An Open Letter from the President of OOSS

September 15, 2015

Re: OOSS Comments to CMS Regarding Office Cataract Surgery

Dear Members, Partners, and Friends of OOSS,

I joined OOSS shortly after founding Chu Surgery Center because I realized that my team and my patients needed a voice in the nation’s capital that had only one priority – representing our unwavering commitment to the delivery of quality surgical care, one patient at a time. As many of you know, CMS is considering a proposal to pay for cataract surgery in the physician’s office. I am proud to say that OOSS has taken a strong and unequivocal position on this matter.

Cataract surgery should be performed only in a facility, such as an ASC or a hospital, that meets rigorous and well-established patient health and safety standards.

Please take a few minutes to review our comments submitted to CMS last week – developed by OOSS Washington Counsel Michael Romansky in close collaboration with leading experts, including surgeons, OR directors, and our Society and industry partners. Our comments are comprehensive and based on sound survey data, and reflect our shared commitment to provide the highest quality and most cost-effective ophthalmic surgical care available to the most deserving of patients.

Many of you submitted comments to CMS on office cataract surgery. Most OOSS members participated in our survey to assess the comorbidities in cataract patients. Kudos to all of you. You are what make our organization so effective.

Sincerely,

Ralph Chu, M.D.
President
September 8, 2015

Andy Slavitt, Acting Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1631-P  
Room 445-G  
Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Washington, DC 20201

Via online submission at www.regulations.gov

RE: Medicare Programs; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY2016 (CMS-1631-P) – Request for Information on Nonfacility Cataract Surgery

Acting Administrator Slavitt:

The Outpatient Ophthalmic Surgery Society (OOSS), in collaboration with the Society for Excellence in EyeCare (SEE), is pleased to submit this comprehensive response to your request for information regarding nonfacility cataract surgery.

OOSS is a professional medical association representing over 1,100 ophthalmologists, nurses, and administrators who specialize in providing high-quality ophthalmic surgical services in cost-effective outpatient surgical environments, particularly ASCs. OOSS was established in 1980 by the pioneers of the first ophthalmic ambulatory surgery centers in the U.S. and has demonstrated a long history of commitment to working with members’ centers, policy-makers and regulators at all levels to encourage and guide innovation in ambulatory surgery while ensuring the safest, highest quality and most affordable surgical care available to patients. SEE promotes quality, safety and cost-effective eye care and the advancement of technology and best practices through education, communication and research.

It is our pleasure to respond to CMS’ Request for Information regarding its
consideration of enhanced payment for the practices expenses of physicians providing
cataract surgery in office surgical suites.

For decades cataract surgery has been one of the success stories in medicine, with
an extremely high success rate, low complication rate, and a significant impact on the
daily lives of patients that is almost unparalleled. These very positive outcomes are a
direct result of these surgeries having been performed in the highly regulated setting of
the hospital and ambulatory surgery center (ASC) environments. The nation’s
approximately one thousand ophthalmic ASCs have demonstrated, by all measures, the
ability to deliver consistently safe, quality and affordable care in the interest of patients
and payers. Accordingly, and in keeping with this historical commitment, any
consideration by CMS that would reimburse for an
d thereby encourage
the furnishing of
 cataract surgery in the office setting should be assessed against the standards and best
practices that have come to define the current ophthalmic ASC model.

Recommendations Regarding Payment for
Office Cataract Surgery

The agency is seeking feedback regarding the viability of encouraging the
performance of cataract surgery in the office-based setting by assigning nonfacility
Practice Expense Relative Value Units under the Medicare Fee Schedule for cataract
surgery. As discussed in detail below, we believe that consideration of
implementation of such payment incentives is ill-advised and premature and should
be deferred until such time as the agency:

1. Further considers the patient health and safety risks to cataract patients who
might be treated in offices rather than ASCs or hospitals.

2. Develops standards of care for office surgical suites that are comparable to
those applied to ASCs with regard to protection of the health and safety of
Medicare beneficiaries.

3. Identifies a model for the appropriate regulation of office-based surgical
facilities and the enforcement of health and safety standards. State office
surgery regulatory programs, where they even exist, are inconsistent and
inadequate to protect the patient. O OSS believes that, if CMS is to advance
payment incentives for the performance of cataract surgery in the office, the
agency should establish a federal program comparable to that established for
ASCs. The agency might consider as an option the accreditation of office-
based facilities; however, we do not believe that existing accreditation
programs for office surgery are sufficiently rigorous to protect the health
and safety of cataract patients.
4. Implements a pilot or demonstration project in limited geographic areas through which quality of care, patient health and safety, and payment in the office cataract facility can be evaluated.

The Ophthalmic ASC

OOSS and SEE have long been advocates of encouraging migration to lower-cost settings, but only if this can be accomplished without compromising the health and safety of the patient. ASCs have proliferated over the past thirty years – with over 5,400 presently operating in the United States, about a thousand of which specialize in the provision of cataract and other ophthalmic surgeries – because of their patient-centric culture and their commitment to the delivery of lower-cost and high quality care in an appropriately regulated environment. These are highly regulated providers. A recent survey of OOSS member and non-member ophthalmic ASCs confirms that virtually all facilities are Medicare-certified; 85 percent are accredited by a CMS-approved agency; and 81 percent are licensed by their states as ASCs.

