

Compliance TODAY

March 2016

A PUBLICATION OF THE HEALTH CARE COMPLIANCE ASSOCIATION

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Physician compensation compliance: Can your plan survive Stark Law scrutiny?

- » Government enforcement of healthcare fraud and abuse laws has evolved to include actions and settlements against medical groups and individual physicians.
- » Three key tenets to focus on when developing physician compensation strategies are fair market value, commercial reasonableness, and the prohibition on taking into account the volume or value of referrals.
- » Healthcare organizations should develop compliance-focused governance processes that specifically focus on physician compensation.
- » Healthcare organizations should consult with compliance and legal professionals to ensure physician compensation strategies are in alignment with new understandings of healthcare fraud and abuse laws.
- » Proper compensation plan implementation is critical to ensuring compensation arrangements are positioned to withstand government scrutiny.

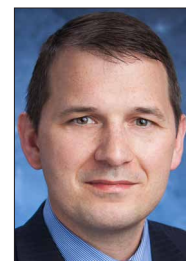
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In today's evolving healthcare landscape, medical groups, hospitals, and health systems are focusing on developing integrated healthcare delivery systems structured around employing physicians. Direct employment of physicians (as opposed to other alignment strategies) results in greater physician alignment and provides healthcare organizations with wider latitude to develop, implement, and incentivize behavior that advances organizational goals and objectives. To achieve the desired level of integration, healthcare 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.

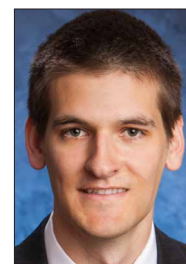
As healthcare organizations adapt and situate themselves in the new value-based

environment, the federal government continues to pursue perceived healthcare fraud and abuse. The current enforcement climate combines aggressive government and whistleblower action with a hyper-technical regulatory framework to make physician compensation compliance particularly challenging for healthcare organizations. Government enforcement continues to primarily focus on the federal physician self-referral law and its implementing regulations (collectively, the Stark Law or Stark).¹ Specifically, enforcement efforts are concentrated on alleged violations related to three key tenets of defensibility (i.e., fair market value, commercial reasonableness, the prohibition on taking into account designated health service [DHS] referrals).

This article focuses on the evolving technical requirements of the Stark Law, the three



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tenets of defensibility, and potential shifts in Stark Law enforcement. It also seeks to provide guidance for healthcare organizations as they assess their compensation governance structures to ensure existing processes and internal controls support compensation-focused compliance in today's shifting enforcement climate.

Although enforcement efforts previously centered almost solely on hospitals, the government and whistleblowers are beginning to pursue enforcement actions against physicians and medical groups. Due to the significant civil penalties associated with recent Stark Law enforcement actions, compensation-focused compliance has become an enterprise risk management issue. As healthcare organizations pursue integration strategies and transition to more innovative compensation plans, such organizations must manage their compliance and enterprise risk by ensuring their compensation arrangements are defensible under the Stark Law. To begin determining whether their compensation arrangements are defensible, healthcare organizations should evaluate their compensation-focused governance structures to ensure existing processes and internal controls support compliance with Stark's technical requirements and three key tenets of defensibility.

Ongoing Stark Law enforcement

As has been the case for a number of years, Stark Law actions are largely initiated through *qui tam* actions pursued by private whistleblowers under the False Claims Act. 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. In 2015, the Department of Health and Human Services (HHS) and the U.S. Department of Justice (DOJ) noted in their annual report on healthcare fraud and abuse that the return on investment

from their joint healthcare fraud enforcement efforts was \$7.70 returned for every \$1.00 spent over the last three years.² The report also noted that the 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 robust and ongoing focus of HHS and the DOJ with respect to healthcare fraud.

Potential shifts in enforcement

Historically, whistleblower and government enforcement actions have focused on hospital activity. However, the recent enforcement actions since 2014 suggest that the dynamic has shifted in some areas, and that there may be more actions against physicians and medical groups coming down the pipeline. Below are some cases and settlements demonstrating this potential shift in enforcement.

- ▶ 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.³
- ▶ 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.⁴ A central issue in the case was whether the Infirmity practice entities were compliant Stark group practices.
- ▶ 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.⁵

- ▶ 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.⁶
- ▶ Columbus Regional Healthcare System agreed to pay up to \$35 million and Dr. Andrew Pippas agreed to pay \$425,000 to resolve violations relating to employment and medical director compensation arrangements that allegedly paid compensation that was not consistent with fair market value.⁷

Although these recent enforcement actions are important because they represent a departure from actions solely against hospitals, they still focus predominately on the key tenets of defensibility. Additionally, Infirmary 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 Stark's group practice requirements. However, what continues to be most important is that from the onset of any arrangement, whether internal group compensation or hospital-physician compensation arrangements, organizations ensure governance processes support defensibility under the Stark Law.

