

Legal Brief

Investigational Treatments

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 July 1, 2015. Readers should consult the most recent versions of referenced statutes, regulations, and cases to ensure there have been no material changes.

Summary

Federal law provides that certain patients may be given drugs or provided other treatments not yet approved for administration to the general public if the patient suffers from a serious or immediately life-threatening disease or condition and certain conditions are met, including U.S. Food and Drug Administration approval of the treatment.

Assuming approval of the treatment under applicable federal law, South Dakota law provides that an eligible patient may request a manufacturer's investigational drug, biological product, or device for treatment if the patient has a disease, medical, or surgical condition that results in significant functional impairment or that is immediately life-threatening, and which disease or condition is not reversible by the administration of current federally-approved and available treatments.

The South Dakota Board of Medical and Osteopathic Examiners is prohibited from revoking, failing to renew, suspending, or taking any action against a health care provider's license based solely on the health care provider's recommendations regarding access to or treatment with an investigational drug, biological product, or device.

Discussion

Certain patients who are suffering from a serious, debilitating disease or condition, or from a disease or condition that is immediately life-threatening, may be eligible for treatment with drugs, biological products, or devices for which final approval has not been given by the U.S. Food and Drug Administration ("FDA"). In order for a physician to offer such treatment, the eligibility and other requirements of both federal and state law must be met.

Investigational Treatment

An investigational treatment is 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 United States Food and Drug Administration and remains under investigation in a United States Food and Drug Administration approved clinical trial.

Eligibility

Before an investigational treatment may be provided to a patient, the following conditions must be met:

1. The patient must suffer from a disease, medical, or surgical condition that results in significant functional impairment or that is immediately life-threatening;

2. There is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition;
3. The potential benefit outweighs the potential risks;
4. Use of the drug, product, or device will not interfere with the normal conduct of clinical investigations or otherwise compromise approval for expanded use;
5. FDA must approve the treatment;
6. The patient must consider all other treatment options currently approved by FDA;
7. The treating physician must recommend the use of the investigational drug, biological product, or device;
8. The patient must give written, informed consent for the use of the investigational drug, biological product, or device; and
9. The patient's treatment physician must document the patient's compliance with requirements 6, 7, and 8.

Requirements 6-9 above are imposed under South Dakota law, but the physician must ensure compliance with all conditions (both those federally imposed and those required by South Dakota law) before proceeding with the investigational treatment.

Informed Consent

Informed consent consists of a signed writing executed by the patient, or the patient's parent or legal guardian if the patient is a minor, or 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, and attested to 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 must include any possibility of worsening symptoms and hastening of death 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 hospice care may be reinstated if the treatment ends and the 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.

Liability Under State Law

Under South Dakota law, a treating physician who is in compliance with the requirements for ensuring patient eligibility and obtaining consent may not be subject to arrest, prosecution, or other penalty. The South Dakota Board of Medical and Osteopathic Examiners ("SDBMOE") may not revoke, fail to renew, suspend, or take any other action against a health care provider's license based solely on the health care provider's recommendations to an eligible patient regarding access to or treatment. Furthermore, state law provides that no official, employee, or agent of this state may block or attempt to block an eligible patient's access to an investigational drug, biological product, or device. Counseling, advice, or a recommendation consistent with medical standards of care from a licensed health care provider recommending against the use of an investigational treatment is not a violation under state law.

South Dakota law does not explicitly provide for immunity from suit for a physician recommending or participating in a course of investigational treatment, but it does state that South Dakota law itself does not create a state law-based cause of action as long as the provider acts in good faith compliance with the law and exercises ordinary care. Unless and until a Court rules otherwise, physicians should assume there is no state law immunity from suit. In any event, state common law still requires the physician to exercise the same care and skill that is the existing standard of care and there is the potential for causes of action arising under federal law.

Liability Under Federal Law

It is *critically important to note* that even if a physician complies with all South Dakota-imposed requirements, the physician would still be at risk for federally-imposed penalties for failure to comply with the federal requirements for FDA approval of a course of investigational treatment, including the related application, administration, and reporting requirements. A complete discussion of the federally-imposed requirements and the possible penalties for failure to comply are beyond the scope of this legal brief.

Other

Under an act passed by the South Dakota Legislature in 2015, if a patient dies while undergoing an investigational treatment, the manufacturer may not seek reimbursement from the patient's estate for any outstanding debt related to the treatment.

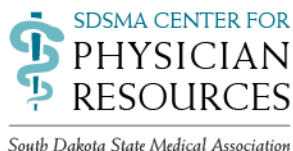
Conclusion

Investigational treatments may be available for certain eligible patients, but only if all the requirements of both federal and state law are met. A physician considering a recommendation of investigational treatment is strongly encouraged to consult with persons with expertise relating to compliance with the federal law requirements before commencing any course of investigational treatment.

South Dakota law prohibits the imposition of penalties or adverse licensing actions against physicians recommending or administering investigational treatments, but federal law requirements must still be met and the physician is at risk of federally-imposed sanctions for failing so to do.

References:

21 CFR 312, Subpart I; 21 CFR 812.36, et. seq.; 21 CFR 812.47, et. seq.;
SDCL Ch. 34-51



SDSMA gratefully acknowledges the SDSMA Foundation for its support of this publication through funds awarded by The Physicians Foundation.