Policies and procedures requirements; and
- (g) Documentation requirements.

Outlined below are the requirements for each of these sections.

#### 2.6.3.1 *Security Standards*

The Security Rule provides a flexible approach to compliance by making its requirements scalable and technology neutral. This allows Covered Entities to consider the factors comprising their practice when they are determining what security measures are necessary to meet the compliance requirements. Those factors include the size, cost of security measures, complexity, technical infrastructure and capabilities of the Covered Entity, and the potential risks to the ePHI in their practice.<sup>256</sup> To meet the compliance requirements, a Covered Entity must have in place reasonable and appropriate administrative, technical, and physical safeguards to ensure the integrity and confidentiality of ePHI. The Security Rule also requires that the Covered Entity protect ePHI against any reasonably anticipated threats or hazards to the security or integrity of the ePHI and against reasonably anticipated unauthorized uses or disclosures of the ePHI.<sup>257</sup>

The Security Rule's administrative, physical and technical safeguards each consists of a number of standards, which, in turn, generally comprise a number of "implementation specifications" (detailed instructions for implementing a particular standard), which are either required or addressable. If an implementation specification is required, a Covered Entity must implement policies and/or procedures that meet those requirements. If an implementation specification is addressable, a Covered Entity must assess whether the addressable specification is a reasonable and appropriate safeguard for its practice. If a Covered Entity decides not to

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<sup>256</sup>45 C.F.R. § 164.306(b).

<sup>257</sup>42 U.S.C. § 1320-2(d).

implement an addressable specification based on its assessment, then it must document the reason and, if reasonable and appropriate, implement an equivalent alternative measure that still meets the intent of the standard. From a legal standpoint, the key is to document compliance decision-making.

2.6.3.2 *Administrative Safeguards*

*Security Management*

The security management standard requires Covered Entities to implement policies and procedures to prevent, detect, contain, and correct security violations. To do this, a Covered Entity must conduct a risk analysis to assess the risks and vulnerabilities that could harm the confidentiality, integrity and availability of the ePHI maintained by the Covered Entity. The probability of PHI becoming corrupted also must be assessed. After conducting the risk analysis, the Covered Entity must manage the risk by implementing cost-effective security measures to reduce the organization's risk to reasonable and appropriate levels that ensure the confidentiality, integrity, and availability of its ePHI. The security management process also requires implementing a sanctions policy that penalizes workforce members for failing to comply with the Covered Entity's security policies and procedures. The final aspect of this standard requires Covered Entities to implement regular internal reviews of their security controls.<sup>258</sup>

*Assigned Security Responsibility*

All Covered Entities must assign security responsibility to one individual who will act as its security manager. The security manager will be responsible for the development and implementation of the policies and procedures required by the Security Rule. The security manager must be a person with authority or must report to a person with authority. The security manager's goal is to create a comprehensive and realistic security management program for the Covered Entity. Many people from the Covered Entity's workforce will be involved in creating the security management program, and all will be involved in its implementation.<sup>259</sup>

*Workforce Security and Access Management*

The workforce security and access management standards go hand in hand. The workforce security standard requires Covered Entities to implement policies and procedures to ensure workforce members have access to ePHI in their practice while preventing access to individuals who should not have it. Access management requires Covered Entities to implement policies and procedures for authorizing access to ePHI that is consistent with the Privacy Rule. There are several implementation specifications under these two standards that are not described here that a Covered Entity must address. These specifications concern authorization procedures for and supervision of the workforce, procedures for terminating workforce members and access procedures, policies and documentation requirements.<sup>260</sup>

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<sup>258</sup> 45 C.F.R. § 164.308(a)(1).

<sup>259</sup> 45 C.F.R. § 164.308(a)(2).

<sup>260</sup> 45 C.F.R. §§ 164.308(a)(3), 164.308(a)(4).

*Security Awareness and Training*

The security awareness and training standard is an essential component of all security strategies and involves the implementation of a security awareness and training program for all workforce members, including management. The training should include, but is not limited to, these elements: password maintenance, incident reporting, contingency plans, viruses and other forms of malicious software and the importance of log-in monitoring. Training should be well documented and done periodically. The amount and timing of training should be a constantly evolving process for environmental and operational changes affecting the security of ePHI.<sup>261</sup> Covered Entities should also use periodic security reminders to heighten their workforce's security awareness.<sup>262</sup>

*Security Incidents and Procedures*

The Security Rule requires Covered Entities to have policies and procedures to address security incidents. These policies and procedures must include provisions requiring the Covered Entity to identify and respond to suspected or known security incidents; to mitigate, to the extent possible, any harmful effects of the security incidents that are known to the Covered Entity and to document the security incidents and their outcomes.<sup>263</sup>

*Contingency Plan*

Covered Entities must have a contingency plan for responding to an emergency or other incident that damages the systems containing ePHI. The contingency plan standard includes required implementation specifications for a data backup plan and a disaster recovery plan. These specifications require Covered Entities to have procedures to create and maintain retrievable exact copies of ePHI and procedures to restore any loss of data. This standard also has two addressable implementation specifications not described here concerning testing and revision of contingency plans and assessing applications and "data criticality analysis."<sup>264</sup>

*Evaluation*

The evaluation standard requires Covered Entities to perform a periodic technical and nontechnical evaluation of their practice regarding the Security Rule, and to respond on an ongoing basis to environmental or operational changes that affect the security of their ePHI.<sup>265</sup>

*Business Associate Contracts*

The Business Associate Contracts standard is the final standard in the administrative safeguards section of the Security Rule. This standard requires Covered Entities to have written

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<sup>261</sup> Health Insurance Reform: Security Standards; Final Rule, 68 Fed. Reg. 8350 (Feb. 20, 2003) (to be codified at 45 C.F.R. 164.308(a)(5)(i)).

