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SURGERY SOCIETY

November 19, 2018

Seema Verma, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-3346-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Via online submission at www.regulations.gov

Re: Medicare and Medicaid Programs: Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction (CMS-3346-P, 83 FR 183, published September 20, 2018)

Dear Administrator Verma:

The Outpatient Ophthalmic Surgery Society (OOSS) is a professional medical society that represents over 4,000 ophthalmologists, nurses, and administrators who specialize in providing high-quality ophthalmic surgical services in cost-effective ASC environments. OOSS is a member of the ASC Quality Collaboration (ASCQC), a cooperative effort of organizations and companies interested in ensuring that ambulatory surgical center (ASC) quality data is appropriately developed and reported. We are also affiliated with the major ASC accreditation agencies.

We appreciate this opportunity to comment on the agency's efforts to reduce regulatory burdens on ambulatory surgical centers (ASC). Our facilities are small businesses that have for several decades demonstrated an ability to contain administrative costs, thereby enabling ASCs to offer high quality care in a convenient and accessible patient-centered environment, conserving billions of dollars each year to the Medicare system and its beneficiaries. We applaud CMS for identifying and modifying several unnecessary and burdensome regulations that will enhance our capacity to reduce costs without compromising patient safety or the quality of care provided within our facilities. With respect to the ophthalmic services our members provide, notably cataract surgery, we are particularly pleased with the agency's proposal to eliminate the requirement that all patients undergoing procedures in ASCs or hospital outpatient departments (HOPD) receive a comprehensive history and physical exam (H&P) within 30 days prior to surgery.

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OOSS has long been an advocate for encouraging migration of surgical cases 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 5,500 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. 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 accreditation agency; and 81 percent are licensed by their states as ASCs. Surgery centers are highly regulated providers and the relief afforded by initiatives such as those embodied in the proposed rule will assist us in devoting maximum resources specific to the delivery of care to our patients.

Elimination of Requirement for History and Physical Examination Within Thirty Days Prior to Surgery

Our organization strongly supports the proposal to eliminate the requirement that all patients undergoing surgery in an ASC or HOPD receive a history and physical exam within 30 days prior to surgery and, in the alternative, allow facilities to establish policies developed in consultation with the operating surgeon and anesthesia provider that establish whether and when a comprehensive H&P should be required. The ophthalmic ASC team is uniquely qualified to define policies that address the special needs and circumstances of patients who are elderly and may be at higher risk of complications and in need of a comprehensive H&P or other external assessment. Every patient in the ASC or HOPD environment requires a thorough preoperative evaluation on the day of surgery of the risks associated with undergoing any procedure performed therein. However, the traditional H&P provided by a primary care physician is often unnecessary and duplicative of the evaluations performed in the clinic when the decision is made to perform surgery and by the clinical staff and anesthesia provider on the day of, but prior to the performance of the procedure.

The proposed rule appropriately contemplates that a comprehensive H&P is not typically required prior to cataract surgery and we support elimination of the requirement. Cataract and other ophthalmic surgeries performed in the ASC embody a low risk of intra- and post-operative



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complications, and do not typically challenge the patient either hemodynamically or from a cardiac perspective. Rather than requiring all patients to receive a pre-operative H&P, the surgeon, acting in a manner consistent with the policies and procedures of the ASC in which the surgery is being performed, should be permitted to determine which patients may require a comprehensive exam and which require only a pre-surgical assessment immediately prior to the procedure. The current requirement that every cataract patient receive a comprehensive H&P is unnecessary, burdensome, and wasteful:

- *The comprehensive H&P confers little if any benefit in terms of reducing complications.* Myriad studies both recent and over the past two decades, including those cited by the agency in the rulemaking, conclude that there is no clinical benefit to requiring that routine preoperative H&Ps be performed on all patients prior to cataract surgery. One study involving over 21,000 cataract surgeries {FN} examined 707 post-operative adverse events that included both systemic and ocular complications. The study found that 353 adverse events occurred in surgeries with pre-operative testing while 354 occurred in surgeries with no such testing, suggesting no correlation between preventing adverse events and the inclusion of preoperative testing as part of the patient assessment. When complications do occur in cataract surgeries, they typically involve ocular comorbidities, such as glaucoma, IFIS (Idiopathic Floppy Iris Syndrome), macular degeneration, pseudoexfoliation, and trauma. These comorbidities would not be identified in a comprehensive H&P performed by a primary care physician or specialist who is focusing on systemic concerns. Rather, they would be diagnosed during the ophthalmologist's preoperative assessment, and communicated directly to the professional staff at the ASC.
- *Requiring a comprehensive H&P causes a hardship for the patient and his or her caregivers.* Requiring a patient to have a comprehensive H&P that will not affect the outcome of the surgery means that the patient must make an unnecessary trip to his or her primary care physician. This is problematic because our patients are typically older with compromised vision and reliant on family or other caregivers to transport them to receive such care. The current requirement that the exam be performed within 30 days of surgery is particularly burdensome for the many patients that are having surgery on both eyes and may be required to undergo a second H&P if the second eye surgery occurs greater than 30 days or more after the initial exam, as currently mandated



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by CMS.

