

Excerpt from State Operations Manual Appendix A

Survey Protocol, Regulations, and Interpretive Guidelines for Hospitals

(Rev. 99, 01-31-14)

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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§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.

A-0942

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§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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§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.

A-0944

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§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.

A-0945

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§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.

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.

A-0952

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§482.51(b) (1) – Prior to surgery or a procedure requiring anesthesia services and except in the case of emergencies:

(i) A medical history and physical examination must be completed and documented no more than 30 days before or 24 hours after admission or registration.

(ii) An updated examination of the patient, including any changes in the patient's condition, must be completed and documented within 24 hours after admission or registration when the medical history and physical examination are completed within 30 days before admission or registration.

Interpretive Guidelines §482.51(b)(1)

There must be a complete history and physical examination (H & P), and an update, if applicable, in the medical record of every patient prior to surgery, or a procedure requiring anesthesia services, except in emergencies.

- The H&P must be conducted in accordance with the requirements of 42 CFR 482.22(c)(5).
- The H&P must be completed and documented no more than 30 days before or 24 hours after admission or registration. In all cases, except for emergencies, the H&P must be completed and documented **before** the surgery or procedure takes place, even if that surgery or procedure occurs less than 24 hours after admission or registration.
- If the H&P was completed within 30 days before admission or registration, then an updated examination must be completed and documented within 24 hours after admission or registration. In all cases, except for emergencies, the update must be completed and documented **before** the surgery or procedure takes place, even if that surgery or procedure occurs less than 24 hours after admission or registration.

Survey Procedures §482.51(b)(1)

Review a sample of open and closed medical records of patients (both inpatient and outpatient) who have had surgery or a procedure requiring anesthesia.

- Determine whether an H&P was conducted and documented in a timely manner.
- Determine whether the H&P was conducted in accordance with the requirements of 42 CFR 482.22(c)(5).
- Determine whether the records of patients who did not have a timely H&P or update indicate that the surgery or procedure was conducted on an emergency basis.

A-0955**(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)****§482.51(b)(2) – A properly executed informed consent form for the operation must be in the patient's chart before surgery, except in emergencies.****Interpretive Guidelines §482.51(b)(2)**

Informed consent is addressed in two other portions of the CMS Hospital CoPs and the SOMI. Surveyors should review the guidelines for §482.13(b)(2) under Patients' Rights and the guidelines for §482.24(c)(2)(v) under Medical Records to understand all requirements related to informed consent.

The primary purpose of the informed consent process for surgical services is to ensure that the patient, or the patient's representative, is provided information necessary to enable him/her to evaluate a proposed surgery before agreeing to the surgery. Typically, this information would include potential short- and longer-term risks and benefits to the patient of the proposed intervention, including the likelihood of each, based on the available clinical evidence, as informed by the responsible practitioner's professional judgment. Informed consent must be obtained, and the informed consent form must be placed in the patient's medical record, prior to surgery, except in the case of emergency surgery.

Hospitals must assure that the practitioner(s) responsible for the surgery obtain informed consent from patients in a manner consistent with the hospital's policies governing the informed consent process.

It should be noted that there is no specific requirement for informed consent within the regulation at §482.52 governing anesthesia services. However, given that surgical procedures generally entail use of anesthesia, hospitals may wish to consider specifically extending their informed consent policies to include obtaining informed consent for the anesthesia component of the surgical procedure.

Surgical Informed Consent Policy

The hospital's surgical informed consent policy should describe the following:

- Who may obtain the patient's informed consent;
- Which procedures require informed consent;
- The circumstances under which surgery is considered an emergency, and may be undertaken without an informed consent;
- The circumstances when a patient's representative, rather than the patient, may give informed consent for a surgery;
- The content of the informed consent form and instructions for completing it;
- The process used to obtain informed consent, including how informed consent is to be documented in the medical record;
- Mechanisms that ensure that the informed consent form is properly executed and is in the patient's medical record prior to the surgery (except in the case of emergency surgery); and
- If the informed consent process and informed consent form are obtained outside the hospital, how the properly executed informed consent form is incorporated into the patient's medical record prior to the surgery.

If there are additional requirements under State law for informed consent, the hospital must comply with those requirements.

Example of a Well-Designed Informed Consent Process

A well-designed informed consent process would include discussion of the following elements:

- A description of the proposed surgery, including the anesthesia to be used;
- The indications for the proposed surgery;
- Material risks and benefits for the patient related to the surgery and anesthesia, including the likelihood of each, based on the available clinical evidence, as informed by the responsible practitioner's clinical judgment. Material risks could include risks with a high degree of likelihood but a low degree of severity, as well as those with a very low degree of likelihood but high degree of severity;
- Treatment alternatives, including the attendant material risks and benefits;
- The probable consequences of declining recommended or alternative therapies;
- Who will conduct the surgical intervention and administer the anesthesia;
- Whether physicians other than the operating practitioner, including but not limited to residents, will be performing important tasks related to the surgery, in accordance with the hospital's policies. Important surgical tasks include: opening and closing, dissecting tissue, removing tissue, harvesting grafts, transplanting tissue, administering anesthesia, implanting devices and placing invasive lines;
 - For surgeries in which residents will perform important parts of the surgery, discussion is encouraged to include the following:
 - That it is anticipated that physicians who are in approved post graduate residency training programs will perform portions of the surgery, based on their availability and level of competence;
 - That it will be decided at the time of the surgery which residents will participate and their manner or participation, and that this will depend on the availability of residents with the necessary competence; the knowledge the operating practitioner/teaching surgeon has of the resident's skill set; and the patient's condition;
 - That residents performing surgical tasks will be under the supervision of the operating practitioner/teaching surgeon; and
 - Whether, based on the resident's level of competence, the operating practitioner/teaching surgeon will not be physically present in the same operating room for some or all of the surgical tasks performed by residents.
- Whether, as permitted by State law, qualified medical practitioners who are not physicians will perform important parts of the surgery or administer the anesthesia, and if so, the types of tasks each type of practitioner will carry out; and that such practitioners will be performing only tasks within their scope of practice for which they have been granted privileges by the hospital.

