AECOS American-European Congress of Ophthalmic Surgery®

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AECOS

GUIDANCE FOR COMPLIANT CO-MANAGEMENT

The information provided in this document does not, and is not intended to, constitute legal advice; AECOS is providing this guidance to its members for general informational purposes only. This document is designed to educate readers generally regarding the principal legal risk that arises in connection with co-management under kickback theories, and to present principles designed to reduce compliance concerns. The document is not a comprehensive review of all federal, state and payor laws and rules that may be applicable to co-management. Readers should contact their attorney to obtain advice with respect to any particular co-management arrangement or other legal matter.

Why Is AECOS Issuing This Guidance?

Since the mid-1980s, when the Medicare statute was amended to allow optometrists to bill for services for which they were licensed to perform, co-management has been the subject of debate and dispute within ophthalmology. Some ophthalmologists supported the practice as a way to allow patients to return to their primary eye care provider following surgery, while others in the profession criticized co-management as a veiled mutual referral arrangement which violated the federal Anti-Kickback Statute. This controversy triggered Senate hearings, investigations by the HHS Office of Inspector General ("OIG") and attempts to amend state law to prohibit co-management.

During the early years of co-management, there was little compliance guidance from the federal government. In one interview, a representative of the OIG suggested that a mutual referral agreement between an ophthalmologist and optometrist might trigger the Anti-Kickback Statute. And when issuing safe harbor regulations for shared services arrangements, the OIG declined to include co-management for safe harbor protection because of concerns about abusive co-management relationships between ophthalmologists and optometrists; instead, it stated that it would determine compliance of such relationships on a case-by-case basis.

For many years there was little heard regarding government enforcement of co-management. One reason for this lack of enforcement activity likely was the fact that billing rules related to Medicare covered services were clear and presented little opportunity for abuse. Medicare requires the surgeon and co-manager to bill separately for the services in the surgery procedure bundle each performs; Medicare sets the global period for surgery, and Medicare sets the amount of payment for the surgery and for the post-operative care. The billing rules became less clear, however, with the development of advanced technology IOLs and the publication of Medicare Ruling 05-03 for presbyopia-correcting IOLs. This Ruling allowed facilities and physicians to bill patients directly for the refractive aspect of the advanced technology IOLs and related non-covered services, respectively. And since the Medicare billing rules do not apply to the non-covered portion, there was no guidance as to setting and collecting the fees for these non-covered services, including expanded co-management services. As a result, while advanced technology IOLs presented a significant clinical advancement for physicians to offer to their patients, the lack of regulation created an environment for co-management relationships that raised compliance concerns. Recently, these concerns were realized with the first enforcement cases related to co-management.

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In 2023 three False Claims Act settlements relating to allegedly improper co-management programs were settled, reflecting significant financial penalties imposed against the ophthalmology practices and, in one case, the ambulatory surgery centers to which they referred cataract surgical cases. There may be other investigations on-going. Significantly, the key allegations in all three cases related to the failure to provide patients with a choice to be co-managed as well as payments to co-managers for post-operative care that did not reflect fair market value for services provided to patients who received advanced technology IOLs. Other ancillary issues further fueled kickback scrutiny, including allegations that the ophthalmology practices provided referring co-managers items of value to induce referrals, such as free continuing education programs, entertainment, and social events. These settlements have generated heightened attention to the compliance risk associated with improper co-management practices. Recognizing that the vast majority of ophthalmologists and optometrists wish to conduct their practices in a compliant manner, and the need for guidance that addresses co-management of non-covered services, AECOS is publishing this document to assist practices operate in a compliant manner.

What Is Co-Management?

Co-management is a cooperative interaction between health care providers to share the medical and surgical care of a patient. When a patient is co-managed, the surgeon and co-manager receive payment for the services each performs. The decision for co-management is made by the patient, subject to the surgeon's clinical assessment that the patient may be transferred to the co-manager for post-operative care. Physicians who participate in a co-management arrangement must assure that the patient is adequately informed about the choice for co-management, that the patient is provided a meaningful chance to opt-in or out of co-management, and that the patient's choice is honored.

Co-management is not unique to ophthalmology. Nevertheless, because co-management between ophthalmic surgeons and optometrists has generated controversy within the profession, and allegations of abusive arrangements have been raised to regulators and enforcers, the need for compliance guidance is critical.

