June 22, 2010

Ms. Marilyn Tavenner
Acting Administrator
Center for Medicare and Medicaid Services
Department of Health and Human Services
Attention: 3217-P
P.O. Box 8010
Baltimore, Maryland 21244-8010

RE: CMS-3217-P, Medicare Program; Ambulatory Surgical Centers, Conditions for Coverage

Dear Ms. Tavenner:

The American Academy of Ophthalmology is the largest association of eye physicians and surgeons – Eye M.D.s – with more than 18,000 members in the United States. AAO members perform the majority of cataract procedures performed in ambulatory surgical centers (ASC) and hospitals.

The American Society of Cataract and Refractive Surgery (ASCRS) is a medical specialty society representing over 10,000 ophthalmologists in the United States and abroad who share a particular interest in cataract and refractive surgical care. ASCRS members perform the vast majority of cataract procedures furnished annually in ASC and hospitals.

The Outpatient Ophthalmic Surgery Society (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.

On behalf of AAO, ASCRS and OOSS, we comment on the proposed rule to revise the Condition for Coverage (CfC) for patient rights, which would clarify the conditions under which a patient may be treated in an ASC the same day he receives notice of his rights. Our organizations are seriously concerned that the proposal (in conjunction with the rule adopted last year), by mandating that patients be notified of their rights at least a day in advance of surgery in an ASC, will unnecessarily diminish access of patients to same day services at ASCs with no corresponding patient health and safety benefit. We respectfully urge CMS to subject ASCs to the same notice standards applied to hospitals admitting patients for same day surgery or otherwise preserve the right of patients, as they did prior to 2009, to elect to be treated the same day that their physician identifies the need for surgery.

OVERVIEW

The nation's 5,100 ASCs are committed to providing Medicare beneficiaries with access to the highest quality surgical care while lowering their cost-sharing obligations and assisting the Medicare program in the containment of health expenditures. Studies conducted by a multitude of federal agencies (including CMS; the Government Accountability Office; the Medicare Payment Advisory Commission; the Office of the Inspector General, HHS; and the Federal Trade Commission) have lauded the work of ASCs, recognizing that surgery centers provide care at levels of quality equal to or surpassing hospital outpatient departments (HOPD), at lower cost to the program and to beneficiaries, and in a patient-friendly and convenient environment that leads to the highest levels of patient satisfaction.

Cataract surgery in the ASC is emblematic of the phenomenon of the ASC becoming the choice of physicians and beneficiaries for site of surgery. About three cataract operations are performed each year; in consultation with their ophthalmic surgeons, more than 60 percent of patients select the ASC over the HOPD as their site of surgery. A study commissioned by MedPAC and undertaken by RAND Health in October, 2006, Further Analyses of Medicare Procedures Provided in Multiple Ambulatory Settings, concluded that, with respect to all statistically significant measurements after risk adjustment, cataract patients had fewer adverse outcomes (endophthalmitis, iris prolapse, cataract fragments, and persistent corneal edema) following surgery furnished in the ASC, as compared with the HOPD.

In an endeavor to assess effectiveness of sterilization techniques, our three organizations designed a comprehensive survey instrument that was completed by 168 OOSS member ASCs, all Medicare-certified, during the period June-July, 2008. These ASCs reported on ophthalmic cases performed in their facilities during the twelve months preceding the survey. Of 455,709 cases reported in ophthalmic ASCs, 52 facilities reported 95 cases of endophthalmitis, of which 36 cultured positive, yielding an infection rate of 0.02%. With respect to toxic anterior segment syndrome (TASS), 16 facilities reported 88 cases, yielding an incidence of 0.019%.

We offer these study and survey results to demonstrate that ophthalmic ASCs take patient health and safety very seriously; our frustration with the patient notice rule issued last year and the April 23 proposal is that it has does not impact on health quality and will, we believe, continue to adversely affect our patient' surgical experience. The patient who is not permitted access same day services in the ASC is confounded with quite an unnecessary and irrational alternative: substantially increase out-of-pocket costs or put off the treatment, further inconveniencing the patient and their family and extending discomfort, vision problems and anxiety.

OUR CONCERNS WITH THE PROPOSED RULE

When CMS issued its proposal to modify the Conditions for Coverage in 2007, we were generally very pleased that the agency had struck a fair balance between the need to optimize quality of care and patient safety and reflect the needs and circumstances of an array of surgical providers that are diverse as to size, specialty, and type of patient. However, we were surprised when the final rule published in 2009 included a provision, never proposed, that mandated that an individual must receive notice of his patient rights in advance of (i.e., at least the day before) surgery, essentially precluding the performance of surgery in an ASC on the same day that the need for surgery is diagnosed. This past year, our concerns have been affirmed; ophthalmic ASCs throughout the country report that their patients, particularly those who have travelled great distances, or who have had family members take off work to accompany them to the physician's

office, express anger and frustration at having to return another day, at great inconvenience and sometimes cost, when a simple procedure might have been performed that same day in the adjoining surgical facility.

