I. Anti-Trust Restrictions and Scrutiny

A. Background

1. The Federal Trade Commission (“FTC”) and Department of Justice (“DOJ”) have not always been successful in challenging mergers involving health system providers. In fact, the 1990s saw the FTC and DOJ fail in their efforts to block six straight hospital mergers.\(^1\) The FTC’s complaint challenging the retrospective merger of two hospitals in Evanston, Illinois on February 10, 2004\(^2\) brought an end to this dry streak and the beginning of a winning era, as the FTC won eight consecutive cases as of its recent victory in the St. Luke’s case before the U.S. Court of Appeals for the Ninth Circuit in February 2015.\(^3\)

2. With the passage of the Affordable Care Act in 2010, the trend towards consolidation has continued as health systems face increased financial pressures to provide high quality care while reducing costs.\(^4\) The result is steady merger activity among healthcare providers.\(^5\)

B. Merger Enforcement in 2015 Involving Health Care Providers

1. October 2015: Two orthopedic practices in Berks County, Pennsylvania were charged with violations of U.S. antitrust law. The FTC alleged that Keystone, which combined six independent practices in 2011, held a 76% share of the market for orthopedic services in the county. This merger eliminated competition and allowed Keystone to raise prices with most health plans in the county. Similarly, Orthopaedic Associates, which split from Keystone in 2014, held a major presence in the same market. The parties reached a proposed settlement, which prohibits Keystone and Orthopaedic Associates from engaging in anticompetitive activity and requires that they obtain prior approval from the FTC before acquiring interests in each other or increasing their membership to other practices or orthopedists in the county.\(^6\)


2. March 2015: The FTC charged Phoebe Putney Health System, Inc., HCA Inc., and the Hospital Authority of Albany-Dougherty County with antitrust violations. The FTC alleged that the Hospital Authority’s acquisition of Palmyra Park Hospital, Inc. from HCA effectively created a hospital monopoly in the Albany, Georgia area. However, an Eleventh Circuit decision allowed the parties to complete the transaction, thereby creating circumstances that precluded divestiture as a form of relief. Instead, the consent agreement with the FTC requires that Phoebe Putney and the Hospital Authority give the FTC prior notice before acquiring any hospital or controlling interest in other healthcare providers for ten years. The agreement also prohibits them from objecting to regulatory applications by potential new hospital providers in the same area for five years.⁷

3. March 2015: The FTC brought charges that Community Health System, Inc.’s $7.6 billion acquisition of Health Management Associates Inc. would likely lessen competition for general acute care inpatient services in two local markets. Health Management is Community Health’s rival in health care systems in certain Alabama and South Carolina counties, so its acquisition by Community Health would eliminate price and quality competition and grant a near monopoly in general acute care services. The final settlement order requires Community Health to sell two medical centers and associated operations and businesses near those same counties to an FTC-approved buyer. Community Health is also required to provide prior notice to the FTC before acquiring a general acute care services provider in those areas for ten years.⁸

4. February 2015: Surgery Center Holdings, Inc. faced charges from the FTC that its acquisition of Symbion Holdings Corporation would likely be anticompetitive. According to the FTC, both companies operate several ambulatory surgery centers across the county that sell and provide outpatient surgical services to commercial health plans and patients. The merger would have combined the only two multi-specialty ambulatory surgical centers in the Orange City/Delton area of Florida, leaving only one alternative to Surgery Center in the area. The final settlement order required Surgery Center to divest Symbion’s ownership interest in the Blue Springs Center in Orange City, Florida to an FTC-approved buyer.⁹

