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Legal Brief

SOUTH DAKOTA STATE MEDICAL ASSOCIATION
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Informed Consent

This Legal Brief was drafted for general informational purposes only. It is not meant to be a comprehensive guide, nor should it be construed as legal advice. The information in this brief is current as of August 1, 2020; readers should consult the most recent versions of referenced statutes, regulations, and cases to ensure there have been no material changes.

Summary

A patient must be informed of the nature of proposed treatment and the risks and benefits associated with that procedure and give consent to the proposed treatment before it is performed. In emergency situations where the patient's life or health are at risk and it is not possible to obtain express consent, the physician may provide treatment on the basis of the patient's implied consent. Special rules apply to consent to organ donation, investigational treatments, forensic medical examination, and abortions.

Discussion

Informed Consent Generally

A physician has a duty to obtain a patient's informed consent to medical treatment before the physician provides the treatment. In order for the patient's consent to be "informed," the physician must disclose to the patient all material information necessary for the patient to make an informed decision concerning the proposed treatment. "Necessary information" is judged by what an average, reasonable person would consider significant and necessary to make an informed judgment. The physician must also take into account the patient's known existing medical condition.

The physician must disclose the nature of the procedure, the material benefits of the procedure, the material risks associated with the procedure, the likelihood those risks will occur, and the consequences of leaving the condition untreated. If an alternative procedure is available, the physician must also disclose the material risks and benefits associated with the alternative procedure. The physician does not have a duty to disclose extremely remote risks, risks already known to the patient, or those of which a person of average sophistication would already be aware.

The patient should be required to sign a document reciting that he or she was fully advised of all the disclosures as listed above prior to performance of the procedure and that the patient consented to the procedure. The signed consent form should be made a part of the patient's permanent medical record. Consent forms (ranging from generic to those specific to a particular procedure) are commercially available.

Competency to Consent to Treatment

The concept of informed consent generally is based on the belief that all adult patients have the right to determine what will be done to or with his or her body. This overarching principle may only be breached in very narrow circumstances, such as when the patient is a danger to himself/herself or others. It may be breached in cases where the physician cannot in good faith form a belief that the patient is competent to consent to treatment. If the physician cannot, based on the

circumstances, form a good faith belief that the patient is competent to provide consent, the physician should conduct a mental status exam. If, given the circumstances, the physician does not feel qualified to determine whether or not the patient is competent to consent to treatment, the physician should refer the patient to a qualified mental health professional. Depending on the third-party payer, preauthorization may be necessary for such referrals.

An adjudication of mental illness or incompetence as to certain matters (e.g., not competent to handle one's own financial affairs) does not in and of itself constitute an adjudication that the patient is not competent to make health care decisions. If the physician is aware that a guardian has been appointed, the physician should ask to see the Court Order and "Letters" (a legal term referring to a document outlining the powers of a guardian) appointing the guardian and inquire of the guardian as to the powers the guardian possesses. If the guardian has been given the power to make healthcare decisions, then the physician may rely on consent given by the guardian.

In some cases, the Order and Letters issued by the Court may be silent as to whether the guardian has the power to make health care decisions. South Dakota law provides that a court-appointed guardian should only exercise his or her authority to the extent necessitated by the protected person's limitations. If there is any doubt about the guardian's authority to consent to treatment, the physician should inform both the patient and the guardian of the nature of the treatment, risks and benefits, and the other elements of informed consent, and then obtain a signed consent form from both the patient and the guardian. If the patient and the guardian do not agree, then the physician should refrain from providing the treatment until there is agreement or a Court Order specifically addressing the patient's ability or inability to consent to treatment.

Generally speaking, a minor cannot consent to treatment on his or her own behalf. Parents or legal guardians must consent to the treatment of the children within their care and custody. (See Treatment of Minors).

Implied Consent to Treatment

Consent is implied if an emergency exists and immediate action is necessary to preserve the patient's life or health and it is not practical to first obtain the consent of the patient or his or her parent or guardian. This is true whether the emergency is the result of an accident or sudden illness or if it arises during the course of some other treatment (most commonly surgery) to which the patient has consented.

If the patient is not capable of consent because of the emergency situation, but there is time available to obtain consent from a close family member, the physician is advised to attempt to obtain consent from the family member. If a patient has expressly refused treatment, the physician is obligated to respect the patient's wishes regardless of the existence of an emergency and regardless of the consequences to the patient.

Abortion

Under South Dakota law, no abortion (except those performed in emergencies) may be performed without a particular form of consent. SDCL 34-23A-10.1. The Abortion Legal Brief should be referenced for specific information regarding consent.

Forensic Medical Examination

A physician, hospital, or clinic may provide a forensic medical examination for rape or other sexual abuse without the consent of a guardian or conservator of a person subject to the guardian's or conservator's supervision (a "protected person") to any such protected person who provides informed consent. Unless the guardian or conservator is the suspected perpetrator, if a patient has a guardian or conservator, the physician, hospital, or clinic shall take reasonable steps to notify the guardian or conservator that an examination has taken place. SDCL 22-22-26.4.

