



Senate

General Assembly

File No. 46

January Session, 2009

Substitute Senate Bill No. 299

Senate, March 9, 2009

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 substitute bill ought to pass.

***AN ACT EXPANDING HEALTH INSURANCE COVERAGE FOR
ROUTINE PATIENT CARE COSTS FOR CLINICAL TRIAL PATIENTS.***

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

1 Section 1. (NEW) (*Effective January 1, 2010*) Each individual health
2 insurance policy providing coverage of the type specified in
3 subdivisions (1), (2), (4), (11) and (12) of section 38a-469 of the general
4 statutes delivered, issued for delivery, renewed, amended or
5 continued in this state shall provide coverage for the routine patient
6 care costs associated with clinical trials for the treatment of serious or
7 life-threatening diseases. As used in this section, (1) "clinical trial for
8 the treatment of serious or life-threatening diseases" means an
9 organized, systematic, scientific study of therapies, tests or other
10 clinical interventions for purposes of treatment or palliation or
11 therapeutic intervention for the prevention of serious or life-
12 threatening diseases in human beings, other than a cancer clinical trial
13 in accordance with sections 38a-504a to 38a-504g, inclusive, of the
14 general statutes, and (2) "routine patient care costs" means (A)

15 coverage for medically necessary health care services that are incurred
16 as a result of the treatment being provided to the insured person for
17 purposes of such clinical trial that would otherwise be covered if such
18 services were not rendered pursuant to such clinical trial. Such services
19 shall include those rendered by a physician, diagnostic or laboratory
20 tests, hospitalization or other services provided to the patient during
21 the course of treatment in such clinical trial for a condition, or one of
22 its complications, that are consistent with the usual and customary
23 standard of care and would be covered if the insured person were not
24 enrolled in such clinical trial; and (B) coverage for routine patient care
25 costs incurred for drugs provided to the insured person, in accordance
26 with section 38a-492b of the general statutes, as amended by this act,
27 provided such drugs have been approved for sale by the federal Food
28 and Drug Administration.

29 Sec. 2. (NEW) (*Effective January 1, 2010*) Each group health insurance
30 policy providing coverage of the type specified in subdivisions (1), (2),
31 (4), (11) and (12) of section 38a-469 of the general statutes delivered,
32 issued for delivery, renewed, amended or continued in this state shall
33 provide coverage for the routine patient care costs associated with
34 clinical trials for the treatment of serious or life-threatening diseases.
35 As used in this section, (1) "clinical trial for the treatment of serious or
36 life-threatening diseases" means an organized, systematic, scientific
37 study of therapies, tests or other clinical interventions for purposes of
38 treatment or palliation or therapeutic intervention for the prevention
39 of serious or life-threatening diseases in human beings, other than a
40 cancer clinical trial in accordance with sections 38a-542a to 38a-542g,
41 inclusive, of the general statutes, and (2) "routine patient care costs"
42 means (A) coverage for medically necessary health care services that
43 are incurred as a result of the treatment being provided to the insured
44 person for purposes of such clinical trial that would otherwise be
45 covered if such services were not rendered pursuant to such clinical
46 trial. Such services shall include those rendered by a physician,
47 diagnostic or laboratory tests, hospitalization or other services
48 provided to the patient during the course of treatment in such clinical
49 trial for a condition, or one of its complications, that are consistent with

50 the usual and customary standard of care and would be covered if the
51 insured person were not enrolled in such clinical trial; and (B)
52 coverage for routine patient care costs incurred for drugs provided to
53 the insured person, in accordance with section 38a-518b of the general
54 statutes, as amended by this act, provided such drugs have been
55 approved for sale by the federal Food and Drug Administration.

56 Sec. 3. Section 38a-492b of the general statutes is repealed and the
57 following is substituted in lieu thereof (*Effective January 1, 2010*):

58 (a) Each individual health insurance policy delivered, issued for
59 delivery, [or] renewed, amended or continued in this state [on or after
60 October 1, 1994, which] that provides coverage for prescribed drugs
61 approved by the federal Food and Drug Administration for treatment
62 of certain types of cancer shall not exclude coverage of any such drug
63 on the basis that such drug has been prescribed for the treatment of a
64 type of cancer for which the drug has not been approved by the federal
65 Food and Drug Administration, provided the drug is recognized for
66 treatment of the specific type of cancer for which the drug has been
67 prescribed in one of the following established reference compendia: (1)
68 The U.S. Pharmacopoeia Drug Information Guide for the Health Care
69 Professional (USP DI); (2) The American Medical Association's Drug
70 Evaluations (AMA DE); or (3) The American Society of Hospital
71 Pharmacists' American Hospital Formulary Service Drug Information
72 (AHFS-DI).

