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New Headaches for Ophthalmic Administrators

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Disclosures

Allison Shuren and Victoria Wallace both are attorneys in the law firm of Arnold & Porter Kaye Scholer.

We represent ophthalmologists and manufacturers of medical devices, pharmaceutical and biologics.

We do not have any disclosures relevant to this presentation.

Agenda

- Bilateral/sequential cataract surgery
- Stark Law – group practice
- Co-management of refractive procedures
- In-office pharmacy
- Compounding pharmacies
- MACRA
- Value-based purchasing

Bilateral/Sequential Cataract Surgery

Bilateral/Sequential Cataract Surgery

- Common for LASIK and other refractive procedures
  - Bilateral surgery has been performed for many years.
- Uncommon for Cataract Surgery
  - In fact, in the mid-1980's PROs and carriers developed standards that effectively prohibited performing second eye surgery within the 90-day post-operative period for the first eye.
  - The obvious concern is the risk of a complication in the first eye – and the extent to which that could influence the decision on the second eye surgery.
  - But now it is not uncommon to perform second eye surgery within 2 weeks,
    1 week, and in some cases, 1 day.
  - A recent study from Kaiser supports bilateral cataract surgery.
- Does this mean that the risks of bilateral cataract surgery have finally been reduced to the risk level of bilateral refractive surgery?

Bilateral/Sequential Cataract Surgery (cont'd)

- From a clinical perspective, how do you assess the comparative risk of bilateral cataract surgery versus bilateral refractive surgery?
- The view of the Insurer: OMIC
  - No underwriting requirements, policy conditions, or exclusions that prohibit performing bilateral cataract surgery. Recommend consideration of:
    - » Health condition of the patient and being subjected to multiple surgeries and anesthesia;
    - » Distance of the patient from the surgeon, making post-operative care more difficult; and
    - » Risk of bilateral endophthalmitis and other blinding complications.
- Reimbursement impact is a reduction in payment for the second eye.
  - That is a positive fact if defending from the physician perspective.
- Most important factor is comprehensive informed consent.

Bilateral/Sequential Cataract Surgery (cont'd)

- The view of the Insurer: OMIC
- Significant underwriting requirements relating to bilateral refractive surgery:
  - Patient must be at low risk for surgical complications - - not permitted for complex surgical cases;
  - Not recommended where there is difficulty in calculating IOL power;
  - Physician must develop protocols to reduce risks of right eye/left eye error;
  - Complete aseptic separation of first and second eye surgeries;
  - Appropriate administration of antibiotics at sufficient dosages;
  - Any complication with first eye must be resolved prior to proceeding with second eye surgery; and
  - Patients must read and sign special bilateral surgery consent.
- Reimbursement impact is a not a reduction in payment for the second eye.
- That is not a positive factor if defending from the physician perspective, although that factor is not significant since it is standard of care.
- Most important factor is comprehensive informed consent.

Stark Law – Group Practice

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-scans 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, Eyelea)
- Diagnostics
  - 76510 Ophth us b & quant a
  - 76511 Ophth us quant a only
  - 76512 Ophth us b w/non-quant a
  - 76513 Echo exam of eye water bath
  - 76514 Echo exam of eye thickness
  - 76516 Echo exam of eye
  - 76519 Echo exam of eye
  - 83861 Tear Lab dry eye diagnostic
  - 92132 Cpmtr ophth dx img ant segmt
  - 92133 Cmptr ophth img optic nerve
  - 92134 Cptr ophth dx img post segmt
  - 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 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 Eyelea.

Co-Management of Refractive Procedures

Co-management of refractive procedures

- Co-management of covered procedures raises limited compliance issues.
  - Even the professional societies now agree on the standards.
  - Medicare (and most insurers) set clear guidance as to the amount they will pay, and require each provider to bill independently.
  - Only potential concern is an agreement to refer.
- But Co-management of refractive surgery presents several potential issues, and conduct appears to be getting more aggressive and risky.
- Continuing belief that refractive procedures are not subject to regulatory compliance requirements.
  - But the federal laws often also apply to refractive procedures.
    - » If part of a premium IOL implant, the procedure is both covered and non-covered.
    - » If the procedure is purely refractive, often the referring OD also refers covered cases to the surgeon, and the federal government will view an improper refractive co-management arrangement to be the remuneration to support the referral of a covered service.
- Even for purely refractive procedures, there are state laws that apply.

