Informed Consent

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Proposal for an Informed Consent Statute for Elective Treatment Decisions in Illinois:

Standards for the Health Care Practitioner

Benefits of an Informed Consent Statute Over Current Case Law

The parameters of the duty to disclose risks associated with elective procedures can become blurry when the physician is unsure whether certain rare and remote risks must be disclosed or whether those risks should be withheld from the patient for the patient’s benefit. Holding the physician accountable for each and every potential risk arising out of an elective procedure places an unnecessary burden upon the physician; for some procedures, the non-disclosure of rare or remote risks would benefit the patient, and with advanced medical treatments, the risks are continually redefined, such that new risks develop and other risks do not occur. The medical specialists, not the courts, know best which risks are likely to occur with certain elective procedures. The legislature can use the expertise of medical specialists to draw appropriate parameters for doctors to follow when disclosing risks to their patients, which could have the effect of strengthening the doctor-patient bond and decreasing the frequency of informed consent medical malpractice litigation.

The current trend in the law in Illinois provides that a physician has a duty to inform patients of the foreseeable risks and results of a given surgical procedure as well as the reasonable alternatives to such procedures. Illinois follows a “reasonable physician” standard, which substitutes a national standard providing sufficient physician disclosure is measured by what a reasonable physician would disclose under the same or similar circumstances. Thus, the physician has a duty to disclose to the patient those risks, results or alternatives that a reasonable medical practitioner in the same school, in the same or similar circumstances, would have disclosed. From the plaintiff’s perspective, in order to prove that a lack of informed consent was the proximate cause of the patient’s injury, the patient need only prove, by a preponderance of the evidence, that disclosure of the risks would have caused a reasonable person in the position of the plaintiff to refuse the surgery or treatment.

To defend a physician in an informed consent case, expert testimony is needed to show the consent obtained conformed with the standard of care. A physician cannot safely rely on court decisions, as they provide no meaningful guidelines as to what remote or rare risks he should disclose and whether he should disclose certain remote or rare risks at all. Under the most recent informed consent case in Illinois, Coryell v. Smith, physicians have no chance of being granted a summary judgment, when plaintiff’s expert claims a certain risk or all risks should have been disclosed and the plaintiff claims that, had his alleged injury been revealed as a risk of the medical procedure he underwent, he would not have consented to the surgery. Allowing the issue of proximate cause to go to the jury increases the chances for expensive and lengthy litigation. A legislative initiative clearly defining what must be disclosed and what each party’s responsibilities include could preserve the doctor-patient relationship, keep patients informed of the risks, and lessen the chance of litigation.
Health care providers and the general public have limited access and exposure to case law, which causes confusion for both. For example, the physician, concerned he needs to disclose any risk, no matter how slight, may tend to disclose each one. This mystifies the risks for the patient who has too much information while creating an extra burden on the physician to disclose every risk if he wants to avoid liability. A patient told of every risk may withdraw from elective surgery, and injure herself further by her own actions. Clarifying the obligations of the physician and patient to discuss and understand the risks of medical procedures is an appropriate goal for legislation.

One approach could be a statute providing that when a patient signs an informed consent form, a presumption that the consent is valid arises, which could be overcome only by a showing of clear and convincing evidence that fraud, duress or undue influence induced the plaintiff to undergo the surgery which caused the injury. In addition, the need for expert testimony to prove the risks and benefits of the disclosure complied with the standard of care could be eliminated, in most cases, if the statute provided for the adoption of clear and meaningful guidelines or standard consent forms for common elective medical procedures. The guidelines could be developed by state medical committees made up of practitioners from the same field of medicine as the procedure at issue. This article will review the status of the need for experts in informed consent lawsuits in Illinois, and the progress of legislative efforts on informed consent law in other states as a framework for an Illinois statute on informed consent.

