**Guidance for Compliant
Co-Management**

***Vision Innovation Partners***

**Table of Contents**

[Introduction and Overview 2](#_Toc141974192)

[Co-Management History and Background 3](#_Toc141974193)

[Co-Management When A Conventional IOL Is Implanted 5](#_Toc141974195)

[Co-Management When A Premium IOL Is Implanted 6](#_Toc141974200)

[Summary: Key Criteria For A Compliant Co-Management Program 9](#_Toc141974204)

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# Introduction and Overview

Co-management is a recognized and approved arrangement for the coordination of patient care by two physicians from independent practices. While co-management is not limited to ophthalmology and optometry, over the past several years there has been significant attention directed to co-management by both the ophthalmology community as well as federal regulators. That attention was triggered by concerns that certain co-management arrangements between ophthalmologists and optometrists may not be in compliance with applicable rules and regulations. Recently, several investigations and litigation relating to allegations of improper co-management relationships have resulted in severe financial penalties for those targeted practices.

Vision Innovation Partners is committed to operating in compliance with all applicable rules and regulations. This commitment extends to all of our staff, affiliated practices, and partners with which we work. We recognize, however, that the rules and regulations that apply to co-management may not always be clear, and in some situations there may be no guidance at all.

For this reason, Vision Innovation Partners has developed this Guidance for Compliant Co-management – to provide assistance to our affiliated practices and partners in understanding what is required to operate a compliant co-management program. We believe that following this guidance will not only provide the best protection against the risk of non-compliance, but also will assure that our patients are treated with respect and dignity.

The contents of this Guidance will set out in detail the steps to follow when co-managing a patient. There are, however, a few simple concepts that are critical to a compliant co-management program, which are set out here:

**Co-management is a matter of patient choice; it is not a decision to be made by the surgeon and/or the optometrist/ophthalmologist.**

**The patient’s decision whether or not to be co-managed must be respected.**

**Co-management must be clinically appropriate; the surgeon may transfer the patient only when it is clinically appropriate to do so.**

**Payment for services performed by the co-manager must reflect the fair market value of those services.**

**Patients must be fully informed and approve of any payment made to the co-manager for non-covered services for which the patient is responsible.**

These concepts serve as the foundation of a compliant co-management program and will be reflected in the guidance presented here.

# Co-Management History and Background

**Co-management** is a process where two physicians from different practices provide care to a patient in connection with a surgical procedure. Each physician is paid for the services he or she performed on behalf of the patient during the global fee period for the surgical procedure. In the context of eye care, a typical co-management arrangement is when an ophthalmologist performs surgery, and, if the patient requests it and it is clinically appropriate, transfers the patient to an optometrist/ophthalmologist to provide the post-operative care.

Co-management in vision care essentially began in the mid-1980s when the Medicare statute was amended to include optometry in the definition of physician. This allowed optometrists/ophthalmologists to bill Medicare directly for the services optometrists/ophthalmologist were licensed to perform under state law. As much of the post-operative care provided falls under the optometric scope of practice, optometrists were able to bill the Medicare program for providing care to patients during the post-operative period following surgery.

For several years following the amendment of the Medicare statute, co-management triggered significant disagreement and controversy within ophthalmology. While some practices worked cooperatively with referring optometrists and willingly accepted co-management arrangements, others objected, and took the position that the operating surgeon was responsible for providing care to the patient during the entire global period. Those who did not support co-management raised concerns about patient abandonment because the operating surgeon did not provide care during the entire post-operative period. Further, more serious accusations were made that co-management constituted a form of kickback. Optometrists were accused of conditioning a referral for surgery on the agreement to refer the patient back for the provision of post-operative care, and ophthalmologists were accused of soliciting surgery referrals with the promise of returning the patient for post-operative care.

Attempts to challenge co-management were directed to Medicare contractors, and some responded by proposing very restrictive limitations on when it would pay for co-managed care. CMS, however, stepped in and rejected these attempts, effectively acknowledging that co-management of cataract surgery was an accepted and recognized process for an ophthalmologist and optometrist to share the surgical and post-operative care of cataract surgery.

