Senate

General Assembly

File No. 801

January Session, 2011

Substitute Senate Bill No. 21

Senate, May 16, 2011

The Committee on Appropriations reported through SEN. HARP of the 10th Dist., Chairperson of the Committee on the part of the Senate, that the substitute bill ought to pass.

AN ACT CONCERNING HEALTH INSURANCE COVERAGE FOR ROUTINE PATIENT CARE COSTS FOR CERTAIN CLINICAL TRIAL PATIENTS.

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

Section 1. Section 38a-504a of the general statutes is repealed and the following is substituted in lieu thereof (*Effective January 1, 2012*):

Each individual health insurance policy providing coverage of the type specified in subdivisions (1), (2), (4), (11) and (12) of section 38a-469 delivered, issued for delivery, **[**or**]** renewed, amended or continued in this state, **[**on or after January 1, 2002,**]** shall provide coverage for the routine patient care costs, as defined in section 38a-504d, as amended by this act, associated with **[**cancer**]** clinical trials, in accordance with sections 38a-504b to 38a-504g, inclusive, as amended by this act. As used in this section and sections 38a-504b to 38a-504g, inclusive, as amended by this act: **[**"cancer clinical**]** (1) "Clinical trial" means an organized, systematic, scientific study of therapies, tests or other clinical interventions for purposes of treatment or palliation or

therapeutic intervention for the prevention of **[**cancer in human beings, except that a clinical trial for the prevention of cancer is eligible for coverage only if it involves a therapeutic intervention and is a phase III clinical trial approved by one of the entities identified in section 38a-504b and is conducted at multiple institutions**]** disabling, progressive or life-threatening medical conditions in human beings, and (2) "disabling, progressive or life threatening medical conditions" means cancer, multiple sclerosis, Parkinson's disease, amyotrophic lateral sclerosis, acquired immunodeficiency syndrome or muscular dystrophy.

Sec. 2. Section 38a-504b of the general statutes is repealed and the following is substituted in lieu thereof (*Effective January 1, 2012*):

A clinical trial for the prevention of cancer shall be eligible for coverage only if it involves a therapeutic intervention, is a phase III clinical trial approved by one of the entities identified in this section and is conducted at multiple institutions. In order to be eligible for coverage of routine patient care costs, as defined in section 38a-504d, as amended by this act, a **[**cancer**]** clinical trial shall be (1) conducted under the auspices of an independent peer-reviewed protocol that has been reviewed and approved by: **[**(1)**]** (A) One of the National Institutes of Health; **[**or (2)**]** (B) a National Cancer Institute affiliated cooperative group; **[**or (3)**]** (C) the federal Food and Drug Administration as part of an investigational new drug or device exemption; or **[**(4)**]** (D) the federal Department of Defense or Veterans Affairs; or (2) qualified to receive Medicare coverage of its routine costs under the Medicare Clinical Trial Policy established under the September 19, 2000, Medicare National Coverage Determination, as amended from time to time. Nothing in sections 38a-504a to 38a-504g, inclusive, as amended by this act, shall be construed to require coverage for any single institution **[**cancer**]** clinical trial conducted solely under the approval of the institutional review board of an institution, or any trial that is no longer approved by an entity identified in **[**subdivision (1), (2), (3) or (4) of this section**]** subparagraph (A), (B), (C) or (D) of subdivision (1) of this subsection.

Sec. 3. Section 38a-504c of the general statutes is repealed and the following is substituted in lieu thereof (*Effective January 1, 2012*):

In order to be eligible for coverage of routine patient care costs, as defined in section 38a-504d, as amended by this act, the insurer, health care center or plan administrator may require that the person or entity seeking coverage for the **[**cancer**]** clinical trial provide: (1) Evidence satisfactory to the insurer, health care center or plan administrator that the insured person receiving coverage meets all of the patient selection criteria for the **[**cancer**]** clinical trial, including credible evidence in the form of clinical or preclinical data showing that the **[**cancer**]** clinical trial is likely to have a benefit for the insured person that is commensurate with the risks of participation in the **[**cancer**]** clinical trial to treat the person's condition; **[**and**]** (2) evidence that the appropriate informed consent has been received from the insured person; **[**and**]** (3) copies of any medical records, protocols, test results or other clinical information used by the physician or institution seeking to enroll the insured person in the **[**cancer**]** clinical trial; **[**and**]** (4) a summary of the anticipated routine patient care costs in excess of the costs for standard treatment; **[**and**]** (5) information from the physician or institution seeking to enroll the insured person in the clinical trial regarding those items, including any routine patient care costs, that are eligible for reimbursement by an entity other than the insurer or health care center, including the entity sponsoring the clinical trial; and (6) any additional information that may be reasonably required for the review of a request for coverage of the **[**cancer**]** clinical trial. The health plan or insurer shall request any additional information about a **[**cancer**]** clinical trial **[**within**]** not later than five business days **[**of**]** after receiving a request for coverage from an insured person or a physician seeking to enroll an insured person in a **[**cancer**]** clinical trial. Nothing in sections 38a-504a to 38a-504g, inclusive, as amended by this act, shall be construed to require the insurer or health care center to provide coverage for routine patient care costs that are eligible for reimbursement by an entity other than the insurer, including the entity sponsoring the **[**cancer**]** clinical trial.

