



# Senate

General Assembly

**File No. 248**

January Session, 2015

Senate Bill No. 418

*Senate, March 26, 2015*

The Committee on Insurance and Real Estate reported through SEN. CRISCO of the 17th Dist., Chairperson of the Committee on the part of the Senate, that the 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 Section 38a-492b of the general statutes is repealed and  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  
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*

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 - Cost	See Below	See Below
The State	Indeterminate - Cost	See Below	See Below

GF & TF = General Fund and Special Transportation Fund

**Municipal Impact:**

Municipalities	Effect	FY 16 \$	FY 17 \$
Various Municipalities	STATE MANDATE - Cost	See Below	See Below

**Explanation**

The bill will result in a cost to the state employee and retiree health plan<sup>1</sup>, municipalities, and the state pursuant to the federal Affordable Care Act (see below). The cost is the result of expanding coverage for off-label drug use<sup>2</sup> to include treatment for any covered condition as well as any medically necessary services for the administration of the drug. The cost to the state and fully insured municipal plans will depend on (1) the specific drugs prescribed and (2) related prescription administration services which are not currently covered. The state employee and retiree health plan's prescription program is approximately \$300 million annually.

<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> "Off-label" refers to a drug prescribed for a condition for which the FDA has not approved it to treat.

The state plans, as well as fully insured municipal plans, do not currently provide coverage for experimental/investigational treatments or off label drugs except for use for individuals with cancer and other disabling or life-threatening chronic disease in accordance with current law.

Lastly, if “prescription drugs approved by the FDA” is interpreted to require coverage for any FDA approved drug for any condition, irrespective of method of administration or to the extent the drug is administered in combination with another drug, this may increase the state and municipal plans’ costs associated with compound drugs. Compound drugs are drugs whose component medications/ingredients have been approved by the FDA for certain conditions, however (1) the method by which the compound drug is being administered and/or (2) the combinations included therein have not been approved by the FDA. In 2014, the state plan spent approximately \$25 million on compound drugs.

### **Municipal Impact**

As previously stated, the bill may increase costs to certain fully insured municipal plans that do not currently provide the prescription coverage required by the bill. 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>3</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

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<sup>3</sup> Grandfathered plans include most group insurance plans and some individual health plans created or purchased on or before March 23, 2010.

health plans (QHPs)<sup>4</sup>, include a federally defined essential health benefits package (EHB). The federal government is allowing states to choose a benchmark plan<sup>5</sup> to serve as the EHB until 2016 when the 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>6</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>4</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>5</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.

<sup>6</sup> Source: Dept. of Health and Human Services. *Frequently Asked Questions on Essential Health Benefits Bulletin* (February 21, 2012).

**OLR Bill Analysis****SB 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 the FDA has not approved it to treat.

The bill:

1. expands the required coverage for off-label drug use to include the treatment of any covered condition;
2. expands the list of sources in which an off-label drug is recognized as treatment for such condition;
3. requires coverage for medically necessary services associated with the administration of such drug;
4. prohibits denial of coverage based on medical necessity, except for reasons unrelated to the legal status of the drug use; and
5. establishes the types of research trial drugs exempt 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

**OFF-LABEL DRUG USE**

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 in a specified source as a treatment for such a condition. The bill requires coverage for off-label drug use in the treatment of a covered condition, instead of only cancer or a disabling or life-threatening chronic disease.

### **RECOGNIZED SOURCES**

Under current law, the drug must be recognized in any of the following three sources as treatment for the condition for which it was prescribed:

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, namely, 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 free 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 those 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.

## **COMMITTEE ACTION**

Insurance and Real Estate Committee

Joint Favorable

Yea 15    Nay 4    (03/12/2015)