C. Antitrust Laws


1. The three primary antitrust laws include the Sherman Act, the Federal Trade Commission Act, and the Clayton Act. A brief overview of these three laws is included below:

a. The Sherman Act prohibits “every contract, combination, or conspiracy in restraint of trade” and any “monopolization, attempted monopolization, or conspiracy or combination to monopolize.”\(^\text{10}\)

b. The Federal Trade Commission Act bans “unfair methods of competition” and “unfair or deceptive acts or practices.”\(^\text{11}\)

c. The Clayton Act addresses arrangements that the Sherman Act does not clearly prohibit, including mergers.\(^\text{12}\) Section 7 of the Clayton Act prohibits mergers and acquisitions where the effect “may be substantially to lessen competition, or to tend to create a monopoly.” The Clayton Act also prohibits certain discriminatory prices, services, and allowances in dealings between merchants. The Hart-Scott-Rodino Act amended the Clayton Act to require companies to notify the FTC and DOJ of proposed mergers or acquisitions of a certain size and allow for the FTC or DOJ to review the proposed arrangement. The Clayton Act also authorizes private parties to sue for triple damages when they have been harmed by conduct that violates either the Sherman or Clayton Act and to obtain a court order prohibiting the anticompetitive practice in the future.\(^\text{13}\)

2. In addition to the federal antitrust laws, many states also have antitrust laws that are enforced by state attorneys general or private plaintiffs. These state laws are often based on the federal antitrust laws.

D. Mergers and Enforcement

1. While some mergers are beneficial to the economy by allowing companies to operate more efficiently, the FTC and DOJ are concerned with mergers that have anti-competitive effects and can lead to higher prices, fewer or lower-quality goods or services, and less innovation.\(^\text{14}\)

2. The FTC and the DOJ Antitrust Division share jurisdiction over merger review and enforcement of federal antitrust laws.\(^\text{15}\) Under the Hart-Scott-Rodino Act, the FTC and DOJ review most of the proposed transactions that affect commerce in the United States and are over a certain size (although there are exceptions, generally the law requires companies to report a

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deal that is valued at more than $76.3 million). Either agency can take legal action to block deals that it believes would “substantially lessen competition.” After companies report a proposed deal, the agencies will conduct a preliminary review. Transactions requiring further review are assigned to one agency on a case-by-case basis depending on which agency has the most expertise in the given area. The parties to the transaction must wait thirty days (fifteen days in the case of a cash tender or bankruptcy transaction) before closing their deal during the preliminary review. Based on the results of its review, the respective agency can: (i) terminate the waiting period and allow the parties to consummate their transaction (referred to as an “early termination”); (ii) let the waiting period expire, which allows the parties to consummate the transaction; or (iii) extend the review and ask the parties to turn over more information so the agency can review in more detail how the transaction will affect competition (referred to as a “second request”). While the majority of deals reviewed by the FTC or DOJ are allowed to proceed after the preliminary review, if a second request is issued, the parties to the transaction must provide additional information. After the parties certify that they have substantially complied with the request, the respective agency has an additional thirty days (ten days in the case of a cash tender or bankruptcy) to complete its review and take any necessary action. The agency may: (i) close the investigation; (ii) enter into a settlement with the parties (also known as a “consent order”); or (iii) take legal action in federal district court or through the FTC’s administrative process to stop the transaction.

E. Health Care Statements

1. The FTC and DOJ have issued numerous publications providing guidance to the healthcare industry over the years, and the ACO Antitrust Policy Statement is not the first time the FTC and DOJ have addressed physician networks. For example, the FTC and DOJ issued the Statements of Antitrust Enforcement Policy in Health Care in 1993 and 1996 (the “Statements”).

2. The Statements specifically addressed physician networks. The Statements explained that the DOJ and FTC would not challenge, absent extraordinary circumstances, arrangements that come within certain “safety zones.” For non-exclusive physician network joint ventures, the safety zone applies if the physician participants share substantial financial risk and constitute thirty percent or less of the physicians in each physician specialty with active hospital staff privileges who practice in the relevant geographic market. For exclusive physician network joint ventures, the percentage is twenty percent. The FTC and DOJ provided examples of types of arrangements that involved sharing substantial financial risk, including capitation and use of financial incentives if the physicians, as a group, achieved certain cost-containment goals. For physician network joint ventures that fall outside the safety zones, the FTC and DOJ will apply the rule of reason analysis if the “physicians’ integration through the network is likely to produce significant efficiencies that benefit consumers, and any price agreements (or other agreements that would otherwise be per se illegal) by the network physicians are reasonably necessary to

17 Id.
18 Id.
19 Id.
realize those efficiencies.”

Physician network joint ventures that have agreed to share substantial financial risk would generally qualify, as would networks that are clinically integrated. As the Statements discuss, this type of clinical integration “can be evidenced by the network implementing an active and ongoing program to evaluate and modify practice patterns by the network’s physician participants and create a high degree of interdependence and cooperation among the physicians to control costs and ensure quality. This program may include: (1) establishing mechanisms to monitor and control utilization of health care services that are designed to control costs and assure quality of care; (2) selectively choosing network physicians who are likely to further these efficiency objectives; and (3) the significant investment of capital, both monetary and human, in the necessary infrastructure and capability to realize the claimed efficiencies.”