<sup>262</sup> 45 C.F.R. § 164.308(a)(5).

<sup>263</sup> 45 C.F.R. § 164.308(a)(6).

<sup>264</sup> 45 C.F.R. § 164.308(a)(7).

<sup>265</sup> 45 C.F.R. § 164.308(a)(8).

agreements with their Business Associates providing reasonable assurances that their Business Associates will protect ePHI according to the Privacy and Security Rules.<sup>266</sup>

### 2.6.3.3 *Physical Safeguards*

The following are the four standards under the physical safeguards component of the Security Rule:

- (1) Facility access controls;
- (2) Workstation use;
- (3) Workstation security; and
- (4) Device and media controls.

Facility access controls require Covered Entities to implement policies and procedures limiting physical access to their electronic information systems and the facilities in which the information systems are housed while ensuring that properly authorized access is allowed to ePHI. There are several addressable implementation specifications under this standard that are not described here but that must be addressed by Covered Entities. These implementation specifications apply to contingency operations, facility security plans and access control and validation procedures.

The workstation use and workstation security standards require Covered Entities to have policies and procedures that specify the functions that can be performed on workstations and the manner in which those functions are to be performed. The workstation policies must address the physical attributes of the surroundings near workstations that have access to ePHI, and they must implement physical safeguards for these workstations.

The device and media controls standard requires Covered Entities to implement policies and procedures that govern the receipt and removal of hardware and other electronic media that contains ePHI into and out of the Covered Entity's facilities. It also requires Covered Entities to implement policies and procedures for the removal of ePHI from electronic media before such media's reuse and for disposing of ePHI and/or the electronic hardware on which it is stored.<sup>267</sup>

### 2.6.3.4 *Technical Safeguards*

Technical safeguards address technology and the policy and procedures for its use that protect ePHI and control access to it. The Security Rule is technology neutral and therefore Covered Entities are required to determine how to implement the technology safeguards by factoring the size, cost of security measures, complexity, technical infrastructure and capabilities of the Covered Entity, as well as the potential risks to ePHI in their practice. Listed below are the technology safeguards standards with commentary on their implementation specifications.

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<sup>266</sup> 45 C.F.R. § 164.308(b)(1).

<sup>267</sup> 45 C.F.R. § 164.310.

*Access Control*

The access control standard requires Covered Entities to implement technical policies and procedures for information systems with ePHI that allow access only to those persons or software programs that have been granted access under the information access management standard discussed above. This standard is the actual implementation of the technical policies and procedures that perform access control functions. It requires unique identifiers to be assigned to track user identities and procedures for obtaining necessary ePHI during an emergency. A Covered Entity must address whether to include automatic log-off procedures and encryption and decryption mechanisms within their practice under this standard.<sup>268</sup>

*Audit Control*

The audit controls standard requires Covered Entities to implement hardware, software, and/or procedural mechanisms that record and examine activity in information systems that contain or use ePHI.<sup>269</sup>

*Integrity*

The integrity standard requires Covered Entities to implement policies and procedures to protect ePHI from improper alteration and destruction. Covered Entities must address whether it is necessary to implement electronic mechanisms within their practice to corroborate that ePHI has not been improperly altered or destroyed.<sup>270</sup>

*Authentication*

The authentication standard requires Covered Entities to implement policies and procedures to verify that a person or entity seeking access to ePHI is actually that person or entity. This standard often works with the access control standard in which a person or entity has specific procedures for authentication once they have been granted appropriate access.<sup>271</sup>

*Transmission Security*

The transmission security standard requires Covered Entities to implement technical security measures to guard against unauthorized access to ePHI being transmitted over electronic communications networks. Covered Entities must address whether they need to implement a mechanism to encrypt ePHI or implement security measures to ensure that electronically transmitted ePHI is not improperly modified without detection until disposed of through the proper process.<sup>272</sup>

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<sup>268</sup> 45 C.F.R. § 164.312(a)(1).

<sup>269</sup> 45 C.F.R. § 164.312(b).

<sup>270</sup> 45 C.F.R. § 164.312(c).

<sup>271</sup> 45 C.F.R. § 164.312(d).

<sup>272</sup> 45 C.F.R. § 164.312(e).