The contemporary cataract surgery operating room is a comprehensive, high tech environment housing phacoemulsification equipment (with or without femtosecond lasers), operating microscopes, delicate surgical instruments, and sterilization systems that have been designed for the ophthalmic microsurgical setting. Staff is trained in the intricacies of ophthalmic care and the use of this specialized equipment. The surgeon, anesthesia professionals, and clinical staff direct their attention to emergent care needs, including patient monitoring equipment, medical gases (e.g., oxygen), crash carts, defibrillators and all other airway and medication requirements. Creating this complex environment of trained professionals and costly equipment is an endeavor that is expensive and requires a substantial attention to details; we are concerned that, in the absence of regulation and appropriate oversight, offices may cut corners in staffing and equipment, resulting in unfavorable outcomes.

CMS’ Assumptions in Consideration of Payment for Office Cataract Surgery Are Flawed

We believe that the agency’s Request for Information is based on questionable assumptions. CMS states that “we believe that it is now possible for cataract surgery to be furnished in an in-office surgical suite, especially for routine cases. For example, routine cases in patients with no comorbidities could be performed in the nonfacility surgical suite, while more complicated cases (for example, pseudoexfoliation) could be scheduled in the ASC or HOPD.” Complications like TASS, endophthalmitis, unplanned anterior vitrectomies, a dropped lens nucleus, a choroidal bleed, as well as systemic events like a cardiac arrhythmia, myocardial infarction or CVA do not occur frequently; however, they do occur and can be life- and vision-threatening. It is important to note that despite the meticulous care and preoperative assessment provided by the surgeon, anesthesiologist, and clinical staff, it is generally unknown whether a complication is likely or not to take place.
The agency seems to characterize cataract patients as typically healthier than they actually present to the ophthalmologist and ambulatory surgical center. As discussed in detail below, cataract patients are commonly older and have far more co-existing conditions than would be expected in a younger population. These patients are generally unable to manage all daily activities (meeting medical necessity for cataract surgery per CMS requirements) until their eyesight is restored. Following is a summary of results from the recent OOSS study and an earlier study reported in *The New England Journal of Medicine*, each of which mutually confirms the profound comorbidity profile of cataract patients and suggest that the trends in presenting comorbidity may, in fact, be worsening.


This sizable study reported in the January 20, 2000 issue of *The New England Journal of Medicine* examined the efficacy of routine preoperative medical testing of cataract patients. A total of 18,189 cataract patients from nine clinical (ambulatory surgery) centers were included and health care providers completed a brief medical history form for documentation of co-existing conditions presented by the patients. As this relatively large sampling of cataract patients confirmed, “Most patients who undergo cataract surgery are Medicare beneficiaries, who are 65 years old or older. As would be anticipated, the prevalence of coexisting illnesses and associated laboratory abnormalities in this age group is high.” Following is a summary of the age and co-existing conditions of patients included in the 2000 study.

Age Profile of Cataract Patients – 2000 - The 2000 study excluded cataract patients under 50 years of age. Of those included, 29% were less than 70 years of age, and 71% were 70+. Only 7% were less than 60 years of age and 24.5% were 80+ years of age.

Coexisting Illnesses – 2000 - Based on the inclusion of 16 categories of coexisting illnesses, the study reported that 76% of the cataract patients presented one or more of the conditions included, and of those, 69% presented two or more coexisting conditions. It is notable that 47% of patients presented the condition of hypertension while 56% presented a combination of cardiovascular conditions, and 25% presented a combination of pulmonary conditions.

B. Summary of OOSS Comorbidity Study – August, 2015

In August of 2015 the Outpatient Ophthalmic Surgery Society, in cooperation with the Association of Ambulatory Surgery Centers (ASCA) and SEE, engaged 170 ophthalmic-driven ambulatory surgery centers in a comorbidity study to randomly sample

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1 Coexisting illnesses referenced in the 2000 study published in *The New England Journal of Medicine* included hypertension, angina, myocardial infarction or conditions treated for coronary-artery bypass grafting, arrhythmia, congestive heart failure, aortic stenosis, other heart disease, thromboembolic disease, transient ischemic attack, chronic obstructive pulmonary disease or asthma, diabetes mellitus, anemia, bleeding disorder, renal disease, thyroid disease, liver disease or none of the above.
the H&P records of 50 of their most recent cataract patient cases. The sampling totaled 8500 cases, representing a total annual case volume of over 400,000 cataract patient cases across the participating facilities, or approximately 13% of the total of all estimated cataract cases performed in the U.S.

**Age Profile of Cataract Patients – 2015** - Of those included, only 2.5% of patients were under the age of 50, although 45% were less than 70 years of age. Of those included, 55% were 70+, while only 12% were less than 60 years of age and 16% were 80+ years of age. A comparison of the two studies suggests that while the overall age profile remains relatively constant, non-Medicare patients are having cataract surgery at an earlier age.

