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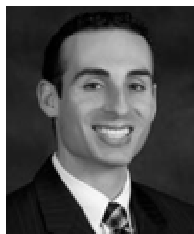
OIG Issues Warning With Regard to 'Company Model' For Arrangements Between Surgery Centers and Anesthesia Service Providers



BY MICHAEL F. SCHAFF AND GLENN P. PRIVES

Introduction

On June 1, the Department of Health and Human Services Office of Inspector General (OIG) released Advisory Opinion 12-06 relating to two proposals regarding the provision of anesthesia services at physician-owned ambulatory surgery centers (collectively, the ''proposed arrangements'').[1] The OIG identified concerns with both proposed arrangements and concluded that, if the requisite intent existed, each of the proposed arrangements could constitute grounds for the imposition of civil monetary penalties (CMPs) and/or administrative sanctions in connection with the enforcement of the federal anti-kickback statute (the AKS).[2]

Importantly, one of the proposed arrangements that the OIG identified as problematic is a form of the popular ''company model'' in which the physician owners of a surgery center form a separate entity that contracts with anesthesia service providers and then provides anesthesia services to the surgery center. The entity owned by the physician owners then bills for the anesthesia services and pays the anesthesia service providers an agreed-upon rate. This model allows the referring surgeons to share in the anesthesia fees.

The general takeaway from the advisory opinion is that the OIG views arrangements between the physician owners of ASCs and the providers of anesthesia services at ASCs whereby the physician owners would profit from the professional services of an anesthesia service provider with suspicion. This article examines the advisory opinion in detail and highlights points that are of importance to providers and their attorneys.

Anti-Kickback Statute

The AKS prohibits the knowing and willful offer, payment, solicitation, or receipt of any remuneration to induce or reward referrals of items or services reimbursable by a federal health care program. Under the AKS, a violation is punishable criminally by up to five years of imprisonment, a fine of $25,000, or both, and by exclusion from participation in the Medicare and Medicaid programs, as well as other potential administrative and civil penalties. HHS has created several safe harbor regulations that define arrangements that are not subject to the AKS.[3] Failure for an arrangement to fit completely within a safe harbor, however, does not mean that the arrangement is an automatic violation of the AKS.

Summary of the Advisory Opinion

An anesthesia services provider (the ''anesthesia provider'') provides anesthesia services on an exclusive basis to several physician-owned ambulatory surgical centers (ASCs). The ASCs bill and collect from Medicare and private payers for the ASC facility services. The anesthesia provider currently bills and collects, indepen-

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[1] Available at http://www.oig.hhs.gov/fraud/docs/advisoryopinions/2012/AdvOpn12-06.pdf.

[2] Section 1128B of the Social Security Act.

[3] 42 C.F.R. § 1001.952.

dently, for the professional anesthesia services provided at the ASCs.

Under the first proposed arrangement (''proposed arrangement A''), the underlying elements of the current arrangements between the anesthesia provider and the ASCs would remain the same, but the anesthesia provider would begin paying the ASCs for ''management services,'' including pre-operative nursing assessments, space for the anesthesia provider's physicians/personnel and records and assistance with transfers of billing documentation to the anesthesia provider's billing office. The anesthesia provider represented that the ASCs already are reimbursed for the management services through the Medicare ASC facility fee and similar private reimbursement. Nonetheless, under proposed arrangement A, the anesthesia provider also would compensate the ASCs for these same management services based on a per-patient fee, which the anesthesia provider represented would be set at fair market value and not take into account the volume or value of referrals or other business generated. Federal health care program beneficiaries would be excluded from the calculation of the management services fee.

Under the second proposed arrangement (''proposed arrangement B''), which is a form of the company model, the ASC's physician owners (the ''physician owners'') would establish separate entities (the ''subsidiaries'') to provide anesthesia services to the ASCs on an exclusive basis. The subsidiaries would employ or contract with anesthesia providers for the clinical services, and would contract with the anesthesia provider to provide all other administrative, management, and operational oversight services for the subsidiaries' operations. The employed or contracted anesthesia providers also would be employees of the anesthesia provider. The subsidiaries would pay the anesthesia provider a negotiated rate for these services out of their collections for anesthesia services, and the physician owners would retain the remaining profit generated from the anesthesia services.