2.6.3.5 *Organizational Policies and Procedures, and Documentation Requirements*

The organizational requirements standard is linked to the Business Associate Contract standard discussed in the administrative safeguards portion of the Security Rule. It requires Business Associate Agreements or other written arrangements between Covered Entities and their Business Associates. The policies and procedures standard requires Covered Entities to implement reasonable and appropriate policies and procedures to comply with the standards, implementation specifications and other requirements of the Security Rule.<sup>273</sup>

The documentation standard requires Covered Entities to maintain implemented policies and procedures, actions, activities or assessments to comply with the Security Rule for a period of six years from the date of creation or the date they were last in effect, whichever is later. These documents must be in a written format, which may be electronic, and must be available to those who are required to implement the policies and procedures associated with them. The documentation standard also requires that a Covered Entity's security policies and procedures be updated, as needed, to respond to changes affecting the security of their ePHI.<sup>274</sup>

2.6.4 Enforcement

CMS has been designated by the secretary of DHHS to enforce the HIPAA administrative simplification provisions, with the exception of the Privacy Rule. Privacy Rule enforcement is the responsibility of the DHHS Office for Civil Rights. Both DHHS and CMS have stated that they will focus on obtaining voluntary compliance by providing technical assistance.<sup>275</sup> They also stated they will use a complaint-driven approach to enforce HIPAA's provisions.

Civil and criminal penalties are provided by HIPAA for violating its standards and requirements. The statute provides that the secretary of the DHHS will impose civil penalties of not more than \$100 for each violation of a particular standard, with the total amount of all violations of the identical requirement not exceeding \$25,000 per year. The statute also provides the following exceptions where civil penalties are not to be imposed: (1) where the offense is punishable under the HIPAA criminal provisions; (2) if the violator did not know, and by exercising reasonable diligence would not have known of the violation; or (3) where the failure to comply is caused by "reasonable cause" rather than "willful neglect" and the alleged violator takes action to cure the failure during the first 30 days following actual knowledge of the noncompliance or when the person should have known of the noncompliance.<sup>276</sup>

The criminal penalties that HIPAA imposes can be severe for certain violations. A person who knowingly, and in violation of the Privacy Rule, discloses PHI to another individual faces a range of possible penalties depending on the facts. The base set of penalties includes a fine of not more than \$50,000 and imprisonment of not more than one year, or both. If the offense is

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<sup>273</sup> 45 C.F.R. §§ 164.314, 164.316(a).

<sup>274</sup> 45 C.F.R. § 164.316(b).

<sup>275</sup> 45 C.F.R. § 160.304.

<sup>276</sup> 42 U.S.C. § 1320d-5.

committed under false pretenses, the person may be fined not more than \$100,000 and imprisoned for not more than five years, or both. If the offense is committed with the intent to sell, transfer, or use PHI for commercial advantage, personal gain, or malicious harm, the person may be fined not more than \$250,000 and imprisoned for not more than 10 years, or both. The DOJ enforces HIPAA's criminal sanctions.<sup>277</sup>

Although HIPAA does not provide an individual a direct and private right of action to enforce violations, it does provide for a complaint process. Individuals cannot directly enforce HIPAA, but violations of the Act could result in liability or increase the liability of practices under other laws. Therefore, HIPAA raises the bar for acceptable privacy and security practices for tort, negligence, and other liability.

### 2.6.5 Preemption

The Privacy and Security Rules preempt state laws that conflict with them. Congress has, however, carved out the following exceptions: (1) more stringent state laws, (2) exceptions determined by the secretary of the DHHS, (3) state reporting laws, and (4) healthcare reporting and informational laws.<sup>278</sup>

### 2.6.6 HIPAA Resources

The following websites are excellent sources of information for attorneys who deal with HIPAA issues when they represent physician and medical practice clients.

- **HHS Office of Civil Rights:** [www.hhs.gov/ocr/hipaa/](http://www.hhs.gov/ocr/hipaa/)
- **CMS-HIPAA:** [www.cms.hhs.gov/hipaa/hipaa2/](http://www.cms.hhs.gov/hipaa/hipaa2/)
- **Code of Federal Regulations 45 CFR 160 through 164:** [www.access.gpo.gov/nara/cfr/waisidx\\_02/45cfrv1\\_02.html](http://www.access.gpo.gov/nara/cfr/waisidx_02/45cfrv1_02.html)
- **Lawyers and HIPAA:** [www.lawyersandhipaa.com](http://www.lawyersandhipaa.com)

## 2.7 Legal Principles Affecting Physician Participation in Telemedicine Services

Telemedicine is generally defined as the use of technology to improve healthcare delivery. Many different definitions are used, but a common definition is “the practice of healthcare delivery, diagnosis, consultation, treatment, transfer of medical data, and education using interactive audio, video or data communications.”<sup>279</sup> Telemedicine is not a recent development but its use has been increasing for almost forty years and interest has increased dramatically since 1990 because of the demand for accessible and cost-effective healthcare.<sup>280</sup> The practice of telemedicine, though, faces many of the legal obstacles discussed below.

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<sup>277</sup> 42 U.S.C. § 1320d-6.

<sup>278</sup> 42 U.S.C. § 1320d-7.

