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Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-07-11

DATE: January 12, 2007

TO: State Survey Agency Directors

FROM: Director

Survey and Certification Group

SUBJECT: Use of Alcohol-based Skin Preparations in Anesthetizing Locations

Memorandum Summary

- This letter addresses risk reduction techniques to permit safe use of alcohol-based skin preparations in inpatient or outpatient anesthetizing locations in hospitals, Critical Access Hospitals (CAH) or Ambulatory Surgical Centers (ASC).
- Alcohol-based skin preparations are considered the most effective and rapid-acting skin antiseptic, but they are also flammable and contribute to risk of fire.
- When alcohol-based skin antiseptics are used in anesthetizing locations that have *not* implemented effective fire risk reduction measures, then the use of such antiseptics should be cited as evidence of noncompliance with §482.41(b), §485.623(d), or §416.44(b).

It is estimated that approximately 100 surgical fires occur each year in the United States, resulting in roughly 20 serious patient injuries, including one to two deaths annually. Fires occur when an ignition source, a fuel source, and an oxidizer come together. Heat-producing devices are potential ignition sources, while alcohol-based skin preparations provide fuel. Procedures involving electro-surgery or the use of cautery or lasers involve heat-producing devices. There is concern that an alcohol-based skin preparation, combined with the oxygen-rich environment of an anesthetizing location, could ignite when exposed to a heat-producing device in an operating room. Specifically, if the alcohol-based skin preparation is improperly applied, the solution may wick into the patient's hair and linens or pool on the patient's skin, resulting in prolonged drying time. Then, if the patient is draped before the solution is completely dry, the alcohol vapors can become trapped under the surgical drapes and channeled to the surgical site. ²

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On the other hand, surgical site infections (SSI) also pose significant risk to patients; according to the Centers for Disease Control and Prevention (CDC), such infections are the third most commonly reported nosocomial, or hospital-acquired infections.³ Although the CDC has stated that there are no definitive studies comparing the effectiveness of the different types of skin antiseptics in preventing SSI, it also states that "Alcohol is readily available, inexpensive, and remains the most effective and rapid-acting skin antiseptic." Hence, in light of alcohol's effectiveness as a skin antiseptic, there is a need to balance the risks of fire related to use of alcohol-based skin preparations with the risk of surgical site infection.

The use of an alcohol-based skin preparation in inpatient or outpatient anesthetizing locations is not considered safe, *unless* appropriate fire risk reduction measures are taken, preferably as part of a systematic approach by the hospital, CAH or ASC to preventing surgery-related fires. A review of recommendations produced by various expert organizations concerning use of alcohol-based skin preparations in anesthetizing locations indicates there is general consensus that the following fire risk reduction measures are appropriate:⁵

- Using skin prep solutions that are: 1) packaged to ensure controlled delivery to the patient in unit dose applicators, swabs, or other similar applicators; and 2) provide clear and explicit manufacturer/supplier instructions and warnings. These instructions for use should be carefully followed.
- Ensuring that the alcohol-based skin prep solution does not soak into the patient's hair or linens. Sterile towels should be placed to absorb drips and runs during application and should then be removed from the anesthetizing location prior to draping the patient.
- Ensuring that the alcohol-based skin prep solution is completely dry prior to draping. This may take a few minutes or more, depending on the amount and location of the solution. The prepped area should be inspected to confirm it is dry prior to draping.
- Verifying that all of the above has occurred prior to initiating the surgical procedure. This can be
 done, for example, as part of a standardized pre-operative "time out" used to verify other essential
 information to minimize the risk of medical errors during the procedure.

Hospitals, CAHs, and ASCs that employ alcohol-based skin preparations in anesthetizing locations should establish appropriate policies and procedures to reduce the associated risk of fire. They should also document the implementation of these policies and procedures in the patient's medical record.

Failure by a hospital, CAH or ASC to develop and implement appropriate measures to reduce the risk of fires associated with the use of alcohol-based skin preparations in anesthetizing locations should be cited as condition-level noncompliance at §482.41, §485.623, or §416.44, as applicable.

In situations where a fire has occurred in an anesthetizing location and an alcohol-based skin preparation was in use, surveyors should evaluate whether an immediate jeopardy situation is present.

If you have any questions concerning this memorandum, please call David Eddinger at (410) 786-3429 or via e-mail at David.Eddinger@cms.hhs.gov; or Mayer Zimmerman at (410) 786-6839 or via e-mail at Mayer.Zimmerman@cms.hhs.gov.

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Effective Date: Please ensure that all appropriate staff are fully apprised of this information within 30 days.

Training: This information should be shared with all appropriate survey and certification staff, surveyors, their managers, and state fire authorities and their staff.

/s/ Thomas E. Hamilton

cc: Survey and Certification Regional Office Management

¹ Association of Operating Room Nurses AORN Guidance Statement: Fire Prevention in the Operating Room (AORN website: http://www.aorn.org/), citing ECRI, "Surgical fire safety," *Health Devices* 35 no 2 (February 2006) 45-66.

² Prepared by ECRI for the Pennsylvania Patient Safety Reporting System, *Patient Safety Advisory* June 2005 (Vol. 2 No. 2) 13.

³ CDC Hospital Infection Control Practices Advisory Committee, "Guideline for Prevention of Surgical Site Infection, 1999," *Infection Control and Hospital Epidemiology* April 1999 (Vol. 20 No. 4) 251.

⁴ *Ibid.*, 257.

⁵ Tentative Interim Amendment (TIA 05-02) to NFPA 99, 2005 edition, 13.4.1.2.2. Germicides and Antiseptics, issued July 29, 2005 and effective August 18, 2005. See also AORN Guidance Statement: Fire Prevention in the Operating Room; and *Patient Safety Advisory* June 2005 (Vol. 2 No. 2) 14, Prepared by ECRI for the Pennsylvania Patient Safety Reporting System.