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Over the past several years, hospitals and health systems have been parties to numerous significant settlements associated with alleged improper compensation arrangements with physicians, including Tuomey ($72 million),[11] Adventist Health System ($118.7 million), North Broward Hospital District ($69.5 million),[21] and recently, Kalispell Regional Healthcare System ($24 million).[31]

And as though that was not enough of a financial blow, the Department of Justice has, and continues to implement, the Yates Memo,[41] which holds individual executives accountable for their role in permitting noncompliant physician arrangements. This includes, among others, Ralph J. Cox III, the chief executive officer of Tuomey Health System, who entered into a personal settlement of $1 million.[51] Although the Centers for Medicare & Medicaid Services (CMS) has indicated it intends to make the Stark Law[61] less burdensome for providers,[71] if and until that time comes, healthcare organizations must continue to be vigilant and precise in their compliance programs, particularly regarding physician compensation arrangements.

Pertinent laws and regulations

The following brief review of the pertinent laws and regulations that affect healthcare organizations will help put the subject matter in context.

The Stark Law

The Physician Self-Referral Law (aka, the Stark Law) was enacted in 1989 to address concerns that financial motives could be used to inappropriately influence a physician’s healthcare decision-making. Specifically, the Stark Law prohibits a physician from referring designated health services (DHS) that are payable by Medicare or Medicaid to a healthcare entity with whom the physician (or the physician's immediate family member) has a financial relationship unless the relationship falls squarely within one of the identified exceptions. If the referral does not meet one of the enumerated exceptions, the law prohibits the healthcare entity from billing for those improperly referred services.

Intent does not matter; if the arrangement doesn't fit precisely within an exception, strict liability ensues. Defensibility against a Stark Law claim requires that the arrangement be fair market value, commercially reasonable, and does not otherwise take into account the
volume or value of the referrals or other business generated by the physician. Violations of the Stark Law carry civil penalties, such as an overpayment/repayment obligation, False Claims Act (FCA) liability, civil monetary penalties, federal healthcare program exclusion for “knowing” violations, potential civil monetary penalty in the amount of $15,000 per prohibited referral/service, and a civil assessment of up to three times the amount claimed.

**Anti-Kickback Statute**

In addition to the Stark Law, the Anti-Kickback Statute (AKS)\[10\] applies to referrals from *anyone* and prohibits the offering, paying, soliciting, or receiving anything of value, in cash or kind, to induce or reward referrals or otherwise generate federal healthcare program business. Additionally, the AKS applies to any items and services and not just DHS. Because the AKS is a criminal law, intent (knowing and willing) must be proven to have an actionable claim.

In contrast to the Stark Law's mandatory exceptions, the AKS provides voluntary safe harbors. This means that an arrangement does not have to fall precisely within the safe harbor to be legal, but the more closely an arrangement fits within a safe harbor, the less risk is involved. Violation of the AKS may result in civil/administrative penalties, such as FCA liability, federal healthcare program exclusion, the potential of a civil monetary penalty of $50,000 per violation, and a civil assessment of up to three times the amount of the kickback. And because it is a criminal statute, a violation carries criminal fines up to $25,000 per violation and up to a five-year prison term.

**False Claims Act**

The False Claims Act\[11\] remains the federal government’s primary tool for enforcing the numerous fraud and abuse laws. The FCA’s intent is to punish providers for knowingly submitting claims for payment to Medicare or Medicaid that it “knows” or “should have known” were false or fraudulent. The “knowing” standard includes not only actual knowledge but also instances where the individual acted in “deliberate ignorance” or “reckless disregard.” Penalties for the FCA include fines of three times the program’s loss plus up to $22,927 per claim filed. And for purposes of this penalty, a claim means every instance of an item or service that was fraudulently or falsely billed. The FCA includes within it the whistleblower provision that permits a private individual to file a claim on behalf of the government (qui tam) and receive a percentage of recoveries. In addition to the civil FCA, a criminal FCA\[12\] exists that could result in imprisonment and criminal fines if a provider is found in violation.

**501(c)(3) and the Intermediate Sanctions Rules**

Congress enacted the Taxpayer Bill of Rights\[13\] in 1996, which gives the Internal Revenue
Service (IRS) the authority to impose “intermediate sanctions” on persons within a 501(c)(3) organization that uses tax-exempt organizational assets for inappropriate personal gain. The final regulations were released by the IRS in 2002. The regulations set forth the penalty excise tax that the IRS can impose on any organizational leader who approved the transaction and the applicable “disqualified person” who is determined to have participated in an “excess benefit transaction” (i.e., one that exceeds fair market value). A disqualified person is defined as one who is determined to have substantial influence over the organization's affairs, which applies to board members who are entitled to vote, chief executive officers, and other members of the executive team. Still others may be deemed disqualified based on the particular facts and circumstances.