<sup>279</sup> CAL. BUS. PROF. CODE § 2290.5(a)(i).

<sup>280</sup> *Cybermedicine: Defying and Redefining Patient Standards of Care*, 37 IND. L. REV. 845, 851 n.50 (2004).

## 2.7.1 State Organization and Licensure Issues

The corporate practice of medicine and fee-splitting prohibitions (discussed in Section 2.4) of both the practitioner's and the patient's states apply to the business organization surrounding the patient's treatment. The arrangement may be permissible in one state but impermissible in another.<sup>281</sup>

Each of the fifty states has rules that govern the ability of healthcare practitioners to "practice medicine."<sup>282</sup> Most states define the practice of medicine broadly to include telemedicine.<sup>283</sup> If the physician is employed by a hospital and provides telemedicine services as part of that employment, the hospital is subject to licensure requirements both in the state where it is located and the state where the patient is physically located.<sup>284</sup> Some states have started to license out-of-state physicians who practice telemedicine in their state.<sup>285</sup>

Although the initial licensing requirements are reasonably uniform among states, there are administrative and financial burdens to getting licenses in multiple states.<sup>286</sup> For example, physicians who physically practice in their home state but provide telemedicine services to patients in five other states must complete one in-state and five out-of-state applications for licensure, with six sets of accompanying documentation. They also must pay six registration fees.<sup>287</sup> Most states also require a physical appearance before the local licensing board for some applicants, which contributes to the time and expense of interstate licensing.<sup>288</sup>

Despite these burdens, telemedicine providers must comply with each state's licensure law. Failing to comply with these requirements may subject the provider to the suspensions, license revocation, and civil or criminal fines and penalties discussed in Section IV A in this chapter.<sup>289</sup>

A number of different licensing models have been proposed as a solution to the interstate licensing problem. These include federal telemedicine licensing legislation that would preempt state licensing statutes, a uniform act governing telemedicine licensing, state licensure solutions, and regional compacts to allow cross-border telemedicine practice.<sup>290</sup> As the demand for

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<sup>281</sup> Serbaroli, *supra* note 152, § 2800.12 (2004).

<sup>282</sup> *See supra* Section 2.4.

<sup>283</sup> *See, e.g.* KAN. STAT. ANN. § 65-2802(a).

<sup>284</sup> Serbaroli, *supra* note 152, § 2800.12 (2004).

<sup>285</sup> *See, e.g.* OHIO REV. CODE ANN. § 4731.296.

<sup>286</sup> Alison M. Sultenic, *Crossing Borders: The Licensure of Interstate Telemedicine Practitioners*, 25 J. LEGIS. 1, 71 (1999); *see also* Am. Med. Assoc., *Physician Licensure: An Update of Trends*, available online at [www.ama-assn.org/ama/pub/category/2378.html](http://www.ama-assn.org/ama/pub/category/2378.html) (hereafter AMA Article).

<sup>287</sup> Am. Med. Assoc., *Physician Licensure: An Update of Trends*, available online at [www.ama-assn.org/ama/pub/category/2378.html](http://www.ama-assn.org/ama/pub/category/2378.html).

<sup>288</sup> *Id.*

<sup>289</sup> Serbaroli, *supra* note 152, § 2800.12 (2004); HEALTH LAW HANDBOOK § 3:2 (Alice G. Gosfield ed., 2001).

<sup>290</sup> HEALTH LAW HANDBOOK § 3:2 (Alice G. Gosfield ed., 2001). *See also* Serbaroli, *supra* note 152, § 2800.12 (2004). *See also* AMA Article, *supra* note 286, at 5.

telemedicine increases, there may be a trend toward national licensure and medical standards and away from traditional state licensing functions.<sup>291</sup>

### 2.7.2 Liability

Another consideration for physicians practicing telemedicine is the malpractice suits. Because of the uncertainty surrounding the duty of care and potential malpractice liability, a physician practicing telemedicine must be covered by his or her medical malpractice or general liability policy.<sup>292</sup> The majority of malpractice policies does not cover unlicensed medical activities and cover only incidents concerning acts that are part of physician-patient face-to-face consultations.<sup>293</sup> If a state has a specific statutory requirement requiring a license, physicians could be exposed to liability if they provide telemedicine services in a state in which they are not licensed because many insurance policies require physicians to be medically licensed as a condition of coverage.<sup>294</sup>

Physicians should also ensure that their medical malpractice or general liability insurance policy covers errors in whatever telecommunication technologies are used. Equipment malfunction or data transmission problems could expose a provider to malpractice liability. To protect against liability, physicians should require that each patient execute an informed consent disclosure indicating the patient's consent to the practice of telemedicine.<sup>295</sup> Physicians practicing telemedicine must also keep accurate and complete medical records as required under both their state's laws and the laws of the state where the patient resides to comply with all applicable laws.<sup>296</sup>

### 2.7.3 Fraud and Abuse/Stark Issues

There are potential fraud and abuse and Stark issues for telemedicine arrangements similar to the traditional practice of medicine. The use of telecommunications technology in the healthcare industry also creates many new issues because of Internet business. Though hospitals may be in the best position to extend telemedicine services to physicians, all parties should be concerned about possible violations. A referral based on the provision of telemedicine equipment may pose fraud and abuse and Stark issues. State and federal regulators have begun closely analyzing telemedicine arrangements for fraud and abuse violations.

