

# In compliance...

## with the new hospital informed consent requirements

by the Division of Advocacy and Health Policy

In April, the Centers for Medicare & Medicaid Services (CMS) released new hospital interpretive guidelines for informed consent that became effective immediately. The new guidelines amend predecessor guidelines that were released in 2004.

### **Background**

The 2004 guidelines required that the informed consent document name any health care professionals who would perform significant surgical tasks and describe what they would do. According to the guidelines, significant parts of an operation include opening and closing the wound(s); harvesting grafts; dissecting, removing, or altering tissue(s); and implanting devices.

The 2004 mandate had the potential to cause havoc at teaching hospitals because the resident's identity is frequently unknown at the time informed consent is obtained. Furthermore, exactly what tasks a resident would perform during a procedure would vary depending on his or her level of knowledge and skills. The College understands that few, if any, punitive actions related to this provision have been taken against teaching hospitals because of the complaints lodged from teaching hospitals, the College, the Association of American Medical Colleges (AAMC), the American Medical Association (AMA), and the American Hospital Association (AHA). CMS immediately committed to revising the 2004 interpretive guidelines and instructed state survey agencies not to enforce the new requirement regarding the use of residents in teaching hospitals.

### **New guidelines**

The 2007 guidelines eliminate the problems for teaching hospitals by creating an exception in instances where a resident will be performing a part of the operation. Instead of being very prescriptive about the role of the resident, the discussion that leads to the execution of the informed consent

document must indicate the following:

- A resident will probably perform portions of the operation.
- The resident who participates will be decided at the time of the surgery.
- Exactly what a resident will do will depend on that resident's skill set and the patient's condition.
- The resident will be under the supervision of the teaching physician.
- Based on the level of competence of the resident, the teaching physician may not be in the operating room for some or all of the tasks the resident performs.\*

The College, the AAMC, the AMA, and the AHA have received very positive feedback for suggesting these modifications to the interpretive guidelines. However, CMS also revised other sections of the guidelines pertaining to the informed consent process. The College's new Patient Safety and Quality Improvement Committee reviewed the guidelines in May and found the following areas of confusion:

- The guidelines suggest that informed consent be obtained for every procedure that is classified as surgery under the Current Procedural Terminology (CPT)<sup>†</sup> and that no services in other sections of CPT required informed consent. This committee believes that the CPT listings are an inaccurate gauge of whether informed consent should be sought. For example, the surgery section of CPT contains codes for placing intravenous tubes, which generally do not require informed consent, and the medicine section contains codes

\*This statement does not alter the rules regarding payment for the teaching physician during surgery. The rules say that payment will only be made to the teaching physician if he or she is present in the operating room for the portion(s) of the procedure that he or she determines are critical or key. (*Medicare Carriers Manual*, Section 15016. A. 7. and 9).

<sup>†</sup>All specific references to CPT (Current Procedural Terminology) terminology and phraseology are © 2006 American Medical Association. All rights reserved.

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for cardiac catheterization, which is an invasive procedure.

- The guidelines suggest that a well-designed surgical informed consent form should contain a description of the proposed anesthesia and the name of the person administering it. The committee wants clarification about the responsibility of the surgeon in the vast majority of hospitals, which have a separate informed consent for anesthesia.

- The guidelines also say that a well-designed informed consent process should include a discussion of the types of tasks that qualified non-physician health care professionals will do. The committee would like some guidance with respect to how much detail the surgeon must give when this situation occurs.

The College has written to CMS about these issues but, as of press time, has not received a response. Additional information will be provided when CMS responds.

### ***Additional College views***

CMS takes a relatively legalistic approach to informed consent, focusing on what the document should contain and related hospital policies. Although these elements demand consideration, it is also important to remember that the informed consent process is primarily for the patient's benefit. In patient education material developed on the principles of informed consent (see [http://www.facs.org/public\\_info/operation/consent.html](http://www.facs.org/public_info/operation/consent.html)), the College tells patients the following:

[The informed consent process] may appear to be a formality, but, in fact, this process should be taken very seriously. Before your operation, frankly discuss with your surgeon any questions or concerns that you have. Of course, not everyone wants to know all the specific details of the surgical procedure itself, but you should seek the answers to questions such as:

- What are the indications that have led your doctor to the opinion that an operation is necessary?
- What, if any, alternative treatments are available for your condition?
- What will be the likely result if you don't have the operation?
- What are the basic procedures involved in the operation?

- What are the risks?
- How is the operation expected to improve your health or quality of life?
- Is hospitalization necessary and, if so, how long can you expect to be hospitalized?
- What can you expect during your recovery period?
- When can you expect to resume normal activities?
- Are there likely to be residual effects from the operation?

As the College's *Statements on Principles* says, "Patients should understand the indications for the operation, the risk involved, and the result that it is hoped to attain." □