



September 6, 2022

The Honorable Chiquita Brooks-LaSure, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1770-P
PO Box 8016
Baltimore Maryland 21244-8016

RE: CMS-1770-P, Revisions to Payment Policies under the Medicare Physician Fee Schedule Quality Payment Program and Other Revisions to Part B for CY 2023

Dear Administrator Brooks-LaSure:

The Outpatient Ophthalmic Surgery Society (OOSS) is a professional medical association representing over 4,000 ophthalmologists, nurses, and administrators who specialize in providing high-quality ophthalmic surgical services in cost-effective, licensed and certified ambulatory surgery centers (ASCs). OOSS was established in 1982 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.

In the NPRM, in its discussion on potentially misvalued codes under the Medicare physician fee schedule, CMS has requested comments regarding the advisability of establishing a non-facility payment rate for cataract, MIGS, and vitrectomy codes. CMS notes that "these codes are complex surgical eye procedures and they require dedicated spaces, similar to facility-based spaces that are not typically found in an ophthalmologist's office, such as a well-lighted and sterile surgical theater, specific eye surgery equipment and possibly clinical staff and other medical personnel trained to assist in these surgeries and the patient's immediate post-surgery recovery, including anesthesia services." We concur with this evaluation and believe that it is just as accurate now as when CMS considered payment for office-based cataract surgery (OBS) in 2015. The essentially unregulated physician office is an entirely inappropriate environment for the furnishing of cataract and other ophthalmic surgical procedures.

For decades cataract surgery has been one of the greatest 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 1, 200 ophthalmic ASCs have demonstrated, by all measures, the ability to deliver consistently safe, high 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 and 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 Future Payment for Office Cataract Surgery

The agency is seeking feedback regarding the advisability of assigning nonfacility Practice Expense Relative Value Units under the Medicare Fee Schedule for cataract and other complex ophthalmic surgical procedures. Such a policy would encourage the furnishing of such procedures in the essentially unregulated office setting, thereby compromising the safety and quality of care provided to the nation's Medicare population. **As discussed in detail below, we believe that consideration of implementation of such payment incentives is premature and should be deferred until such time as the agency:**

- **Further considers the patient health and safety risks to cataract patients who might be treated in offices rather than ASCs or hospitals.**
- **Develops standards of care for office surgical suites that are comparable to those applied to ASCs in terms of protecting the health and safety of Medicare beneficiaries.**
- **Identifies an appropriate model for the 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. OOSS 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 the office-based facility, although, as discussed in detail below, we do not believe that existing accreditation programs for office surgery are sufficiently rigorous to protect the health and safety of cataract patients.**

The Ophthalmic ASC

OOSS has long been the most prominent advocate for encouraging the migration of ophthalmic surgical care to lower-cost settings, but only if it can be accomplished without compromising the health and safety of the patient. ASC facilities have proliferated over the past fifty years – with over 6,000 Medicare certified ASCs currently operating in the United States, over a fifth of which specialize in the provision of cataract and other ophthalmic surgeries. These ophthalmic ASCs offer a patient-centric culture and commitment to the delivery of a lower-cost and high-quality of care environment. These are highly regulated facility providers. An August,

2022 survey of OOSS member and non-member ophthalmic ASCs confirms that virtually all ASC facilities are Medicare-certified, 85% are accredited by a CMS-approved accrediting organization (such as AAAHC, the Joint Commission, or AAAASF), and 83.5% are licensed by their states as ASCs.

Ophthalmic office-based surgical centers (OBS), of which there are presently very few, accounting for well under one percent of annual cataract cases. In contrast, they are neither Medicare-certified nor state-licensed. Promoters of OBS state that their facilities are accredited by the same accreditation agencies as ASCs, implying that they are meeting the same rigorous ASC standards. This could not be further from the truth; while some office-based centers are accredited, the applicable accreditation standards are significantly less robust and vary based on the accrediting organization and scope of care. This lack of consistency in OBS regulations and standards opens the door to variability in the standard of care from one OBS facility to the next. Relevant accreditation standards are not remotely comparable to the CMS ASC Conditions for Coverage or the standards applied by the accrediting organizations that make “deemed status” determinations for purposes of Medicare certification. This calls into question the ability of physician offices to consistently ensure the health and safety of cataract patients in this surgical setting.

