



House of Representatives

General Assembly

File No. 170

January Session, 2015

Substitute House Bill No. 6709

House of Representatives, March 23, 2015

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:

1 Section 1. (NEW) (*Effective October 1, 2015*) (a) For purposes of this
2 section and sections 2 to 5, inclusive, of this act:

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

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

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

13 370 of the general statutes who has primary responsibility for the
14 medical care of the patient and treatment of the patient's terminal
15 illness.

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

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

36 (c) A patient gives written informed consent when the patient, or if
37 the patient is a minor the patient's parent or legal guardian, signs a
38 written document, verified by the patient's treating physician and a
39 witness that at a minimum: (1) Explains the currently approved
40 products and treatments for the terminal illness from which the patient
41 suffers, (2) verifies the fact that the patient concurs with his or her
42 treating physician in believing that all currently approved and
43 conventionally recognized treatments are unlikely to prolong the
44 patient's life, (3) clearly identifies the specific proposed investigational
45 drug, biological product or device with which the patient is seeking to

46 be treated, (4) describes the potentially best and worst outcomes of
47 using the investigational drug, biological product or device with a
48 realistic description of the most likely outcome, including the
49 possibility that new, unanticipated, different or worse symptoms
50 might result and that death could be hastened by the proposed
51 treatment based on the treating physician's knowledge of the proposed
52 treatment in conjunction with an awareness of the patient's condition,
53 (5) makes clear that the patient's health insurer, treating physician or
54 other health care provider is not obligated to pay for any care or
55 treatments resulting from the use of the investigational drug,
56 biological product or device, (6) makes clear that the patient's
57 eligibility for hospice care may be withdrawn if the patient begins
58 treatment with an investigational drug, biological product or device,
59 but that hospice care may be reinstated if such treatment ends and the
60 patient meets hospice eligibility requirements, (7) makes clear that in-
61 home health care may be denied if such treatment begins, and (8)
62 states that the patient understands that the patient is liable for all
63 expenses resulting from the use of the investigational drug, biological
64 product or device and that this liability extends to the patient's estate,
65 unless a contract between the patient and the manufacturer of the
66 drug, biological product or device states otherwise.

67 Sec. 2. (NEW) (*Effective October 1, 2015*) A manufacturer of an
68 investigational drug, biological product or device may make available
69 the manufacturer's investigational drug, biological product or device
70 to a patient, who is eligible under subsection (b) of section 1 of this act,
71 and may (1) provide the investigational drug, biological product or
72 device to such patient without receiving compensation, or (2) require
73 such patient to pay the costs of, or associated with, the manufacture of
74 the investigational drug, biological product or device.

75 Sec. 3. (NEW) (*Effective October 1, 2015*) (a) A health insurer may
76 provide coverage for the cost of an investigational drug, biological
77 product or device made available to a patient, who is eligible under
78 subsection (b) of section 1 of this act, pursuant to section 2 of this act.

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

86 (c) Nothing in this section shall affect the provisions of sections 38a-
87 504a to 38a-504g, inclusive, and 38a-542a to 38a-542g, inclusive, of the
88 general statutes concerning insurance coverage for certain costs
89 associated with clinical trials. Treatment with an investigational drug,
90 biological product or device pursuant to sections 1 to 5, inclusive, of
91 this act is not considered a clinical trial for purposes of said sections.

92 Sec. 4. (NEW) (*Effective October 1, 2015*) (a) Notwithstanding the
93 provisions of chapter 370 of the general statutes, the Department of
94 Public Health or the Connecticut Medical Examining Board shall not
95 revoke, fail to renew, suspend or take any disciplinary action against a
96 physician based solely on the physician's recommendation to a patient
97 regarding access to, or treatment with, an investigational drug,
98 biological product or device, provided such recommendation is
99 consistent with medical standards of care.

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

104 Sec. 5. (NEW) (*Effective October 1, 2015*) Nothing in sections 1 to 4,
105 inclusive, of this act shall create a private cause of action against a
106 manufacturer of an investigational drug, biological product or device
107 or against the patient's treating physician or any other person or entity
108 involved in the care of a patient being treated with an investigational
109 drug, biological product or device for any harm done to such patient
110 resulting from the investigational drug, biological product or device.

This act shall take effect as follows and shall amend the following sections:		
Section 1	<i>October 1, 2015</i>	New section
Sec. 2	<i>October 1, 2015</i>	New section
Sec. 3	<i>October 1, 2015</i>	New section
Sec. 4	<i>October 1, 2015</i>	New section
Sec. 5	<i>October 1, 2015</i>	New section

PH *Joint Favorable Subst.*

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 is not anticipated to result in a fiscal impact to the state employee and retiree health plan or fully insured municipal health plans as it does not require health insurers to provide coverage for investigational drugs or health coverage during the time a patient is being treated with the investigational drug. The state health plan does not currently provide coverage of investigational treatments.

The bill which also adds protections for a physician against disciplinary action solely based on recommending that a patient take an investigational drug is not anticipated to have a fiscal impact.

The Out Years

State Impact: None

Municipal Impact: None

OLR Bill Analysis

sHB 6709

AN ACT CONCERNING THE RIGHT TO TRY EXPERIMENTAL DRUGS.

SUMMARY:

Under specified conditions, this bill allows 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. Among other eligibility criteria, patients must complete a detailed informed consent document.

The bill allows manufacturers to provide investigational drugs to eligible patients. If they provide these drugs, they can charge patients for them. The bill does not require health insurers to cover these drugs, and it specifies when insurers 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 done by an investigational drug.

The bill prohibits the Department of Public Health or Medical Examining Board from taking any disciplinary action against a physician solely for recommending that a patient take or use an investigational drug, as long as the recommendation is consistent with medical standards of care. It also prohibits state officials, employees, or agents from preventing or attempting to prevent an eligible patient from accessing such a drug.

It is unclear how the bill interacts with federal law, which vests in the FDA the authority to approve drugs before they can be sold. The FDA also has a 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 the request to the FDA for approval (see BACKGROUND).

EFFECTIVE DATE: October 1, 2015

INVESTIGATIONAL DRUGS

Patient Eligibility and Documentation

The bill allows terminally ill patients to receive treatment 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 an inpatient at a hospital;
3. consider 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 where the patient is a minor or lacks the capacity to provide informed consent, a parent or legal guardian 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 make clear that:

1. the patient's health insurer, 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 insurers may cover investigational drugs for eligible patients but are not required to do so. While the patient is taking the drug and for the following six months, insurers 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, Clinical Trials, 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. According to the FDA, Phase 1 trials focus on the drug's safety and typically involve 20 to 80 subjects. Phase 2 trials focus on effectiveness and typically involve hundreds of subjects. Phase 3 trials focus on safety, effectiveness, and related issues (such as interactions with other drugs), and involve thousands of subjects.

For individual patients seeking access to investigational drugs that have not yet received FDA approval for sale, 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 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 CFR § 312.305).

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

COMMITTEE ACTION

Public Health Committee

Joint Favorable Substitute

Yea 25 Nay 0 (03/04/2015)