**Comorbidities – 2015** - Based on the inclusion of six categories of comorbidity conditions\(^2\), the OOSS study reported that 94% of cataract patients presented one or more of the conditions included, and of those, 88% presented two or more comorbidity conditions. This compares to 76% as reported in the 2000 study. It is notable that in the OOSS study, 64% of patients presented the comorbidity of hypertension, compared to 47% in the 2000 study. Overall, it appears that while the age profile may be migrating slightly to younger ages, the overall comorbidity profile appears to be worsening. In addition, the OOSS survey assessed the number of medications being taken by cataract patients finding that over 69% are taking 5 or more medications and another 23% are taking 3 to 4 medications. The bottom line, in terms of identifying “routine” cataract cases, i.e., is that, currently, only six percent of cataract cases present without any comorbidities, and most are taking multiple prescription medications associated with comorbidities. Thus virtually all cataract patients are potentially at risk unless their surgery is performed in office facilities that meet standards of care comparable to those of ASCs and hospitals.

The Request for Information also suggests that the frequent use of “local anesthesia” mitigates the need for the highly regulated ASC or hospital environments. The anesthesia protocol is commonly a combination of intravenous, oral, and/or topical agents. The age, comorbidities and regular usage of one or more prescription medications of the typical cataract patient render it even more necessary to have a qualified anesthesia provider present. As the surgeon’s gaze and attention is focused through an operating microscope, he or she is simply not in a place to divert attention away to the patient’s’ systemic needs during the surgical procedure. And ophthalmic surgeons are typically not critical care experts in the event of an emergency.

**Office Surgical Facilities Should be Subject to Rigorous Patient Health and Safety Standards Comparable to the Medicare Conditions for Coverage for ASCs**

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\(^2\) Comorbidity conditions referenced in the 2015 OOSS study included hypertension, cardiovascular disease, cerebrovascular disease, pulmonary disease, endocrine disease, cancer and none of the above.
In summary, while an office-based surgical environment offers the potential for reduced costs to the Medicare program, the overwhelming majority of cataract patients present comorbidity profiles that warrant the rigorous attention to patient health and safety inherent in the federal regulations that govern hospitals and ASCs. These include detailed rules pertaining to infection control, environment, anesthesia, nursing, governance and supervision. They are reflective of a well established mindset in Medicare-certified and state-licensed ASCs and hospitals of commitment to patient health and safety and appropriate and regular governmental and accreditation organization (e.g., AAAHC, JCAHO) oversight. The aging cataract populations that our member surgeons treat are entitled to the most optimal of surgical care and the safest of surgical environments. The Medicare ASC Conditions for Coverage (CfC) provide a framework for appropriate regulation of safe surgical settings, including the physician’s office that furnishes cataract surgery. If CMS insists on paying for office cataract surgery, the agency should apply these necessary standards to office facilities, and establish a program of federal oversight to ensure that the Medicare patient’s health and safety are as well protected in this setting as they are in the ASC or HOPD sites of service.

Below, we review those standards encompassed within the ambulatory surgical center CfCs that must migrate to the office if the agency is determined to provide additional practice expense reimbursement for surgery performed in the non-ASC or hospital setting.

Environment

416.44 sets forth standards for the surgical environment, including operating room design and equipment, infection control, separate recovery room, emergency equipment and personnel. These standards are not only vital to the patient’s safety but to achieving optimal outcomes. CMS has properly assigned these requirements to the ASC and it would be irrational to not apply them to an office-based facility. We have concerns regarding the ability of an office center to comply with them. Offices are often located within multi-story buildings and maintaining proper control over all safety and ventilation issues within the building can be challenging, especially with regard to fire safety with proper firewall structures, fire safety equipment, and sprinkler systems. When many entities are leasing within the same building, a surgical suite inside the building may be vulnerable if any one entity does not meet proper Life Safety Code requirements. The surgical suite would also be in danger if proper firewall structures did not exist or ventilation structures within the building were adjoined without proper separations.

If the office based suite does not reside in what CMS has deemed necessary and appropriate for a safe surgical environment, there is little need to further discuss whether surgery should be performed in the facility. We strongly believe that the requirements for proper surgical and emergency equipment as well as for monitoring, inspecting, testing, and maintenance should apply to any facility – hospital, ASC, or office – that provides cataract surgery:
• Each operating room must be designed and equipped so that the type of surgery conducted can be performed in a manner that protects the lives and assures the physical safety of all individuals in the area [416.44(a)(1)]. This includes the development and implementation of policies that are in line with acceptable practices for infection control, such as the State’s operating room HVAC requirements for temperature and humidity, as well as ability to maintain air exchanges and positive pressure.

• Separate recovery and waiting areas must exist to ensure compliance with infection control standards and protection of the patient’s right to privacy and confidentiality [416.44(a)(2)].

• The medical staff and governing body must coordinate, develop, and revise policies and procedures to specify the types of emergency equipment required for use in the operating room. The equipment must meet the following requirements [416.44(c)]:
  
  a. Be immediately available for use during emergency situations [416.44(c)(1)]
  
  b. Be appropriate for the facility’s patient population [416.44(c)(2)]
  
  c. Be maintained by appropriate personnel [416.44(c)(3)] As discussed below, it is imperative that cataract surgery patients be treated in the operating room environment by licensed nursing personnel.

• Personnel trained in the use of emergency equipment and in cardiopulmonary resuscitation must be available whenever there is a patient present [416.44(d)] Again, the use of licensed professional health care personnel should be required.

