Show Me the Money!

Audit physician compensation arrangements

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Physician employment and professional services arrangements have required robust review and audit processes. Now the revisions to both the Physician Self-Referral law, commonly referred to as the Stark Law, and the Anti-Kickback Statute (AKS), allow innovative new arrangements to promote quality outcomes and health system efficiencies. You must pay purposeful and persistent attention to physician compensation arrangements to ensure that the entire spectrum of services physicians provide and are compensated for are evaluated.

Alternative physician compensation arrangements come in a variety of forms, some of which may already be on your organization's radar for inquiry, such as medical director positions and on-call coverage arrangements. Other positions are emerging and deserve similar attention. Examples of other titles that may be covered by alternative physician compensation arrangements are summarized in Exhibit 1.

Exhibit 1 – Titles with potential compensation arrangements

1. Physician administrator
2. Vice president of medical affairs
3. Chief medical information officer
4. Chief medical officer
5. Chief of staff
6. Section chief
7. Department director
8. Teaching physician
9. Locum tenens physician
10. Chief administrative officer
11. Researcher

You should focus on two categories of high-risk compensation arrangements:

- Physicians serving as medical directors of hospitals, health systems and other healthcare organizations
- Physicians who have financial interactions with manufacturers of drugs, devices, biologicals and medical supplies

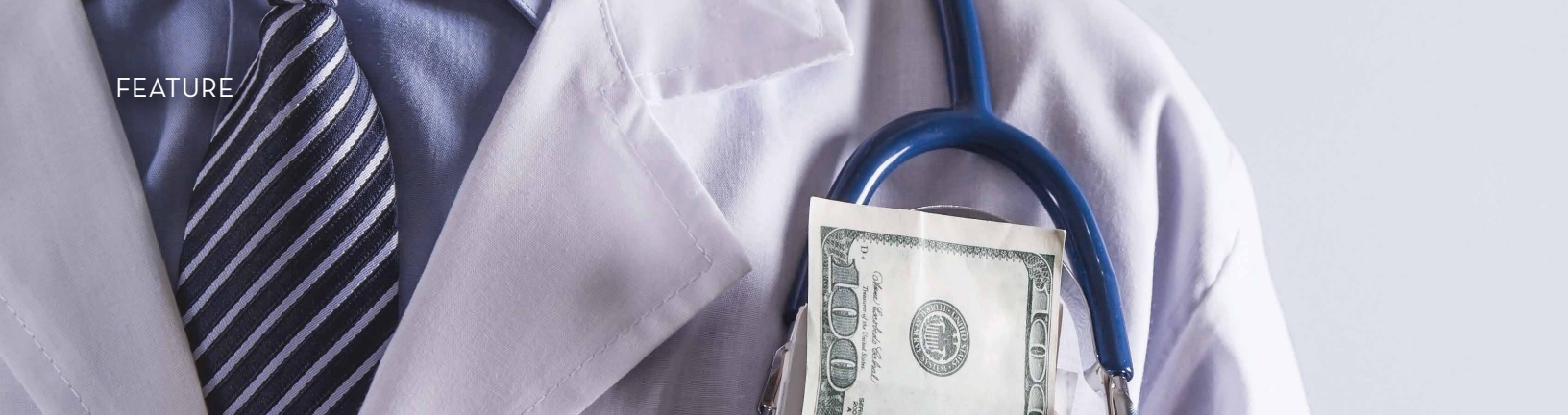
Medical directorships

Medical directors fulfill programmatic needs where a physician's administrative and/or clinical expertise is required to coordinate medical care and help develop, implement and evaluate patient policies and procedures that reflect current standards of practice. Also, medical director positions are required by Centers for Medicare and Medicaid Services (CMS) regulations for providers to obtain governmental reimbursement and/or comply with accreditation standards.

Medical directors can fulfill roles and responsibilities such as:

1. Oversight, planning and direction of service line activities (e.g., oncology, cardiology, orthopedics, etc.)
2. Developing quality improvement programs
3. Establishing and implementing policies and procedures to facilitate compliance with regulatory requirements
4. Evaluating clinical activities
5. Analyzing patient care audit results and the resulting implementation oversight
6. Resolving patient care issues
7. Medical education and training
8. Facilitating collaboration between providers

Medical directorships have been subject to regulatory scrutiny for quite some time. However, a fraud alert issued on June 9, 2016, by the Department of Health and Human Services Office of Inspector General (HHS OIG) specifically



addressed and brought heightened attention to these types of physician arrangements.