Concerns about co-management were also directed to the Office of Inspector General (OIG) of the Department of Health and Human Services. As a result, when it finalized a regulation that provided safe harbor protection for shared services arrangements, it carved out an exception that effectively eliminated co-management between ophthalmologist and optometrists for protection. Importantly, however, the OIG did not state that co-management itself was prohibited, nor did it limit its application. Instead, the OIG stated that it would determine the propriety of a co-management arrangement based on the facts presented.  By way of further guidance, apparently in response to the concerns raised by those who challenged the propriety of co-management, the OIG noted that routine co-management or transfer of care referral arrangements were not appropriate and may violate the Federal Anti-Kickback Statute. Therefore, in no situation should there be a mutual agreement or understanding between an operating ophthalmologist and a referring optometrist to send patients back to the optometrist/ophthalmologist for post-operative care.

Finally, attempts to restrict co-management also were made at the state level. While most of those efforts did not result in the enactment of formal legislation, there were a few states that did adopt legislation addressing co-management. Ironically, none of those states prohibited the practice; instead, they established criteria that must be met in order to co-manage in a compliant manner. Those criteria are generally reflected in the guidance set out here.

## Patient Choice: A Critical Element of a Compliant Co-Management Program

As noted above, while the OIG did not prohibit co-management, it noted that it would review any arrangement based on the facts presented. Further, it noted that routine co-management, which is a co-management program where there is an agreement between the surgeon and the co-manager to refer patients back after surgery, would not be viewed favorably, and could constitute a violation of the Anti-Kickback Statute. Thus, a co-management program where the decision to co-manage is not made by the surgeon or the co-managing physician but is a decision that is made by the patient, should successfully rebut any allegation that co-management is routine. It is also worth noting that state legislation that sets our criteria for a compliant co-management program includes patient choice as a necessary criterion. Finally, in the cases where the propriety of a co-management program was challenged, allegations included the fact that patients were directed to return to their referring optometrists/ophthalmologists for post-operative care; in other words, there was no patient choice.

Thus, while a compliant co-management program requires meeting several criteria, assuring patient choice is, perhaps, the single most important. When a patient is able to make a decision to obtain post-operative care from the ophthalmology practice or to return to his or her optometrist/ophthalmologist for post-operative care, it provides a strong rebuttal against an allegation of a routine co-management relationship or of a referral agreement between the surgeon and the optometrist/ophthalmologist. Further, if the patient elects to return to his or her optometrist/ophthalmologist for post-operative care, it becomes difficult to allege that the surgeon has abandoned the patient or that the surgeon is guilty of a negligent referral.

Finally, patient choice must be meaningful; in other words, the patient must be fully informed of the opportunity either to return to his or her optometrist/ophthalmologist for post-operative care, or to stay with the practice of the operating surgeon for post-operative care. Further, the patient must understand fully not only the clinical implications of co-management, but also the financial implications of that decision and must confirm the decision in writing. More specific elements of this process are addressed later in this Guidance.

# Co-Management When A Conventional IOL Is Implanted

The purpose of a conventional IOL is to replace a cataractous lens in order to restore a patient’s vision that has been compromised by a cataract. While conventional IOL implants often provide a collateral refractive benefit by restoring a patient’s distance vision (or, in some instances, near vision), the purpose of conventional IOL implant surgery is to address vision loss by removing the cataract,

When a patient chooses to be co-managed, surgeons and co-managers should maintain open communication to facilitate coordination of care throughout the post-operative care process. Further, surgeons and co-managers are encouraged to develop and follow clinical protocols that assure that all patients receive the same high-quality care, regardless of who provides post-operative care to the patient. Finally, even if the patient elects to be co-managed, the surgeon (or another appropriately trained ophthalmologist) must be available during the entire post-operative period in case of an emergency that is beyond the scope of practice of the co-manager, or if the patient decides to return to the ophthalmologist for care.

## Regulatory/Compliance Issues

###  Anti-Kickback and Routine Referral

The principal regulatory and compliance issue relating to co-management of a standard IOL patient is an improper referral relationship between the surgeon and the co-manager. Because the Medicare and Medicaid programs and most private insurers require each caregiver to bill for the services they perform, and because those payers determine the amount that will be paid for those services, the risk of a potential kickback issue is limited. Thus, as long as patient choice is assured and there is no agreement between the surgeon and co-manager to refer patients back to the referring optometrist/ophthalmologist for post-operative care following cataract surgery, there should be no regulatory or compliance issue relating to anti-kickback or routine referral concerns.