As noted above, in 2011, DOJ and FTC published the ACO Antitrust Policy Statement, which was “intended to ensure that health care providers have the antitrust clarity and guidance needed to form procompetitive ACOs that participate in both the Medicare and commercial markets.” Where applicable, the ACO Antitrust Policy Statement provides that “the Agencies will treat joint negotiations with private payers as reasonably necessary to an ACO’s primary purpose of improving health care delivery, and will afford rule of reason treatment to an ACO that meets CMS’s eligibility requirements for, and participates in, the Shared Savings Program and uses the same governance and leadership structures and clinical and administrative processes it uses in the Shared Savings Program to serve patients in the commercial markets.”

The ACO Antitrust Policy Statement includes an antitrust “safety zone” for certain ACOs which are seen as “highly unlikely to raise significant competitive concerns and, therefore, will not be challenged by the Agencies [i.e., DOJ or FTC] under the antitrust laws, absent extraordinary circumstances.” Other ACOs, which fall outside of the safety zone, will be subject to “rule of reason” analysis and will not invite antitrust challenge if they do not impede the functioning of a competitive market.

Since issuing the joint Statements with the DOJ, the FTC has issued several favorable advisory opinions on clinical integration arrangements.

21 Id.
22 Id.
25 76 Fed. Reg. at 67028. Generally, ACOs that are so regarded have relatively low combined shares (i.e., 30% or less) of “common service” in each ACO participant’s “primary service area.”
26 See FED. TRADE COMM’N, TriState Health Partners, Inc. Advisory Opinion (Apr. 13, 2009) [hereinafter TriState] (issuing a favorable opinion to a clinical integration program involving a selective application process, a $2,500 “joining fee”, a participating provider contract requiring cooperation with TriState’s clinical integration program and an agreement to be trained in and use TriState’s health information technology capabilities); see also FED. TRADE COMM’N, Greater Rochester Independent Practice Association, Inc. (“GRIPA”) Advisory Opinion (Sept. 17, 2007) [hereinafter GRIPA]. Although GRIPA’s physician members paid $1,650 per share to capitalize risk contracting, to initiate clinical integration, GRIPA planned to invest (rather than distribute to physicians) monies earned under its risk contracts to finance information technology valued at $7,000 per physician and physicians were required to invest “substantial human capital” valued at $3,200 per physician in lost patient revenue for training sessions on the use of information technology and the clinical integration program, plus physicians were required to make ongoing significant investments of time to contribute data, collaborate in patient care, comply with GRIPA guidelines and serve on GRIPA committees, valued at $2,400 per year per physician. See id.; see also FED. TRADE COMM’N,
Collectively, the FTC’s advisory opinions on clinically-integrated organizations demonstrate that if an agreement to jointly negotiate prices (i) is likely to benefit consumers served by the arrangement and (ii) is reasonably necessary to create a clinically-integrated program, then such agreement is adequately justified.\(^\text{27}\) Thus, such advisory opinions indicate that joint contracting activity that is reasonably necessary to a network’s achievement of significant efficiencies, will be evaluated under a rule of reason approach and found to be generally permissible, so long as any anticompetitive effects do not outweigh the network’s procompetitive benefits.

