State Operations Manual
Appendix A - Survey Protocol, Regulations and Interpretive Guidelines for Hospitals

Table of Contents
(Rev. 176, 12-29-17)

evaluations. Are the results/reports and other clinical findings of those consultative evaluations included in the patient's medical record?

A-0465
(Rev. 95, Issued: 12-12-13, Effective: 06-07-13, Implementation: 06-07-13)

[All records must document the following, as appropriate:]

§482.24(c)(4)(iv) - Documentation of complications, hospital acquired infections, and unfavorable reactions to drugs and anesthesia.

Interpretive Guidelines §482.24(c)(4)(iv)

All patient medical records, both inpatient and outpatient, must document:

- Complication;
- Hospital-acquired infections;
- Unfavorable reactions to drugs; and
- Unfavorable reactions to anesthesia.

Survey Procedures §482.24(c)(4)(iv)

Through observations, interviews, and reviews of hospital reports and documentation, determine if patient complications, hospital-acquired infections, unfavorable reactions to drugs/anesthesia have been documented in the applicable patient's medical record.

A-0466
(Rev. 95, Issued: 12-12-13, Effective: 06-07-13, Implementation: 06-07-13)

[All records must document the following, as appropriate:]

§482.24(c)(4)(v) - Properly executed informed consent forms for procedures and treatments specified by the medical staff, or by Federal or State law if applicable, to require written patient consent.

Interpretive Guidelines §482.24(c)(4)(v)

Informed consent is discussed in three locations in the CMS Hospital CoPs. See also the guidelines for 42 CFR 482.13(b)(2) pertaining to patients' rights, and the guidelines for 42 CFR 482.51(b)(2), pertaining to surgical services.

The medical record must contain a document recording the patient's informed consent for those procedures and treatments that have been specified as requiring informed consent. Medical staff policies should address which procedures and treatments require written informed consent. There may also be applicable Federal or State law requiring informed consent. The informed consent form contained in the medical record should provide evidence that it was properly executed.

Informed Consent Forms

A properly executed informed consent form should reflect the patient consent process. Except as specified for emergency situations in the hospital's informed consent policies, all inpatient and outpatient medical records must contain a properly executed informed consent form prior to conducting any procedure or other type of treatment that requires informed consent. An informed consent form, in order to be properly executed, must be consistent with hospital policies as well as applicable State and Federal law or regulation. A properly executed informed consent form contains the following minimum elements:

- Name of the hospital where the procedure or other type of medical treatment is to take place;
- Name of the specific procedure, or other type of medical treatment for which consent is being given;
- Name of the responsible practitioner who is performing the procedure or administering the medical treatment;
- Statement that the procedure or treatment, including the anticipated benefits, material risks, and alternative therapies, was explained to the patient or the patient's legal representative; (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. Hospitals are free to delegate to the responsible practitioner, who uses the available clinical evidence as informed by the practitioner's professional judgment, the determination of which material risks, benefits and alternatives will be discussed with the patient.)
- Signature of the patient or the patient's legal representative; and
- Date and time the informed consent form is signed by the patient or the patient's legal representative.

If there is applicable State law governing the content of the informed consent form, then the hospital's form must comply with those requirements.

A well-designed informed consent form might also include the following additional information:

- Name of the practitioner who conducted the informed consent discussion with the patient or the patient's representative.

- Date, time, and signature of the person witnessing the patient or the patient's legal representative signing the consent form.

- Indication or listing of the material risks of the procedure or treatment that were discussed with the patient or the patient's representative;

- Statement, if applicable, that 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 and, in the case of residents, based on their skill set and under the supervision of the responsible practitioner.

- Statement, if applicable, that qualified medical practitioners who are not physicians who will perform important parts of the surgery or administration of anesthesia will be performing only tasks that are within their scope of practice, as determined under State law and regulation, and for which they have been granted privileges by the hospital.

Survey Procedures §482.24(c)(4)(v)

- Verify that the hospital has assured that the medical staff has specified which procedures and treatments require written patient consent.

- Verify that the hospital's standard informed consent form contains the elements listed above as the minimum elements of a properly executed informed consent.

- Compare the hospital's standard informed consent form to the hospital's policies on informed consent, to verify that the form is consistent with the policies. If there is applicable State law, verify that the form is consistent with the requirements of that law.

- Review a minimum of six random medical records of patients who have, are undergoing, or are about to under a procedure or treatment that requires informed consent. Verify that each medical record contains informed consent forms.

- Verify that each completed informed consent form contains the information for each of the elements listed above as the minimum elements of a properly executed informed consent, as well as any additional elements required by State law and/or the hospital's policy.

(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.

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.

- 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.

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: 10-17-08; 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. 116, I ssued: 06-06-14 Effective: 06-06-14, Implementation 06-06-14)

§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 provided to all surgical patients, including same-day surgery patients, in accordance with acceptable standards of practice.
- A post-operative care area, usually referred to as the post-anesthesia care unit (PACU), is a separate area of the hospital. Access is limited to authorized personnel.
- Policies and procedures specify transfer requirements to and from the PACU.