The primary bodies of law to be considered are the federal Anti-Kickback Statute and the Stark law, though state law also should be considered.<sup>297</sup> As previously discussed, the federal Anti-Kickback Statute prohibits the offer, solicitation, payment, or receipt of any remuneration—whether direct or indirect, overt or covert, or in cash or in kind—intended to induce, or in return

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<sup>291</sup> Serbaroli, *supra* note 152, § 2800.12 (2004).

<sup>292</sup> Robert A Gergerry, *Legal Ramifications of Digital Hospitals*, 14 HEALTH LAWYER 27, 30 (2002).

<sup>293</sup> *Id.*

<sup>294</sup> *Id.*

<sup>295</sup> *Id.*

<sup>296</sup> *Id.*

<sup>297</sup> See the discussions above in Sections 2.1 and 2.2 for a more in-depth discussion of the statutes.

for, a referral of patients paid in whole or in part by Medicare or Medicaid.<sup>298</sup> Although some telemedicine arrangements may fall under safe harbors, “some promotional tools that are common in e-commerce, such as ‘per click’ payment arrangements, can be problematic in the E-health context.”<sup>299</sup> And although the per-click payment arrangements do not necessarily violate the Anti-Kickback Statute, they are likely to be closely reviewed. If the per-click payment arrangement links directly to an Internet purchase (*i.e.*, a physician’s organization’s website that links to a pharmacy), it may violate the Anti-Kickback Statute because the healthcare provider receives remuneration based on the referral rate provided by the fee charged per click.<sup>300</sup>

Promotional banners and other types of promotional and marketing tools commonly used by Internet businesses may violate the Anti-Kickback Statute if they either advertise for or link to online purchases.<sup>301</sup> Other arrangements that may be in violation of the Anti-Kickback Statute are the offer of free email services, online publications, or computer equipment by companies that sell items or services reimbursable under Medicare or Medicaid.<sup>302</sup>

The OIG has begun issuing advisory opinions on telemedicine arrangements.<sup>303</sup> In Advisory Opinion 98-18, the OIG analyzed an arrangement in which an ophthalmologist, through teleconferencing equipment, would provide consultations with patients of an optometrist to determine whether the patients required services beyond what the optometrist could provide.<sup>304</sup> The “host” optometrist would not receive any remuneration from the ophthalmologist and would not advertise the telemedicine consultations, and neither the ophthalmologist nor the optometrist would bill the patient or any third party for the telemedicine consultations. The OIG therefore determined that the host physician was not receiving any value for the consultations, and it would not impose sanctions on the relationship.<sup>305</sup>

In Advisory Opinion No. 99-14, the OIG considered whether a tax-exempt health system could continue to subsidize the expenses of a rural telemedicine program after the expiration of a federal grant program.<sup>306</sup> Here the equipment would be provided without charge, distinguishing it from the situation in Advisory Opinion No. 98-18, where the recipient of the consultation would make a payment at fair market value for the use of the telemedicine equipment, and the arrangement would be safe harbored.<sup>307</sup> Nonetheless, assuming the program would be operated in compliance with the requirements of the relevant federal grant programs, the OIG was satisfied that the system’s support of the network was consistent with congressional intent and

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<sup>298</sup> 42 U.S.C. §§ 1320a-7b(b)(1); (2).

<sup>299</sup> HEALTH LAW HANDBOOK § 13:16 (Alice G. Gosfield ed., 2004).

<sup>300</sup> *Id.*

<sup>301</sup> *Id.*

<sup>302</sup> *Id.*

<sup>303</sup> The full opinions are *available online at* [www.oig.hhs.gov](http://www.oig.hhs.gov).

<sup>304</sup> Office of Inspector Gen., U.S. Dep’t of Health & Human Servs., Adv. Op. No. 98-18 (issued Nov. 25, 1998, posted Dec. 3, 1998).

<sup>305</sup> *Id.*

<sup>306</sup> Office of Inspector Gen., U.S. Dep’t of Health & Human Servs., Adv. Op. No. 99-14 (issued Dec. 28, 1999, posted Jan. 6, 2000).

<sup>307</sup> *Id.*

the continued operation of the network presented an opportunity for significant community benefit.<sup>308</sup>

In Advisory Opinion 04-07, the OIG analyzed a health system’s provision of professional consultative services to low-income schoolchildren in predominantly rural areas through a sponsored telemedicine network.<sup>309</sup> Though many of the students receiving services were potential Medicare or Medicaid beneficiaries, no state or federal healthcare program currently provided any reimbursement.<sup>310</sup> The OIG found that, though the arrangement may generate prohibited remuneration under the Anti-Kickback Statute if the requisite intent to induce or reward referrals of federal healthcare program business were present, it would not impose sanctions in connection with the arrangement.<sup>311</sup>

