



# 127th MAINE LEGISLATURE

## FIRST REGULAR SESSION-2015

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Legislative Document

No. 180

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H.P. 138

House of Representatives, January 27, 2015

### **An Act To Allow Terminally Ill Patients To Choose To Use Experimental Treatments**

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Reference to the Committee on Health and Human Services suggested and ordered printed.

A handwritten signature in cursive script that reads "Robert B. Hunt".

ROBERT B. HUNT  
Clerk

Presented by Representative LONGSTAFF of Waterville.  
Cosponsored by Representative WARD of Dedham, Senator BRAKEY of Androscoggin and  
Representatives: DUNPHY of Old Town, ESPLING of New Gloucester, FOWLE of  
Vassalboro, NADEAU of Winslow, PICCHIOTTI of Fairfield, SAUCIER of Presque Isle,  
SCHNECK of Bangor, Senator: PATRICK of Oxford.

1 **Be it enacted by the People of the State of Maine as follows:**

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

3 **CHAPTER 602-A**

4 **ACCESS TO INVESTIGATIONAL TREATMENTS FOR TERMINALLY ILL**  
5 **PATIENTS**

6 **§2671. Definitions**

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

9 **1. Carrier.** "Carrier" has the same meaning as in Title 24-A, section 4301-A,  
10 subsection 3.

11 **2. Eligible patient.** "Eligible patient" means a person who has:

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

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

16 C. Been unable to participate in a clinical trial for treatment of the terminal illness  
17 within 100 miles of the person's home address or has not been accepted into a clinical  
18 trial within one week of completion of the clinical trial application process;

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

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

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

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

32 **4. Terminal illness.** "Terminal illness" means a disease or condition that, without  
33 life-sustaining measures, is reasonably expected to result in death within 6 months.

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

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

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

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

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

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

21           E. A statement that the patient's carrier is not obligated to pay for any care or  
22 treatments consequent to the use of the investigational drug, biological product or  
23 device identified under paragraph C, unless the carrier is specifically required to do  
24 so by law or contract;

25           F. A statement that the patient's eligibility for hospice services may be withdrawn if  
26 the patient begins curative treatment with the investigational drug, biological product  
27 or device identified under paragraph C and that hospice services may be reinstated if  
28 the curative treatment ends and the patient meets hospice eligibility requirements;

29           G. A statement that the patient may not be eligible for in-home health care services if  
30 treatment with the investigational drug, biological product or device identified under  
31 paragraph C begins; and

32           H. A statement that the patient understands that the patient is liable for all expenses  
33 consequent to the use of the investigational drug, biological product or device  
34 identified under paragraph C and that the liability extends to the patient's estate,  
35 unless a contract between the patient and the manufacturer of the investigational  
36 drug, biological product or device states otherwise.

37           **§2672. Availability of investigational drug, biological product or device by**  
38 **manufacturer**

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

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

3            **2. Costs.** A manufacturer may require an eligible patient to pay the costs of or  
4 associated with the manufacture of an investigational drug, biological product or device.

5            **§2673. Insurance**

6            This chapter does not expand the coverage required of a carrier under the Maine  
7 Insurance Code.

8            **1. Coverage.** A carrier may provide coverage for an investigational drug, biological  
9 product or device.

10           **2. Coverage denial.** Unless specifically required to provide coverage by law or  
11 contract, a carrier may deny coverage to an eligible patient from the time the eligible  
12 patient begins use of an investigational drug, biological product or device through a  
13 period not to exceed 6 months from the time the investigational drug, biological product  
14 or device is no longer used by the eligible patient. A carrier may not deny coverage for a  
15 preexisting condition or coverage for benefits that commenced prior to the time the  
16 eligible patient began use of the investigational drug, biological product or device.

17           **§2674. Action against health care practitioner license prohibited**

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

24           **§2675. Officials, employees and agents of the State**

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

27           **2. Penalty.** An official, employee or agent of the State who violates this section  
28 commits a Class E crime.

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

32           **§2676. No cause of action created**

33           This chapter does not create a private cause of action against a manufacturer of an  
34 investigational drug, biological product or device or against any other person or entity  
35 involved in the care of an eligible patient using the investigational drug, biological  
36 product or device for any harm done to the eligible patient resulting from the  
37 investigational drug, biological product or device if the manufacturer or other person or

1 entity is complying in good faith with the provisions of this chapter and has exercised  
2 reasonable care.

3 **§2677. Clinical trial coverage**

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

6 **SUMMARY**

7 This bill authorizes manufacturers of drugs, biological products and devices that have  
8 completed Phase I of a United States Food and Drug Administration-approved clinical  
9 trial but have not yet been approved for general use and remain under clinical  
10 investigation to make them available to eligible terminally ill patients. The bill does not  
11 require health insurers to provide coverage for the cost of such a drug, biological product  
12 or device but authorizes insurers to provide such coverage. The bill prohibits licensing  
13 boards from revoking, refusing to renew or suspending the license of or taking any other  
14 action against a health care practitioner based solely on the practitioner's recommendation  
15 to an eligible patient regarding access to or treatment with such a drug, biological product  
16 or device. It prohibits any official, employee or agent of the State from blocking or  
17 attempting to block access by an eligible patient to such a drug, biological product or  
18 device.