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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 “ ” 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

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

3 **2. Investigational drug, biological product or device.** "Investigational drug,
4 biological product or device" means a drug, biological product or device that has
5 successfully completed Phase I of a United States Food and Drug Administration-
6 approved clinical trial but has not yet been approved for general use by the United States
7 Food and Drug Administration and remains under investigation in such a clinical trial.

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

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

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

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

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

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

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

33 **§2672. Availability of investigational drug, biological product or device by**
34 **manufacturer**

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

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

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

1 **§2673. Action against health care practitioner or health care provider license**
2 **prohibited**

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

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

13 **§2674. Officials, employees and agents of the State**

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

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

19 **§2675. No cause of action created**

20 This chapter does not create a private cause of action against a manufacturer of an
21 investigational drug, biological product or device or against any other person or entity
22 involved in the care of an eligible patient using the investigational drug, biological
23 product or device for any harm done to the eligible patient resulting from the
24 investigational drug, biological product or device if the manufacturer or other person or
25 entity is complying in good faith with the provisions of this chapter and has exercised
26 reasonable care.

27 **§2676. Clinical trial coverage**

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

30 **§2677. Optional participation of health care practitioners and providers**

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

34 **SUMMARY**

35 This amendment does the following.

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

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

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

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

12 5. It strikes the section dealing with insurance issues.

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

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

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