Minnesota Alliance for Patient Safety (MAPS)
Informed Consent: A Model Facility Policy

Model policy: Informed consent for surgical and invasive procedures[1]

Definitions:

Capacity: A *clinical* term that refers to the ability to make rational and reasonably well informed decisions by a particular patient in their treatment and/or life decisions. Decision-making capacity refers to the ability of a patient to understand the significant benefits, risks, and alternatives to proposed health care treatment options and to make and communicate a health care decision[2]. Includes the ability to understand information about treatment; to appreciate how that information applies to their situation; to reason with that information; and the ability to make a choice and express it.

Competency: A *legal* term that refers to the ability to make rational and reasonably well informed decisions by a particular person in their treatment and/or life decisions. A patient, considered legally incompetent to make decisions is an individual who, for reasons other than being a minor, is impaired to the extent of lacking sufficient understanding or capacity to make or communicate responsible personal decisions, inability to meet personal needs for medical care, nutrition, clothing, shelter, or safety, even with appropriate technological assistance[3]. Patients (wards) generally are assigned a court-appointed legal guardian.

Advanced medical directive: Refers to treatment preferences and the designation of a surrogate decision-maker in the event that a person should become unable to make medical decisions on her or his own behalf. Advance directives generally fall into three categories: living will, power of attorney, and health care proxy.

- Living Will: This is a written document that specifies what types of medical treatment are desired should the individual become incapacitated and may include information regarding an individual's desire for such services such as pain relief, antibiotics, hydration, feeding, CPR and the use of life-support equipment including ventilators.
- Health Care Proxy: This is a legal document in which an individual designates another person to make health care decisions if rendered incapable of making their wishes known. The health care proxy has, in essence, the same rights to request or refuse treatment that the individual would have if capable of making and communicating decisions.
- Durable Power of Attorney: This legal document gives the surrogate decision-maker power to execute legal documents condition (bank transactions, sign Social Security checks, apply for disability, or simply write checks to pay the utility bill) while an individual is medically incapacitated.

Emergency: An emergency medical condition exists when the patient's condition is such that failure to provide treatment or hospitalization would result in undue suffering or endanger life or limb.

Legal Guardian: A guardianship is a legal relationship created when a person or institution is assigned by the court to take care of minor children or incompetent adults to make decisions about health care for a protected person (ward)[4].

Informed consent: Informed consent is an ethical obligation and a legal requirement that health care providers (physicians and/or other clinicians performing procedures) disclose the benefits, risks, and alternatives to the proposed treatment, non-treatment, or procedure[5]. Information must be presented in a

1 In April of 2007, the Centers for Medicare and Medicaid Services (CMS) issued interpretive guidelines for informed-consent documentation [Statute 42 CFR §482.24(c)(2)(v)] for hospitals. These instructions to assist its surveyors on how to apply the regulations http://www.cms.gov/surveycertificationgeninfo/downloads/scletter07-17.pdf. In 2009, CMS issued interpretive guidelines for Conditions for Coverage for Ambulatory Surgical Centers effective as of 5/18/2009. http://www.ascassociation.org/guidelines.pdf. The following model policy outlines elements facilities might consider including in their facility policies to meet the guidance given to surveyors.

2 Minn. Stat. §§145C.01 Subd. 1b.

3 Minn. Stat. §524.5-102 Subd. 6.

4 Minn. Stat. §524.5-301, §524.5-310, §524.5-313

5 Mosby's Medical Dictionary, 8th edition. © 2009, Elsevier.

way that enables the patient or the patient's decision-making surrogate to voluntarily decide whether or not to consent to the recommended treatment, non-treatment, or procedure.

Informed Consent Process: The informed consent process is the process by which fully informed persons are involved in choices about their health care. Throughout the process health care providers (physicians and/or other clinicians performing procedures) and patients engage in meaningful discussion about proposed treatment and in a way that educates the patient or the patient's decision-making surrogate in terms that the patient understands ("lay language").

Informed Consent Form: A legal document verifying that the informed consent conversation occurred between the health care provider (physician and/or other clinician performing procedure) and the patient or their decision-making surrogate and that the patient understands what procedure is being recommended, why it is needed, and what are the risks and benefits of the care, treatment and services or procedure and/or alternatives. The form is signed by the patient or authorized person, the physician, and a witness.

Invasive Procedures: Invasive procedures are those involving a skin incision, puncture, or insertion of an instrument or foreign material into the body including, but not limited to: open surgical procedures, percutaneous aspiration, selected injections, biopsy, percutaneous cardiac and vascular diagnostic or interventional procedures, laparoscopies, and endoscopies.

Licensed Independent Practitioner: Physician, dentist, nurse practitioner, and nurse midwife or any other individual permitted by law and the organization to provide care and services without direction or supervision, within the scope of the individual's license and consistent with individually granted clinical privileges. Facilities should determine which individuals, including staff that may not be covered.

Material risks: Material risk is that which the physician knows would be regarded as significant by a reasonable person in the patient's position when deciding to accept or reject the recommended medical procedure[6]. Minnesota follows patient-based standard wherein what is needed for an adequate disclosure of risk should be measured by what a reasonable patient would want to know about the proposed treatment, its risks and consequences, and any treatment alternatives before deciding what course to follow.

