New Survey Process for Duodenoscopes/ Endoscopes/ Reusable Medical Devices

The Centers for Disease Control and Prevention (CDC), in conjunction with the Food and Drug Administration (FDA), has issued a Health Advisory through their Health Alert Network urging healthcare administrators, providers, and facilities to immediately review procedures for cleaning, disinfecting, and sterilizing reusable medical devices. The Centers for Medicare & Medicaid Services (CMS) continues to rely on CDC and FDA guidance during facility surveys to assess for compliance with infection control regulations. Recent survey results, even after multiple media reports and investigations of infectious disease outbreaks, continue to reveal problems with the cleaning and disinfection of reusable medical devices.

CMS strongly supports the recommendations that facilities assess their reprocessing and sterilization procedures, including: training of personnel who reprocess medical devices; adherence to cleaning, disinfection, sterilization, and device storage procedures; and infection control policies and procedures. In this Health Advisory, CDC recommends steps that facilities should take to ensure patient and healthcare personnel safety. Most of these recommendations would be observed by surveyors during a survey in a CMS certified or deemed facility. The CMS Hospital Infection Control Surveyor Worksheet is an excellent self-assessment tool for facilities to use. The Survey and Certification policy memorandum, S&C 15-32, provides more in depth recommendations on duodenoscope/endoscope reprocessing. A facility which uses the self-assessment tools will not only protect patients from the potential transmission of infectious diseases, but also be considered more successful in application of infection control procedures and more likely to demonstrate compliance to surveyors.

After close consultation with CDC and FDA, CMS has specified two new policies during the survey process. First, in accordance with policy memorandum S&C-15-32, surveyors entering a facility, will inquire whether that facility performs Endoscopic Retrograde Cholangiopancreatography (ERCP) using a duodenoscope. If so, surveyors will request a copy of the manufacturer's instructions for use for cleaning and disinfecting the duodenoscope, as well as any automatic endoscope reprocessors the facility uses in reprocessing duodenoscopes. Further, surveyors must observe endoscopes being reprocessed and should ask the responsible staff to explain and demonstrate how they adhere to manufacturer's instructions and multisociety guidance. Second, policy memorandum S&C- 14-44 makes clear that facilities that sterilize reusable surgical instruments must not use immediate use steam sterilization as a routine method of sterilization. CMS is highlighting these policy changes to alert facilities that surveyors will be observing these practices to assess compliance with the regulations. By highlighting this Health Advisory, CMS encourages facilities to review their current practices and correct any potential deficiencies to be compliant with CMS policy and reduce the risk of infectious disease transmission.

Questions can be sent to HospitalSCG@cms.hhs.gov.