GUIDANCE ON PERFORMING AN OBJECTIVE REVIEW OF YOUR COMANAGEMENT PROGRAM

Take steps now to mitigate your risk of violating the Federal False Claims Act and Anti-Kickback Statute.

BY LAURA STRAUB, EDITOR-IN-CHIEF

Comanagement is recognized as a legitimate practice by medical professionals and payers. For the past 35 years, however, it has been the subject of controversy in the ophthalmology community because of its potential for abuse. Some ophthalmologists argue that comanagement is a legitimate practice that respects patient choice by allowing patients to return to their primary vision care provider for care after a surgical procedure. Others, however, allege that it is a veiled form of kickback between surgeons and optometrists.

The Medicare program recognizes comanagement as an appropriate practice and makes payments to the surgeon and comanager for the services that each performs. Neither CMS nor the Office of Inspector General (OIG), however, has provided detailed guidance on what constitutes compliant and noncompliant behavior in a comanagement relationship. The lack of detailed guidance has contributed to a recent increase in the number of comanagement practices that have been challenged as violating the Federal Anti-Kickback Statute and the Federal False Claims Act. These challenges allege that the optometrist's referrals to the surgeon are contingent on the surgeon providing the referring optometrist with *something of value* in return—a violation of the Federal Anti-Kickback Statute.

Something of value can come in the form of a high comanagmement fee payment for performing additional postoperative care following cataract surgery with a premium IOL, other collateral benefits such as free continuing education or tickets to concerts or sporting events, and even an agreement to refer the patient back to the optometrist for postoperative care following cataract surgery with a conventional IOL.

A violation of the Anti-Kickback Statute can result in criminal penalties. The law also provides that any claim originating from an arrangement that violates the Anti-Kickback Statute is a violation of the False Claims Act. A false claim can trigger significant civil penalties, including triple damages plus a penalty of up to $22,000 per claim. As a result, most of these cases are filed under the False Claims Act, where whistleblowers can get a percentage of the recovery, which can be anywhere from 15% to 30%. (For more on the Federal Anti-Kickback Statute, scan the QR code to read "There Is No Such Thing as the Stark Anti-Kickback Statute.")

READ IT NOW

This article summarizes recent developments in the investigations and litigation of several cases involving the practice of comanagement presented by attorneys Allison W. Shuren, JD, and Alan E. Reider, JD, MPH, during a webinar sponsored by the American-European Congress of Ophthalmic Surgery. The article also reviews key take-home points for ophthalmologists to protect themselves in any comanagement relationship. The goal of the webinar was to outline steps that surgeons can take to mitigate their risk of violating these federal laws.

LEARNING FROM CURRENT LITIGATION

Most of the complaints alleging that ophthalmology practices that comanage patients with optometrists are engaging in conduct that violates the Anti-Kickback Statute and the False Claims Act are currently in the investigative stage; at least one is in active litigation. No final resolution yet articulates what conduct is and is not compliant, but reviewing the allegations made in the following

five cases offers important lessons on what conduct is subject to challenge and potential vulnerability. It is to be hoped that these cases offer important lessons on how to keep your practice safe from comanagement litigation.

Case No. 1. In 2018, the OIG investigated an ophthalmology practice that was comanaging approximately 50% of its premium IOL patients. For the patients who were comanaged, the practice would pay the comanager a fixed amount to reflect the value of the additional noncovered postoperative services provided by the comanager. The complaint, which is believed to have been made by a competitor, alleged that a patient who receives a premium IOL requires no more postoperative care than a patient who receives a standard monofocal IOL. Thus, according to the complaint, the additional payment to the comanager was a sham made only to induce the referral.

In this case, the ophthalmology practice disputed the claim that premium IOL patients require no more care than conventional IOL patients. The practice provided documentation to the OIG demonstrating that, when practice patients were not comanaged, the practice provided additional postoperative care beyond what was provided to patients who received conventional IOLs. It also showed that the additional amount charged for care reflected the value of the additional services performed. Patients who were comanaged were therefore treated exactly the same as those who were not, and both the practice and the comanagers provided the same additional postoperative care to premium IOL patients.

The OIG closed the investigation of the practice based on this information. The agents, however, noted concern that comanagement could be abused and might not be conducted properly by all ophthalmologists and advised that they would bring concerns to the Central Office of the OIG for further consideration.

