



Senate

File No. 792

General Assembly

January Session, 2007

(Reprint of File No. 215)

Substitute Senate Bill No. 389
As Amended by Senate Amendment Schedule
"A" and House Amendment Schedule "A"

Approved by the Legislative Commissioner
May 7, 2007

**AN ACT CONCERNING HOSPITALIZATION AT AN OUT-OF-
NETWORK FACILITY DURING TREATMENT IN CANCER CLINICAL
TRIALS.**

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

1 Section 1. Section 38a-504d of the general statutes is repealed and
2 the following is substituted in lieu thereof (*Effective from passage*):

3 (a) For purposes of sections 38a-504a to 38a-504g, inclusive, "routine
4 patient care costs" means: (1) Coverage for medically necessary health
5 care services that are incurred as a result of the treatment being
6 provided to the insured person for purposes of the cancer clinical trial
7 that would otherwise be covered if such services were not rendered
8 pursuant to a cancer clinical trial. Such services shall include those
9 rendered by a physician, diagnostic or laboratory tests, hospitalization
10 or other services provided to the patient during the course of treatment
11 in the cancer clinical trial for a condition, or one of its complications,
12 that is consistent with the usual and customary standard of care and
13 would be covered if the insured person were not enrolled in a cancer
14 clinical trial. Such hospitalization shall include treatment at an out-of-

15 network facility if such treatment is not available in-network and not
16 eligible for reimbursement by the sponsors of such clinical trial; and (2)
17 coverage for routine patient care costs incurred for drugs provided to
18 the insured person, in accordance with section 38a-518b, provided
19 such drugs have been approved for sale by the federal Food and Drug
20 Administration.

21 (b) Routine patient care costs shall be subject to the terms,
22 conditions, restrictions, exclusions and limitations of the contract or
23 certificate of insurance between the subscriber and the insurer or
24 health plan, including limitations on out-of-network care, except that
25 treatment at an out-of-network hospital as provided in subdivision (1)
26 of subsection (a) of this section shall be made available by the out-of-
27 network hospital and the insurer or health care center at no greater
28 cost to the insured person than if such treatment was available in-
29 network. The insurer or health care center may require that any
30 routine tests or services required under the cancer clinical trial protocol
31 be performed by providers or institutions under contract with the
32 insurer or health care center.

33 (c) Notwithstanding the provisions of subsection (a) of this section,
34 routine patient care costs shall not include: (1) The cost of an
35 investigational new drug or device that has not been approved for
36 market for any indication by the federal Food and Drug
37 Administration; (2) the cost of a non-health-care service that an insured
38 person may be required to receive as a result of the treatment being
39 provided for the purposes of the cancer clinical trial; (3) facility,
40 ancillary, professional services and drug costs that are paid for by
41 grants or funding for the cancer clinical trial; (4) costs of services that
42 (A) are inconsistent with widely accepted and established regional or
43 national standards of care for a particular diagnosis, or (B) are
44 performed specifically to meet the requirements of the cancer clinical
45 trial; (5) costs that would not be covered under the insured person's
46 policy for noninvestigational treatments, including, but not limited to,
47 items excluded from coverage under the insured person's contract
48 with the insurer or health plan; and (6) transportation, lodging, food or

49 any other expenses associated with travel to or from a facility
50 providing the cancer clinical trial, for the insured person or any family
51 member or companion.

52 Sec. 2. Section 38a-542d of the general statutes is repealed and the
53 following is substituted in lieu thereof (*Effective from passage*):

54 (a) For purposes of sections 38a-542a to 38a-542g, inclusive, "routine
55 patient care costs" means: (1) Coverage for medically necessary health
56 care services that are incurred as a result of the treatment being
57 provided to the insured person for purposes of the cancer clinical trial
58 that would otherwise be covered if such services were not rendered
59 pursuant to a cancer clinical trial. Such services shall include those
60 rendered by a physician, diagnostic or laboratory tests, hospitalization
61 or other services provided to the patient during the course of treatment
62 in the cancer clinical trial for a condition, or one of its complications,
63 that is consistent with the usual and customary standard of care and
64 would be covered if the insured person were not enrolled in a cancer
65 clinical trial. Such hospitalization shall include treatment at an out-of-
66 network facility if such treatment is not available in-network and not
67 eligible for reimbursement by the sponsors of such clinical trial; and (2)
68 coverage for routine patient care costs incurred for drugs provided to
69 the insured person, in accordance with section 38a-518b, provided
70 such drugs have been approved for sale by the federal Food and Drug
71 Administration.

72 (b) Routine patient care costs shall be subject to the terms,
73 conditions, restrictions, exclusions and limitations of the contract or
74 certificate of insurance between the subscriber and the insurer or
75 health plan, including limitations on out-of-network care, except that
76 treatment at an out-of-network hospital as provided in subdivision (1)
77 of subsection (a) of this section shall be made available by the out-of-
78 network hospital and the insurer or health care center at no greater
79 cost to the insured person than if such treatment was available in-
80 network. The insurer or health care center may require that any
81 routine tests or services required under the cancer clinical trial protocol

82 be performed by providers or institutions under contract with the
83 insurer or health care center.

