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► CLIENT ALERT ◀

CMS Revises Hospital Interpretive Guidelines for Informed Consent

The CMS Conditions of Participation for Hospitals contain three provisions governing informed consent. Each of these has Interpretive Guidelines, found in an appendix to the State Operations Manual, that explain the provision in more detail and serve as the primary guidance for State surveyors regarding compliance. On April 13, 2007, CMS issued revised Interpretive Guidelines for informed consent, which are quite different from the Interpretive Guidelines that were issued a mere two years prior. The 2005 Interpretive Guidelines had come under heavy criticism from the American Medical Association and other stakeholders, particularly the requirement that an informed consent form include not only of the name of the surgeon, but also the name and specific significant surgical task that will be performed by each other practitioner.

The revised Interpretive Guidelines mandate that hospitals have one or more written policies governing the informed consent process for “surgery,” which is defined as any procedure that is listed as a surgical procedure in any of the billing coding systems used by CMS or the hospital. The “surgical services” provisions of the Interpretive Guidelines do not apply to non-surgical procedures, such as the use of contrast material for imaging studies. Nevertheless, hospitals may want to make the surgical services provisions of the CMS Interpretive Guidelines applicable to all procedures requiring informed consent to avoid any inconsistencies.

Pursuant to the Interpretive Guidelines, a 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.

The revised Interpretive Guidelines also include examples of what a "well-designed" informed consent process would include. According to CMS, a well-designed informed consent process would include a 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 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;
- 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.

The revised Interpretive Guidelines also say that, 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.

In addition to dealing with the surgical informed consent process, the revised Interpretive Guidelines mandate the content of informed consent forms. According to CMS, the following are the minimum elements that must be contained in a properly executed informed consent form:

- 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.

In addition, CMS says in the revised Interpretive Guidelines that 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.

Lastly, CMS now requires hospitals to have policies concerning the following:

- A patient's right to make informed decisions, including how the hospital assures the patient's ability to exercise this right.
- Delegation of the patient's right to a representative.
- A patient's right to have information on his/her medical status, diagnosis and prognosis, including the hospital's process for assuring that patients have this information.
- How a patient will be involved in his/her care planning and treatment.
- How patient refusal of treatment will be handled.
- How patient requests for treatment will be handled, in particular, the circumstances under which a patient request for treatment can be denied.

ACTION REQUIRED

Hospitals which do not have a written policy governing the informed consent process will need to adopt one immediately, and those with a policy will need to make certain it complies with the new standards. Additionally, informed consent forms may need to be modified to comport with the new requirements. Lastly, hospitals will need to make certain that they have all the other policies in place that are required by the revised Interpretive Guidelines.

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This Client Alert was prepared as a service to our clients. The information discussed is general in nature and may not apply to your specific situation. Legal advice should be sought before taking action based on the information contained in this Client Alert.