Office Based Cataract Surgery
Exploring the Options

Presenters Information

Allison W. Shuren, Partner
Arnold & Porter LLP
601 Massachusetts Ave., NW
Washington, DC 20001
Allison.shuren@aporter.com

Nikki Hurley, BSRN, MBA, COE
Key Whitman Surgery Center
2801 Lemmon Ave., Suite 400
Dallas, TX 75204
Nikki.hurley@keywhitman.com

Dan Chambers, Executive Director
Key Whitman Eye Center
2801 Lemmon Ave, Suite 400
Dallas, TX 75204
Dan.chambers@keywhitman.com

Stephen C. Sheppard, CPA, COE
Medical Consulting Group, LLC
2808 S. Ingram Mill Rd., Bldg B
Springfield, MO 65804
Steve@medcgroup.com

E. Ann Rose
Rose & Associates Healthcare Consultants
402 W. Wheatland, Suite 150
Duncanville, TX 75116
Arose@roseandassociates.com

Don Holmes
Cincinnati Eye Institute
1545 CEI Dr.
Cincinnati, OH 45242
dholmes@cincinnatieye.com

Financial Disclosures

Dan Chambers
Consultant: DCOM Services Inc.
Various Speaking Arrangements

Ann Rose
None

Nikki Hurley
None

Allison Shuren
Steve Sheppard
Don Holmes

The Medicare Request

- The 2016 Medicare Physician Fee Schedule Proposed Rule included a request for information related to creation of payment for cataract surgery in the physician office
- CMS questioned whether it is now possible for cataract surgery to be performed in an office-based surgical suite, especially for “routine cases” due to advances in technology, reduced operating time and improved safety
- CMS is not proposing to implement payment at this time

Medicare Payment Rates

- CMS has the authority to establish a payment rate for in-office cataract surgery
  - Payment rate would be determined according to usual procedures governing physician fee schedules
  - RVUs for physician work would remain the same. CMS would create a new ‘non-facility’ rate for practice expenses for the in-office procedure
- Creation of an in-office rate would not change ASC payment rates
  - If over time more than 50% of cataracts were performed in-office, CMS would consider it an office-based procedure. Under this scenario, the ASC rate could not exceed the payment made for practice expenses in the physician office setting.
- Transition to in-office standard will most likely evolve over time such as the transition from hospital settings to ASCs
Regulation of Physician Offices

- CMS is not attempting to regulate physician offices, defers to state laws in this area
- CMS does not survey and certify physician offices as it does ASCs and other facilities
- CMS does not appear to have the authority to establish conditions of coverage for physician offices, even if they are doing an extensive amount of surgeries
- States are free to define ASCs as they choose and could regard an office as an ASC even if the Medicare program does not
- States that have CON laws could apply these same requirements to offices performing in-office surgeries, even if they do not do so today

Payment for Lenses

- CMS Rulings on premium IOLs appear to extend to insertion of these lenses in physician offices (need to clarify at some point)
- However, statutory provision to provide for extra Medicare payment for certain ‘new technology’ (NTIOLs) applies only in ASCs
- Whether CMS would be prepared to permit additional Medicare payment for designed NTIOLs when inserted in physician offices is an open question

CMS Pass-Through Status

- Medicare creates transitional pass-through payment status for new drugs or biologicals that triggers a separate payment in addition to the APC payment if it meets the following criteria:
  - A new FDA approved product
  - Cost is not insignificant (must be over cost floor set by Medicare)
- Period for extra payment lasts for 24-36 months and provide physicians an opportunity to try new technologies while being budget neutral with respect to cost reporting data
- Application of pass-through status for new technologies currently approved for licensed surgical facilities
- Clarification necessary to determine its application to in-office procedures

IOL Reimbursement

Q. Is the cost of the IOL reimbursed when implanted in a physician’s office?

A. Yes. As of January 2014, reimbursement for an IOL is set according to the DMEPOS fee schedule. As of 2015, it is $113.49. The DMEPOS fee schedule increases about 1-3% annually.

Ophthalmologists Divided

**Potential Pros**
- Greater flexibility for surgeons
- Gives surgeons more control of technology
- More convenient for patients
- Could be a work around CON requirements

**Potential Cons**
- Safety and quality must be maintained
- Could lead to decreased payment for cataract surgery
- Negative impact on investments in ASCs

An Opportunity?