Compensation-focused compliance

The Stark Law prohibits a physician from making referrals of certain designated health services 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. This prohibition applies regardless of the reasons for the financial relationship and the DHS referral, making the Stark Law a strict liability statute.

Although 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 healthcare programs and may result in the 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.⁸ Similar to the Anti-Kickback Statute, a Stark Law violation may also serve as the basis for liability under the False Claims Act.

From a compliance and process perspective, healthcare organizations must ensure that all compensation arrangements with referring physicians meet Stark's technical requirements and fit squarely within an applicable exception. For organizations adopting direct physician employment models, arrangements are likely to be structured to meet either the exception for bona fide employment relationships or the in-office ancillary services exception (IOAS). The employment exception is generally considered the broadest and most commonly used compensation exception available under Stark. However, the exception does not protect 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.⁹

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.” As a threshold matter, the physician practice entity must meet all nine structural and operational requirements for being a group practice.¹⁰ Stark group practices can pay productivity bonuses for DHS that are “incident-to” a physician’s personally performed services and can also 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. This favored treatment and additional latitude with respect to physician compensation is statutory. 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 Medicaid and Medicare 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.¹¹

Healthcare 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.

Key tenets of defensibility

Though each Stark exception carries its own technical requirements, as a central premise there are three key tenets of defensibility that many of the Stark exceptions share. Notably, the compensation: (1) must be consistent with fair market value; (2) must be paid under an arrangement that is commercially reasonable; and (3) 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 found in most exceptions, physician compensation policies and procedures should take special care to document compliance with these three tenets, regardless of the exception that is ultimately relied upon.

Fair market value

The first tenet, fair market value, is defined in both the Stark statute and its implementing regulations.¹² 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. Because the Stark Law covers a wide variety of arrangements, CMS has acknowledged that no single valuation method would apply universally to all arrangements covered by Stark. Instead, CMS has endorsed referencing multiple, objective, and independently-published surveys and the use of independent appraisers as a means of supporting fair market value. Although the Stark Law does not necessitate the use of independent appraisers, many healthcare organizations regularly engage appraisers to issue written opinions confirming that the compensation paid under an arrangement is consistent with fair market value.

Commercial reasonableness

The second tenet, commercial reasonableness, is not defined under the Stark Law; therefore, there are inherent challenges to meeting this standard. To document compliance with the commercial reasonableness standard, organizations and appraisers generally focus on published CMS commentary that describes the standard as being met by certain subjective and objective qualitative factors.¹³ Evaluating commercial reasonableness involves considering 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. Appraisers frequently opine on the commercial reasonableness standard and are often willing to incorporate their commercial reasonableness analysis and conclusions into a more comprehensive and robust written opinion.

Volume or value prohibition

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 made 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. In one case, a U.S. District Court interpreted the term “referral” as encompassing both actual and anticipated referrals.¹⁴

For compliance purposes, as a threshold matter, healthcare organizations should ensure their compensation formulas do not calculate compensation in any manner that is based on a physician’s DHS referral activity. Further, to the extent possible, governance processes should emphasize and document the proper non-referral purposes supporting all compensation arrangements and should prevent any actions or communications that may be misconstrued as being in violation of this standard.

Historically, the government has largely alleged Stark Law violations based on these

three tenets of defensibility. Thus, in addition to strict technical compliance with an exception, organizations looking to manage their Stark Law risk should focus their attention on documenting their compliance with these tenets.

Compensation-focused compliance

As discussed throughout this article, healthcare organizations should develop compliance-focused governance processes that encompass Stark’s technical requirements and key tenets of defensibility. When determining the best approach to achieving compliance, healthcare organizations should consider their market dynamics, existing governance framework, tax-exempt status, organizational size and complexity, risk tolerance, and other factors unique to their particular circumstances.

An important component to any compliance-focused physician compensation governance process will include a consideration of the Stark regulations and the applicable guidance from CMS, the OIG, and the Internal Revenue Service (IRS). Each agency has developed guidance that can be drawn upon by healthcare organizations.