Sec. 4. Section 38a-504d of the general statutes is repealed and the following is substituted in lieu thereof (*Effective January 1, 2012*):

(a) For purposes of sections 38a-504a to 38a-504g, inclusive, as amended by this act, "routine patient care costs" means: (1) **[**Coverage for medically**]** Medically necessary health care services that are incurred as a result of the treatment being provided to the insured person for purposes of the **[**cancer**]** clinical trial that would otherwise be covered if such services were not rendered pursuant to a **[**cancer**]** clinical trial. Such services shall include those rendered by a physician, diagnostic or laboratory tests, hospitalization or other services provided to the **[**patient**]** insured person during the course of treatment in the **[**cancer**]** clinical trial for a condition, or one of its complications, that is consistent with the usual and customary standard of care and would be covered if the insured person were not enrolled in a **[**cancer**]** clinical trial. Such hospitalization shall include treatment at an out-of-network facility if such treatment is not available in-network and not eligible for reimbursement by the sponsors of such clinical trial, **[**;**]** and (2) **[**coverage for routine patient care**]** costs incurred for drugs provided to the insured person, in accordance with section **[**38a-518b**]** 38a-492b, as amended by this act, provided such drugs have been approved for sale by the federal Food and Drug Administration.

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

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

Sec. 5. Section 38a-504e of the general statutes is repealed and the following is substituted in lieu thereof (*Effective January 1, 2012*):

(a) Providers, hospitals and institutions that provide routine patient care services as set forth in subsection (a) of section 38a-504d, as amended by this act, as part of a **[**cancer**]** clinical trial that meets the requirements of sections 38a-504a to 38a-504g, inclusive, as amended by this act, and is approved for coverage by the insurer or health care center shall not bill the insurer or health care center or the insured person for any facility, ancillary or professional services or costs that are not routine patient care services as set forth in subsection (a) of section 38a-504d, as amended by this act, or for any product or service that is paid by the entity sponsoring or funding the **[**cancer**]** clinical trial.

(b) Providers, hospitals, institutions and insured persons may

appeal a health plan's denials of payment for services only to the extent permitted by the contract between the insurer or health care center and the provider, hospital or institution.

(c) Providers, hospitals or institutions that have contracts with the insurer or health care center to render covered routine patient care services to insured persons as part of a **[**cancer**]** clinical trial **[**may**]** shall not bill the insured person for the cost of any covered routine patient care service.

(d) Providers, hospitals or institutions that do not have a contract with the insurer or health care center to render covered routine patient care services to insured persons as part of a **[**cancer**]** clinical trial **[**may**]** shall not bill the insured person for the cost of any covered routine patient care service.

(e) Nothing in this section shall be construed to prohibit a provider, hospital or institution from collecting a deductible or copayment as set forth in the insured person's contract for any covered routine patient care service.

(f) Pursuant to subsection (b) of section 38a-504d, as amended by this act, insurers or health care centers shall be required to pay providers, hospitals and institutions that do not have a contract with the insurer or health care center to render covered routine patient care services to insured persons the lesser of (1) the lowest contracted per diem, fee schedule rate or case rate that the insurer or health care center pays to any participating provider in the state of Connecticut for similar in-network services, or (2) the billed charges. Providers, hospitals or institutions **[**may**]** shall not collect any amount more than the total amount paid by the insurer or health care center and the insured person in the form of a deductible or copayment set forth in the insured person's contract. Such amount shall be deemed by the provider, hospital or institution to be payment in full.

Sec. 6. Section 38a-504f of the general statutes is repealed and the following is substituted in lieu thereof (*Effective January 1, 2012*):

(a) (1) For purposes of cancer clinical trials, the Insurance Department, in cooperation with the Connecticut Oncology Association, the American Cancer Society, the Connecticut Association of Health Plans and Anthem Blue Cross of Connecticut, shall develop a standardized form that all providers, hospitals and institutions shall submit to the insurer or health care center when seeking to enroll an insured person in a cancer clinical trial. An insurer or health care center [may] shall not substitute any other approval request form for the form developed by the department, except that any insurer or health care center that has entered into an agreement to provide coverage for cancer clinical trials approved pursuant to section 38a-504g, as amended by this act, may use the form or process established by such agreement.

(2) For purposes of clinical trials other than cancer clinical trials, the Insurance Department, in cooperation with at least one state nonprofit research or advocacy organization concerned with the subject of the clinical trial, at least one national nonprofit research or advocacy organization concerned with the subject of the clinical trial, the Connecticut Association of Health Plans and Anthem Blue Cross of Connecticut, shall develop a standardized form that all providers, hospitals and institutions shall submit to the insurer or health care center when seeking to enroll an insured person in a clinical trial. An insurer or health care center shall not substitute any other approval request form for the form developed by the department, except that any insurer or health care center that has entered into an agreement to provide coverage for clinical trials approved pursuant to section 38a-504g, as amended by this act, may use the form or process established by such agreement.