### Life Safety Code

Chapters 20/21 of the Life Safety Code address Ambulatory Health Occupancy and proscribe a level of life safety from fire that is greater than that typically found in business occupancies (like a clinic). The Life Safety Code requires that facilities with 4 or more patients incapable of self-preservation must be in a building properly protected as an ASC. CMS applies a stricter definition of an ambulatory surgery health care occupancy for one or more persons incapable of self-preservation. Generally, the clinic located within a business occupancy follows a much less rigorous set of requirements, potentially jeopardizing the safety of patients treated therein. Clinics operating under the standards found in the business occupancy chapters are adhering to the same standards as banks, insurance offices, physician offices and other business entities with little to no risk of patient harm. This is of grave concern. It is not hyperbole to state that this gap in the standard of care in the hospital or ASC and the office can represent the difference between life and death for the patient. Fire safety, smoke and firewall protection around
the surgical suite, and emergency backup power conditions are but a few such examples. We recognize that the 2012 edition of the Life Safety Code will soon be enforced by CMS and believe that all office facilities should be held accountable to the same safety standards found in the Ambulatory Health Occupancy chapters.

These standards require that all ambulatory health facilities be designed, constructed, maintained, and operated to minimize the possibility of a fire emergency requiring evacuation of occupants. Chapter 20 section 20.1.1.3 outlines the concept objective to be accomplished within the context of the total physical facility, the type of activities undertaken, the provision for the capabilities of staff, and the needs of all occupants through requirements directed at (1) prevention of ignition, (2) detection of fire, (3) control of fire development, (4) confinement of the effects of the fire, (5) extinguishment of fire, (6) provision of refuge or evacuation of facility, and (7) staff reaction. All of these objectives, when combined, facilitate the establishment of a physical environment that is safe from fire. Not only is the environment constructed of materials that will stand-up to the effects of smoke and fire longer, especially in multi-story buildings, but the facility also adheres to plans and procedures that address life-saving initial actions during a fire emergency. As an example, employees in an ASC occupancy classification have four times as many fire drills compared to facilities meeting the business occupancy classification.

The clinic residing in a business occupancy is permitted to have other tenants within the building that have hazardous contents on the premises. One can imagine a fire in a hair salon, dry cleaner, or other business that relies on chemicals as part of their trade sharing a building wherein someone is having surgery without the protection of the one-hour occupancy separation or other total concept objectives discussed in this document. One small oversight, mistake, or unattended smoker can result in a catastrophic fire event for the occupants of the building. ASC’s are required to have fire watches, environmental safety rounds, and policies in place that address fire safety concerns. Non-healthcare related occupancies classified as containing high hazard contents are not permitted in buildings housing ASCs, yet they are permitted in facilities housing clinics.

The following is a summary of several key life safety code components, focusing on the differences between their application to ASCs and to clinics:

- **ASC’s constructed within an existing structure (facility) shall be separated from any existing structure not conforming to the provisions within the ASC chapter by a fire barrier having not less than a 2-hour fire resistance rating. Clinics must conform to building separation per local jurisdiction for building type, most likely of a 1-hour or less separation.**

- **Egress Doors – The ASC’s doors are permitted to be locked to confine and protect patients, while clinic doors are not allowed to be locked,**

- **Minimum Construction Type - ASC’s are required to meet NFPA 220 construction type for single story facilities, while clinics are not subject to such a regulation.**
• Door Width- ASC’s require a minimum door width of 32 inches clear width or 34 inches in leaf width in accordance with section 21.2.4.3. Clinics require a minimum of 28 inches for a door leaf width in accordance with 7.2.1.2.3.2.

• Exiting- ASC’s require a minimum of two exit access doors from a suite of more than 2,500 square feet in accordance with 21.2.3.4 or if common path of travel with single door would be excessive and with a travel distance of less than 150 feet. Clinics require a second exit access door if common path of travel with a single door would be excessive per section 39.2.5.3, and with a travel distance of less than 200 feet.

• Smoke Compartmentation – ASC’s require, per section 21.3.7, separation from other tenants and subdivisions within the center by smoke barriers, unless the facility is under 5,000 SF, in which case the facility must install a comprehensive smoke detection system. If an approved fire sprinkler system is installed, the area requirement can be increased to less than 10,000 SF. Clinics are not required to have smoke barriers.

• Evacuation or Relocation Plan – ASC’s require, per section 21.7.1, an evacuation plan while Clinics are not required to have either a plan of action or relevant documentation.

• Corridor Clearance – ASC’s corridors must have a clear minimum width of 44 inches for exit access corridors. Clinics are only required to have a minimum clear corridor width where such corridors serve an occupant load of 50 or more.

• Electrical Systems – ASC’s are required to be equipped with emergency lighting and standby power if medical procedures requiring general anesthesia are practiced, or if life support equipment is used for other than emergency purposes. Ambulatory healthcare facilities are required to be served by electrical systems meeting the criteria for essential electrical systems as detailed in NFPA 99. A facility would not be required to have an emergency generator if, as normal practice, the following conditions apply: (1) management maintains polices that preclude the provision of care for any patient who might need to be sustained by electrical life support equipment such as respirators or suction apparatus; (2) no surgical treatment requiring general anesthesia is offered; and, (3) if battery operated systems or equipment are provided that maintain power to exit lights and illumination for egress corridors, stairways, medical preparation areas and the like for a minimum of 90 minutes with battery required to be supplied to all alarm systems. Clinics are not required to adhere to such requirements.