- The current conversation may invite ability to create specific standards for ophthalmic ASCs that make sense and don’t create unnecessary burden or administrative expenses
- Participation: Ophthalmologists are in the best position to provide input regarding practice expenses such as cost of expensive equipment, investment in HVAC, generators, crash carts, RNs, space needs, regulatory requirements, etc. which could lead to a better outcome if implemented.
- Pilot: Consider proposing a demonstration or pilot program to try the idea out on a small scale while focusing on whether clinical outcomes are acceptable and infection problems occur
Through the Looking Glass

- Expected cost savings one driving factor
- It will happen at some point – question is when?
- Commercial payers beginning to implement prior authorization process for performing cataract surgery in HOPD
- Will it begin with commercial based payers or CMS?
- As a result, will hospitals stop blocking push to move to ASCs?
- Currently 36 states + DC have CON requirements – will this change?
- Regulatory requirements to be governed by whom? State, Federal or none? (Joan Rivers case…) 
- Possible dual certification for ASCs? Some days used as ASC and for office based surgery at other times

Financial Disclosure

Steve Sheppard is a Managing Principal with Medical Consulting Group, LLC and acknowledges a financial interest in the subject matter of this presentation.

Institutional Assumptions

- 2014 Facility Guidelines Institute standards (or similar) will ultimately apply.
- Something approximating CMS certification or accreditation by one of the national bodies will be required.
- Approximately 1,750 square feet of space will be required to meet these standards.

Revenue Assumptions

- The “facility fee” for this model is $625.00 per eye, in addition to the professional fee.
- 1,250 billable cataract surgeries will be performed annually and escalate at 3.00%
- All commercial payers that contract with the facility pay 100% of the Medicare rate.

Major Operating Expenses

- Surgical supplies cost per case average $250.00 in year one and escalate at 2.00% annually.
- 3.60 Full-time equivalent employees are required for this case volume.
- Relevant labor benchmarks are:
  - 5.99 labor hours per incisional surgery.
  - 347 incisional cases per FTE.
- All other operating expenses total approximately $135,000 annually.

Physical Plant and Construction Costs

- Tenant finish costs of an existing “warm shell” will equal $175.00 per square foot.
- Architect and engineering fees equal 9.00% of the construction costs, approximately $27,500.
- Other soft cost will approximate $147,500.
- Total “all-in” physical plant costs approximate $506,000.
- The building shell is leased for $13.00 annually with 3.00% annual increases.
Financing and Capital Structure

- Equipment, furniture and fixtures costs for one OR equipped for anterior segment only are $563,500.
- Completion of the licensure and/or certification process is assumed to require approximately 4 months and will require a Working Capital Line of Credit of approximately $210,000.
- Capital contributions for the construction and equipment costs are assumed to be $275,000.
- Total construction and equipment costs are approximately $1,110,000.

Summary

- The facility will not reach positive cash flow until year six of operations.
- A very unique practice setting will be required to make such a project economically feasible.
- Unless state and federal regulators materialistically relax the physical plant, infection control and QAPI requirements, the cost for such suites will be significant.
- Except for CON states, physicians have little to no incentive to unwind their existing ASC relationships.

Office Based Cataract Surgery

- CMS Conditions for Coverage set strict standards for ASCs in interest of the protection of patients.
- CMS currently has no conditions to monitor or inspect clinics conducting office based surgery.
- Ever increasing regulation make it hard to believe CMS could set new standards with lesser burdens – but never say never.
- There are some fundamental CICs, however, that should be followed by any entity performing cataract surgery.
- AAAHC does have accreditation for office based centers to those choosing to be accredited, but the vast differences are hard to ignore and could lead to greater risk for CMS' covered lives.

Office Based Cataract Surgery

- AAAHC defines office based surgery setting has 4 or fewer physicians with 2 or fewer procedure rooms.
- States definitions vary.
- Most OASCs believe that equal treatment should be provided to the CMS beneficiary no matter the location of service.

Patient Rights

AAAHC Office Based

- Does not provide for extensive patient rights.

CMS CICs

- Provides extensive patient right standards – most importantly defining that a patient has a right to be fully inform about the procedure and possible outcomes prior to surgery. [416.50(e)(1)(ii)]
### Governance
**AAAHC Office Based**
- In emergent situations allows for several methods of transferring patient care to any nearby hospital with no stipulation of continued care at a Medicare approved hospital.