(b) Any insurer or health care center that receives the department form from a provider, hospital or institution seeking coverage for the routine patient care costs of an insured person in a [cancer] clinical trial shall approve or deny coverage for such services [within] not later than five business days [of] after receiving such request and any other reasonable supporting materials requested by the insurer or health

plan pursuant to section 38a-504c, as amended by this act, except that an insurer or health care center that utilizes independent experts to review such requests shall respond **[**within**]** not later than ten business days after receiving such request and supporting materials. Requests for coverage of phase III clinical trials for the prevention of cancer pursuant to section **[**38a-504a**]** 38a-504b, as amended by this act, shall be approved or denied **[**within**]** not later than fourteen business days after receiving such request and supporting materials.

(c) The insured, or the provider with the insured's written consent, may appeal any denial of coverage for medical necessity to an external, independent review pursuant to section 38a-478n. Such external review shall be conducted by a properly qualified review agent whom the department has determined does not have a conflict of interest regarding the **[**cancer**]** clinical trial.

(d) The Insurance Commissioner shall adopt regulations, in accordance with chapter 54, to implement the provisions of this section.

Sec. 7. Section 38a-504g of the general statutes is repealed and the following is substituted in lieu thereof (*Effective January 1, 2012*):

(a) Any insurer or health care center with coverage policies for care in **[**cancer**]** clinical trials shall submit such policies to the Insurance Department for evaluation and approval. The department shall certify whether the insurer's or health care center's coverage policy for routine patient care costs associated with **[**cancer**]** clinical trials is substantially equivalent to the requirements of sections 38a-504a to 38a-504g, inclusive, as amended by this act. If the department finds that such coverage is substantially equivalent to the requirements of sections 38a-504a to 38a-504g, inclusive, as amended by this act, the insurer or health care center shall be exempt from the provisions of sections 38a-504a to 38a-504g, inclusive, as amended by this act.

(b) Any such insurer or health care center shall report annually, in writing, to the department that there have been no changes in the

policy as certified by the department. If there has been any change in the policy, the insurer or health care center shall resubmit its policy for certification by the department.

(c) Any insurer or health care center coverage policy found by the department not to be substantially equivalent to the requirements of sections 38a-504a to 38a-504g, inclusive, as amended by this act, shall abide by the requirements of sections 38a-504a to 38a-504g, inclusive, as amended by this act, until the insurer or health care center has received such certification by the department.

Sec. 8. Section 38a-542a of the general statutes is repealed and the following is substituted in lieu thereof (*Effective January 1, 2012*):

Each group health insurance policy providing coverage of the type specified in subdivisions (1), (2), (4), (11) and (12) of section 38a-469 delivered, issued for delivery, **[**or**]** renewed, amended or continued in this state, **[**on or after January 1, 2002,**]** shall provide coverage for the routine patient care costs, as defined in section 38a-542d, as amended by this act, associated with **[**cancer**]** clinical trials, in accordance with sections 38a-542b to 38a-542g, inclusive, as amended by this act. As used in this section and sections 38a-542b to 38a-542g, inclusive, as amended by this act: **[**"cancer clinical**]** (1) "Clinical trial" means an organized, systematic, scientific study of therapies, tests or other clinical interventions for purposes of treatment or palliation or therapeutic intervention for the prevention of **[**cancer in human beings, except that a clinical trial for the prevention of cancer is eligible for coverage only if it involves a therapeutic intervention and is a phase III clinical trial approved by one of the entities identified in section 38a-542b and is conducted at multiple institutions**]** disabling, progressive or life-threatening medical conditions in human beings, and (2) "disabling, progressive or life threatening medical conditions" means cancer, multiple sclerosis, Parkinson's disease, amyotrophic lateral sclerosis, acquired immunodeficiency syndrome or muscular dystrophy.

Sec. 9. Section 38a-542b of the general statutes is repealed and the

following is substituted in lieu thereof (*Effective January 1, 2012*):

A clinical trial for the prevention of cancer shall be eligible for coverage only if it involves a therapeutic intervention, is a phase III clinical trial approved by one of the entities identified in this section and is conducted at multiple institutions. In order to be eligible for coverage of routine patient care costs, as defined in section 38a-542d, as amended by this act, a **[**cancer**]** clinical trial shall be (1) conducted under the auspices of an independent peer-reviewed protocol that has been reviewed and approved by: **[**(1)**]** (A) One of the National Institutes of Health; **[**or (2)**]** (B) a National Cancer Institute affiliated cooperative group; **[**or (3)**]** (C) the federal Food and Drug Administration as part of an investigational new drug or device exemption; or **[**(4)**]** (D) the federal Department of Defense or Veterans Affairs; or (2) qualified to receive Medicare coverage of its routine costs under the Medicare Clinical Trial Policy established under the September 19, 2000, Medicare National Coverage Determination, as amended from time to time. Nothing in sections 38a-542a to 38a-542g, inclusive, as amended by this act, shall be construed to require coverage for any single institution **[**cancer**]** clinical trial conducted solely under the approval of the institutional review board of an institution, or any trial that is no longer approved by an entity identified in **[**subdivision (1), (2), (3) or (4) of this section**]** subparagraph (A), (B), (C) or (D) of subdivision (1) of this subsection.

