REGULATORY RISKS IN COMANAGEMENT

Lessons from recent federal settlements.

BY ALAN E. REIDER, JD, MPH, AND ALLISON SHUREN, JD

In the October 2020 issue of *CRST*, we provided an overview of regulatory issues related to comanagement. It included a history of comanagement beginning with the 1986 amendment to the Medicare statute, which allowed optometrists to bill Medicare for services within their scope of practice and established the foundation for comanagement between ophthalmologists and optometrists. The article also reviewed the ensuing controversy within the profession, with some considering comanagement a reasonable approach to patient care and others arguing it was unethical or even illegal.

Our earlier piece addressed the compliance risks associated with comanagement, including positions taken by CMS and the Office of Inspector General. Both agencies acknowledged comanagement as an acceptable practice, provided specific guidelines are followed. We noted how the compliance risks increased with the evolution of the premium IOL channel because comanagement in these cases involves both covered and noncovered services under Medicare. Despite these increased risks, as of 2020, there had been no enforcement activity related to the comanagement of premium IOL patients. (Scan the QR code to read our November 2020 article.)

READ IT NOW

Things have changed. In 2023, three federal investigations were resolved within a 3-month period, resulting in multimillion-dollar settlements by three ophthalmology practices. Each was accused of engaging in improper comanagement relationships with optometric referral sources. Although each case had unique facts, the core allegations were similar: (1) the practices failed to give patients the choice to be comanaged, and (2) payments to optometrists for additional comanagement services for premium IOL patients could not be justified by the level of care provided. Other similarities among these cases warrant discussion. This article summarizes key facts, with the goal of helping readers avoid similar compliance pitfalls.

CASE NO. 1: TEXAS

This case was filed under the False Claims Act (FCA) by a whistleblower, an oculoplastics physician terminated by the practice after she raised concerns about her compensation. Interestingly, the same physician had previously filed a whistleblower action against a prior employer, an ophthalmology practice in Florida.

ALAN E. REIDER, JD, MPH
- Retired Partner, Arnold & Porter, Washington, DC
- Founder and Owner, LSR Consulting
- Member, *CRST* Editorial Advisory Board
- alan.reider@lsrconsult.com
- Financial disclosure: None

ALLISON SHUREN, JD
- Partner, Arnold & Porter, Washington, DC
- allison.shuren@arnoldporter.com
- Financial disclosure: None

The principal allegations in the Texas case centered on improper practices related to the comanagement program. The whistleblower claimed that comanagement was routine, that patients were not given the option to choose providers for postoperative care, and that they were automatically referred back to their ODs. She referenced guidance from the AAO stipulating that comanagement should be the exception rather than the rule. Additionally, she alleged that comanagers received kickbacks for managing premium IOL patients and extra payments for surgeries involving femtosecond lasers. Furthermore, she alleged that the ophthalmology practice's collection of comanagement fees and subsequent payments to comanagers constituted a violation of law.

The whistleblower made several other allegations unrelated to the comanagement program. These allegations were not pertinent to the final outcome of the case and generally misrepresented Medicare program requirements. The claims included the following:

- Markups on premium IOLs exceeded the allowable $30 to $50 handling fee;
- The practice rather than the ambulatory surgery center billed for premium IOLs;
- The practice performed unnecessary cataract surgeries, as evidenced by the fact that 90% of patients underwent second-eye surgery within weeks of the first;
- The practice improperly used brightness acuity testing to justify cataract surgery; and
- The practice performed unnecessary Nd:YAG procedures, based on the fact that its rates exceeded the national average.

The government investigated the allegations and expressed concerns about the comanagement program. To avoid litigation, the Texas practice settled the case for approximately $2.9 million and agreed to cooperate with further government investigations.

Following the settlement, the Justice Department issued a press release detailing its concerns about the comanagement program:

- The practice ensured patients were returned to the referring OD for postoperative care. In other words, patients were not given the choice whether to be comanaged, and
- Payments to comanagers for noncovered services were unrelated to the value of the services provided.

The Justice Department identified additional issues not raised by the whistleblower but deemed improper:

- The practice provided free continuing education to referring ODs, and
- The practice rewarded referring ODs with expensive dinners and tickets to sporting events.

CASE NO. 2: RHODE ISLAND

This case involved a practice with a single ophthalmologist. Similar to the Texas case, an FCA complaint was filed by two whistleblowers, both disgruntled former employees who had been terminated. According to the complaint, they were fired for raising allegations of misconduct, which the practice denied. The allegations related to improper conduct surrounding the practice's comanagement program.

Unlike in the Texas case, the FBI executed a search warrant, with 40 agents entering the practice unannounced. The final result suggests this was an overreaction by the government.

