Warning: This information is not intended to constitute legal advice and should not be relied upon in lieu of consultation with appropriate legal advisors in your own jurisdiction. It may not be current as the laws in the area of informed consent change frequently.

I. Discussion of the Informed Consent Doctrine

The United States currently has no federal statute which comprehensively addresses informed consent to healthcare procedures. Rather, each of the fifty states has one or more informed consent statutes, each of which is subject to amendment during each session of the states’ legislatures. Furthermore, a state’s statute(s) addressing informed consent may be supplemented by common-law (judicially enacted) concepts. This memo summarizes “best practices” as they can be gleaned from a review of state-level informed consent laws, ethical standards and accreditation standards in the healthcare industry.

II. Legal Concepts Surrounding Informed Consent

A. Elements Of A Valid Informed Consent

While users of consent forms should consult with legal counsel familiar with the laws in their jurisdictions to ensure that the forms used comply with any special requirements of the relevant state law or the user’s situation, certain common elements should be included in all consent forms. Those elements are:

- the diagnosis;
- the nature and purpose of the procedure(s) for which consent is sought;
• all material risks and consequences of the procedure(s);

• an assessment of the likelihood that the procedure(s) will accomplish the desired objectives;

• any reasonably feasible alternatives for treatment, with the same supporting information as is required regarding the proposed procedure(s); and

• the prognosis if no treatment is provided.

B. How The Consent Is Obtained

In order to ensure that informed consent is properly obtained, the physician should actually discuss with the patient each of the procedures to be performed, detailing its nature, risks and alternatives. This conversation should take place before the patient is under the influence of pre-operative medications. Thus, the consent form should provide blanks for the date and precise time of signature by both the patient or his responsible party, and the physician. The patient should also be given an opportunity to ask questions concerning the proposed treatment and the written consent should confirm that the opportunity has been given. The consent should be signed by the patient or responsible party in the presence of an attesting witness.
C. Variation In State Laws As To How Much Information Is Considered Adequate

The states are far from uniform in their views of how much information should be disclosed for a truly informed consent. States tend to adopt one of three approaches:

- Reasonable physician standard: what would a typical physician say about this procedure? This standard allows the physician to determine what information is appropriate to disclose. In 1972, virtually all jurisdictions adhered to this rule in measuring a physician’s duty to disclose. This somewhat paternalistic approach has begun to lose favor in recent years because it is deemed to be inconsistent with the goals of informed consent, as the focus is on the physician rather than on what the patient needs to know.

- Reasonable patient standard: what would the average patient need to know in order to be an informed participant in the decision? This standard focuses on considering what a patient would need to know in order to understand the decision at hand.

- Subjective standard: what would this particular patient need to know and understand in order to make an informed decision? This standard is the most challenging to incorporate into practice since it requires tailoring information to each patient.
Since 1972, there has been a gradual movement toward adopting the reasonable patient standard or the subjective standard, but these rules remain the minority position. This concept is one example of the tailoring which must be done by the physician, according to the particular state’s approach.

D. What Sorts Of Interventions Require Informed Consent?

State laws also vary as to which health interventions require a signed consent form. Some states require a written consent only for surgery, anesthesia or other invasive procedures. Other states require an informed consent for a broader range of procedures, including screening tests.

E. Duty To Inform Of Alternative Treatment Options

Where there are viable and medically appropriate alternative treatment options, it is generally held that physicians have a duty to inform a patient of those alternatives. In some states, however, alternative treatment options are not required to be disclosed unless a plaintiff can establish that a reasonably prudent patient would have actually chosen the alternative treatment. Where alternative treatments are required, all possible alternatives are not required; only medically acceptable and feasible options need be disclosed.