A physician, hospital, or clinic which in good faith believes a patient is incapable of giving informed consent may not be subject to criminal prosecution, civil liability, or professional discipline for failing to follow the patient's direction or for making the determination. SDCL 22-22-26.4.

Similarly, a physician, hospital, or clinic who in good faith believes that a patient *is capable* of giving informed consent may not be subject to criminal prosecution, civil liability, or professional discipline for following a patient's direction concerning the examination.

Investigational Treatments

Before investigational treatment otherwise permitted under federal and state law may be undertaken, an eligible patient must provide written consent which complies with South Dakota law. The term "investigational treatment" means treatment with a drug, biological product, or device that has successfully completed phase 1 of a clinical trial but has not yet been approved for general use by the U.S. Food and Drug Administration ("FDA") and which remains under investigation through an FDA-approved clinical trial.

South Dakota law requires a writing signed by the patient, parent, legal guardian if the patient is a minor, substitute informed consent from an appointed guardian, an attorney-in-fact, or a person with authority pursuant to SDCL chapter 34-12C if the patient is incapacitated as defined in SDCL 34-12C-1, which writing must be countersigned by the treating physician, that:

1. Explains the currently approved products and treatments for the disease or condition from which the patient suffers;
2. Attests to the fact that the patient concurs with his or her treating physician that no current United States Food and Drug Administration approved treatment would likely prolong the patient's life;
3. Clearly identifies the specific proposed investigational drug, biological product, or device that the patient is seeking to use;
4. Describes the potential outcomes of using investigational drug, biological product, or device. The description shall include any possibility of worsening symptoms and death hastened by the treatment;
5. Contains a statement that the patient's health insurance carrier is not obligated to pay for any care or treatments consequent to the use of the investigational drug, biological product, or device;
6. Makes clear that the patient's eligibility for hospice care may be withdrawn if the patient begins curative treatment with the investigational drug, biological product, or device and that care may be reinstated if this treatment ends and patient meets hospice eligibility requirements; and
7. Makes clear that patient understands that he or she is liable for all expense consequent to the use of the investigational drug, biological product, or device.

SDCL 34-51-3.

Only "eligible" patients may be given investigational treatment, and then only after compliance with applicable federal requirements. See 21 CFR 312.300, et. seq. An "eligible" patient is any patient who meets all of the following qualifications:

1. Has an advanced illness, attested by the patient's treating physician;
2. Has considered all other treatment options currently approved by the United States Food and Drug Administration;
3. Has received a recommendation from patient's treating physician for an investigational drug, biological product, or device;
4. Has given written, informed consent for the use of the investigational drug, biological product, or device; and
5. Has documentation from the patient's treating physician that the patient meets outlined above.

(See also Investigational Treatments legal brief).

Organ Donation

South Dakota has adopted the Revised Uniform Anatomical Gift Act (SDCL 34-26-48 to 34-26-72, inclusive). Under that Act, any adult or person of at least fourteen years of age may give all or any part of his body to:

1. A hospital, accredited medical school, dental school, college, university, or other appropriate person or entity for the purposes of research or education;
2. An individual designated by the donor, provided the individual is the recipient of the body part; or
3. An eye bank or tissue bank.

If no specific person is designated to receive the gift, or if the specified person cannot receive transplantation of the body part, then it passes to the appropriate eye or tissue bank or appropriate organ procurement organization.

If the donor is younger than eighteen, a parent or guardian must give consent for the donation regardless of whether the designation is made on a minors drivers' license.

Unless the potential donor has prohibited anatomical gifts during his lifetime by certain writings or orally to at least two (2) adults, any of the following persons, in order of priority stated, when persons in prior classes are not available at the time of death, may give all or any part of a decedent's body for any approved purpose:

1. An agent of the decedent under a durable power of attorney for health care;
2. The spouse;
3. An adult son or daughter;
4. Either parent;
5. An adult brother or sister;
6. An adult grandchild;
7. A grandparent;
8. An adult who exhibited special care and concern for the decedent;
9. A guardian of the person or the decedent at the time of his death;
10. Any other person authorized to dispose of the body.

SDCL 34-26-56.

The gift of all or part of the body may be made by notation on the person's drivers' license, in a will, or by some other document, or by any form of communication to two (2) adults (one [1] of whom must be a disinterested person) made during a terminal illness or injury. First responders and hospitals have a duty to search the body for evidence of the decedent's desire to be an organ donor. The most common form of such evidence is likely to be the decedent's drivers' license. Whoever locates any such document has an obligation to promptly send it to the hospital where the decedent's body is taken.

Only the potential organ donor or other person permitted by law to authorize an organ donation may revoke a previous decision by the donor to become an organ donor. The gift may be revoked by a later executed document (explicitly or by implication), by destruction of the gift document, or through a document executed by at least two (2) adults who were told by a potential donor unable to sign that he or she desires to revoke the gift. SDCL 34-26-53.

Conclusion

A patient must provide informed consent prior to administering medical treatment. Informed consent requires communication regarding the nature of proposed treatment and the risks and benefits associated with that procedure. In emergency situations where the patient's life or health are at risk and it is not possible to obtain express consent, the physician may provide treatment on the basis of the patient's implied consent. Special rules apply to consent to organ donation, investigational treatments, forensic medical examination and abortions.

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