CMS revises informed consent guidelines

he Centers for Medicare and Medicaid Services (CMS) has eliminated the requirement that surgical consent forms list the names of practitioners who will assist the surgeon and tasks they will perform.

Surgeons and perioperative nurses had pressed for the change, saying they often could not know in advance who would assist.

The change came in an April 13 memo revising the CMS interpretive guidelines on informed consent. The guidelines are used by state surveyors to check compliance with the Medicare hospital conditions of participation. The language was effective immediately. CMS said it will update the online State Operations Manual as soon as possible.

The requirement was eliminated from 2 sections of the guidelines, which appear in Appendix A of the manual:

- **Medical records**: Tag A-0238 for 42 CFR 482.24(c)(2)(v), outlining what a “properly executed informed consent form” should contain.
- **Surgical services**: Tag A-0392 for 42 CFR 482.51(b)(2), describing what a surgical informed consent policy should consist of.

CMS still encourages discussion of any planned participation by residents and other assistants as part of a “well-designed” informed consent process.

CMS also revised the patient rights section, which outlines rights of patients or their representatives to make informed decisions about care. See Tag A-0049 for 42 CFR 482.13(b)(2).

This section says surveyors will look for evidence that the hospital complies with its policy by reviewing records, interviewing patients, and interviewing personnel to see how well they understand and carry out the policy.

**What must be in a consent form?**

CMS says that except in emergencies, which should be defined in the hospital’s informed consent policies, all inpatient and outpatient medical records must have a properly executed informed consent form prior to any procedure or treatment that requires informed consent.

Under the revised language, CMS says a properly executed informed consent form has these minimum elements:

- name of hospital where the procedure or medical treatment is to take place
- name of specific procedure or medical treatment for which consent is being given
- name of 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
- signature of the patient or the patient’s legal representative
- date and time the informed consent form is signed by the patient or the patient’s legal representative.

If there is a state law governing the content of the informed consent form, the hospital must comply with those requirements.

The guidelines list other information that may be included.
In checking compliance, surveyors are supposed to verify that the consent form includes the minimum elements and to compare the hospital’s consent form to its informed consent policies.

Surveyors are expected to review at least 6 random medical records for patients who have had procedures to see that the record contains the informed consent form. Surveyors are supposed to verify that the consent forms have the information plus any additional information required by state law and/or hospital policy.

**What should be in a policy?**

The updated guidelines also spell out what a hospital’s surgical informed consent policy should address. This is new. This section also says hospitals must ensure that the practitioner responsible for the surgery obtains informed consent in a manner consistent with the hospital’s policies.

According to the guidelines, the hospital’s policy should describe:

- 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 done 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 the informed consent form is properly executed and is in the patient’s medical record prior to surgery (except in emergencies)
- if the informed consent process and informed consent form are obtained outside the hospital, how the form is incorporated into the patient’s record prior to surgery.

**A “well-designed” process**

CMS outlines an example of what a well-designed informed consent process would consist of:

- a description of the proposed surgery, including the anesthesia to be used
- the indications for the proposed surgery
- material risks and benefits to the patient related to the surgery and anesthesia, including the likelihood of each, based on the evidence and the responsible practitioner’s clinical judgment
- treatment alternatives, including the attendant material risks and benefits
- the probable consequences of declining the recommended or alternative therapies
- who will conduct the surgery and administer the anesthesia
- whether physicians other than the operating practitioner, such as residents, will be performing important tasks related to the surgery, in accord with hospital policies; if so, CMS encourages discussing the fact that their participation will depend on their availability and level of competence, they will be supervised by the operating physician or teaching surgeon, and so forth.
- whether other practitioners, as permitted by law, will participate and if so, the types of tasks they will perform, and that they will perform only tasks within their scope of practice and hospital privileges.

*The CMS memo (S&C-07-17) is at www.cms.hhs.gov/SurveyCertificationGenInfo/downloads/SCLetter07-17.pdf*