"Moonlighting" resident or fellow: A postgraduate medical trainee who is practicing independently, outside the scope of his/her residency training program and would be treated as a physician within the scope of the privileges granted by the hospital.

Ordering, administering, and/or supervising practitioner: The physician, or other clinician with the appropriate credentials, who orders the procedure, administers the procedure, and/or provides medical supervision of other licensed healthcare practitioners.

Shared decision making (SDM): SDM is a process where providers determine the extent to which a patient wants to be involved in making medical decisions and if the patient wants to participate, the provider presents information about treatment options considering the patients values - in terms patients can understand and with the level of detail the patient prefers. *Both* the doctor and the patient arrive at a mutually acceptable decision based on their shared knowledge.[7]-

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6 Sard v. Hardy, 281 Md. 432, 444, 379 A.2d 1014, 1022 (1977). Canterbury, 464 F. 2d at 786. Russell v. Johnson, 608 N.W. 2d 895 (Minn. App. 2000).

7 Wilkes M, Johns M (2008) Informed Consent and Shared Decision-Making: A Requirement to Disclose to Patients Off-Label Prescriptions. PLoS Med 5(11): e223. doi:10.1371/journal.pmed.0050223. Accessed via the World Wide Web at /www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.0050223 on February 17, 2011.

Significant surgical tasks: Include opening and closing, harvesting grafts, dissecting tissue, removing tissue, implanting devices, altering tissues.

Surgery: For the purposes of determining compliance with the hospital surgical services Conditions of Participation (CoP), CMS relies, with minor modification, upon the definition of surgery developed by the American College of Surgeons. Accordingly, the following definition is used to determine whether or not a procedure constitutes surgery and is subject to CoP[8]:

> *"Surgery is performed for the purpose of structurally altering the human body by the incision or destruction of tissues and is part of the practice of medicine. Surgery also is the diagnostic or therapeutic treatment of conditions or disease processes by any instruments causing localized alteration or transposition of live human tissue which include lasers, ultrasound, ionizing radiation, scalpels, probes, and needles. The tissue can be cut, burned, vaporized, frozen, sutured, probed, or manipulated by closed reductions for major dislocations or fractures, or otherwise altered by mechanical, thermal, light-based, electromagnetic, or chemical means. Injection of diagnostic or therapeutic substances into body cavities, internal organs, joints, sensory organs, and the central nervous system also is considered to be surgery (this does not include the administration by nursing personnel of some injections, subcutaneous, intramuscular, and intravenous, when ordered by a physician). All of these surgical procedures are invasive, including those that are performed with lasers, and the risks of any surgical procedure are not eliminated by using a light knife or laser in place of a metal knife, or scalpel. Patient safety and quality of care are paramount and, therefore, patients should be assured that individuals who perform these types of surgery are licensed physicians (physicians as defined in 482.12(c)(1)) who are working within their scope of practice, hospital privileges, and who meet appropriate professional standards*."

Surrogate decision-maker: A surrogate decision-maker that is not a court appointed representative. A surrogate is someone specified in advance through documents such as a durable power of attorney for health care decisions that knows the patient and can specify their preferences. Surrogates do not have decision-making authority over competent patients except in the rare circumstance in which a competent patient explicitly yields authority to the surrogate well enough to try to estimate what the patient would want in a given situation.

Unexpected complication: Any emergency situation where care is immediately necessary and presents an imminently life-threatening risk to the patient preserve the patient life or limb beyond what is agreed to in the informed consent.

8 CMS Interpretive Guidelines §482.51, Interpretive Guidelines & Updated State Operations Manual (SOM). April 11, 2008. Page 306

Policy:

I. Statement of the patient's right to information and to make informed decisions (Required for CMS Survey)

Model policy statement: **Facility XXX** recognizes a patient's right to be informed of surgical or medical procedures and the patient has the right to accept or refuse such surgical or medical procedure. To assure informed decision-making and consent, patients must have information on their medical status, diagnosis and prognosis. Informed consent must be documented pursuant to this policy before proceeding with surgical and medical procedures.

II. Responsibility for obtaining the patient's informed consent (Required for CMS Survey)

Model policy statement: The duty and responsibility for discussing, obtaining, and documenting informed consent rests solely with the ordering, administering, and/or supervising practitioner. This practitioner is responsible for certifying in the medical record that the informed consent process has taken place and that the patient is well-informed and has consented to the treatment or procedure.

A. *Delegation of the informed consent dialogue*: The ordering, administering, and/or supervising practitioner can delegate the informed consent dialogue to another licensed independent practitioner with hospital privileges to perform the specific procedure for which consent is being obtained. This includes: a surgeon, intern, resident, or fellow familiar with the specific procedure for which consent is being obtained. Medical students may not obtain informed consent for any procedure. In the event that a delegate obtains consent, the ordering, administering, and/or supervising practitioner remains legally responsible for ensuring that their delegate obtains consent in a manner consistent with the hospital's policy.
B. *Collaboration for patient education*: The ordering, administering, and/or supervising practitioner may collaborate with other clinicians who assist in the informed consent process through use of patient education tools (i.e., video, written information sheets). The ordering, administering, and/or supervising practitioner is responsible for obtaining the patient's informed consent and certifying that the process has occurred.
C. *Other providers performing the procedure*: In cases where another surgeon or resident performs the procedure, the ordering, administering, and/or supervising practitioner is legally responsible for informed consent and certifying that the process has occurred.