Informed Consent in Illinois

Informed consent is not a new concept in the law. In 1914, Justice Cardozo wrote, “[e]very human of adult years and sound mind has a right to determine what shall be done with his own body....” In one of the first cases in Illinois addressing informed consent, Guebard v. Jabaay, the plaintiff/patient claimed that, because the defendant/physician did not adequately inform her that she had osteoporosis which could have prevented a particular knee surgery from being successful, and that he did not inform her that an alternative treatment would yield the desired improvements, she was injured. The Illinois Appellate Court for the Second District evaluated whether the sufficiency of the physician’s disclosure constituted breach of the duty to obtain informed consent according to the “reasonable physician” or “national standard.” This standard measures the sufficiency of physician disclosure by what a reasonable physician would disclose under the same or similar circumstances, and is established by expert testimony. The Court found that there was insufficient proof that the physician met this standard such that the plaintiff’s consent to the procedure performed was informed.

The Court also addressed whether plaintiff’s resulting condition was proximately caused by the absence of informed consent, holding that causation for a lack of informed consent, is up to the jury to determine on its own, as opposed to requiring expert testimony substantiating whether a reasonable person in the plaintiff’s position would have foregone the procedure had she known the associated risks.

In Pardy v. The United States of America, the experts on both sides agreed there did not have to be disclosure of the remote risks of the 1 in 14,000 chance of severe reaction (severe drop in blood pressure or cardiopulmonary collapse) or the 1 in 40,000 chance of dying from the treatment. Yet, if the plaintiff’s expert claims all risks must be disclosed for certain procedures, even remote risks, the remote risks defense can fail.

For example, in Ramos v. Pyati, the plaintiff underwent surgery to repair his thumb tendon. The physician obtained the patient’s informed consent that a tendon in the thumb would be operated on. The physician, upon encountering complications during the surgery, used a tendon from the ring finger to fuse the thumb tendon, requiring numerous incisions. The plaintiff claimed that he did not
consent to a graft of his ring finger tendon or any other tendon, and had he been informed of the risk 
the physician may have to go beyond the scope of the consent given, the patient would not have 
undergone the procedure. The plaintiff further claimed that the lack of informed consent proximately 
caused the plaintiff’s injuries.11 Despite the doctor’s argument that the risk of using the ring finger 
tendon was remote, the court noted that the use of the ring finger tendon (as opposed to the wrist 
tendon) was not a “remote” or “unforeseeable” risk, and that the consent obtained was only for repair 
of the thumb with two incisions in the wrist.12 The court, in light of the plaintiff’s expert testimony 
stating that another tendon would have been preferred over the tendon from the ring finger because of 
the ring finger’s tendon’s lack of elasticity, and because two medical texts supported the notion that 
the ring finger tendon should be used as the last choice among tendons, found that the physician did 
not meet the standard of care in informing the patient of that “remote” risk.13

The Court evaluated whether that breach of the standard of disclosure proximately caused any 
damages.14 The Court found it “…incomprehensible to believe that a prudent person would consent to 
further impairment of an already impaired hand for which he is seeking treatment.”15 Although not 
requiring expert testimony to prove causation, the court used the plaintiff’s expert testimony, that 
another tendon would have been preferred over the ring finger tendon, to satisfy Guebard’s objective 
standard of proximate causation.16 The Ramos case implies all risks, if foreseeable, are not remote and 
must be disclosed.

In Coryell v. Smith, the Appellate Court for the First District found again that expert evidence was 
not required to prove that a failure to disclose risks of a procedure proximately caused the alleged 
plaintiff’s injuries.17 In that case, the plaintiff claimed that the defendant physician did not disclose the 
risk of post-operative (abdominoplasty) scar tissue, and that had she been informed of that risk, she 
would not have elected to undergo the surgery.18 Following the standard in Guebard, the court 
reversed a lower court’s summary judgment for the defendant, noting the plaintiff was not required to 
present expert evidence as to proximate causation; the plaintiff must simply prove by a preponderance 
of the evidence that disclosure of the risks would have caused a reasonable person in the position of 
the patient to refuse the surgery or therapy.19 Following Coryell, a defense motion for summary 
judgment cannot succeed if the plaintiff’s expert opines all risks, even rare or remote, should be 
disclosed, and the plaintiff asserts that she would not have undergone the procedure had she been 
informed of all risks-remote and rare- in order to raise an issue of material fact upon which to proceed 
with litigation.