**CMS CfCs**
- Depicts that one of the following is met [416.41(b)(3)]
  - Written transfer agreement with a hospital that meets CMS requirements listed in 416.41(b)(2) OR
  - All physicians performing surgery in the center have admitting privileges at a hospital meeting CMS requirements

### Administration
**AAAHC Office Based**
- No requirements listed for personnel of the center.
  - Does not even suggest that at least one employee should be a nurse.

**CMS CfCs**
- Requires nursing services be directed by an RN [416.46]
  - Nursing services assures that all nursing needs of all patients are met. [416.46]
  - Registered nurse must be available for emergency treatment whenever there is a patient in the center. [416.46(a)]

### QAPI
**AAAHC Office Based**
- Sets some reasonable standards, but does not involve strict safety elements as CMS.
  - No mechanism for CMS to evaluate the safety of patients through reported measures.

**CMS CfCs**
- Ongoing, demonstrating measurable improvement for outcomes and patient safety. [416.43(a)(1)]
  - Governing body oversight. [416.43(e)(1) and (2)]
  - Clearly establishes safety expectations [416.43(e)(4)]
  - ASCORS reporting for safety measures is required

### Infection Control
**AAAHC Office Based**
- No specific requirement for nationally recognized standards.
  - No specific parameters for sterilization processes.

**CMS CfCs**
- 416.51(b) must be enforced: Infection Prevention and Control Program should include documentation that ASC has implemented nationally recognized guidelines.
  - Uses strict Infection Control Survey (latest version July 2015) when inspecting facilities.

### Facilities & Environment
**AAAHC Office Based**
- No standard exists stating that Life Safety Code must be followed.
  - No requirements for facility design.
  - No requirements for emergency power/equipment.

**CMS CfCs**
- Requires firewall and emergency back up power.
  - Depicts separate recovery and waiting areas. [416.44(a)(2)]
  - Depicts specific parameters for emergency equipment and staff training [416.44(c) and (d)]

### Anesthesia Services
**AAAHC Office Based**
- Does state necessity for proper personnel...
  - Also states “other qualified healthcare professionals are acceptable if they are approved by the governing body.”
  - Depicts that direct care givers have BCLS and that an ACLS trained professional is onsite until the last patient is physically discharged.

**CMS CfCs**
- Requires qualified anesthesiologist, physician, CRNA, or anesthesiologist’s assistant. [416.42(b)(2)]
Surgical Services

AAAHC Office Based
- No written requirement for all H&P information to be completed and in chart prior to surgery.
- Only states that medications and dosages be listed “when available.”

CMS CfCs
- H&P must be completed 30 days or less prior to the procedure with medications and dosages; reassessment on day of surgery. [416.52(a)(1)]
- Many specific requirements, including discharge requirements. 426.52

Pharmaceutical Services

AAAHC Office Based
- Covers a great deal of detail, but lacks 2 important patient safety requirements when compared with CMS CfCs.

CMS CfCs
- Verbal orders must be followed by a written order and signed by the prescribing physician [416.48(a)(3)]
- Adverse reactions must be reported to the physician and documented in the chart. [416.48(a)(3)]

Office Based Surgery

- Patient safety is of primary concern, as well as visual outcomes
- AAAHC accreditation for Office Based Centers is a good start; however, standards are not as strict… and how many are actually accredited?
- Cataract patients today show a much higher comorbidity rate and present with much more complicated health issues other than the need for cataract surgery.
- In an office setting with no oversight by CMS, it is easy to see increased risk to patient safety is of utmost concern.
- Patient safety should be the primary goal for CMS – it is hard to see the future of office based cataract surgery without regulatory oversight.

Primary Concerns

- Surgical Risks viewed by Ophthalmologists
- Co-Morbidity with Cataract Patients
- Joan River’s Case
- Dental Anesthesia in office Surgery in Texas

Recovery Capabilities

- What could possibly go wrong?
- What Ophthalmologist have told me....

