House File 2203 - Reprinted

HOUSE FILE 2203
BY COMMITTEE ON HUMAN RESOURCES

(SUCCESSOR TO HF 2010)

(As Amended and Passed by the House March 2, 2022)

A BILL FOR

An Act relating to health care including protections for health care providers against disciplinary actions for acts or omissions related to COVID-19 and to experimental treatments for terminally ill persons, and including effective date provisions.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

Section 1. Section 144E.2, subsection 1, paragraphs a, c, and e, Code 2022, are amended to read as follows:

a. Has a terminal illness, attested to by ~~the patient's~~ a treating physician, or is receiving mechanical ventilation to prolong life.

c. Has received a recommendation from ~~the individual's~~ a physician for an investigational drug, biological product, or device.

e. Has documentation from ~~the individual's~~ a physician that the individual meets the requirements of this subsection.

Sec. 2. Section 144E.2, subsection 2, Code 2022, is amended to read as follows:

2. *"Investigational drug, biological product, or device"* means ~~a~~ any of the following:

a. A drug, biological product, or device that has successfully completed phase 1 of a United States food and drug administration-approved 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.

b. An off-label use of a drug.

Sec. 3. Section 144E.2, Code 2022, is amended by adding the following new subsection:

NEW SUBSECTION. 2A. *"Off-label use of a drug"* means the legal, prescribed use of a drug in a manner different from that described on the United States food and drug administration-approved drug label, including the use of a drug for a different disease or medical condition or giving a drug at a different dose or through a different route of administration other than that approved by the United States food and drug administration.

Sec. 4. Section 144E.2, subsection 4, unnumbered paragraph 1, Code 2022, is amended to read as follows:

"Written informed consent" means a written document that is signed by the 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~~ a treating physician and a witness and that includes all of the following:

Sec. 5. Section 144E.2, subsection 4, paragraphs b and d, Code 2022, are amended to read as follows:

b. An attestation that the patient concurs with ~~the patient's~~ a treating physician in believing that all products and treatments approved by the United States food and drug administration are unlikely to prolong the patient's life.

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~~ a treating physician's knowledge of the proposed investigational drug, biological product, or device in conjunction with an awareness of the patient's condition.

Sec. 6. Section 144E.4, Code 2022, is amended by adding the following new subsection:

NEW SUBSECTION. 5. This chapter does not create a duty for a hospital licensed under chapter 135B to credential any physician.

Sec. 7. Section 144E.8, subsection 1, Code 2022, is amended to read as follows:

1. This chapter shall not create a private cause of action against a manufacturer of an investigational drug, biological product, or device, against a physician, health care practitioner, or facility that provides necessary follow-up care, or against any other person or entity involved in the care of an eligible patient using the investigational drug, biological product, or device for any harm done to the eligible patient resulting from the investigational drug, biological

product, or device, if the manufacturer or other person or entity is complying in good faith with the terms of this chapter and has exercised reasonable care.

Sec. 8. Section 144E.9, Code 2022, is amended to read as follows:

144E.9 Assisting suicide.

This chapter shall not be construed to allow a ~~patient's treating~~ physician to assist ~~the~~ a patient in committing or attempting to commit suicide as prohibited in section 707A.2.

Sec. 9. Section 686D.6, Code 2022, is amended to read as follows:

686D.6 Liability of and disciplinary actions against health care providers.

1. A health care provider shall not be liable for civil damages or subject to disciplinary action by the health care provider's licensing board for causing or contributing, directly or indirectly, to the death or injury of an individual as a result of the health care provider's acts or omissions while providing or arranging health care in support of the state's response to COVID-19. This subsection shall apply to all of the following:

a. Injury or death resulting from screening, assessing, diagnosing, caring for, or treating individuals with a suspected or confirmed case of COVID-19.

b. Prescribing, administering, or dispensing a pharmaceutical for off-label use to treat a patient with a suspected or confirmed case of COVID-19.

c. Acts or omissions while providing health care to individuals unrelated to COVID-19 when those acts or omissions support the state's response to COVID-19, including any of the following:

(1) Delaying or canceling nonurgent or elective dental, medical, or surgical procedures, or altering the diagnosis or treatment of an individual in response to any federal or state statute, regulation, order, or public health guidance.

(2) Diagnosing or treating patients outside the normal scope of the health care provider's license or practice.

(3) Using medical devices, equipment, or supplies outside of their normal use for the provision of health care, including using or modifying medical devices, equipment, or supplies for an unapproved use.

(4) Conducting tests or providing treatment to any individual outside the premises of a health care facility.

(5) Acts or omissions undertaken by a health care provider because of a lack of staffing, facilities, medical devices, equipment, supplies, or other resources attributable to COVID-19 that renders the health care provider unable to provide the level or manner of care to any person that otherwise would have been required in the absence of COVID-19.

(6) Acts or omissions undertaken by a health care provider relating to use or nonuse of personal protective equipment.

2. This section shall not relieve any person of liability for civil damages or a health care provider from disciplinary action by the health care provider's licensing board for any act or omission which constitutes recklessness or willful misconduct.

Sec. 10. EFFECTIVE DATE. This Act, being deemed of immediate importance, takes effect upon enactment.