



General Assembly

Amendment

January Session, 2015

LCO No. 8266



Offered by:

SEN. LOONEY, 11th Dist.

SEN. CRISCO, 17th Dist.

REP. MEGNA, 97th Dist.

To: Subst. Senate Bill No. 418

File No. 869

Cal. No. 191

"AN ACT CONCERNING OFF-LABEL PRESCRIPTION DRUGS."

1 Strike everything after the enacting clause and substitute the
2 following in lieu thereof:

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 Section 38a-492b of the general statutes is repealed and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

5 (a) (1) Each individual health insurance policy delivered, issued for
6 delivery, renewed, amended or continued in this state, that provides
7 coverage for [prescribed] prescription drugs approved by the federal
8 Food and Drug Administration for treatment of [certain types of
9 cancer or disabling or life-threatening chronic diseases] a covered
10 condition, shall not exclude coverage of any such drug on the basis
11 that such drug has been prescribed for the treatment of a [type of
12 cancer or a disabling or life-threatening chronic disease] covered
13 condition for which the drug has not been approved by the federal

14 Food and Drug Administration, provided the drug is recognized for
15 treatment of the specific [type of cancer or a disabling or life-
16 threatening chronic disease] covered condition for which the drug has
17 been prescribed in one of the following established reference
18 compendia or in peer-reviewed medical literature generally
19 recognized by the relevant medical community: [(1)] (A) The U.S.
20 Pharmacopoeia Drug Information Guide for the Health Care
21 Professional; [(USP DI); (2)] (B) The American Medical Association's
22 Drug Evaluations; [(AMA DE); or (3)] or (C) The American Society of
23 [Hospital] Health-System Pharmacists' American Hospital Formulary
24 Service Drug Information. [(AHFS-DI).] As used in this section, "peer-
25 reviewed medical literature" means a published study in a journal or
26 other publication in which original manuscripts have been critically
27 reviewed for scientific accuracy, validity and reliability by unbiased
28 international experts, and that has been determined by the
29 International Committee of Medical Journal Editors to have met its
30 Uniform Requirements for Manuscripts Submitted to Biomedical
31 Journals. "Peer-reviewed medical literature" does not include
32 publications or supplements to publications that are sponsored to a
33 significant extent by a pharmaceutical manufacturing company or any
34 health insurer, health care center, hospital service corporation, medical
35 service corporation or fraternal benefit society that delivers, issues for
36 delivery, renews, amends or continues a health insurance policy in this
37 state.

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

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

44 (b) Nothing in subsection (a) of this section shall be construed to
45 require coverage for (1) any [experimental or investigational drugs or]
46 drug used in a research trial sponsored by a drug manufacturer or a

47 government entity, (2) any drug or service furnished in a research trial
48 if the research trial sponsor furnishes the drug or service to an insured
49 participating in such trial without charge, or (3) any drug [which] that
50 the federal Food and Drug Administration has determined to be
51 contraindicated for treatment of the specific [type of cancer or
52 disabling or life-threatening chronic disease] covered condition for
53 which the drug has been prescribed.

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

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

59 (a) (1) Each group health insurance policy delivered, issued for
60 delivery, renewed, amended or continued in this state, that provides
61 coverage for [prescribed] prescription drugs approved by the federal
62 Food and Drug Administration for treatment of [certain types of
63 cancer or disabling or life-threatening chronic diseases] a covered
64 condition, shall not exclude coverage of any such drug on the basis
65 that such drug has been prescribed for the treatment of a [type of
66 cancer or a disabling or life-threatening chronic disease] covered
67 condition for which the drug has not been approved by the federal
68 Food and Drug Administration, provided the drug is recognized for
69 treatment of the specific [type of cancer or a disabling or life-
70 threatening chronic disease] covered condition for which the drug has
71 been prescribed in one of the following established reference
72 compendia or in peer-reviewed medical literature generally
73 recognized by the relevant medical community: [(1)] (A) The U.S.
74 Pharmacopoeia Drug Information Guide for the Health Care
75 Professional; [(USP DI); (2)] (B) The American Medical Association's
76 Drug Evaluations; [(AMA DE); or (3)] or (C) The American Society of
77 [Hospital] Health-System Pharmacists' American Hospital Formulary
78 Service Drug Information. [(AHFS-DI).] As used in this section, "peer-
79 reviewed medical literature" means a published study in a journal or

80 other publication in which original manuscripts have been critically
81 reviewed for scientific accuracy, validity and reliability by unbiased
82 international experts, and that has been determined by the
83 International Committee of Medical Journal Editors to have met its
84 Uniform Requirements for Manuscripts Submitted to Biomedical
85 Journals. "Peer-reviewed medical literature" does not include
86 publications or supplements to publications that are sponsored to a
87 significant extent by a pharmaceutical manufacturing company or any
88 health insurer, health care center, hospital service corporation, medical
89 service corporation or fraternal benefit society that delivers, issues for
90 delivery, renews, amends or continues a health insurance policy in this
91 state.

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

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

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

108 [(c) Except as specified, nothing in this section shall be construed to
109 create, impair, limit or modify authority to provide reimbursement for
110 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