



# Minnesota Alliance for Patient Safety (MAPS) Informed Consent Initiative

*Model policy and informed consent form*

Update March 2011

## **Why did MAPS develop a surgical and invasive procedures informed consent form and model policy?**

In 2004, the Centers for Medicare and Medicaid Services (CMS) issued revised Conditions of Participation (May 2004) and interpretive guidelines (April 2007, June 2009) stating that a “properly executed” informed consent “form” for procedures and treatments must be in the patient’s chart before surgery. They also required hospitals to have policies in place that outline a process for obtaining informed consent that adheres to principles of patient-centered care and health literacy, so as to improve shared medical decision making.

In 2007, MAPS started a statewide informed consent initiative in response to the CMS Conditions of Participation and interpretive guidelines. MAPS quickly realized that forms and policies varied across Minnesota’s organizations. Additionally, informed consent forms were not easily understandable to the patient. In response, MAPS worked to develop a common interpretation of the CMS regulations and worked collaboratively to develop a template informed consent form applying health literacy principles. MAPS has two informed consent forms, written at a 4<sup>th</sup> grade reading level, from which organizations can choose.

## **Why did MAPS decide to develop a more comprehensive model policy in 2010?**

In 2009, MAPS learned that facilities were faced with implementation issues as they put policies into place for informed consent. The MAPS informed consent work group was reconvened to resolve several implementation issues and developed a model policy that facilities can easily implement.

## **Do the MAPS informed consent forms and model policy include all of the necessary elements defined in the CMS Conditions of Participation?**

### *Model policy*

The “MAPS Model policy” follows CMS’s guidance for Surveyors. The policies are ideal, example policies developed through a collaborative stakeholder process. The model policy is intended to provide support and guidance to facilities on informed consent policies based on common community practices, state law and statute, and consensus. It is not meant to be the authoritative policy on informed consent, nor is it mandated in anyway.

### *Consent forms*

There are varying required elements, based on whether the facility is a PPS Hospital or a Critical Access Hospital. There are not regulatory requirements for documenting informed consent in ambulatory clinics, but MAPS advocates that a meaningful, patient-centered informed consent is an ethical and professional requirement for all physicians.

### *PPS Hospital - Properly-executed vs. Well-designed*

The form titled [Informed Consent Form For PPS Hospitals and Clinics](#) includes the minimum elements as outlined in the [State Operations Manual Appendix A - Survey Protocol, Regulations and Interpretive Guidelines for Hospitals](#) for a “properly executed” form, plus some elements that are suggested for a “well-designed” form and other standard informed consent elements.

CMS requires a “properly-executed” form include: the name of the patient or legal guardian, the facility name, the procedure name, name of the responsible provider performing the procedure, a statement that the procedure and its risks, benefits and alternatives were discussed, and a signature from the patient or their legal guardian.

If a facility so chooses it may also consider including elements and CMS would consider the form a “well-designed” form. The MAPS [Informed Consent Form for PPS Hospitals and Clinics](#) also includes the following “elective” items: the name and signature of the provider that talked to the patient about the procedure and obtained consent, the date, time and signature of “professional person” witnessing the patient/patient representative signing the consent form. Other optional elements that may be added are: a listing of the material risks that were discussed, a statement that physicians other than the operating practitioner (i.e., residents, other physicians) will be performing important tasks related to the surgery, in accordance with their skills and hospital policies, and a statement that qualified medical professionals who are not physicians, will perform important tasks that are within their scope of practice determined by law and for which they are granted privileges.

#### *Critical Access Hospital - Properly-executed*

The form titled [Informed Consent Form For Critical Access Hospitals](#) includes the minimum elements as outlined in [State Operations Manual Appendix W - Survey Protocol, Regulations and Interpretive Guidelines for Critical Access Hospitals \(CAHs\) and Swing-Beds in CAHs](#) for a “properly executed” form and other elements that are standard in informed consent.

CMS requires a “properly-executed” form include: the name of patient, name of facility where the procedure is taking place, the name of the patient or legal guardian, the facility name, the procedure name, name of the responsible provider performing the procedure and the names of practitioners performing important aspects of the procedures, a statement that the procedure and its risks, benefits and alternatives were discussed, a signature from the patient or their legal guardian, the name and signature of the provider that talked to the patient about the procedure and obtained consent, and the date, time and signature of “professional person” witnessing the patient/patient representative signing the consent form.

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

Evidence will 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.

#### **Why is the language of the informed consent form 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.

#### **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.

Questions may be directed to David Eddinger at CMS, email at [david.eddinger@cms.hhs.gov](mailto:david.eddinger@cms.hhs.gov)

**To download the form or the policy, visit [www.mnpatientsafety.org](http://www.mnpatientsafety.org).**