



# Senate

General Assembly

**File No. 869**

January Session, 2015

Substitute Senate Bill No. 418

*Senate, May 20, 2015*

The Committee on Appropriations reported through SEN. BYE of the 5th Dist., Chairperson of the Committee on the part of the Senate, that the substitute bill ought to pass.

## ***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 Section 38a-492b of the general statutes is repealed and  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.*

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:**

Agency Affected	Fund-Effect	FY 16 \$	FY 17 \$
State Comptroller - Fringe Benefits (State Employee and Retiree Health accounts)	GF, TF - Potential Cost	See Below	See Below
The State	Potential Cost	See Below	See Below

Note: GF=General Fund; TF = Transportation Fund

**Municipal Impact:**

Municipalities	Effect	FY 16 \$	FY 17 \$
Various Municipalities	Potential Cost	See Below	See Below

**Explanation**

The bill is not anticipated to result in a cost to the state employee health plan or fully insured municipalities. The bill (1) expands the list of sources in which an off-label drug may be recognized as treatment for such conditions already covered under current law, (2) requires coverage for medically necessary services associated with the administration of drugs for conditions and prescriptions already covered under current law, (3) prohibits the denial of coverage based on medical necessity for reasons unrelated to the legal status of the drug used, and (4) establishes the types of research trial drugs that are exempt from coverage under the bill.

However, it is unclear if the bill's provision requiring coverage for medically necessary services associated with the administration of drugs already required to be covered under current law is a new mandate interpreted to require coverage of new services or a codification of current practice. If the bill is interpreted as a new

mandate and requires additional services to be covered there is a potential cost to the state employee and retiree health plans, fully insured municipal plans, and the state pursuant to the federal Affordable Care Act (ACA).<sup>1</sup> The potential cost to the state and municipalities will depend on whether or not the bill is considered a new mandate under the ACA and which, if any, additional services are required to be covered.

### **Municipal Impact**

As previously stated, the bill may result in a potential cost to certain fully insured, municipal plans if the bill is interpreted to require coverage for additional prescription administration services. The coverage requirements may result in increased premium costs when municipalities enter into new health insurance contracts after January 1, 2016. In addition, many municipal health plans are recognized as “grandfathered” health plans under the ACA.<sup>2</sup> It is unclear what effect the adoption of certain health mandates will have on the grandfathered status of certain municipal plans under ACA. Pursuant to federal law, self-insured health plans are exempt from state health mandates.

### **The State and the federal ACA**

Lastly, the ACA requires that, the state’s health exchange’s qualified health plans (QHPs)<sup>3</sup>, include a federally defined essential health benefits package (EHB). The federal government is allowing states to choose a benchmark plan<sup>4</sup> to serve as the EHB until 2016 when the

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<sup>1</sup> The state employee and retiree health plan is a self-insured health plan. Pursuant to federal law, self-insured health plans are exempt from state health mandates. However, the state has traditionally adopted all state health mandates.

<sup>2</sup> Grandfathered plans include most group insurance plans and some individual health plans created or purchased on or before March 23, 2010.

<sup>3</sup> The state’s health exchange, Access Health CT, opened its marketplace for Connecticut residents to purchase QHPs from carriers, with coverage starting January 1, 2014.

<sup>4</sup> The state’s benchmark plan is the Connecticare HMO plan with supplemental coverage for pediatric dental and vision care as required by the ACA.

federal government is anticipated to revisit the EHB.

While states are allowed to mandate benefits in excess of the EHB, the federal law requires the state to defray the cost of any such additional mandated benefits for all plans sold in the exchange, by reimbursing the carrier or the insured for the excess coverage. State mandated benefits enacted after December 31, 2011 cannot be considered part of the EHB for 2014-2015 unless they are already part of the benchmark plan.<sup>5</sup> However, neither the agency nor the mechanism for the state to pay these costs has been established.

