



November 19, 2018

Seema Verma  
Administrator  
Centers for Medicare and Medicaid Services  
U.S. Department of Health and Human Services  
Washington, DC 20201

**Re: Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction**

Dear Administrator Verma:

The American Society of Cataract and Refractive Surgery (ASCRS) is a medical specialty society representing nearly 9,000 ophthalmologists in the United States and abroad who share a particular interest in cataract and refractive surgical care.

We appreciate this opportunity to provide comments in response to this proposed rule on regulatory provisions to promote program efficiency, transparency and burden reduction. ASCRS supports several of the provisions included in this proposed rule aimed at reducing regulatory burdens on physicians and healthcare facilities.

**Proposal to Remove Requirement for H&Ps**

Chiefly, we support the proposal to remove requirements that all patients undergoing surgery in ambulatory surgery centers (ASCs) or hospital outpatient departments (HOPDs) receive a comprehensive history and physical exam (H&P) within 30 days prior to surgery, and instead give facilities the ability to establish policies, developed in conjunction with the clinical judgement of operating surgeons, that designate when an H&P should be performed. Ophthalmic surgery, such as cataract surgery, is performed solely in ASCs or HOPDs, and while highly intense, the risk of systemic complications is extremely low. When rare complications do occur, they are generally ocular complications, which ophthalmologists are vigilant to anticipate and address, but cannot be prevented by an H&P. We agree with the conclusions of the studies cited in the proposed rule demonstrating no difference in either ocular or systemic intra- or post-operative complications when H&Ps are performed on all patients and with the concerns that the requirement may be contributing to unnecessary Medicare expenditures. We urge CMS to finalize these proposals to reduce the burden physicians, facilities and patients, and potentially reduce costs to the Medicare program.

In addition, we support the following provisions of the proposed rule:

- **Support for the elimination of written transfer agreements between ASCs and hospitals and the requirement that physicians operating in ASCs have admitting privileges at the hospital with the transfer agreement.** In an effort to reduce competition from lower-cost ASCs, many

hospitals are refusing to enter into these agreements with ASCs or providing surgeons operating in ASCs with admitting privileges. In addition, we agree with CMS' assessment that EMTALA would require any hospital to accept a patient from an ASC if a rare complication were to occur. The current requirements for a written agreement and admitting privileges are burdensome and does not confer any additional benefit to patients and should be removed.

- **Support for the proposal to increase flexibility and reduce burdens associated with facilities' emergency preparedness programs.** While we are committed to ensuring the safety of patients and preparing for emergencies, current regulations may require more planning and testing than is required by all facilities. We support decreasing the frequency of emergency program reviews from once a year to once every two years; eliminating documentation of efforts to contact emergency responders and officials; reducing the frequency of emergency preparedness training; and reducing the frequency of emergency testing exercises from twice a year to once a year.

Full comments on these issues are below.

#### **Elimination of Required Pre-Operative History and Physical Exam**

**ASCRS strongly supports CMS' proposals to eliminate the requirement that all patients undergoing procedures in ASCs or HOPD receive a comprehensive H&P no later than 30 days prior to the surgery. We support CMS' proposal to leave the decision to perform an H&P to the physician's clinical judgement and require facilities to establish their own policies and procedures for designating on which patients these exams should be performed. Ophthalmic surgery, and cataract surgery in particular, is solely performed in outpatient settings and research has shown that pre-operative H&Ps do not reduce potential ocular or systemic complications or improve outcomes, and in fact, are increasing unnecessary Medicare expenditures. We urge CMS to finalize this proposal to reduce burden on physicians, facilities, and patients, and provide financial savings to the Medicare program.**

- **Clinical research has concluded that there is no clinical benefit to requiring routine pre-operative H&Ps be performed on all patients for cataract surgery.** CMS itself sites several recent studies in the proposed rule that recommend against pre-operative testing on all patients undergoing cataract surgery. One such study examined the 707 post-operative adverse events, which included both systemic, such as hypertension, hypotension, and arrhythmia, and ocular complications, such as posterior capsule ruptures and posterior capsule ruptures with vitreous loss. Out of 21,531 cataract surgeries, the study found that 353 adverse events occurred in surgeries with pre-operative testing, while 354 events occurred in surgeries with no pre-operative testing, suggesting no correlation between preventing adverse events and pre-operative testing.<sup>1</sup> When rare ocular complications do occur in cataract surgery, they are generally due to ocular co-morbidities, such as glaucoma or macular degeneration, previous eye injuries, pseudoexfoliation, or intra-operative floppy iris syndrome caused by the patient taking tamsulosin. These ocular co-morbidities, if not already known to the ophthalmologist, would be diagnosed during the ophthalmic pre-operative evaluation that must be done to determine, among other things, intraocular lens (IOL) measurement and selection. These ocular co-morbidities would not be determined by a comprehensive physical exam focusing on systemic

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<sup>1</sup> Keay, L., et.al., Routine preoperative medical testing for cataract surgery. *The Cochrane Collaboration*, 2012.

issues. Therefore, **ASCRS supports the proposal to eliminate routine H&Ps on all patients undergoing cataract surgery because they do not reduce either ocular or systemic inter-operative or post-operative complications.**

