

Compensation-Focused Compliance: Is Your Physician Compensation Governance Process Ready for Shifts in Stark Law Enforcement?

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Compliance issues related to physician compensation have been a key area of discussion in health care for a number of years. This area continues to grow in importance as the demands of health care reform and value-based payments accelerate the need for health care organizations to have an aligned physician workforce. As such, adoption of a compliant and innovative physician compensation plan that incentivizes quality of care and cost effectiveness, while encouraging optimal physician productivity, is a necessity for health care organizations.

In response to these changing market dynamics, medical groups, hospitals, and health systems are focusing on developing integrated health care delivery systems structured around acquiring, employing, and directly compensating their aligned physicians. From multiple perspectives, employment (as opposed to other alignment strategies) is generally the preferred integration model because employed physicians are more tightly aligned and provide these organizations with wider latitude to develop, implement, and incentivize behavior that advances the organization's integration strategies and business objectives. Health care organizations are allocating substantial time and resources toward integrating their employed physicians and overhauling their existing compensation models to position themselves for success in a new value-based world.

Simultaneously, as evidenced by a wave of recent cases and provider settlements, the federal government continues to focus on pursuing health care fraud and abuse. A combination of aggressive enforcement efforts and a hyper-technical regulatory framework make today's environment particularly challenging for health care organizations. Enforcement continues to focus on the federal physician self-referral law and its implementing regulations (collectively, the Stark Law or Stark).¹ Specifically, government enforcement efforts concentrate on alleged violations related to compensation-focused compliance (e.g., fair market value, commercial reasonableness, the prohibition on taking into account designated health service referrals, etc.). Historically, enforcement efforts centered almost solely on hospitals, even though physicians and medical groups have been intimately involved in the compensation arrangements. The dynamic has shifted somewhat, however, and it appears that whistleblowers and the government are now expanding their focus to enforcement actions against

physicians and medical groups.²

Given the substantial awards and settlements in recent Stark Law enforcement actions, compensation-focused compliance has become more than just a compliance issue: it is an enterprise risk management issue. As medical groups, hospitals, and health systems pursue integration strategies and transition to more innovative compensation plans, these organizations must manage their compliance and enterprise risk by ensuring their compensation arrangements are defensible under the Stark Law.³ These health care organizations, independent, hospital and system-affiliated groups in particular, should evaluate their compensation-focused governance structures to ensure existing processes and internal controls support compliance with Stark's technical requirements and key tenets of defensibility (e.g., fair market value, commercial reasonableness, and not taking into account designated health service referrals, etc.) in case their physician compensation arrangements are ever challenged.

This article focuses on the Stark Law's underlying technical requirements, related tenets of defensibility, and potential shifts in Stark Law enforcement. It also seeks to provide guidance for medical groups, hospitals, and health systems as they assess their compensation governance structures to ensure existing processes and internal controls support compensation-focused compliance in today's shifting enforcement climate.

Compensation-Focused Compliance

Stark Overview

The Stark Law prohibits a physician from making referrals of certain designated health services (DHS) to any entity with which the physician has a financial relationship, unless the arrangement qualifies for one of Stark's specified exceptions. No entity furnishing DHS may submit a claim to Medicare for services performed pursuant to a physician's prohibited DHS referral.⁴ This prohibition applies regardless of the reasons for the financial relationship and the DHS referral. Unlike fraud and abuse laws such as the Anti-Kickback Statute, no finding of unlawful intent is required under the Stark Law.⁵

While it has the features of a fraud and abuse law, the Stark Law is fundamentally a billing and payment rule. In cases where an entity bills and collects for DHS referred in violation of the Stark Law, the entity must refund the inappropriately collected amount in a timely manner. The government may impose a civil penalty of up to \$15,000 for each claim related to the DHS billed by a person or entity who knew, or should have known, that the DHS was referred in violation of the Stark Law.

