

**A-0951**

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## **§482.51(b) Standard: Delivery of Service**

**Surgical services must be consistent with needs and resources. Policies governing surgical care must be designed to assure the achievement and maintenance of high standards of medical practice and patient care.**

### **Interpretive Guidelines §482.51(b)**

Policies governing surgical care should contain:

- Aseptic and sterile surveillance and practice, including scrub techniques;
- Identification of infected and non-infected cases;

- Housekeeping requirements/procedures;
- Patient care requirements:
  - Preoperative work-up;
  - Patient consents and releases;
  - Clinical procedures;
  - Safety practices;
  - Patient identification procedures;
- Duties of scrub and circulating nurse;
- Safety practices;
- The requirement to conduct surgical counts in accordance with accepted standards of practice;
- Scheduling of patients for surgery;
- Personnel policies unique to the O.R.;
- Resuscitative techniques;
- DNR status;
- Care of surgical specimens;
- Malignant hyperthermia;
- Appropriate protocols for all surgical procedures performed. These may be procedure-specific or general in nature and will include a list of equipment, materials, and supplies necessary to properly carry out job assignment;
- Sterilization and disinfection procedures;
- Acceptable operating room attire;
- Handling infections and biomedical/medical waste; and
- Outpatient surgery post-operative care planning and coordination, and provisions for follow-up care.

Policies and procedures must be written, implemented and enforced. Surgical services' policies must be in accordance with acceptable standards of medical practice and surgical patient care.

**NOTE:** Use of Alcohol-based Skin Preparations in Anesthetizing Locations. Alcohol-based skin preparations are considered the most effective and rapid-acting skin antiseptic, but they are also flammable and contribute to the risk of fire.

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. (ECRI, “Surgical Fire Safety,” Health Devices 35 no 2 (February, 2006) 45-66)) 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. (ECRI for Pennsylvania Patient Safety Advisory 2, No. 2 (June, 2005) 13)

On the other hand, surgical site infections (SSI) also pose significant risks to patients; according to the Centers for Disease Control and Prevention (CDC), such infections are the third most commonly reported hospital-acquired infections. 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.” (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, 257) 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 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 risk reduction measures are appropriate:

- 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 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 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.

### **Survey Procedures §482.51(b)**

- Review policies and procedures to determine whether they address the elements specified in the interpretive guidelines. If the hospital uses alcohol-based skin preparations in anesthetizing locations, determine whether it has adopted policies and procedures to minimize the risk of surgical fires.
- Interview surgical services staff to determine whether they are aware of and follow hospital policies and procedures.