Coryell distinguishes the straightforward malpractice case from the informed consent case. The 
negligence or malpractice case, because of the technical and specialized nature of the practice of 
medicine, or directly requires expert testimony to establish proximate cause. In the informed consent 
case, the plaintiff’s bare testimony is enough to get to the jury on the proximate cause issue of whether 
a prudent patient in similar circumstances would have proceeded with the treatment.

A Framework for an Informed Consent Statute

Informed consent statutes have been adopted in a number of other states.20 Illinois could draw 
provisions from other states’ statutes to develop a statute, which could (1) include a presumption of 
validity that the patient has accepted the risks of elective surgery if he signed the approved informed 
consent form which can only be rebutted by clear and convincing evidence that the physician used 
fraud or duress or some other means to induce the patient to undergo surgery; (2) include the present 
defense of therapeutic privilege defined over the years as statutory defenses for the health care 
provider who did not fully disclose for reasons accepted under the law; (3) incorporate national 
guidelines, including exceptions for unique patients and (4) set up state approved standards for 
informed consent for common elective medical procedures.
Presumption of Validity for a Signed Consent Form

The framework of this aspect of the informed consent doctrine is best provided in Utah’s and North Carolina’s statutes. The Utah statute provides when the patient has executed a written consent form which (1) sets forth the nature and purpose of the intended health care, (2) contains an acknowledgment that the health care providers explained the patient’s condition and the proposed health care along with its attendant risks, and (3) contains a declaration that the patient accepts the risk of substantial and serious harm in hopes of obtaining the desired beneficial results, the written consent is a presumptive defense to a charge of lack of informed consent. The statute also provides that the defense is undermined when the person giving consent lacked the capacity to do so, or when the patient proves that the execution of the written consent was induced by the defendant’s acts of fraudulent misrepresentation or fraudulent omission to state material facts by a standard of clear and convincing evidence.

North Carolina’s statute presumes valid consent where the action of the provider in obtaining the consent of the patient was in accordance with the standards of practice among the members of the same profession with similar training and experience, situated in the same or similar community, and where a reasonable person, from the information provided under the circumstances, would have a general understanding of the procedures or treatments and of the usual and most frequent risks and hazards in the proposed procedures or treatment. More importantly, a consent signed by the patient, which meets the foregoing standards, is presumed to be a valid consent, subject to rebuttal only upon proof that such consent was obtained by fraud, deception or misrepresentation of a material fact.

Statutory Defenses if Risks are Not Disclosed

A health care provider frequently encounters patients who do not want or should not be told of all possible consequences or alternatives in order to make the treatment(s) more beneficial for the patient. For this reason, and because some post-operative sequelae are relatively minor, a comprehensive oral or written consent should not be mandatory for each case. However, patients will continue to file claims against physicians for lack of informed consent. Thus, there must be defenses to non-disclosure which the physician can utilize in these cases. The statute should mirror those in Utah and New York.

The informed consent statute in Utah provides that any one of the following are defenses for an alleged failure to obtain informed consent: (1) the risk of serious harm which the patient actually suffered was relatively minor; (2) the risk of serious harm to the patient from the health care provided was commonly known to the public; (3) the patient stated that he would undergo the procedure regardless of the risk, or the patient simply did not want to be informed, (4) the health care provider reasonably believed that additional disclosures could be expected to have substantial and adverse effects on the patient’s condition; (5) the informed consent is written and signed by the patient or the patient’s representative who has read and accepted the risks of the procedure.

The New York statute includes the provisions of the Utah statute, and adds a provision that when consent by or on behalf of the patient was not reasonably possible, the health care provider has an affirmative defense against a lack of informed consent cause of action. These two statutes provide fair guidelines for a health care provider’s affirmative defenses to lack of informed consent.
Illinois courts also recognize a “therapeutic privilege” serving as an exception to full disclosure. In *Miceikis v. Field*, the patient/plaintiff claimed that the physician who reattached a part of the patient’s finger should have informed him of the possibility that the entire finger might have to be amputated later. In denying the plaintiff’s prayer for relief, the court reasoned that excessive disclosure of remote risks may do more harm than good to the patient, and the physician-patient relationship requires that the doctor exercise sound discretion in prudently disclosing information in accordance with his patient’s best interests, where disclosure of more than what is material would run counter to the responsibility assumed through the relationship. Further, when there is no reasonable alternative to the procedure, full disclosure is not necessary, and the prudent person standard is still satisfied.

