

### **Interpretive Guidelines §482.45(b)(1) –(3)**

If you have questions concerning the facility membership in the Organ Procurement and Transplantation Network; you may verify the membership by contacting the CMS regional office or by calling the United Network for Organ sharing (UNOS) at 1-804-330-8500.

### **Survey Procedures §482.45(b)(1) – (3)**

Verify by review, one year of reports submitted by the facility to the OPTN, the Scientific Registry, the OPOs, and any data submitted to the Department per request of the Secretary.

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## **A-0940**

*(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)*

### **§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.

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## **A-0941**

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### **§482.51(a) Standard: Organization and Staffing**

**The organization of the surgical services must be appropriate to the scope of the services offered.**

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

When the hospital offers surgical services, the hospital must provide the appropriate equipment and the appropriate types and numbers of qualified personnel necessary to furnish the surgical services offered by the hospital in accordance with acceptable standards of practice.

The scope of surgical services provided by the hospital should be defined in writing and approved by the medical staff.

**Survey Procedures §482.51(a)**

Review the hospital's organizational chart displaying the relationship of the operating room service to other services. Confirm that the operating room's organization chart indicates lines of authority and delegation of responsibility within the department or service.

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**A-0942**

*(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)*

**§482.51(a)(1) - The operating rooms must be supervised by an experienced registered nurse or a doctor of medicine or osteopathy.**

**Interpretive Guidelines §482.51(a)(1)**

The operating room (inpatient and outpatient) must be supervised by an experienced RN or MD/DO. The RN or MD/DO supervising the operating room must demonstrate appropriate education, background working in surgical services, and specialized training in the provision of surgical services/management of surgical service operations. The hospital should address its required qualifications for the supervisor of the hospital's operating rooms in its policies and the supervisor's personnel file should contain information demonstrating compliance with the hospital's established qualifications.

**Survey Procedures §482.51(a)(1)**

- Verify that an RN or a doctor of medicine or osteopathy is assigned responsibility for supervision of the operating rooms.
- Request a copy of the supervisor's position description to determine that it specifies qualifications, duties and responsibilities of the position. Verify that the supervisor is experienced and competent in the management of surgical services.

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## **A-0943**

*(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)*

**§482.51(a)(2) - Licensed practical nurses (LPNs) and surgical technologists (operating room technicians) may serve as “scrub nurses” under the supervision of a registered nurse.**

### **Interpretive Guidelines §482.51(a)(2)**

If the hospital utilizes LPN or operating room technicians as “scrub nurses,” those personnel must be under the supervision of an RN who is immediately available to physically intervene and provide care.

### **Survey Procedures §482.51(a)(2)**

- Determine that an RN is available for supervision in the department or service. Validate the availability by requesting and reviewing a staffing schedule for the OR.
- Review staffing schedules to determine adequacy of staff and RN supervision.

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## **A-0944**

*(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)*

**§482.51(a)(3) - Qualified registered nurses may perform circulating duties in the operating room. In accordance with applicable State laws and approved medical staff policies and procedures, LPNs and surgical technologists may assist in circulatory duties under the supervision of a qualified registered nurse who is immediately available to respond to emergencies.**

### **Interpretive Guidelines §482.51(a)(3)**

The circulating nurse must be an RN. An LPN or surgical technologist may assist an RN in carrying out circulatory duties (in accordance with applicable State laws and medical-staff approved hospital policy) but the LPN or surgical technologist must be under the supervision of the circulating RN who is in the operating suite and who is available to immediately and physically respond/intervene to provide necessary interventions in emergencies. The supervising RN would not be considered immediately available if the RN was located outside the operating suite or engaged in other activities/duties which prevent the RN from immediately intervening and assuming whatever circulating

activities/duties that were being provided by the LPN or surgical technologist. The hospital, in accordance with State law and acceptable standards of practice, must establish the qualifications required for RNs who perform circulating duties and LPNs and surgical technologists who assist with circulating duties.

#### **Survey Procedures §482.51(a)(3)**

- If LPNs and surgical technologists (STs) are assisting with circulating duties, verify that they do so in accordance with applicable State laws and medical-staff approved policies and procedures.
  - Verify in situations where LPNs and STs are permitted to assist with circulating duties that a qualified RN supervisor is immediately available to respond to emergencies.
  - Verify that RNs working as circulating nurses are working in accordance with applicable State laws and medical-staff approved policies and procedures.
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#### **A-0945**

*(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)*

**§482.51(a)(4) - Surgical privileges must be delineated for all practitioners performing surgery in accordance with the competencies of each practitioner. The surgical service must maintain a roster of practitioners specifying the surgical privileges of each practitioner.**

#### **Interpretive Guidelines §482.51(a)(4)**

Surgical privileges should be reviewed and updated at least every 2 years. A current roster listing each practitioner's specific surgical privileges must be available in the surgical suite and area/location where the scheduling of surgical procedures is done. A current list of surgeons suspended from surgical privileges or whose surgical privileges have been restricted must also be retained in these areas/locations.

The hospital must delineate the surgical privileges of all practitioners performing surgery and surgical procedures. The medical staff is accountable to the governing body for the quality of care provided to patients. The medical staff bylaws must include criteria for determining the privileges to be granted to an individual practitioner and a procedure for applying the criteria to individuals requesting privileges. Surgical privileges are granted in accordance with the competencies of each practitioner. The medical staff appraisal procedures must evaluate each individual practitioner's training, education, experience, and demonstrated competence as established by the hospital's QAPI program, credentialing process, the practitioner's adherence to hospital policies and procedures, and in accordance with scope of practice and other State laws and regulations.

The hospital must specify the surgical privileges for each practitioner that performs surgical tasks. This would include practitioners such as MD/DO, dentists, oral surgeons, podiatrists, RN first assistants, nurse practitioners, surgical physician assistants, surgical technicians, etc. When a practitioner may perform certain surgical procedures under supervision, the specific tasks/procedures and the degree of supervision (to include whether or not the supervising practitioner is physically present in the same OR, in line of sight of the practitioner being supervised) be delineated in that practitioner's surgical privileges and included on the surgical roster.

If the hospital utilizes RN First Assistants, surgical PA, or other non-MD/DO surgical assistants, the hospital must establish criteria, qualifications and a credentialing process to grant specific privileges to individual practitioners based on each individual practitioner's compliance with the privileging/credentialing criteria and in accordance with Federal and State laws and regulations. This would include surgical services tasks conducted by these practitioners while under the supervision of an MD/DO.

When practitioners whose scope of practice for conducting surgical procedures requires the direct supervision of an MD/DO surgeon, the term "supervision" would mean the supervising MD/DO surgeon is present in the same room, working with the same patient.

Surgery and all surgical procedures must be conducted by a practitioner who meets the medical staff criteria and procedures for the privileges granted, who has been granted specific surgical privileges by the governing body in accordance with those criteria, and who is working within the scope of those granted and documented privileges.

#### **Survey Procedures §482.51(a)(4)**

- Review the hospital's method for reviewing the surgical privileges of practitioners. This method should require a written assessment of the practitioner's training, experience, health status, and performance.
- Determine that a current roster listing each practitioner's specific surgical privileges is available in the surgical suite and the area where the scheduling of surgical procedures is done.
- Determine that a current list of surgeons suspended from surgical privileges or who have restricted surgical privileges is retained in these areas/locations.

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#### **A-0951**

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