House of Representatives

General Assembly

File No. 106

February Session, 2016

Substitute House Bill No. 5270

House of Representatives, March 22, 2016

The Committee on Public Health reported through REP. RITTER of the 1st Dist., Chairperson of the Committee on the part of the House, that the substitute bill ought to pass.

AN ACT CONCERNING THE RIGHT TO TRY EXPERIMENTAL DRUGS.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. (NEW) (*Effective October 1, 2016*) (a) For purposes of this section and sections 2 to 5, inclusive, of this act:

(1) "Investigational drug, biological product or device" means a drug, biological product or biological device that has successfully completed phase one of a clinical trial but has not yet been approved for general use by the federal Food and Drug Administration and remains under investigation in a clinical trial approved by the federal Food and Drug Administration.

(2) "Patient" means a person who has a terminal illness, verified by the patient's treating physician, and is not being treated as an inpatient in a hospital licensed under chapter 368v of the general statutes.

(3) "Treating physician" means a physician licensed under chapter

370 of the general statutes who has primary responsibility for the medical care of the patient and treatment of the patient's terminal illness.

(4) "Terminal illness" means a medical condition that a patient's treating physician anticipates, with reasonable medical judgment, will result in a patient's death or a state of permanent unconsciousness from which recovery is unlikely within a period of one year.

(b) A patient is eligible to receive treatment with an investigational drug, biological product or device if the patient has (1) considered all other treatment options currently approved by the federal Food and Drug Administration, (2) been unable to participate in a clinical trial for the terminal illness not more than one hundred miles from the patient's home address, or not been accepted to a clinical trial not more than one week after completion of the clinical trial application process, (3) received a recommendation from his or her treating physician for an investigational drug, biological product or device, (4) given written, informed consent, as provided in subsection (c) of this section, for the use of the investigational drug, biological product or device or, if the patient is a minor or lacks the mental capacity to provide informed consent, a parent of the minor or a legal guardian of the minor or adult patient has given such written, informed consent on the patient's behalf, and (5) obtained written documentation from his or her treating physician stating that the patient meets the requirements of this subsection.

(c) A patient gives written informed consent when the patient, or if the patient is a minor or lacks the mental capacity to provide informed consent, a parent of the minor or the legal guardian of the minor or adult patient, signs a written document, verified by the patient's treating physician and a witness that at a minimum: (1) Explains the currently approved products and treatments for the terminal illness from which the patient suffers; (2) verifies the fact that the patient concurs with his or her treating physician in believing that all currently approved and conventionally recognized treatments are unlikely to

prolong the patient's life; (3) clearly identifies the specific proposed investigational drug, biological product or device with which the patient is seeking to be treated; (4) describes the potentially best and worst outcomes of using the investigational drug, biological product or device with a realistic description of the most likely outcome, including the possibility that new, unanticipated, different or worse symptoms might result and that death could be hastened by the proposed treatment based on the treating physician's knowledge of the proposed treatment in conjunction with an awareness of the patient's condition; (5) states clearly that the patient's health carrier, as defined in section 38a-477aa of the general statutes, treating physician or other health care provider is not obligated to pay for any care or treatments resulting from the use of the investigational drug, biological product or device; (6) states clearly that the patient's eligibility for hospice care may be withdrawn if the patient begins treatment with an investigational drug, biological product or device, but that hospice care may be reinstated if such treatment ends and the patient meets hospice eligibility requirements; (7) states clearly that in-home health care may be denied if such treatment begins; and (8) states that the patient understands that the patient is liable for all expenses resulting from the use of the investigational drug, biological product or device and that this liability extends to the patient's estate, unless a contract between the patient and the manufacturer of the drug, biological product or device states otherwise.

Sec. 2. (NEW) (*Effective October 1, 2016*) A manufacturer of an investigational drug, biological product or device may make available the manufacturer's investigational drug, biological product or device to a patient, who is eligible under subsection (b) of section 1 of this act, and may (1) provide the investigational drug, biological product or device to such patient without receiving compensation, or (2) require such patient to pay the costs of, or associated with, the manufacture of the investigational drug, biological product or device.

Sec. 3. (NEW) (*Effective October 1, 2016*) (a) A health carrier, as defined in section 38a-477aa of the general statutes, may provide

coverage for the cost of an investigational drug, biological product or device made available, pursuant to section 2 of this act, to a patient who is eligible under subsection (b) of section 1 of this act.

