Informed Consent to Medical Treatment

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Section 1. Legal Duty to Obtain Informed Consent

I. Basic Rules

- A. In most circumstances, a health care provider may not treat a patient without consent. A health care provider could be held liable:
 - 1. For battery, if the provider treats a patient without consent, or
 - 2. For negligence, even if the provider obtains consent, if that consent is not adequately informed.
- B. Consent must be given voluntarily by a person who has both the legal authority *and* the decisional capacity to make health care decisions for the patient.
 - 1. Consent is voluntary if it is given freely, without coercion or duress.
 - 2. The issues of legal authority and decisional capacity are discussed in Section 2, Part I of this outline.
- C. Consent must be informed. In general, this means the health care provider has a legal duty to inform the patient about the treatment, its risks and benefits, and the risks and benefits of alternatives—including the alternative of forgoing treatment. This issue is discussed in more detail in Section 3 of this outline.
- II. North Carolina's Informed Consent Statute (G.S. 90-21.13)
- A. G.S. 90-21.13 describes the standards that a health care provider must meet in obtaining informed consent:
 - 1. In most circumstances,
 - a. the health care provider must disclose information about the treatment that is sufficient to give a reasonable person a general understanding of the procedures or treatments, and of the risks, and
 - b. the provider's action in obtaining informed consent must conform to the standards of practice in the community.
 - 2. In some circumstances, the statute will permit a provider to avoid liability even if he or she does not disclose information, if a reasonable person would have undergone the treatment after a proper disclosure of information about the treatment.

- B. The statute also provides that written consent will be presumed valid, but the presumption can be rebutted by evidence that the consent was obtained by fraud, deception, or misrepresentation of a material fact.
- C. Finally, G.S. 90-21.13 states that a person must be competent to give valid consent.

Section 2. Who May Give Informed Consent to Treatment?

I. Key Concepts: Legal Authority and Decisional Capacity

- A. To be valid, informed consent to treatment must be given by a person who has <u>both</u> the legal authority to consent and the decisional capacity to make health care decisions for the patient.
- B. A person has *legal authority* to consent to treatment if he or she is the person the law recognizes as authorized to make health care decisions for a particular patient. In general:
 - The person with legal authority to consent to treatment for an adult patient is the patient himself.
 - The person with legal authority to consent to treatment for a minor patient is the minor's parent.

Of course there are exceptions to these general statements, which are discussed in more detail below.

C. A person has *decisional capacity* to make health care decisions if he or she is capable of understanding information about the health care decision to be made, including information about the condition, the treatment, alternatives to treatment, and the risks and benefits of the treatment and alternatives. This is sometimes described as being "competent" to make health care decisions.

II. Who May Consent to Treatment for an Adult (Age 18 or Older)?

- A. General rule: Adult patients consent to their own treatment.
 - 1. *Legal authority:* Adults have legal authority to consent to treatment.
 - 2. *Decisional capacity:* Adults are legally presumed to have decisional capacity. The presumption can be rebutted by evidence of incompetence.
 - 3. *Exceptions to the general rule* (each discussed in more detail below):
 - a. Adults without decisional capacity
 - b. Emergencies
- B. Adults without decisional capacity
 - 1. When does an adult lack decisional capacity?

- a. Adults are presumed to have decisional capacity. This means that health care providers need not undertake an individualized assessment of every adult patient to ensure that he or she is capable of making health care decisions—rather, the provider may assume the patient is capable.
- b. However, if a health care provider encounters information or evidence that causes the provider to suspect the patient is not capable of making health care decisions, the provider should probe further.
 - i. What kind of evidence might make a provider suspect incapacity? There is no clear answer to this question in the law. Most likely it will be the patient's behavior that will cause a health care provider to suspect that the patient lacks decisional capacity. Also, certain factors such as residence in extended care, or diagnoses that affect mental processes might prompt a provider to consider the issue of decisional capacity more carefully. However, it is not appropriate to create bright-line rules that conclude that all patients with particular circumstances or conditions are decisionally incapable. Each patient's situation should be considered individually.
- c. If a health care provider determines an adult patient lacks decisional capacity, the provider should seek consent to treatment from a *substituted decision-maker*.
- 2. Who can serve as a substituted decision-maker for an adult without decisional capacity?
 - a. A patient may have a "formal" decision-maker—that is, a person who has been formally granted the legal authority to make health care decisions for the patient.
 - A legal guardian may have the authority to consent to treatment on behalf of the patient who is the subject of the guardianship order. However, legal guardianship orders do not always grant the authority to make health care decisions.
 - A person with health care power of attorney (also known as a "health care agent") can consent to treatment on behalf of the patient who executed the power of attorney. Health care providers should be aware that the document granting health care power of attorney may limit the health care agent's authority to consent to treatment to particular circumstances.
 - b. If an adult without decisional capacity does not have a formal decisionmaker, it is likely that someone is acting informally to make his health care decisions for him—perhaps a spouse, adult child, or other relative. The North Carolina informed consent statute indirectly acknowledges informal decision-makers when it states that a health care provider who