III. Procedures requiring informed consent (Required for CMS Survey)

Model policy statement: Facility policy and medical staff bylaws should address the circumstances under which non-physician practitioners are permitted to perform procedures (based on state law, generally accepted standards of care, and licensure and privileges), which procedures require an informed consent dialogue between the patient and the ordering, administering, and/or supervising practitioner, and which require a properly executed informed consent form. It bears repeating that the ordering physician is solely responsible for obtaining consent.

Normally federal and state law, rules of accrediting organizations, and/or similar regulatory bodies require a properly-executed, written informed consent form for the following:

A. *Procedure*:
    i. Surgical procedures[9] (not including simple laceration repair and minor dermatological procedures performed in out-patient settings);
    ii. Experimental procedures or treatment;
    iii. Abortion[10]; (See letter E for state regulations that require additional documentation and consent for abortions)
    iv. Administration of blood or blood products (NOTE: The MAPS informed consent form includes consent for blood or blood products related to surgery [perioperative and throughout the hospital stay]. Facilities may choose to develop a specific policy and form for obtaining consent for therapeutic blood transfusions or blood products);

9 "Surgery" definition changed in CMS Interpretive Guidelines §482.51, Interpretive Guidelines & Updated State Operations Manual (SOM). April 11, 2008. Page 306

10 Minn. Stat. §145.4242

v. Electro-convulsive therapy (ECT);
vi. Neuroleptic medication[11] when prescribed for the treatment of mental illness[12] or developmental disability[13], but not when prescribed for other purposes;
vii. Any medical treatment necessary to preserve the life or health of a patient committed under the Minnesota Civil Commitment and Treatment Act[14];
viii. Radiation therapy;
ix. Invasive medical imaging;
x. Procedures involving moderate to deep sedation where there is a risk of loss of protective reflexes. (See D for guidance on separate anesthesia-specific informed consent form.)
xi. Invasive procedures involving a skin incision or puncture (excluding venipuncture or intravenous therapy) including, but not limited to:
    - Percutaneous aspiration of body fluids through the skin (e.g., arthrocentesis, bone marrow aspiration, lumbar puncture, paracentesis, thoracentesis, suprapubic catheterization);
    - Injections into a joint space or body cavity;
    - Biopsy;
    - Percutaneous cardiac and vascular diagnostic or interventional procedures (e.g., cardiac catheterization, cardiac pacemaker implantation, angioplasty, stent implantation, intra-aortic balloon catheter insertion);

11 Minn. § 253B.092

12 Subd. 20.Mental illness.

(a) "Mental illness" means an organic disorder of the brain or a clinically significant disorder of thought, mood, perception, orientation, memory, or behavior that is listed in the clinical manual of the International Classification of Diseases (ICD-9-CM), current edition, code range 290.0 to 302.99 or 306.0 to 316.0 or the corresponding code in the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders (DSM-MD), current edition, Axes I, II, or III, and that seriously limits a person's capacity to function in primary aspects of daily living such as personal relations, living arrangements, work, and recreation.

(b) An "adult with acute mental illness" means an adult who has a mental illness that is serious enough to require prompt intervention.

(c) For purposes of case management and community support services, a "person with serious and persistent mental illness" means an adult who has a mental illness and meets at least one of the following criteria:

(1) the adult has undergone two or more episodes of inpatient care for a mental illness within the preceding 24 months;

(2) the adult has experienced a continuous psychiatric hospitalization or residential treatment exceeding six months' duration within the preceding 12 months;

(3) the adult has been treated by a crisis team two or more times within the preceding 24 months;

(4) the adult:

(i) has a diagnosis of schizophrenia, bipolar disorder, major depression, or borderline personality disorder;

(ii) indicates a significant impairment in functioning; and

(iii) has a written opinion from a mental health professional, in the last three years, stating that the adult is reasonably likely to have future episodes requiring inpatient or residential treatment, of a frequency described in clause (1) or (2), unless ongoing case management or community support services are provided;

(5) the adult has, in the last three years, been committed by a court as a person who is mentally ill under chapter 253B, or the adult's commitment has been stayed or continued; or

(6) the adult (i) was eligible under clauses (1) to (5), but the specified time period has expired or the adult was eligible as a child under section 245.4871, subdivision 6; and (ii) has a written opinion from a mental health professional, in the last three years, stating that the adult is reasonably likely to have future episodes requiring inpatient or residential treatment, of a frequency described in clause (1) or (2), unless ongoing case management or community support services are provided.

13 Minn. § 253B.02.Subd. 14

Developmentally disabled person (not developmental disability) is defined in Minn. Stat. 253B.02 Subd 14 as: "Developmentally disabled person" means any person:

(1) who has been diagnosed as having significantly subaverage intellectual functioning existing concurrently with demonstrated deficits in adaptive behavior and who manifests these conditions prior to the person's 22nd birthday; and

(2) whose recent conduct is a result of a developmental disability and poses a substantial likelihood of physical harm to self or others in that there has been (i) a recent attempt or threat to physically harm self or others, or (ii) a failure and inability to obtain necessary food, clothing, shelter, safety, or medical care.