Co-management of refractive procedures (cont'd)

- Premium IOL procedures have created the opportunity for surgeons to provide a non-covered device that is supported by non-covered services not otherwise provided in connection with the provision of a covered service, for which the patient pays a significant premium.
- They also have inspired co-management arrangements that likely would be viewed as problematic by regulators.
  - The key question is what additional services are performed by the co-manager that the co-manager does not perform when a conventional IOL is implanted?
    - » Does the implantation of premium IOL alone justify an increased co-management fee?
    - » Does the provision of additional diagnostic tests justify an increased co-management fee?
    - » Does the use of the femtosecond laser justify an increased co-management fee?
- A co-manager is entitled to additional payment for any additional services performed.
    - » If the co-manager provides no additional services, the co-manager is entitled to no additional payment.

In-Office Pharmacy

In-office drug dispensing

- An old idea coming around again with a resurgence of turn-key vendors marketing a new profit center for your practice. This may be the case, but proceed cautiously and with your own counsel.
- Pros: increased patient compliance with obtaining drug, new revenue for practice, possibly cheaper for patient.
- Cons: possibly will lead to increased prescription writing for more costly drugs with larger margins, eliminates quality and safety checks of pharmacist, highly regulated.

State and federal law implications

- State
  - Pharmacy dispensing rules
  - Limitations through medical practice act
  - Self-referral limitations
- Federal
  - Stark Law
  - Patient inducement
  - Medicare coverage rules
  - DEA
  - Compounding rules

Risk management

- Do not practice outside of your specialty, and dispense prescriptions only for the conditions that you treat.
- Think carefully before stocking controlled substances.
- Establish quality- and safety-control protocols to reduce the risk of medication errors, drug-drug interactions, multiple prescribers with controlled substances.
- Educate office staff regarding the dispensing system and their roles. Establish clear policies regarding staff limitations in the dispensing process.
- Make sure that medication education is provided to the patient and documented in the medical record at the time of dispensing.

Vendor services

- Interface with your electronic health record system and patient database.
- Have the capability to check for allergies, interactions, and contraindications online.
- Include patient education information that is similar to the information provided by a pharmacy.
- Provide patient information in a format and at a reading level that the majority of your patients can understand.
- Produce medication labels that include the patient's name, date, physician and practice names with phone number, medication name, dosing information, and any warnings and/or specific instructions (e.g,, "may cause drowsiness," "do not drive or operate machinery," or "take with food").
- Offer an insurance/billing interface and have bar code or similar technology.

Compounding Pharmacies

Pharmaceutical Compounding

- New England Compounding Center (NECC)
  - 503A facility
  - FDA Warning Letter 10/31/2008:
    - FDA asserted that NECC's "repackaging is *not consistent with Avastin's® approved labeling*, where you repackage the drug from vials into syringes, and where the labeled precautions include "discard any unused portion left in a vial. …" (emphasis added)
    - FDA expressed concern about the manipulation of sterile products when a sterile container is opened or otherwise entered to conduct manipulations. "The moment a sterile container is opened and manipulated, a quality standard (sterility) is destroyed and previous studies supporting the standard(s) are compromised and are no longer valid," FDA stated.
    - "We are especially concerned with the potential microbial contamination associated with splitting Avastin®-a single-use, preservative-free vial-into multiple doses. When used intravitreally, microbes could cause endophthalmitis, which has a high probability for significant vision loss."
- RC Compounding Services, LLC
  - 503B facility
  - FDA Warning Letter 07/14/2014: "During the inspection, our investigators observed that you were repackaging Avastin for ophthalmic use under conditions not appropriate for ensuring the sterility of the product. An FDA Form 483 was issued to your firm on February 7, 2013."