The violation also may cause the person or entity to be excluded from federal health care programs and may result in imposition of a civil penalty of up to \$100,000 against any parties that enter into a scheme to circumvent the Stark Law's prohibition.⁶ Similar to the Anti-Kickback Statute, a Stark Law violation may also serve as the basis for liability under the False Claims Act.⁷

From a compliance and process perspective, health care organizations should ensure that all compensation arrangements with referring physicians meet Stark's technical requirements and fit squarely within an applicable exception.⁸ In particular, for organizations adopting direct physician employment models, arrangements are likely to be structured to meet either the exception for *bona fide* employment relationships⁹ or the in-office ancillary services exception (IOAS).¹⁰ The employment exception is generally considered the broadest and most commonly used *compensation* exception available under Stark.¹¹ The exception does not protect, however, physician members of a group practice who also function as owners. Financial relationships involving physician ownership generally must meet the IOAS, which is applicable to both *compensation* and *ownership* financial arrangements.¹²

The IOAS provides additional compensation flexibility for independent, hospital or system-affiliated physician practice entities, provided they are separately organized and operated primarily for the purpose of being a physician "group practice."¹³ As a threshold matter, the physician practice entity must meet all nine structural and operational requirements for being a "group practice."¹⁴ Stark group practices can pay productivity bonuses for DHS that are "incident to" a physician's personally performed services and also can distribute overall profits derived from DHS to the group or to subcomponents of the group, provided the distribution methodology does not directly take into account DHS referrals.¹⁵ This favored treatment and additional latitude with respect to physician compensation is statutory.¹⁶ Ensuring and documenting compliance with the hyper-technical requirements of the group practice definition and IOAS exception is a prudent practice that will enhance defensibility in the event a group practice's compensation arrangements are ever challenged. The Centers for Medicare & Medicaid Services (CMS) has specifically noted in agency commentary that group practices that choose to take advantage of the IOAS should at all times be prepared to demonstrate compliance with the relevant statutory and regulatory standards.¹⁷

Health care organizations pursuing alternative alignment models that do not fit within the *bona fide* employment exception or the IOAS should ensure their structures are defensible under one of the many other exceptions available under the Stark Law.¹⁸

Key Tenets of Defensibility

Though each Stark exception carries its own technical requirements, three key tenets of defensibility are common to most of them: (1) the compensation must be consistent with *fair market value*; (2) the compensation must be paid under an arrangement that is *commercially reasonable*; and (3) the compensation cannot be determined in a manner that *takes into account* the *volume or value* of the physician's referrals of DHS. Because these tenets of defensibility are common to most exceptions, governance processes and procedures should support and document compliance with these tenets regardless of the exception that is ultimately relied upon. Notably, the guidance in

the regulations and agency commentary on the three tenets of defensibility provides additional context.

- » The first tenet, *fair market value*, is defined in both the Stark statute and its implementing regulations.¹⁹ CMS has provided some general explanatory guidance on this topic, but has declined to set forth a specific methodology for determining whether the fair market value standard has been satisfied, noting that no single method could apply universally to the wide variety of arrangements, services, and markets covered by Stark.²⁰ Significantly, CMS has endorsed referencing multiple, objective, and independently published surveys as a prudent practice for evaluating fair market value and has recognized the use of independent valuation consultants as one means of supporting fair market value.²¹ Although an independent valuation is not required by the Stark Law, it has become a routine practice for health care organizations to engage valuation consultants to issue a written valuation opinion confirming that the compensation paid under an arrangement is consistent with fair market value.
- » The second tenet, *commercial reasonableness*, is not defined under either the Stark statute or its implementing regulations. Therefore, there are inherent challenges to meeting this standard. For compliance and documentation purposes, organizations and valuation consultants generally look to published CMS commentary that describes the standard as being met by certain subjective and objective qualitative factors.²² Health care organizations evaluating commercial reasonableness should consider whether the financial arrangement appears to be a sensible, prudent business agreement from the perspective of the parties, even in the absence of any potential DHS referrals. Many valuation consultants have developed expertise in assessing and confirming compliance with the commercial reasonableness standard. These consultants are often willing to incorporate their commercial reasonableness analysis and conclusions into a more comprehensive and robust written valuation opinion.
- » Finally, the third tenet, sometimes referred to as the *volume or value standard*, prohibits paying compensation that is determined in a manner that takes into account, directly or indirectly, the volume or value of DHS referrals by the referring physician. This tenet has inherent challenges as well, in part because of the potential for a broad reading of the phrase "takes into account" and also because of court interpretations indicating that compensation based on *anticipated* DHS referrals can implicate the standard.²³ For compliance purposes, as a threshold matter, health care organizations should ensure their compensation formulas do not calculate compensation in any manner that is based on a physician's DHS referral activity.²⁴ Further, to the extent possible, governance processes should emphasize and document the proper non-referral purposes supporting all compensation arrangements and should avoid any actions or communications that may be misconstrued as being in violation of this standard.

