Arrangement Audits: Don't Forget the Follow-Up

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Introduction

Physician compensation arrangements take a variety of forms, some of which may already be part of an organization's audit plan. These include, but are not limited to, arrangements with physician administrators, medical affairs vice presidents, chief medical and medical information officers, chiefs of staff, and chief administrative officers. Newer, emerging positions, such as chief physician executives, chief quality officers, and chief wellness officers, comprise some of these arrangements as well. However, two types of compensation arrangements continue to garner the interest of regulators. These involve physicians serving as medical directors of hospitals, health systems, and other healthcare organizations, and 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, Centers for Medicare & Medicaid Services (CMS) regulations require hospitals to have medical directors obtain governmental reimbursement and/or comply with accreditation standards.

Medical directorships have been subject to regulatory scrutiny for quite some time. A fraud alert issued June 9, 2016, by the Department of Health and Human Services Office of Inspector General specifically addressed and brought heightened attention to these types of physician arrangements. Multiple complaints and allegations of improper medical director payments and "sham" medical director agreements intended to induce referrals continue to make headlines.

In order to not run afoul of various regulatory requirements, including the Anti-Kickback Statute and the Stark Law, regular reviews of medical director arrangements—both pre- and post-implementation—are critical. While not all-encompassing, the following considerations provide an approach to evaluating medical director arrangements.

Evaluate the Medical Director Philosophy

Annually review the organization's current medical director policy or initiate its development if one does not exist. 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/or has no similar advertised positions.

Perform Routine Program Maintenance

Evaluate whether the policy for the documentation of services is tracked through a monthly or otherwise regularly scheduled audit of timesheets or other required deliverables. Review 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 an organization, through collaboration within the healthcare industry. 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 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 where the pursuit of financial gain may compromise patient care. Recognizing the inadequacy of the voluntary disclosure model, and balancing that concern against the importance of healthcare industry investment in innovation and research, lawmakers enacted federal legislation to address professional conflicts of interest. That legislation, titled the Physician Payments Sunshine Act (PPSA) (or Sunshine Act), is 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. While not all-encompassing, certain considerations are critical for 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, an 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 timely investigating reports of conflicts.

Review the Open Payments Database for Each Provider

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

Audit the Medical Necessity of Services Provided by Physicians

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, prescriptions for off-label use of medications, or high-cost drugs and devices could bolster allegations of questionable medical necessity.

Conclusion

Compensation arrangements with medical directors and arrangements where physicians have financial relationships with manufacturers of drugs, devices, biologicals, and medical supplies can be extensive and seem overwhelming. However, ensuring the arrangements are compliant with regulatory and legal considerations via regular and detailed audits is necessary. Arrangement audits, including the resulting control and process enhancements, can help build lasting protection for an organization's finances, reputation, and culture.

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