Sec. 10. Section 38a-542c of the general statutes is repealed and the following is substituted in lieu thereof (*Effective January 1, 2012*):

In order to be eligible for coverage of routine patient care costs, as defined in section 38a-542d, as amended by this act, the insurer, health care center or plan administrator may require that the person or entity seeking coverage for the **[**cancer**]** clinical trial provide: (1) Evidence satisfactory to the insurer, health care center or plan administrator that the insured person receiving coverage meets all of the patient selection criteria for the **[**cancer**]** clinical trial, including credible evidence in the form of clinical or pre-clinical data showing that the **[**cancer**]** clinical

trial is likely to have a benefit for the insured person that is commensurate with the risks of participation in the **[**cancer**]** clinical trial to treat the person's condition; **[**and**]** (2) evidence that the appropriate informed consent has been received from the insured person; **[**and**]** (3) copies of any medical records, protocols, test results or other clinical information used by the physician or institution seeking to enroll the insured person in the **[**cancer**]** clinical trial; **[**and**]** (4) a summary of the anticipated routine patient care costs in excess of the costs for standard treatment; **[**and**]** (5) information from the physician or institution seeking to enroll the insured person in the clinical trial regarding those items, including any routine patient care costs, that are eligible for reimbursement by an entity other than the insurer or health care center, including the entity sponsoring the clinical trial; and (6) any additional information that may be reasonably required for the review of a request for coverage of the **[**cancer**]** clinical trial. The health plan or insurer shall request any additional information about a **[**cancer**]** clinical trial **[**within**]** not later than five business days **[**of**]** after receiving a request for coverage from an insured person or a physician seeking to enroll an insured person in a **[**cancer**]** clinical trial. Nothing in sections 38a-542a to 38a-542g, inclusive, as amended by this act, shall be construed to require the insurer or health care center to provide coverage for routine patient care costs that are eligible for reimbursement by an entity other than the insurer, including the entity sponsoring the **[**cancer**]** clinical trial.

Sec. 11. Section 38a-542d of the general statutes is repealed and the following is substituted in lieu thereof (*Effective January 1, 2012*):

(a) For purposes of sections 38a-542a to 38a-542g, inclusive, as amended by this act, "routine patient care costs" means: (1) **[**Coverage for medically**]** Medically necessary health care services that are incurred as a result of the treatment being provided to the insured person for purposes of the **[**cancer**]** clinical trial that would otherwise be covered if such services were not rendered pursuant to a **[**cancer**]** clinical trial. Such services shall include those rendered by a physician, diagnostic or laboratory tests, hospitalization or other services

provided to the [patient] insured person during the course of treatment in the [cancer] clinical trial for a condition, or one of its complications, that is consistent with the usual and customary standard of care and would be covered if the insured person were not enrolled in a [cancer] clinical trial. Such hospitalization shall include treatment at an out-of-network facility if such treatment is not available in-network and not eligible for reimbursement by the sponsors of such clinical trial; and (2) [coverage for routine patient care] costs incurred for drugs provided to the insured person, in accordance with section 38a-518b, as amended by this act, provided such drugs have been approved for sale by the federal Food and Drug Administration.

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

(c) Notwithstanding the provisions of subsection (a) of this section, routine patient care costs shall not include: (1) The cost of an investigational new drug or device that has not been approved for market for any indication by the federal Food and Drug Administration; (2) the cost of a non-health-care service that an insured person may be required to receive as a result of the treatment being provided for the purposes of the cancer clinical trial; (3) facility, ancillary, professional services and drug costs that are paid for by grants or funding for the [cancer] clinical trial; (4) costs of services that (A) are inconsistent with widely accepted and established regional or

national standards of care for a particular diagnosis, or (B) are performed specifically to meet the requirements of the **[**cancer**]** clinical trial; (5) costs that would not be covered under the insured person's policy for noninvestigational treatments, including, but not limited to, items excluded from coverage under the insured person's contract with the insurer or health plan; and (6) transportation, lodging, food or any other expenses associated with travel to or from a facility providing the **[**cancer**]** clinical trial, for the insured person or any family member or companion.

Sec. 12. Section 38a-542e of the general statutes is repealed and the following is substituted in lieu thereof (*Effective January 1, 2012*):

(a) Providers, hospitals and institutions that provide routine patient care services as set forth in subsection (a) of section 38a-542d, as amended by this act, as part of a **[**cancer**]** clinical trial that meets the requirements of sections 38a-542a to 38a-542g, inclusive, as amended by this act, and is approved for coverage by the insurer or health care center shall not bill the insurer or health care center or the insured person for any facility, ancillary or professional services or costs that are not routine patient care services as set forth in subsection (a) of section 38a-542d, as amended by this act, or for any product or service that is paid by the entity sponsoring or funding the **[**cancer**]** clinical trial.