NOTE: A “moonlighting” resident or fellow is a postgraduate medical trainee who is practicing independently, outside the scope of his/her residency training program and would be treated as a physician within the scope of the privileges granted by the hospital.

Informed Consent Forms

See the guidelines for §482.24(c)(2)(v) under Medical Records for discussion of the content of a properly executed informed consent form.

Survey Procedures §482.51(b)(2)

- Verify that the hospital has assured that the medical staff has specified which procedures are considered surgery and, thus, are those that require a properly executed informed consent form.
- Verify that the hospital's informed consent policies address the circumstances when a surgery would be considered an emergency and thus not require an informed consent form be placed in the medical record prior to surgery.

- Review a minimum of six medical records of surgical patients and verify that they did not involve emergency surgery and that they contain informed consent forms that were executed prior to the surgery. When possible, review medical records of patients who are about to undergo surgery, or who are located in a surgical recovery area.
- Interview two or three post-surgical patients, as appropriate based on their ability to provide a cogent response, or the patients' representatives to see how satisfied they are with the informed consent discussion prior to their surgery.

A-0956**(Rev. 37, Issued: 0-17-08; Effective/Implementation Date: 10-17-08)****§482.51(b)(3) – The following equipment must be available to the operating room suites: call-in system, cardiac monitor, resuscitator, defibrillator, aspirator, and tracheotomy set.****Survey Procedures §482.51(b)(3)**

- Check to determine that the operating room suite has available the items listed:
 - On-call system;
 - Cardiac monitor;
 - Resuscitator;
 - Defibrillator;
 - Aspirator (suction equipment); and
 - Tracheotomy set (a cricothyroidotomy set is not a substitute).

Verify that all equipment is working and, as applicable, in compliance with the hospital's biomedical equipment inspection, testing, and maintenance program.

A-0957**(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)****§482.51(b)(4) – There must be adequate provisions for immediate post-operative care.****Interpretive Guidelines §482.51(b)(4)**

Adequate provisions for immediate post-operative care means:

- Post operative care must be in accordance with acceptable standards of practice.
- The post-operative care area or recovery room is a separate area of the hospital. Access is limited to authorized personnel.
- Policies and procedures specify transfer requirements to and from the recovery room. Depending on the type of anesthesia and length of surgery, the post-operative check before transferring the patient from the recovery room should include some of the following:
 - Level of activity;
 - Respirations;
 - Blood pressure;
 - Level of consciousness;
 - Patient color; and
- If the patients are not transferred to the recovery room, determine that provisions are made for close observation until they have regained consciousness, e.g., direct observation by a qualified RN in the patient's room.

Survey Procedures §482.51(b)(4)

- Verify that the hospital has provisions for post-operative care.
- Determine that there are policies and procedures that govern the recovery room area.

A-0958**(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)****§482.51(b)(5) – The operating room register must be complete and up-to-date.****Interpretive Guidelines §482.51(b)(5)**

The register includes at least the following information:

- Patient's name;
- Patient's hospital identification number;
- Date of the operation;
- Inclusive or total time of the operation;
- Name of the surgeon and any assistant(s);
- Name of nursing personnel (scrub and circulating);
- Type of anesthesia used and name of person administering it;
- Operation performed;
- Pre and post-op diagnosis; and
- Age of patient.

Survey Procedures §482.51(b)(5)

Examine the OR register or equivalent record which lists all surgery performed by the surgery service. Determine that the register includes items specified in the interpretive guidelines.

A-0959**(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)****§482.51(b)(6) – An operative report describing techniques, findings, and tissues removed or altered must be written or dictated immediately following surgery and signed by the surgeon.****Interpretive Guidelines §482.51(b)(6)**

The operative report includes at least:

- Name and hospital identification number of the patient;
- Date and times of the surgery;
- Name(s) of the surgeon(s) and assistants or other practitioners who performed surgical tasks (even when performing those tasks under supervision);
- Pre-operative and post-operative diagnosis;
- Name of the specific surgical procedure(s) performed;
- Type of anesthesia administered;
- Complications, if any;
- A description of techniques, findings, and tissues removed or altered;
- Surgeons or practitioners name(s) and a description of the specific significant surgical tasks that were conducted by practitioners other than the primary surgeon/practitioner (significant surgical procedures include: opening and closing, harvesting grafts, dissecting tissue, removing tissue, implanting devices, altering tissues); and
- Prosthetic devices, grafts, tissues, transplants, or devices implanted, if any.

Survey Procedures §482.51(b)(6)

Review a minimum of six random medical records of patients who had a surgical encounter. Verify that they contain a surgical report that is dated and signed by the responsible surgeon and includes the information specified in the interpretive guidelines.

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

“Anesthesia” involves the administration of a medication to produce a blunting or loss of:

- pain perception (analgesia);
- voluntary and involuntary movements;
- autonomic function; and
- memory and/or consciousness,

depending on where along the central neuraxial (brain and spinal cord) the medication is delivered.