In many organizations, certain physicians have substantial influence over decision-making in particular segments of a healthcare organization, such as an entity’s heart institute or cancer center where revenues from the program are substantial. These physicians may be viewed as potential disqualified persons. If an organization demonstrates that the compensation paid to a disqualified person is reasonable as of the time the parties enter into the compensation arrangement, organizations are afforded a rebuttable presumption of reasonableness by the IRS, so long as the governing body approves the transaction (having relied on fair market value comparability data) and adequate documentation is retained. For this reason, many organizations seek board approval of some, if not all, physician compensation arrangements.

Governance

In order to describe an effective physician compensation governance process, it is helpful to discuss the meaning of governance. Governance is described as encompassing three primary components, (1) authority, (2) decision-making, and (3) accountability. These principles are informative when establishing a physician compensation governance structure—who has the authority to act, how decisions are made, and how individuals will be held accountable. In a complex healthcare organization, the authority to act, with respect to physician compensation arrangements and the direction an organization will take in developing an effective process, will come from the governing body itself.

Board oversight duties

It is well understood that in serving on an entity’s board of directors/managers, governing body members have three basic fiduciary duties: (1) the duty of loyalty, (2) the duty of care, and (3) the duty of obedience. This means that directors/managers must perform their duties in good faith, in a manner they reasonably believe to be in the best interest of the organization, and with the care an ordinarily prudent person would exercise under similar circumstances.
A couple of key cases provide some direction to boards on what their obligation is with regard to their duty of care. The *In re Caremark* court provided that “a director's obligation includes a duty in good faith to assure that a corporate information and reporting system, which the Board concludes is adequate, exists, and the failure to do so under some circumstances, may in theory at least, render a director liable for losses caused by noncompliance with applicable legal standards.”[14]

Similarly, the *In re Walt Disney Company* court reiterated those same principles by describing the director’s adherence to a reasonable process as key. “Compliance with a director's duty of care can never be appropriately judicially determined by reference to the content of the board decision that leads to the corporate loss,” *apart from the good faith or rationality of the process employed* (emphasis added).[15]

The Federal Sentencing Guidelines provide that “[t]he organization's governing authority shall be knowledgeable about the content and operation of the compliance and ethics program and shall exercise *reasonable oversight* with respect to the implementation and effectiveness of the compliance and ethics program (emphasis added).”[16] Because of the complexity of the laws and regulations that govern physician compensation arrangements, an organization may find itself under a lengthy corporate integrity agreement (CIA) with substantial financial settlements or liability. In some cases, individuals may be excluded from the federal governmental payer programs and face individual fines if an effective physician compensation governance process is not employed.

Numerous guidance documents over the years have provided governing body members with guidance on their roles in overseeing their organization's compliance program.[17] Among other key areas of responsibility, the guidance provides that effective oversight requires the governing body members to ask the right questions of organizational leadership so that it may determine whether the compliance program is *adequate* and *effective*. As such, boards are in a position to ensure and expect that an effective physician compensation governance process is in place and that its leaders are held accountable in the development of and adherence to this process.

**Effective physician compensation governance programs**

Organizational compliance programs are intended to prevent, detect, and correct compliance issues. Despite the multiple and seemingly continuous costly settlements that result from alleged improper physician compensation practices, organizations struggle with implementing an effective physician compensation governance process. Every organization should be conducting an annual risk assessment as part of its compliance program planning process. Any organization that has arrangements with physicians will undoubtedly have physician arrangements identified as a high-risk item, because any misstep with respect to the Stark Law could lead to hefty fines or other penalties. The best way to address this high-
risk area is through prevention by means of a standardized process that involves the organization's key stakeholders, addresses certain vital elements, has all of the appropriate approvals in place and, importantly, is not only followed but is expected to be followed before an arrangement is executed.