In addition to other allegations, the fraud alert indicated that the compensation paid under the medical directorship arrangements in question constituted improper remuneration under the AKS. The arrangements did not reflect fair market value (FMV) for the services that were to be performed and the contracted physicians did not provide the medical directorship services required by the agreements. When compensation is provided for services purportedly not required, the need for a particular medical director, and ultimately the commercial reasonableness of the position, may be called into question.

While not all-encompassing, the following considerations are critical to evaluating a medical director arrangement.

Evaluate the medical director philosophy

Review your organization's current medical director policy or initiate development if one is not already in existence. The medical director policy should outline the mission of the organization's medical director program, as well as the process for determining the need for medical directors.

The policy should also address how the provision of such services is documented (e.g., timesheets) and clarify the organization's nomenclature for physicians who provide defined medical director duties. For example, an organization may use the titles of administrative physician or managing physician, program director or medical director synonymously. If the organization does not clearly categorize such positions, the potential increases for duplicative compensation for the same and/or overlapping duties.

Identify the need

Determine if the medical director position is required by federal and/or state law or otherwise required for regulatory or accreditation purposes. Evaluate whether market comparisons, such as similar positions or survey benchmark data, are available for the identified position.

Further, consider the number of hours provided, the size of the department where services will be provided, the number of locations to be overseen by the medical director, and the robustness of duties required by the position, among other possible factors. Be aware that the need for a desired position may be called into question if it is not required by federal, state or accrediting organizations, has no published compensation data, and has no similar positions advertised.

Perform routine program maintenance

Evaluate whether the policy for the documentation of services is being followed through a monthly or otherwise regularly scheduled audit of timesheets or other required deliverables. Perform a review of individual medical director agreements focused on identifying reasons for continued need, the time incurred, and the resulting accomplishments compared to identified expectations. Follow up on any potential risk areas.

Physician financial interactions with manufacturers

As highly trained specialists, physicians and clinical researchers have a unique opportunity to improve and advance patient care, as well as to support the mission of your organization, through collaboration within the healthcare industry. Anticipate that many physicians have some form of financial interaction with manufacturers of drugs, devices, biologicals and medical supplies.

The influence of industry interests on the integrity of the medical profession, and ultimately, patient care, has been recognized as having the potential to corrupt a medical professional's independence, objectivity and professional behavior. Conflicts of interest (COI) are believed to be inherent in industry financial relationships between physicians and the retail healthcare industry, such as drug and device manufacturers. In response, leading healthcare organizations established principles of medical professionalism including, but not limited to, provisions addressing COIs.

The purpose of these principles and the resulting COI policies and procedures is to identify potential issues that can lead to the compromise of patient care over the pursuit of financial gain or other interests. Recognizing

the inadequacy of the voluntary disclosure model and balancing that concern against the importance of health-care industry investment in innovation and research, Congress enacted the Physician Payments Sunshine Act, also known as Section 6002 of the 2010 Affordable Care Act (ACA).

The Sunshine Act requires medical product manufacturers to disclose to CMS any payments or other transfers of value made to physicians, researchers or teaching hospitals. Payments and value can include, but are not limited to, payments for meals, consulting or speaker fees, and direct research funding. Additionally, certain manufacturers and group purchasing organizations must disclose any physician ownership or investment interests held in those companies. Exhibit 2 summarizes the Sunshine Act reporting requirements.

