



General Assembly

Substitute Bill No. 418

January Session, 2015



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 Section 38a-492b of the general statutes is repealed and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 cancer
7 or disabling or life-threatening chronic diseases, shall not exclude
8 coverage of any such drug on the basis that such drug has been
9 prescribed for the treatment of a type of cancer or a disabling or life-
10 threatening chronic disease for which the drug has not been approved
11 by the federal Food and Drug Administration, provided the drug is
12 recognized for treatment of the specific type of cancer or a disabling or
13 life-threatening chronic disease for which the drug has been prescribed
14 in one of the following established reference compendia or in peer-
15 reviewed medical literature generally recognized by the relevant
16 medical community: [(1)] (A) The U.S. Pharmacopoeia Drug
17 Information Guide for the Health Care Professional; [(USP DI); (2)] (B)
18 The American Medical Association's Drug Evaluations; [(AMA DE); or
19 (3)] or (C) The American Society of [Hospital] Health-System
20 Pharmacists' American Hospital Formulary Service Drug Information.

21 [(AHFS-DI.)] As used in this section, "peer-reviewed medical
22 literature" means a published study in a journal or other publication in
23 which original manuscripts have been critically reviewed for scientific
24 accuracy, validity and reliability by unbiased international experts,
25 and that has been determined by the International Committee of
26 Medical Journal Editors to have met its Uniform Requirements for
27 Manuscripts Submitted to Biomedical Journals. "Peer-reviewed
28 medical literature" does not include publications or supplements to
29 publications that are sponsored to a significant extent by a
30 pharmaceutical manufacturing company or any health insurer, health
31 care center, hospital service corporation, medical service corporation
32 or fraternal benefit society that delivers, issues for delivery, renews,
33 amends or continues a health insurance policy in this state.

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

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

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

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

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

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

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

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

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

102 (c) Except as specified, nothing in this section shall be construed to
103 create, impair, limit or modify authority to provide reimbursement for
104 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

APP *Joint Favorable Subst.*