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# An Office Surgical Suite is Not an ASC: Patient Health and Safety Considerations

**T**he contemporary cataract surgery operating environment in an ASC 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 licensed and 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 substantial attention to detail.

A recent survey of Outpatient Ophthalmic Surgery Society (OOSS) member and non-member ophthalmic ASCs confirms that virtually all facilities are Medicare-certified; 85% are accredited by a CMS-approved agency as an ASC; and 81% are licensed by their states as ASCs. By contrast, office-based facilities are essentially unregulated. No states currently license such facilities, nor do they establish standards for the surgery provided therein. Advocates for office cataract surgery note that their facilities are “accredited.” However, these facilities are accredited as “offices,” with adherence to minimal standards that bear little resemblance to those applied to ASCs.

We are concerned that, in the absence of regulation and appropriate oversight, offices may compromise spending on staffing and equipment, resulting in adverse outcomes for patients.

## THE CATARACT DEMOGRAPHIC

Those furnishing cataract surgery in the office state that they will treat healthier and younger patients than those

served by ASCs. However, typically, cataract patients are older and have far more coexisting conditions than would be expected in a younger population.

In August of 2015, OOSS, in cooperation with the Association of Ambulatory Surgery Centers (ASCA) and the Society for Excellence in Eyecare, engaged 170 ophthalmic-driven ASCs in a comorbidity study to randomly sample the H&P records of 50 of their most recent cataract patient cases. The sampling totaled 8,500 cases, representing a total annual case volume of more than 400,000 cataract patient cases across the participating facilities, or approximately 13% of the total of all estimated cataract cases performed in the United States. Of patients included, 55% were 70+, while only 12% were younger than 60 years of age and 16% were 80+ years of age.

Based on six categories of comorbidity conditions (i.e., hypertension, cerebrovascular disease, pulmonary disease, endocrine disease, cancer, or none of the above), 88% of the patients presented two or more comorbidity conditions. The bottom line, in terms of identifying “routine” cataract cases, is that, currently, only 6% of cataract cases present without any comorbidities and most are taking multiple prescription medications associated with comorbidities.

Advocates for office cataract surgery suggest that the use of local anesthesia, or the use of oral medication as the sole anesthetic agent, mitigates the need for the highly regulated ASC or hospital surgical environment. However, this does not represent the current standard of care for cataract anesthesia. In a July 2020 survey of OOSS members, 72% of facilities reported that all patients having a surgical procedure get IV access, with 78% of these providing a Hep Loc and 22% IV with fluids. Respondents reported that in 83% of cases, IV access is provided by the anesthetist. Oral sedation is provided in only 35% of facilities. The accreditation standards that apply to office suites require neither the presence of anesthesia

professionals (nor even licensed nursing personnel), as required in the ASC—a problem potentially exacerbated by inadequately trained and/or non-licensed personnel assisting in the OR while also monitoring multiple patients' vital systems and recoveries.

### PHYSICAL ENVIRONMENT AND STAFFING

Medicare and Accreditation Association for Ambulatory Health Care (AAAHC) ASC standards—which must be equal to or more rigorous than those imposed by CMS if an accredited facility is to be “deemed” to be eligible for ASC facility reimbursement—set forth detailed requirements for the surgical environment, including operating room design and equipment, infection control, separate recovery room, emergency equipment, and personnel.

Office accreditation standards are far less rigorous. Offices are often located within multistory buildings; maintaining proper control over all safety and ventilation issues within a multi-use office building can be challenging, especially with regard to fire safety with proper firewall structures, fire safety equipment, and sprinkler systems. It is not hyperbole to suggest 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 surgical patients. Fire safety, smoke barrier and firewall protection around the surgical suite, and emergency backup power conditions are but a few such examples.

We strongly believe that the ASC requirements for life safety and 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.

CMS and AAAHC (again, for deemed status purposes) also require that the ASC have a separate recovery room and waiting area, which are not to be shared with another healthcare facility, such as the clinic. The AAAHC office accreditation program, on the other hand, has no such requirement. It is imperative that the office suite have a separate recovery area in order to properly monitor the patient before discharge.

Moreover, staffing must also be adequate to maintain patient monitoring throughout the surgical process. One nurse cannot monitor multiple patients in multiple areas without potential incident.

The postoperative patient recovering from anesthesia must be closely monitored and approved for discharge. If the surgical room is to be used for postoperative monitoring,

then patients may be rushed in order to make room for the next surgical patient. If office-based suites don't adhere to proper circulation patterns of patients, visitors, or staff, the result will be cross-circulation patterns that will lead to increased rates of infection. Importantly, ASCs are required to have Advanced Cardio Life Support (ACLS) personnel trained in the use of emergency equipment and cardiopulmonary resuscitation whenever there is a patient in the ASC.

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Medicare and AAAHC accreditation standards provide that the nursing service must be directed under the leadership of an RN and that there must be sufficient professional staff with the appropriate qualifications to ensure that the nursing needs of all patients are met.

Again, office accreditation standards are less rigorous, stating that RNs “or other healthcare professionals” must be available in sufficient numbers. In the office setting, the physician, for cost containment purposes, could determine that fewer than necessary nurses will be available in the surgical suite.

For example, one nurse cannot effectively act as the anesthesia/sedation provider and the postoperative care nurse unless only one operation is scheduled. Patients may require more sedation, either oral or IV, which can lead to longer recovery periods. One nurse cannot manage all roles without potential incident. At a minimum, office suites must be required to maintain licensed nursing staff and be managed under the direction of an RN.

### INFECTION CONTROL

Compliance with CMS and AAAHC ASC standards require that the surgery center provide a functional and sanitary environment for the provision of surgical services by adhering to professionally acceptable standards of practice (includ-

ing ventilation and water quality controls, safe air handling systems, techniques for cleaning and disinfecting surfaces, techniques for disposal of regulated and nonregulated waste, and pest control).

While the accreditation office standard does require a written program describing how infections and communicable diseases are prevented, identified, and managed, the standard does not proscribe in meaningful detail the professionally accepted standards of practice that are applicable to the ASC and hospitals and should be applied to offices.

### WHAT DO OUR PATIENTS DESERVE?

For decades, cataract surgery has been one of the great and unparalleled success stories in medicine, with an extremely high success rate, low complication rate, and significant impact on the daily lives of patients. These very positive outcomes are a direct result of cataract surgery having been performed in the highly regulated setting of the ASC and hospital 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, the furnishing of cataract surgery in the physician's office should be assessed against the standards and best practices that have come to define the current ophthalmic ASC model, as defined by the standards set forth by CMS and the deemed status ASC accreditation standards.

In a future issue, the ASC and OBS business models, short-term and long-term investment opportunities, risk management, and operational considerations will be explored. The evaluation will assist ophthalmologists in determining the most effective, efficient surgical facility while assessing the annual revenue potential of an ASC or OBS in order to build a marketable asset that will appreciate in value. ■

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