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, all designed for the ophthalmic microsurgical setting. Staff is licensed and highly 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 routine patient care activities and readiness to identify and respond to the potential for emergent medical care. This readiness requires ongoing training of the ASC staff, patient monitoring equipment, medical gases (e.g., oxygen), vacuum, fully stocked and equipped crash carts, defibrillators, and all other supply, equipment, and medication needs that may emerge based on the patient clinical condition. Creating this complex environment of trained professionals and costly supplies and equipment is an expensive endeavor that requires substantial attention to detail. In the absence of regulation and appropriate oversight, office-based facilities may cut corners in staffing and equipment, resulting in, at a minimum increased patient risk and, at maximum, adverse outcomes.

Should Cataract and other Complex Ophthalmic Surgeries Be Performed in an OBS Facility

Advocates for office cataract surgery state that they will provide surgery in the office for "routine" cases, for patients with few or no comorbidities, and individuals not requiring IV sedation, thus mitigating the need for professional anesthesia personnel and licensed nurses.

Complications like TASS, endophthalmitis, unplanned anterior vitrectomy, a dropped lens nucleus, a choroidal bleed, as well as systemic events like 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 attention to preoperative patient

assessment by the surgeon, anesthesiologist, and nursing staff in an ASC, the potential for complications or a medical emergency remains and is generally unpredictable.

Those providing cataract surgery in the office also claim that they will treat healthier and younger patients than those served by ASCs. However, cataracts are primarily an age-related phenomenon. Thus, the patients are older and more likely to have more comorbid conditions than would be typical in a younger population. These patients are often unable to manage their daily activities, i.e., meeting the medical necessity criteria of Medicare and private payers, until their eyesight is restored.

NEJM Study

A large 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 anticipated, the prevalence of co-existing illnesses and associated laboratory abnormalities in this age group is high." The 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.

Based on the inclusion of 16 categories of co-existing illnesses {FN}, the study reported that 76% of the cataract patients presented one or more of the conditions included. Of those, 69% presented two or more co-existing conditions. Notably, 47% of patients presented the condition of hypertension while 56% presented a combination of cardiovascular conditions, and 25% presented a combination of pulmonary conditions.

2022 OOSS Comorbidity Survey

In August of 2022, the Outpatient Ophthalmic Surgery Society engaged 217 ophthalmic-driven ambulatory surgery centers in a comorbidity study to randomly sample the H&P records of 50 of their most recent consecutive cataract patient cases. The sampling totaled 10,850 cases, representing a total annual case volume of over 796,000 cataract patient cases across the participating facilities, or over 20% of the total of all estimated cataract cases performed in the U.S.

Age Profile of Cataract Patients – 2022 – Of those included, only 3.7% of patients were under 50, 57% were 70+, while only 13% were less than 60 years of age and 18.4% 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 – 2022 – The survey included six categories of comorbidity conditions (i.e., hypertension, cerebrovascular disease, pulmonary disease, endocrine disease, cancer, or none of the above). The OOSS study reported that 94% of cataract patients presented one or more of the

conditions included, and of those, 90% presented two or more comorbidity conditions. Notably, in the OOSS study, 63.8% of patients presented the comorbidity of hypertension, compared to 47% in the 2000 study. While the age profile may be migrating slightly to younger ages, the overall comorbidity profile appears to be worsening.

In addition, the 2022 OOSS survey assessed the number of medications taken by cataract patients and found over 50% are taking five or more medications, and another 29% are taking 3 to 4 medications. The bottom line: when identifying cataract cases that might be appropriately performed in the office setting, currently, only 6% of cataract cases present without any comorbidities, and most are taking multiple prescription medications associated with comorbidities. Thus, a significant majority of cataract patients are potentially at risk unless their surgery is performed in an office facility that meets the same standards of care found in ASCs.

Advocates for office cataract surgery suggest that the use of local anesthesia and/or light sedation mitigates the need for regulation such as is applied to ASCs. *This is not the current standard of care for cataract anesthesia.* The cataract surgery anesthesia protocol is commonly a combination of intravenous, oral, and/or topical agents. In a July 2020 survey of OOSS members, respondents reported the anesthesiologist provides IV access in 83% of cataract cases. Only 35% of respondents used oral sedation. 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, even if the surgeon anticipates that IV sedation will not be required.

