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CMS/
CENTERS for MEDICARE & MEDICAID SERVICES

Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-08-20

DATE: **May 16, 2008**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Safe Injection Practices in Ambulatory Surgical Centers (ASCs)

Memorandum Summary

- **Safe Practices**: 42 CFR 416.44(a)(3) requires every ASC to establish a program for identifying and preventing infections, maintaining a sanitary environment, and reporting the results to appropriate authorities.

- **Alerts**: Recently the State of Nevada and federal epidemiologists identified a cluster of hepatitis C infections where the infected individuals all had procedures in the same ASC. Subsequent survey of that ASC identified unsafe injection practices

- **Resources**: The Centers for Disease Control and Prevention (CDC) has developed pertinent information on safe injection practices. State Agencies (SAs) should disseminate this information to certified ASCs in their States, and should also ensure that all surveyors who conduct ASC surveys are familiar with this material.

- **Priority for Surveys:** Beginning in 2006 the Centers for Medicare & Medicaid Services (CMS) raised the priority for targeted surveys of ASCs. Targeted surveys (5% of all ASCs) are conducted as a priority in Tier 2, while the remaining ASCs are prioritized in Tiers 3 and 4. SAs must ensure that they complete this work. CMS will also be making additional resources available in FY 09 to expand the size of the Tier 2 sample.

Recently the State of Nevada and federal epidemiologists identified a cluster of hepatitis C virus (HCV) infections where the infected individuals all had procedures in the same ASC, which performed endoscopy procedures. Subsequent survey of that ASC identified unsafe injection practices related to the re-use of syringes and multiple re-use, among multiple patients, of single-use anesthesia medication vials. As a result, over 40,000 individuals who were treated at that ASC in recent years were notified of a potential exposure to bloodborne infectious diseases (i.e., HCV, hepatitis B virus, and HIV). Nevada has also identified other ASCs in the State that employ deficient infection control practices.

Unfortunately, this recent incident in Nevada is not the only one where unsafe injection practices and other deficient infection control practices in ambulatory care facilities have resulted in outbreaks of infectious diseases that could and should have been prevented. According to the CDC, in 2001 19 HCV cases in New York City were likely due to contamination of multiple-dose anesthesia medication vials in an endoscopy clinic.   In 2002, 99 cases of HCV were associated with infection control breaches related to catheter flushing in an oncology clinic in Nebraska.   According to the CDC, additional outbreaks of a similar nature have occurred in a number of other states in a variety of ambulatory care settings.

CDC Infection Control Information and Guidelines

A recent CDC presentation on Unsafe Injection Practices, along with audio and a transcript of the presentation are available at:
http://www.cdc.gov/ncidod/dhqp/COCA_Unsafe_Injection_Practices.html

Additional CDC information related to infection control may be found at:

• Re: infection control and injection practices
http://www.cdc.gov/ncidod/dhqp/ps_providerInfo.html

• Re: protecting patients from bloodborne pathogens in healthcare settings
http://www.cdc.gov/ncidod/dhqp/bp_patient.html

• Re: prevention of surgical site infections
http://www.cdc.gov/ncidod/dhqp/gl_surgicalsite.html

• Re: hand hygiene in healthcare facilities
http://www.cdc.gov/handhygiene/

• Re: healthcare facility physical environment and infection control
http://www.cdc.gov/ncidod/dhqp/gl_environinfection.html

CDC's home page for infection control provides links to additional information:
http://www.cdc.gov/ncidod/dhqp/index.html

ASC Infection Control Regulatory Requirements

42 CFR 416.44(a)(3) requires every ASC to establish a program for identifying and preventing infections, maintaining a sanitary environment, and reporting the results to appropriate authorities. Serious breaches of the requirements of this provision must be cited as a Condition-level deficiency for the Environment Condition for Coverage, found at 42 CFR 416.44.

In order to ensure that ASCs are aware of these infection control requirements and are well informed about basic infection control practices, including injection safety, CMS requests that you share this memorandum with all ASCs in your state. The CDC information identified above should be useful

in helping both ASCs and surveyors to understand what is considered the standard of practice for infection control.

Surveyors who examine compliance of ASCs, as well as other non-long term care facilities, with applicable infection control regulatory requirements are expected to be familiar with current infection control practices. Although CDC guidelines have not been specifically incorporated into the regulation, it is appropriate for surveyors to use these guidelines as a resource when reviewing infection control practices. However, any deficiency citations must be framed in terms of the specific deficient practice(s) identified and the resulting failure of the ASC to prevent infection or maintain a sanitary environment.

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.

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management