



Minnesota Informed Consent

FAQ

Why did the Minnesota Alliance for Patient Safety (MAPS) develop a new surgical and invasive procedures informed consent form?

MAPS developed this form in response to the 2004 Centers for Medicare and Medicaid Services (CMS) issuance of new Conditions of Participation (CoP) and interpretive guidelines (April 2007) for Patients' Rights, Medical Records and Surgical Services. These new conditions require facilities to adopt a written informed consent process and form that ensures patients understand his or her health status, patients are part of care planning, and patients have the opportunity to object to particular treatments.

What is the purpose of the informed consent process?

CMS defines 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 of the procedure to the patient. Risks will be based on the available clinical evidence and 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.

When does the informed consent process begin?

Informed consent involves much more than just obtaining a signature. The informed consent process is ongoing and interactive. The process might begin in the outpatient office; involve several providers; and occur over time rather than occur as a one-time information session prior to procedure. It is expected that all treatment decisions will be made only after a fully informed and shared decision-making discussion between the patient and clinician.

How will CMS evaluate compliance with these new informed consent regulations?

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.

Does the MAPS standardized informed consent form consider all of the necessary elements defined in the Conditions of Participation?

Yes. The form includes all of the minimum elements and includes those that make up an ideal informed consent form, as defined by CMS. This form also incorporates standards set by The Joint Commission and Occupational Safety and Health Administration (OSHA).

CMS states a "properly executed" informed consent form should contain the following minimum elements:

- Name of the facility where the procedure or other 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 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, with date and time.

What surgeries does this apply to?

“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.

Medical staff by-laws should address which procedures and treatments require written informed consent.

Does this apply to anesthesiology services?

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.

Does the informed consent form have to include more information, such as risks and benefits of the procedure?

No. An early draft of interpretive guidelines did include this requirement; however, in the final guidelines CMS deleted the requirement that the patient sign a form that identifies in the informed consent form itself the risks and benefits of the proposed procedure, and the alternatives to the procedure and their risks and benefits. The patient’s signature on a consent form provides written evidence that the patient has been *informed* of the risks of the recommended procedure and of alternative options and that he or she has consented to undergo the procedure based on that information.

We have consent forms we currently use to inform patients of risks and benefits and obtain informed consent. Can we continue to use those forms?

MAPS set out to develop a template form that every outpatient setting could utilize to facilitate the informed consent process and every hospital and surgical center in Minnesota would accept as comprehensive informed consent documentation. In addition to meeting CMS CoP for Patients’ Rights, Medical Records and Surgical Services and minimizing barriers to patient understanding, the form can minimize administrative burdens and increase efficiencies. This standardized form does not preclude a prior in-depth conversation with the patient nor the use of patient education materials to outline risks and benefits of the procedures.

Why is the language so simple? It may not provide enough information for some patients.

Health-care providers must provide adequate information in a manner that a patient can understand, to assure that he or she can effectively exercise the right to make informed decisions about the plan of care, medical or surgical interventions, and care after discharge. During times of illness and stressful events, all patients could benefit from easy-to-understand health-care forms. The simplified reading level of this form does not prohibit a more in-depth conversation for patients that desire more detailed information.

CMS’s review procedure will also include interviewing two or three post-surgical patients or the patients’ representatives, to determine their ability to provide a clear explanation of the informed consent process and to determine how satisfied they are with the informed consent discussion prior to their surgery.

What should be included in the facility informed consent policy?

Facility surgical informed consent policies 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.

Where can I find more information?

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 interpretive guidelines revised April 2007 for Tags A-0049 (Patients' Rights), A-0238 (Medical Records), and A-0392 (Surgical Services) replace the guidelines issued in May 2004.

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