meets certain standards will not be held liable for failing to obtain the consent "of the patient or the patient's spouse, parent, guardian, nearest relative or other person authorized to give consent for the patient." This statute is a little troublesome because it does not specifically give a spouse, parent, guardian, or nearest relative the legal authority to consent to treatment. Instead, it seems almost to assume they already have that legal authority—but if they do, it is not clearly stated in the law. However, as a matter of practice, most health care providers will permit a spouse, parent, guardian, or other relative to consent to a decisionally incapable adult's treatment, and they rely on this statute to insulate them from liability. That seems like a reasonable position to take.

C. Emergencies

1. In an emergency, a health care provider may treat an incapacitated adult without consent. This applies whether the incapacity is temporary (e.g., unconsciousness) or permanent (e.g., incompetence).

III. Who May Consent to Treatment for a Minor Child (Under Age 18)?

- A. General rule: Minors may not consent to their own treatment. The minor's parent, legal guardian, or person acting in loco parentis must provide consent.
 - 1. *Legal authority:* In most cases, unemancipated minors lack the legal authority to consent to medical treatment. The major exception to this general rule is the "minor's consent rule" (G.S. 90-21.5).
 - 2. *Decisional capacity:* This is a much more difficult issue for minors than for adults. All infants lack decisional capacity but most 17-year-olds have it. There is no "minimum age" or other bright-line rule that clearly establishes when a minor acquires decisional capacity. Instead, the law presumes that minors lack decisional capacity and the burden is on the health care provider to determine that a particular minor does in fact have decisional capacity before accepting the minor's consent for treatment under the minor's consent rule.
 - 3. *Exceptions to the general rule* (each discussed in detail below):
 - a. Emergencies or other urgent circumstances
 - b. Parent's temporary absence
 - c. Minor's consent rule
 - d. Emancipated minors

NOTE: The remainder of this outline uses the term "parent" to mean a parent, legal guardian, or person acting in loco parentis, and the term "parental consent" to mean the consent of a parent, legal guardian, or person acting in loco parentis.

- B. Emergencies or other urgent circumstances (G.S. 90-21.1)
 - 1. G.S. 90-21.1 authorizes physicians to treat a minor without parental consent under the following emergency or urgent circumstances:
 - a. The parent cannot be located or contacted with reasonable diligence during the time within which the minor needs the treatment.
 - b. The minor's identity is unknown.
 - c. The need for immediate treatment is so apparent that any effort to secure parental consent would delay the treatment so long as to endanger the minor's life.
 - d. An effort to contact the parent would result in a delay that would seriously worsen the minor's physical condition.
 - e. The parent refuses to consent, and the need for immediate treatment is so apparent that the delay required to obtain a court order would endanger the minor's life or seriously worsen the minor's physical condition, and two licensed physicians agree that the treatment is necessary to prevent immediate harm to the minor.
 - i. If parents refuse to consent to emergency treatment and two physicians are not available, there is a procedure for obtaining a judge's approval for the treatment (by phone, if necessary) in G.S. 7B-3600.
 - 2. *Special rule for surgery:* Before performing surgery without parental consent under any of the above exceptions, two surgeons must agree that the surgery is necessary. There is an exception to this requirement for rural communities or other areas in which it is impossible to get the opinion of a second surgeon in a timely manner. G.S. 90-21.3.
- C. Parent's temporary absence
 - A parent may authorize another person to consent to the minor's care during a period in which the parent or guardian is unavailable. G.S. 32A-28 through 32A-34. However, a parent may not authorize another person to consent to the withdrawal of life-sustaining treatment.
 - 2. *Special rule for immunizations*: A physician or local health department may immunize a minor who is presented for immunization by an adult who signs a statement that he or she has been authorized by the child's parent, guardian, or person standing in loco parentis to obtain the immunization. G.S. 130A-153(d).
 - a. We sometimes say that an adult who presents a child for immunization under this provision has "consented" to the immunization—but strictly speaking, that isn't correct. The parent, guardian, or person standing in loco parentis has consented to the immunization. The non-parent is simply acting on behalf of the parent, guardian, or person standing in loco parentis by presenting the child to the health care provider.

- D. Minor's consent rule (G.S. 90-21.5)
 - 1. G.S. 90-21.5 gives unemancipated minors the *legal authority* to consent to treatment for the prevention, diagnosis, or treatment of:
 - reportable communicable diseases
 - pregnancy
 - abuse of controlled substances or alcohol
 - emotional disturbance

However, the law does not authorize an unemancipated minor to consent to sterilization, abortion, or admission to a 24-hour mental health or substance abuse facility (except that the minor may consent to admission to such a facility in an emergency).