- **Facilities should develop policies on when a pre-operative H&P should be performed in conjunction with the surgeons operating in the facility, and the policies should be based on the surgeons' clinical judgement.** Cataract and other ophthalmic surgeries performed in ASCs or HOPDs have a low risk of intra- and post-operative complications, however, ophthalmic surgery still involves some systemic risk. While it may not be appropriate to perform pre-operative H&Ps on most patients, more extensive pre-operative exams may be appropriate if a patient requires deeper levels of anesthesia or has significant systemic co-morbidities. Rather than require all patients to undergo a pre-operative H&P, the surgeon should be able to determine based on clinical judgement which patients may need a comprehensive exam, and which patients only require a pre-surgical assessment immediately prior to the procedure. Surgeons and facilities should work together to establish policies and protocols to identify which types of patients undergoing certain procedures are likely to need a full H&P. **We support CMS' proposal to eliminate the requirement that H&Ps be performed on all patients undergoing cataract or other ophthalmic surgery and leave the decision to perform the exam to clinical judgement. We also support the requirement that facilities develop a policy to identify which patients need the H&P.**
- **Requiring an H&P for all ophthalmic procedures performed in an ASC or HOPD within 30 days prior to surgery is burdensome to the patient.** Cataract, and other ophthalmic surgery, is often performed on an older cohort of patients. Elderly ophthalmic patients may have reduced vision and rely on family or other caregivers to transport them to receive medical care. Requiring a patient to receive a comprehensive H&P that likely does not impact the outcome of the ophthalmic procedure, means the patient will have to take an additional trip to their primary care physician's office, beyond pre-operative testing and post-operative follow-up visits and the surgery itself. The existing requirements that the exam be performed no more than 30 days prior to the procedure are additionally burdensome for ophthalmic patients who are undergoing surgery on both eyes and may have to receive two exams if the second eye's surgery occurs 31 or more days following the initial exam. **We support the proposal to eliminate the requirement that an H&P be performed for all ophthalmic procedures, and the H&P only be performed when the physician determines it to be necessary in conjunction with the facility.**
- **Removing the requirement that an H&P be performed before all ASC and HOPD surgeries will confer a significant savings to the Medicare program.** Cataract surgery is the most frequently reimbursed procedure in the Medicare program, and is the most frequent surgery performed in ASCs. In addition, the millions of ophthalmic surgeries performed each year are solely in outpatient settings. By eliminating the requirement that the H&P be performed on all patients and allowing physicians to use their clinical judgement to identify the limited number of patients for whom the H&P is warranted, CMS will realize substantial savings to the Medicare program. Ophthalmologists have already embraced the need to make efficient use of scarce resources and made extensive strides in perfecting the safety and outcomes of ophthalmic surgery so that it can be performed in the lower cost outpatient setting. **ASCRS believes that removing the requirement that H&Ps be performed on all patients is yet another step in improving efficiency, without adding additional risk.**

### **Elimination of Hospital Transfer Agreements and Admitting Privileges**

- **ASCRS supports CMS' proposal to eliminate the requirement that ASCs have a written transfer agreement with a hospital, and that surgeons operating in the ASC have admitting privileges at that hospital.** As noted above, ophthalmic surgery, especially cataract surgery, is overwhelmingly successful with minimal risk of intra- or post-operative systemic adverse events that would require the patient be transferred to an acute care hospital. Given that hospitals may see lower cost ASCs as potential competition, they may be unwilling to enter into a written agreement to accept patient transfers from the ASC, or provide surgeons operating in the ASC with admitting privileges at the hospital, and so complying with current requirements may be difficult for some ASCs. In addition, as CMS notes in the proposed rule, in the unlikely event that a patient undergoing ophthalmic surgery in an ASC were to suffer complications that required emergency transfer to a hospital, the hospital would be required to treat the patient based on EMTALA, regardless of whether it had a written agreement with the ASC or not. **ASCRS recommends CMS finalize this proposal as it will eliminate an unnecessary and burdensome regulation for ASCs.**

### **Emergency Preparedness**

- **ASCRS supports CMS' proposals to reduce the burdens associated with emergency preparedness. We support the proposals to:**
  - **Reduce the frequency of emergency program reviews from once a year to once every two years;**
  - **Eliminate documentation in the emergency plan of efforts to contact local, tribal, regional, state, and federal emergency responders and officials;**
  - **Reduce the frequency of emergency preparedness training to once annually; and**
  - **Reduce the frequency of emergency testing exercises from twice a year to once a year for outpatient facilities.**
- **CMS' proposals to reduce the burdens associated with emergency preparedness will have a positive impact on ASCs, where most ophthalmologists perform surgery.** As noted above, clinical advances have reduced the risk associated with ophthalmic surgery, such as cataract surgery, and enabled ophthalmologists to perform most procedures in lower cost ASCs. Since reimbursement for procedures performed in ASCs is about 50% less than in HOPDs, ASCs have smaller profit margins and fewer resources to expend on overhead. While ASCs are committed to preparing and planning to protect patients in the event of man-made or natural disasters, or other emergencies, excessive requirements related to emergency preparedness may be burdensome on facilities. Some facilities may determine that it is sufficient to conduct planning reviews and training less frequently, and should have the flexibility to conduct these activities as they are needed. We appreciate that CMS has recognized this and is proposing to reduce or

eliminate some emergency preparedness requirements and allow an ASC, or other facility, to determine what steps to take beyond CMS' minimum requirements that may be appropriate for a particular facility. **We recommend CMS finalize its proposals related to emergency preparedness.**

**Conclusion**

ASCRS thanks CMS for the proposals included in this proposed rule that reduce regulatory burden and improve efficiency. **We support the proposals to eliminate mandatory H&P testing on ophthalmic procedures performed in ASCs or HOPDs, eliminate the requirement that ASCs have written transfer agreements with hospitals and surgeons have admitting privileges at those hospitals, and the modifications to current emergency preparedness requirements.** We believe these proposals will reduce burden and improve efficiency in the Medicare program. Most importantly, these proposals do not confer additional risk to patients. We encourage CMS to finalize these proposals.

If you have questions, please contact Allison Madson, manager of regulatory affairs, at [amadson@ascrs.org](mailto:amadson@ascrs.org) or 703-591-2220.

Sincerely,



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President, ASCRS