• Fire Drills – ASC’s are required to conduct and document fire drills on a quarterly basis and for each shift. Clinics are only required to perform a fire drill annually.
We strongly believe that if an organization performs any surgical procedures like cataract surgery, it should be subject to the same safeguards applied to a hospital or ASC, including emergency power, a fire resistant building and well trained staff that have practiced fire suppression, rescue, and evacuation.

**Infection Control -- Section 416.51 Requirements**

**416.51** includes requirements for infection control in a surgical environment. While each section in the CfCs that we are addressing incorporates some component of infection control measures, this section reviews measures in detail. CMS must be cognizant of the special needs of the typical cataract patient. While complications like TASS and endophthalmitis are infrequent, they do occur and are potentially serious and vision-threatening.

Through modifications to the CfCs and Medicare ASC interpretive guidelines as well as other policy transmittals, CMS continues to augment the requirements that ASCs must meet to ensure that patient risk of infection is minimized. As recently as August of 2014, the agency issued a change in policy limiting the use of immediate use steam sterilization (IUSS) on a routine basis in the ASC and establishing parameters for short cycle sterilization. {Change in Terminology and Update of Survey and Certification (S&C) Memorandum 09-55 Regarding Immediate Use Steam Sterilization (IUSS) in Surgical Settings}. This policy will likely have the effect of precluding the use of less expensive, non-terminal sterilizers and require the purchase of more costly units, a cost that we are concerned office facilities will not bear. The document clarifies that facilities must meticulously adhere to manufacturers’ directions for use (DFU) for sterilizers and instruments with respect to dry times, wrapping, containers, and storage for later use. It is incongruous for CMS to amplify requirements for patients having eye surgery in the ASC and, concurrently, encourage the conduct of surgery on beneficiaries in facilities that are subject to little or no regulation governing infection control.

It is imperative that each surgical environment maintain an infection control program commensurate with that contemplated in the Medicare ASC program and incorporate similar rigorous oversight. In Section 416.51:

- The facility must provide a functional and sanitary environment for surgical services to avoid sources and transmission of infections and communicable diseases
- Be based on nationally recognized infection control guidelines
- Be directed by a designated health care professional with training in infection control (and be approved by the governing body for these activities).
- Be ongoing and include actions to prevent, identify and manage infections and communicable diseases. The facility must investigate and review reported infections and follow outcomes.
• Include a mechanism to immediately implement corrective actions and preventive measures that improve the control of infection (which should be linked to ASC quality reporting, as discussed below)

416.44(c) also incorporates detailed standards for infection control as it relates to the sterilization equipment. Specifically, “Equipment for rapid emergency sterilization of OR equipment/materials whose sterility has been compromised must be available on-site; however, routine use of sterilization procedures intended for emergency use only as its standard method of sterilization between cases, in order to reuse surgical instruments, must currently be cited in ASCs. The requirement should apply to any surgical setting.

**Infection Control -- Healthcare-Associated Infections**

The CfCs also address the mitigation of risks that contribute to healthcare-associated infections (HAI) in Section 416.51. These measures include:

• Implementation of appropriate prophylaxis to prevent surgical site infection

• Addressing aseptic technique practices used in surgery, including sterilization or high-level disinfection of instruments

• Promotion of hand hygiene, including alcohol based hand sanitizers

• Measures specific to safe practices for injecting medications and saline or other infusates

• Requirements for disinfectants and germicides to be used in accordance with manufacturer’s instructions

• Appropriate use of facility and medical equipment, including air filtration equipment

• Education of patients, visitors, and staff as appropriate about infections and communicable diseases and method to reduce transmission

**Infection Control -- CMS Survey Compliance Instrument for ASCs**

CMS has developed a very thorough and useful infection control survey instrument for purposes of inspections of ASCs for compliance with the CfCs. We believe that this document can serve as a useful tool for purposes of assessing compliance by office facilities with appropriate infection control standards. To our knowledge, no states require that office facilities meet such standards despite the need for rigorous infection control protections for patients undergoing intraocular procedures.
The following elements of the survey instrument should apply to the office surgical facility:

- The center must have an explicit infection control program and follow nationally recognized infection control guidelines.

- There must be systematic processes for identifying infections as they occur that may be related to the procedure in order to prevent further instances and protect patient safety and outcomes.

- Instruments must be pre-cleaned, visually inspected for any residual bio-burden, packaged, and sterilized, according to manufacturer’s instructions (DFUs). Items must be appropriately contained and handled during the sterilization process to assure no compromise has occurred. A chemical indicator must be placed in each load, and a biological indicator must be used at least weekly for each sterilizer and with every load containing implants. Monitoring of each load with time, temperature, and pressure, as well as documentation for each piece of sterilized material, must be performed. After sterilization, medical devices must be stored in a designated clean area to avoid compromising sterility and when these items are used, they must first be inspected for integrity. All of these measures ensure the sterility of items, protects patients, and prevents infections. In the absence of such requirements being applied to office-based facilities that perform cataract surgery on Medicare beneficiaries, patient health and safety will be compromised.

- Immediate Use Steam Sterilization (IUSS) must never be used on a routine basis nor for implants, post-procedure decontamination of instruments used on patients with Creutzfeldt-Jakob Disease or similar disorders, devices that have not been validated for such use, or for single use devices. The sterilizer function must be monitored and the processed items must be immediately transferred, using aseptic technique, from the sterilizer to the actual point of use (sterile field in an ongoing procedure).