Identify key stakeholders

The first step in developing an effective physician compensation governance process is to identify the key stakeholders who should be involved. It is critical that the group of key stakeholders include the highest levels of leadership, because this group will set the standards for physician compensation and other arrangements, and importantly, will facilitate holding each other accountable for following the same process. Depending on the size of the organization, key stakeholders may include the recruitment leaders who have direct contact with a physician candidate/contractor, the executive in charge of the physician group, the chief compliance officer, chief legal officer, chief medical officer, chief financial officer, and chief executive officer. However, our guidance would be to include anyone in leadership whose job description includes the authority to contract with physicians.

Define physician compensation philosophy/policy

Next, time should be spent developing the organization's physician compensation philosophy or policy. This process may take a lengthy period, but it is one of the fundamental activities the governance group must engage in, because it will provide the structure and framework within which the organization will operate. Any well-designed compensation policy document will support the organization's strategic plan, business goals, and objectives; be consistent with its manpower needs study; and take into account the organization's competitive environment and financial constraints, if any. During this process, the governance group should discuss and agree upon pay parameters and compensation components.

The policy sets the boundaries within which the organization will play and determines what options it has in its playbook. For example, the group should discuss if, how, and under what parameters the following will be paid: base salary, incentive pay, conversion factors, compensation caps, relocation bonuses, signing bonuses, educational loan repayment, medical directorships, continuing medical education, licensure, dues, vacation time (how much and whether it is carried over), on-call pay, advanced practitioner oversight, quality pay, etc.

Within each of these categories, the limits of what the organization will pay for must be determined. For example, if an organization decides that it will pay signing bonuses, the next question should be, up to what amount? Or, in the case of educational loan repayment,
what terms and amount would the organization be willing to provide?

The physician compensation governance group may also wish to discuss specific performance expectations in the physician arrangements. Many organizations find it helpful to engage a third party to facilitate this process. Some questions for discussion include:

- What are the expectations for patient contact hours in a week and days per week worked?
- Will outside activities will be permitted and, if so, what kind?
- When must patient records be completed?
- What are the non-compete and/or non-solicitation parameters? and
- What other areas does the group consider important?

The group may want to establish total compensation pay parameters that it expects most arrangements will fall within, and set criteria and special approvals for when those parameters may be exceeded. The group should also establish a timeline for review and resetting of constraints as necessary. Once this arduous process is completed and agreed upon, it is helpful to have legal counsel draft an agreement template that addresses all of the various potential compensation components and ensures all necessary legal provisions are included.

**Determine pre-approval procedures**

For many organizations, the approval procedure begins with the assembly of a pre-transactional review group that is made up of the key stakeholders and is scheduled to meet regularly (depending on how many proposed arrangements come forth for review). In advance of a meeting, the individual proposing the arrangement might prepare a term sheet, which is standardized to include the agreed-upon parameters and all of the relevant proposed compensation terms. Doing so affords the compensation group adequate time to review the proposal and ensures a consistent approach. The individual proposing the arrangement should also provide documentation of the business need for the arrangement as well as a pro forma (i.e., a financial statement that shows the projected effects of the hire), so the compensation group can adequately evaluate the proposal. Individual term sheets may want to cite market survey data related to compensation levels, so the group members have a sense of market competitiveness. Importantly, documentation of any special circumstances or unique characteristics of the provider, situation, or arrangement should be gathered to support the business need and commercial reasonableness of the arrangement.

Once the compensation group has reviewed the proposed arrangement and any changes
are established and agreed upon, the proposed arrangement should be evaluated for fair market value/commercial reasonableness. If the proposed compensation changes during the negotiation process, the proposal should be returned to the committee for review and approval of the changes and be re-confirmed as being fair market value and commercially reasonable.

Document fair market value/commercial reasonableness

Fair market value/commercial reasonableness is one of the tenets of defensibility of physician compensation arrangements, yet the Stark Law regulations provide little guidance defining fair market value as the value in arms’ length transactions, consistent with “general market value.” General market value means the compensation: (1) is the result of bona fide bargaining between well-informed parties who are not otherwise in a position to generate business for each other, (2) has been included in other contemporaneous bona fide service agreements with comparable terms, and (3) is not determined in any manner that takes into account the volume or value of anticipated or actual referrals.\textsuperscript{18} Further, the Stark Law regulations fail to define commercial reasonableness at all.

Many organizations take the approach of setting standard compensation parameters defined within particular percentiles of national survey data, often at the median or 75th percentile. In certain landmark Stark Law cases, governmental experts had previously stated a “preference” for compensation parameters falling within the median to 75th percentile range, depending on the particular facts and circumstances; however, more recent settlements indicate increased scrutiny with compensation falling below the median.\textsuperscript{19} However, national survey data is at times criticized, because several of these surveys are made up of self-reported (and thus, unverified) data.

