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Center for Medicaid and State Operations/Survey & Certification Group

Ref: S&C: 10-14-ALL

DATE: **April 2, 2010**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Guidance to Surveyors Regarding the STERIS SYSTEM 1® Sterile Processing System (SS1)

Memorandum Summary

- ***The Food and Drug Administration (FDA) Has Issued a Notice on the SS1:*** The FDA has reported that the manufacturer of the SS1 has significantly modified the device, and the FDA has not approved or cleared this modified product. Thus, the FDA has not determined whether the SS1 is safe or effective for its labeled claims.
- ***18-Month Period Identified for Transition:*** The FDA recommends an 18-month period during which healthcare facilities should identify legally marketed equipment to replace the use of the SS1. This applies to any healthcare facility using the SS1.
- ***Citation Related to Continued Use of the SS1:*** Instructions are outlined for when and at what level surveyors should cite continued use of the SS1.
- ***Guidance May Change:*** The manufacturer is seeking FDA approval of the modified SS1. Updated guidance will be provided if approval is granted.

The SS1 is tabletop sterile processing system that uses peracetic acid to achieve low temperature sterilization of immersible surgical and diagnostic devices. The SS1 is commonly used in hospitals as well as many outpatient/ambulatory care settings.

On December 3, 2009 the FDA issued a Notice and Recommendations regarding the SS1. The full text of this notice is available at http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm191585.htm. In this notice, the FDA reported that modifications by the manufacturer to the SS1 system have not been approved or cleared. For that reason, the FDA has not determined whether the SS1 is safe or effective for its labeled claims.

The FDA has urged health care facilities to find acceptable alternatives to the SS1 to meet their sterilization and disinfection needs. A list of FDA cleared sterilization and disinfection products that are acceptable alternatives to the SS1 can be found at http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm194429.htm.

The FDA has indicated that its action is not a recall and that it does not expect that use of the SS1 be immediately discontinued. On February 2, 2010 the FDA updated the December 3, 2009 notice to extend the time period for facilities to transition to a legally-marketed alternative. The updated information is available at http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm199567.htm.

Facilities should be able to transition to a legally marketed alternative within 18 months of the February 2, 2010 update. In addition, the manufacturer, STERIS, has submitted a new 510(k) pre-market notification to the FDA to have the modified SS1 cleared (i.e., approved). Depending on the results of that process, the instructions provided below may change; we will send out an update if this occurs.

It has been reported that there are over 20,000 SS1 units in use. As a result it is likely that State Agencies will encounter use of the SS1 during surveys of some health care facilities. Infection control deficiencies related to continued use of the SS1 are to be handled in the following manner:

Through August 2011, surveyors will ***not*** cite an infection control deficiency in Medicare-certified facilities using the SS1. Surveyors must, however, inquire whether the facility is aware of the FDA action with respect to the SS1. Facilities that are aware of the FDA action should be in the planning or implementation phase of transitioning to an FDA-approved substitute. Facilities that were not aware of the FDA action prior to the survey should expeditiously start the transition to an alternative product.

After August 2011, surveyors who observe use of the SS1 should cite the facility under the applicable infection control standards. A deficiency would be cited at the standard-level if the facility is actively transitioning to an approved alternate system. Such facilities must be able to establish that replacement of the SS1 is underway, e.g., by provision of copies of a completed order for replacement equipment. For facilities that are using the SS1 and that are unable to show (e.g., through documentation) they are in the process of obtaining a legally marketed alternative, a condition-level citation should be considered.

Effective Date: Immediately. Please ensure that all appropriate staff are fully informed within 30 days of the date of this memorandum.

Training: The information contained in this letter should be shared with all survey and certification staff, their managers, and the State/RO training coordinators.

Questions about this memorandum should be addressed to Marilyn Hanchett RN at marilyn.hanchett@cms.hhs.gov.

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management