In several of the recent enforcement cases, the government has expressly alleged Stark Law violations based on these three tenets of defensibility. Thus, in addition to ensuring strict technical compliance with an exception, organizations looking to manage their Stark Law risk should focus their attention on confirming and documenting their compliance with these tenets.

Ongoing Stark Law Enforcement

Due to favorable judgments and settlements, and positive returns on its investment in enforcement, it is likely the government will continue to aggressively pursue potential fraud. Recently, the Department of Health and Human Services (HHS) and Department of Justice (DOJ) noted in their *Annual Report of the Departments of Health and Human Services: Health Care Fraud and Abuse Control Program* (Report) that the return on investment from their joint health care fraud enforcement efforts was \$7.70 returned for every \$1.00 spent over the last three years.²⁵ The Report also noted that Office of General Counsel will continue to assist the DOJ with assessments of complex issues in enforcement actions involving the Stark Law. The Report highlights the ongoing and joint focus of HHS and DOJ with respect to health care fraud.

As has been the case for a number of years, Stark Law actions are largely initiated by private whistleblowers under the False Claims Act's qui tam provisions.²⁶ The following cases and settlements from 2014 and 2015 suggest a continued focus on alleged Stark Law violations related to the key tenets of defensibility (i.e., fair market value, commercial reasonableness, and the volume or value standard).

- » Halifax Hospital agreed to pay \$85 million to resolve alleged Stark Law violations relating to oncology bonus arrangements that allegedly took into account the volume or value of DHS referrals and neurosurgery compensation arrangements that allegedly exceeded fair market value.²⁷
- » All Children's Health System, Inc. agreed to pay \$7 million to resolve alleged Stark Law violations relating to physician compensation arrangements that allegedly exceeded fair market value.²⁸
- » Citizens Medical Center agreed to pay \$21.75 million to resolve alleged Stark Law violations relating to cardiology and emergency department physician salaries that allegedly took into account DHS referrals, were not commercially reasonable and exceeded fair market value.²⁹
- » Westchester Medical Center agreed to pay \$18.8 million to resolve alleged Stark Law violations relating to consulting and fellowship arrangements with referring cardiologists that allegedly took into account DHS referrals, were not commercially reasonable and exceeded fair market value.³⁰
- » King's Daughters Medical Center agreed to pay \$40.9 million to resolve alleged Stark Law violations relating to cardiology salaries that allegedly exceeded fair market value.³¹

These cases and settlements demonstrate the government's continued focus on Stark enforcement and underscore the importance of developing processes that support and appropriately document compliance with the key tenets of defensibility. Though the government's focus is, in one sense, somewhat predictable, the following cases display how Stark Law enforcement is constantly evolving.

Potential Shifts in Enforcement

Historically, enforcement efforts generally focused on hospital activity. The following cases from 2014 suggest that the dynamic has shifted in some areas, and that more actions against physicians and medical groups may be coming down the pipeline.