F. Disclosure Of Physician’s Financial Interest Or Personal Information
In some jurisdictions the doctrine of informed consent has been held to require disclosures beyond those relating to the risks and alternatives of a contemplated treatment or procedure. For example, the doctrine of informed consent has been held to require a physician to inform a patient as to the physician’s research and economic interest unrelated to the patient’s health, where that interest may affect the physician’s medical judgment. For instance, in Moore v. The Regents of the University of California, 271 Cal. Rptr. 146, 793 P.2d 479 (1990), a plaintiff sought treatment for leukemia. The physician recommended that the plaintiff’s spleen be removed, and arranged to use portions of the removed spleen for potentially lucrative medical research. The physician failed to disclose the pre-existing research and his economic interest prior to extracting the spleen. The Supreme Court of California held that the plaintiff stated a cause of action for the breach of a fiduciary duty and lack of informed consent. It opined that a physician must disclose personal interests unrelated to the patient’s health, whether for research or economic gain, in obtaining consent to medical treatment because of conflicting loyalties.

In contrast, several courts have held that the doctrine of informed consent does not require disclosure of information concerning the personal characteristics of the physician, such as his academic qualifications, licensure status or lack of experience in performing the procedure.

G. Documenting Limitations On Treatment

It would be very difficult for a patient who indicates no limitations or prohibition in a space provided for that purpose on a consent form to assert at a later time that a physician had
agreed that certain things would or would not be done in the course of treatment. If the patient imposes some limitation based on religious belief, such as the refusal of blood transfusion by a Jehovah’s Witness, it may be advisable to have a separate release form executed to deal with such limitation in more detail. However, providing a place in the consent form for the patient to specify any limitation is advisable.

H. Format Of Consents

Informed consents may be subject to challenge if they contain too much legalese or technical medical terminology. It is also advisable that the format of any informed consent document be easy to follow (large print, logical spacing and organization, numbered and captioned paragraphs).

III. Industry Standards

A. The Model Act

One common reference point for determining best practices in an area of law is enactments of the National Conference of Commissioners on Uniform State Laws. The National Conference was organized in 1892 to promote uniformity in state law on subjects where uniformity is deemed to be desirable and practical. The uniform acts that are adopted by the National Conference are often incorporated into state laws by voluntary action of state legislatures.
The Model Health-Care Consent Act (the “Model Act”) was approved in 1982 by the National Conference of Commissioners on Uniform State Laws. While it has only been incorporated into the laws of the State of Indiana (with minor variations in 1987) and the Virgin Islands (in 1993), other jurisdictions have adopted portions of the Act.

The Model Act is for the most part procedural in nature and narrow in scope. It designates the individuals who may consent to healthcare for themselves. It provides a triggering mechanism to determine when an individual is incapable of consenting. The Model Act provides a mechanism for determining a proxy decision-maker to act for one incapable of consenting, and permits family members authorized to consent for another to delegate their authority to make healthcare decisions. Therefore, the Act is focused on the mechanism for authorization of consent to healthcare rather than on the many substantive acts of consent, for instance, what constitutes informed consent, whether informed consent is required or under what circumstances one has a right to refuse treatment. Because of the narrow procedural scope of the Act, it does not provide a complete model to guide providers in how to structure boilerplate consent forms.

B. JCAHO Standards For Consent

Many healthcare organizations voluntarily seek accreditation from recognized accrediting bodies, the most prominent being the Joint Commission on Accreditation of Healthcare
Organizations (JCAHO). For purposes of this memo, we have reviewed the voluntary accreditation standards for ambulatory care and for office-based surgery practices.

1. Ambulatory Care Standards

Standard R1.1.2.2 requires that informed consent be obtained. The intent is stated as follows:

Informed consent is not merely a signed document. It is an ongoing process that considers patient needs and preferences, compliance with law and regulation and patient education.

The above cited JCAHO standard requires that the patient and family be given information as to:

- the patient’s condition;
- proposed treatments, procedures, or research activities;
- potential benefits and drawbacks of proposed treatments or procedures;
- problems related to recuperation;
• alternative treatment(s) or procedure(s);

• the physician or other practitioner primarily responsible for the patient’s care;

• others authorizing or performing procedures or treatments; and

• any business relationships among individuals treating the patient, or between the organization and any other healthcare, service, or educational institutions involved in the patient’s care.

