



Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-07-17

DATE: April 13, 2007

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Revisions to the Hospital Interpretive Guidelines for Informed Consent

Memorandum Summary

- Requirements related to informed consent for hospitals are found in the Patients' Rights Condition of Participation (CoP) at 42 CFR 482.13(b)(2); the Medical Records CoP at 482.24(c)(2)(v); and the Surgical Services CoP at 482.51(b)(2).
- The attached interpretive guidelines for Tags A-0049 (Patients' Rights), A-0238 (Medical Records), and A-0392 (Surgical Services) replace the guidelines issued in May 2004.

The hospital interpretive guidelines regarding informed decision-making and informed consent in Appendix A of the State Operations Manual have been revised.

- Tag A-0049 (42 CFR 482.13(b)(2)) in the Patients' Rights CoP discusses the patient's or patient's representative's right to make informed decisions regarding the patient's care. In addition, Tags A-0050, A-0051 and A-0052 are being consolidated into Tag A-0049. Surveyors should cease citing these three Tags.
- Tag A-0238 (42 CFR 482.24(c)(2)(v)) in the Medical Records CoP discusses the requirement that the hospital must ensure that patient medical records contain properly executed informed consent forms for procedures or treatments specified by the hospital Medical Staff, or by Federal or State law if applicable, to require written patient consent.
- Tag A-0392 (42 CFR 482.51(b)(2)) in the Surgical Services CoP discusses the requirement that the hospital must ensure that a properly executed informed consent form is in the patient's medical record before surgery, except in emergencies.

The revised Interpretive Guidelines are attached. They discuss the applicable requirements for each CoP and the survey procedures to be used to determine compliance for that CoP. They also contain discussion and examples of practices which hospitals are encouraged to adopt, but which are not necessarily required by the CoPs.

If you have questions, please contact David Eddinger via email at david.eddinger@cms.hhs.gov

System Adjustments: The Tag and guidelines language in ASPEN will be updated as soon as possible. However, there will be some lag time between issuance of this memorandum and the system changes needed to reflect the updated guidance and, in the case of the Tags related to informed consent provisions within the Patients' Rights CoP, the consolidation of four Tags into one. Until the system changes are implemented, surveyors are reminded to use only Tag A-0049 when citing for violations of the provisions at 42 CFR 482.13(b)(2).

Effective Date: The revised guidelines are effective immediately. Please ensure that all surveyors are appropriately informed as to using the revised guidance within 30 days of this memorandum.

Training: The information contained in this letter should be shared with all survey and certification staff, their managers, and the State/RO training coordinators.

/s/

Thomas E. Hamilton

Attachments: 3

cc: Survey and Certification Regional Office Management

A-0049 [Eliminate Tags A-0050, A-0051 and A0052 and consolidate into A-0049]

§482.13(b)(2) The patient or his or her representative (as allowed under State law) has the right to make informed decisions regarding his or her care. *The patient's rights include being informed of his or her health status, being involved in care planning and treatment, and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate.*

Interpretive Guidelines §482.13(b)(2)

The right to make informed decisions means that the patient or patient's representative is given the information needed in order to make "informed" decisions regarding his/her care.

A patient may wish to delegate his/her right to make informed decisions to *another person*. To the degree permitted by State law, and to the maximum extent practicable, the hospital must respect the patient's wishes and follow that process. In some cases, the patient may be unconscious or otherwise incapacitated. If the patient is unable to make a decision, the hospital must consult the patient's advance directives, medical power of attorney or patient representative, *if any of these are available*. In the advance directive *or the medical power of attorney*, the patient may provide guidance as to his/her wishes in certain situations, or may delegate decision-making to another individual as permitted by State law. If such an individual has been selected by the patient, *or if a person willing and able under applicable State law is available to make treatment decisions*, relevant information should be provided to *the representative* so that informed health care decisions can be made for the patient. However, as soon as the patient is able to be informed of his/her rights, the hospital should provide that information to the patient.

The right to make informed decisions regarding care *presumes that the patient has been provided information about his/her health status, diagnosis and prognosis. Furthermore, it includes the patient's participation in the development of the plan of care, including providing consent to, or refusal of, medical or surgical interventions, and in planning for care after discharge from the hospital. The patient or the patient's representative should receive adequate information, provided in a manner that the patient or the patient's representative can understand, to assure that the patient can effectively exercise the right to make informed decisions.*

Hospitals must establish processes to assure that each patient or the patient's representative is given information on the patient's health status, diagnosis and prognosis.

Giving informed consent to a treatment or a surgical procedure is one type of informed decision that a patient or patient's representative may need to make regarding the patient's plan of care. Hospitals must utilize an informed consent process that assures patients or their representatives are given the information and disclosures needed to make an informed decision about whether to consent to a procedure, intervention, or type of care that requires consent. See the guidelines for 482.51(b)(2) pertaining to surgical services informed consent and the guidelines for 482.24(c)(2)(v) pertaining to medical records for further detail.

Informed decisions related to care planning also extend to discharge planning for the patient's post-acute care. See the guidelines for 482.43(c) pertaining to discharge planning for discussion of pertinent requirements.

Hospitals must also establish policies and procedures that assure a patient's right to request or refuse treatment. Such policies should indicate how the patient's request will be addressed. However, hospitals are under no obligation to fulfill a patient's request for a treatment or service that the responsible practitioner has deemed medically unnecessary or even inappropriate.

Survey Procedures §482.13(b)(2)

*Is there a hospital policy addressing the patient's right to make informed decisions?
Does it articulate how the hospital assures patients' ability to exercise this right?*

Is there a hospital policy that addresses delegation of the patient's rights to a representative?

Is there a hospital policy addressing the patient's right to have information on his/her medical status, diagnosis and prognosis? Does it articulate the hospital's process for assuring that patients have this information?

Is there a hospital policy addressing how the patient will be involved in his/her care planning and treatment?

Is there a hospital policy addressing how patient refusal of treatment will be handled?

Is there a hospital policy addressing how patient requests for treatment will be handled, in particular, the circumstances under which a patient request for treatment can be denied?

Are there also State laws or regulations governing patients' rights and do the hospital's policies comply with them?

*Is there evidence that the hospital routinely complies with its policies? Evidence would be obtained through review of medical records, interviewing current patients and/or interviewing hospital personnel to determine their understanding of the hospital's informed decision-making policies and how they are implemented. Review of evidence would be designed to determine **whether** patients/patient representatives are provided **adequate** information about the patient's medical status, diagnosis, and prognosis and then allowed to make informed decisions about their care planning and treatment.*

A-0392 Surgical Services

§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 Conditions of Participation and State Operations Manual. 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.

"Surgery" includes any procedure that is listed as a surgical procedure in any of the various billing coding systems used by CMS or the hospital, regardless of whether Medicare pays for that surgical procedure.

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; and*
 - *That residents performing surgical tasks will be under the supervision of the operating practitioner/teaching surgeon.*
 - *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.
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- 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-0238 Medical Records

§482.24(c)(2)(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)(2)(v)

Informed consent is discussed in three locations in the CMS Hospital Conditions of Participation. See also the guidelines for 482.13(b)(2) pertaining to patients' rights, and the guidelines for 482.24(c)(2)(v), 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 by-laws 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 §482.51(b)(2)

- *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.*