(b) A health carrier may deny coverage to such patient from the time such patient begins treatment with the investigational drug, biological product or device for a period not to exceed six months from the date such patient ceases treatment with the investigational drug, biological product or device, except coverage may not be denied for a preexisting condition or for coverage for benefits that commenced prior to the date such patient begins such treatment.

(c) Nothing in this section shall affect the provisions of sections 38a-504a to 38a-504g, inclusive, and 38a-542a to 38a-542g, inclusive, of the general statutes concerning insurance coverage for certain costs associated with clinical trials. Treatment with an investigational drug, biological product or device pursuant to sections 1 to 5, inclusive, of this act is not considered a clinical trial for purposes of said sections.

Sec. 4. (NEW) (*Effective October 1, 2016*) (a) Notwithstanding the provisions of chapter 370 of the general statutes, the Department of Public Health or the Connecticut Medical Examining Board shall not revoke, fail to renew, suspend or take any disciplinary action against a physician based solely on the treating physician's recommendation to a patient regarding access to, or treatment with, an investigational drug, biological product or device, provided such recommendation is consistent with medical standards of care.

(b) No official, employee or agent of the state shall prevent, or attempt to prevent, a patient who is eligible under subsection (b) of section 1 of this act from accessing an investigational drug, biological product or device.

Sec. 5. (NEW) (*Effective October 1, 2016*) Nothing in sections 1 to 4, inclusive, of this act shall create a private cause of action against a manufacturer of an investigational drug, biological product or device or against the patient's treating physician or any other person or entity

involved in the care of a patient being treated with an investigational drug, biological product or device for any harm done to such patient resulting from the investigational drug, biological product or device.

This act shall take effect as follows and shall amend the following sections:		
Section 1	*October 1, 2016*	New section
Sec. 2	*October 1, 2016*	New section
Sec. 3	*October 1, 2016*	New section
Sec. 4	*October 1, 2016*	New section
Sec. 5	*October 1, 2016*	New section

Statement of Legislative Commissioners:
In section 1(b)(5), "written documentation" was changed to "obtained written documentation" for clarity.

PH *Joint Favorable Subst. -LCO*

The following Fiscal Impact Statement and Bill Analysis are prepared for the benefit of the members of the General Assembly, solely for purposes of information, summarization and explanation and do not represent the intent of the General Assembly or either chamber thereof for any purpose. In general, fiscal impacts are based upon a variety of informational sources, including the analyst's professional knowledge. Whenever applicable, agency data is consulted as part of the analysis, however final products do not necessarily reflect an assessment from any specific department.

OFA Fiscal Note

State Impact: None

Municipal Impact: None

Explanation

The bill, which allows certain terminally ill patients to access medications not approved for general use by the federal Food and Drug Administration, among other provisions, does not result in a fiscal impact to the state, or municipalities.

The Out Years

State Impact: None

Municipal Impact: None

OLR Bill Analysis

sHB 5270

AN ACT CONCERNING THE RIGHT TO TRY EXPERIMENTAL DRUGS.

SUMMARY:

Under specified conditions, this bill allows certain terminally ill patients to access medications not approved for general use by the federal Food and Drug Administration (FDA). The bill applies to investigational drugs, biological products, or devices (hereinafter "investigational drugs") that have completed Phase 1 of an FDA-approved clinical trial and are still part of the clinical trial. To qualify, patients must complete a detailed informed consent document and meet other eligibility criteria. Even if a patient is eligible, manufacturers of investigational drugs are allowed but not required to provide them.

Under the bill, manufacturers can charge eligible patients for the investigational drugs they provide. The bill does not require health carriers to cover these drugs, and it specifies when carriers can deny coverage to patients being treated with them.

The bill specifies that it does not create a private cause of action against an investigational drug manufacturer, the treating physician, or other people or entities involved in the patient's care for any harm caused by an investigational drug.

The bill prohibits the Department of Public Health and Medical Examining Board from taking any disciplinary action against a physician based solely on his or her recommendation on a patient's access to or use of an investigational drug, as long as the recommendation is consistent with medical standards of care. It also prohibits state officials, employees, and agents from preventing or

attempting to prevent an eligible patient from accessing such a drug.