Exhibit 2 – Sunshine Act reporting summary

1. Who must report payments?

- Manufacturers and distributors of drugs, biologics and medical devices that are covered for payment under Medicare, Medicaid or Children's Health Insurance Program (CHIP)
- Group Purchasing Organizations (GPOs) and physician-owned distributors of medical devices

2. What kind of providers are required to be reported?

- All licensed physicians: medical doctors, doctors of osteopathic medicine, dentists, podiatrists, optometrists, chiropractors
- Teaching hospitals that receive direct or indirect graduate medical education funding from Medicare

3. What must be reported?

- General payments, in-kind items or services, consulting and speaker fees, gifts, honoraria, travel and entertainment expenses, meals, education, charitable contributions, and grants
- Ownership or investment interests by physicians and immediate family members
- Research payments for clinical investigations

4. What does not need to be reported?

- A payment less than $10, unless total payments exceed $100 per year
- Product samples, discounts and rebates; in-kind products for the provision of charity care; educational materials for patients; loaned devices for research; and items or services provided under a contractual warranty, where the terms of the warranty are set forth in the purchase or lease agreement

5. What is the timeline for reporting?

- Manufacturers and GPOs must complete their reporting by the 90th day of the following calendar year, which is March 31 (March 30 in leap years)

6. What are the consequences of a failure to report?

- Manufacturers and GPOs may be fined $1000–$10,000 per unreported payment, up to an annual maximum of $150,000
- For deliberately failing to report, fines can be $10,000–$100,000 per payment, up to a maximum penalty of $1,000,000 per year

Open Payments database

The data is published annually in the publicly searchable CMS Open Payments database, which can facilitate reviews of individual providers. Additionally, the Open Payments database can be downloaded and compared against an organization's medical staff roster and physician accounts payable data.

Physicians have 45 days after receipt of notification to review and approve or dispute the accuracy and completeness of Sunshine Act data prior to the data becoming available to the public. A lack of response from a physician is deemed by CMS as approval of the data.

The Sunshine Act also considers financial investment and ownership interests in medical devices, including, but not limited to, spine implants, pain management devices and pharmaceutical innovations. Physician investment and ownership can result in physician owned distributorships (PODs). The POD's revenue is based on selling or arranging the sale of implantable medical devices ordered by physician-owners for procedures performed on their patients.

Attempts have been made to increase transparency around POD financial relationships in the hopes that disclosure would help to reduce their negative consequences without unnecessarily blocking constructive partnerships. In 2013, the HHS OIG issued a special fraud alert stating that PODs create "a strong potential for improper inducements" between PODs, physician-investors and the healthcare organizations that purchase medical products. Attorneys for the HHS OIG stated that improper payments to physicians can alter a physician's judgment about patients' true healthcare needs and drive up healthcare costs for everyone.

Currently, the required Sunshine Act reporting process applies to physicians, researchers and teaching hospitals. The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act of 2018 (SUPPORT Act) expands the Sunshine Act's required reporting obligations. Section 6111 of the SUPPORT Act, "Fighting the Opioid Epidemic with Sunshine," extends the parties subject to the Sunshine Act's reporting requirements to additional health professional affiliates. The professionals now include physician assistants, nurse practitioners, clinical nurse specialists, certified nurse-midwives and certified registered nurse anesthetists.

As of January 1, 2021, affected manufacturers and health professionals need to track payments and other transfers of value for the March 2022 reporting period. In regard to the Sunshine Act, these changes will go into effect for "information required to be submitted … on or after January 1, 2022."

Audit considerations

While not all-encompassing, certain considerations are critical to evaluating financial arrangements between physicians and manufacturers of drugs, devices, biologicals and medical supplies.

Review and monitor COI policies

To create the desired culture of ethical behavior and address unacceptable financial conflicts, your organization must implement processes to ensure conflicts are identified and resolved appropriately. Monitoring and auditing COI processes may include reporting disclosures by physicians to leadership, tracking completion of disclosure forms, comparing disclosures with publicly available data, and investigating reports of conflicts in a timely manner.

Review the Open Payments database for each provider

An annual review should be performed of the Open Payments database for each of your organization's individual providers. The review involves downloading the most currently available data and comparing the data to your organization's medical staff roster, physician accounts payable data and physician disclosures.

Audit the medical necessity of services provided

Audit the medical necessity of treatments, procedures and clinical trials provided by physicians who receive payments from drug and device manufacturers. Oversight agencies or whistleblowers could use Open Payments information to call into question the medical necessity of treatments provided. An analysis of claims tied to physicians, including the number of surgeries conducted and prescriptions for off-label use of medications or high-cost drugs and devices could bolster allegations of questionable medical necessity.