(b) Providers, hospitals, institutions and insured persons may appeal a health plan's denials of payment for services only to the extent permitted by the contract between the insurer or health care center and the provider, hospital or institution.

(c) Providers, hospitals or institutions that have contracts with the insurer or health care center to render covered routine patient care services to insured persons as part of a **[**cancer**]** clinical trial **[**may**]** shall not bill the insured person for the cost of any covered routine patient care service.

(d) Providers, hospitals or institutions that do not have a contract

with the insurer or health care center to render covered routine patient care services to insured persons as part of a [cancer] clinical trial [may] shall not bill the insured person for the cost of any covered routine patient care service.

(e) Nothing in this section shall be construed to prohibit a provider, hospital or institution from collecting a deductible or copayment as set forth in the insured person's contract for any covered routine patient care service.

(f) Pursuant to subsection (b) of section 38a-542d, as amended by this act, insurers or health care centers shall be required to pay providers, hospitals and institutions that do not have a contract with the insurer or health care center to render covered routine patient care services to insured persons the lesser of (1) the lowest contracted per diem, fee schedule rate or case rate that the insurer or health care center pays to any participating provider in the state of Connecticut for similar in-network services, or (2) the billed charges. Providers, hospitals or institutions [may] shall not collect any amount more than the total amount paid by the insurer or health care center and the insured person in the form of a deductible or copayment set forth in the insured person's contract. Such amount shall be deemed by the provider, hospital or institution to be payment in full.

Sec. 13. Section 38a-542f of the general statutes is repealed and the following is substituted in lieu thereof (*Effective January 1, 2012*):

(a) (1) For purposes of cancer clinical trials, the Insurance Department, in cooperation with the Connecticut Oncology Association, the American Cancer Society, the Connecticut Association of Health Plans and Anthem Blue Cross of Connecticut, shall develop a standardized form that all providers, hospitals and institutions shall submit to the insurer or health care center when seeking to enroll an insured person in a cancer clinical trial. An insurer or health care center [may] shall not substitute any other approval request form for the form developed by the department, except that any insurer or health care center that has entered into an agreement to provide

coverage for cancer clinical trials approved pursuant to section 38a-542g, as amended by this act, may use the form or process established by such agreement.

(2) For purposes of clinical trials other than cancer clinical trials, the Insurance Department, in cooperation with at least one state nonprofit research or advocacy organization concerned with the subject of the clinical trial, at least one national nonprofit research or advocacy organization concerned with the subject of the clinical trial, the Connecticut Association of Health Plans and Anthem Blue Cross of Connecticut, shall develop a standardized form that all providers, hospitals and institutions shall submit to the insurer or health care center when seeking to enroll an insured person in a clinical trial. An insurer or health care center shall not substitute any other approval request form for the form developed by the department, except that any insurer or health care center that has entered into an agreement to provide coverage for clinical trials approved pursuant to section 38a-504g, as amended by this act, may use the form or process established by such agreement.

(b) Any insurer or health care center that receives the department form from a provider, hospital or institution seeking coverage for the routine patient care costs of an insured person in a **[**cancer**]** clinical trial shall approve or deny coverage for such services **[**within**]** not later than five business days **[**of**]** after receiving such request and any other reasonable supporting materials requested by the insurer or health plan pursuant to section 38a-542c, as amended by this act, except that an insurer or health care center that utilizes independent experts to review such requests shall respond **[**within**]** not later than ten business days after receiving such request and supporting materials. Requests for coverage of phase III clinical trials for the prevention of cancer pursuant to section **[**38a-542a**]** 38-542b, as amended by this act, shall be approved or denied **[**within**]** not later than fourteen business days after receiving such request and supporting materials.

(c) The insured, or the provider with the insured's written consent,

may appeal any denial of coverage for medical necessity to an external, independent review pursuant to section 38a-478n. Such external review shall be conducted by a properly qualified review agent whom the department has determined does not have a conflict of interest regarding the **[**cancer**]** clinical trial.

(d) The Insurance Commissioner shall adopt regulations, in accordance with chapter 54, to implement the provisions of this section.

Sec. 14. Section 38a-542g of the general statutes is repealed and the following is substituted in lieu thereof (*Effective January 1, 2012*):

(a) Any insurer or health care center with coverage policies for care in **[**cancer**]** clinical trials shall submit such policies to the Insurance Department for evaluation and approval. The department shall certify whether the insurer's or health care center's coverage policy for routine patient care costs associated with **[**cancer**]** clinical trials is substantially equivalent to the requirements of sections 38a-542a to 38a-542g, inclusive, as amended by this act. If the department finds that such coverage is substantially equivalent to the requirements of sections 38a-542a to 38a-542g, inclusive, as amended by this act, the insurer or health care center shall be exempt from the provisions of sections 38a-542a to 38a-542g, inclusive, as amended by this act.

(b) Any such insurer or health care center shall report annually, in writing, to the department that there have been no changes in the policy as certified by the department. If there has been any change in the policy, the insurer or health care center shall resubmit its policy for certification by the department.