In *Miceikis*, where the court found excessive disclosure of remote risks would tend to do more harm than good, the therapeutic privilege accounts for the special doctor-patient relationship, requiring the doctor to exercise discretion in prudently disclosing information in his patient’s best interests in order to preserve their unique relationship.

The therapeutic disclosure defense is exemplified in *St. Gemme v. Tomlin*, where the defendant/dentist did not warn the plaintiff of the risk of paresthesia of the lip as a result of tooth extraction. The court reasoned that because extraction of the tooth was the only viable solution—otherwise the patient could have developed an infection which, if untreated, may have led to death—the physician’s duty was to disclose only the risks which were in accordance with the patient’s best interests.

For the consumer’s benefit, the statute should include a provision whereby the health care provider must modify the disclosure for those unique patients who have more risk factors than the otherwise “healthy” patient electing to undergo surgery. For example, a patient with a history of heart valve replacement visiting a dentist for a tooth extraction may require a different set of disclosures than for an otherwise healthy patient. A typical standard for a tooth extraction might require that the patient be informed of the following risks: paresthesia, anesthesia, bone fracture, pain, excessive bleeding, retained root tips, swelling, and infection. For the cardiac patient, additional risks, such as subacute bacterial endocarditis (SBE), require that the treater provide the patient with the additional information explaining that, even with the appropriate pre-medication, the patient is still at risk of developing SBE.

**State-Approved Standards of Informed Consent**

The statute may also allow a presumption that the informed consent was in compliance with the standard of care for the reasonably prudent health care practitioner performing similar procedures based on disclosure consistent with clinical guidelines established by state approved medical committees. This aspect is best evaluated in light of other legislation. For example, the Hawaiian Legislature allows a board of medical examiners to establish standards of informed consent. The Act provides, if the standards established by the medical board of examiners include provisions which are designed to reasonably inform a patient, or a patient’s guardian, of the condition being treated; the nature and character of the proposed treatment or surgical procedure; the anticipated results; the recognized possible alternatives forms of treatment; the recognized serious possible risks, complications, and anticipated benefits involved in the treatment and in the recognized possible alternative forms of treatment, including non-treatment, then the standards shall be admissible as evidence of the standard of care required of the health care providers.

These standards can be compared to analogous standards of developing clinical practice guidelines or clinical care pathways. In the 1980s, faced with the growing concern of malpractice litigation and its associated costs, various medical and dental groups encouraged the development of physician practice parameters often referred to as “clinical practice guidelines” or “pathways,” which are
systematically developed statements to assist practitioner and patient decisions about appropriate health care for a specific clinical circumstance.37 These were intended to serve as tools by which scientifically valid and reliable standards of clinical practice can be implemented.38

Although other states have passed legislation where practice guidelines can be introduced into a medical malpractice action in some way, Maine has passed legislation allowing practice guidelines to be used as an affirmative defense to medical malpractice suits.39 Florida has endorsed 150 guidelines allowing affirmative defense in C-section malpractice cases. Vermont allows the defense in arbitration and mediation, but only after every state resident has health care insurance; Minnesota enacted a statute to allow proof of compliance with guidelines as an absolute defense against an allegation that the provider did not comply with accepted standards of practice in the community, but repealed it, and Maryland developed guidelines, but prohibited their use as a defense in malpractice suits.40

Maine initiated an experimental 5-year Medical Liability Demonstration Project which became effective in January 1992 and ended in January 1997 which made state-developed physician practice guidelines for certain specialties admissible as an affirmative defense in medical malpractice cases.41 These guidelines were developed by medical specialty advisory committees appointed by the Maine Board of Registration in Medicine. When a physician was named in a malpractice action, the physician could raise the guideline as an affirmative defense,42 but would need to prove that the guideline was followed.43 The plaintiff would then be required to prove either the physician did not follow the guideline or that the guideline was not applicable. Under the Maine plan, plaintiffs could not prove, in their case in chief, that the physician’s care was below the standard of care for the procedure based on the state guidelines.44

**Effect of the Maine Project**

To date, there have been no reported cases where the physician has used the statutory affirmative defense.45 Because some believe that the Maine Project’s methodology is sound, it was extended for an additional three years, now running until the end of 1999.46 Gordon Smith, executive vice president of the Maine Medical Association, believes the success of the Maine Project, or other similar efforts by legislatures, depends upon how well the guidelines are drafted; “[T]ight enough for the courts, but flexible enough so as to preclude “cookbook” medicine.”