- » A cardiologist and his physician practice agreed to pay \$1 million to resolve an enforcement action related to

arrangements with two Ohio hospitals that allegedly violated the Stark Law.³²

- » Infirmity Health System Inc. (Infirmity) agreed to pay \$24.5 million to resolve alleged Stark Law violations related to bonus payments to physicians that allegedly took into account the volume or value of DHS referrals.³³ A central issue in the case was whether the Infirmity practice entities could meet the definition of a Stark group practice for purposes of the IOAS.
- » New York Heart Center (New York Heart), an independent cardiology physician practice, agreed to pay \$1.33 million to resolve alleged Stark Law violations relating to an internal compensation formula that allegedly directly took into account the volume or value of each physician's DHS referrals, primarily their referrals for nuclear scans and CT scans.³⁴
- » Two cardiologists and their physician practice agreed to pay \$380,000 to resolve alleged Stark Law violations relating to management agreements that allegedly were not commercially reasonable.³⁵

Although these recent cases are important because they represent a departure from actions solely against hospitals, these cases still focus predominately on the key tenets of defensibility. Additionally, Infirmity and New York Heart are particularly interesting because they may be indicative of an increased regulatory focus on internal group practice dynamics and compliance with the IOAS and group practice requirements. What continues to be most important, however, is that from the onset of any arrangement, whether internal group compensation or hospital-physician compensation arrangements, organizations should ensure governance processes support defensibility under the Stark Law.

Compensation-Focused Compliance

As discussed throughout this article, health care organizations should adopt governance processes that support compliance with Stark's technical requirements and key tenets of defensibility. There is no one-size-fits-all strategy to achieve compensation focused compliance. Health care organizations will utilize different approaches to demonstrate compliance due to their different market dynamics, existing governance framework, tax-exempt status, organizational size and complexity, risk tolerance, and other factors unique to their particular circumstances.

Regardless of the organization's ultimate approach, however, a recommended starting point for all health care organizations is a careful examination of the Stark regulations and applicable guidance from CMS, the HHS Office of Inspector General (OIG), and as applicable, the Internal Revenue Service (IRS) to ensure compensation governance structures support compliance. The OIG has developed a series of voluntary compliance program guidance documents intended to encourage development and use of internal controls to monitor regulatory compliance.³⁶ The OIG's 2000 *Compliance Program for Individual and Small Group Physician Practices* (Practice Guidance) and 2005 *Supplemental Program Guidance for Hospitals* (Hospital Guidance) are particularly informative.³⁷ Although these documents were initially directed at slightly different segments of the health care industry, when examined together they provide a comprehensive framework that is applicable to integrated health care delivery systems. In particular, the Practice Guidance and Hospital Guid-

ance documents identify seven basic components of an effective compliance program that serve as a solid basis for evaluating ongoing compensation-focused compliance efforts.³⁸

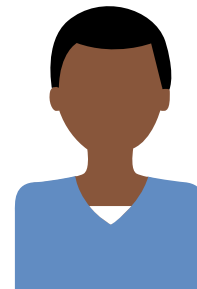
The considerations below, while neither exhaustive nor comprehensive, are intended to provide health care organizations with issues to identify as they begin to evaluate their compensation-focused governance processes.