14 Minn. §253B.01

- Central vascular access device insertion (e.g., Swan-Ganz catheter, percutaneous intravascular catheter [PIC] line, Hickman catheter)[15];
- Laparoscopies (e.g., laparoscopic cholecystectomy, laparoscopic nephrectomy);
- Endoscopies(e.g., colonoscopy, bronchoscopy, esophagogastric endoscopy, cystoscopy, Percutaneous Endoscopic Gastrostomy (PEG), and J-tube placements), nephrostomy tube placements);
- Invasive radiology procedures (e.g., angiography, angioplasty, percutaneous biopsy),
- Laser therapy (e.g., eye, ear, nose, and throat [ENT])
- Dermatology Procedures (e.g., biopsy, excision and deep cryotherapy for malignant lesions - excluding cryotherapy for benign lesions);
- Invasive ophthalmic procedures(e.g., procedures involving implants);
- Oral surgical procedures (e.g., tooth extraction, gingival biopsy);
- Podiatric invasive procedures (removal of ingrown toenail, etc.);
- Skin or wound debridement performed in an operating room;
- Renal dialysis.

xii. Diagnostic procedures that carry a significant, material risk;
xiii. Circumcision;
xiv. Sterilization; (If Federal funding, for example Medicaid, pays for the patient's care, certain procedures must be met. See F and G below for federal and state regulations that require additional documentation and consent for sterilization. Seek internal legal counsel regarding application of these procedures to privately funded patients.)

B. *Clinical research*: The MAPS informed consent form for surgery or invasive procedures does not include all of the necessary components for informed consent for research. **Facility XXX** requires an additional form.
C. *Continuation of a do-not-resuscitate or -intubate order* (DNR or DNI) [16]*:* The ordering, administering, supervising practitioner and/or the anesthesiologist should review DNR or DNI status with the patient, family or the appropriate surrogate decision-maker prior to surgery and document the decision in the progress note of the medical record. Medical staff should discuss with the patient and other appropriate persons the level of actions to be taken in the event of a cardiopulmonary arrest and whether to suspend the DNR/DNI during surgery and the recovery from anesthesia. If a patient has a DNR/DNI advanced directive the anesthesiologist and/or ordering, administering, supervising practitioner should review and discuss with the patient their resuscitation status during the procedure and post-operatively.
D. *Anesthesia*: CMS does not require a separate consent form for anesthesia. The 2007 MAPS Informed Consent Form for Surgery or Invasive Procedures does not include all of the components necessary for informed consent for anesthesia as outlined by the American Society of Anesthesiology in its guidelines for Documentation of Anesthesia Care[17]. Therefore, a separate discussion of anesthesia risks by the anesthesia provider might be discussed and documented.
E. *Abortion*[18]: State law requires that the woman has to be informed, by phone or in person, by the physician performing the abortion OR the referring physician, at least 24 hours prior the abortion of the following: The risks, including infection, hemorrhage, breast cancer, danger to subsequent pregnancies, and infertility; probable gestational age; medical risks associated with carrying to term; for post-20 week abortions, whether or not an anesthetic would eliminate or alleviate pain to the fetus and the benefits/risks of the anesthetic; that medical assistance benefits may be available for prenatal care, childbirth, and neonatal care; that the father is liable to assist in the support of her child, even if the father has offered to pay for the abortion; that she has the right to

15 Regardless of which clinician performs the procedure, the Minnesota Board of Nursing states that the physician must obtain informed consent.

16 American Society of Anesthesiologists House of Delegates Affirmed October 2008. Ethical Guidelines for the Anesthesia Care of Patients with DNR Orders or Other Directives That Limit Treatment. Accessed via the World Wide Web on January 31, 2011 at http://www.asahq.org/For-Healthcare-Professionals/Standards-Guidelines-and-Statements.aspx

17 American Society of Anesthesiologists House of Delegates Affirmed October 2008. Statement on Documentation of Anesthesia Care. Accessed via the World Wide Web on January 31, 2011 at http://asahq.org/For-Healthcare-Professionals/Standards-Guidelines-and-Statements.aspx

18 Minn. Stat. §145.4242

review the printed educational materials on abortion on the Minnesota Department of Health website. The woman has to certify in writing, before the abortion, that she has been given this information and informed of her opportunity to review the information on the website/printed materials; and the physician or physician's agent must obtain a copy of the written certification and retain it for at least 3 years. Prior to anesthesia, physician also must disclose any additional cost of the procedure for administering anesthesia/analgesic. If the woman is seeking an abortion for a fetus diagnosed with a fetal anomaly incompatible with life, she has to be informed of available perinatal hospice services and offered this as an alternative to abortion. If it's a medical emergency that compels the abortion, the physician has to inform the female, before the abortion if possible, of medical indications supporting this judgment. Providers are required to report to the Minnesota Department of Health[19] using the process and form found at: http://www.health.state.mn.us/wrtk/rptconabt06.pdf

F. *Hysterectomy*[20]: Federal and Minnesota state regulations require additional documentation and consent for hysterectomy for patients whose care is paid for through Federal funding (Medicaid). Department of Health and Human Services (DHHS) requires that a hysterectomy acknowledgement statement (HAS) is signed by the patient and the provider at least 30 days but not more than 180days prior to the procedure. The patient or her guardian must sign a document that states the provider informed the recipient that she would be incapable of reproducing due to the hysterectomy is permissible. Below is a sample HAS. It is not mandatory for the provider to use this sample hysterectomy acknowledgment statement. This form is *in addition to* the standard surgical or procedural informed consent obtained and signed by the patient or guardian at the hospital or same day surgery center. Seek internal legal counsel regarding application of these procedures to privately funded patients.