It is our hope that the agency will expand the proposed exception. We believe that it is important that patients understand their rights, have knowledge of the facility's advance directive policies, and be aware of physician ownership. We have presented comments supportive of these policies in the past. However, the new notice and disclosure requirements, as related to timing and delivery to the patient in advance of the date of surgery, are neither practical nor feasible. If we believed that these requirements would result in improvements in patient care or patient health and safety, we would embrace them. We have come to the unfortunate conclusion, based upon a year's experience with the patient notice provision, that these will not accomplish this objective, and, instead, they have been disruptive to the delivery of optimal patient care.

Medical necessity is but one of several factors that might legitimately result in the scheduling of services on the same day. Over the course of the past quarter-century, patients have come to expect that providers will do their utmost to provide care in a manner that optimizes patient convenience and minimizes time and travel demands, not just for the patient, but for the family members of the patient, those dedicated caregivers who may need to accompany them on the visit to their provider. One of the great appeals of the ASC is that the patient and family member can be spared additional inconvenience and transportation expense by having surgery on a same day basis if it is medically appropriate. We emphasize that scheduling the patient for surgery the same day as diagnosis is for the benefit of the patient, not the surgeon or facility.

The agency's policy of disallowing the performance of surgery in an ASC on the day of referral, except in very limited cases, causes unnecessary inconvenience and economic hardship to many ophthalmic patients throughout the country. Perhaps it would be helpful to illustrate how this proposal (and its precursor adopted last year) actually impacts upon the ophthalmic patient seeking care in the ASC. A patient living in rural Tennessee notices decreased vision in one or both eyes and decides to visit the closest ophthalmologist, located 90 miles away. He is 85 years old and no longer drives, so his daughter takes a day off of work to drive him to the appointment. The patient had cataract surgery in both eyes during the prior decade, had excellent vision for several years, but his vision has deteriorated progressively. The physician performs a complete examination, including dilation, and discovers that the vision has declined because of posterior capsule opacity, which is treated very effectively with a posterior capsulotomy, utilizing a YAG laser. The patient, his daughter and the ophthalmologist have a detailed discussion about the condition, the surgical procedure, and other matters relating to informed consent.

Prior to May, 2009, when the CfCs were revised, the patient would have been escorted to the ASC, which typically adjoins the office, the ASC staff would have provided him and his daughter with an explanation of his rights, the procedure being performed, and in less than an hour, they would have been on their way home. Under the new requirement that the patient be informed of his rights at least a day in advance of his surgery, the patient remains in a state of discomfort and visual infirmity for another day, week, or month until he is able to return to the facility, and perhaps anxious and angry that he isn't able to have the simple procedure performed that day. He must now travel to and from the facility on another occasion. There could be loss of income or vacation time by accompanying family members. Patients are typically frustrated by this scenario and complain to physicians and ASC staff. As surgeons and ASC owners, we can explain that government regulations require us to make our patients return to the facility another day. However, our frustration is that we are unable to provide a rational basis for the policy.

Patient notice requirements should be applied equally in all settings. Just as our organizations have argued that payment policies should be aligned to the maximum extent possible across care settings, so, too, should policies that impact upon the selection of surgical site. In the hospital, the notice of patient's rights may be provided "in advance of furnishing or discontinuing care whenever possible." (Sec. 482.13(a)(1). Notice of physician ownership may be provided "at the beginning of the patient's hospital stay or outpatient visit," which is further defined to begin with the "provision of a package of information regarding scheduled preadmission testing and registration for a planned. . . outpatient admission." (Sec 483.13(b)(2) and 42CFR 489.20(u).) As such, if the surgeon believes that his patient believe that the appropriate surgical environment is the hospital, the patient can be operated on the same day as the referral; however, if the surgeon and patient believe that the ASC is the preferred place for surgery, the patient must return for his surgical care another day. The proposed rule provides an unnecessary and inequitable hindrance for care to be provided in the ASC.

RECOMMENDATIONS

AAO, ASCRS, and OOSS recommend that the proposed rule be substantially broadened to permit the patient, in consultation with his surgeon, to elect to have surgery on the same day that he is provided notice of his rights in the ASC. This might be accomplished in several ways:

- Reverting to the CfC patient rights language in existence from 1982 through 2009;
- Subjecting ASCs to the same notice standards applied to hospitals admitting patients for same day surgery; or,
- Implementing a process through which a patient (or family or surrogate of the patient) who would be subject to significant inconvenience or financial hardship by a delay in surgery would sign a waiver permitting the ASC to provide the surgery on the day notice is provided.

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Thank you for providing our organizations with the opportunity to present our comments on the proposed rule. Should you have any questions or require further information please feel free to contact us at: Cherie McNett, Director of Health Policy, AAO, cmcnett@aaodc.org, 202.737.6662; Emily Graham, Associate Director of Government Relations, ASCRS, egraham@ASCRS.org, 703.591.2220; or, Michael Romansky, JD, Washington Counsel, OOSS, mromansky@OOSS.org, 301.332.6474.

Thank you for your consideration of our views.

Sincerely,

American Academy of Ophthalmology
American Society of Cataract and Refractive Surgery
Outpatient Ophthalmic Surgery Society