



General Assembly

February Session, 2016

Raised Bill No. 371

LCO No. 1335



Referred to Committee on INSURANCE AND REAL ESTATE

Introduced by:
(INS)

AN ACT CONCERNING THE USE OF EXPERIMENTAL DRUGS.

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

1 Section 1. (NEW) (*Effective October 1, 2016*) (a) For purposes of this
2 section:

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

16 (4) "Terminal illness" means a medical condition that a patient's
17 treating physician anticipates, with reasonable medical judgment, will
18 result in the 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 that is not more than one hundred miles from
25 the patient's home address, or not been accepted to a clinical trial not
26 more than one week after completion of the clinical trial application
27 process, (3) received a recommendation from his or her treating
28 physician for an investigational drug, biological product or device, (4)
29 given written, informed consent, as provided in subsection (c) of this
30 section, for the use of the investigational drug, biological product or
31 device or, if the patient is a minor or lacks the mental capacity to
32 provide informed consent, a parent of the minor or a legal guardian of
33 the minor or adult patient has given such written, informed consent on
34 the patient's behalf, and (5) written documentation from his or her
35 treating physician stating that the patient meets the requirements of
36 this subsection.

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

46 prolong the patient's life; (3) clearly identifies the specific proposed
47 investigational drug, biological product or device with which the
48 patient is seeking to be treated; (4) describes the potentially best and
49 worst outcomes of using the investigational drug, biological product or
50 device with a realistic description of the most likely outcome,
51 including the possibility that new, unanticipated, different or worse
52 symptoms might result and that death could be hastened by the
53 proposed treatment, based on the treating physician's knowledge of
54 the proposed treatment in conjunction with an awareness of the
55 patient's condition; (5) states clearly that the patient's health carrier, as
56 defined in section 3 of this act, treating physician or other health care
57 provider is not obligated to pay for any care or treatments resulting
58 from the use of the investigational drug, biological product or device;
59 (6) states clearly that the patient's eligibility for hospice care may be
60 withdrawn if the patient begins treatment with an investigational
61 drug, biological product or device but that hospice care may be
62 reinstated if such treatment ends and the patient meets hospice
63 eligibility requirements; (7) states clearly that in-home health care may
64 be denied if such treatment begins; and (8) states that the patient
65 understands that the patient is liable for the costs of, or associated
66 with, the investigational drug, biological product or device and that
67 this liability extends to the patient's estate, unless a contract between
68 the patient and the manufacturer of the investigational drug, biological
69 product or device states otherwise.

70 (d) Notwithstanding the provisions of chapter 370 of the general
71 statutes, the Department of Public Health or the Connecticut Medical
72 Examining Board shall not revoke, fail to renew, suspend or take any
73 disciplinary action against a physician based solely on the treating
74 physician's recommendation to a patient regarding access to, or
75 treatment with, an investigational drug, biological product or device,
76 provided such recommendation is consistent with medical standards
77 of care.

78 (e) No official, employee or agent of the state shall prevent, or

79 attempt to prevent, a patient who is eligible under subsection (b) of
80 this section from accessing an investigational drug, biological product
81 or device.

82 (f) Nothing in this section shall create a cause of action against the
83 patient's treating physician or any other person or entity involved in
84 the care of a patient being treated with an investigational drug,
85 biological product or device for any harm done to such patient
86 resulting from the investigational drug, biological product or device.

87 Sec. 2. (NEW) (*Effective October 1, 2016*) (a) A manufacturer of an
88 investigational drug, biological product or device, as defined in section
89 1 of this act, may make available the manufacturer's investigational
90 drug, biological product or device to a patient who is eligible under
91 subsection (b) of section 1 of this act and may (1) provide the
92 investigational drug, biological product or device to such patient
93 without receiving compensation, or (2) require such patient to pay the
94 costs of, or associated with, the manufacture of the investigational
95 drug, biological product or device.

96 (b) Nothing in this section shall create a cause of action against a
97 manufacturer of an investigational drug, biological product or device
98 that makes available such investigational drug, biological product or
99 device to an eligible patient for any harm done to such patient
100 resulting from the investigational drug, biological product or device.

101 Sec. 3. (NEW) (*Effective October 1, 2016*) (a) As used in this section,
102 "health carrier" means an insurance company, health care center,
103 hospital service corporation, medical service corporation, fraternal
104 benefit society or other entity that delivers, issues for delivery, renews,
105 amends or continues a health insurance policy providing coverage of
106 the type provided in subdivisions (1), (2), (4), (11), (12) and (16) of
107 section 38a-469 of the general statutes in this state.

108 (b) A health carrier may provide coverage for an investigational
109 drug, biological product or device, as defined in section 1 of this act,

110 that is made available pursuant to section 2 of this act to an insured
111 patient who is eligible under subsection (b) of section 1 of this act.

112 (c) A health carrier may deny coverage to an insured patient from
113 the time such patient begins treatment with the investigational drug,
114 biological product or device for a period not to exceed six months from
115 the date such patient ceases treatment with the investigational drug,
116 biological product or device, except coverage may not be denied for a
117 preexisting condition or for coverage for benefits that commenced
118 prior to the date such patient begins such treatment.

119 (d) Nothing in this section shall affect the provisions of sections 38a-
120 504a to 38a-504g, inclusive, and 38a-542a to 38a-542g, inclusive, of the
121 general statutes concerning insurance coverage for certain costs
122 associated with clinical trials. Treatment with an investigational drug,
123 biological product or device is not considered a clinical trial for
124 purposes of said sections.

125 (e) Nothing in this section shall create a cause of action against a
126 health carrier that provides coverage for an investigational drug,
127 biological product or device pursuant to subsection (b) of this section
128 or denies coverage in accordance with subsection (c) of this section to
129 an insured patient who begins treatment with an investigational drug,
130 biological product or device.

This act shall take effect as follows and shall amend the following sections:		
Section 1	<i>October 1, 2016</i>	New section
Sec. 2	<i>October 1, 2016</i>	New section
Sec. 3	<i>October 1, 2016</i>	New section

Statement of Purpose:

To allow the use of investigational drugs, biological products or devices by patients with terminal conditions.

[Proposed deletions are enclosed in brackets. Proposed additions are indicated by underline, except that when the entire text of a bill or resolution or a section of a bill or resolution is new, it is not underlined.]