G. *Sterilizations*[21]: Federal and Minnesota state regulations require additional documentation and consent for sterilization for patients whose care is paid for through Federal funding (Medicaid). The Sterilization Consent Form must be completed. This requires exact language and a DHHS approved form. This form is required by DHHS/CMS for Medicaid paid sterilizations and must be submitted with the bill. Any alternate form would have to be approved the Secretary of DHHS. This form is *in addition to* the standard surgical or procedural informed consent obtained and signed by the patient or guardian at the hospital or same day surgery center. Seek internal legal counsel regarding application of these procedures to privately funded patients.

- Men's English: http://edocs.dhs.state.mn.us/lfserver/Legacy/DHS-2511-ENG
- Women's English: http://edocs.dhs.state.mn.us/lfserver/Legacy/DHS-2510-ENG
- Men's Spanish: http://edocs.dhs.state.mn.us/lfserver/Legacy/DHS-2511-SPA
- Women's Spanish: http://edocs.dhs.state.mn.us/lfserver/Legacy/DHS-2510-SPA

Sample Hysterectomy Acknowledgment Statement
My doctor informed me, both orally and with written materials, that the performance of a hysterectomy would make me sterile (not able to have children).

Signed_____ Date _____

Note: If the recipient signs the acknowledgment after the hysterectomy, the acknowledgment must show that the recipient was informed of the consequences of the hysterectomy before the procedure was performed.

IV. When surgery may be performed without an informed consent (Required for CMS Survey)

19 Minn. Stat §145.4246. Subd. 6.

20 Requirements related to hysterectomy and sterilizations are under Title 42: Public Health Subpart F—Sterilizations § 441.258 Consent form requirements and § 441.256 Additional condition for Federal financial participation (FFP). The Minnesota Department of Human Services MHCP provider manual, chapter 10-Sterilizations is available at:
http://www.dhs.state.mn.us/main/idcplg?IdcService=GET_DYNAMIC_CONVERSION&RevisionSelectionMethod=LatestReleased&dDocName=dhs16_137815.

21 Ibid.

Model Policy Statement

A. *Emergencies*: If an emergency medical condition makes it impossible or impractical to obtain informed consent without jeopardizing the patient's life or health, emergency treatment may be provided to preserve the patient's life or health. Once the physician has determined that an emergency condition exists, the ordering, administering, and/or supervising practitioner should document in the medical record the facts that make the situation an emergency. The treatment rendered must be limited to that which is necessary to prevent the patient's death or severe disability, or to alleviate severe pain. Emergency treatment may continue until the patient gains decision-making capacity, or until the patient's surrogate decision-maker or legal guardian is available to make decisions on the patient's behalf, at which time informed consent must be obtained from the patient, their surrogate, or legal guardian. The emergency exception does not apply if the patient has previously clearly made known that he or she does not wish to receive the proposed emergency treatment under the present circumstances.
B. *Unexpected complications*: If medical complications or unanticipated abnormalities are encountered in the operating room an ordering, administering, and/or supervising practitioner is allowed to surgically resolve situation only if it is an emergency or a life-threatening situation.
C. *Court-ordered treatment:* Treatment may be provided to an individual without the individual's informed consent and over the patient's objection if ordered by a court. In these cases the court has heard testimony about the proposed treatment, risks, and benefits and has either ordered the patient to have the treatment or authorized the provider to provide the treatment. The court's order authorizing treatment must be documented and included in the patient's record.

V. Patient who may give informed consent for themselves (Required for CMS Survey)

Model Policy Statement

A. *Adults with decision-making capacity:* Adults, statutorily defined as an adult age 18 or over[22], are presumed to have decision-making capacity. Patients with decision-making capacity are the only person who may consent to their treatment unless there is convincing evidence to the contrary of their diminished decision-making capacity (see C below).

VI. Situations when informed consent must be granted by the patient's surrogate or guardian (Required for CMS Survey)

Model Policy Statement: Surrogate decision-makers or legal guardians are entitled to the same information as the patient before consent to treatment is given. Patients that require a surrogate or guardian decision–maker are:

A. *Minors*: Minors are statutorily defined as persons under the age of 18[23] and may not receive health care services without their parents' or legal guardians' consent. Exceptions to minor consent specified in Minnesota statute include:
    i. *Minors living separately from parents or guardians*[24]: While no formal system exists in Minnesota for a judge to legally emancipate a minor, a minor living separate from parents or guardians, and managing her own financial affairs, may seek medical treatment without the consent of a parent or guardian. This exception applies to a minor regardless of whether the minor's parents have consented to the minor living apart, or regardless of the extent or source of the minor's income
    ii. *Mental health, obstetric care, or sexual health*: Minnesota statute allows the following exceptions to minor consent for medical, mental, or other health services: to determine the presence or treatment of pregnancy and conditions associated with pregnancy; for sexually transmitted infections; for alcohol or other drug abuse[25] hepatitis B vaccinations[26] and; blood donation (only those 17 and over).[27]

22 Minn. Stat. §645.451
23 Minn. Stat. §645.451
24 Minn. Stat. §144.341
25 Minn. Stat. §144.343
26 Minn. Stat. §144.3441
27 Minn. Stat. §145.41

iii. *Married minors or minors that have given birth*[28]: Minnesota statute allows the following exceptions to minor consent for any minor who has been married or has given birth may consent for personal medical, mental, dental, or other health services or for services for the minor's child.
iv. *Treatment in a mental health facility*[29]*:* Minnesota statute allows the following exceptions to minor consent for any person 16 years or older may request informal admission to a treatment facility for observation or treatment of mental illness, chemical dependency, or mental retardation and may give valid consent for hospitalization, routine diagnostic evaluation, and emergency or short-term acute care.