The Stark law is discussed more comprehensively in Section I of this chapter. It prohibits self-referral arrangements, barring physicians from making referrals for certain designated health services reimbursable under Medicare and Medicaid to entities in which they have financial or ownership relationships unless the relationship falls within an exception.<sup>312</sup> The Stark law assumes a financial relationship is prohibited unless it falls within an exception. It may be implicated in marketing arrangements similar to those examined under the Anti-Kickback Statute.<sup>313</sup>

In designing a telemedicine program, counsel to hospitals and physicians should review both the state and federal anti-kickback and fraud and abuse laws and the Stark law to ensure that prohibited remuneration is not offered by the hospital to the physician or by any provider to the patient for participation in the telemedicine service.<sup>314</sup>

#### 2.7.4 Medicare and Medicaid Reimbursement

##### 2.7.4.1 *Medicare*

Though industry representatives have been pushing for flexibility and freedom for telemedicine services for many years, CMS still has several restrictions for Medicare telemedicine reimbursement. On January 1, 2002, CMS’ final rule regarding reimbursement for telemedicine (CMS refers to telemedicine as “telehealth services”) under the Medicare, Medicaid and the State Children’s Health Insurance Program Benefits Improvement and Protection Act of 2000 (BIPA) went into effect.<sup>315</sup> Although BIPA expands reimbursable telemedicine, there are still many limitations.

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<sup>308</sup> *Id.*

<sup>309</sup> Office of Inspector Gen., U.S. Dep’t of Health & Human Servs., Adv. Op. No. 04-07 (issued June 17, 2004, posted June 24, 2004).

<sup>310</sup> *Id.*

<sup>311</sup> *Id.*

<sup>312</sup> 42 U.S.C. § 1395nn(a); *see supra* Section 2.1.

<sup>313</sup> HEALTH LAW HANDBOOK § 13:16 (Alice G. Gosfield ed., 2004).

<sup>314</sup> Robert A Gergerry, *Legal Ramifications of Digital Hospitals*, 14 HEALTH LAWYER 27, 32 (2002).

<sup>315</sup> The complete final rule is *available online at* [www.cms.hhs.gov](http://www.cms.hhs.gov).

Currently, BIPA covers telemedicine provided to an eligible beneficiary in an originating site (the site where the patient is being treated) in a county outside of an MSA, an originating site in a federally designated HPSA, or from any entity that participated in a federal telemedicine project that was approved by or received funding from the DHHS as of December 31, 2000, regardless of location.<sup>316</sup> Although BIPA has expanded geographic eligibility—from including only HPSAs to include non-MSAs—it limits coverage in HPSAs by defining originating sites as the site where the patient is when the service is provided.<sup>317</sup> The originating site must be a physician or practitioner’s office, a critical access hospital, a rural health clinic, or a federally qualified health center.<sup>318</sup>

Additionally, BIPA expands the types of care covered. Medicare will now reimburse for office visits, outpatient visits, professional consultations, psychiatric diagnostic interview examinations, individual psychotherapy and pharmacologic management.<sup>319</sup> Medical professionals who may bill for telemedicine under BIPA include physicians, nurse practitioners, physician’s assistants, nurse midwives and specialists.<sup>320</sup> The physician or practitioner must be legally authorized to practice by the state in which he or she performs the services.<sup>321</sup>

As a condition for Medicare payment, BIPA also requires the use of an “interactive telecommunications system” that allows real-time audio and video communication between the physician or practitioner and the patient.<sup>322</sup> Email systems, telephones, facsimile machines and store and forward technologies do not meet the requirements of an interactive telecommunications system.<sup>323</sup>

A physician or practitioner furnishing telemedicine to an eligible beneficiary will be paid equal to the current fee schedule amount that the physician or practitioner would have been paid under Medicare had the service been furnished in person.<sup>324</sup> The Act also provides for a facility fee payment to the originating site.<sup>325</sup> For services furnished from October 1, 2001 through December 31, 2002, the payment to the originating site is the lesser of the actual charge or the originating site facility fee of \$20.<sup>326</sup> For each subsequent year, the facility fee will be increased by the percentage increase in the Medicare Economic Index.<sup>327</sup>

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<sup>316</sup> 42 C.F.R. § 410.78(b)(4).

<sup>317</sup> 42 C.F.R. § 410.78(a)(4).

<sup>318</sup> 42 C.F.R. § 410.78(b)(3).

<sup>319</sup> 42 C.F.R. § 410.78(b).

<sup>320</sup> 42 C.F.R. § 410.78(b)(2). A physician or practitioner telepresenter is not required unless the physician or practitioner determines that it is medically necessary. 42 C.F.R. § 410.78(c).

<sup>321</sup> 42 C.F.R. §§ 410.78(b)(1).

<sup>322</sup> 42 C.F.R. § 410.78(a)(3); (b).

<sup>323</sup> 42 C.F.R. § 410.78(a)(3). There is an exception to the interactive telecommunications system requirement for federal telemedicine demonstration programs in Alaska or Hawaii only. 42 C.F.R. § 410.78(d).

<sup>324</sup> 42 C.F.R. § 414.65(a)(1).