As the surgeon's gaze and attention is focused through an operating microscope, it is simply not safe or practical to divert attention away from the patient's eye, and toward the patient's systemic needs during the surgical procedure. Ophthalmic surgeons are typically not critical care experts prepared to manage a medical emergency. According to the 2022 OOSS survey, in the ASC, 92% of facilities utilize anesthesiologists or CRNAs to manage the sedation of the patient. Few, if any, states or accreditation bodies require anesthesia professionals or even licensed nursing personnel to be responsible for anesthesia in an OBS facility. This scenario increases patient risk. *The lack of trained and licensed nursing and anesthesia personnel in the OBSC immediately dismisses the claim of a comparable environment of quality and safety between the ASC and OBSC.*

In summary, while an office based surgical environment offers the potential for reduced costs, most cataract patients present comorbidity profiles that warrant particular attention to patient health and safety, as detailed in the ASC Conditions for Coverage. The aging cataract population treated by our member surgeons is entitled to optimal surgical care and the safest surgical environment. The Medicare ASC Conditions for Coverage establish minimum standards for the development and operation of ASCs. Additionally, CMS, via state agencies, provides ongoing oversight and enforcement to assure Medicare beneficiaries receive services in ASCs that maintain ongoing compliance with these national standards.

The office based environment is radically different. The most prevalent example of office based surgery is cosmetic surgery. In fact, it was numerous bad outcomes, including death and botched surgery, exposed on national television and in the national news, that prompted many

states to establish some level of regulation over office based surgery as far back as the 1990s. Office based surgery is devoid of regulation in many states. There are at least 15 states which do not impose **any** regulation on office based surgery. Of the states which do regulate office-based surgery, some regulations are issued by the board of medicine. In other states, the department of health issues the regulations. Neither state agency has a budget/program for ongoing and critical oversight and enforcement.

Consequently, some states require accreditation of office-based facilities in the hopes that there will be on site review of the surgical operation at least every 3 years. This hit-or-miss approach to establishing consistent minimum standards and attendant oversight deprives Medicare beneficiaries of the peace of mind and security that every effort has been made to mitigate the risks inherent in a surgical procedure. It also underscores the fact that the standard of care in an OBS facility is **NOT COMPARABLE** to an ASC.

Patient Access to Cataract Surgery

Promoters of in-office cataract surgery suggest that patient access to cataract and other ophthalmic surgical procedures are now or will in the future be denied care because of extensive backlogs of cases in the ASC environment. There is no evidence to suggest that existing ASCs and hospitals lack the capacity to provide care to our patients on a timely basis now or in the future. In our 2022 survey of OOSS members and non-member ASCs, 58% of facilities reported wait times of less than 30 days and 19% reported wait times of 31 to 60 days. No facilities reported wait times of greater than 90 days.

Application of Standards Comparable to the Medicare Conditions for Coverage (CfC) Are Essential to Ensure the Health and Safety of Patients Undergoing Cataract and other Ophthalmic Surgeries in the Office-Based Facility

While not exhaustive, below is a review of select Medicare ASC Conditions for Coverage that address patient health and safety and highlight the glaring disparity between the standard of care in a Medicare-certified ASC and an OBS cataract facility.

PHYSICAL ENVIRONMENT

416.44 Condition for Coverage: Environment

The ASC must have a safe and sanitary environment, properly constructed, equipped, and maintained to protect the health and safety of patients.

416.44(a) Standard: Physical Environment

The ASC must provide a functional and sanitary environment for the provision of surgical services.

- (1) Each operating room must be designed and equipped so that the types of surgery conducted can be performed in a manner that protects the lives and assures the physical safety of all individuals in the area.*
- (2) The ASC must have a separate recovery room and waiting area.*

416.44(b) Standard: Safety from Fire

- (1) Except as otherwise provided in this section, the ASC must meet the provisions applicable to Ambulatory Health Care Occupancies, regardless of the number of patients served, and must proceed in accordance with the Life Safety Code (NFPA 101 and Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4).*

This condition establishes the environmental standards for ASCs, including but not limited to compliance with the NFPA 101 Life Safety Code, 2012 version, to protect patients and staff in the event of a fire or other life-threatening emergency. This condition and following standards address:

- Temperature and humidity control
- Sanitation
- Design standards, including a separate recovery and waiting area
- Infection control
- Equipment
 - Facility infrastructure e.g., lighting, emergency power, air-handler, air filtration, medical gas systems, vacuum systems, etc.
 - Medical equipment e.g., biomedical equipment, OR tables, stretchers, IV infusion equipment, ventilators, surgical instruments, anesthesia equipment
- Emergency power
- Safety from fire
- Emergency equipment
- Safety from inadvertent cross-circulation of staff, patients, visitors and office personnel with the surgical environment.