Medicare Payment

- Today you’ve heard all about the Pros and Cons of establishing an in-office cataract surgical suite
- Now the big question is:
  - Will you be reimbursed by Medicare? By other payers?
  - Or, will it be patient’s financial responsibility?
Medicare Payment

- Physician's Professional Fee
  - Yes - will be paid based on Medicare Physician Fee Schedule
  - $648.42 - 2016 National Payment
  - No site-of-service differential
  - RVUs are same regardless of where surgery performed
  - Geographic Practice Cost Index (GPCI) still applies
  - Payment varies based on payment locality

Notes:
- Geographical Practice Cost Index (GPCI) still applies
- Payment varies based on payment locality

Medicare Payment

- Office-Based Facility Payment
  - Maybe
    - CMS considering establishing facility payment for cataract surgery performed in a physician’s office
    - Will no doubt be much lower than current HOPD or ASC facility fee payments
    - 2016 national ASC facility fee for cataract surgery is $976.17
    - If CMS goes forward
      - Ophthalmology societies willing to work with CMS to provide facility expenses such as equipment and surgical supplies, IOL costs, etc.

Notes:
- CMS considering establishing facility payment for cataract surgery performed in a physician’s office
- Will no doubt be much lower than current HOPD or ASC facility fee payments
- Ophthalmology societies willing to work with CMS to provide facility expenses such as equipment and surgical supplies, IOL costs, etc.

Medicare Payment

- Conventional IOLs
  - Medicare allows separate payment of IOL for office-based cataract surgery
    - Based on reasonable charge for codes:
      - V2630 – anterior chamber intraocular lens
      - V2631 – Iris supported intraocular lens
      - V2632 – Posterior chamber intraocular lens
    - Medicare allowable for conventional IOL
      - $113.04 – January 1, 2016
      - Patient co-pay and deductible will apply

Notes:
- Medicare allows separate payment of IOL for office-based cataract surgery
- Medicare allowable for conventional IOL
- Patient co-pay and deductible will apply

Medicare Payment

- Premium IOLs
  - Regardless if a conventional or premium IOL is implanted in a physician’s office
  - Medicare will still pay the conventional aspect of the IOL
  - Unclear at this point if CMS will permit physician to bill patient for extra work involved in implanting a premium IOL in an “in-office” surgical suite
    - Need further clarification on ruling

Notes:
- Medicare will still pay the conventional aspect of the IOL
- Unclear at this point if CMS will permit physician to bill patient for extra work involved in implanting a premium IOL in an “in-office” surgical suite
- Need further clarification on ruling

Medicare Payment

- New Technology lenses (NTIOLs)
  - May not apply to office-based cataract surgery
  - If not, will have to either:
    - Absorb the cost, or
    - Treat those patients in an ASC
  - Pass-through drugs
    - ASCs can bill certain drugs to Medicare in addition to ASC facility fee
    - These may be included in office-based facility payment

Notes:
- May not apply to office-based cataract surgery
- If not, will have to either: Absorb the cost, or Treat those patients in an ASC
- ASCs can bill certain drugs to Medicare in addition to ASC facility fee
- These may be included in office-based facility payment

Third Party Payers

- Obtaining payment from commercial/other payers may be difficult
  - May have to canvas each payer individually
    - Will they be willing to pay an office-based facility fee?
    - Will they bundle facility fee payment in with physician’s professional fee?
      - If so, what will the payment be?
    - Will be time consuming to do
    - May require extra billing staff to handle
    - May find that a lot of commercial payers are not interested in paying office-based facility fees at all

Notes:
- Obtaining payment from commercial/other payers may be difficult
- May have to canvas each payer individually
- Will they be willing to pay an office-based facility fee?
- Will they bundle facility fee payment in with physician’s professional fee?
- Will be time consuming to do
- May require extra billing staff to handle
- May find that a lot of commercial payers are not interested in paying office-based facility fees at all
**Third Party Payers**

- **Capitation**
  - Some payers may be more interested in capitated rates for office-based surgery to save money
  - Makes more sense since not all patients will have office-based cataract surgery
  - Capitation is a set fee for a certain time period regardless of the number of surgeries performed
  - Might be better for smaller practices

**Things to Think About**

- Put together cost analysis for:
  - Equipment and supplies
  - Nursing/CRNA costs
  - Surgical supplies
  - IOLs – conventional and premium
  - Other overhead expenses
- Will you be able to use existing staff or need to hire additional staff?
  - Be sure to include that in start-up cost analysis

**Things to Think About**

- Will you be able to recover costs based on Medicare or other payer payments?
  - Physician plus facility payment
  - Will it be a breakeven venture or will you lose money?
- Remember
  - Medicare’s goal for even considering payment of office-based cataract surgery is to reduce Medicare spending
  - They won’t be generous in their payment
  - Neither will commercial payers