Fair Market Value and Commercial Reasonableness of LASIK/PRK Patient Co-management

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Presentation Outline
I. Co-management Overview
II. Legal/Regulatory Issues
III. Valuation Approaches and Methods
IV. Co-management Agreements

Cataract Co-management
“Optometrists and ophthalmologists may work together as a team to provide complete preoperative, intraoperative, and postoperative care to meet the patient's needs. This cooperative care provided by doctors of optometry and opthalmic surgeons for patients with eye disease or requiring eye surgery has come to be known as ‘co-management’.”

**LASIK/PRK Co-management**

- Patient education regarding:
  - Expectations regarding risks, benefits, and enhancement potential
  - Alternative procedures
  - Normal symptoms and side effects
  - Complications
  - Certain pre-operative testing
  - Post-operative visits at predetermined intervals

**Legal/Regulatory Issues**

- **Big picture**
  - Optometrists are in a position to make referrals to ophthalmologists
  - Various prohibitions on payments for referrals
  - Concern that remuneration flowing from the ophthalmologist/practice not be disguised remuneration in exchange for referrals past, present or future.

**Potentially Applicable Federal Laws**

- “Stark” physician self-referral law
  - Exceptions for IOLs and for eyeglasses and contact lenses following cataract surgery.
- Anti-Kickback Law
  - Under AKS, it is illegal “knowingly and willfully” to offer to pay “remuneration” – directly or indirectly, overtly or covertly, in cash or in kind – to “induce” someone to do any of the following:
    - “Refer” an individual to a person for the furnishing of a covered item or service.
    - “Purchase” or “order” any covered item or service.
    - “Arrange for” the purchase or order of a covered item or service.
    - “recommend” the purchase or order of a covered item or service.

**Anti-Kickback Basics Penalties**

- **Criminal**
  - Felony, punishable with a fine of up to $25,000, imprisonment of up to 5 years, or both.
- **Civil**
  - Civil monetary penalties of up to $50,000 per violation
  - Treble Damages
  - Federal Health Care Program exclusion
- **False Claims Act Liability**
  - Statutory civil penalties of $5,500 - $11,000 per false claim
  - Treble damages
Anti-Kickback Basics

Elements of AKS

• “Intent”
  • Requires proof of a “knowing and willful” intent to induce referrals.
  • PPACA added provision clarifying that "a person need not have actual knowledge of this section or specific intent to commit a violation of this section."
• “Covered Item or Service”
  • Any item or service that is paid for, in whole or in part, by any “federal health care program.”
    • Medicare
    • Medicaid
    • TriCare, etc.

Applicability to LASIK/PRK?

• Not themselves “covered items or services”
• But plenty of other ophthalmology services are
• Payment for LASIK/PRK co-management services could be deemed to be disguised remuneration in exchange for referrals for such other services.
  • “Swapping” theory
  • And state laws may still apply....

State Laws

• Stark or AKS Analogues
  • Some restricted to insurance-reimbursable items or services (e.g., Ohio Revised Code 3999.22); others not.
• Fee-splitting prohibitions
  • Often found in state medical or optometric board rules regarding “unprofessional conduct”

Regulatory Safe Harbor?

• AKS safe harbor for “referral arrangements for specialty services”
  • Where one party refers a patient to the other party in return for an agreement to refer the patient back.
    • Must be clinically appropriate
    • Service for which the referral is made is not within the expertise of the referring party
    • The parties receive no payment from each other for the referral and do not share or split a global fee.
    • The only exchange of value is the remuneration the parties receive directly from payors/patients.
Regulatory Safe Harbor?

- 1999 OIG preamble—Specifically declined to cover split of global/bundled fees.
- “Whether a particular referral arrangement for specialty services violates the anti-kickback statute depends on a case-by-case analysis of all of the facts and circumstances, including, but not limited to, whether the specialty services are medically necessary, whether the timing of the referrals is clinically appropriate, and whether the services performed are commensurate with the portion of the global fee received.”

Cataract Co-management

- Despite OIG’s tepid response, these arrangements are common
- Updated AAO/ASCRS Joint Position Paper
- For cataract co-management, CMS recognizes an 80/20 split between surgical and post-op
- Thus, CMS has answered the question regarding FMV for co-management services
- This is but one element of the AKS/fee-splitting analysis.
- But our focus for present purposes is the fee...