These environmental standards protect the lives and physical safety of ASC cataract patients and ASC staff as a minimum standard of care. Before providing payment incentives of cataract surgery in the office facility, CMS should insist that this minimum environmental standard be applied for the surgical encounter in an office-based setting as is the case with respect to the ASC.

MEDICAL EMERGENCY MANAGEMENT

416.41(b) Standard: Hospitalization

- (1) The ASC must have an effective procedure for the immediate transfer, to a hospital, of patients requiring emergency medical care beyond the capabilities of the ASC.*
- (2) This hospital must be a local, Medicare participating hospital or a local, nonparticipating hospital that meets the requirements for payment for emergency services under §482.2 of this chapter.*

(3) The ASC must periodically provide the local hospital with written notice of its operations and the patient population served.

Having the equipment, processes, and trained personnel in place to manage a medical emergency effectively and safely, is a prerequisite to a safe environment of care. Even this is not a minimum standard consistently required in an OBS facility. Without this requirement, cataract patients are exposed to unnecessary risk.

NURSING SERVICES

416.46 Condition for Coverage: Nursing Service

The nursing services of the ASC must be directed and staffed to assure that the nursing needs of all patients are met.

416.46(a) Standard: Organization and Staffing

Patient care responsibilities must be delineated for all nursing service personnel. Nursing services must be provided in accordance with recognized standards of practice. There must be a registered nurse available for emergency treatment whenever there is a patient in the ASC.

There is no consistent requirement for licensed nursing personnel to staff an OBS facility. While some states require an RN presence when higher levels of anesthesia are offered, few if any states mandate RN staffing in office-based surgery settings when minimal or light sedation is utilized. In many offices, the facility is staffed by clinic personnel, Ophthalmic Technicians, and/or Assistants, at a much lower cost and with less hassle. Even if emergency equipment and supplies are in place, their value in an emergency is directly related to the availability of *licensed* personnel properly trained in emergency medical management and Advanced Cardiac Life Support (ACLS).

INFECTION CONTROL

416.51 Conditions for Coverage: Infection Control

The ASC must maintain an infection control program that seeks to minimize infections and communicable diseases.

416.51(a) Standard: Sanitary Environment

The ASC must provide a functional and sanitary environment for the provision of surgical services by adhering to professionally acceptable standards of practice.

416.51(b) Standard: Infection control program.

The ASC must maintain an ongoing program designed to prevent, control, and investigate infections and communicable diseases. In addition, the infection control and prevention program must include documentation that the ASC has considered, selected, and implemented nationally recognized infection control guidelines. The program is:

(1) Under the direction of a designated and qualified professional who has training in infection control;

- (2) *An integral part of the ASC's quality assessment and performance improvement program; and*
- (3) *Responsible for providing a plan of action for preventing, identifying, and managing infections and communicable diseases and for immediately implementing corrective and preventive measures that result in improvement.*

The Center for Disease Control (CDC) defines surgical site infections (SSIs) as infections related to an operative procedure that occurs at or near the surgical incision within 30 days of the procedure. SSIs are among the most common preventable complications after surgery. SSIs occur in 2% to 4% of all patients undergoing inpatient surgical procedures. Although SSIs are less common following ambulatory surgery than after inpatient procedures, they are a frequent source of morbidity in these patients as well. Concerns about SSIs and the shift of surgical procedures to outpatient settings prompted the CDC to publish the *CDC Guide to Infection Prevention in Outpatient Settings* in Nov 2015. In this document, the CDC acknowledges that "outpatient settings have traditionally lacked infrastructure and resources to support infection prevention and surveillance activities". This is a helpful resource; however, there is no obligation for an office facility to adopt and implement this guidebook and no system for oversight and enforcement.

Major complications of cataract surgery are potentially sight-threatening and include infectious endophthalmitis and toxic anterior segment syndrome (TASS). Although TASS is a complication and not technically a surgical site infection, its cause has been linked to sterile processing and disinfection processes. Without meticulous adherence to nationally recognized infection control guidelines, the risk of TASS and SSI is increased.