73 (b) Nothing in subsection (a) of this section shall be construed to
74 require coverage for any experimental or investigational drugs or any
75 drug which the federal Food and Drug Administration has determined
76 to be contraindicated for treatment of the specific type of cancer for
77 which the drug has been prescribed.

78 (c) [Nothing] Except as provided in section 1 of this act, nothing in
79 this section shall be construed to create, impair, limit or modify
80 authority to provide reimbursement for drugs used in the treatment of
81 any other disease or condition.

82 Sec. 4. Section 38a-518b of the general statutes is repealed and the
83 following is substituted in lieu thereof (*Effective January 1, 2010*):

84 (a) Each group health insurance policy delivered, issued for
85 delivery, [or] renewed, amended or continued in this state [on or after
86 October 1, 1994, which] that provides coverage for prescribed drugs
87 approved by the federal Food and Drug Administration for treatment
88 of certain types of cancer shall not exclude coverage of any such drug
89 on the basis that such drug has been prescribed for the treatment of a
90 type of cancer for which the drug has not been approved by the federal
91 Food and Drug Administration, provided the drug is recognized for
92 treatment of the specific type of cancer for which the drug has been
93 prescribed in one of the following established reference compendia: (1)
94 The U.S. Pharmacopoeia Drug Information Guide for the Health Care
95 Professional (USP DI); (2) The American Medical Association's Drug
96 Evaluations (AMA DE); or (3) The American Society of Hospital
97 Pharmacists' American Hospital Formulary Service Drug Information
98 (AHFS-DI).

99 (b) Nothing in subsection (a) of this section shall be construed to
100 require coverage for any experimental or investigational drugs or any
101 drug which the federal Food and Drug Administration has determined
102 to be contraindicated for treatment of the specific type of cancer for
103 which the drug has been prescribed.

104 (c) [Nothing] Except as provided in section 2 of this act, nothing in
105 this section shall be construed to create, impair, limit or modify
106 authority to provide reimbursement for drugs used in the treatment of
107 any other disease or condition.

This act shall take effect as follows and shall amend the following sections:		
Section 1	<i>January 1, 2010</i>	New section
Sec. 2	<i>January 1, 2010</i>	New section
Sec. 3	<i>January 1, 2010</i>	38a-492b
Sec. 4	<i>January 1, 2010</i>	38a-518b

Statement of Legislative Commissioners:

In sections 1 and 2, the comma after "cancer clinical trial" was moved to after "human beings" for statutory consistency.

INS *Joint Favorable Subst.-LCO*

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: None in FY 10 & FY 11; See Below for Out Year Impact

Municipal Impact:

Municipalities	Effect	FY 10 \$	FY 11 \$
Various Municipalities	STATE MANDATE - Cost	Potential	Potential

Explanation

The bill requires certain individual and group health insurance policies to cover routine patient care costs associated with or resulting from clinical trials for the treatment of serious or life-threatening diseases. The bill applies to individual and group medical plans and policies delivered, issued or renewed after January 1, 2010 that offer coverage for expenses including basic hospital, basic medical-surgical, major-medical; and hospital and medical.

According to the state's employees and retiree health plans subscriber agreement, services associated with or as follow-up to use of any experimental or investigational treatment are not covered, unless approved by the plan provider on a case-by-case basis. As it is not possible to determine which routine services may or may not be authorized in each case, the fiscal impact to the state cannot be determined. Any incurred cost as a result of this mandate would not be effective until the policy is renewed on July 1, 2011.

To the extent that municipalities do not provide coverage for routine care for insured participants in clinical trials, there may be

increased costs to provide it. The bill's impact on municipalities depends on how many municipalities provide this coverage and that cannot be determined at this time. The coverage requirements effective January 1, 2010 may result in increased premium costs when municipalities enter into new contracts for health insurance. Due to federal law, municipalities with self-insured health plans are exempt from state health insurance benefit mandates.

The Out Years

As previously noted, the future fiscal impact to the state cannot be determined as it is not possible to assess which routine services may or may not be authorized under current plan provisions. Those mandated services not being covered will result in a cost to the state health plan upon plan renewal in FY 12. The annualized ongoing fiscal impact identified above would continue into the future subject to inflation.

Sources: Office of the State Comptroller, State Employee Health Plan Subscriber Agreement, Municipal Employees Health Insurance Plan (MEHIP) Schedule of Benefits.