TAKE-HOME POINTS

- Avoid explicit or implicit agreements or understandings with comanagers that patients will be referred back to them for postoperative care.
- Ensure that patients are educated about their choice to be comanaged, that they can freely exercise that choice, and that their choice is honored.
- Document a patient's choice in writing and retain it in their record.
- Ensure that fees received by comanagers for postoperative care related to premium IOLs are for services rendered and reflect fair market value.
- Educate all comanagers on the services they are expected to perform to support any additional payment received.
- Maintain contact with comanagers through the exchange of clinical information to confirm that services are performed.
- Be clear that it is the patient, not the practice, who is paying any additional fees for noncovered services; patients should be informed about the fees paid to the comanager and the services that are covered by those fees.
- Move toward having optometrists set and collect their own fees.
- Understand that free educational programs may be acceptable but that your legal risk increases if continuing education credits and/or elaborate meals are provided free of charge.
- If holiday gifts are given to comanagers, ensure they are modest; avoid varying the value of the gift based on referral volume or value.
- Do not limit gifts to referral sources only.
- No gift should be cash or cash equivalents (ie, gift cards).
- Seek legal guidance related to other types of gifts, perks, and entertainment offerings.

Case No. 2. A search warrant executed by the FBI was conducted at an ophthalmology practice after a whistleblower reported improper comanagement of both premium and conventional IOL patients. The preliminary information from this case suggests that the prosecutors did not understand the concept of comanagement or that Medicare specifically recognized the practice of comanagement. The defense believes that the prosecutors were given false information. The defense also hopes that educating the prosecutors addresses a significant part of the case as it relates to the comanagement of covered services. This case is ongoing.

Case No. 3. A Civil Investigative Demand (a form of a subpoena) was issued to a large multilocation ophthalmology practice to produce the following:

- All documents (eg, electronic and hard copies of paperwork, emails, text messages) relating to comanagement;
- A list of referral sources;
- All documents relating to the tracking of referrals;
- Information describing any remuneration provided to referral sources, including continuing education, dinners, entertainment, and gifts;
- Information provided to patients regarding comanagement, including information on patient choice;
- Information on how fees were split for both conventional and premium IOLs; and
- Allegations relating to patient harm in connection with cataract surgery.

In this case, investigators are looking to determine whether patients are given enough information

to make a meaningful decision whether to be comanaged. This case is in the early stages of development; there is strong suspicion that it was triggered by a whistleblower complaint.

Case No. 4. Federal agents contacted former employees of a large surgical practice with multiple locations to inquire about the practice's comanagement program. Specifically, questioning has revolved around the amounts paid to comanagers for the postoperative care of premium IOL patients. Information on this case is anecdotal at the time of this writing.

Case No. 5. A whistleblower complaint was filed in a federal district court in April 2017 alleging that the comanagement program of the defendants—a physician practice and its ambulatory surgery centers—was supplemented by free continuing education programs and other benefits provided to referring optometrists, including outings, holiday gifts, lunches, and forms of entertainment that violated the Federal Anti-Kickback Statute and Federal False Claims Act. The whistleblowers are the current executive director and a past president of the state association of optometrists.

According to the complaint, between 75% and 90% of all patients seen by the practice are comanaged, compared to 22.3% statewide. Comanagers were paid $270 per eye for toric IOLs and $420 per eye for presbyopia-correcting IOLs—amounts that the whistleblowers alleged exceed the value of the services provided. The whistleblowers also alleged that patients of the practice did not have a choice about whether to be comanaged. The case is scheduled for trial early in the first quarter of 2023.

CONCLUSION

How the cases described in this article will play out is uncertain at this time. Nevertheless, lessons can be learned from the allegations, including what type of comanagement conduct is subject to challenge. Additionally, these cases show that comanagement arrangements—arrangements that are becoming increasingly common as the specialty moves toward greater integration of shared care in response to the current and future shortage of ophthalmic surgeons—are under scrutiny. Care must therefore be taken to ensure compliance with all applicable rules.

Now is the time to protect yourself. The take-home points featured in the accompanying sidebar on the previous page can help you perform an objective review of your comanagement program. ■

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