### ***The Out Years***

The annualized ongoing fiscal impact identified above would continue into the future subject to inflation.

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<sup>5</sup> Source: Dept. of Health and Human Services. *Frequently Asked Questions on Essential Health Benefits Bulletin* (February 21, 2012).

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**OLR Bill Analysis****sSB 418****AN ACT CONCERNING OFF-LABEL PRESCRIPTION DRUGS.****SUMMARY:**

This bill expands coverage under certain health insurance policies for off-label use of U.S. Food and Drug Administration (FDA) – approved drugs. A drug is used “off-label,” when it is prescribed to treat a condition other than one for which it has been approved by the FDA.

It expands coverage by:

1. expanding the list of sources that recognize an off-label drug for treatment of a condition to include peer reviewed medical literature;
2. requiring coverage for medically necessary services associated with the administration of such a drug; and
3. prohibiting denial of coverage based on medical necessity, except for reasons unrelated to the legal status of the drug.

It also exempts certain types of research trial drugs from the required coverage.

It also makes conforming and technical changes.

The bill applies to individual and group health insurance policies delivered, issued, renewed, amended, or continued in Connecticut.

EFFECTIVE DATE: January 1, 2016

**SOURCES FOR TREATMENT WITH OFF-LABEL DRUGS**

Under existing law, health insurance policies that cover a

prescription drug FDA-approved to treat a certain type of cancer or disabling or life-threatening chronic disease must also cover the drug when it is used to treat another type of cancer or disabling or life-threatening chronic disease if it is recognized as treatment for such a condition in the:

1. U.S. Pharmacopoeia Drug Information Guide for the Health Care Professional,
2. American Medical Association's Drug Evaluations, or
3. American Society of Health-System Pharmacists' American Hospital Formulary Service Drug Information.

The bill adds a fourth source: peer reviewed medical literature generally recognized by the relevant medical community.

#### ***Peer Reviewed Medical Literature***

Under the bill, "peer-reviewed medical literature" is a published study in a journal or other publication (1) in which manuscripts are critically reviewed for scientific accuracy, validity, and reliability by unbiased medical experts and (2) that the International Committee of Medical Journal Editors has determined meets the Uniform Requirements for Manuscripts Submitted to Biomedical Journals. It does not include publications or supplements sponsored to a significant extent by a (1) pharmaceutical manufacturing company or (2) health insurer, health care center, hospital service corporation, medical service corporation, or fraternal benefit society that issues, delivers, renews, amends, or continues a health insurance policy in Connecticut.

#### **COVERAGE EXCEPTIONS FOR RESEARCH TRIAL DRUGS**

Under current law, coverage is not required for experimental or investigational drugs. The bill specifies that coverage is not required for (1) any drug used in a research trial sponsored by a drug manufacturer or a government entity and (2) a drug or service furnished by a research trial's sponsor at no cost to an insured

participating in the trial. By law, coverage is not required for any drug the FDA has determined contraindicated for the treatment of a given condition.

**BACKGROUND**

***Related Federal Law***

Under the federal Patient Protection and Affordable Care Act (P.L. 111-148), a state may require health plans sold through the state’s health insurance exchange to offer benefits beyond those included in the required “essential health benefits,” provided the state defrays the cost of these additional benefits. The requirement applies to benefit mandates a state enacts after December 31, 2011. Thus, the state must pay the insurance carrier or enrollee to defray the cost of any new benefits mandated after that date.

***Legislative History***

The Senate referred the bill (File 248) to the Appropriations Committee, which favorably reported a substitute removing provisions requiring certain health insurance policies to cover the off-label use of FDA-approved drugs to treat any covered condition.

**COMMITTEE ACTION**

Insurance and Real Estate Committee

Joint Favorable

Yea 15 Nay 4 (03/12/2015)

Appropriations Committee

Joint Favorable Substitute

Yea 54 Nay 1 (05/11/2015)