(c) Any insurer or health care center coverage policy found by the department not to be substantially equivalent to the requirements of sections 38a-542a to 38a-542g, inclusive, as amended by this act, shall abide by the requirements of sections 38a-542a to 38a-542g, inclusive, as amended by this act, until the insurer or health care center has received such certification by the department.

Sec. 15. Section 38a-492b of the general statutes is repealed and the following is substituted in lieu thereof (*Effective January 1, 2012*):

(a) Each individual health insurance policy delivered, issued for delivery, **[**or**]** renewed, amended or continued in this state, **[**on or after October 1, 1994, which**]** that provides coverage for prescribed drugs approved by the federal Food and Drug Administration for treatment of certain types of cancer and disabling, progressive or life-threatening medical conditions, as defined in section 38a-504a, as amended by this act, shall not exclude coverage of any such drug on the basis that such drug has been prescribed for the treatment of a type of cancer or a disabling, progressive or life-threatening medical condition for which the drug has not been approved by the federal Food and Drug Administration, provided the drug is recognized for treatment of the specific type of cancer or a disabling, progressive or life-threatening medical condition for which the drug has been prescribed in one of the following established reference compendia: (1) The U.S. Pharmacopoeia Drug Information Guide for the Health Care Professional (USP DI); (2) The American Medical Association's Drug Evaluations (AMA DE); or (3) The American Society of Hospital Pharmacists' American Hospital Formulary Service Drug Information (AHFS-DI).

(b) Nothing in subsection (a) of this section shall be construed to require coverage for any experimental or investigational drugs or any drug which the federal Food and Drug Administration has determined to be contraindicated for treatment of the specific type of cancer or disabling, progressive or life-threatening medical condition for which the drug has been prescribed.

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

Sec. 16. Section 38a-518b of the general statutes is repealed and the following is substituted in lieu thereof (*Effective January 1, 2012*):

(a) Each group health insurance policy delivered, issued for delivery, [or] renewed, amended or continued in this state, [on or after October 1, 1994, which] that provides coverage for prescribed drugs approved by the federal Food and Drug Administration for treatment of certain types of cancer and disabling, progressive or life-threatening medical conditions, as defined in section 38a-542a, as amended by this act, shall not exclude coverage of any such drug on the basis that such drug has been prescribed for the treatment of a type of cancer or a disabling, progressive or life-threatening medical condition for which the drug has not been approved by the federal Food and Drug Administration, provided the drug is recognized for treatment of the specific type of cancer or a disabling, progressive or life-threatening medical condition for which the drug has been prescribed in one of the following established reference compendia: (1) The U.S. Pharmacopoeia Drug Information Guide for the Health Care Professional (USP DI); (2) The American Medical Association's Drug Evaluations (AMA DE); or (3) The American Society of Hospital Pharmacists' American Hospital Formulary Service Drug Information (AHFS-DI).

(b) Nothing in subsection (a) of this section shall be construed to require coverage for any experimental or investigational drugs or any drug which the federal Food and Drug Administration has determined to be contraindicated for treatment of the specific type of cancer or a disabling, progressive or life-threatening medical condition for which the drug has been prescribed.

(c) [Nothing] Except as specified, nothing in this section shall be construed to create, impair, limit or modify authority to provide reimbursement for 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, 2012*	38a-504a
Sec. 2	*January 1, 2012*	38a-504b

Sec. 3	*January 1, 2012*	38a-504c
Sec. 4	*January 1, 2012*	38a-504d
Sec. 5	*January 1, 2012*	38a-504e
Sec. 6	*January 1, 2012*	38a-504f
Sec. 7	*January 1, 2012*	38a-504g
Sec. 8	*January 1, 2012*	38a-542a
Sec. 9	*January 1, 2012*	38a-542b
Sec. 10	*January 1, 2012*	38a-542c
Sec. 11	*January 1, 2012*	38a-542d
Sec. 12	*January 1, 2012*	38a-542e
Sec. 13	*January 1, 2012*	38a-542f
Sec. 14	*January 1, 2012*	38a-542g
Sec. 15	*January 1, 2012*	38a-492b
Sec. 16	*January 1, 2012*	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 12 $	FY 13 $
Comptroller Misc. Accounts (Fringe Benefits)	GF & TF- Cost	Potential	Potential

Note: GF=General Fund and TF= Transportation Fund

Municipal Impact:

Municipalities	Effect	FY 12 $	FY 13 $
Various Municipalities	STATE MANDATE - Cost	Potential	Potential

Explanation

As of July 1, 2010, the State Employees' Health plan went self-insured. Pursuant to current federal law, self-insured health plans are exempt from state health mandates, however in previous self-funded arrangements the state has traditionally adopted all state mandates. To the extent the state continues this practice of voluntary mandate adoption, the following impacts are anticipated.

