

**A-0940**

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### **§482.51 Condition of Participation: Surgical Services**

**If the hospital provides surgical services, the services must be well organized and provided in accordance with acceptable standards of practice. If outpatient surgical services are offered the services must be consistent in quality with inpatient care in accordance with the complexity of services offered.**

## **Interpretive Guidelines §482.51**

The provision of surgical services is an optional hospital service. However, if a hospital provides any degree of surgical services to its patients, the hospital must comply with all the requirements of this Condition of Participation (CoP).

### **What constitutes “surgery”?**

For the purposes of determining compliance with the hospital surgical services CoP, CMS relies, with minor modification, upon the definition of surgery developed by the American College of Surgeons. Accordingly, the following definition is used to determine whether or not a procedure constitutes surgery and is subject to this CoP:

Surgery is performed for the purpose of structurally altering the human body by the incision or destruction of tissues and is part of the practice of medicine. Surgery also is the diagnostic or therapeutic treatment of conditions or disease processes by any instruments causing localized alteration or transposition of live human tissue which include lasers, ultrasound, ionizing radiation, scalpels, probes, and needles. The tissue can be cut, burned, vaporized, frozen, sutured, probed, or manipulated by closed reductions for major dislocations or fractures, or otherwise altered by mechanical, thermal, light-based, electromagnetic, or chemical means. Injection of diagnostic or therapeutic substances into body cavities, internal organs, joints, sensory organs, and the central nervous system also is considered to be surgery (this does not include the administration by nursing personnel of some injections, subcutaneous, intramuscular, and intravenous, when ordered by a physician). All of these surgical procedures are invasive, including those that are performed with lasers, and the risks of any surgical procedure are not eliminated by using a light knife or laser in place of a metal knife, or scalpel. Patient safety and quality of care are paramount and, therefore, patients should be assured that individuals who perform these types of surgery are licensed physicians (physicians as defined in 482.12(c)(1)) who are working within their scope of practice, hospital privileges, and who meet appropriate professional standards.

If surgical services are provided, they must be organized and staffed in such a manner to ensure the health and safety of patients.

Acceptable standards of practice include maintaining compliance with applicable Federal and State laws, regulations and guidelines governing surgical services or surgical service locations, as well as, any standards and recommendations promoted by or established by nationally recognized professional organizations (e.g., the American Medical Association, American College of Surgeons, Association of Operating Room Nurses, Association for Professionals in Infection Control and Epidemiology, etc.)

Outpatient surgical services must be in compliance with all hospital CoPs including the surgical services CoP. Outpatient surgical services must be provided in accordance with acceptable standards of practice. Additionally, the hospital’s outpatient surgical services must be consistent in quality with the hospital’s inpatient surgical services. Post-operative care planning, coordination for the provision of needed post-operative care and appropriate provisions for follow-up care of outpatient surgery patients must be consistent in quality with inpatient care in accordance with the complexity of the services offered and the needs of the patient.

The hospital’s inpatient and outpatient surgical services must be integrated into its hospital-wide QAPI program.

## **Survey Procedures §482.51**

Inspect all inpatient and outpatient operative rooms/suites. Request the use of proper attire for the inspection. Observe the practices to determine if the services are provided in accordance with acceptable standards of practice. Observe:

- That access to the operative and recovery area is limited to authorized personnel and that the traffic flow pattern adheres to accepted standards of practice;
- The conformance to aseptic and sterile technique by all individuals in the surgical area;
- That there is appropriate cleaning between surgical cases and appropriate terminal cleaning applied;
- That operating room attire is suitable for the kind of surgical case performed, that persons working in the operating suite must wear only clean surgical costumes, that surgical costumes are designed for maximum skin and hair coverage;
- That equipment is available for rapid and routine sterilization of operating room materials;
- That equipment is monitored, inspected, tested, and maintained by the hospital's biomedical equipment program and in accordance with Federal and State law, regulations and guidelines and manufacturer's recommendations;
- That sterilized materials are packaged, handled, labeled, and stored in a manner that ensures sterility e.g., in a moisture and dust controlled environment and policies and procedures for expiration dates have been developed and are followed in accordance with accepted standards of practice.
- That temperature and humidity are monitored and maintained within accepted standards of practice;
- That medical/surgical devices and equipment are checked and maintained routinely by clinical/biomedical engineers.
- Verify that all surgical service activities and locations are integrated into the hospital-wide QAPI program.