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However, while the bulk of the physician compensation guidance is articulated by CMS in the commentary to the Stark Law, the OIG provides the most comprehensive guidance on how to develop physician compensation processes that support compliance.

Notably, the OIG has issued voluntary compliance program guidance documents that are intended to encourage the development and implementation of internal

controls to monitor regulatory compliance. The OIG has published Practice Guidance and Hospital Guidance documents that are of particular value to healthcare organizations.¹⁵ Collectively, these documents provide a baseline structure for a voluntary compliance program. In particular, the Practice Guidance and Hospital Guidance documents identify basic components of an effective compliance program that serve as a solid basis for evaluating ongoing compensation-focused compliance efforts.

In addition to relevant agency guidance, the considerations below, while neither exhaustive nor comprehensive, may provide healthcare organizations with issues to identify as they begin to evaluate their compensation-focused governance processes.

Initial governance process considerations

Integration with compliance program

Healthcare organizations should consider integrating their compensation governance processes with their existing compliance program structures. For example, an organization's compliance officer could participate actively in the development of physician compensation plans and employment arrangements.

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. Due to the potential risks involved with a violation of the Stark Law, any time a healthcare organization or an individual within a healthcare organization is uncomfortable with the physician compensation arrangement, legal counsel should be called upon to analyze and advise on the appropriate course of action. This may include educating the healthcare organization as to why an issue was or was not present. 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 healthcare valuation issues.

Engagement of a qualified third-party appraiser

Appraisers perform many duties in the physician compensation realm, such as performance of financial projections, compensation planning and design (e.g., examination of market trends, conceptual modeling, etc.), and issuance of an objective third-party opinion validating fair market value and commercial reasonableness. Similar to the selection of appropriate legal counsel, healthcare organizations should engage appraisers that have the requisite expertise to opine on compliance with the Stark Law's definitions of fair market value and commercial reasonableness. Consideration should be given to engagement directly by legal counsel to ensure that the communications related to the appraisal and any written reports obtained under the engagement may be protected under the attorney-client privilege. Additionally, for healthcare organizations unfamiliar with the appraisal process, experienced legal counsel often will assist with identifying potential reputable appraisers and management of the valuation process.

Physician engagement

An important but often underrated aspect of developing compliant physician compensation plans and arrangements is positive physician relationships. Healthcare organizations can develop positive physician relationships by communicating new physician compensation strategies, seeking physician feedback on compensation plan development, and ensuring physicians thoroughly understand their own compensation arrangements prior to implementation.

Focus on plan implementation

Once the terms of a compensation arrangement are established, healthcare organizations should take care to ensure the arrangement is properly implemented and consistently followed. Healthcare organizations should consider the necessary processes that will need to be developed. This includes considering who would implement the plan in case of employee turnover. Recent enforcement actions highlight the dangers of establishing, but then failing to implement and follow the terms of compensation plans and policies.

Compliance training and education

Employees and members of the board and compensation committee should receive compensation-related compliance training on at least an annual basis to ensure that they are fully capable of executing their roles in accordance with rules, regulations, and other standards applicable to physician compensation. In addition, healthcare organizations may consider educating physicians on the laws related to physician compensation and recent enforcement actions. The OIG Hospital Guidance and Practice Guidance identify a number of common factors that healthcare organizations can consider as they evaluate their training and education programs.

Processes for compensation oversight

Healthcare 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.

Parameters for compensation review

Healthcare organizations should work with their appraiser to develop compensation parameters/thresholds that trigger additional governance processes. Once such 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. Failing to properly follow processes governing additional compensation review may be viewed negatively in the case of a government investigation. Additional and appropriate support may include survey data supporting the arrangement, documentation of the underlying business rationale, and/or a written opinion from a third-party appraiser.

Governance documents

The following governance documents, in addition to others, will help support compensation-focused compliance.

Compensation committee charter

The compensation charter could 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: (1) identification of the guiding principles and objectives that form the basis of the organization's compensation philosophy; (2) governance roles and responsibilities; (3) physician compensation formulas and parameters; and (4) a process 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 healthcare 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 healthcare organization's policies should establish compensation-focused compliance standards and processes for: (1) requesting contracts; (2) developing compliant terms; (3) reviewing the arrangement for technical Stark compliance; (4) supporting the key tenets of defensibility with analysis and documentation; and (5) approving of compensation arrangements by management and/or the compensation committee, depending on the identified approval authority.

Once a compensation plan or policies are established, counsel and/or a compliance officer should take care to ensure that they are consistently followed. Recent whistleblower lawsuits highlight the dangers of establishing but then failing to universally follow a compensation plan and/or compensation policies.