According to the state employee and retiree health plan, 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. The state employee and retiree health plan currently provides coverage for routine patient costs in association with cancer clinical trials. The bill expands this coverage to include multiple sclerosis, Parkinson's disease, amyotrophic lateral sclerosis, AIDS and muscular dystrophy. As it is not possible to determine which routine services or off label prescription drugs may or may not be provided and authorized for the diseases specified, the

fiscal impact to the state cannot be determined.

To the extent that fully insured municipalities do not provide coverage for routine care or off label prescriptions for insured participants in clinical trials for the diseases specified, there may be an increased cost to provide the coverage mandated. The coverage requirements may result in increased premium costs when municipalities enter into new health insurance contracts after January 1, 2012. Due to current federal law, municipalities with self-insured plans are exempt from state health insurance mandates.

The state employee health plan and many municipal health plans are recognized as "grandfathered" health plans under the Patient Protection and Affordable Care Act (PPACA)[1]. It is unclear what effect the adoption of certain health mandates will have on the grandfathered status of the state employee health plan or grandfathered municipal plans PPACA[2].

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 and off label prescriptions may or may not be provided and authorized for the diseases included in the bill. Those mandated services not currently covered will result in a cost to the state employee and retiree health plan and municipalities. The annualized ongoing fiscal impact

[1] Grandfathered plans include most group insurance plans and some individual health plans created or purchased on or before March 23, 2010. Pursuant to the PPACA, all health plans, including those with grandfathered status are required to provide the following as of September 23, 2010: 1) No lifetime limits on coverage, 2) No rescissions of coverage when individual gets sick or has previously made an unintentional error on an application, and 3) Extension of parents' coverage to young adults until age 26. (www.healthcare.gov)

[2] According to the PPACA, compared to the plans' policies as of March 23, 2010, grandfathered plans who make any of the following changes within a certain margin may lose their grandfathered status: 1) Significantly cut or reduce benefits, 2) Raise co-insurance charges, 3) Significantly raise co-payment charges, 4) Significantly raise deductibles, 5) Significantly lower employer contributions, and 5) Add or tighten annual limits on what insurer pays. (www.healthcare.gov)

identified above would continue into the future subject to inflation.

The federal health care reform act requires that, effective January 1, 2014, all states must establish a health benefit exchange, which will offer qualified plans that must include a federally defined essential benefits package. While states are allowed to mandate benefits in excess of the basic package, the federal law appears to require the state to pay the cost of any such additional mandated benefits. The extent of these costs will depend on the mandates included in the federal essential benefit package, which have not yet been determined. Neither the agency nor mechanism for the state to pay these costs has been established.

OLR Bill Analysis

sSB 21

AN ACT CONCERNING HEALTH INSURANCE COVERAGE FOR ROUTINE PATIENT CARE COSTS FOR CERTAIN CLINICAL TRIAL PATIENTS.

SUMMARY:

By law, individual and group health insurance policies and HMO contracts must cover (1) medically necessary hospitalization services and other routine patient care costs associated with cancer clinical trials and (2) off-label cancer prescription drugs. This bill expands the coverage requirements to include certain disabling, progressive, or life-threatening medical conditions rather than cancer only.

The bill applies 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.

The bill also makes technical and conforming changes.

EFFECTIVE DATE: January 1, 2012

CLINICAL TRIALS

The bill defines a "clinical trial" as an organized, systemic, scientific study of interventions for the treatment of disabling, progressive, or life-threatening medical conditions, or therapeutic intervention for prevention. Under the bill, "disabling, progressive, or life-threatening medical conditions" includes cancer, multiple sclerosis, Parkinson's disease, amyotrophic lateral sclerosis, acquired immunodeficiency

syndrome (AIDS), and muscular dystrophy.

By law, a clinical trial for cancer prevention 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 bill does not require this for other types of preventive clinical trials it covers, but maintains it for cancer clinical trials.

Eligibility for Coverage

By law, to be eligible for coverage, a cancer clinical trial must be conducted under an independent, peer-reviewed protocol approved by one of the National Institutes of Health, a National Cancer Institute-affiliated cooperative group, the federal Food and Drug Administration (FDA) as part of an investigational new drug or device exemption, or the U.S. departments of Defense or Veterans' Affairs. The bill applies this requirement to clinical trials for disabling, progressive, or life-threatening medical conditions designated by the bill. It also makes eligible for coverage clinical trials for the designated disabling, progressive, or life-threatening medical conditions that qualify for Medicare coverage under the Medicare Clinical Trials Policy established under the September 19, 2000 Medicare National Coverage Determination.

The insurer, HMO, or plan administrator may require the person or entity seeking coverage for the clinical trial to provide:

1. evidence that the patient meets all selection criteria for the clinical trial, including credible clinical evidence showing the clinical trial is likely to benefit the person compared to the risks of participation;

2. evidence that the patient has given his or her informed consent;

3. copies of medical records, protocols, test results, or other clinical information used to enroll the patient in the clinical trial;

4. a summary of the anticipated routine patient costs in excess of

the standard treatment costs;

5. information regarding items that are eligible for reimbursement from other sources, including the entity sponsoring the clinical trial; and

6. additional information reasonably required to review the coverage request.