This balancing test entails three separate inquiries. First, the FTC will examine the horizontal effects of the multi-provider network—the program’s impact on competition in the services it will provide. Second, the FTC will determine if the network is vertically anticompetitive. Vertical issues arise when the “network’s power in one market in which it operates enables it to limit competition in another market.”\(^\text{28}\) And third, CIPs must avoid creating “spillover effects”—enabling others to engage in anticompetitive behavior.\(^\text{29}\)

II. Non-Profit Status

A. Background

Unlike for-profit entities, non-profit entities exist to produce some kind of public benefit and perform charitable work.\(^\text{30}\) Unlike for-profit entities, the assets of an non-profit “are in essence held in trust for and dedicated to public use. Consequently, any transfer or disposition of those assets whatsoever, including in connection with a merger or conversion, is subject to more onerous state law constraints.”\(^\text{31}\)

Many (if not most) [non-profits] are also tax-exempt. Tax exemption typically covers federal and state income taxes, and other state and local taxes as well. Not surprisingly, receipt of tax-exempt status under the tax law comes with a variety of constraints on [a non-profit’s] ability to either merge or convert. As a general proposition, the relevant taxing authorities will scrutinize any activity or transaction undertaken by [a non-profit] to ensure compliance and consistency with the basis on which exempt status was granted, as well as with the more generic tax law principles that the assets of an exempt organization — whether tangible or intangible, actual or contingent — are safeguarded, retained and applied toward achieving the organization’s tax-exempt mission. In connection with any plan to merge with another [non-profit], and probably more so in connection with a plan to convert to for-profit status, these tax law constraints must be fully explored.\(^\text{32}\)

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\(^\text{27}\) GRIPA, supra note 26, at 10.

\(^\text{28}\) DOJ/FTC Statements, supra note 20, at 119.

\(^\text{29}\) Norman, supra note 26, at 20.


\(^\text{31}\) Id. at 1.

\(^\text{32}\) Id. at 2.
B. Tax Exempt Status

To maintain tax-exempt status under section 501(c)(3) of the Internal Revenue Code (the "Code"), tax-exempt entities must be and remain organized and operated exclusively for charitable purposes. One component of the so-called “operational test” is the prohibition on impermissible private benefit at section 1.501(c)(3)-1(d)(1)(ii) of the Treasury Regulations which provides that an organization is not operated exclusively for exempt purposes unless it serves a public rather than a private interest and the organization may not be operated for the benefit of private interests. In the context of joint ventures between nonprofit and for-profit entities, the activities of a joint venture are considered to be activities of its tax-exempt partners for purposes of determining exemption under Section 501(c)(3) of the Code. The Treasury Regulations provide that an organization will not be regarded as operating exclusively for charitable purposes if more than an insubstantial part of its activities is not in furtherance of an exempt purpose. Even if participation in a joint venture is an insubstantial part of a tax-exempt organization’s overall activities, the joint venture can still result in unrelated business income to the nonprofit if the activities of the joint venture are not substantially related to the tax-exempt organization’s charitable functions.

For the activities of a joint venture to be substantially related to the tax-exempt purposes of a nonprofit partner in the joint venture, the activities must contribute importantly to the accomplishment of the nonprofit partner’s exempt purposes. The analysis for determining whether a nonprofit organization’s participation in a joint venture contributes importantly to the accomplishment of its charitable purposes focuses on the nature of the activities themselves and the degree of control the nonprofit organization has over the manner in which the activities of the joint venture are conducted. In order to avoid unrelated business income, a nonprofit organization must maintain control over a joint venture sufficient to ensure that its charitable purposes are furthered through the activities of the joint venture. Another component of the so-called “operational test” relating to tax-exempt organizations is the prohibition on inurement set forth at section 1.501(c)(3)-1(c)(2) of the Treasury Regulations which provides that an organization is not operated exclusively for exempt purposes if its net earnings inure in whole or in part to the benefit of private shareholders or individuals. Often commingled with the prohibition on impermissible private benefit, the prohibition on inurement applies only to “insiders” who have a pre-existing relationship with the tax-exempt organization and who receive a benefit as a result of the person’s control or influence over such organization. Such insiders include shareholders, founders, directors, officers, major contributors and any other persons who exercise substantial influence over the entire operations or significant

34 26 C.F.R. § 1.501(c)(3)-1(c)(1).
35 Id.
36 26 C.F.R. § 1.513-1(d)(2).
38 See e.g. Redlands Surgical Services v. Commissioner, 113 T.C. 47 (1999), aff’d 242 F.3d 904 (9th Cir. 2001) (holding that a nonprofit organization that participated in an ambulatory surgery center joint venture did not qualify for tax-exempt status when it lacked formal or informal control over the joint venture sufficient to ensure furtherance of charitable purposes); St. David’s Health Care System v. United States, 349 F.3d 232 (5th Cir. 2003) (holding that nonprofit partner of joint venture must have the capacity to ensure that the partnership’s operations further charitable purposes).
components of the organization. Moreover, the ban on inurement is absolute - no amount of inurement is permitted. For the most part, inurement is generally measured in economic terms.

