CMS Manual System

Pub. 100-07 State Operations Provider Certification

Department of Health & Human Services (DHHS) Centers for Medicare & Medicaid Services (CMS)

Transmittal 220 **Date: April 19, 2024**

SUBJECT: Revisions to State Operations Manual (SOM) Appendix A-Hospitals

I. SUMMARY OF CHANGES: This Transmittal includes a revision to the interpretive guidance in SOM Appendix A 42 CFR 482.51(b)(2) to provide an emphasis on patient informed consent prior to performing sensitive examinations and examinations performed by students for teaching purposes. This transmittal is a follow-up to a memo QSO 24-10 released April 1, 2024.

NEW/REVISED MATERIAL - EFFECTIVE DATE*: April 19, 2024
IMPLEMENTATION DATE: April 19, 2024

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (*N/A if manual not updated.*)
(R = REVISED, N = NEW, D = DELETED) – (*Only One Per Row.*)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	Appendix A/A-0955/ §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.

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.
Or
Funding for implementation activities will be provided to contractors through the regular budget process.

IV. ATTACHMENTS:

	Business Requirements
x	**Manual Instruction**
	Confidential Requirements
	One-Time Notification
	One-Time Notification -Confidential
	Recurring Update Notification

***Unless otherwise specified, the effective date is the date of service.**

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

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(Rev. 220; Issued: 04-19-24)

A-0955

(Rev. 220; Issued: 04-19-24; Effective: 04-19-24; Implementation: 04-19-24)

§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 SOM. 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, *medical, advanced practice provider (such as nurse practitioners and physician assistants), and other applicable students*, will be performing important tasks related to the surgery, *or examinations or invasive procedures for educational and training purposes*, 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. *Examinations or invasive procedures conducted for educational and training purposes include, but are not limited to, breast, pelvic, prostate, and rectal examinations, as well as others specified under state law.*

    - 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.