- There must be a policy in place to comply with State notifiable disease reporting requirements. A licensed health care professional, qualified through training, must oversee this program and all staff is required to undergo infection control training on a continual basis. This is a very important step to ensure staff awareness of prevention measures.

- All patient care areas must have soap and water available, as well as alcohol based hand rubs. If the alcohol containers are placed on the wall for dispensing, the Life Safety Code must be followed (alcohol hand rubs and electrical outlets). This is extremely important for patient safety, as it helps prevent alcohol-fires.
• Staff must perform hand hygiene before and after direct patient contact, after removing gloves and before performing invasive procedures. This is a personal protective practice and it is important for the safety of all involved. A hand hygiene program must be in place and hand hygiene must be monitored and documented.

• The worksheet is very thorough with respect to medication vials and drawing, requiring the following: the rubber septum must always be disinfected with alcohol prior to piercing; entered with a new needle and a new syringe; and any medication pre-drawn must be labeled with date, time of withdrawal, and initials of the person drawing, medication name, strength, and beyond-use date and time. Single dose medication vials and bags of IV fluids must be used for only one patient, a vital element of patient safety. In addition, all tubing and connectors must also be used for only one patient. We note that clinical offices currently do not have to abide by any regulations regarding single versus multi-use.

• Multi-dose vials must be dated when opened and discarded within 28 days unless the manufacturer specifies a different date; this aids in the prevention of infections. If these vials are used for more than one patient, they must be stored appropriately and never enter immediate patient care areas.

• All sharps must be disposed in a puncture-resistant sharps container, which must be replaced when the fill line is reached. This ensures the safety of all involved.

• Devices that are reprocessed must have FDA labeling to that effect and reprocessing must be undertaken in an entity that has been certified for such purposes by the FDA. Single use items that are re-used without appropriate reprocessing can cause patient injury, particularly when dealing with intraocular instruments and supplies. At the end of each day, terminal cleaning of the ORs must be completed by personnel with documented training.

• Operating rooms must be cleaned and disinfected after each surgical or invasive procedure with an EPA-registered disinfectant and terminally cleaned each day. All surfaces in patient care areas must be cleaned and disinfected on a regular basis, when spill occur, and when surfaces are visibly contaminated. These measures are vitally important for the cleanliness of ORs and prevention of infections.

• We do not believe that there are any regulatory requirements for an office based surgical setting to possess and use a glucometer, an extremely vital tool when providing care for elder, sicker patients (many of whom have diabetes). When used, the staff must perform hand hygiene before and after the finger stick procedure and wear gloves for the procedure. If the glucometer device can be used for more than one patient, then it must be cleaned and disinfected.
after every use according to DFUs, and if not covered in the DFUs, then the device should not be used for more than one patient.

**Governing Body and Management**

416.41 requires that the ASC have a governing body with specific responsibilities. Regardless of setting, a facility should have an overseeing body of more than one individual to establish appropriate policies and procedures, provide oversight of the quality assessment and performance improvement programs, and ensure the quality of healthcare services, the safety of the environment, and maintenance of a disaster preparedness plan as it relates to both internal and external disasters. Importantly, the governing body has the primary responsibility for ensuring that infection control measures are strictly adhered to, care is provided in a safe and effective manner, the physical environment is safe for the patient, and that the facility is prepared to care for the patient in any impending emergency. These emergencies include, but are not limited to cardiac or respiratory failure or other systemic events, and/or isolation in case of communicable disease, fire, weather-related emergencies, bomb threat, and bioterrorism.

416.41 (b) requires that an ASC must have an effective procedure for the immediate transfer of a patient to a local, Medicare participating, hospital in the event of emergency. The ASC must have a written transfer agreement with a local hospital that is equipped to deal with such adverse events and ensure that all physicians performing surgery in the ASC have admitting privileges at a hospital.

Regardless of setting, these governance and supervision requirements are essential for any facility to meet the emergent needs of its patients, particularly cataract patients who typically have multiple comorbidities. We would imagine that office facilities can secure such a transfer agreement and appropriate physician privileges. We do, however, have reservations regarding the ability of offices located above the ground floor to safely transfer a patient in respiratory or cardiac arrest safely if the building does not have at least one large elevator (affording room for airway management and continual CPR with patient on flat bed surface and multiple attendees).

**Surgical Services/Anesthesia**

416.42 addresses surgical services and anesthesia and mandates that physicians must be qualified to perform their approved privileges and that policies and procedures must exist for reviewing physician credentials and determining that granted privileges are within the scope of practice of each physician. We believe that this is an effective standard for the protection of all patients, but particularly those undergoing intraocular surgery for the preservation of their vision. It is imperative that office based centers be held to the same standard.
416.42(a) provides detailed standards encompassing anesthetic risk and evaluation, requiring that a physician examine the patient immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed. As discussed above, the typical cataract patient has multiple comorbidities and presents with greater risks than younger and healthier patients. The physician and anesthesia professional and clinical staff must re-examine the patient to ensure that the patient is still stable and able to have surgery in the ambulatory setting. The CfCs are quite explicit regarding anesthesia classes, basically stating that patients at great risk should be canceled. If no requirement exists for patients to be re-examined and anesthesia risks to be reviewed in the office environment, these older and sicker patients are placed at greater risk. With respect to anesthesia, office centers should be subject to identical standards as ASCs and hospitals.