Compensation Governance Process Considerations

1. Initial Governance Considerations.

- a. *Integration with Compliance Program.* Compensation-focused compliance is potentially an enterprise risk management issue. Thus, health care organizations should align their compensation governance processes with their existing compliance program structures. For example, an organization's compliance officer could participate actively in the compensation committee meetings and governance process or compliance department liaisons could be integrated into the underlying processes, such as reviewing compensation models for compliance purposes, developing compensation-focused compliance policies, and performing monitoring or audit functions.
- b. *Engagement of Legal Counsel.* Legal counsel's role often focuses on advising management and the board or compensation committee on the legal and regulatory risks of the organization's physician compensation arrangements. Additional duties may include providing compliance training, governance and oversight counseling, management of the valuation process (e.g., facilitating selection of a valuation firm, assessment of valuation opinions for defensibility, etc.), assistance with compensation model and plan development, and legal assessments of the compensation arrangements under applicable laws. Legal counsel may be tasked with monitoring regulatory changes, the industry's enforcement climate, and areas of identified risk. Due to the unique regulatory framework, it is critical for counsel to be experienced with the Stark Law, physician compensation, and health care valuation issues.
- c. *Engagement of a Qualified Third-Party Valuation Consultant.* The valuation consultant's role may include performance of financial projections, compensation planning and design (e.g., examination of national trends, conceptual modeling, etc.), development of compensation structures and compliance parameters, providing expertise, and issuance of an objective third-party opinion validating fair market value and commercial reasonableness. Consideration should be given to engagement directly by legal counsel to ensure that the communications related to the valuation and any written reports obtained under the engagement are protected under the attorney-client privilege. Consistent with the terms of the privilege, the valuator should work at the direction and under the control of legal counsel. Health care organizations should engage valuation consultants that have the requisite expertise to opine on compliance with the Stark Law's definitions of fair market value and commercial reasonableness. Further, valuation consultants should not "take into account" the volume or value of past, present, or future DHS referrals and should state the same in their written valuation opinions and work papers.

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- d. *Focus on Plan Implementation.* Once the terms of a compensation arrangement are established, health care organizations should take care to ensure that they are properly implemented and consistently followed. Recent enforcement actions highlight the dangers of establishing, but then failing to follow the terms of a compensation plan and/or compensation policies.
2. **Compliance Training and Education.** Compensation-focused training and education programs help ensure that physicians, employees, and members of the board and compensation committee are fully capable of executing their roles in accordance with rules, regulations, and other standards applicable to physician compensation. The Hospital Guidance and Practice Guidance identify a number of common factors that health care organizations can consider as they evaluate their training and education programs.³⁹
 3. **Processes for Compensation Oversight.** Health care organizations should consider establishing a standing compensation committee of the governing board with delegated responsibility for oversight, modifications, adjustments, and/or exceptions to the organization's physician compensation arrangements. The role of the management team in physician compensation matters (e.g., reporting requirements, recommendation authority, etc.) should also be defined. The compensation committee should receive regular reports from the functional areas discussed above regarding compensation governance and the organization's efforts to mitigate risk.
 4. **Parameters for Compensation Review.** Health care organizations should work with their valuation consultant to develop compensation parameters/thresholds that trigger additional governance processes. Once thresholds are triggered, the organization could perform additional internal or external analyses to confirm and document that the facts and circumstances support compliance with the fair market value and commercial reasonableness standards. Appropriate support may include survey data supporting the arrangement, documentation of the underlying business rationale, and/or a written valuation opinion from a third-party valuation consultant.

