Financial Disclosures

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Stark Compensation and Bonus Rules

- Employment Agreement Compensation Term
  - Physician shall be paid 35% of collections for all professional services
    - “Professional Services” include:
      - All items and services personally performed by the physician
      - Services provided by others but ordered and supervised by the physician (i.e., incident-to services)
      - Diagnostic tests ordered and supervised by the physician (e.g., OCTs, A-scan performed by a technician)
  - OK?
  - In order to meet the definition of a “Group Practice” under the Stark Law, productivity based compensation is an allocation of dollars that result from the fruits of a physician’s own labors. This means that the physician must literally provide the Designated Health Service herself to be given dollar-for-dollar credit for it.
  - Thus, in our example, payment to the physician based on collections for the technical component of the diagnostic tests (paid for by Medicare) is prohibited.
Key DHS for Ophthalmology

- Outpatient Drugs (e.g., Lucentis, Eyelex)
- Diagnostics
  - 76510 Ophthalm us b & quant a
  - 76511 Ophthalm us quant a only
  - 76512 Ophthalm us b w/non-quant a
  - 76513 Echo exam of eye water bath
  - 76514 Echo exam of eye thickness
  - 76515 Echo exam of eye
  - 87661 Tear Lab dry eye diagnostic
  - 92132 Cmptr opth dx img ant segment
  - 92133 Cmptr opth img optic nerve
  - 92134 Cmptr opth img post segment
  - 92227 Remote dx retinal imaging
  - 92228 Remote retinal imaging mgmt
- Post-cataract eyeglasses

Stark Compensation and Bonus Rules

- So what?
  - Failure to satisfy the profit sharing and productivity payment rules causes the practice to no longer fit the definition of a “group practice”. This means that none of the diagnostic tests performed by the practice (that are designated health services) are properly payable by Medicare. If claims have been paid, you have money that needs to be returned to Medicare.
    - For example, every OCT billed to Medicare
  - Can I avoid this mess?
  - Carve out payments received from Medicare for designated health services into a separate pool and divide according to a metric other than physician referral. For example, apportion the dollars based on physician’s total patient encounters or relative value units (RVUs) or based on non-designated health service revenues.

- There is one exception from this rule where revenues derived from DHS are less than 5% of the group’s total revenues and the allocated portion is less than 5% of the physician’s total compensation from the group.
  - Difficult exception for retina only practices to meet given the revenue associated with Lucentis or Eyelex.

Dealing with Unfavorable Audits

- CMS has contracted with multiple review and audit entities which has resulted in a dramatic increase in the number of audits of physician practices.
- CMS also has issued regulations and guidelines stating clearly that when a provider has credible information relating to a potential overpayment, there is an obligation to undertake reasonable diligence to determine if an overpayment has been made, the extent of the overpayment and, once determined, to make a repayment within 60 days.
- Credible evidence includes not only receipt of notice from a government contractor, but also information from a provider-contracted expert consultant.
Dealing with Unfavorable Audits

- Historically, some practices have appealed unfavorable government contractor audits but not changed their conduct.
  - We are now seeing follow up audits from contractors within a few months to determine if the provider’s practices have changed.
- With respect to external audits, some have tried to avoid potential liability with a review of prospective claims, rather than paid claims.
  - But an unfavorable finding of a prospective claim still puts the provider on notice that there is credible information of an overpayment.
- What should you do if you disagree with the results of an outside audit?

Lack of Medical Necessity Treated as Fraud

- The government has demonstrated an increased willingness to use the False Claims Act (FCA) to challenge the medical necessity of services provided to Medicare beneficiaries.
  - Often, there is no dispute that the services have been provided to Medicare beneficiaries and that the billing accurately reflects the services provided. Nevertheless, whistleblowers/government will assert that the services actually provided were not “reasonable and necessary” and, therefore, should not have been provided and billed. Sometimes the ground are retrospective audits.
  - Historically, these situations would be handled as overpayments subject to administrative appeal rights.
- Areas of scrutiny
  - Diagnostic testing
  - Complex cardiac
  - Office visits at the time of intraarterial injections
  - Frequency of intraarterial injections
  - Interventional procedures
  - Home health services
  - Hospice services

Some Potential Relief

**Concept of Objective Falsity**

**U.S. ex rel Presser v. Acacia Mental Health Clinic (N.D. Ala. 2016)**
- “Many potential relators could claim that ‘in my experience, this is not the way things are done.’ However, relators may not be in a position to see the entire picture or may simply have a subjective disagreement with the other party on the most prudent course of action. Further, their perspective may be colored by considerable bias or self-interest, such as in the case of a disgruntled employee. The heightened possibility of mistake or bias supports the need for a higher standard of specificity for fraud, compared to other civil litigation.”

- A mere difference of opinion between physicians is not enough to establish falsity under the False Claims Act.
  - Relator relied on guidelines from the American Heart Association/American Stroke Association

**Takeaways**
- Know if your clinical practice is an outlier and be prepared with scientific/clinical support for your treatment protocols
- Pay attention to audit requests
Providing Non-Covered Services

- Many practices offer non-covered services to their patients and believe that there are no regulatory risks because the items are not covered by federal programs or commercial payers.
  - Charges relating to the implantation of a PC-IOL or AC-IOL often include additional diagnostic tests, use of a femtosecond laser, and increased post-op care.
    - Question: Are all of the additional services justified; i.e., are they required for good patient care?
    - Question: Do the additional charges reasonably reflect the fair market value of the additional services?
- Practices may offer patients health or dietary supplements, or refer patients to companies providing such items and receive a dividend or rebate.
    - Question: Is there any prohibition in state law from doing so?
    - Question: Even if there is no prohibition, is there a disclosure requirement?
- Practices may promote screening services for its patients.
    - Question: Are there any state law guidelines that must be followed?