C. Unrelated Trade or Business

Even if an organization is recognized as tax exempt, it may be liable for tax on its unrelated business income. For most organizations, unrelated business income is “income from a trade or business, regularly carried on, that is not substantially related to the charitable, educational, or other purpose that is the basis of the organization's exemption.” A tax exempt organization that has $1,000 or more of gross income from an unrelated business must file Form 990-T.

Unrelated business income is “the income from a trade or business regularly conducted by an exempt organization and not substantially related to the performance by the organization of its exempt purpose or function, except that the organization uses the profits derived from this activity.”

- Regularly carried on

In determining whether trade or business from which a particular amount of gross income derives is regularly carried on, regard must be had to the frequency and continuity with which the activities productive of the income are conducted and the manner in which they are pursued. This requirement must be applied in light of the purpose of the unrelated business income tax to place exempt organization business activities upon the same tax basis as the nonexempt business endeavors with which they compete.

- Not substantially related

A business activity is not substantially related to an organization's exempt purpose if the conduct of the trade or business which produces the income is not substantially related (other than through the production of funds) to the purposes for which exemption is granted. This requires an examination of the relationship between the business activities which generate the particular income in question and the accomplishment of the organization's exempt purposes.

In determining whether activities contribute importantly to the accomplishment of an exempt purpose, the IRS uses the following principles:

- Selling of products of exempt functions

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40 Id.
42 26 C.F.R. § 1.513-1(c).
43 Id.
44 26 C.F.R. § 1.513-1(d).
45 Id.
46 Internal Revenue Serv., Pub. 598, supra note 41.
Ordinarily, gross income from the sale of products which result from the performance of exempt functions does not constitute gross income from the conduct of unrelated trade or business if the product is sold in substantially the same state it is in on completion of the exempt functions. . . . On the other hand, if a product resulting from an exempt function is utilized or exploited in further business endeavor beyond that reasonably appropriate or necessary for disposition in the state it is in upon completion of exempt functions, the gross income derived therefrom would be from conduct of unrelated trade or business.  

- **Dual use of assets or facilities**

In certain cases, an asset or facility necessary to the conduct of exempt functions may also be employed in a commercial endeavor. In such cases, the mere fact of the use of the asset or facility in exempt functions does not, by itself, make the income from the commercial endeavor gross income from related trade or business. The test, instead, is whether the activities productive of the income in question contribute importantly to the accomplishment of exempt purposes.

- **Exploitation of exempt functions**

In certain cases, activities carried on by an organization in the performance of exempt functions may generate good will or other intangibles which are capable of being exploited in commercial endeavors. Where an organization exploits such an intangible in commercial activities, the mere fact that the resultant income depends in part upon an exempt function of the organization does not make it gross income from related trade or business. In such cases, unless the commercial activities themselves contribute importantly to the accomplishment of an exempt purpose, the income which they produce is gross income from the conduct of unrelated trade or business.

### III. Fraud and Abuse Compliance

#### A. Stark Law

The Stark Law prohibits physicians having a direct or indirect “financial relationship” with an “entity” from referring patients to such entity for designated health services (“DHS”) paid under a federal health care program, unless such financial relationship meets one of the exceptions enumerated under the statute or the regulations promulgated thereunder. DHS include, among other things, inpatient and outpatient hospital services. The Stark Law also prohibits any entity from billing any individual, Medicare or other payor for DHS furnished pursuant to a prohibited referral. Any payments (including co-payments) received in violation of this prohibition must be promptly refunded. A financial relationship regulated under the Stark Law can take the form of

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47 Id. § 1.513-1(d)(4)(ii).
48 Id. § 1.513-1(d)(4)(iii).
49 Id. § 1.513-1(d)(4)(iv).
51 42 U.S.C. § 1395nn(h)(6); 42 C.F.R. § 411.351.
a direct or indirect ownership interest or compensation arrangement. The regulations promulgated under the Stark Law (the “Stark Regulations”) by CMS specifically define the characteristics of the indirect compensation arrangements that are implicated under the statute.

