

LAWS

OF THE

STATE OF MAINE

AS PASSED BY THE

ONE HUNDRED AND TWENTY-SEVENTH LEGISLATURE

SECOND REGULAR SESSION January 6, 2016 to April 29, 2016

THE GENERAL EFFECTIVE DATE FOR SECOND REGULAR SESSION NON-EMERGENCY LAWS IS JULY 29, 2016

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tor from making all payments required under subsection 2.

10. Mass layoff. Whenever an employer lays off 100 or more employees at a covered establishment, the employer within 7 days of such a layoff shall report to the director the expected duration of the layoff and whether it is of indefinite or definite duration. The director shall, from time to time, but no less frequently than every 30 days, require the employer to report such facts as the director considers relevant to a determination or relocation under this section or whether there is a substantial reason to believe the affected employees will be recalled within a reasonable time.

See title page for effective date.

CHAPTER 418

H.P. 138 - L.D. 180

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

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

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.

<u>§2672. Availability of investigational drug,</u> <u>biological product or device by</u> <u>manufacturer</u>

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.

<u>§2673. Action against health care practitioner or</u> <u>health care provider license prohibited</u>

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

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

<u>§2677. Optional participation of health care</u> 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.

See title page for effective date.

CHAPTER 419

H.P. 1041 - L.D. 1516

An Act To Clarify the Authority of County Sheriffs To Grant Law Enforcement Powers

Emergency preamble. Whereas, acts and resolves of the Legislature do not become effective until 90 days after adjournment unless enacted as emergencies; and

Whereas, the enforcement of Maine's laws by county sheriffs requires additional personnel that are available through deputizing municipal law enforcement officers; and

Whereas, this legislation needs to take effect immediately in order to ensure that Maine's county sheriffs are adequately staffed to perform their law enforcement duties; and

Whereas, in the judgment of the Legislature, these facts create an emergency within the meaning of the Constitution of Maine and require the following legislation as immediately necessary for the preservation of the public peace, health and safety; now, therefore,

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

Sec. 1. 30-A MRSA §2674, as amended by PL 2013, c. 261, §2, is further amended by adding at the end a new paragraph to read:

Notwithstanding section 501 and except as otherwise provided by municipal charter or ordinance, the municipal officers may authorize the chief of police or other designee to request a county sheriff to appoint as a deputy sheriff a municipal law enforcement officer who has satisfied the training requirements of Title 25,