Cataract vs. LASIK/PRK Co-management

- 80/20 cataract split is based only on the professional component
  - Facility fee is a separate piece
- LASIK/PRK fee is likely global, inclusive of professional component and facility fee
- Blindly applying 80/20 split to that may result in something other than FMV fee split

Cataract vs. LASIK/PRK Co-management

- 80/20 cataract split assumes the standard 90 day post-op period
  - Post-op period for LASIK/PRK may be longer
- Pre-op services not included in cataract split
  - Initial exam/determination of candidacy for LASIK/PRK?
- Other variances in the scope and intensity of services required by the co-managing optometrist?
**LASIK/PRK Co-Management Fee**

- In the arrangement discussed in Ad-Op 11-14, the surgeon and co-managing optometrist did not simply split the fees for the non-covered (premium IOL) services 80/20.
  - Surgeon charged flat $500 fee for additional services.
  - Unclear what optometrist charged
- If each side charges the patient directly for its respective services, less risky
- But if the fees are bundled together, then it becomes more important that the OD’s fee can stand on its own as FMV

**Fair Market Value and Commercial Reasonableness**

- Included in most AKS safe harbors:
  - “The aggregate compensation is set in advance and is consistent with fair market value in arms-length transactions.”
  - “Arrangement would be commercially reasonable even if no referrals were made between the parties.”
- Similar requirements built into most Stark exceptions
- Distinct, but related, concepts

**Fair Market Value and Commercial Reasonableness**

- CMS commentary:
  - “Ultimately, the appropriate method for determining fair market value will depend on the nature of the transaction, its location, and other factors.”
  - A good faith reliance on an independent valuation/appraisal may be relevant to a party’s intent.
    - Though doesn’t establish the ultimate issue of the accuracy of the valuation...

**Two “Standards” of Value**

- Conforms to common practices for dealers in the type of asset/agreement
- Price current in any recognized market at the time of the transaction
- Hypothetical willing buyer and willing seller
**Standard of Value**

- **Investment Value**
  - Value to a particular investor

- **Fair Value**
  - Depends on the jurisdiction

- **Fair Market Value**
  - Hypothetical willing buyer & willing seller

**Commercially Reasonable – Stark**

- In the usual manner on any recognized market;
- At the price current in any recognized market at the time of the transaction; or
- Otherwise in conformity with reasonable commercial practices among dealers in the type of asset/agreement/service, etc. that was the subject of the transaction.

**Income Approach Based Methods**

- A formulaic determination of value through the conversion of some measure of earnings such as:
  - Net income
  - Operating income
  - Others, depending on the circumstance
- Earnings are converted to a present value using a capitalization or discount rate
- Capitalization or discount rate based upon risk
- **Co-management opportunity cost?**
- Regulatory concerns
  - “Top-down” approach
  - Volume/value of referrals
Market Approach Based Methods

- An exercise of finding market “comps” considering the following:
  - Compensation levels paid by similarly situated organizations for functionally comparable services.
  - Location of organizations, including the availability of similar specialties, service capabilities and the existence of competitive forces in the area.
  - Independent surveys and market based comparisons.
  - Actual purchased services arrangements, payments or offers to pay from similar institutions for similar services or positions.
  - Productivity and performance of the operating unit providing the service(s).

Cost Approach Based Methods

- Often considered the most basic level of value
  - “Buy versus build”
  - “Bottom-up” approach
- Considers the cost of inputs required to produce a product or provide a service
  - Staff salaries and benefit costs
  - Rent, utilities, etc.
  - General and administrative costs
- Is cost reimbursement alone fair market value?

Co-management Agreements

- Refractive surgery patients should be informed of Co-management agreements, specifically in regard to:
  - The logistics of the arrangement
  - Financial details of the surgery
  - Acknowledgement of the co-managing provider’s qualifications to provide care
  - Authorization for the providers to share information regarding the patient’s health and vision
  - Acknowledgement that the patient will be returned to the ophthalmologist in the case of any complications
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