Principles of a Compliant Co-Management Program

For those practices that elect to offer patients an option to be co-managed, the following principles should be applied to any co-management arrangement, regardless of whether the services performed are paid for by a government or commercial payor or solely by the patient.

- Any agreement (implicit or explicit) between the operating surgeon and another eye care professional for the pre-determined referral of patients for co-management is prohibited.
- Financial considerations may not influence a co-management arrangement or referral decisions.
- Patients should receive sufficient information about post-operative care requirements and the eye care professionals who can provide the post-operative care so that the patient is able to make an informed decision whether to be co-managed.
- A patient's decision for co-management should be in writing and is subject to the surgeon's decision that co-management will not present clinical risk to the patient.
- Co-management may not be appropriate if a complication arises following surgery or if the medical condition of a particular patient requires continued treatment by the operating surgeon.
- The patient must be given the option to return to the operating surgeon at any time during the post-operative care period.

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- If the patient elects to be co-managed by another eye care professional, the operating surgeon (or another surgeon designated to cover in the absence of the operating surgeon) must be available during the post-operative period should complications arise.
- The surgeon and co-manager should bill for their respective services consistent with applicable payor rules.

Application of Co-Management Principles to Covered Procedures

Co-management of procedures that are covered solely by Medicare present limited opportunity for abuse. Medicare requires that the provider of care bill for the services performed, and the fees for the services rendered are set by Medicare. The limited risk of potential abuse arises where the surgeon and the co-manager enter into an agreement - - either explicit or implicit - - to refer to each other with no consideration of the patient's choice and/or base referrals on financial considerations. As noted above, in connection with the recent case settlements as well as with respect to the principles of a compliant co-management program, patients must be given the genuine choice to be co-managed and that choice must be respected. If that guidance is followed, co-management of covered services alone should not present compliance risk.

A similar analysis applies to co-management of covered services for patients covered solely by private insurance. Assuring patient choice is critical to decreasing risk associated with co-management. An additional issue arises, however, where the insurer does not credential optometrists as panel providers, in which case the co-manager may not bill for the post-operative care provided. Some practices have addressed this issue by contacting the insurer and advising that their subscriber wishes to obtain care from the caregiver of their choice but is precluded from doing so because of the plan's policy. Here, the practice has proposed to bill and collect the global fee for the cataract surgery, with the understanding that the practice is collecting on behalf of the co-manager and will apply the Medicare fee allocation (i.e., 80% of the Medicare payment covers the pre- and intra-operative physician service and the remaining 20% is allocated to the post-operative care). Care must be taken, however, to assure such an arrangement does not run afoul of payor contract terms and state laws that prohibit the splitting of professional fees between referral sources.

Application of Co-Management Principles to Non-Covered Procedures

Where the co-management of a patient arises in the context of a surgical procedure for which the patient pays in whole or in part such as refractive surgery (e.g., LASIK, SMILE, astigmatism management) or the implantation of an advanced technology IOL, the principles set out above should be followed with similar attention. Because the non-covered procedures are the financial responsibility of the patient, and because the utilization of modifiers 54 and 55 does not apply to the provision of non-covered services, some believe the kickback risk is eliminated. This is not the case; in fact, there are additional risks to be addressed. The federal Anti-Kickback Statute continues to be applicable to arrangements involving any referrals between the surgeon and co-manager for items or services covered by federal health care programs (e.g., cataract surgery with an advanced technology IOL). The federal law also may be implicated by financial relationships between surgeons and co-managers involving self-pay procedures such as LASIK, SMILE or RLE where the co-manager refers both covered and non-covered services. Co-management fees above fair market value for services associated with self-pay procedures can be alleged to be an improper inducement for referrals

of covered services. Further, state anti-kickback laws may apply to co-management relationships for both covered and patient pay services. The areas of additional risk focus largely on the following:

- What are the services furnished by the co-manager that are subject to patient payment? Where a patient chooses an advanced technology IOL or other refractive correction procedure performed in connection with cataract surgery, a determination must be made as to what services furnished to the patient are covered as part of standard cataract surgery and what services are related to the refractive aspects of the surgery and therefore non-covered. For example, those patients electing monovision may require additional non-covered services such as a contact lens trial. This may vary from practice to practice; the surgeon's clinical protocol for the post-operative care of advanced technology IOL patients sets the foundation, but ultimately the co-manager controls the services he/she furnishes.
- What is the fair market value of the additional services performed by the co-manager? Recent studies relating to the pre-operative[1] and post-operative[2] care of patients undergoing cataract surgery with advanced technology IOLs support the proposition that many of these patients require more frequent and labor-intensive services. The co-manager is entitled to be paid for the additional services the co-manager provides to the patient at a rate that reflects the fair market value for the non-covered services provided. Some physicians and co-managers have adopted the Medicare standard of the 80/20 split to determine the patient fees related to the non-covered professional services. Relying on this standard to set a co-management fee could be risky, as the 20% may not reflect fair market for the services furnished. Instead, the co-manager should set his/her fee based on the fair market value of the additional services performed. Since the co-manager controls the services, he/she furnishes, the co-manager is in the best position to set the fee for those services not covered by a governmental or private payor.
- Who pays the co-manager for the additional services? Because these are non-covered services for which the patient is financially responsible, the patient is making the payment for the non-covered services. Ideally, the patient makes separate payments to the surgeon and to the co-manager. If, however, the patient makes a single global payment to the surgeon, the patient must be advised that the surgeon is collecting the co-manager's fee and will transfer the fee accordingly. The patient should approve the payment amount to each physician in writing.

Compliance Tips When Discussing Co-Management with Patients

Practices present the concept of co-management to patients in a variety of ways. In all cases, the surgeon should assure that the patient has the opportunity to ask questions regarding co-management. In order to document a compliant co-management program, practices should consider the following:

- Provide patients with a written description of the need for post-operative care (tailored to reflect the global period based on the surgical procedure to be performed), and the option to return to the surgeon's practice or to obtain post-operative care from the co-manager. The document should explain that the patient may return to the surgeon's practice at any time during the post-operative period.

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[1] Oshika, Tetsuro et al. "Comparison of preoperative chair time between monofocal and multifocal intraocular lenses." *Journal of cataract and refractive surgery* vol. 48,5 (2022): 632-633.

[2] Maloney RK, Doane J, Weinstock R, Donaldson KE; AECOS Postoperative Care Study Group. Work Intensity of Postoperative Care Following Implantation of Presbyopia-Correcting versus Monofocal Intraocular Lenses. Clin Ophthalmol. 2023 Jul 17;17:1993-2001.

- If the patient has elected to have an advanced technology IOL implant or other refractive correction procedure performed in connection with cataract surgery, provide the patient with a summary of the additional services to be performed by the co-manager and the fee to be paid to the co-manager for those services.
- Do not attempt to influence a patient to choose co-management.
- Educate your staff, particularly those who interact with patients, about the need for compliance with these guidelines.
- If the patient elects to be co-managed, it is appropriate to coordinate scheduling the patient's initial post-operative visit with the co-manager, but the final decision to co-manage the patient should be made after surgery, once the surgeon has confirmed that it is clinically acceptable to transfer the patient to the care of the co-manager.
- The transfer of care must be in writing and indicate that the patient is stable for transfer.

Compliance Tips When Discussing Co-Management with Optometrists

- Do not have an agreement between the operating surgeon and another eye care professional for the routine referral of patients.
- Do not discuss the financial benefits of co-management with optometrists.
- Be clear with a co-manager that you will not influence a patient's choice whether to be co-managed or to receive post-operative care with your practice.
- Do not refer to patients as "your patients" when discussing co-management with optometrists - - refer to patients as "our patients."
- Be sure that each co-manager has a clear understanding of his/her role and responsibility, as well as the role and responsibility of the surgeon in order to assure that no aspect of the patient's care is neglected or duplicated during the course of care.
- Advise the co-manager that the surgeon (or appropriate designee) is available during the co-management period for consultation or, if necessary, to take over care of the patient. Educate optometrists about the need to follow guidelines for compliant co-management, and explain that they, as well as you, may be subject to allegations of a violation of federal and/or state anti-kickback prohibitions for non-compliant conduct.
- Co-managers should assure their medical records document the additional non-covered services furnished to patients for which payment is received.

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