Pursuant to the “stand in the shoes” rule at 42 CFR § 411.354(c), physician owners of a physician organization are deemed to “stand in the shoes” of the physician organization for purposes of analyzing financial relationships under the Stark Law. Physicians that are not owners of the physician practice are also permitted to “stand in the shoes” of their physician practice for purposes of analyzing financial relationships under the Stark Law.

Financial relationship with physician results in prohibition on referral and billing of designated health services to Medicare patients under the Stark Law unless the financial relationship meets an exception. While the Stark Law exceptions vary, they typically require: (i) a written agreement specifying terms; (ii) fair market value consideration set in advance that does not vary based on referrals; and (iii) commercial reasonableness.

One such exception, the indirect compensation exception, provides that an indirect compensation arrangement is not considered a “financial relationship” if the following conditions are satisfied: (i) compensation is fair market value for services and items actually provided and not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician for the entity furnishing DHS; (ii) the 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; and (iii) the arrangement does not violate the anti-kickback statute, or any federal or state law or regulation governing billing or claims submission.

B. Anti-Kickback Statute

The anti-kickback statute (“AKS”) prohibits the knowing and willful offer, payment, solicitation, or receipt of any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward referrals of items or services reimbursable by a federal health care program. The AKS ascribes criminal liability to parties on both sides of an impermissible kickback transaction, and in addition to criminal penalties, violations of the AKS can lead to the imposition of civil sanctions and/or administrative exclusion from participation in federal health care programs (which carries a lower burden of proof than that which is required to sustain a criminal conviction). In order to prove a violation of the AKS, the government must show that an entity: “(a) knowingly and willfully; (b) with the intent to induce the referral of federal health plan business; (c) solicited, received, offered, or paid remuneration.”

Courts have interpreted the AKS to prohibit arrangements if one purpose of the arrangement is the inducement of referrals of federal health care program patients, regardless of whether there

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52 42 C.F.R. § 411.357 (p).
53 Id.
54 42 U.S.C. § 1320a-7b(b). A “federal health care program” includes any plan or program that provides health benefits, whether directly, through insurance, or otherwise which is funded directly, in whole or in part by the federal government. 42 U.S.C. § 1320a-7b(f).
55 Hanlester Network v. Shalala, 51 F.3d 1390, 1397-1400 (9th Cir. 1995).
are other appropriate purposes for the arrangement. The mens rea requirement of knowledge and willfulness under the AKS has generally been held to require proof that the defendant intended to commit an act he or she knew to be “wrongful.” The Fifth Circuit has reasoned that the term “willfully” under the statute means “that the act was committed voluntarily and purposely with the specific intent to do something the law forbids; that is to say with bad purpose whether to disobey or disregard the law.” Several courts, as well as the Office of Inspector General of the Department of Health and Human Services (the “OIG”), also have indicated that certain facts and circumstances, such as paying greater than fair market value for services or items, can support an inference that the improper intent to induce referrals exists.

Hanlester Network v. Shalala was the first decision to address the question of what constitutes “inducement” under the AKS, and remains the only federal case to do so in the context of joint ventures. In Hanlester, the Secretary of the Department of Health and Human Services sought to exclude certain physician-owned limited partnerships, their general partner (Hanlester), and a number of individuals that had promoted the limited partnerships, arguing in part that they had violated the AKS by offering limited partnership interests in joint venture clinical laboratories only to physicians in a position to refer lab work. The Ninth Circuit accepted the Secretary’s definition of “inducement” as “an intent to exercise influence over the reason or judgment of another in an effort to cause the referral of program-related business.” However, the court specifically rejected the Secretary’s argument that marketing limited partnership interests to physician investors who were in a position to refer substantial quantities of tests, and thus could profit indirectly from such referrals, unlawfully induced referrals in violation of the AKS. Thus, the court found that merely allowing a person the opportunity to profit from referrals through a bona fide investment in a joint venture does not, without more, result in prohibited referrals.