5. **Governance Documents.** The following governance documents, in addition to others, may be necessary:
- Compensation Committee Charter.* The compensation charter should define the compensation committee's purpose, member composition, responsibilities, and processes by which it will carry out those responsibilities.
 - Compensation Plan.* The compensation plan could address some or all of the following: (i) identification of the guiding principles and objectives that form the basis of the organization's compensation philosophy; (ii) governance roles and responsibilities; (iii) physician compensation formulas and parameters; and (iv) a processes for monitoring and documenting compliance with the fair market value and commercial reasonableness regulatory standards.
 - Contractual Support for Compensation Review.* The contract terms in a health care organization's physician employment agreements and compensation plan should allow for periodic evaluation of projected and actual compensation and should facilitate the withholding and modification of such compensation when necessary to maintain regulatory compliance.
 - Physician Compensation Policies.* A health care organization's policies should establish compensation-focused compliance standards and processes for: (i) requesting contracts; (ii) developing compliant terms; (iii) reviewing the arrangement for technical Stark compliance; (iv) supporting the key tenets of defensibility with analysis and documentation; and (v) approving of compensation arrangements by management and/or the compensation committee depending on the identified approval authority.
6. **The Rebuttable Presumption.** Tax-exempt organizations should consider whether the compensation approval process supports the establishment of a rebuttable presumption under the Internal Revenue Code of 1986.⁴⁰ For this presumption to exist, the Code generally requires the following factors: (i) the compensation arrangement must be approved in advance by an authorized body of disinterested individuals; (ii) the authorized body must rely upon "appropriate data as to comparability" in making its determination; and (iii) the authorized body must adequately document the basis for its determination concurrently with that determination.
7. **Quality Based Compensation.** Health care organizations that are transitioning to models that incentivize quality and cost savings should develop processes for evaluating compliance with Section 1128A(b)(1)-(2) of the Social Security Act (the "CMP"). The CMP establishes a civil monetary penalty of up to \$2,000 per covered patient against any hospital that knowingly makes a payment directly or indirectly to a physician (and any physician who received such payment) as an inducement to reduce or limit services provided with respect to Medicare or Medicaid beneficiaries under such physician's direct care. Appropriate governance processes may include documentation of the evidence and clinical outcomes supporting the quality and cost savings measures and development of sufficient safeguards to protect against inappropriate reductions in care.

8. **Approaches for Documenting Compliance.**

- Legal Analysis.* Health care organizations should define legal counsel's role in documenting compliance. They also should consider requesting formal written assessments of the compensation arrangement or plan's compliance with the underlying technical requirements of the applicable laws (e.g., Anti-Kickback Statute, Stark Law, Intermediate Sanctions Law, etc.). These assessments could be performed and updated periodically to address changes in the regulations and shifts in Stark Law enforcement.
- Valuation Analysis.* Health care organizations should also define the valuation consultant's role in documenting compliance.⁴¹ They should also consider obtaining a formal written valuation opinion documenting compliance with the key tenets of fair market value and commercial reasonableness.
- The Volume or Value Standard.* Governance process should emphasize and document the proper non-referral business rationale supporting all compensation arrangements. Health care organizations should also avoid any actions or communications that may be misconstrued as violating the prohibition on taking into account DHS referrals.
- Documentation Supporting Group Practice Requirements.* Independent, hospital or system-affiliated physician practice entities that rely on the group practice definition and the IOAS should develop processes for evaluating and documenting compliance with the hyper-technical underlying requirements.

9. **Internal Monitoring and Auditing.** Health care organizations should consistently monitor and periodically audit their compensation-focused compliance protocols to confirm they are being followed and to ensure they can support the technical requirements and key tenets of defensibility of the Stark Law if their arrangements are ever challenged. The Practice Guidance and Hospital Guidance collectively identify a number of factors that health care organizations can consider as they evaluate their monitoring and audit programs.⁴²

The resulting goal of the critical analysis performed by a health care organization is to anticipate the continued changing market conditions and shifting Stark Law enforcement trends. Although it can be difficult to anticipate shifting enforcement trends and how Stark may be construed under specific fact patterns, health care organizations can nonetheless still strive to be consistent with historical understandings of government enforcement.

Governance Process as a Solution

Health care organizations face significant potential liability in the current regulatory environment. Given these risks under the Stark Law, it is of the utmost importance that health care organizations continue to enhance their compensation-focused governance processes. Specifically, health organizations should focus on the key tenets of defensibility and organizational planning. Health care organizations can be assured that Stark Law enforcement will continue; however, by planning and enhancing the key tenets of defensibility and ensuring compensation-focused compliance, risks of enforcement can be significantly reduced. **C**

