Co-management arrangements are not per se illegal under the federal healthcare fraud and abuse laws, but they raise many red flags that need to be carefully considered by physicians involved in such arrangements or contemplating entering into them.
o-management of patients is a common practice for many ophthalmologists and optometrists. Such arrangements, where ophthalmologists and optometrists share patient care responsibilities according to a patient’s needs for both specialized and more general eyecare, can benefit the patient and the medical professionals involved. These arrangements, however, can also implicate federal healthcare laws and regulations concerning the financial relationships between healthcare professionals, including the prohibition on physician self-referral (commonly referred to as the Stark law) and the anti-kickback statute.

Basic provisions
The Stark law prohibits physicians from referring patients for certain “designated healthcare services” (DHS), including outpatient hospital services and post-cataract eyewear, to any entity or individual with which that physician has a financial relationship. Because the statute is based on strict liability—meaning that the mere presence of a prohibited relationship is illegal regardless of the parties’ intent—all co-management arrangements that include provisions for payment between an ophthalmologist and optometrist fall under this law. Therefore, the only way to avoid penalties for self-referral in such situations is to meet one of the statutory or regulatory exceptions to the Stark law. However, because of an exception for post-cataract eyewear that ASCRS•ASOA was able to secure many years ago, Stark does not apply to the referral of eyeglasses or contacts following cataract surgery.

The anti-kickback statute, however, does apply to cataract surgery, as well as any other procedures covered by Medicare or Medicaid. The anti-kickback statute prohibits the offer, solicitation, or receipt of “remuneration” in exchange for referring patients. “Remuneration” includes the transfer of anything of value, including the opportunity to bill. Where co-management arrangements involve payments between ophthalmologists and optometrists, or where referrals are required between the professionals, the anti-kickback statute may violate this law.

Unlike the Stark law, however, the anti-kickback statute requires that the parties intend to induce referrals before the arrangement is deemed illegal. Still, if even one purpose of the arrangement is to induce referrals, the requirement for intent is satisfied. Such instances are examined on a case-by-case basis, with respect to the facts and circumstances of each arrangement.

Statutory and regulatory safe harbors exist to insulate arrangements from potential investigation, but unlike with the Stark law, arrangements are not required to fit within a safe harbor to be legal.

Assessing compliance
Both the Centers for Medicare and Medicaid Services (CMS, which oversees Stark law compliance) and the Office of the Inspector General (OIG) for the Department of Health and Human Services (which administers penalties for violations of the anti-kickback statute) offer processes whereby healthcare professionals and entities can obtain advisory opinions regarding a particular arrangement’s compliance with federal laws and regulations. Recently, the OIG issued an advisory opinion regarding an arrangement involving ophthalmologist and optometrist co-management of cataract surgery patients and the arrangement’s compliance with the anti-kickback statute.

OIG Advisory Opinion 11-14 was issued on September 30, 2011. Under the arrangement in question, a group practice of ophthalmologists wished to enter into an understanding with external optometrists in which the optometrists could resume management of the patients they originally referred to the ophthalmologists for cataract surgery following the surgery. For Medicare patients, this could potentially result in a split fee, where the ophthalmologist received payment for the surgery and the optometrist received payment for post-op management.

Specifically, the proposed arrangement involved cataract surgeries in which premium intraocular lenses (IOLs) were used. The arrangement results in additional billing opportunities for both the physician doing the surgery and the optometrist overseeing the post-op recovery. Thus, remuneration could be involved in the form of the optometrist’s opportunity to earn a fee in the event that he or she takes over post-op management of cataract surgery patients.

Under the proposed arrangement that was the subject of the advisory opinion, the ophthalmologists would not enter into written agreements for post-op management by the optometrists. In addition, transfer of any patient’s post-op care would only be done at the patient’s request and only if clinically appropriate. Patients would be notified of the potential for the optometrists to charge additional fees for the post-op services. The OIG considered each of these factors in determining whether the arrangement involved prohibited remuneration. After also noting that the increased costs associated with the cataract surgeries and post-op management of patients receiving premium IOLs would not be borne by the Medicare program, the OIG determined that the arrangement did not violate the anti-kickback statute. The OIG made this determination without the application of a safe

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harbor, based solely on the lack of prohibited transfer of value between the ophthalmologists and optometrists in exchange for referrals.

Analysis
Advisory Opinion 11-14 deals with a fairly narrow and conservative co-management arrangement. The proposed arrangement has no requirement for referrals between the ophthalmologists and the optometrists and involves no payments between the physicians, although the optometrists gained the opportunity to bill Medicare and the patients for the post-op care provided. Other more formalized arrangements for co-management may create much more risk of compliance issues under the anti-kickback statute, as well as the Stark law.

In fact, the OIG has already flagged ophthalmologist/optometrist co-management arrangements as potentially abusive. While discussing a new safe harbor covering referral agreements for specialty services, the OIG indicated that co-management arrangements involving splitting of Medicare reimbursement were problematic, and it took steps to explicitly exclude such arrangements from the new safe harbor’s protection. The OIG went on to say, however, that “[b]y limiting the safe harbor, we do not mean to suggest that all specialty referral arrangements involving splitting of global fees are illegal under the anti-kickback statute.”

Turning first to compliance concerns related to the Stark law, any payments or agreements for the provision of services or compensation (monetary or in-kind) between an ophthalmologist and optometrist who refer DHS to each other implicate the prohibition on physician self-referral, with the Stark law requiring an exception to be met in order for the arrangement to be permissible. For ophthalmologists, the most common DHS are post-cataract eyewear, outpatient hospital services, and A-scans and B-scans. As noted above, there is an exception under Stark for post-cataract eyewear that exempts the referral of eyeglasses or contact lenses following cataract surgery. For referrals of other DHS, the co-management arrangement may be able to fit within the Stark personal services exception, which requires (among other things) a signed written agreement, minimum 1-year term, and compensation that is set in advance that does not take into account the volume or value of referrals or other business generated between the parties.

As indicated by OIG’s strong interest in this area, co-management arrangements are more likely to implicate the anti-kickback statute. While it is not a requirement for such arrangements to fit within a safe harbor, a safe harbor analogous to the Stark personal services arrangements exception does exist. That safe harbor has many of the same requirements but also requires an exact schedule be established for the services to be rendered, something likely to prove challenging for co-management arrangements structured around the specific medical needs of patients. And, as previously noted, OIG has deliberately structured other potentially applicable safe harbors to exclude arrangements where the reimbursement from Medicare is shared through fee splitting. Nonetheless, each arrangement must be analyzed individually to determine whether it in fact violates the anti-kickback statute by having at least one purpose be the trading of something of value (e.g., money, items, opportunities to earn a fee) for referrals.

Evaluating risk
While OIG has recently deemed one co-management arrangement to not violate the anti-kickback statute, that arrangement was narrow and relatively benign. Ophthalmologists and optometrists involved in co-management arrangements should be very aware of the potential compliance risks such arrangements raise. Care should be exercised to make certain the co-management arrangements satisfy at least one of the Stark law exceptions when there is a financial relationship between the physicians and at least one of them is rendering DHS. In addition, care must be exercised to avoid structuring the arrangements as exchanges of value for referrals between the physicians. Co-management arrangements are not per se illegal under the federal healthcare fraud and abuse laws, but they raise many red flags that need to be carefully considered by physicians involved in such arrangements or contemplating entering into them. To this end, ophthalmologists are encouraged to review joint co-management guidelines issued by ASCRS•ASOA and the Academy for ways of structuring lawful co-management arrangements. Those guidelines are available in the Government section of the ASOA website (www.ASOA.org) under “Co-Management.”