JCAHO Standard R1.1.2.4 requires that patients involved in investigational studies and clinical trials participate in care decisions throughout the care process. The informed consent to research studies should document that the patient has the right to withdraw from a research protocol, and that the patients have received information that specifies the risks and benefits of engaging in the research activities.

JCAHO Standard R1.1.3.4 specifies that consent forms and educational materials are to be available in the primary languages of the common populations served.

Standard TX.5.2 specifies that, before obtaining an informed consent, the risks, benefits and potential complications associated with the procedure(s) should be discussed with the patient and family.
Standard TX.5.2.1 requires that alternatives to the planned procedure be discussed.

Standard TX.2.1 requires that anesthesia options and risks be discussed with the patient and family prior to administration. The medical record should document that the patient was informed of the type of anesthesia to be used, the risks involved and the name and qualifications of the person administering the anesthesia. There should be documentation that the patient was asked to discuss any previous problems with anesthesia, allergies, and medications that may affect the outcome of surgery and any concerns the patient expressed about the use of anesthesia and the ways in which those concerns were addressed. (Typically a separate anesthesia consent form would document these steps.)

Standard TX.5.2 addresses disclosure of the risks and benefits of treatment. Before obtaining informed consent, the risks, benefits and potential complications associated with the procedures should be discussed with the patient and family, and alternative options considered.

2. Office-Based Surgery Standards

The JCAHO Standards for office-based surgery practices reflect similar concepts as those for ambulatory care. They require that the patient (and family as appropriate) be given information about:

- the patient’s condition;
• proposed treatments, procedures, or research activities;

• potential benefits and drawbacks of proposed treatments or procedures;

• post-treatment recuperation;

• alternative treatment(s) or procedure(s) and risk of no treatment;

• when blood or blood components may be used, the risk of and alternatives to the use of blood or blood components;

• the surgeon(s) responsible for the procedure;

• the practitioner(s) primarily responsible for the sedation and anesthesia;

• others authorizing or performing procedures or treatments; and

• any business relationship among individuals treating the patient or between the practice and any other healthcare, service or educational institution involved in the patient’s care.

C. AMA Ethical Standards
The American Medical Association’s Code of Medical Ethics and Current Opinions, states as follows with regard to informed patient consent:

8.08. The patient’s right of self-decision can be effectively exercised only if the patient possesses enough information to enable an intelligent choice. The patient should make his or her own determination on treatment. The physician’s obligation is to present the medical facts accurately to the patient or to the individual responsible for the patient’s care and to make recommendations for management in accordance with good medical practice. The physician has an ethical obligation to help the patient make choices from among the therapeutic alternatives consistent with good medical practice. Informed consent is a basic social policy for which exceptions are permitted: (1) where the patient is unconscious or otherwise incapable of consenting and harm from failure to treat is imminent; or (2) when risk-disclosure poses such a serious psychological threat of detriment to the patient as to be medically contra-indicated. Social policy does not accept the paternalistic view that the physician may remain silent because divulgence might prompt the patient to forego needed therapy. Rational, informed patients should not be expected to act uniformly, even under similar circumstances, in agreeing to or refusing treatment.
The AMA policies therefore reflect concepts of patient self-determination for treatment, accurate and full disclosure of relevant medical facts, and disclosure of therapeutic alternatives to the treatment being consented to.
Physician's Surgical Procedure Disclosure and Patient’s Consent

TO THE PATIENT: You have the right to be informed about your condition and the recommended surgical, medical or diagnostic procedure so that you may make the decision whether or not to undergo the procedures after knowing the risks involved and any treatment alternatives available to you. This information is not meant to alarm you; it is an effort to make you better informed so that you may give or withhold your consent to the procedure. If you do not understand any of the information provided, ask your physician to explain it.

