



General Assembly

January Session, 2015

Committee Bill No. 418

LCO No. 3557



Referred to Committee on INSURANCE AND REAL ESTATE

Introduced by:
(INS)

AN ACT CONCERNING OFF-LABEL PRESCRIPTION DRUGS.

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

1 Section 1. Section 38a-492b of the general statutes is repealed and
2 the following is substituted in lieu thereof (*Effective January 1, 2016*):

3 (a) (1) Each individual health insurance policy delivered, issued for
4 delivery, renewed, amended or continued in this state, that provides
5 coverage for [prescribed] prescription drugs approved by the federal
6 Food and Drug Administration for treatment of [certain types of
7 cancer or disabling or life-threatening chronic diseases] a covered
8 condition, shall not exclude coverage of any such drug on the basis
9 that such drug has been prescribed for the treatment of a [type of
10 cancer or a disabling or life-threatening chronic disease] covered
11 condition for which the drug has not been approved by the federal
12 Food and Drug Administration, provided the drug is recognized for
13 treatment of the specific [type of cancer or a disabling or life-
14 threatening chronic disease] covered condition for which the drug has
15 been prescribed in one of the following established reference
16 compendia or in peer-reviewed medical literature generally
17 recognized by the relevant medical community: [(1)] (A) The U.S.

18 Pharmacopoeia Drug Information Guide for the Health Care
19 Professional; [(USP DI); (2)] (B) The American Medical Association's
20 Drug Evaluations; [(AMA DE); or (3)] or (C) The American Society of
21 [Hospital] Health-System Pharmacists' American Hospital Formulary
22 Service Drug Information. [(AHFS-DI).] As used in this section, "peer-
23 reviewed medical literature" means a published study in a journal or
24 other publication in which original manuscripts have been critically
25 reviewed for scientific accuracy, validity and reliability by unbiased
26 international experts, and that has been determined by the
27 International Committee of Medical Journal Editors to have met its
28 Uniform Requirements for Manuscripts Submitted to Biomedical
29 Journals. "Peer-reviewed medical literature" does not include
30 publications or supplements to publications that are sponsored to a
31 significant extent by a pharmaceutical manufacturing company or any
32 health insurer, health care center, hospital service corporation, medical
33 service corporation or fraternal benefit society that delivers, issues for
34 delivery, renews, amends or continues a health insurance policy in this
35 state.

36 (2) The coverage required under subdivision (1) of this subsection
37 shall include medically necessary services associated with the
38 administration of such drug.

39 (3) A drug use covered under subdivision (1) of this subsection shall
40 not be denied based on medical necessity except for reasons that are
41 unrelated to the legal status of the drug use.

42 (b) Nothing in subsection (a) of this section shall be construed to
43 require coverage for (1) any [experimental or investigational drugs or]
44 drug used in a research trial sponsored by a drug manufacturer or a
45 government entity, (2) any drug or service furnished in a research trial
46 if the research trial sponsor furnishes the drug or service to an insured
47 participating in such trial without charge, or (3) any drug [which] that
48 the federal Food and Drug Administration has determined to be
49 contraindicated for treatment of the specific [type of cancer or
50 disabling or life-threatening chronic disease] covered condition for

51 which the drug has been prescribed.

52 [(c) Except as specified, nothing in this section shall be construed to
53 create, impair, limit or modify authority to provide reimbursement for
54 drugs used in the treatment of any other disease or condition.]

55 Sec. 2. Section 38a-518b of the general statutes is repealed and the
56 following is substituted in lieu thereof (*Effective January 1, 2016*):

57 (a) (1) Each group health insurance policy delivered, issued for
58 delivery, renewed, amended or continued in this state, that provides
59 coverage for [prescribed] prescription drugs approved by the federal
60 Food and Drug Administration for treatment of [certain types of
61 cancer or disabling or life-threatening chronic diseases] a covered
62 condition, shall not exclude coverage of any such drug on the basis
63 that such drug has been prescribed for the treatment of a [type of
64 cancer or a disabling or life-threatening chronic disease] covered
65 condition for which the drug has not been approved by the federal
66 Food and Drug Administration, provided the drug is recognized for
67 treatment of the specific [type of cancer or a disabling or life-
68 threatening chronic disease] covered condition for which the drug has
69 been prescribed in one of the following established reference
70 compendia or in peer-reviewed medical literature generally
71 recognized by the relevant medical community: [(1)] (A) The U.S.
72 Pharmacopoeia Drug Information Guide for the Health Care
73 Professional; [(USP DI); (2)] (B) The American Medical Association's
74 Drug Evaluations; [(AMA DE); or (3)] or (C) The American Society of
75 [Hospital] Health-System Pharmacists' American Hospital Formulary
76 Service Drug Information. [(AHFS-DI).] As used in this section, "peer-
77 reviewed medical literature" means a published study in a journal or
78 other publication in which original manuscripts have been critically
79 reviewed for scientific accuracy, validity and reliability by unbiased
80 international experts, and that has been determined by the
81 International Committee of Medical Journal Editors to have met its
82 Uniform Requirements for Manuscripts Submitted to Biomedical
83 Journals. "Peer-reviewed medical literature" does not include

84 publications or supplements to publications that are sponsored to a
 85 significant extent by a pharmaceutical manufacturing company or any
 86 health insurer, health care center, hospital service corporation, medical
 87 service corporation or fraternal benefit society that delivers, issues for
 88 delivery, renews, amends or continues a health insurance policy in this
 89 state.

90 (2) The coverage required under subdivision (1) of this subsection
 91 shall include medically necessary services associated with the
 92 administration of such drug.

93 (3) A drug use covered under subdivision (1) of this subsection shall
 94 not be denied based on medical necessity except for reasons that are
 95 unrelated to the legal status of the drug use.

96 (b) Nothing in subsection (a) of this section shall be construed to
 97 require coverage for (1) any [experimental or investigational drugs or]
 98 drug used in a research trial sponsored by a drug manufacturer or a
 99 government entity, (2) any drug or service furnished in a research trial
 100 if the research trial sponsor furnishes the drug or service to an insured
 101 participating in such trial without charge, or (3) any drug [which] that
 102 the federal Food and Drug Administration has determined to be
 103 contraindicated for treatment of the specific [type of cancer or a
 104 disabling or life-threatening chronic disease] covered condition for
 105 which the drug has been prescribed.

106 [(c) Except as specified, nothing in this section shall be construed to
 107 create, impair, limit or modify authority to provide reimbursement for
 108 drugs used in the treatment of any other disease or condition.]

This act shall take effect as follows and shall amend the following sections:		
Section 1	January 1, 2016	38a-492b
Sec. 2	January 1, 2016	38a-518b

INS *Joint Favorable*