Recent OIG Advisory Opinions Address Physician Business Relationships with Hospitals and Physician Practices

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Several recent advisory opinions issued by the U.S. Department of Health and Human Services Office of Inspector General (OIG) have addressed common aspects to physician practice business relationships with hospitals and other providers. Although the OIG’s comments in an advisory opinion are limited to a specific proposed arrangement, the OIG’s comments indicate how certain aspects of a hospital’s current or proposed arrangement with physicians may be scrutinized under the federal anti-kickback statute and other fraud and abuse laws.

OIG Unfavorable Advisory Opinion on Purchasing the Technical Component of Anatomic Pathology Services

On September 25, 2023, the OIG issued Advisory Opinion 23-06, in which the OIG concluded that the risk of fraud and abuse was not sufficiently low under the federal anti-kickback statute in a proposed arrangement by the operator of several anatomic pathology laboratories to purchase the technical component (TC) of anatomic pathology services from other clinical laboratories for anatomic pathology tests for commercially-insured patients.

Under the proposed arrangement, the operator of several anatomic pathology laboratories (Anatomic Path Labs) would enter into agreements with both physician-owned laboratories (Physician Labs) and non-physician owned laboratories (Non-Physician Labs) that would require the Anatomic Path Labs to purchase the TC of anatomic pathology services from the Physician Labs and the Non-Physician Labs for certain anatomic pathology tests provided to commercially-insured patients.

The primary reason that the Physician Labs and Non-Physician Labs desired to enter into the proposed arrangements was because these labs either do not have a provider agreement with certain commercial payers or they are not in-network with certain commercial payers. This proposed arrangement would not involve the referral of or billing for anatomic pathology services reimbursable by federal healthcare programs. In other words, the labs in their request for an advisory opinion provided that any lab tests for federal healthcare program beneficiaries would be “carved out” of the proposed arrangement.

The parties also certified to the OIG that the fee that the labs would pay to the Physician Labs and Non-Physician Labs under the proposed arrangement would be fair market value for the TC services. The Anatomic Path Labs that purchased the TC services would purchase the professional component (PC) of the anatomic pathology tests and would bill commercial payers a global claim as an in-network provider for both the TC and PC of the anatomic pathology tests.
The Anatomic Path Labs also certified to OIG that its agreements with these other laboratories would satisfy the conditions set forth in the “personal services and management contracts and outcomes-based payment arrangements” safe harbor (42 C.F.R. § 1001.952(d)) to the federal anti-kickback statute, except the requirement that the aggregate services contracted for would not exceed those which are reasonably necessary to accomplish the commercially-reasonable business purpose of the services.

The takeaways that may be helpful to similar Hospital arrangements in this advisory opinion include:

- The OIG still considers arrangements that “care out” services provided to federal healthcare program beneficiaries to implicate and potentially violate the federal anti-kickback statute.
- A fair market value (FMV) or FMV-based fee or compensation may still result in a potential violation of the federal anti-kickback state.
- Hospitals and other parties need to be able to demonstrate (and document in writing) that the aggregate services contracted for in an arrangement would not exceed those that are reasonably necessary to accomplish the commercially-reasonable business purpose of an arrangement. In the proposed arrangement, the Anatomic Path Lab informed the OIG in requesting this advisory opinion that it was unable to certify the commercial reasonableness of this arrangement since the Anatomic Path Lab is capable of performing both components of anatomic pathology services without referring the TC to a third-party lab, and performing both components in-house is generally more efficient and cost efficient than referring to a third-party lab.
- The result of this advisory opinion (i.e., favorable instead of unfavorable) may have been different if the parties had articulated reasons for the arrangement unrelated to federal healthcare program business, such as to avoid the administrative costs associated with billing patients for out-of-network fees or to leverage centrally located digital pathology scanners.

**OIG Approves Paying Employed Physicians Profits from ASCs Operated by a Physician Practice Employer**

On October 13, 2023, the OIG issued Advisory Opinion 23-07, approving a multi-specialty physician practice’s proposal to pay its employed physicians a portion of the profits from the facility fee collections attributable to the physician’s procedures performed at ambulatory surgical centers (ASCs) operated by the practice.