1. DIAGNOSIS: I (we) voluntarily request my physician, __________________, and such associates, technical assistants, and other health care providers as they may deem necessary, to treat my CONDITION:

________________________________________________________________________

2. PROCEDURE(S): I (we) understand that the following surgical procedure or procedures are planned for me on or about ________________________(month)
________________________(day) ________________________(year). I voluntarily consent to and authorize this (these) PROCEDURE(S)

g for the following purpose:________________________________________________________________________

________________________________________________________________________

3. MATERIAL RISKS: Just as there many risks and hazards in continuing my present condition without treatment, there are also risks related to the performance of the surgical, medical and/or diagnostic procedure planned for me. I (we) realize that common to surgical, medical and/or diagnostic procedures is the potential for infection, blood clots in veins or lungs, hemorrhage, allergic reactions and even death. I (we) also realize that the following additional RISKS may occur in connection with this (these) procedure(s):

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

4. ALTERNATIVES TO PROCEDURE: The following feasible alternatives to this procedure have been discussed with me:

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

5. PROGNOSIS IF NO TREATMENT: I have been informed of the prognosis if no treatment is provided, as follows:

________________________________________________________________________

________________________________________________________________________
6. ANESTHESIA: I (we) understand that anesthesia involves additional risks but I(we) request the use of an anesthetic for the relief and protection from pain during the planned and additional procedure(s), if any. I (we) realize the anesthesia may have to be changed without explanation to me (us).

I (we) understand that certain complications may result from the use of any anesthetic, including respiratory problems, drug reaction, paralysis, brain damage, or even death. Other risks and hazards which may result for the use of general anesthetics range from minor discomfort or injury to the vocal cords, teeth or eyes. I (we) understand other risks and hazards resulting from spinal or epidural anesthetics include headaches and chronic pain.

Additional anesthesia information supplied to the patient:
______________________________________________________________________________
______________________________________________________________________________
______________________________________________________________________________

I consent that anesthesia be administered by, or under the direction and supervision of ____________________________.

7. TREATMENT LIMITATIONS: I impose no specific limitations or prohibitions regarding treatment other than those that follow:
[If none, so state.]
______________________________________________________________________________
______________________________________________________________________________
______________________________________________________________________________

8. DISPOSAL OF TISSUE: I (we) authorize the disposal of any surgically removed tissue or parts resulting from the procedure according to accustomed practice.

9. BLOOD PRODUCTS: I (we), (do) (do not) consent to the use/administration/transfusion of blood products as deemed necessary.

10. CONSENT TO TRAINING PARTICIPATION: Since this facility may have an educational role in the training of paramedical personnel, I (we) (do) ____ (do not) ____ consent to the admittance and participation of students and/or technical representatives for the purpose of advancing medical education and/or product usage.

11. CONSENT TO TREATMENT OF UNFORESEEN CONDITIONS: I (we) understand that my physician may encounter or discover other or different conditions which require additional or different procedures than those planned. I (we) authorize my physician, and associated technical assistants, and other health care providers to perform such other procedures which are advisable in their professional judgment.

12. OUTCOME: I (we) understand that the practice of medicine is not an exact science, and that no warranty or guarantee has been made to me as to result or cure.
Consent:

I (we) have been given sufficient opportunity to ask questions about my condition, alternative treatments, risks of treatment, the procedures to be used, and the risks and hazards involved. All of my questions have been answered to my satisfaction, and I (we) have sufficient information to give this informed consent. I hereby consent to the above described procedure.

I (we) certify that this form has been fully explained to me (us), and that I have read it, or have had it read to me (us), that the blank spaces have been filled in and that I (we) understand its contents.

______________________________________          Date:____________
Patient or Legally Responsible Person          Time:____________  (A.M./P.M.)
_________________________________________________________
Signature of Witness (Include Position / Title)

________________________________________________
Printed Name of Witness

To Be Completed By Physician After Patient Consent Completed:

I certify that the procedure(s) described above, including the risks, possible complications, anticipated results, alternative treatment options, including non-treatment, have been explained by me to the patient or his or her legal representative before the patient or his/her legal representative consented.

_____________________________________________
Treating Physician
Date:________________
Time: ______________ (A.M./P.M.)