With respect to comanagement, the complaint alleged that the practice (1) paid comanagers amounts exceeding fair market value and (2) engaged in blanket, routine comanagement, depriving patients of choice. The complaint included anecdotal statements, such as an employee's remark that "the referring doctor needs to get a piece of the pie" and a referring doctor's statement that he was waiting for payment "not for post-surgical care rendered but for the patient referrals." Additionally, it was reported that, when interviewed by the FBI, one comanager responded, "I don't know," when asked why he received an additional payment from the practice. Remarkably, however, the complaint did not reference premium IOLs or additional payments to ODs for noncovered postoperative care.

The complaint included unrelated allegations, many of which reflected ignorance of Medicare program requirements on the part of the whistleblowers. These included claims that the practice overbilled for postoperative care by performing only the 1-day visit and transferring the patient on day 9 and that using a billing company in India violated CMS prohibitions on outsourcing Medicare contractor system functions overseas.

Although the complaint demonstrated a lack of understanding of Medicare requirements and failed to substantiate any noncompliant conduct related to the comanagement of premium IOL patients, the government's investigation focused on these issues. To avoid litigation, the physician agreed to a settlement of approximately $1.2 million. In the formal settlement agreement, the government expressed concern about payments to referring ODs whose patients elected laser cataract surgery, for which they paid up to $2,900 per eye. Despite the whistleblowers' minimal allegations regarding the source of improper conduct, they received a whistleblower award of 22% of the recovery ($256,535).

CASE NO. 3: TENNESSEE

This case involved a complaint against a large practice in Tennessee filed by whistleblowers under the FCA. Unlike in the Texas and Rhode Island cases, the whistleblowers in this instance were not disgruntled former employees. Instead, they were the president and executive director of the State Optometric Society, who were concerned about declining attendance at Society Continuing Education (CE) programs. These programs generated revenue for the Society, and reduced attendance negatively affected the Society's finances. Upon learning that a large ophthalmology practice was offering free CE programs for optometrists, the whistleblowers attended the sessions. What they observed formed the basis for their complaint.

According to the complaint, the ophthalmology practice not only provided free CE but also served expensive

meals during the sessions. Additionally, the complaint alleged that, during their presentations, the ophthalmologists promoted the financial benefits of comanagement with their practice. They assured attendees that patients would be returned for postoperative and primary care. The complaint further alleged that the ophthalmologists paid comanaging optometrists for providing postoperative care to patients receiving premium IOL implants and claimed that the payments were both excessive and unlawful.

Unlike in the Texas and Rhode Island cases, the Tennessee case was prosecuted by the whistleblowers. The government did not take over the case in a timely manner, and when it later attempted to do so, the court denied the government's motion to intervene. As a result, the whistleblowers remained in charge of the case. After years of discovery and numerous court motions, the parties reached a settlement. Due to the size of the practice and the duration covered by the complaint, the settlement was significant: $17 million. Because the whistleblowers prosecuted the case, they received a 28% share, amounting to $4,760,000. The FCA provides that, when a whistleblower prosecutes the case, the whistleblower is entitled to up to 30% of the recovered amount.

LESSONS LEARNED

The three settlements discussed in this article make it clear that comanagement can pose compliance risks if not properly structured or if abused by participants. Although no new settlements have been reported since 2023, investigations into other cases continue, and additional resolutions may emerge. Practices should therefore evaluate their comanagement programs carefully and avoid conduct that may raise compliance concerns. The following guidelines summarize lessons learned from the cases discussed in this article and other unpublished or confidential cases.

Patient choice must be offered and documented. Written confirmation that the patient has elected to be comanaged should be obtained.

Compensation must reflect fair market value. Payments to comanagers for noncovered postoperative care should correspond to the fair market value of the services provided.

No additional payment should be made to a comanager unless additional care is provided by that comanager. If no additional care is provided or anticipated, the comanager is not entitled to further payment.

Payments made directly to the comanager by the patient reduce compliance risks. Although payments by ophthalmology practices to comanagers for noncovered postoperative care are not inherently illegal, the risk of improper conduct allegations decreases if patients pay the comanager directly.

Patient awareness and approval are essential. Regardless of how payments are made, patients must be informed of and approve payments to comanagers.

Fee reductions by the surgeon must reflect fair market value. When a surgeon reduces a global fee for noncovered services due to comanagement, the lower fee should align with the fair market value of services the practice would otherwise provide.

Comanagers should set their fees. Fees charged by comanagers should be determined independently. If fees match the surgeon's reduced fee, it must be clear that the comanager, not the surgeon, made the decision.

Employee education is critical. Practice staff should be trained on compliance requirements for comanagement programs. Ill-advised statements from employees can serve as evidence against the practice.

Comanager education is critical. Comanagers should also be educated on compliance requirements. Their statements can serve as evidence against the practice.

The focus should be on patient care, not financial benefits. When describing comanagement programs, ophthalmologists should emphasize respect for patients' decisions and proper postoperative care. Discussions should not reference financial benefits to either party.

Additional benefits to comanagers should be avoided. Offering benefits such as free CE, expensive meals, and event tickets can exacerbate concerns about improper relationships between ophthalmologists and optometrists. ■