<sup>325</sup> 42 C.F.R. § 414.65(b)(1).

<sup>326</sup> *Id.*

<sup>327</sup> *Id.*

2.7.4.2 *Medicaid*

CMS has not formally defined what constitutes telemedicine for the Medicaid program, and federal Medicaid law does not recognize telemedicine as a distinct service. Currently, at least eighteen states are allowing services provided via telemedicine for reasons that include improved access to specialists for rural communities and reduced transportation costs.<sup>328</sup>

Federal Medicaid guidelines require that all physicians practice within the scope of their state practice act.<sup>329</sup> Some states have enacted legislation that requires providers using telemedicine technology across state lines to have a valid state license in the state where the patient is located.<sup>330</sup> These requirements and restrictions placed on physicians by the state are binding under current Medicaid rules. Additionally, Medicaid covered services, including those with telemedicine applications, must satisfy federal requirements of efficiency, economy and quality of care.<sup>331</sup>

2.7.4.3 *Private Insurers*

Many private insurers will not reimburse for telemedicine, although some states, such as California and Kentucky, have statutorily required that they reimburse the same as they would for traditional, face-to-face consultations.<sup>332</sup> Since 2001, some private insurers have covered physician-patient email visits and web-based visits.<sup>333</sup> There is no uniformity among states or private health plans, so counsel should consult his or her physician client's applicable state law and the terms and conditions of the applicable private health insurance plan.

2.7.5 Privacy and Confidentiality

2.7.5.1 *Federal Law*

The movement to telemedicine creates unique problems regarding the privacy and integrity of a patient's confidential medical records. Medical records and personal health information maintained by health plans, healthcare clearinghouses, and healthcare providers who transmit health information in electronic form as part of a standard transaction are protected under HIPAA regulations.<sup>334</sup> The Privacy Rule protects all "individually identifiable health information" held or transmitted by a Covered Entity or its Business Associate, in *any* form or media, whether electronic, paper, or oral.<sup>335</sup>

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<sup>328</sup> Donel Lauderdale et al., *Medicaid and Telemedicine in 2002*, available online at [tie.telemed.org/legal/medic/medicaid2002.pdf](http://tie.telemed.org/legal/medic/medicaid2002.pdf). See [www.cms.hhs.gov/states/telelist.asp](http://www.cms.hhs.gov/states/telelist.asp) for a summary of state Medicaid laws relating to telemedicine.

<sup>329</sup> 42 U.S.C. § 1396r-2.

<sup>330</sup> Centers for Medicare & Medicaid Services, *Medicaid and Telemedicine*, available online at [www.cms.hhs.gov/states/telemed.asp](http://www.cms.hhs.gov/states/telemed.asp).

<sup>331</sup> *Id.*

<sup>332</sup> See, e.g., CAL. HEALTH & SAFETY CODE § 1374.13; KY. REV. STAT. ANN. § 304.17A-138.

<sup>333</sup> See HEALTH LAW HANDBOOK § 13:15 (Alice G. Gosfield ed., 2004).

<sup>334</sup> 42 U.S.C. § 1320d-1(a). From 14 HEALTH LAWYER 27, 29.

<sup>335</sup> 45 C.F.R. § 160.103.

The Privacy Rule is discussed in depth in Section 2.6.3. Individuals' PHI protections apply to telemedicine in the same way they do for traditional medicine. A physician interested in telemedicine should note that a "Business Associate" may include a website or software company that establishes a digital network for a hospital.<sup>336</sup> A Covered Entity may disclose protected health information to a Business Associate only if that Business Associate has provided the Covered Entity with adequate assurances that it will protect the confidentiality of the information.<sup>337</sup> A Covered Entity should enter into a written Business Associate Agreement and document those assurances with any entity that may receive protected patient information.<sup>338</sup>

The Security Rule, which applies to Covered Entities that transmit ePHI, is discussed in detail in Section 2.6.4. With a compliance date of April 20, 2005, all physicians practicing telemedicine should ensure that they have a Security Rule compliance plan in place. An entity that does not comply with HIPAA's regulations may face extensive civil and criminal penalties.<sup>339</sup> Any telemedicine arrangement must therefore be structured with HIPAA individual rights and minimum necessary requirements in mind.

#### 2.7.5.2 *State Law*

In general, state laws that are contrary to the Privacy Rule are preempted by federal requirements.<sup>340</sup> The preemption does not apply to state laws that provide greater privacy protections or privacy rights for such information.<sup>341</sup> Most states have some form of protection for health information. However, many state laws address confidentiality and privacy with statutes, regulations and/or cases, leaving both unanswered questions and overlap in the laws.<sup>342</sup> Though many state laws do not specifically include electronic health information, the laws defining the information protected are often broad enough to cover information in electronic form. A few states have enacted statutes specifically addressing the need to protect privacy and confidentiality for health information electronically transmitted or stored.<sup>343</sup>

Questions remain about the applicability of state statutes regulating privacy and security. The protections clearly apply to providers located in the respective states. It is unclear, though, whether the protections apply to out-of-state physicians delivering telemedicine services to patients located in the states.<sup>344</sup> Failure to follow the confidentiality requirements will generally result in a penalty to the provider, and thus the uncertainty and risk of being subject to such penalties may discourage providers from offering telemedicine services, especially across state lines.<sup>345</sup>

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<sup>336</sup> Robert A Gergerry, *Legal Ramifications of Digital Hospitals*, 14 HEALTH LAWYER 27, 30 (2002).