B. *Legally incompetent adults unable to make medical decisions*: In most cases, a legally incompetent person has an appointed guardian or a health care agent authorized in a power of attorney or advanced health care directive. Non-emergent medical or surgical consent should be obtained from the following: legal representative (a court appointed guardian), durable power of attorney for health care, conservator (conservatorship papers must expressly grant this authority). If a patient has neither a court appointed guardian, agent, nor conservator consent may be obtained from the patient's closest available relative[30]. The ordering, administering, and/or supervising practitioner must ensure that when they obtain informed consent on behalf of incompetent individuals, they have obtained it from the correct person/persons. A copy of any documents authorizing a legal representative to consent to treatment on behalf of the patient should be filed in the patient's medical record.
C. *Legally competent adults temporarily unable to make medical decisions*: A patient might temporarily be unable to make decisions about their health care due to state of consciousness, or serious medical illness. Examples include impairment due to the administration of sedatives and narcotics or when a patient is in great pain. The ordering, administering, and/or supervising practitioner should assess the patient's capacity and conclude whether a patient has sufficient capacity to make decisions. This should be noted in a patient's record with the reasons supporting that decision. In cases where the patient is unable to make medical decisions, the ordering, administering, and/or supervising practitioner is ethically obliged to make a "reasonable inquiry" as to whether the patient has a health care proxy or power of attorney for health care. If there is no one with power of attorney for health care and no temporary guardianship, physicians may then seek out a surrogate decision-maker.
    i. *Hierarchy:* Minnesota law does not prescribe a hierarchy of surrogate decision-makers in cases where none are defined in powers of attorney or advanced directives. Facilities should develop internal policies that apply a standard process for determining surrogate decision-making. (Examples include Minn Statute 524.2-103 "Share of heirs other than surviving spouse"; Minn Statute 253B.03 Subd. 6c "Rights of patients"). If no appropriate surrogate decision-maker is available, the ordering, administering, and/or supervising practitioner is expected to act in the best interest of the patient until a surrogate is found or appointed. If multiple surrogate decision-makers at the same level are present the physician should try to help them achieve consensus about medical treatment.
    ii. *Telephone consent*: If consent is sought from the patient's legal guardian, decision-making surrogate, or family member who cannot be physically present to sign the consent form before the procedure, informed consent by telephone may be obtained. The discussion should be witnessed by two staff, documented on the consent form with a note that the consent was obtained by telephone, and signed by the person obtaining consent and the person witnessing consent.

VII. Process for obtaining informed consent (Required for CMS Survey)
See Section III E-G for specific information in state law that is required for consent for abortion, hysterectomy, and sterilization.

28 Minn. Stat. §144.342

29 Minn. Stat. §253B.03

30 Minn. Stat. §253B.03 Subd. 6. (c)

Model Policy Statement: Informed consent involves more that obtaining a signature. The informed consent process requires a detailed conversation between the patient and/or surrogate decision-maker and the provider about risks, benefits, and treatment alternatives.

Shared decision making (SDM) is a process that allows providers and patients or surrogate decision-makers to work collaboratively to decide which treatment is best for the patient as well as determining the extent to which the patient wants to participate in decision-making, their individual preferences and values, and the amount of information they desire about various treatment options and treatment risks. . Patients may experience decisional conflict or be ambivalent if they feel uninformed, are unclear about their values, or are unsupported in decision making. Physicians can help patients move towards a decision by explaining the current scientific evidence and by helping patients clarify preferences and values with decision aids.

After a decision is made informed consent is used to disclose the relative safety, efficacy, risks and benefits of a procedure to ensure the patient has all of the relevant information. The informed consent conversation might involve information about a proposed medical or surgical procedure paired with more detailed written materials, it might occur in one session or over time, and it might involve more than one practitioner or clinician. Providers might also ask the patient or surrogate decision maker to 'teach back,' in his or her own words, key information about the proposed treatments or procedures for which he or she is being asked to provide consent.