- 2. The minor's consent rule gives unemancipated minors the legal capacity to consent to care, regardless of age. However, the health care provider may not accept the minor's consent unless the minor also has decisional capacity.
- E. Emancipated minors
 - 1. An emancipated minor is a child under the age of 18 who
 - is married, or
 - who has been granted an order of emancipation by a court.

See G.S. 7B-3500 et seq. These are the only two ways for a minor to become emancipated under North Carolina law. It is particularly important to note that having a child does not emancipate a minor. Although a minor who is a parent has the same responsibilities to her child that an adult parent would, she does *not* have full adult rights and responsibilities for herself.

- 2. Emancipated minors are treated the same as adults:
 - a. they have legal authority to consent to treatment (see G.S. 90-21.5(b)), and
 - b. they are presumed to have decisional capacity to make health care decisions.

Section 3. Obtaining Informed Consent

- I. Informing the patient
- A. As the term implies, informed consent requires a health care provider to inform the patient about certain things. Legal requirements in this area come from North Carolina's informed consent statute and the common law of informed consent.
- B. G.S. 90-21.13 provides protection from liability to a health care provider who discloses information about the treatment that is sufficient to give a reasonable person a general

understanding of two things: (1) the procedure or treatment, and (2) the usual or most frequent risks and hazards inherent in the proposed procedure or treatment.

- 1. In order to provide a patient with a "general understanding" of a procedure or treatment, a health care provider should tell the patient what the treatment is for, what it consists of (for example, any procedures that are involved), and the anticipated consequences of the treatment (including anticipated adverse effects as well as anticipated benefits).
- 2. In addition to informing the patient about the usual or most frequent risks or hazards, a health care provider should identify risks that may not be usual or frequent but that are nevertheless constitute "material" risks—that is, risks that are likely to be relevant to the patient's decision-making process. Thus, severe risks ought to be disclosed, even if they are rare.
- C. The health care provider should also inform the patient of treatment alternatives. Refusing treatment altogether is an alternative and a choice that a patient may wish to make. The provider should inform the patients of anticipated consequences and material risks of that choice as well.

II. Must consent be written?

- A. Consent to treatment ordinarily does not have to be in writing. (There are rare statutory exceptions to this.)
- B. G.S. 90-21.13(b) states that a written consent signed by the patient (or the substituted decision-maker) will be presumed to be valid. A patient who challenged the validity of a written consent would have the burden of proving that the consent was obtained by fraud, deception, or misrepresentation of a material fact.
 - 1. A written consent would therefore be important evidence in a claim for failure to obtain informed consent.
 - 2. However, it is probably impractical to obtain written consent for every aspect of medical treatment. Health care providers should have policies and procedures for obtaining written consent for surgery, invasive procedures, use of anesthesia, procedures for which written consent is required by law, and any other procedure or treatment that poses more than a minimal risk of harm to the patient.
- C. Many health care providers require their patients to sign general or "blanket" consent to treatment forms, probably in the hope that the form will give the provider the benefit of the presumption in G.S. 90-21.13 in the event of a lawsuit. The forms are probably harmless, but they are also probably worthless, since they likely do not provide a patient sufficient information about the patient's specific treatment for the consent to be considered informed.

Section 4. Treatments that are Required by Law

I. The Public Health "Exception" to the Informed Consent Requirement

- A. Medical procedures or treatments are sometimes required by law in order to protect the public health. The list of treatments required by North Carolina law includes:
 - 1. Immunizations (G.S. 130A-152).
 - 2. Examinations or treatments that are communicable disease control measures (G.S. 130A-144(f)).
 - 3. HIV and hepatitis B tests that are ordered after a bloodborne pathogen exposure incident (10A N.C.A.C. 41A.0202(4)).
 - 4. Examinations or treatments ordered by the State Health Director in the exercise of her bioterrorism authorities (G.S. 130A-475(a)).
- B. When a treatment is required by law, the patient does not have the legal right to refuse the treatment.
 - 1. This is an exception to the general rule: when treatment is required by law, a patient's consent is coerced, not voluntary; and there is no weighing of options and making an informed choice. However, a health care provider administering a required treatment still should inform the patient about the nature of the treatment, why it is being done, and the anticipated consequences (both adverse and beneficial).
 - 2. Furthermore, a patient who resists treatment should not be restrained and treated by force. The appropriate remedy for a patient's refusal of a legally required treatment is to enforce the law against the patient through the usual legal mechanisms.
 - a. For example, suppose a source person in a bloodborne pathogen exposure incident refuses to submit to a blood test for HIV. The health care provider should not attempt to restrain the person and draw her blood. The proper way to enforce the patient's compliance with the bloodborne pathogen laws is to either (1) seek a court order requiring her to submit to the procedure, or (2) charge her with a misdemeanor violation of G.S. 130A-144(f), the statute that requires all persons to comply with N.C. communicable disease laws.