<sup>337</sup> 45 C.F.R. § 164.502(e).

<sup>338</sup> 45 C.F.R. §§ 164.502(e); 164.504(e).

<sup>339</sup> *See supra* Section 2.6.

<sup>340</sup> 45 C.F.R. § 160.203. *See supra* Section 2.6.

<sup>341</sup> 45 C.F.R. § 160.203(b).

<sup>342</sup> *See* HEALTH LAW HANDBOOK § 3:14 (Alice G. Gosfield ed., 2001).

<sup>343</sup> *See id.*

<sup>344</sup> *Id.*

<sup>345</sup> *Id.*

### 2.7.6 Other Agencies

Several other administrative agencies have regulatory authority over specific aspects of telemedicine. The Food and Drug Administration (FDA) has primary authority over the regulation of advertising and promotion of prescription drugs and medical devices. The agency also regulates the labeling of medical devices and prescription and over-the-counter drugs. Websites selling prescription drugs must comply with both the Food, Drug and Cosmetic Act<sup>346</sup> and state laws governing pharmacy licensure.<sup>347</sup> The FDA's Center for Devices and Radiological Health also is charged with ensuring the effectiveness and safety of medical devices used in telemedicine.<sup>348</sup>

The Federal Communications Commission has been involved in the promotion of telemedicine through its Rule Health Care Program.<sup>349</sup> The Securities and Exchange Commission may also become involved with any healthcare company issuing securities to investors and posting hyperlinks on its website.<sup>350</sup> The FTC is also involved in regulating telemedicine because of its role in investigating fraudulent websites under the Deceptive and Unfair Trade Practices Act.<sup>351</sup> The FTC has set forth the following goals for healthcare marketing:

- To help consumers find truthful and accurate information about products and services;
- To assist consumers in distinguishing legitimate health products and services from health scams; and
- To protect vulnerable consumers from injury.<sup>352</sup>

The FTC also has played a role in privacy enforcement.<sup>353</sup> The role of the DOJ is discussed above and applies equally to telemedicine and the traditional practice of medicine<sup>354</sup>

### 2.7.7 The Future

Obviously, there is a complex maze of federal and state laws, rules and regulations to consider when advising a physician on the practice of telemedicine. As reimbursement for telemedicine services becomes more accepted and more physicians provide care via telemedicine, the pressure for more uniform and national standards will increase.

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<sup>346</sup> 21 U.S.C. §§ 301 *et seq.*

<sup>347</sup> See HEALTH LAW HANDBOOK § 13:3 (Alice G. Gosfield ed., 2004).

<sup>348</sup> *Id.*

<sup>349</sup> See [www.rhc.universalservice.org](http://www.rhc.universalservice.org) for information on the program.

<sup>350</sup> See HEALTH LAW HANDBOOK § 13:5 (Alice G. Gosfield ed., 2004).

<sup>351</sup> 15 U.S.C. §§ 45 *et seq.*; see HEALTH LAW HANDBOOK § 13:5 (Alice G. Gosfield ed., 2004).

<sup>352</sup> *Id.* (citing Richard Cleland, Senior Attorney, Division of Advertising Practices, Bureau of Consumer Protection, Federal Trade Commission, White Paper: *The Promotion of Health Care Products and Services on the Internet: The Role of the Federal Trade Commission* (Sept. 11, 2000)).

<sup>353</sup> See HEALTH LAW HANDBOOK § 13:6 (Alice G. Gosfield ed., 2004).

<sup>354</sup> See *supra* Section 2.5.

## 2.8 Conclusion

Many of the key laws and regulations that regulate physician activity are complex and require a thorough understanding of the physician's or medical group's activity. Fortunately, guidance is available from the government agencies charged with enforcement of these laws and regulations. Some of this guidance is provided through formal means as detailed in this chapter. Further, much of the valuable guidance to legal counsel for physicians is available on a more informal basis through telephone consultation and discussion with representatives of the enforcement agency or agencies. It is good practice to get to know the counsel and administrative personnel for these agencies who are assigned responsibility for interpreting the laws they enforce.

Many will discuss hypothetical situations (where the client is not disclosed) to provide a sense of how the laws they enforce would apply to activity that is under consideration. This can be an invaluable tool, especially where application about particular laws and regulations and other published guidance concerning a client's situation or proposed activity is not clear. Attorneys for physicians and medical groups may decide that more formal guidance, such as an advisory opinion, is needed (and is likely to be provided if requested), or that more formal guidance is not necessary, or that an action or structure under consideration must either be abandoned or substantially revised. Therefore, building relationships with enforcement agency personnel through continuing legal education conference activity, bar association or medical society interaction with applicable enforcement agencies, and informal discussion is recommended.