**The Impact of Guidelines on Reducing Litigation**

Some studies of lawsuits involving the use of practice guidelines have been conducted. Interested in how practice guidelines were actually used in malpractice litigation, one study reviewed 259 claims at two liability insurance companies, and 578 surveys gleaned from personal injury lawyers.47 The most significant findings were that the guidelines were used for both inculpatory and exculpatory purposes, and over 27 percent of respondents reported that a guideline had influenced their decision to settle a case.48 Also, about 26 percent of plaintiffs’ attorneys reported that guidelines had been influential in a decision not to take a case.49 Although some believe that practice guidelines will result in “cookbook” medicine, these studies suggest that clearly drafted practice guidelines will benefit physicians and consumers.50

**The Illinois Advantage**
Initiating a program similar to the one in Maine would place Illinois in the forefront of the national medical malpractice litigation reform. One benefit would be that both the standards and the informed consent statute would be readily accessible to patients, lawyers, and health care workers. “[T]he affirmative defense should make doctors more willing to rely on guidelines. The cost-containment benefits of reducing defensive medicine and insurance premiums may be maximized through reduced malpractice litigation. Doctors are more likely to keep up with practice guidelines if they know the standard of care. Therefore, the focused attention devoted to standards should advance the educational goals of the program.”51 Thus, a program, which can be studied during and after its use, could be very beneficial to the healing arts and the public at large.

In Illinois, professional associations, in conjunction with medical specialty groups, may draw guidelines that mirror the Illinois case law using the reasonable physician or national standard to prove the health care provider acted within the realm of ordinary care as his peers are required to act.52 The Illinois Legislature could look to the professional associations to assist them in forming medical advisory committees to draw guidelines for the informed consent statute. Illinois is in the enviable position of being the headquarters for the American Medical Association (AMA), the American Dental Association (ADA), and the American Osteopathic Association (AOA). Members from these prestigious organizations could form a committee like the medical specialty advisory committees appointed by the Maine Board of Registration in Medicine.

This type of informed consent statute would not drastically change the current status of Illinois case law on informed consent, but should have the benefit of reducing litigation. The health care practitioner is still required to disclose, and if informed consent standards for some common elective medical procedures were promulgated by the professional associations of state health care providers, the physician who proved he followed the standards would have a presumption he complied with the standard of care established by his peers. Further, if there is a written informed consent and the physician can demonstrate the standards were followed, a presumption under the statute would be created that could only be rebutted by clear and convincing evidence of fraud, duress, or other inducement. If the physician chooses not to use the State-approved standard forms, or there was none applicable, then the physician’s disclosure of the risks or lack thereof would be defended under the exceptions to the statute, and the plaintiff would only have to prove his case by a preponderance of the evidence.

**Conclusion**

Public policy should support reducing medical malpractice litigation and improving patient care. If state approved medical committees began promulgating standard informed consent guidelines and disclosure forms for common elective medical procedures, and physicians could rely on those guidelines being accepted as evidence of conforming to the standard of care in most cases, patients should be properly advised of risks, and litigation deterred on the issue of informed consent. For physicians, the informed consent statute would offer further incentive to use written consent forms, while, at the same time, remind providers to recognize the need to vary their disclosures to a standard written consent form as needed for unique patients. Patients would be put on notice that reading, questioning and signing the consent form creates a presumption that the provider has obtained informed consent, thereby raising the level of patient awareness and providing the patient with a sense that he is involved with the procedure performed on his body.