In contrast, the court held that one of the agents associated with Hanlester clearly violated the AKS in marketing the limited partnership interests by implying to prospective limited partners that eligibility to purchase shares depended on the level of referrals made to the labs and stating that partners who did not refer business would be pressured to leave the limited partnerships. The court held that this agent’s representations to prospective limited partners constituted offers of payment to induce referrals of federal health care program business. Thus, the decision in Hanlester illustrates an important distinction between legitimate joint venture arrangements where referrals may result in indirect profits to investors as opposed to the marketing of investment interests with the specific intent to influence the reason and judgment behind referral decisions. This distinction has been reinforced by the Tenth Circuit’s approval of jury instructions that distinguish between the hope, expectation or belief that referrals would ensue from a financial relationship, or the mere oral encouragement to refer, and the intent to influence

57 United States v. Jain, 93 F.3d 436, 441 (8th Cir. 1996).
58 Davis, 132 F.3d at 1094.
60 51 F.3d 1390 (9th Cir. 1995).
61 Id. at 1398.
the reason and judgment behind a person’s patient referral decisions.\textsuperscript{62} Only the latter would give rise to a violation of the AKS.

- **Safe Harbor Regulations**

In response to concerns that the AKS could be read to render otherwise legitimate business arrangements unlawful, Congress required the OIG to promulgate safe harbor regulations identifying transactions that would not be subject to criminal prosecution or exclusion proceedings.\textsuperscript{63} Unlike the exceptions to the Stark Law (discussed below), the failure of a transaction to meet all the criteria of a specific safe harbor does not necessarily mean that such transaction violates the AKS, however it is not immune from being found to violate the AKS and may be subject to closer scrutiny than a transaction that meets all the criteria of a specific safe harbor.\textsuperscript{64} The OIG has created safe harbors that protect certain investment interests, and the corresponding distributions related to such investment interests, as well as payments made pursuant to certain types of agreements, such as personal services and management contracts.

- **OIG Guidance**

For joint venture transactions that do not fit within a regulatory safe harbor under the AKS, the OIG has provided general guidance to the health care community regarding what it believes to be “questionable features” of joint ventures. The OIG issued a Special Fraud Alert on Joint Venture Arrangements in 1989, reprinted in the Federal Register in 1994, identifying a number of factors it viewed as indicators of potentially unlawful activity, which separately or taken together may result in a business arrangement that violates the AKS.\textsuperscript{65} In the OIG’s view, these arrangements were not intended “to raise investment capital legitimately to start a business, but to lock up a stream of referrals from the physician investors and to compensate them indirectly for these referrals.” The OIG identified several “questionable features” as potential indicators of a “suspect joint venture” that should be taken into consideration.

In accordance with the requirements of the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), the OIG has also issued advisory opinions regarding joint ventures with physicians. While these opinions are issued only to the requestor and cannot be relied upon by any other person, they can provide useful insight into how the OIG is currently reviewing certain arrangements under the AKS.

In the event a joint venture transaction cannot be arranged to fit squarely within a safe harbor, the transaction should be structured to meet as many of the safe harbor requirements as possible and to minimize the “questionable features” highlighted by the OIG in its fraud alert and advisory opinion guidance. Good faith efforts to comply with the safe harbor requirements and avoid

\textsuperscript{62} See United States v. McClatchey, 217 F.3d 823, 834 (10th Cir. 2000); United States v. LaHue, 261 F.3d 993, 1002 (10th Cir. 2001).


\textsuperscript{64} Medicare and State Health Care Programs: Fraud and Abuse; Safe Harbors for Protecting Health Plans, 61 Fed. Reg. 2122, 2123 (January 25, 1996).

“questionable features” outlined by the OIG are still relevant to analysis under the AKS because the statute requires an individual or entity to “knowingly and willfully” violate its provisions.

IV. Insurance

Although involving interstate commerce, health insurance is largely regulated by the states. State regulators oversee the regulation of the insurance industry to ensure the solvency of insurers and to ensure the rules enacted by the state legislature are carried out for the benefit of insurance consumers.