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Endnotes

- 1 42 U.S.C. § 1395nn.
- 2 See generally Danielle M. Sloane, Lauren M. Gaffney & Amy Sanders, *Fallen Halos, Excessive Salaries, and Turning Yourself In: A Look Back at 2014 Stark Law Enforcement*, AHLA CONNECTIONS, Feb. 2015, at 36.
- 3 See 42 U.S.C. § 1395nn. Because of the significant exposure for health care organizations, the Stark Law is viewed as a threshold compliance statute. That being said, compliance with the Stark Law will not ensure compliance under the federal Anti-Kickback Statute or the Internal Revenue Code of 1986.
- 4 42 C.F.R. § 411.353(b).
- 5 See 42 U.S.C. § 1320a-7b(b). The relevant inquiry in an action brought under the Anti-Kickback Statute focuses on the subjective intent of the parties to exchange remuneration for referrals.
- 6 Social Security Act § 1877(g); 42 U.S.C. § 1395nn(g); 42 C.F.R. §§ 411.351(b)-(d).
- 7 42 U.S.C. 1320a-7b.
- 8 See OIG Supplemental Compliance Program Guidance for Hospitals, 70 Fed. Reg. 4858 (Jan. 31, 2005).
- 9 See 42 C.F.R. § 411.357(c) (2015).
- 10 42 C.F.R. § 411.355(b).
- 11 See 42 C.F.R. § 411.357(c). Further, the employment exception lacks many of the requirements that trigger technical Stark issues under other exceptions (e.g., that compensation must be "set-in-advance," that the arrangement be evidenced by a signed written agreement, that the arrangement have a term of at least a year, etc.).
- 12 42 C.F.R. § 411.355.
- 13 *Id.*
- 14 42 C.F.R. § 411.352; see also 69 Fed. Reg. at 16077 (Mar. 26, 2004).
- 15 42 C.F.R. § 411.352; see also 66 Fed. Reg. at 909 (Jan. 4, 2001). CMS has identified safe harbored methodologies for distributing productivity bonuses and profit shares that it *deems to be indirect*. Group practices may use other methodologies provided they are reasonable, objectively verifiable, and are only indirectly related to DHS referrals.
- 16 42 U.S.C. § 1395nn; see also 69 Fed. Reg. at 16077 (Mar. 26, 2004).
- 17 66 Fed. Reg. at 909 (Jan. 4, 2001).
- 18 See 42 C.F.R. § 411.357.
- 19 42 U.S.C. § 1395nn(h)(3); 42 C.F.R. § 411.351.
- 20 See 69 Fed. Reg. 16107 (Mar. 26, 2004); see also 72 Fed. Reg. at 51015-16 (Sep. 5, 2007). In 2004 CMS created a "safe harbor" provision in the definition of "fair market value" under Stark for hourly payments made to physicians for their personal services. Due in part to concerns regarding the availability of the surveys identified in the safe harbor, the fair market value safe harbor was eliminated by CMS in 2007.