OLR Bill Analysis**sSB 299*****AN ACT EXPANDING HEALTH INSURANCE COVERAGE FOR ROUTINE PATIENT CARE COSTS FOR CLINICAL TRIAL PATIENTS.*****SUMMARY:**

This bill requires certain health insurance policies to cover routine patient care costs incurred while a patient was participating in a clinical trial treating serious or life-threatening diseases. (The bill does not specify payment criteria for the clinical trials, other than to require coverage.)

It applies the law that requires insurance coverage for certain off-label cancer drugs under insurance policies delivered, issued, or renewed in Connecticut to policies amended or continued here.

The bill also makes technical and conforming changes.

EFFECTIVE DATE: January 1, 2010

DEFINITIONS***Routine Patient Care Costs***

The bill defines “routine patient care costs” as medically necessary services resulting from the patient’s treatment during the clinical trial that the policy would cover if the person were not in the trial. These include physicians’ services, diagnostic and laboratory tests, hospitalization, and other services rendered for a patient’s condition, or a complication related to it, that are consistent with the usual and customary standard of care. The covered costs also include those for off-label cancer drugs, in accordance with law.

Clinical Trial to Treat Serious or Life-Threatening Diseases

Under the bill, a “clinical trial for treating serious or life-threatening diseases” is an organized, systematic, scientific study of interventions to treat, palliate, or prevent a serious or life-threatening disease. It excludes certain clinical trials for treating cancer, the costs of which policies must cover pursuant to a separate law (see BACKGROUND). But it apparently includes cancer clinical trials not otherwise covered under that law, including Phase I and Phase II clinical trial for cancer prevention.

APPLICABILITY

The bill applies the serious or life-threatening disease clinical trial coverage requirement to individual and group health insurance policies delivered, issued, renewed, amended, or continued in Connecticut that cover (1) basic hospital expenses; (2) basic medical-surgical expenses; (3) major medical expenses; and (4) hospital or medical services, including coverage under an HMO plan.

Due to federal law (ERISA), state insurance benefit mandates do not apply to self-insured benefit plans.

BACKGROUND

Cancer Clinical Trial Coverage

The law requires insurance coverage for routine patient care costs incurred during certain cancer clinical trials. It defines a “cancer clinical trial” as an organized, systematic, scientific study of interventions for cancer (1) treatment or palliation or (2) prevention. If the trial is for cancer prevention, it must be a Phase III trial conducted at multiple institutions. (Phase III clinical trials compare a new drug or surgical procedure to the current standard of treatment.)

The law applies to trials conducted under an independent, peer-reviewed protocol approved by (1) one of the National Institutes of Health, (2) a National Cancer Institute-affiliated cooperative group, (3) the Food and Drug Administration as part of an investigational new drug or device exemption, or (4) the U. S. Departments of Defense or Veterans' Affairs.

The law specifies requirements for patient eligibility, provider billing and payments, and coverage application forms. It also defines routine patient care costs for cancer clinical trials, including specific exclusions.

Off-Label Cancer Drugs

An off-label cancer drug is an FDA-approved (Food and Drug Administration) drug that is prescribed or used to treat a type of cancer other than the one for which it was approved.

The law requires insurance coverage for off-label cancer drugs, except those that are (1) experimental or investigational (2) or that the FDA has determined to be contraindicated for the cancer for which it was prescribed.

For a policy to cover the drug, one of three publications—(1) U.S. Pharmacopeia Drug Information Guide for the Health Care Professional, (2) American Medical Association’s Drug Evaluations, or (3) American Society of Hospital Pharmacist’s American Hospital Formulary Service Drug Information—must recognize it as a treatment for the cancer for which it was prescribed.

Medically Necessary

The law defines “medically necessary” as health care services that a physician, exercising prudent clinical judgment, would provide to a patient to prevent, evaluate, diagnose, or treat an illness, injury, disease, or its symptoms, and that are:

1. in accordance with generally accepted standards of medical practice;
2. clinically appropriate, in terms of type, frequency, extent, site, and duration and considered effective for the patient’s illness, injury, or disease;
3. not primarily for the convenience of the patient, physician, or other health care provider; and

4. not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results.

“Generally accepted standards of medical practice” means standards that are (1) based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community or (2) otherwise consistent with the standards set forth in policy issues involving clinical judgment.

COMMITTEE ACTION

Insurance and Real Estate Committee

Joint Favorable

Yea 11 Nay 8 (02/19/2009)