503A: Traditional Compounding

- Section 503A applies to all licensed physicians and pharmacists who are engaged in compounding for *individual patients* pursuant to a valid prescription.
- If a compounding pharmacy abides by 503A, it is exempt from:
  - cGMP (FDCA 501(a)(2)(B));
  - FDA Approved Labeling (FDCA 502(f)(1)); and
  - Submitting a New Drug Application (FDCA 505)

503A Requirements

1. The drug product is compounded for an identified individual patient based on the receipt of a valid prescription order;
2. The compounding is performed by a licensed pharmacist in a state-licensed pharmacy or by a licensed physician;
3. The drug product is compounded in compliance with the United States Pharmacopoeia (USP) chapters on pharmacy compounding using bulk drug substances, as defined in 21 C.F.R. 207.3(a)(4), that comply with the standards of an applicable USP or National Formulary (NF) monograph, if one exists.
4. The drug product is compounded using bulk drug substances that are manufactured by an establishment that is registered with FDA under Section 510 of the FDCA.
5. The drug product is compounded using bulk drug substances that are accompanied by valid certificates of analysis for each bulk drug substance.
6. The drug product is compounded using ingredients (other than bulk drug substances) that comply with the standards of an applicable USP or NF monograph, if one exists, and the USP chapters on pharmacy compounding.
7. The drug product does not appear on the list, that includes drug products that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective.
8. The licensed pharmacist or physician does not compound regularly or in inordinate amounts any drug products that are essentially copies of commercially available drug products.
9. The drug product is not identified by FDA by regulation as a drug product that presents demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of that drug product.
10. The drug product is compounded in a state that has entered into a memorandum of understanding (MOU) with FDA that addresses the distribution of inordinate amounts of compounded drug products interstate and provides for appropriate investigation by a State agency of complaints relating to compounded drug products distributed outside such State.

503B: Outsourcing Facilities

- A new hybrid entity between traditional pharmacies and drug manufacturers that compound sterile drugs.
- If an entity complies with 503B, it is exempt from:
  - FDA Approved Labeling (FDCA 502(f)(1));
  - Submitting a New Drug Application (FDCA 505); and
  - Track/Trace Requirements (FDCA 582)
- Can fill patient specific and non-patient specific prescriptions
- Does not have to be a pharmacy
  - But, compounding must be done under the direct supervision of a licensed pharmacist
- Must comply with cGMP standards

503B: Outsourcing Facilities (cont'd)

- Must undergo risk-based inspections
- Must comply with adverse event reporting reqs.
- Must package/label compounded products
  - "This is a compounded drug"
  - Lot or batch #; established drug name;
  - Dosage form/strength; date drug was compounded;
  - Storage and handling instructions; and "Not for resale"
- Register as an outsourcing facility (voluntary)
- Must pay user/registration fees

503B Requirements

- Similar conditions as 503A Traditional Compounders

1. The bulk drug substance appears on a list, established by the Secretary, for which there is clinical need.
2. Where a monograph exists under the USP, the NF, or another compendium or pharmacopeia, the bulk substance must comply with that monograph;
3. The bulk substances are each manufactured by an establishment registered under section 510;
4. The bulk drug substances are each accompanied by a valid certificate of analysis.
5. Any non-bulk ingredients that are used in compounding the drug must comply with the standards of applicable Pharmacopeia and NF monograph.
6. The drug compounded cannot appear on a list of drugs that have been withdrawn or removed from the market because of issues regarding safety or effectiveness.
7. The compounded drug cannot be one that is "essentially a copy of one or more approved drugs."
8. The compounded drug cannot be on FDA's list of drugs that present "demonstrable difficulties" for compounding, that are reasonably likely to lead to an adverse effect on the safety or effectiveness of the drug or category of drugs, unless it has been compounded in accordance with all applicable conditions identified by FDA as conditions that are necessary to prevent the drug from presenting such demonstrable difficulties.
9. In the case of a drug compounded from a drug that is subject to a risk evaluation and mitigation strategy (REMS) approved with elements to assure safe use, the outsourcing facility must show FDA, prior to beginning compounding, that such facility will utilize controls comparable to those under the REMS.