- 21 *Id.*
- 22 See 63 Fed. Reg. 1700 (Jan. 9, 1998) and 69 Fed. Reg. 16093 (Mar. 26, 2004).
- 23 The federal district court in *United States ex rel. Singh v. Bradford Reg'l Med. Ctr.*, 752 F. Supp. 2d 602 (W.D. Pa. 2010) interpreted that the term "referral" encompasses both actual and anticipated referrals.
- 24 42 C.F.R. § 411.352. The Stark Law permits payment of bonuses and profit shares that include DHS revenues, provided the distribution methodology meets certain conditions.
- 25 Department of Health and Human Services and the Department of Justice, *Health Care Fraud and Abuse Control Program Annual Report for Fiscal Year 2014* (Mar. 19, 2015), available at <https://oig.hhs.gov/publications/docs/hcfac/FY2014-hcfac.pdf>.
- 26 Press Release, Department of Justice (DOJ), Justice Department Recovers Nearly \$6 Billion from False Claims Act Cases in Fiscal Year 2014 (Nov. 20, 2014), available at www.justice.gov/opa/pr/justice-department-recovers-nearly-6-billion-false-claims-act-cases-fiscal-year-2014.
- 27 Press Release, DOJ, Florida Hospital System Agrees to Pay the Government \$85 Million to Settle Allegations of Improper Financial Relationships with Referring Physicians (Mar. 11, 2014), available at www.justice.gov/opa/pr/florida-hospital-system-agrees-pay-government-85-million-settle-allegations-improper.
- 28 *United States ex rel. Schubert v. All Children's Health Sys.*, Case No.: 8:11-cv-01687-T-27EAJ, 2013 U.S. Dist. LEXIS 163075, at *2-5 (M.D. Fla. Nov. 15, 2013).
- 29 Press Release, DOJ, Texas-Based Citizens Medical Center Agrees to Pay United States \$21.75 Million to Settle Alleged False Claims Act Violations (Apr. 21, 2015), available at www.justice.gov/opa/pr/texas-based-citizens-medical-center-agrees-pay-united-states-2175-million-settle-alleged.
- 30 Press Release, DOJ, Manhattan U.S. Attorney Settles Civil Fraud Claims Against Westchester Medical Center Arising From Its Violations Of The Anti-Kickback Statute And The Stark Law (May 14, 2015), available at www.justice.gov/usao-sdny/pr/manhattan-us-attorney-settles-civil-fraud-claims-against-westchester-medical-center.
- 31 Press Release, DOJ, King's Daughters Medical Center to Pay Nearly \$41 Million to Resolve Allegations of False Billing for Unnecessary Cardiac Procedures and Kickbacks (May 28, 2014), available at www.justice.gov/opa/pr/king-s-daughters-medical-center-pay-nearly-41-million-resolve-allegations-false-billing.
- 32 Press Release, DOJ, Health Care Providers to Pay \$1 million for False Claims, Improper Referrals (Apr. 17, 2014), available at www.justice.gov/usao-ndwp/pr/health-care-providers-pay-1-million-false-claims-improper-referrals.
- 33 *United States ex rel. Heesch v. Diagnostic Physicians Grp.*, No. 1:11-cv-00364-KD-B (S.D. Ala. Sept. 4, 2014).
- 34 Press Release, DOJ, New York Heart Center To Pay More Than \$1.33 Million To Settle Allegations Of False Claims Act And Stark Law Violations (Aug. 14, 2014), available at www.justice.gov/usao-ndny/pr/new-york-heart-center-pay-more-133-million-settle-allegations-false-claims-act-and.
- 35 Press Release, DOJ, Kentucky Cardiologists Agree to Pay \$380,000 to Settle False Claims Act Allegations Based on Illegal Referrals (Oct. 21, 2014), available at www.justice.gov/opa/pr/kentucky-cardiologists-agree-pay-380000-settle-falseclaims-act-allegations-based-illegal.
- 36 OIG Compliance Guidance, available at <http://oig.hhs.gov/compliance/compliance-guidance/index.asp>.
- 37 See Supplemental Compliance Program Guidance for Hospitals, 70 Fed. Reg. 4858 (Jan. 31, 2005); see also Compliance Program for Individual and Small Group Physician Practices, 65 Fed. Reg. 59434 (Oct. 5, 2000).
- 38 *Id.* The OIG identifies seven factors that are often observed in effective compliance programs: (1) designation of a compliance officer and compliance committee; (2) development of compliance policies and procedures, including standards of conduct; (3) developing open lines of communication; (4) appropriate training and education; (5) internal monitoring and auditing; (6) response to detected efficiencies; and (7) enforcement of disciplinary standards.
- 39 *Id.*
- 40 Treas. Regs. § 53.4958-6(a).
- 41 See Supplemental Compliance Program Guidance for Hospitals, 70 Fed. Reg. 4858 (Jan. 31, 2005); see also Compliance Program for Individual and Small Group Physician Practices, 65 Fed. Reg. 59434 (Oct. 5, 2000).
- 42 *Id.*

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