- *Requiring a comprehensive H&P is wasteful of Medicare program resources.* Cataract surgery is the highest volume Medicare surgical procedure and, as CMS states in the proposed rule's budgetary impact analysis, tens of millions of dollars are expended annually on services that provide no benefit in terms of quality of care or patient health and safety. Elimination of the mandatory H&P requirement will generate significant program savings and improve efficiencies in the delivery of care to our patients.

There are other ophthalmic surgical services that by virtue of their minimal invasiveness will virtually never require extensive preoperative assessment. These include, but are not limited to, all ocular laser procedures, including: YAG laser capsulotomy; YAG laser peripheral iridotomy; YAG laser vitreolysis; selective laser trabeculoplasty; Argon laser trabeculoplasty, Argon pan retinal photocoagulation; and topical refractive error treatments, such as LASIK, PRK, or limbal relaxation incisions.

Although the cataract patient will not typically need a comprehensive H&P, there are some patients having ophthalmic surgery who by virtue of their health status or the complexity of the procedure they are undergoing should be referred to an outside physician for further evaluation and assessment. The American Society of Anesthesiologists' Practice Advisory for Pre-anesthesia Evaluation states that: "It is the obligation of the health care system to, at a minimum, provide pertinent information to the anesthesiologist for the appropriate assessment of the severity of the medical condition of the patient and invasiveness of the proposed surgical procedure well in advance of the anticipated day of procedure for all elective patients." We respect this position and take this responsibility very seriously. Patients with cataracts and other ophthalmic conditions are typically older and have multiple comorbidities. The ophthalmologist and ASC clinical staff are neither trained nor equipped to conduct the assessment of the severity of all medical conditions and most facilities currently have policies regarding the referral of these patients to other providers as appropriate. The referral could be to a primary care physician or to a specialist such as a cardiologist, pulmonologist, endocrinologist, nephrologist, neurologist or other appropriate specialist.

Examples of patients whose health profiles may require such a referral for a more comprehensive evaluation prior to the day of surgery include those scheduled for intraocular/incisional surgery having histories of:



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- Myocardial infarction, cardiac event or surgery, or stroke in the past six months;
- COPD or asthma with poor lung sounds or shortness of breath;
- Uncontrolled diabetes, or signs of noncompliance with medications such as observed in diabetic retinopathy;
- Recent seizures, fainting, dizziness;
- Recent MRSA or active open wounds.
- Renal or liver disease

There are also non-cataract procedures that are more invasive and complex that may require a referral for a more comprehensive preoperative assessment prior to the day of surgery, including corneal transplants, oculoplastic procedures with extended periods of sedation, more complex retina procedures, and procedures requiring a retro-bulbar block, e.g., glaucoma valve implantation. As reflected in the proposed rule, the surgery center, in consultation with its operating surgeons and anesthesia providers, should be charged with developing policies and protocols for determining whether and when patients should be referred to external providers for more extensive evaluation.

OOSS strongly supports the agency's proposal to eliminate the requirement that all patients undergoing procedures in ASCs or hospital outpatient departments (HOPD) receive a comprehensive history and physical exam (H&P) within 30 days prior to surgery.

Governing Body and Management – Hospitalization Requirements

Under current Medicare ASC Conditions for Coverage, the ASC must either have a hospital transfer agreement with a local hospital or all physician providers of services in the ASC must have staff privileges at a local hospital. Both options available to the ASC and its physicians require good faith on the part of the hospital, a condition that has been lacking in some communities. Hospitals often use this requirement to garner a competitive advantage against the local ASC or impose unreasonably onerous “on call” arrangements as a prerequisite to granting admitting privileges.

The patient, the ASC, and the hospital are best served by the execution of a transfer agreement that will facilitate the coordination of patient care. However, ASCs should not have to close or be denied certification because of the lack of good faith on the part of the hospital. As the



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proposed rule reflects, the Emergency Medical Treatment and Labor Act (EMTALA) regulations will continue to address emergency transfers of patients from the ASC to the nearby hospital and ASCs will continue to be required to have procedures in place to ensure that patients can be immediately transferred to a hospital when emergency medical care beyond the ASC's capabilities is needed.

OOSS strongly supports the agency's proposal to eliminate the requirement that the ASC must either have a hospital transfer agreement with a local hospital or all physician providers of services in the ASC must have staff privileges at a local hospital.

Emergency Preparedness for Providers and Suppliers

OOSS strongly supports the agency's proposal to reduce the burdens on ASCs associated with emergency preparedness. These include: reducing the frequency of emergency program reviews from once a year to once every two years; eliminating documentation in the emergency plan of efforts to contact local, tribal, regional, state, and federal emergency responders and officials; reducing the frequency of emergency preparedness training to once annually; and, reducing the frequency of emergency testing exercises from twice a year to once a year for outpatient facilities. While ASCs are an important and integral part of the health care delivery system, most procedures performed in these facilities are elective in nature, and our centers do not face emergency situations to the extent that hospitals do. The flexibility afforded by the proposed rule will enable our facilities to devote more resources to providing the highest quality care to our patients.

Thank you for providing the Outpatient Ophthalmic Surgery Society with this opportunity to comment on this important rulemaking. Should you have any further questions, please contact our Washington Counsel, Michael A. Romansky, JD at mromansky@OOSS.org or 301-332-6474.

With best regards,

A handwritten signature in black ink, appearing to read 'Maria C. Scott', is written over a light blue horizontal line.

Maria C. Scott, MD
President, OOSS