Federal law vests in the FDA the authority to approve drugs before they can be sold. The FDA has a separate process to make investigational drugs available outside of a clinical trial before all phases of the trial are complete. Under this process (called "expanded access"), the patient's physician must submit a request to the FDA for approval (see BACKGROUND).

EFFECTIVE DATE: October 1, 2016

INVESTIGATIONAL DRUGS

Patient Eligibility and Documentation

The bill allows manufacturers to provide terminally ill patients with investigational drugs under certain conditions. It defines a "terminal illness" as a medical condition that the treating physician anticipates, with reasonable medical judgment, will result in a patient's death or a state of unconsciousness from which recovery is unlikely within a year.

Under the bill, to be eligible to receive treatment with an investigational drug, a patient must:

1. have a terminal illness verified by his or her treating physician (a state-licensed physician with primary responsibility for the patient's medical care and treatment of the terminal illness);

2. not be a hospital inpatient;

3. have considered all other FDA-approved treatment options;

4. be unable to participate in a clinical trial within 100 miles of his or her home, or not be accepted into a clinical trial no more than a week after the end of the trial application process;

5. receive a recommendation for the drug from his or her treating physician;

6. give written informed consent for the drug's use (see below); and

7. obtain from the treating physician written documentation that the patient meets requirements (3) through (6).

The required informed consent document must be verified by the treating physician and a witness. The document must be signed by the patient, except that if the patient is a minor or lacks the capacity to provide informed consent, a parent of the minor or legal guardian of the minor or adult patient must consent on the patient's behalf.

The document must:

1. explain the currently approved products and treatments for the terminal illness;

2. verify that the patient agrees with the treating physician in believing that all currently approved and conventional treatments are unlikely to prolong the patient's life;

3. clearly identify the specific proposed investigational drug with which the patient is seeking treatment;

4. describe the potentially best and worst outcomes of using the drug with a realistic description of the most likely outcome, including the possibility that new, unanticipated, or worse symptoms may result and that the treatment could hasten death, based on the physician's knowledge of the treatment and awareness of the patient's condition; and

5. state that the patient understands that he or she is liable for all expenses resulting from taking the drug and that this liability extends to the patient's estate, unless a contract between the patient and the drug manufacturer provides otherwise.

The document must also clearly state that:

1. the patient's health carrier, treating physician, or other

providers are not obligated to pay for any care or treatment resulting from taking the investigational drug;

2. the patient's hospice eligibility may be withdrawn if the patient begins treatment with such a drug, but hospice care may be reinstated if the treatment ends and the patient is hospice eligible; and

3. in-home health care may be denied if the treatment begins.

Insurance Provisions

Under the bill, health carriers may cover investigational drugs made available as set forth above to eligible patients, but are not required to do so. While the patient is taking the drug and for the following six months, carriers may deny coverage to the patient except for (1) preexisting conditions or (2) benefits that began before treatment with the drug.

The bill specifies that (1) treatment with investigational drugs as set forth in the bill is not considered a clinical trial for purposes of the law's requirements for insurance coverage of certain clinical trial costs and (2) it does not affect those requirements.

BACKGROUND

FDA Drug Approval Process and Expanded Access

Drug companies seeking to have a new drug approved for sale in the United States must receive FDA approval. This process involves several steps, including clinical trials.

For individual patients seeking access to investigational drugs that have not yet received FDA approval, a physician can apply to the FDA under the "expanded access" process. Federal law and regulations specify the conditions under which the FDA can grant such access. Among other things, the FDA must determine that:

1. the patient has a serious or immediately life-threatening condition and there is no comparable or satisfactory alternative

therapy,

2. the potential benefit justifies the potential risks and those risks are not unreasonable in the context of the condition, and

3. providing the drug for the requested use will not interfere with clinical investigations that could support marketing approval of the expanded access use or otherwise compromise the potential development of that use (21 C.F.R. § 312.305).

Even where the FDA grants approval, manufacturers are not required to provide the drug.

Related Bill

The Insurance and Real Estate Committee favorably reported a similar bill (SB 371) on patient access to investigational drugs.

COMMITTEE ACTION

Public Health Committee

Joint Favorable
Yea 24 Nay 2 (03/07/2016)