General Assembly

Committee Bill No. 21

January Session, 2011

LCO No. **2304**

02304SB00021INS

Referred to Committee on Insurance and Real Estate

Introduced by:
(INS)

AN ACT CONCERNING 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:

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 Section 38a-504a of the general statutes is repealed and the following is substituted in lieu thereof (*Effective January 1, 2012*):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

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 Section 38a-504b of the general statutes is repealed and the following is substituted in lieu thereof (*Effective January 1, 2012*):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 pertaining to the subject of the clinical trial, at least one national nonprofit research or advocacy organization pertaining to 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**]** "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.

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 pertaining to the subject of the clinical trial, at least one national nonprofit research or advocacy organization pertaining to 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 other disabling, progressive or life-threatening medical conditions 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 other 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 other 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

other 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 other disabling, progressive or life-threatening medical conditions 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 other 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 other 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 other 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

Statement of Purpose:

To require individual and group health insurance coverage of routine patient costs associated with clinical trials for the treatment of disabling, progressive or life-threatening medical conditions.

[Proposed deletions are enclosed in brackets. Proposed additions are indicated by underline, except that when the entire text of a bill or resolution or a section of a bill or resolution is new, it is not underlined.]

Co-Sponsors: SEN. LOONEY, 11th Dist.

S.B. 21