Staffing/Nursing Service

416.46 encompasses the standards for nursing services and staffing as they relate to the care of patients. It is imperative, if offices perform cataract services, that they meet these same rigorous standards to ensure that, at a minimum, infection control standards are adhered to. ASCs acknowledge that the intervention of licensed nurses is necessary to minimize risk to the patient’s health and safety. Regardless of surgical setting, it would be unconscionable to entrust our patients, who are aged and have multiple comorbidities, to the care of non-licensed and potentially unqualified personnel. The following should be required of any site providing surgical care:

- Nursing services are directed under the leadership of a Registered Nurse [416.46]
- The nursing service must assure that all nursing needs of all patients are met [416.46]
- Patient care responsibilities must be delineated for all nursing services personnel [416.46(a)]
- A registered nurse must be available for emergency treatment whenever there is a patient in the center [416.46(a)]

We note that quality of care in ASCs is overseen and evaluated through claims-based reporting as well as QNet annual reporting by the nursing staff. Moreover, for infection control purposes, CMS is currently requiring ASCs to report on flu vaccination of the surgical staff through the National Health Safety Network. ASCs also presently report on multiple quality measures, including patient burns, patient transfers to hospitals, patient falls, and wrong site/side/patient/procedure. CMS is presently considering the requirement that ASCs report on the incidence of unplanned vitrectomies during cataract surgery, a measure developed by the ASC Quality Collaboration (on whose Board, O OSS sits). ASCQC has also submitted for review by the National Quality Forum (NQF) a measure regarding the incidence of TASS.
It is imperative that offices that perform cataract surgery meet rigorous infection control standards, as well as report on quality measures that relate directly to the quality of care provided within a facility and that proper nursing staff is available to oversee these matters. Unless the Physician Quality Reporting System (PQRS) is substantially expanded to include mandatory reporting on these types of measures and office cataract surgery is regulated by Medicare (which we believe is an imperative), our patients will be deprived of the benefits of quality reporting, which include the ability to compare the quality of care at facilities and to be treated in centers that take actions to improve care in response to reporting results.

**Patient Admission/Assessment Throughout Surgical Process**

416.52 relates to surgical services. These provisions are as necessary in the office surgical facility as in the ASC:

- Not more than 30 days before the date of the scheduled surgery, each patient must have a comprehensive medical history and physical assessment completed by a physician or other qualified practitioner [416.52(a)(1)] As discussed above, it is essential to understand the health, including comorbidities, of the patient undergoing surgery in an office setting.

- The patient’s medical history and physical assessment must be placed in the patient’s clinical record prior to the surgical procedure [416.52(a)(3)], ensuring that all staff can access needed documentation if an emergency arises.

- Upon admission, each patient must have a pre-surgical assessment completed by a physician or other qualified practitioner [416.52(a)(2)].

- An updated medical record entry documenting an examination for any changes in the patient’s condition since completion of the most recently documented medical H&P [416.52(a)(2)]

- Documentation of allergies to drugs and biologicals [416.52(a)(2)] for patient safety.

- A physician must examine the patient immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed [416.52(a)(1)], which is, again, highly important when dealing with older patients with higher comorbidity rates. This exercise determines whether the patient is still stable and able to undergo the procedure. Correct monitoring equipment for these procedures should include blood pressure, pulse, and heart rate/rhythm.

- A safe environment for treating surgical patients, including adequate safeguards to protect the patient from cross-infection, is ensured through the provision of adequate space, equipment, supplies, and personnel [416.51(a)].
• The patient must have the appropriate pre-surgical and post-surgical assessments completed and that all elements of the discharge requirements are completed [416.52]

• The patient’s post surgical condition must be assessed and documented in the medical record by a physician, or other qualified practitioner, or a registered nurse with appropriate experience [416.52(b)(1)]

• Post surgical needs must be addressed and included in the discharge notes [416.52(b)(2)]

• The facility must provide each patient with written discharge instructions and overnight supplies. When appropriate, a follow up appointment with the physician is required, and the facility must ensure that all patients are informed, either in advance of their surgical procedure or prior to leaving the ASC, of their prescriptions, post-operative instructions and physician contact [416.52(c)(1)]

• The facility must ensure that all patients are discharged in the company of a responsible adult [416.52(c)(3)]. This requirement is necessary in the office setting for the safety of the patient and the public at large.

**Administration and Oversight of Drugs**

416.48 delineates the parameters for pharmaceutical needs and the administration of drugs. This section is important for both IV drug administration as well as topical and intraocular injections. Personnel providing medication by any route should be acting within their scope of trained practice. Manufacturer’s labels should be followed, including storage of drugs and biologicals and disposal of expired medications. Single dose vials should be used for one patient only, a specific Condition applicable to ASCs. This section is important with respect to all surgeries, but particularly vital when dealing with intraocular injections. Also, any use of narcotics for the purposes of sedation must be rigorously overseen. Patient health and safety dictates that office facilities must be subject to these same requirements:

• Accountability procedures must exist to ensure control of distribution, use, and disposition of all scheduled drugs. The regulation provides, appropriately, that licensed personnel must receive, log and lock up all controlled substances.