84 (c) Notwithstanding the provisions of subsection (a) of this section,
85 routine patient care costs shall not include: (1) The cost of an
86 investigational new drug or device that has not been approved for
87 market for any indication by the federal Food and Drug
88 Administration; (2) the cost of a non-health-care service that an insured
89 person may be required to receive as a result of the treatment being
90 provided for the purposes of the cancer clinical trial; (3) facility,
91 ancillary, professional services and drug costs that are paid for by
92 grants or funding for the cancer clinical trial; (4) costs of services that
93 (A) are inconsistent with widely accepted and established regional or
94 national standards of care for a particular diagnosis, or (B) are
95 performed specifically to meet the requirements of the cancer clinical
96 trial; (5) costs that would not be covered under the insured person's
97 policy for noninvestigational treatments, including, but not limited to,
98 items excluded from coverage under the insured person's contract
99 with the insurer or health plan; and (6) transportation, lodging, food or
100 any other expenses associated with travel to or from a facility
101 providing the cancer clinical trial, for the insured person or any family
102 member or companion.

This act shall take effect as follows and shall amend the following sections:		
Section 1	<i>from passage</i>	38a-504d
Sec. 2	<i>from passage</i>	38a-542d

The following fiscal impact statement and bill analysis are prepared for the benefit of members of the General Assembly, solely for the purpose of information, summarization, and explanation, and do not represent the intent of the General Assembly or either chamber thereof for any purpose:

OFA Fiscal Note

State Impact:

Agency Affected	Fund-Effect	FY 08 \$	FY 09 \$
State Comptroller - Fringe Benefits	All Funds - Cost	None	Potential

Municipal Impact:

Municipalities	Effect	FY 08 \$	FY 09 \$
	Cost	Potential	Potential

Explanation

The bill as amended, by limiting the routine patient care costs that may be charged to the insured person, may result in increased costs to the state when contracts are renewed in FY 09 and to municipal health insurance premiums that cannot be determined at this time.

Senate "A" strikes the underlying bill and has the fiscal impact described above.

House "A" adds clarifying language and has no fiscal impact.

The Out Years

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

OLR Bill Analysis**sSB 389 (File 215, as amended by Senate "A" and House "A")******AN ACT CONCERNING HOSPITALIZATION AT AN OUT-OF-NETWORK FACILITY DURING TREATMENT IN CANCER CLINICAL TRIALS.*****SUMMARY:**

By law, individual and group health insurance policies and HMO contracts must cover medically necessary hospitalization services (and other routine patient care costs) associated with certain cancer clinical trials. They must do so subject to plan terms and limitations, including out-of-network limitations. This bill specifies that the required hospitalization coverage includes treatment at an out-of-network facility if it is not (1) available at an in-network facility and (2) paid for by the clinical trial sponsors. (An out-of-network facility is one that has not contracted with the insurer or HMO to provide health care services to enrollees. An in-network facility has contracted.)

Current law subjects the routine patient care costs to the terms and limitations of the policy or contract, including out-of-network limitations. The bill excludes from this requirement out-of-network hospitalization that meets the criteria described above. It requires the out-of-network hospital and insurer or HMO to make the out-of-network hospital treatment available at no greater cost to the patient than if treatment was provided at an in-network facility. Thus, the patient is only responsible to pay any copayment, coinsurance, or deductible required under the policy or contract for in-network services.

*Senate Amendment "A" (1) extends the application of the original bill (File 215) to individual (in addition to group) health insurance policies and HMO contracts and (2) requires the specified out-of-

network hospitalization to be available at the in-network level of benefits under the policy or contract.

*House Amendment "A" specifies that it is the out-of-network hospital and insurer or HMO that must make the out-of-network hospitalization available at no greater cost to the insured person than if the hospital was in-network.

EFFECTIVE DATE: Upon passage

BACKGROUND

Coverage for Cancer Clinical Trials

By law, private health insurers and HMOs must cover routine patient care costs associated with Phase III cancer clinical trials for treatment or palliation that involve therapeutic intervention and are 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 (FDA) as part of an investigational new drug or device exemption, or (4) the U.S. Departments of Defense or Veterans' Affairs.

It defines "routine patient care costs" as coverage (1) for medically necessary services resulting from the treatment provided in the trial that would be covered even if they were not provided in a trial and (2) as routine patient care costs incurred in providing FDA-approved "off-label use" drugs and devices. Medically necessary services include physicians' services, diagnostic and lab tests, hospitalization, or other services provided during the trials for a condition or a related complication that are consistent with the usual and customary standard of care and would be covered if the person were not in the trial. An "off-label use" drug is one the FDA has approved to treat a cancer other than the type for which it is being prescribed. It must be

recognized by one of several national groups for treatment of the specific cancer for which it is being prescribed.

The law specifically excludes the following from routine care costs:

1. investigational drugs and devices the FDA has not approved for any use;
2. non-healthcare services a participant may need because of the trial;
3. facility, ancillary, and professional services and drugs for which the clinical trial receives funding;
4. services that are inconsistent with widely accepted and established national or regional standards of care for a particular diagnosis or that are performed specifically to meet the trial's requirements;
5. costs that would not be covered by the trial participant's insurance policy for noninvestigational treatment, including items excluded under the policy; and
6. transportation, lodging, food, and other expenses connected with the participant or the participant's family traveling to and from a trial facility.

Payment to Out-of-Network Providers

By law, an insurer or HMO must pay out-of-network providers (including hospitals) the lesser of (1) the lowest contracted daily fee schedule or case rate it pays its Connecticut in-network providers for similar services or (2) billed charges. Out-of-network providers are prohibited from collecting more than the total of the amount paid by the insurer or HMO and the insured's deductible and copayment.

COMMITTEE ACTION

Insurance and Real Estate Committee

Joint Favorable Substitute

Yea 19 Nay 0 (03/15/2007)