Don’t Think That There is No Risk When Performing Non-Covered Services

- Board of Medicine Case #1
  - Patient complaint: I paid for a Toric IOL and didn’t receive one. Physician charges for an astigmatism correction package.
    - BOM did not pursue further investigation
- Board of Medicine Case #2
  - Patient complaint: I was charged for use of a laser for my cataract surgery with a monofocal IOL. Patient also had an incision.
    - BOM pending
- Board of Medicine Case #3
  - Patient complaint: I was charged for services that are covered by Medicare.
    - BOM did not pursue further investigation
- District Attorney Case #1
  - Patient complaint: I should have been notified in advance of all the charges and for what services I was being charged. I was told I would not need reading glasses after the surgery and that is not true. I have to use reading glasses every day.
    - Physician required to refund money to patient

Pre-Exam Testing

- In an effort to promote efficiency, a consultant has recommended that your practice initiate a program of testing patients before they see your physician.
  - Your new cataract patients are examined by an OD and those who are diagnosed with cataracts will have pre-op testing, including the A-scan.
  - Your new retina patients receive an OCT, fluorescein angiography, and fundus photo.
- Any problem with this approach?
- Does it matter whether the tests are billed?
**Modifier 25**

- The CPT description of modifier 25
  - Significant, Separately Identifiable Evaluation and Management Service by the Same Physician or Other Qualified Health Care Professional on the Same Day of the Procedure or Other Service
- Issue arises frequently in the context of the administration of an intravitreal injection
  - Some take the position that unless there is a completely unrelated reason for the exam (e.g., other eye problem), you may not use modifier 25 and bill an office visit
  - Some argue that as long as the purpose of the visit was not for the injection (i.e., the injection was not already scheduled), you may bill an exam
  - Some argue that even if the visit was for the injection, as long as you perform an exam, you can bill for it

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**Modifier 25**

- In September 2015 the OIG published a Report identifying certain billing issues by ophthalmologists that it viewed as abusive, and encouraged further review of outlier practices. One of these billing issues related to the use of modifier 25. (Questionable Billing for Medicare Ophthalmology Services, Office of Inspector General, OIG-04-12-00280).
- We are aware of several ophthalmology practices that are currently under audit by MACs and ZPICs, or, in some cases, under investigation by US Attorney’s Offices, relating to their use of modifier 25.
- Beyond the CPT descriptor there is little guidance from definitive sources
  - While there are MAC LCDs addressing the use of modifier 25 in connection with certain procedures, there is no LCD that addresses use of modifier 25 in connection with an intravitreal injection.
  - Representatives of the AAO have published articles on the use of modifier 25, but no formal preferred practice pattern.
  - In response to the confusion, in 2016 ASRS published a preferred practice pattern guideline.
- While there is yet no definitive guidance on proper use of modifier 25 for billing purposes, practices should be aware that this is an issue under close scrutiny.

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**Product Samples**

- Product samples may be given to patients free of charge, seeking payment from any payer for the samples, including patients if unlawful.
- Samples are not replacement product that can be intermingled with your stock medication.
- Records should not be revised to “assign” sample product to a patient for whom payment has been denied.
- Issues raised involving some AMD drugs.
- Several urologists pled guilty to charges of conspiracy, paid restitution in the tens of thousands of dollars, and received sanctions against their medical licenses for billing Medicare for injectable prostate cancer drugs they received for free from two pharmaceutical companies.
Our Patients Are Our Best Referral Source

- A successful LASIK practice decides to combine public relations with marketing. It wants to thank its patients who have had successful surgery and hopes to encourage them to promote the Practice to their friends. Their marketing director proposes the following programs:
  - Give each LASIK patient a coupon for a $25 discount on a pair of sunglasses at the Practice optical shop following surgery.
  - Give each LASIK patient a coupon for a $25 discount on a pair of sunglasses at the Practice optical shop for every 2 patients referred to the Practice who eventually have surgery.

Our Patients Are Our Best Referral Source

- Discount on sunglasses for new LASIK patients
  - is it a kickback?
  - is it a prohibited patient inducement?
  - is there anything wrong with providing a discount on one good when purchasing another?
- Discount on sunglasses for 2 successful LASIK referrals
  - is it a kickback?
  - is it a prohibited patient inducement?
  - does it matter that LASIK is not a Medicare covered service?
  - would it matter if the offer were not limited to prior LASIK patients?

A Word About Email, Texts and Other Communication

- Email and texts can be the single most important category of evidence in government investigations to show intent
- Avoid helping to build a case against yourself and your practice through your electronic communications within the practice or external to the practice
- Think about how many communications you might have that discuss the topics we just reviewed
- Messages that suggest a discussion be taken off-line peak government interest
- Enforce strict email policies for all practice personnel, including the physician and yourself
- Avoid practice business on personal accounts