A. *The informed consent dialogue*: The following must be addressed in the conversation:
    i. A description of the proposed procedure, including the anesthesia to be used if applicable (note: a separate conversation with the anesthesia care provider is recommended);
    ii. The indications for the proposed procedure;
    iii. Material risks and benefits for the patient related to the procedure and anesthesia if applicable, including the likelihood of each
    iv. Treatment alternatives, including the attendant material risks and benefits;
    v. The probable consequences of declining recommended or alternative therapies;
    vi. Who will conduct the surgical intervention and administer the anesthesia if applicable;
    vii. To the extent it is known, whether physicians other than the ordering, administering, and/or supervising practitioner, including but not limited to other licensed independent practitioners, residents, and fellows, will be performing significant tasks related to the surgery or procedure;
        - Discussion with the patient should explain that only physicians who are in approved post graduate residency training programs will perform portions of the surgery or other invasive procedure, based on availability and level of competence and that it will be decided at the time of the procedure which residents will participate and their manner or participation.
        - The supervision of the resident by the ordering, administering, and/or supervising practitioner and whether the ordering, administering, and/or supervising practitioner will not be physically present in the same operating room for some or all of the surgical tasks performed by residents.
    vii. Whether qualified medical practitioners who are not physicians (e.g., CRNAs, nurse practitioners, RN first assistants, physician assistants, etc.) will perform significant parts of the surgery or administer the anesthesia and if so, the types of tasks each type of practitioner will carry out.
    viii. The patient, surrogate decision-maker, or legal guardian should be given an opportunity to ask questions and to have them answered to their satisfaction.
B. *Scope of consent obtained*: The scope of a patient's consent depends on what the ordering, administering, and/or supervising practitioner has discussed and what the patient has consented to. Both the practitioner and patient should be clear as to what the patient has consented to, and their understanding is clearly documented on the informed consent form or

elsewhere in the medical record. The patient can rescind consent at any time prior to the procedure.

i. *Frequency*: A patient may consent to:
   - A one-time treatment or procedure (e.g., appendectomy),
   - Routine care of a particular condition that may include a variety of discrete procedures or treatments (e.g., pre-natal care), or
   - A series of the same treatment (e.g., dialysis).

ii. *Unanticipated non-emergent and emergent conditions during surgery*: The surgeon must use reasonable judgment when they encounter an unanticipated condition during surgery. Before the ordering, administering, and/or supervising practitioner proceeds they must determine if the unanticipated condition is an emergent or non-emergent condition. For non-emergent conditions, the physician should wait until informed consent has been given. In emergent situations the physician is responsible for informing the patient, legal guardian or surrogate decision-maker at the first available opportunity.

C. *Timeliness of the consent:* If there is a delay between when the patient initially consented and when the procedure is performed consent should be revisited, especially where there has been a significant deviation from the treatment plan or facts have changed since the ordering, administering, and/or supervising practitioner's discussion with the patient such that it would be reasonable for the patient to be informed of the change.

D. *Day of procedure*: In addition to signing the form on the day of the procedure, the ordering, administering, and/or supervising practitioner should note in the patient's record that a mutual agreement between the patient and ordering, administering, and/or supervising practitioner regarding the course of the treatment was reached and that all questions have been answered. Even if there has been no significant change since the original dialogue, a ordering, administering, and/or supervising practitioner should discuss and confirm the proposed treatment with the patient again.

VIII. Content of the informed consent form (Required for CMS Survey)

Model Policy Statement

A. All medical records must contain a properly executed informed consent form prior to conducting any procedure or other type of treatment that requires informed consent, except in situations as specified in this policy.

B. According the CMS Conditions of participation for PPS Hospitals, the form must contain the following minimum elements[31]

i. Name of the hospital where the procedure or other type of medical treatment is to take place;
ii. Name of the specific procedure, or other type of medical treatment for which consent is being given;
iii. Name of the responsible practitioner who is performing the procedure or administering the medical treatment;
iv. 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.)
v. Signature of the patient or the patient's legal representative; and
vi. Date and time the informed consent form is signed by the patient or the patient's legal representative.

A well-designed informed consent form might also include the following additional information:

i. Name of the practitioner who conducted the informed consent discussion with the patient or the patient's representative.
ii. Date, time, and signature of the person witnessing the patient or the patient's legal representative signing the consent form.

[31] Revisions to the Hospital Interpretive Guidelines for Informed Consent (2007) Access via the World Wide Web www.cms.gov/surveycertificationgeninfo/downloads/scletter07-17.pdf.

iii. Indication or listing of the material risks of the procedure or treatment that were discussed with the patient or the patient's representative;
iv. 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.
v. 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.

C. According the CMS Conditions of participation for Critical Access Hospitals (CAH), a properly executed consent form contains at least the following:
i. Name of patient, and when appropriate, patient's legal guardian;
ii. Name of CAH;
iii. Name of procedure(s);
iv. Name of practitioner(s) performing the procedures(s);
v. Signature of patient or legal guardian;
vi. Date and time consent is obtained;
vii. Statement that procedure was explained to patient or guardian;
viii. Signature of professional person witnessing the consent;
ix. Name/signature of person who explained the procedure to the patient or guardian.

D. The Minnesota Alliance for Patient Safety (MAPS) Informed Consent form includes several additional elements that are intended to help patients better understand the care they are about to receive and to prompt the provider of topics they should discuss with the patient prior to the surgery or procedure. The MAPS form includes a statement outlining the reason for the procedure, information about sedation, care planning, and HIV testing. The MAPS form also incorporates statements about students viewing of the procedure, facility recording of the surgery or procedure, and removal, testing, and disposition of the tissue[32]. The patient or their guardian have the right to cross off any statement on the form with which they don't agree given it does not significantly impact the care plan or their safety. The provider should discuss with the patient their wishes, concerns, and respect the patient wishes.