Audit strategy

Compensation arrangements with medical directors and arrangements where physicians have financial relationships with manufacturers of drugs, devices, biologicals and medical supplies can be extensive. Ensuring that the arrangements are compliant with regulatory and legal considerations can seem overwhelming, but are necessary.

Violations of federal regulatory requirements can not only be costly but also embarrassing to a health system, its physicians and its executives—potentially causing

long-lasting reputational damage. Several healthcare organizations have paid significant penalties for excessive or improper physician compensation arrangements that exceeded FMV and may not have been commercially reasonable.

By completing regular, detailed physician compensation arrangement reviews as part of your annual audit plan, many potential compliance violations can be mitigated or even prevented.

Exhibit 3 provides a high-level overview of key steps for completing an audit of physician arrangements.

Impact of Covid-19 waivers

Issues related to Covid-19 waivers, exceptions and relief funding are extremely important considerations regarding physician financial relationships. Most noteworthy are the OIG's blanket waivers of sanctions under the Stark Law that were effective March 1, 2020, and will extend for the duration of the national health emergency. Changes in physician compensation processes in your organization should be tracked and documented properly to ensure program requirements are met. The changes should also be included in your audit plan.

Exhibit 3 – Audit program

1. Identify the different types of physician compensation arrangements

- Types of clinical services offered
- Medical staff structure
- Medical director or administrative positions (e.g., required by federal and/or state law, accreditation agencies, established by the hospital)

2. Gather information for review

- Contracts (including documentation related to contract development, review and approval)
- FMV documentation
- Timesheets and activity logs
- Performance information
- Payment information
- Financial interests (COIs)

3. Evaluate the information

- Policies
- Bylaws
- Regulatory requirements
- Industry news

4. Audit communication

- Consider restricting communications by conducting audits under attorney-client privilege
- Ensure that all aspects of the financial relationships, organizational policies, regulatory requirements, payment sources, and effect on revenue are thoroughly evaluated.
- Recognize common audit recommendations for:
  - Tracking relationships
  - Documentation and analysis prior to execution of the contract and any agreements made during the contract period
  - More robust contract review and approval processes involving legal, finance, compliance and the board
  - More accurate and available documentation of payments, performance, time keeping, etc.

Stark and AKS at a glance

Stark

- A physician is prohibited from making referrals for certain designated health services payable by Medicare to an entity with which he or she has a financial relationship unless an exception applies.
- Strict liability is applied (proof of specific intent to violate the law is not required).
- Penalties can include the amount of reimbursement for prohibited claims, civil monetary penalties and treble damages.
- Arrangements that fit within exceptions for ownership interests or compensation arrangements are protected (e.g., employment agreement, lease of space/equipment, personal services arrangements, etc.).
- Exceptions involve FMV, commercial reasonableness, and compensation set in advance, but does not consider the volume or value of referrals or other business generated between the parties, and the presence of written, signed agreements.

AKS

- Asking for, receiving, offering or giving anything of value to induce or reward referrals of federal healthcare program business is illegal.
- Examples of value include cash, free rent, expensive hotel stays, meals, excessive compensation, gifts/gratuities/business courtesies, and free services (e.g., labor, education).
- The intent to induce referrals does not need to be the primary or sole reason for the remuneration, but need only be one among many, otherwise legitimate, reasons (one-purpose test).
- Penalties can include civil monetary penalties plus treble damages, incarceration and exclusion from federal healthcare programs.
- Arrangements that fit within certain safe harbors are protected (e.g., space rental, management services); however, arrangements that do not fit within a safe harbor are not automatic violations, but are subject to scrutiny.
- The safe harbors involve FMV, commercial reasonableness, compensation set in advance, compensation not tied to volume or value of referrals or other business generated, and the presence of written, signed agreements.

Conclusion

Your regular, detailed audits of all types of physician financial arrangements can provide your organization with the information needed to proactively identify potential risks, as well as to assure regulatory compliance. Any resulting control and process enhancements can reduce your organization's exposure while strengthening its policies and procedures. Alternative physician compensation arrangement audits, including the resulting improvement plans, can help build lasting protection for your organization's finances, reputation and culture. **NP**

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