Under the proposed arrangement, the physician practice would pay each of its physician-employees a quarterly bonus equal to 30% of the practice’s net profits from the ASC’s facility fee collections attributable to the physician’s procedures performed at either of the practice’s ASCs for the preceding quarter. These bonuses would be in addition to the base compensation the physician practice pays the employees.

An important aspect to the background of this proposed arrangement is that the physician practice would operate the two ASCs as corporate divisions of the physician practice (i.e., as divisions within the same corporate legal entity and not as subsidiaries of the practice. The physician practice also certified to the OIG that each of the ASCs would be a “distinct entity” (pursuant to the definition of an ASC at 42 CFR § 416.2) and would otherwise comply with the Medicare conditions for coverage applicable to the ASCs.

The OIG concluded that the proposed bonus payments would be protected by the statutory exception and regulatory safe harbor bona fide employees to the federal anti-kickback statute because: (1) the physician employees would be bona fide employees of the physician practice in accordance with the definition of employee in 26 USC §3121(d)(2); and (2) the bonus
compensation would constitute an amount paid by an employer to an employee for employment in the furnishing of any item or service for which payment may be made in whole or part under Medicare, Medicaid, art other federal healthcare programs.

Important takeaways from the advisory opinion include:

- The employment safe harbor to the federal anti-kickback statute does not require payments to be consistent with fair market value, and it can protect payments that vary with the volume and value of federal healthcare program business that a recipient generates.

- Similar compensation payments to independent contractor physicians or under a different corporate structure are not protected by the employment safe harbors, such as sales commissions for marketing services.

- An important aspect is that the physician practice certified that it did not furnish any of the “designated health services” that are subject to the Stark Law.

OIG Issues Unfavorable Advisory Opinion on Proposed Arrangement with a Physician-Owned Intraoperative Neuromonitoring Company

On August 18, 2023, the OIG issued Advisory Opinion 23-05, in which the OIG concluded that a proposed arrangement by a company to assist surgeons in forming an entity to perform intraoperative neuromonitoring (IONM) services in conjunction with surgeries performed by the surgeons could result in prohibited remuneration in violation of the federal anti-kickback statute.

The OIG emphasized in this advisory opinion that this proposed arrangement included many of the long-standing issues raised by the OIG under fraud and abuse laws regarding contractual arrangements with physician-owned entities that are dependent in part on referrals from physician investors and substantially all of the operations of the physician-owned entity are obtained on a turnkey basis from other entities already in the same type of business.

Under the proposed arrangement, the requestor of the advisory opinion proposed to assist physicians who perform surgeries for which IONM is used, and who currently make referrals to the requester for IONM services, with the formation and operation of a turnkey entity that would perform IONM services. The surgeon owners of this IONM service entity would have limited participation in the entities day-to-day business operation and would instead contract with the requester of the advisory opinion and a physician practice for the performance of the technical and professional components of IONM services for surgeries at ASCs and hospitals. The proposed arrangement would also not be utilized for patients covered under a federal healthcare program.

The OIG commented that the proposed arrangement would involve several forms of remuneration that could induce the surgeon owners of this new IONM service entity to make referrals of IONM services for which payment would be made by a federal healthcare program. The forms of revenue of concern to the OIG included:

1. Discounts offered to the new IONM service entity for its purchase of professional IONM services.

2. The opportunity for the new IONM service entity to generate “substantial profits” through the difference between the IONM service entity’s payments for administrative and professional services and the new IONM service entity’s revenue from billing payors directly for IONM services that were previously billed by the company that would form the new IONM service entity for the surgeons.

3. Returns on investment interests in the new IONM service entity to the surgeon-owners.
The OIG concluded that the proposed arrangement would present a significant risk of fraud and abuse under the federal anti-kickback statute, including patient steering, unfair competition, inappropriate utilization, and increased costs to federal healthcare programs.

The OIG also commented that the “carve out” of the federal healthcare program patients not be dispositive with respect to whether the proposed arrangement would implicate and potentially violate the federal anti-kickback statute. The OIG reiterated its long standing and continuing concerns about arrangements under which parties carve out referrals of federal healthcare program beneficiaries from otherwise questionable financial arrangements.

This advisory opinion offers hospitals and other providers guidance on the OIG’s scrutiny of arrangements with physician-owned providers, as well as potential distinguishable facts and safeguards that may be included in a compliant arrangement.

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