



CMS Clarifies Policy to Permit Use of Short Cycle Steam Sterilization in Ophthalmic ASCs February 5, 2015

Following strong advocacy efforts by the American Academy of Ophthalmology (the Academy), the American Society of Cataract and Refractive Surgery (ASCRS), and the Outpatient Ophthalmic Surgery Society (OOSS), the Centers for Medicare & Medicaid Services has clarified that the practices of most ophthalmic ASCs would be in compliance with its rules governing instrument sterilization.

In order to comply with Medicare regulations and avoid citation in a facility survey, the ASC must adhere to the sterilizer manufacturer's directions for use (DFUs).

This past fall, our organizations reported that the Centers for Medicare and Medicaid Services (CMS) had issued an update to the Medicare ASC Conditions for Coverage mandating that immediate use steam sterilization (IUSS) could no longer be used in the ASC on a routine basis. Such a policy appeared to require ASCs to utilize terminal sterilization units and perhaps acquire many more sets of instruments. In response, the Academy, ASCRS, and OOSS met on two occasions with the agency to express our concerns about the new policy, focusing on educating CMS staff regarding the etiology of toxic anterior segment syndrome (TASS) and endophthalmitis and to provide the results of a recent survey of ASCs of their current sterilization and instrument cleaning practices.

The confusion related to the nomenclature used to describe the sterilization processes. CMS believes that the term IUSS, which is now prohibited on a routine basis, refers to the practice formerly known as "flash" sterilization. According to CMS, the vast majority of ophthalmic ASCs are practicing short-cycle steam sterilization, which is permissible as long as the DFU's are followed. The agency will be educating Medicare surveyors regarding this clarification of its policy.

The Academy, ASCRS, and OOSS have convened an expert panel to update existing guidelines regarding the cleaning and sterilization of ophthalmic instruments.

Should you have any questions, please contact Nancey McCann, ASCRS/ASOA Director of Government Relations, at nmccann@ascrs.org or 703-591-2220.