This proposal will improve communication among all participants in the healing arts by establishing parameters for informed consent to at least the more common elective medical procedures. Clearly drawn, appropriate standards will improve patient
care, decrease litigation, and promote awareness among practitioners that their duties are to follow state-approved written guidelines established by their peers in their same profession, or be in a position to document and to credibly explain why the standards were not applicable.

Endnotes

5 See Coryell, 274 Ill.App.3d 543.
6 Schloendorf v. Society of New York Hospital, 211 N.Y. 125, 105 N.E. 92 (1914).
7 Guebard, 117 Ill.App.3d 1, at 7.
8 117 Ill.App.3d 1, 9 (1983).
9 Pardy, 783 F.2d 710, at 710.
11 179 Ill.App.3d 214, at 225.
12 Id. at 225.
13 Id. at 220.
14 Id. at 225.
15 Id. at 225.
16 Id. at 225.
18 Coryell, 653 N.E.2d 1317.
19 652 N.E.2d 1317, at 1318.
22 UTAH CODE ANN. §§78-14-5, 78-14-3(1), see also 24 M.R.S. § 2905 (1996) (“A consent which is evidenced in writing and which meets the foregoing standards, and which is signed by the patient or other authorized person, shall be presumed to be valid consent. This presumption, however, may be subject to rebuttal only upon proof that such consent was obtained through fraud, deception or misrepresentation of material fact”).
23 UTAH CODE ANN. §§78-14-5 (2)(e).
26 UTAH CODE ANN. §§78-14-5 (2)(a)-(e).
29 Micekis, 347 N.E.2d 320.
30 Id. at 324.
33 St. Gemme, 118 Ill.App.3d 766.
34 Id. at 768.
36 HAW REV. STAT. §671-3 (1996); see also TEX. REV. STAT. art 4590(I), §6.03 (c) (Supp. 1994) (Texas has a panel made up of six physicians and three lawyers to set up guidelines for informed consent.)


41 24 M.R.S. §§2971 et seq (1993); see also Begel, supra note 36 at 78 (explaining that the guidelines were comprised of revised versions of national standards of the American Society of Anesthesiologists (ASA)-governing preanesthesia evaluation and documentation, the American College of Radiology (ACR)-govern screening mamography, antepartum ultrasound, outpatient angiography, and the performance of adult barium enema examinations, and the American College of Obstetricians and Gynecologists (ACOG)-contain practice parameters regarding cesarean deliveries, hysterectomies, tocolysis, ectopic pregnancies, breech deliveries, perinatal herpes simplex virus infections, intrapartum fetal distress and prolonged pregnancy-, each containing their own guidelines for their own specialty, and noting that in order for a physician to use the guideline(s) as an affirmative defense, the physician must have been a participant in the Demonstration Project, the affirmative defense would have to be asserted to a medical panel, where the panel’s chairperson would then submit the issue to the superior court who then decides of summary judgment should be granted).

42 M.R.S. Ann. tit. 24, 2975(1).

43 See Begel, supra note 36 at 82 (explaining that “burden of proof” means both the burden of persuasion as well as the burden of producing evidence). Id.

44 24 M.R.S. §§2975, see also Begel, supra note 36 at 93 (suggesting that if Maine’s legislation were invoked, and a panel or court prohibited a plaintiff from offering the guideline into evidence if the physician has not first offered it, the legislation may be challenged as a violation of Equal Protection and/or Due Process).

45 See Begel, supra note 36 at 84 (predicting that physicians, via defense attorneys, will have a very difficult time winning summary judgment due to the inherent obstacles presented by the prelitigation screening panel provisions; “...merely raising the affirmative defense of compliance will not be dispositive of the legal issue of the standard of care. This is not to suggest that the particular...guidelines are flawed...it is a recognition of the fact that decisions of medical care rest upon the nuances and facts of each particular case”). Id.


48 Id.

49 Id.

50 William O. Roberts, Practice Guidelines, 24 Physician and Sports Medicine 86 (March 1996) (“[I]f guidelines are “cookbook medicine,” remember that even the best chef starts with a cookbook. The difference between the good and the best is often the subtle use of spices. The spice of medicine-intelligent reasoning and clinical intuition-and the art of medicine will not be supplanted by guidelines”).


52 Guebard, 117 Ill.App.3d 1, at 7.