

653—13.13(144E,147,148,272C) Standards of practice—experimental treatments for patients with a terminal illness.

13.13(1) *Exemption from discipline.* To the extent consistent with state law, the board shall not revoke, fail to renew, suspend, or take any action against a physician's license based solely on the physician's recommendations to an eligible patient regarding access to or treatment with an investigational drug, biological product, or device.

13.13(2) *Eligible patient.* A physician shall ensure that a patient meets all of the following conditions prior to the use of an investigational drug, biological product, or device pursuant to this rule:

- a. The patient has a terminal illness, attested to by the patient's treating physician.
- b. The patient has considered and rejected or has tried and failed to respond to all other treatment options approved by the U.S. Food and Drug Administration (FDA).
- c. The patient has received a recommendation from the patient's physician for an investigational drug, biological product, or device.
- d. The patient has given written informed consent for the use of the investigational drug, biological product, or device.
- e. The patient has documentation from the patient's physician that the patient meets the requirements of this rule.

13.13(3) *Investigational drug, biological product, or device.* A physician may recommend access to or treatment with an investigational drug, biological product, or device that has successfully completed phase 1 of an FDA-approved clinical trial but has not yet been approved for general use by the FDA and remains under investigation in an FDA-approved clinical trial.

13.13(4) *Terminal illness.* A physician shall ensure that a patient has a terminal illness prior to the use of an investigational drug, biological product, or device pursuant to this rule. A terminal illness is a progressive disease or medical or surgical condition that entails significant functional impairment and that is not considered by a treating physician to be reversible even with administration of treatments approved by the FDA and that, without life-sustaining procedures, will result in death.

13.13(5) *Written informed consent.* A physician shall obtain written informed consent prior to the use of an investigational drug, biological product, or device pursuant to this rule. Written informed consent is a written document that is signed by a patient, a parent of a minor patient, or a legal guardian or other legal representative of the patient and attested to by the patient's treating physician and a witness and that includes all of the following:

- a. An explanation of the products and treatments approved by the FDA for the disease or condition from which the patient suffers.
- b. An attestation that the patient concurs with the patient's treating physician in believing that all products and treatments approved by the FDA are unlikely to prolong the patient's life.
- c. Clear identification of the specific proposed investigational drug, biological product, or device that the patient is seeking to use.
- d. A description of the best and worst potential outcomes of using the investigational drug, biological product, or device and a realistic description of the most likely outcome. The description shall include the possibility that new, unanticipated, different, or worse symptoms might result and that death could be hastened by use of the proposed investigational drug, biological product, or device. The description shall be based on the treating physician's knowledge of the proposed investigational drug, biological product, or device in conjunction with an awareness of the patient's condition.
- e. A statement that the patient's health plan or third-party administrator and provider are not obligated to pay for any care or treatments consequent to the use of the investigational drug, biological product, or device, unless the patient's health plan or third-party administrator and provider are specifically required to do so by law or contract.
- f. A statement 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 treatment ends and the patient meets hospice eligibility requirements.
- g. A statement that the patient understands that the patient is liable for all expenses consequent to the use of the investigational drug, biological product, or device and that this liability extends to the patient's

estate unless a contract between the patient and the manufacturer of the investigational drug, biological product, or device states otherwise.

13.13(6) *Assisting suicide.* This rule shall not be construed to allow a patient's treating physician to assist the patient in committing or attempting to commit suicide as prohibited in Iowa Code section 707A.2.

13.13(7) *Grounds for discipline.* A physician may be subject to disciplinary action for violation of rule 653—13.13(144E,147,148,272C) or 653—Chapter 23. Grounds for discipline include, but are not limited to, the following:

a. The physician recommends access to or treatment with an investigational drug, biological product, or device to an individual who is not an eligible patient pursuant to this rule.

b. The physician fails to obtain appropriate written informed consent prior to recommending access to or treatment with an investigational drug, biological product, or device pursuant to this rule.

c. The physician assists the patient in committing or attempting to commit suicide as prohibited in Iowa Code section 707A.2.

This rule is intended to implement Iowa Code chapters 144E, 147, 148 and 272C.

[ARC 3588C, IAB 1/17/18, effective 2/21/18]