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. For this presumption to exist, the Code generally requires the following factors: (1) the compensation arrangement must be approved in advance by an authorized body of disinterested individuals; (2) the authorized body must rely upon "appropriate data as to comparability" in making its determination; and (3) the authorized body must adequately document the basis for its determination concurrently with that determination.

Approaches for documenting compliance

Legal analysis

Healthcare organizations should define legal counsel's role in documenting compliance. 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

Healthcare organizations should also define the appraiser's role in documenting compliance. Consider obtaining a formal written 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. Healthcare 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.

Internal monitoring and auditing

Healthcare 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 OIG Practice Guidance and Hospital Guidance collectively identify a number of factors that healthcare organizations can consider as they evaluate their monitoring and audit programs.

Information technology systems

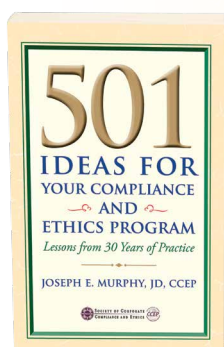
Healthcare organizations should ensure that they have appropriate systems to assist them in their physician compensation governance processes. Some functions that healthcare organizations should focus on in choosing proper systems include contract storage and organization capabilities, tracking of contract start and end dates, and the ability to clearly identify terms necessary for contract drafting. Developing and choosing strong systems can also assist healthcare organization employees in their monitoring and auditing functions.

Governance process as a solution

Although it can be difficult to anticipate shifting enforcement trends and how Stark may be construed under specific fact patterns, an examination of the considerations above will help healthcare organizations as they strive to develop compliant physician compensation arrangements.

Healthcare organizations face significant potential liability in the current regulatory environment. Given these risks under the Stark Law, it is of the utmost importance that healthcare organizations continue to enhance their compensation-focused governance processes. Specifically, healthcare organizations should focus on technical compliance and the three key tenets of defensibility. Healthcare organizations can be assured that Stark Law enforcement will continue; however, by maintaining this focus the risks of enforcement can be significantly reduced. ■

1. 42 U.S.C. § 1395nn.
2. Department of Health and Human Services and the Department of Justice: Health Care Fraud and Abuse Control Program Annual Report for Fiscal Year 2014. March 19, 2015. Available at <http://1.usa.gov/IP8iDMY>
3. Department of Justice press release: "Health Care Providers to Pay \$1 Million for False Claims, Improper Referrals" April 17, 2014. Available at <http://1.usa.gov/1ZOWFoV>
4. *United States ex rel. Heesch v. Diagnostic Physicians Group*, No. 1:11-cv-00364-KD-B (S.D. Ala. Sept. 4, 2014).
5. Department of Justice press release: "New York Heart Center To Pay More Than \$1.33 Million To Settle Allegations Of False Claims Act And Stark Law Violations" August 14, 2014. Available at <http://1.usa.gov/1nAzY6x>
6. Department of Justice press release: "Kentucky Cardiologists Agree to Pay \$380,000 to Settle False Claims Act Allegations Based on Illegal Referrals" October 21, 2014. Available at <http://1.usa.gov/1SzH5sF>
7. Department of Justice press release: "Georgia Hospital System and Physician to Pay More than \$25 Million to Settle Alleged False Claims Act and Stark Law Violations" September 4, 2015. Available at <http://1.usa.gov/1Pkwqlp>
8. Social Security Act § 1877(g); 42 U.S.C. § 1395nn(g); 42 C.F.R. §§ 411.351(b)-(d).
9. 42 C.F.R. § 411.355.
10. 42 C.F.R. § 411.352; *see also* 69 Fed. Reg. at 16077 (Mar. 26, 2004).
11. 66 Fed. Reg. at 909 (Jan. 4, 2001).
12. U.S.C. 1395nn(h)(3); 42 C.F.R. 411.351.
13. *See* 63 Fed. Reg. 1700 (Jan. 9, 1998) and 69 Fed. Reg. 16093 (Mar. 26, 2004).
14. *See U.S. ex rel. Singh v. Bradford Regional Medical Center*, 752 F. Supp. 2d 602 (W.D. Pa. 2010)
15. *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).



501 IDEAS FOR YOUR COMPLIANCE AND ETHICS PROGRAM

Lessons from 30 Years of Practice

Author Joe Murphy has compiled the most effective ideas that he and other compliance professionals have tried.

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