CMS plans changes in guidelines for consent, alcohol-based preps

The Centers for Medicare and Medicaid Services (CMS) plans to make changes in its interpretive guidelines on two issues of particular concern to OR managers—listing names of individuals on the consent form who will be assisting the surgeon and use of alcohol-based prep solutions.

A CMS official described the planned revisions Dec 6 in an interview with OR Manager. The new language is expected early in 2007.

The interpretive guidelines are in the CMS State Operations Manual used by surveyors to assess compliance with the Medicare conditions of participation. The guidelines are an official explanation of how CMS expects its regulations to be carried out. Hospitals also use the guidelines as a reference for complying with the standards.

Informed consent

The guidelines require a “properly executed and completed written informed consent form for all procedures specified by the hospital’s medical staff, state or federal laws or regulations.” There is a list of what must be included in the consent form (sidebar).

OR managers have been troubled by one requirement—that the consent form include names of practitioners besides the primary surgeon who will perform the procedure plus their “specific significant surgical tasks.”

Managers say it is often impossible to know in advance who will assist and what duties they will perform. The surgeon usually makes this decision at the time of the procedure.

The revised language will no longer require individual names or specific tasks the individuals will be doing, the official said. But the form will have to describe the categories of practitioners who will be involved, such as residents and RN first assistants (RNFAQs), and their general tasks.

For example, the consent might state: “An RN first assistant will harvest the saphenous vein” but would not need to name the specific person.

CMS also plans to modify the definition of “significant surgical tasks” assistants perform by removing the phrase “altering tissues.” The term was too broad and confusing, the official said. Other tasks currently listed are “harvesting grafts, dissecting tissue, removing tissue, and implanting devices.”

Until the revision is issued, hospitals will still be surveyed under the current language. In the meantime, “we have told the surveyors that hospitals don’t have to specifically name the individual residents who will be involved in surgery,” said the official. “We realize hospitals can’t control which residents may be assigned and what tasks they will be performing.”

The official said he is not aware of any hospitals cited for not listing individual names in the consent. Citations don’t indicate which specific aspects were violated. When citations are issued, often it’s because there was no consent at all.

“You’d be surprised how often we find no informed consent on the chart,” he said. “We have a problem with hospitals not having a system that protects patients by having an informed consent on the chart prior to surgery.”
**Witness to consent**

In one other change for the informed consent, CMS will no longer require the signature of a “professional person” as witness to the consent.

The new language likely will say the witness can be a person who is qualified to witness legal documents under state law. Generally, that is a competent adult.

There may be other revisions CMS is not ready to announce.

**Alcohol-based prep solutions**

In at least 2 states, Nebraska and Pennsylvania, state officials have cited hospitals for use of alcohol-based prep solutions, saying this violates the National Fire Protection Association (NFPA) 99 standard for health care facilities.

CMS plans to issue a letter to state agencies stating that hospitals are in compliance if they follow recommendations of the Association of periOperative Registered Nurses (AORN) and the NFPA technical amendment issued in 2005.

“If we go into a hospital and find you have a standard policy that follows the NFPA technical amendment, we won’t cite you,” the official said.

In general, the NFPA technical amendment recommends:

- using unit-dose applicators
- allowing time for the prep solution to dry before draping
- avoiding or drying up any pooling of solution
- having a time-out before surgery to verify these steps have been followed.

**How revisions will be announced**

The revisions will be sent to state agencies in a Survey & Certification letter. These letters are posted on the CMS web site (see Resources). The official said CMS also plans to inform organizations that have been involved in the discussions, including AORN, the American Hospital Association, the American College of Surgeons, and others.

**Resources**


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**CMS guidelines for consent**

The interpretive guidelines for informed consent are in the CMS State Operations Manual, Appendix A: Hospitals.

Informed consent is covered under sections on:

- Medical Record Services: 482.24(c)(2)(v)
- Surgical Services: 482.51(b)(2)

In the current wording, both sections state, in addition to other requirements, that a properly executed informed consent form contains at least the following:

- name of patient and, when appropriate, patient’s legal guardian
- name of hospital
- name of procedure(s)
- name of practitioner(s) performing the procedure(s) or important aspects of the
procedure(s), as well as the name(s) and specific significant surgical tasks that will be conducted by practitioners other than the primary surgeon/practitioner. (Significant surgical tasks include: opening and closing, harvesting grafts, dissecting tissue, removing tissue, implanting devices, altering tissues)

- risks
- alternative procedures and treatments
- signature of patient or legal guardian
- date and time consent is obtained
- statement that procedure was explained to patient or guardian
- signature of professional person witnessing the consent
- name/signature of person who explained the procedure to the patient or guardian.