The CMS Conditions for Coverage for ASCs, appropriately demand a rigorous and robust, comprehensive infection control program with trained leadership, environmental standards, ongoing surveillance, staff training, and regular reporting consistent with nationally recognized guidelines and standards of care. There is no such similar requirement in most states for office based surgical settings. This is an obvious risk and concern for cataract patients undergoing surgery in a physician's office.

SURGICAL SERVICES

416.42 Condition for Coverage: Surgical Services

Surgical procedures must be performed in a safe manner by qualified physicians who have been granted clinical privileges by the governing body of the ASC in accordance with approved policies and procedures of the ASC.

416.42(a) Standard: Anesthetic Risk and Evaluation

- (1) *Immediately before surgery:*
 - (ii) *A physician or anesthetist as defined at §410.69(b) of this chapter must examine the patient to evaluate the risk of anesthesia.*
- (2) *Before discharge from the ASC, each patient must be evaluated by a physician or by an anesthetist as defined at §410.69(b) of this chapter, in accordance with applicable State*

health and safety laws, standards of practice, and ASC policy, for proper anesthesia recovery.

416.42(b) Standard: Administration of Anesthesia

Anesthetics must be administered by only:

- (1) A qualified anesthesiologist, or*
- (2) A physician qualified to administer anesthesia, a certified registered nurse anesthetist (CRNA) or an anesthesiologist's assistant as defined in §410.69(b) of this chapter, or a supervised trainee in an approved educational program. In those cases in which a non-physician administers the anesthesia, unless exempted in accordance with paragraph (c) of this section, the anesthetist must be under the supervision of the operating physician, and in the case of an anesthesiologist's assistant, under the supervision of an anesthesiologist.*

The ASC Conditions for Coverage rightly recognize the inherent risks associated with any surgical procedure and establish quality standards to ensure providers in the ASC are appropriately trained, qualified, and privileged to perform specific procedures. CMS further mandates a preoperative evaluation by a physician and an anesthetic risk assessment by a qualified anesthesia provider to mitigate risk to the greatest extent possible and ensure the highest standard of safe and quality care for the ASC patient.

As discussed above, the typical cataract patient has multiple comorbidities and presents with greater risks than younger, healthier patients. The surgeon, anesthesia professional, and clinical staff must re-examine the patient on the day of surgery to confirm the patient is still an appropriate candidate for surgery in the ASC setting and to avoid unreasonable risks. Essentially, this is an important collaborative exercise involving more than just the surgeon who likely is not current on internal medicine standards of practice. This is the last line of defense to avoid bad outcomes that could have been precluded. A similar requirement should be a minimum standard in the office-based setting.

QUALITY ASSESSMENT AND PERFORMANCE IMPROVEMENT

416.43 Condition for Coverage: *Quality Assessment and Performance Improvement*

The ASC must develop, implement and maintain an ongoing, data-driven quality assessment and performance improvement (QAPI) program.

416.43(a) Standard: Program Scope

- (1) The program must include, but not be limited to, an ongoing program that demonstrates measurable improvement in patient health outcomes and improves patient safety by using quality indicators or performance measures associated with improved health outcomes and by the identification and reduction of medical errors.*
- (2) The ASC must measure, analyze, and track quality indicators, adverse patient events, infection control and other aspects of performance that includes care and services furnished in the ASC.*

§416.43(b) Standard: Program Data

- (1) The program must incorporate quality indicator data, including patient care and other relevant data regarding services furnished in the ASC.*
- (2) The ASC must use the data collected to –*
 - (i) Monitor the effectiveness and safety of its services, and quality of its care.*
 - (ii) Identify opportunities that could lead to improvements and changes in its patient care.*

416.43(c) Standard: Program Activities

- (1) The ASC must set priorities for its performance improvement activities that –*
 - (i) Focus on high risk, high volume, and problem-prone areas.*
 - (ii) Consider incidence, prevalence and severity of problems in those areas.*
 - (iii) Affect health outcomes, patient safety and quality of care.*
- (1) Performance improvement activities must track adverse patient events, examine their causes, implement improvements, and ensure that improvements are sustained over time.*
- (2) The ASC must implement preventive strategies throughout the facility targeting adverse patient events and ensure that all staff are familiar with these strategies.*