IX. Instructions for filling out the informed consent form (Required for CMS Survey)

Model Policy Statement

A. *Procedural components*: The person filling out the procedural components on the informed consent form must be familiar with the patient, the procedure to be completed (including laterality and level, where appropriate), and must use terminology informed by the physician's order. The terms must be understandable by the patient, surrogate decision-maker, or legal guardian.
B. *Multiple procedures on one form:* In cases where multiple procedures are to be performed by several practitioners, the names of the practitioners and which significant surgical tasks they will be conducting should be included in the informed consent form. The form must clearly identify the procedures being consented to and be signed by all practitioners.
C. *Source documents*: The person completing the informed consent form should verify the patient's identity, the procedure and procedure site (including laterality and level, where appropriate), applicable medical record data, the history and physical, and applicable diagnostics when completing the informed consent form.
D. *Patient edits*: Patients can remove items from the written inform consent form by drawing a line through the statement as long as they don't impact statements required by state or federal law or alter the intent of the form significantly. The ordering, performing, and/or supervising physician has the ability to stop a procedure if the edited form poses a significant risk.
E. *Abbreviations*: Abbreviations related to the procedure may not be used on the consent form.

[32] Minn. Stat. 145.1621 outlines requirements for disposition of the remains of a human fetus.

F. *Blood transfusions or blood products during surgery:* The patient's informed consent for blood products during surgery is predicated on a conversation between the patient and the ordering, administering, and/or supervising practitioner outlining the likelihood, risks, benefits, and alternatives. If the patient refuses intra-operative products, the ordering, administering, and/or supervising practitioner must decide whether to proceed and an alternative course. Patient refusal must be documented in medical record. (Note: The MAPS informed consent form includes consent for blood or blood products related to surgery [perioperative and throughout the hospital stay]. Facilities may choose to develop a specific policy and form for obtaining consent for therapeutic blood transfusions or blood products.)

G. *Clinician's Signature*: The ordering, administering, and/or supervising practitioner must sign the informed consent form on the day of the surgery or invasive procedure, before the procedure can be performed. The ordering, administering, and/or supervising practitioner's signature on the informed consent form certifies the appropriate information was provided[33].

H. *Verification of patient's signature by witness*: Hospital staff members (including all nurses and other employees) may serve as a witness by verifying that the signature on the informed consent form is that of the patient, surrogate decision-maker, or legal guardian.

   i. *Employee witness observes patient signing*: A facility employee who observes the patient signing the form may verify that fact by signing the informed consent form as a witness to the signature. It is not necessary for a facility employee to witness personally the informed consent conversation between the clinician and patient.

   ii. *When signed out of employee witness's presence*: If the form was signed by the patient out of the presence of a facility employee, an employee must confirm with the patient that the signature on the form is that of the patient and that the patient consents to the procedure. The employee must sign the informed consent form as a witness.

   iii. *When signed and witnessed out of employee witness's presence*: If another witness (e.g., a nurse in the clinician's office) has already signed the form, the facility employee may co-sign the form or note in the record that the employee verified the patient's signature.

X. How patient refusal of treatment will be handled (Required for CMS Survey)

Model Policy Statement: Competent adult patients or their legally empowered representatives have the right to refuse medical treatment. Faced with such a refusal, the ordering, administering, and/or supervising practitioner should disclose any foreseeable risks or consequences to the patient's health that could be expected to result from such refusal as well as reasonable therapeutic alternatives. The progress notes should reflect the reason for the patient's refusal as well as any information provided to the patient or the patient's representative.

XI. Circumstances under which a patient request for treatment can be denied: (Required for CMS Survey)

Model policy statement:

This is an ambiguous requirement and MAPS found no model policy exists to address denials of patient requests for treatment. Facilities should develop their own policies for when they might consider limiting a patient's right to care.

XII. External documentation of the informed consent process and informed consent (Required for CMS Survey)

Model policy statement: Informed consent can be obtained by the ordering, administering, and/or supervising practitioner in the physician clinic rather than the hospital. The progress notes should clearly document the consent process. At a minimum the note should specifically state that the procedure, alternatives, material risks and complications were discussed and the patient's questions were answered. While the note need not be a verbatim transcript of the discussion, key elements especially

33 In cases where the ordering, administering, or supervising practitioner cannot be physically present to sign the form prior to the procedure (e.g., insertion of a central line) the ordering, administering, or supervising practitioner may certify that the informed consent conversation took place and that the patient consented. The clinician must follow the facility's procedure for accepting an order by telephone.

regarding risks should be noted, as well as any specific questions raised by the patient and answers provided by the physician. Documentation in the form of a signed written informed consent should be in the patient's hospital medical record prior to the procedure as evidence that consent has been obtained.

XIII. How the patients will be involved in their care planning (which includes discharge planning) and treatment (Required for CMS Survey)

Model policy statement: The patient has the right to be involved in the decision-making of all aspects of their care. The patient has the right to reasonably informed participation in decisions involving their healthcare. To the degree possible, this should be based on a clear, concise explanation of his condition and of all proposed technical procedures, including the possibilities of any risk of mortality or serious side effects, problems related to recuperation, and probability of success. The patient should not be subjected to any procedure without his/her voluntary, competent, and understanding consent, or that of their legally authorized representative. Where medically significant alternatives for care or treatment exist, the patient shall be so informed.