Further, the preamble to the Stark Law regulations provides that:

\begin{quote}
while internally generated surveys can be appropriate as a method of establishing fair market value in some circumstances, due to their susceptibility to manipulation and absent independent verification, such surveys do not have strong evidentiary value and, therefore, may be subject to more intensive scrutiny than an independent survey.\textsuperscript{20}
\end{quote}

As a result, many organizations choose to have fair market value and commercial reasonableness determined by an independent valuator who has access to multiple market surveys and can assist in confirming the commercial reasonableness of a particular compensation approach. They typically also have exposure to market situations based on their work with a variety of clients in multiple situations.

Board approval

Following the operational approval of the proposed compensation arrangement and
The documentation of fair market value/commercial reasonableness, the proposed arrangement should be presented to the board or a board committee for approval. Alternatively, some boards approve certain compensation policies and require a subset of arrangements to be approved by the board.

The approval process allows the board to fulfill its fiduciary duty of care to the organization, affords another level of control in ensuring the pre-established procedures have been followed, or where there is a variance, permits an exchange of information between the senior leaders and the board regarding the factors in support of the variance.

And finally, where applicable, the approval process permits the organization and the individuals involved in setting and approving the proposed arrangement to establish the rebuttable presumption of reasonableness under the IRS rules. If an organization opts to obtain the rebuttable presumption of reasonableness, it must seek the approval prior to execution of the agreement. The board minutes must document whether any of the board members had a conflict of interest with any of the proposed arrangements and document how the conflict was handled. The minutes must also document who voted.

Documentation

As an organization establishes its governance process and works through the above steps, the physician compensation policy and procedure should be approved by the organization's senior executives and board. The policy and procedure document the organization's standardized and consistent approach to physician compensation and serves as a mechanism for ensuring accountability. In addition to a written policy and procedure, the importance of accurate and complete documentation of each step of the process cannot be overstated. The documentation tells the story of an individual's qualifications, the organization's rationale for employing them, and the particular facts and circumstances surrounding the particular arrangement.

Ongoing compliance

An organization's policy and procedure should include parameters for ongoing monitoring of physician compensation arrangements. Best practices include an annual review of each arrangement by a valuation firm to ensure the compensation remains fair market value with adjustments as necessary. Also, scheduled audits of high-producing physicians should be conducted to review documentation, coding, and medical necessity. Importantly, physicians receiving medical director/administrative pay should have an annual timesheet or documentation audit to ensure that the necessary duties are performed, they are adequately documented, and they are paid per provider contract and organizational policy. Any performance-based pay (i.e., quality) should be validated to ensure the data has been collected following established definitions, and credit is given to the physician according to
program design. Finally, work relative value units (work RVUs) credited to physicians should be periodically reviewed to ensure that the physician is receiving credit only for personally performed services.

**Conclusion**

Physician compensation arrangements pose one of the highest risks to healthcare organizations. As (alleged) Stark Law and False Claims Act violations continue to be pursued by governmental agencies and filed by local qui tam relators, organizations must remain vigilant, conscientious, and apply a reasoned, consistent approach to physician compensation. Establishing an effective physician compensation governance program will assist an organization in defense of its procedures and physician compensation structure if it finds itself under scrutiny.

**Takeaways**

- Physician compensation arrangements remain a key compliance risk.
- Develop a physician compensation policy and procedure.
- Implement a physician compensation governance committee.
- Ensure documentation of fair market value/commercial reasonableness for each physician compensation arrangement.
- Audit and monitor physician compensation arrangements over time.

6. 42 U.S.C. 1395nn – Limitation on certain physician referrals
8. CMS.gov, Physician Self Referral. [https://go.cms.gov/2XUrZ7s](https://go.cms.gov/2XUrZ7s)
42 U.S.C. 1320a-7b(b) Criminal penalties for acts involving Federal health care programs
31 U.S.C. 3729-3733 False Claims
18 U.S.C. 287 False, fictitious or fraudulent claims
Internal Revenue Code of 1986, as amended at 4958, Intermediate sanctions
Institute on Governance, defining governance.https://bit.ly/2HyWn1i
In re Caremark Int’l, Inc. Derivative Litig., 698 A.2d 959 (Del. Ch. 1996)
In Re Walt Disney Co. Derivative Litig., 906 A.2d 27 (Del. June 8, 2006)
42 C.F.R. 411.351 Definitions