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L.D. 180
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HEALTH AND HUMAN SERVICES

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STATE OF MAINE

HOUSE OF REPRESENTATIVES

127TH LEGISLATURE

SECOND REGULAR SESSION

COMMITTEE AMENDMENT "A" to H.P. 138, L.D. 180, Bill, "An Act To Allow Terminally Ill Patients To Choose To Use Experimental Treatments"

Amend the bill by striking out all of section 1 and inserting the following:

'**Sec. 1. 22 MRSA c. 602-A** is enacted to read:

CHAPTER 602-A

ACCESS TO INVESTIGATIONAL TREATMENTS FOR TERMINALLY ILL PATIENTS

§2671. Definitions

As used in this chapter, unless the context otherwise indicates, the following terms have the following meanings.

1. Eligible patient. "Eligible patient" means a person who has:

A. Received a diagnosis of a terminal illness for which no standard treatment is effective and the diagnosis has been attested by the person's treating physician;

B. Considered all treatment options approved by the United States Food and Drug Administration;

C. Not been accepted into a clinical trial within one week of completion of the clinical trial application process;

D. Received a recommendation from the person's treating physician for an investigational drug, biological product or device;

E. Given written, informed consent for the use of the investigational drug, biological product or device under paragraph D or, if the person is a minor or lacks the mental capacity to provide informed consent, whose parent or legal guardian has given written, informed consent on the person's behalf; and

F. Received documentation from the person's treating physician that the person meets all of the conditions in this subsection.

2. Investigational drug, biological product or device. "Investigational drug, biological product or device" means a drug, biological product or device that has successfully completed Phase I 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 such a clinical trial.

3. Terminal illness. "Terminal illness" means a disease or condition that, without life-sustaining measures, will soon result in death or in a state of permanent unconsciousness from which recovery is unlikely.

4. Treating physician. "Treating physician" means a physician who has primary responsibility for the care of a patient and treatment of that patient's terminal illness.

5. Written, informed consent. "Written, informed consent" means a written document signed by a patient or, if the patient is a minor or lacks the mental capacity to provide informed consent, a parent or legal guardian of the patient. The document must be attested by the patient's treating physician and a witness and include the following information:

A. An explanation of the United States Food and Drug Administration-approved treatments for the disease or condition from which the patient suffers;

B. A statement that the patient concurs with the patient's treating physician that all United States Food and Drug Administration-approved and standard treatments for the disease or condition from which the patient suffers are unlikely to prolong the patient's life;

C. Clear identification of the specific investigational drug, biological product or device that the patient is seeking to use; and

D. A description of the best and worst potential outcomes of using the investigational drug, biological product or device identified under paragraph C with a description of the most likely outcome. The description must include the possibility that new, unanticipated, different or worse symptoms might result and that death could be hastened by the proposed treatment. The description must be based on the treating physician's knowledge of the proposed treatment in conjunction with the treating physician's knowledge of the patient's overall medical condition.

§2672. Availability of investigational drug, biological product or device by manufacturer

A manufacturer of an investigational drug, biological product or device may make available the investigational drug, biological product or device to an eligible patient.

1. Compensation. A manufacturer may provide an investigational drug, biological product or device to an eligible patient with or without receiving compensation.

2. Costs. A manufacturer may require an eligible patient to pay the costs of manufacturing the dosage of an investigational drug, a biological product or a device dispensed to that eligible patient.

§2673. Action against health care practitioner or health care provider license prohibited

A licensing board may not revoke, refuse to renew or suspend the license of or take any action against a health care practitioner as defined in Title 24, section 2502, subsection 1-A based solely on the health care practitioner's recommendations to an eligible patient regarding access to or treatment with an investigational drug, biological product or device, as long as the recommendations are consistent with medical standards of care.

The licensing agency may not revoke, refuse to renew or suspend the license of or take any action against a health care provider as defined in Title 24, section 2502, subsection 2 based solely on the health care provider's involvement in the care of an eligible patient using an investigational drug, biological product or device.

§2674. Officials, employees and agents of the State

1. Violation. An official, employee or agent of the State may not block or attempt to block an eligible patient's access to an investigational drug, biological product or device.

2. Medical standards of care. This section does not prohibit an official, employee or agent of the State from providing counseling, advice or a recommendation consistent with medical standards of care.

§2675. No cause of action created

This chapter does not create a private cause of action against a manufacturer of an investigational drug, biological product or device 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 provisions of this chapter and has exercised reasonable care.

§2676. Clinical trial coverage

This chapter does not affect the mandatory health care coverage for participation in clinical trials pursuant to Title 24-A, section 4310.

§2677. Optional participation of health care practitioners and providers

This chapter does not require a health care practitioner who is licensed in the State or a health care provider that is licensed in the State to provide any service related to an investigational drug, biological product or device.'

SUMMARY

This amendment does the following.

1. It amends the definition of "eligible patient" in the bill by eliminating the condition that requires a patient to have been unable to participate in a clinical trial for treatment of the terminal illness within 100 miles of that person's home address.

2. It amends the definition of "terminal illness" in the bill to provide that the condition need not reasonably be expected to result in death within 6 months but instead will soon result in death or in a state of permanent unconsciousness from which recovery is unlikely.

3. It amends the definition of "written, informed consent" in the bill to remove certain requirements involving insurance implications, home health care services and hospice care and patient liability for certain expenses.

4. It amends the provision that provides for the costs that are allowed to be charged by the manufacturer to ensure that the patient is being charged only for the costs of manufacturing the dosage of an investigational drug, a biological product or a device dispensed to that patient.

5. It strikes the section dealing with insurance issues.

6. It provides protection to health care providers who choose to provide care to an eligible patient using an investigational drug, biological product or device.

7. It eliminates the penalty for blocking an eligible patient from access to an investigational drug, biological product or device.

8. It makes it clear that the provision of services related to an investigational drug, biological product or device by health care practitioners and providers is optional.