Takeaways for Compounded Drugs

- Do not use a pharmacy that has received a 483/Warning Letter/Consent Decree from FDA
- Do not use 503A facilities
- Do not use any 503B facilities that have not registered with or been inspected by FDA

MACRA

Moving from FFS to Quality-Based Payment

- MACRA affects only fee-for-service payments on the Physician Fee Schedule (PFS) – not Medicare Advantage, PACE, or SNF payment systems
  - BUT, you have to report data for **all payors** for all performance categories except cost.
- 2 choices: MIPS or Advanced APMs
  - Most physicians in MIPS in 2017
  - CMS letters of MIPS participation mailed April/May 2017
- MIPS Components:
  - Quality
  - Cost
  - Advancing Care Information
  - Improvement Activities

Key Questions to Ask Your Group

- Are we planning to report as a group?
- Is our EHR compliant with certification requirements?
- Have we established processes to record HCPCS codes for the quality measures we plan to report?
- What improvement activities are we planning, and do they fit within QPP rules?
- How can we use the QPP to improve care for our patients?
- How will QPP affect my evaluation within the group and/or my salary?

Summary: How to Get Ready for MIPS

- 2017 is a transition year; requirements will increase in future and CMS will be less flexible – now is the time to learn!
- Get educated! Lots of information at www.qpp.cms.gov
- Understand your choices and pick a path for participation
- Choose measures: pick from lists at www.qpp.cms.gov
- Review your past years' QRURs
- Look yourself up on Physician Compare

Keep records!

- MIPS is an "attestation-based" system …
  …but you still have to do the activities you attest to!
- CMS published data validation and auditing criteria on April 26, 2017.
- For the practice improvement category specifically, you must maintain documentation to validate the activities you attest to.
  - Example: Use of tools to assist patient self-management; documentation in patient record or EHR showing use of Patient Activation Measure, How's My Health, or similar tools to assess patients need for support for self-management

Value-Based Purchasing

Value-Based Contracts

- Arrangements under which a customer price or particular discount depends on a patient health outcome or other patient experience.
  - E.g., avoidance of hospitalization, rate at which a patient meets testing guidelines or measures, etc.
- Value-based contracts may have benefits across the healthcare delivery spectrum – payors, manufacturers, providers, and patients. For example,
  - For physicians, value-based contracts may reduce the risk of paying for a product with unpredictable benefits and may reduce costs overall.
  - For manufacturers, value-based contracts may improve patient access to products or procedures (particularly upon launch).

Recent Example 1

- In 2016, Cigna and Aetna entered into value-based agreements with Novartis for its heart failure drug, Entresto.
- Under the agreements, Novartis will reduce the price of Entresto based on certain metrics.
  - For Cigna, payments will be linked to rates of heart failure hospitalization.
    - Cigna has stated that it "will be tracking the outcomes based on our own claims data of our customers."
    - The agreement applies to Cigna's commercial business only (no Medicaid or Medicare plans).
  - Aetna has stated that its agreement is based on the drug replicating results that it achieved during clinical trials.

Recent Example 2

- In 2016, Merck and Aetna entered into an agreement whereby Aetna will receive incremental rebates for Januvia and Janumet based, in part, on their ability to help Aetna's commercial members with Type 2 diabetes achieve or maintain treatment goals.
- Under the arrangement, Merck will pay rebates if patients who are prescribed the drugs do not achieve their treatment goals and require further therapy, as determined by their physicians.

Legal & Business Considerations

- The federal healthcare Anti-Kickback Statute prohibits the provision of any value (in cash or in kind) in exchange for the referral or recommendation of items or services reimbursable by the federal government.
- There is a statutory exception and regulatory safe harbor for "discounts," however because value-based arrangements often contain performance components, it is not clear whether these arrangements fall into the exception or safe harbor.
  - A recent Department of Justice Statement of Interest in a case involving Coloplast suggests that a reduction in price conditioned on more than just the purchase of a particular product or service would not meet the safe harbor.
- Because this area of the law still is emerging, carefully consider any proposed arrangements for value or outcomes purchasing to mitigate legal risks.
  - Consult legal counsel to ensure contract language considers important factors, including that the independent medical decision making of any healthcare professionals is independent of the value-based arrangement.
- Ensure your practice is able to execute any proposed value-based arrangement (including with regard to the aggregation and provision of any data necessary to support pricing or discounts owed by a manufacturer).