Routine Patient Care Costs

By law, and extended to all clinical trials by the bill, "routine patient care costs" are (1) medically necessary health care services, including physician services, diagnostic or laboratory tests, and hospitalization, incurred as a result of the treatment being provided that would otherwise be covered if they were not rendered as part of a clinical trial and (2) costs incurred for federal FDA-approved drugs. The services must be consistent with the usual and customary standard of care.

Hospitalization must include treatment at an out-of-network facility if such treatment is not available in-network and is not eligible for reimbursement by the clinical trial.

Routine patient care costs must be subject to the terms, conditions, restrictions, exclusions, and limitations of the insurance contract or certificate, including limitations on out-of network care. But treatment at an out-of-network hospital must be made available by the out-of-network hospital and the insurer or HMO at no greater cost to the insured person than if such treatment was available in-network. The insurer or HMO may require that any routine tests or services required under the clinical trial be performed by contracted providers.

Routine patient care costs do not include:

1. the cost of an investigational new drug or device that is not FDA-approved;

2. the cost of a non-health-care service that an insured person may be required to receive as a result of the clinical trial;

3. facility, ancillary, professional services, and drug costs that are paid for by grants or funding for the clinical trial;

4. costs of services that are (a) inconsistent with widely accepted and established regional or national standards of care for a particular diagnosis, or (b) performed specifically to meet the requirements of the clinical trials;

5. costs that would not be covered under the insured person's policy for noninvestigational treatments, including items excluded from coverage under the person's insurance contract; and

6. transportation, lodging, food, or any other expenses associated with travel to or from the clinical trial facility.

Health care providers, including hospitals and institutions, that provide routine patient care services approved for coverage cannot bill the insurer, HMO, or insured for any (1) services or costs that do not meet the definition of routine patient care services or (2) product or service for which the clinical trial sponsor is paying.

Payment to Out-of-Network Providers

An insurer or HMO must pay out-of-network providers 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 amount paid by the insurer or HMO and the insured's deductible and copayment.

Coverage Request Form

The bill requires the Insurance Department to develop a standardized form that all providers must submit to the insurer or HMO when seeking to enroll an insured patient in a clinical trial for the designated disabling, progressive, or life-threatening medical condition, excluding cancer. The department must develop the form in consultation with:

1. at least one state nonprofit research or advocacy organization related to the clinical trial's subject,

2. at least one national nonprofit research or advocacy organization related to the clinical trial's subject,

3. the Connecticut Association of Health Plans, and

4. Anthem Blue Cross of Connecticut.

An insurer or HMO must use the department's form unless it is exempt because its coverage is certified to be substantially the same as the bill requires and it has the department's approval to use another form.

An insurer or HMO that receives a completed form from a provider requesting coverage for routine patient care costs for clinical trials other than cancer must approve or deny the request within five business days or, if using independent experts to review clinical trial requests, 10 business days. By law, requests for coverage of Phase III cancer clinical trials must be approved or denied within 14 business days.

Under existing law, the Insurance Department has to (1) develop a form for use with cancer clinical trials and (2) adopt regulations to implement the coverage request form requirements, which the bill extends to other clinical trials.

Exemption from Requirements

Insurers and HMOs must submit their coverage policies for clinical trials to the Insurance Department for evaluation and approval. The department must certify whether the coverage policy is substantially equivalent to the bill's requirements. If it is, the insurer or HMO is exempt from the bill's requirements.

An exempt insurer or HMO must annually report in writing to the department that there have been no changes to the coverage policy. If there have been changes, the insurer or HMO must resubmit the policy

for the department's certification.

OFF-LABEL DRUGS

By law, individual and group health insurance policies that cover a prescription drug that is FDA-approved to treat a certain type of cancer must also cover the drug when it is used for another type of cancer (known as "off-label" drugs) if it is recognized as a cancer treatment in one of three sources.

The bill also requires coverage for off-label drug use for FDA-approved drugs to treat the designated disabling, progressive, or life-threatening medical conditions. The drug must be recognized for the treatment of 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 Hospital Pharmacists' American Hospital Formulary Service Drug Information.

The bill specifies that it does not require coverage for experimental or investigational drugs or any drug that the FDA has determined to be contraindicated for the treatment of a specific disabling, progressive, or life-threatening medical condition covered by the bill. This is already law with respect to cancer drugs.

BACKGROUND

Legislative History

On April 27, the Senate referred the bill (File 15) to the Appropriations Committee, which favorably reported a substitute that limits insurance coverage for clinical trials to those for cancer, multiple sclerosis, Parkinson's disease, amyotrophic lateral sclerosis, AIDS, and muscular dystrophy, instead of all disabling, progressive, or life threatening conditions.

COMMITTEE ACTION

Insurance and Real Estate Committee

Joint Favorable
Yea 10 Nay 9 (02/10/2011)

Insurance and Real Estate Committee

Joint Favorable
Yea 19 Nay 0 (02/10/2011)

Appropriations Committee

Joint Favorable Substitute
Yea 34 Nay 20 (05/04/2011)