• Records of the receipt and disposition of all scheduled drugs must be current and accurate

• Licensed health professionals who are designated responsible for the ASCs pharmaceutical services are responsible for determining that all drug records are in order and that an account of all scheduled drugs is maintained and reconciled.
• The record system, delineated in policies and procedures, must track movement of all scheduled drugs from the point of entry into the facility to the point of departure, either through administration to the patient, destruction, or return to the manufacturer.

• All drug records are in order and an account of all scheduled drugs is maintained and any discrepancies in count are reconciled promptly.

• The ASC’s system is capable of readily identifying loss or diversion of all controlled substances in such a manner as to minimize the time frame between actual loss or diversion to the time of detection and determination of the extent of loss or diversion.

• Orders given orally for drugs and biologicals must be followed by a written order and signed by the prescribing physician [416.48(a)(3)], which ensures that there is an account of an order for medications given to the patient.

• Adverse reactions must be reported to the physician responsible for the patient and must be documented in the record [416.48(a)(1)], which is specifically important for cataract patients that may receive both intravenous and intraocular pharmaceutical injections. Recording adverse reactions can prevent further complications for the patient in the future.

Quality Assessment/Performance Improvement

416.43 provides standards for the internal monitoring of effectiveness and safety of services and the quality of care provided. Office-based centers should adhere to these same requirements. If the office is not required to constantly review patient care protocols, procedural policies, and infection control programs, it is not possible for safety concerns to be addressed in a timely manner, and additional complications and adverse events will inevitably occur. The following are minimal measures that should be met.

• The Quality Assurance/Performance Improvement (QAPI) must be ongoing and demonstrate measurable improvement in patient health outcomes and improve patient safety by using quality indicators or performance measures associated with improved health outcomes and by the identification and reduction of medical errors.[416.43(a)(1)]

• Facilities must measure, analyze, and track quality indicators, adverse patient events, infection control, and other aspects of performance that includes care and services furnished. [416.43(a)(2)]

• The governing body must oversee the QAPI program and ensure it is well defined, implemented, and maintained and addresses concerning priorities. All improvements should be evaluated for effectiveness. [416.43(e)(1) and (2)]
• The program should include provision for specific data collection methods, frequency, and details [416.43(e)(3)]

• Distinct improvement projects are annually conducted and must reflect the scope and complexity of the services and operations provided [416.43(d)(1)]

• The program should definitively establish its expectations for safety [416.43(e)(4)]

• The center should allocate sufficient staff, time, information systems, and training to implement the QAPI program [416.43(e)(5)]

**Medical Records**

416.47 provides detailed requirements regarding patient charting. In instances where a Medicare-certified ASC is adjacent or otherwise integrated with the clinical practice, the ASC is required to keep the records of the patient in the ASC separate and apart from the clinic. We do not believe that office facilities need to maintain separate and exclusive charts. However, there are minimal requirements addressing patient safety that should be applied to the office as well as ASC and hospital.

• The ASC record must include the patient’s medical history and results of the physical examination (which is specifically important given the previously discussed comorbidity rates of cataract patients) [416.47(b)(2)]

• Preoperative diagnostic studies should be entered into the medical record before surgery is performed, allowing all information to be referenced during surgical services [416.47(b)(3)]

• The chart should include any allergies and abnormal drug reactions occurring during or after the surgery prior to discharge, which leads to better safety precautions for the patient in future appointments [416.47(b)(5)]

• Documentation of a properly executed informed patient consent must be present [416.57(b)(7)]

• Discussion with the patient concerning the necessity, appropriateness, and risks of the procedure, as well as discussion of treatment alternatives, as applicable, must be incorporated within the patient’s clinical record [416.47(b)]

• There should be a policy in place for the secure release and security of information, including accountability for editing, deletion, and access of clinical record content [416.47(a)]
We have not discussed all of the ASC Conditions for Coverage, but rather have focused on those that we strongly believe should be essential requirements for office-based facilities that wish to provide cataract surgery. It is beyond comprehension that a senior patient with multiple comorbidities should be afforded these protections in one surgical facility and not another. The eye is a delicate and wondrous organ, and preservation of a patient’s eyesight and his overall safety depends on the surgical setting to adhere to rigorous standards. We believe that a regulatory structure that encompasses the aforementioned standards will ensure that our patients receive the safe and effective treatment that they deserve.

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Our member centers and association partners are willing and able to participate in serious collaborative efforts with CMS to closely examine these standards and best practices. Through such a vigorous exercise, policy-makers can ascertain whether and to what extent they may be transferable to variations of the current ASC setting.

Thank you for providing the Outpatient Ophthalmic Surgery Society, and the Society for Excellence in Eye Care with the opportunity to present our views on CMS’ Request for Information regarding its consideration of enhanced payment for the practices expenses of physicians providing cataract surgery in office surgical suites. Should you have any questions or require further information please feel free to contact Michael A. Romansky, JD, OOSS Washington Counsel, at mromansky@O OSS.org or 301.332.6474; and, Allison Shuren, JD, Counsel, SEE at Allison.Shuren@aporter or (202) 942-6525.

Sincerely,

Ralph Chu, M.D.          Ferrell Tyson, MD
President, OOSS          President, SEE