With respect to proposed arrangement A, the OIG first concluded that the ''carve out'' of federal program beneficiaries from the anesthesia provider's payment for management services to the ASCs would not reduce the risk of fraud and abuse. The OIG raised its long-standing concern related to carve outs of federal program business, and indicated that, because the anesthesia provider would be the exclusive provider of anesthesia services under proposed arrangement A, the carve out would not reduce the risk that the management services fee for nonfederal program patients would be paid to induce referrals for federal beneficiaries. The OIG then noted that the ASCs would be paid twice for the management services they provide under proposed arrangement A, and found that the management services fee paid by the anesthesia provider could be found to be an improper inducement for the ASCs' federal program beneficiary referrals.

In proposed arrangement B, the OIG first found that the ASC safe harbor under the AKS would not apply to the subsidiaries because they would not be providing surgical services, which is a required element of the ASC safe harbor. In addition, the OIG indicated that for an ASC to qualify as a Medicare-certified ASC, it must be operated exclusively for the purpose of providing surgical services, and if an ASC provides anesthesia services, which are not surgical services, the ASC cannot be a Medicare-certified ASC.

The OIG also concluded that neither the employment safe harbor nor the personal services and management contracts safe harbor would protect the profits distributed to the physician owners. The OIG then found that proposed arrangement B has many of the hallmarks of arrangements which OIG has warned against in prior opinions and the ''Contractual Joint Ventures'' Special Advisory Bulletin (68 Fed. Reg. 23,148, April 30, 2003), and that it would pose more than a minimal risk of fraud and abuse for the following reasons:

(1) The physician owners would be expanding into a related line of business wholly dependent on the ASC's referrals;

(2) The ASCs would contract virtually the entire operation of the subsidiaries to the anesthesia provider;

(3) The physician owners' business risk in the subsidiaries would be minimal due to their control of the referral stream;

(4) The anesthesia provider is an established provider of the same services as the subsidiaries, and otherwise would be a competitor but for the proposed arrangement;

(5) The anesthesia provider and the physician owners would share in the economic benefit of the subsidiaries; and

(6) The anesthesia provider represented that it is under competitive pressure to consider the proposed arrangements or risk loss of business.

The OIG found problematic that proposed arrangement B appeared to be designed to permit the physician owners to receive compensation, in the form of a portion of the anesthesia provider's anesthesia services revenues, in return for the physician owners' referrals to the anesthesia provider.

Important Points

There are some important takeaways for providers and their attorneys from this advisory opinion.

1. This advisory opinion does not depart from previous guidance issued by the OIG. The OIG merely has applied its previous analysis to a new set of facts and reiterated its long-standing concerns.

2. The ''carve out'' of federal program beneficiaries will not reduce the risk of fraud and abuse in the eyes of the OIG and will not help an arrangement avoid scrutiny. This point not only applies to arrangements similar to the proposed arrangements, but should be heeded when structuring all forms of arrangements.

3. The unfavorable treatment provided by the OIG to the proposed arrangements brings to light the fact that any form of the company model needs to be heavily scrutinized to comply with applicable laws and guidance. Each arrangement must be reviewed separately based upon its own unique facts and circumstances, but if an arrangement includes any or all of the factors highlighted in the advisory opinion, such an arrangement may present a higher risk of fraud and abuse.

4. A restructure of an arrangement between an ASC and an anesthesia services provider which is providing anesthesia services at the ASC at the time of the restructure or which previously provided anesthesia services at the ASC not long before the restructure can raise the suspicion that the arrangement is being restructured to reward referrals.

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5. The ASC safe harbor protects returns on investments only in circumstances where the investment entity itself is a Medicare-certified entity under 42 C.F.R. Part 416. Part 416 limits a Medicare-certified entity to one that exclusively provides surgical services to patients who do not require hospitalization. Anesthesia services are not surgical services. Therefore, an ASC cannot be Medicare-certified if the ASC provides and bills for anesthesia services.

Conclusion

Based on the advisory opinion, it is vital to scrutinize all relationships between ASCs and all nonsurgical service providers to ensure compliance with applicable laws and guidance. Each arrangement must be evaluated on an individual basis based on all of the facts and circumstances. The bottom line is that company model ventures are fraught with kickback danger for all parties involved. Although it may be possible that a particular instance qualifies for safe harbor protection, the OIG's position as expressed in the advisory opinion and previous guidance demonstrates that these arrangements are subject to special scrutiny. Parties currently engaged in or considering the company model or similar arrangements should carefully review this and other relevant OIG guidance and consider the steps necessary to ensure compliance with the AKS.