416.43(d) Standard: Performance Improvement Projects

- (1) The number and scope of distinct improvement projects conducted annually must reflect the scope and complexity of the ASC's services and operations.*
- (2) The ASC must document the projects that are being conducted. The documentation, at a minimum, must include the reason(s) for implementing the project, and a description of the project's results.*

416.43(e) Governing Body Responsibilities

- (1) The governing body must ensure that the QAPI program:*
- (2) Is defined, implemented, and maintained by the ASC.*
- (3) Addresses the ASC's priorities and that all improvements are evaluated for effectiveness.*
- (4) Specifies data collection methods, frequency, and details.*
- (5) Clearly establishes its expectations for safety.*
- (6) Adequately allocates sufficient staff, time, information systems and training to implement the QAPI program.*

The QAPI CfC requires an ASC to take a proactive, comprehensive, and ongoing approach to improve the quality and safety of delivered surgical services. These guidelines presume that ASCs employ a systematic approach to evaluating their protocols and processes, identifying problems that have occurred or may potentially result from the ASC's practices, and getting to the root causes of problems rather than superficially addressing one issue at a time. This quality control process is essential to optimize the quality and safety of the ASC surgical environment. Quality control and improvement are essential characteristics of every healthy organization. It is vital to manufacturing. How much more vital is it to healthcare organizations that deliver highly sophisticated intraocular microsurgery? A robust, data-driven, facility-wide QAPI program must be a minimum standard in every surgical setting, including the office-based facility.

EMERGENCY PREPAREDNESS PLAN

416.54 Condition for Coverage: Emergency Preparedness

ASCs must comply with the applicable emergency preparedness requirements referenced in Appendix Z of the State Operations Manual.

ASCs must utilize an integrated all-hazards approach to emergency preparedness that focuses on identifying hazards and developing emergency preparedness capacities and capabilities that can address those as well as a wide spectrum of emergencies or disasters. This approach includes preparedness for natural, man-made, and or facility emergencies that may include but is not limited to: care-related emergencies; equipment and power failures; interruptions in communications, including cyber-attacks; loss of a portion or all of a facility; and, interruptions in the normal supply of essentials, such as water and food.

The emergency preparedness program describes the ASC's comprehensive approach to meeting the health, safety and security needs of the facility, its staff, its patient population, and community prior to, during, and after an emergency or disaster. The program encompasses four core elements: an Emergency Plan based on a Risk Assessment and incorporates an all-hazards approach; Policies and Procedures; Communication Plan; and the Training and Testing Program.

The ASC emergency plan provides the framework for the emergency preparedness program. The emergency plan is developed based on facility- and community-based risk assessments that assist a facility in anticipating and addressing facility, patient, staff, and community needs and support continuity of business operations. From the hurricanes of Florida to the tornadoes in Mississippi and Oklahoma to the earthquakes of California to the COVID pandemic, one thing is certain: emergencies are real, at times unpredictable, and given the magnitude of responsibility inherent in being a facility provider, devoting appropriate time and attention to developing and maintaining a current emergency preparedness plan (including the initial training and retraining of all staff) is essential to providing safe care.

At a minimum, offices that perform cataract and other ophthalmic procedures must be required to develop an emergency preparedness plan on the same scale to assure the health, safety, and security of the patients it serves.

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/her overall safety depends on the surgical facility strictly adhering to very 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.

Conclusion

With an extremely high success rate, low complication rate, and a significant positive impact on patients' daily lives, cataract surgery has been one of the great, unparalleled success stories in medicine for decades. These very positive outcomes are a direct result of cataract surgery being performed in the highly regulated setting of the hospital and ASC environments.

The nation's 6,000 ASCs, including 1,200 ophthalmic facilities, have demonstrated, by all measures, the ability to deliver consistently safe, high quality, and affordable care in the interest of patients and payers. Accordingly, and in keeping with this historical commitment, the provision of cataract surgery in the physician's office should be assessed against the national standards and best practices that have come to define the current ophthalmic ASC model, as dictated by the CMS ASC Conditions for Coverage. Until such time as office-based ophthalmic facilities are subject to such standards, patient health and safety will be potentially compromised in the office-based facility and it would be inappropriate to provide financial incentives such as nonfacility payments in the interim.

Thank you for providing the Outpatient Ophthalmic Surgery Society 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@OOSS.org or 301.332.6474.

Sincerely,

A handwritten signature in cursive script, appearing to read "D. S. George".

David S. George, MD
President, OOSS

REFERENCES

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