###  Transfer of Care

The Medicare Program requires that a co-management arrangement must be supported by written documentation reflecting a formal Transfer of Care. That written documentation should be in the form of a letter or form sent from the ophthalmologist to the co-manager. The Transfer of Care documentation must include information about the surgery performed, any discharge instructions from the surgeon, and the effective date of the transfer. The effective date of transfer may be completed only after surgery, or the date of the last post-operative visit performed. The date of transfer is necessary to assure proper billing for that portion of the post-operative period covered by each provider of care.

The co-manager assumes the care of the patient on the day following the transfer date. The effective date of the transfer of care may be on or before the patient’s appointment for the initial post-operative visit with the co-manager. However, the co-manager may submit a claim for services only after he/she has seen the patient.

Finally, a transfer of care may be made only if it is clinically appropriate. The surgeon must determine that the co-manager is properly trained to address the clinical needs of the patient at the time of transfer.

## Billing Issues

As noted above, in the context of conventional IOL implant surgery, Medicare, Medicaid, and other federal health care programs usually dictate that each provider of care must bill for the services he or she performs. In addition, these programs generally determine the amount that will be paid for the services performed and impose strict limitations on the amount that the physician may charge.

There is, however, one compliance issue that may arise where a patient wishes to return to the referring optometrist/ophthalmologist, but the optometrist/ophthalmologist is not enrolled in Medicare, Medicaid, or another federal health care program. In this case it is not appropriate for the ophthalmology practice to bill for the entire global fee and make a payment to the optometrist/ophthalmologist for the post-operative care; such an arrangement could trigger a violation of the prohibition against reassignment of benefits, which could result in administrative sanctions. Instead, the ophthalmology practice should bill for the services it performs and if the patient wishes to return to the referring optometrist/ophthalmologist, the referring optometrist/ophthalmologist may bill the patient directly, or waive the fee.

Similarly, a patient may be covered by a commercial insurer and the co-managing optometrist/ophthalmologist may not be enrolled in the plan as a participating provider, either because the plan does not recognize optometrists as participating physicians, because the plan is not accepting additional physicians to participate in the plan, or because an optometrist elects not to participate in a plan. Because the obligations of providers of care are based on the terms of the participation agreement with the insurer, it may be possible to work with the insurer to structure a mechanism for each physician to be paid for the services each performs. However, each plan is different, and any consideration by the ophthalmology practice to bill for global fee and make payment to the co-managing optometrist/ophthalmologist must be referred to our Compliance Office for consideration and approval.

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# Co-Management When A Premium IOL Is Implanted

The purpose of a premium IOL implant is twofold: (1) to replace a cataractous lens to restore a patient’s vision; and (2) to provide a refractive benefit to reduce, and perhaps eliminate, the patient’s need for glasses. As a result, during the post-operative period the patient must be monitored not only for the clinical concerns that arise in the context of a conventional IOL implant, but also to determine the patient’s progress in achieving the desired refractive result. Further, if a patient does not achieve the desired refractive result, it is necessary to diagnose any issues that may be responsible for the failure to achieve that result, and to recommend any additional procedures to address the problem. Consistent with the standard established in the context of refractive surgical procedures, the global postoperative period when a premium IOL is implanted often extends beyond the 90-day global period for a conventional IOL implant and may be up to 180 days. It is expected that anyone who co-manages adheres to this additional global period to treat the patient. Any patient complaint on visual outcomes should be referred back to the practice to be seen there. In addition, the following protocol is desirable:

1. Post operative week 1
	1. Refraction
	2. Evaluation of vision and eye pressure
	3. Anterior segment evaluation for corneal edema, epithelial defect, ocular surface dryness, anterior chamber cell
2. Post operative month 1
	1. Same evaluation as post operative week 1
	2. Refraction
	3. Retinal evaluation/OCT macula to assess for Irvine Gass or other causes of macular edema in the post operative period if best corrected vision is limited
3. Post operative Month 3
	1. Vision, pressure, anterior segment evaluation as above
	2. Dilated Eye Examination - assessing for posterior capsule opacity
4. Expected management of typical post operative medical pathology in the post operative period included in co-management includes:
	1. Persistent iritis
	2. Corneal edema
		1. if not responsive to medical therapy and present at 90 days post op, can refer back to See Clearly for corneal evaluation to consider surgical intervention
	3. Ocular surface disease contributing to blurred vision
	4. Macular edema / Irvine Gass - if not responsive to medical therapy (NSAIDS) will referral to Retina specialist for evaluation/ management
	5. Treatment of ocular surface disease and counseling regarding dysphotopsias which can be noted in patients with multifocal lenses
5. Early referral back to See Clearly if urgent surgical intervention required:
	1. Dislocated IOL/Subluxed IOL
	2. Retained nuclear fragment not amenable to medical therapy

## Regulatory/Compliance Issues

###  Anti-Kickback and Routine Referral

The Medicare program treats the implant of a premium IOL as a bifurcated procedure: it is a covered cataract surgery procedure and also a non-covered refractive surgery procedure. Consistent with this structure, there are essentially 2 separate billing protocols followed: one where Medicare is billed and pays for the covered surgical procedure as if a conventional IOL were implanted, and the other where the patient is billed and pays for the non-covered refractive procedure. As a result of this construct, when a premium IOL is implanted, all of the regulatory and compliance issues identified above apply here as well. However, because a premium IOL implant includes a second, refractive procedure with its independent billing and payment, there are additional regulatory and compliance issues that must be addressed, particularly in the context of co-management.

Patients who elect to have a premium IOL implanted are responsible for an additional out-of-pocket fee for the additional non-covered services that are provided as part of the refractive procedure package. That fee includes an amount for the premium IOL as well as for additional diagnostic testing designed to determine whether the patient is a candidate for a premium IOL implant, as well as to determine the most appropriate IOL to meet the patient’s needs. In addition, premium IOL patients generally require more chair time, both pre- and post-operatively, than patients who elect to have a conventional IOL implant. Further, if the premium package includes a post-operative period of 180 days or 1 year, there may be additional visits for these patients beyond the 90-day post-operative period for conventional IOL patients.

It is generally understood that a portion of the patient’s out-of-pocket obligation reflects each of the additional items and services identified above, including the additional post-operative care required by premium IOL patients compared to conventional IOL patients. Therefore, if a premium IOL patient elects to be seen post-operatively by his or her optometrist/ophthalmologist, the optometrist/ophthalmologist will be responsible for the performance of the additional post-operative services required by these patients. Unlike co-management of patients following conventional IOL implant surgery, however, co-management of premium IOL patients may trigger compliance issues beyond the improper referral concern. When a premium IOL is implanted, the co-manager will not only be paid for the post-operative care performed in connection with the covered cataract procedure (a payment that will generally come from Medicare, other federal health care program, or from a commercial insurer) but will be paid an additional fee for the additional post-operative care provided to these premium IOL patients. This additional fee relates to the refractive component of

the surgery and is paid by the patient.

Unlike conventional IOL surgery, where the fee is set by Medicare or other third-party payer, the fee for the non-covered refractive portion of premium IOL surgery is set by the surgeon and, in some cases, the co-manager (for that portion of the fee that relates to the post-operative care). As a result, there are additional compliance concerns that may arise from the payment of an additional co-management fee to a referring optometrist/ophthalmologist:

* If the co-manager provides additional services for which the co-manager is compensated, the question arises whether those services were appropriate, or if they were performed to justify the additional fee. It is important, therefore, that the co-manager perform post-operative services similar to the post-operative services performed by the ophthalmology practice for those patients who are not co-managed. This is most easily addressed if the surgeon provides a clinical protocol reflecting the care provided by the surgeon to non-co-managed patients, with the understanding that the co-manager is expected to follow a similar protocol. The surgeons at ECS do not compensate for the co-management of premium.
* Often when a patient elects to be co-managed, the surgeon will reduce the fee for a premium IOL package to reflect the fact that the surgeon will not provide those additional post-operative services. If the co-manager receives an additional fee that is comparable to the reduction from the surgeon but fails to provide post-operative services comparable to care the surgeon provides to non-co-managed patients, that also raises compliance concerns. Again, a clinical protocol which is followed by the surgeon and co-managers will address this concern.
* Even if the additional post-operative services performed by the optometrist/ophthalmologist are appropriate and consistent with the services that the surgeon would otherwise perform, the payment amount that the co-manager receives must reflect the value of the services performed. If the surgeon reduces the fee from a premium package by an amount that is greater than the value of the post-operative services it allegedly covers, and this amount is paid to the co-managing optometrist/ophthalmologist, it raises the concern that the excess amount may reflect a payment for the referral.
* Because the payment for the non-covered services is the responsibility of the patient, the patient must be fully informed about the amount of payment that is made to the surgeon as well as to the co-manager. Failure to inform the patient about the payment amount to the co-manage may raise concerns that the patient may believe that the co-manager’s fee was more than the value of the co-manager’s services. If a case arises where a patient must be managed outside, the transfer of care form will include the protocol expected to be followed.
* Finally, in each of the cases that recently settled, the allegations included the fact that because the ophthalmology practice made a payment to the co-manager, the Anti-Kickback statute was violated. We believe it is acceptable for an ophthalmology practice to collect the co-manager’s fee and transfer it to the co-manager (essentially serving as a collection agent for the convenience of the patient), as long as the patient is fully informed about the amount that is paid to the co-manager and approves of the payment. Nevertheless, in order to avoid such allegations, we recommend strongly that, whenever possible, the patient make the payment directly to the co-manager.

## Billing Issues

Because premium IOL implant surgery is comprised of both a covered service and a non-covered service, surgeons and co-managers must follow the same procedure for billing as if a conventional IOL were implanted, which addresses the covered portion of the surgery. With respect to the non-covered portion, however, since the patient is responsible for paying the additional fee, there is no formal structure that must be followed with respect to billing patients for these additional services. Nevertheless, as noted in the discussion above relating to Regulatory/Compliance Issues, there are significant compliance risks if proper safeguards are not followed when billing patients for non-covered services.

# Summary: Key Criteria For A Compliant Co-Management Program

Based on the provisions outlined above, the following reflect the essential elements of a compliant co-management arrangement.

* The patient has been appropriately informed about the need for post-operative care, has been advised of the availability of such care by the operating ophthalmologist, and has elected to receive post-operative care from a co-manager.
* Once the patient elects to be co-managed, the patient’s decision is confirmed in writing.
* The operating ophthalmologist determines the operative eye is sufficiently stable and clinically appropriate for transfer of care.

* The optometrist/ophthalmologist is qualified and willing to accept the care of the patient.
* All relevant clinical information is exchanged between the operating ophthalmologist and the co-managing optometrist/ophthalmologist. Transfer of care is documented in the medical record as required by the health plan/payer policy.
* During the entire post-operative period the operating ophthalmologist or an appropriately trained ophthalmologist is available upon request from either the patient or co-managing optometrist/ophthalmologist to provide medically necessary care to the patient related to the surgical procedure.

* The services performed by the co-manager are appropriate and not provided simply to justify a fee. Ideally, the additional services performed by the co-manager are comparable to the additional services performed by the surgeon for patients who decline to be co-managed.
* Payment for the additional services performed by the co-manager for a premium IOL patient must reflect the value of the services.

* The patient must be fully informed about the additional amount to be paid to the co-manager for non-covered services for which the patient is responsible. The patient must agree with the financial arrangement in writing.

* Whenever possible, the patient should pay the co-manager directly for the additional post-operative services performed by the co-manager. If, however, the ophthalmology practice collects a global fee that includes the additional fee relating to the addition post-operative care, the ophthalmology practice must provide the patient with a form that reflects the amount to be paid to the co-manager for the additional post-operative services, and the patient must consent in writing to that payment.

## Additional Areas for Consideration

 Technical Billing Guidance

 Clinical Protocol

 Step-By-Step Process

 FAQ

 Forms

 Pre-Op Exam and Consultation Request

 Patient Choice for Co-Management

Patient Financial Disclosure and Approval for Premium IOL Co-Management

 Transfer of Care

 Post-Operative Care Form