[States license insurance companies by requiring that they obtain a “certificate of authority” [(COA)] to conduct business in that state. In order to obtain a COA, an insurer must submit certain information to the insurance department and agree to submit to that state’s regulatory authority. Licensure requirements exist to ensure that, upon initial entry into a state, the insurer possesses the financial resources and infrastructure necessary to service the products sold. Licensure also provides the ongoing authorization to operate in a state and is closely tied to a state regulator’s ability to enforce applicable laws and regulations, including solvency standards. For companies, obtaining and maintaining a COA is a significant undertaking, not only because of the resources necessary to make the initial application for it, but also because of the impact of having to satisfy ongoing financial and solvency requirements.]

An important issue is determining which state(s) have regulatory jurisdiction over the insurer or the product being issues. States generally consider where the insurance policy is delivered or issued for delivery in making a determination about regulatory jurisdiction, but there may be other factors that certain states take into consideration when determining whether they have a regulatory interest in the transaction of insurance.

Most states have adopted insurance laws, in various forms and degrees, addressing consumer protections related to health insurance around the following key issues:

- **Provider access** – laws requiring direct access to certain types of providers irrespective of network.
- **Utilization Review, Grievance Review, External Review** – laws requiring certain guidelines around (i) utilization reviews used to monitor use, medical necessity and efficacy of health care services, (ii) internal procedures for resolving complaints from covered persons, and (iii) the process under which a covered person is able to receive an independent review from a qualified outside person relating to denial of coverage.
- **Prompt Pay** – laws requiring adjudication and payment of claims within a certain number of days.
- **Mandated Benefits** – laws requiring health insurance policies to include or offer coverage for certain conditions, procedures or services, or for certain populations.

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As health plans have evolved to design narrower provider networks focused on delivering lower-cost plan options, there has been more recent focus by states on ensuring that these provider networks still provide adequate provider access through adoption of laws on network adequacy requirements that address many of the following types of issues:

- Accurate information about providers
- Timely access to care
- Adequate number of providers
- Adequate types of providers
- Inclusion of essential community providers
- Adequate geographic distribution of providers
- Access to out-of-state providers
- Accessible hours
- Language-accessible care
- Rights to go out of network
- Continuity of care

V. Questions to Ask an Appraiser for a Health Plan Valuation Assignment

Health plans are unique businesses which require a valuation expert with experience and background in the industry.

Appraiser Experience. When evaluating an appraiser the following questions should be addressed in the selection process:

1) Does the appraiser have significant experience in the health plan industry in a valuation capacity?

2) Can the appraiser provide references or a list of prior valuation or consulting assignments specific to this industry?

Questions to ask professional references of the appraiser:

- Was the appraisal completed in a timely fashion?
- Were the professional fees consistent with the provided fee quote and the quality of the work product delivered?
- Did the appraiser convey adequate expertise in the industry both during the process and in the deliverable.
- Did the appraiser approach the project as an independent third party?
- Was the appraiser both available and dependable for client conference calls, face-to-face meetings, and achieving deliverable deadlines?
- Were the deliverables (valuation schedules, report, & presentation) comprehensive and would they stand-up to potential regulatory scrutiny.

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67 For specific examples from different states, see FamiliesUSA, Standards for Health Insurance Provider Networks: Example from the States (November 2014), available at www.familiesusa.org.
3) What steps will the appraiser take to deliver an expert report that will withstand regulatory scrutiny?

The following should be including in the response:

- Analyze both historical and prospective financial performance of a business understanding it operates in a unique and specialized industry with its own “terms of art” (premiums, medical loss ratio, administrative costs, members, member months, etc.).
- Understand the highly regulated operating environment and the implications of this environment on the operations of the business (e.g. ACA, risk based capital requirements).
- Interpret the competitive environment and the impact on the subject business.
- Identify key value drivers and the resulting impact on the economics of the business.
- Develop a depth of understanding of comparable precedent transactions and the valuation metrics from those transactions.
- Apply appropriate valuation methodologies to the subject business (market approach, discounted cash flow approach, cost approach).
- Provide a valuation conclusion and report which is comprehensive and can be relied upon by the end users.

4) Will the appraiser (or their firm) be available at a future date to address any questions or defend their opinion?