Substitute Senate Bill No. 325  
Public Act No. 01-171

AN ACT CONCERNING HEALTH INSURANCE COVERAGE FOR CANCER CLINICAL TRIALS, HEARING AIDS FOR CHILDREN AGE TWELVE AND YOUNGER, PAP SMEAR TESTS, COLORECTAL CANCER SCREENING AND MAMMOGRAMS, PSYCHOTROPIC DRUG AVAILABILITY AND MEDICAID COVERAGE FOR MAMMOGRAMS.

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

Section 1. (NEW) Each group health insurance policy providing coverage of the type specified in subdivisions (1), (2), (4), (11) and (12) of section 38a-469 of the general statutes delivered, issued for delivery or renewed in this state on or after January 1, 2002, shall provide coverage for the routine patient care costs, as defined in section 4 of this act, associated with cancer clinical trials, in accordance with sections 2 to 7, inclusive, of this act. As used in this section and sections 2 to 7, inclusive, of this act, "cancer 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 2 of this act and is conducted at multiple institutions.

Sec. 2. (NEW) In order to be eligible for coverage of routine patient care costs, as defined in section 4 of this act, a cancer clinical trial shall be conducted under the auspices of an independent peer-reviewed protocol that has been reviewed and approved by: (1) One of the National Institutes of Health; or (2) a National Cancer Institute affiliated cooperative group; or (3) the federal Food and Drug Administration as part of an investigational new drug or device exemption; or (4) the federal Department of Defense or Veterans Affairs. Nothing in sections 1 to 7, inclusive, of 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.

Sec. 3. (NEW) In order to be eligible for coverage of routine patient care costs, as defined in section 4 of 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 five business days of 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 1 to 7, inclusive, of 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. (NEW) (a) For purposes of sections 1 to 7, inclusive, of this act, "routine patient care costs" means: (1) Coverage for 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 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; and (2) coverage for routine patient care costs incurred for drugs provided to the insured person, in accordance with section 38a-518b of the general statutes, 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. 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 nonhealth 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. (NEW) (a) Providers, hospitals and institutions that provide routine patient care services as set forth in subsection (a) of section 4 of this act as part of a cancer clinical trial that meets the requirements of sections 1 to 7, inclusive, of 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 4 of 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 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 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 4 of 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 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. (NEW) (a) 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 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 7 of 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 five business days of receiving such request and any other reasonable supporting materials requested by the insurer or health plan pursuant to section 3 of this act, except that an insurer or health care center that utilizes independent experts to review such requests shall respond within ten business days. Requests for coverage of phase III clinical trials for the prevention of cancer pursuant to section 1 of this act shall be approved or denied within fourteen business days.

(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 of the general statutes. 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 of the general statutes, to implement the provisions of this section.

Sec. 7. (NEW) (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 1 to 7, inclusive, of this act. If the department finds that such coverage is substantially equivalent to the requirements of sections 1 to 7, inclusive, of this act, the insurer or health care center shall be exempt from the provisions of sections 1 to 7, inclusive, of 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 1 to 7, inclusive, of this act shall abide by the requirements of sections 1 to 7, inclusive, of this act until the insurer or health care center has received such certification by the department.

Sec. 8. (NEW) Each individual health insurance policy providing coverage of the type specified in subdivisions (1), (2), (4), (11) and (12) of section 38a-469 of the general statutes delivered, issued for delivery or renewed in this state on or after January 1, 2002, shall provide coverage for the routine patient care costs, as defined in section 11 of this act, associated with cancer clinical trials, in accordance with sections 9 to 14, inclusive, of this act. As used in this section and sections 9 to 14, inclusive, of this act, "cancer 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 9 of this act and is conducted at multiple institutions.

Sec. 9. (NEW) In order to be eligible for coverage of routine patient care costs, as defined in section 11 of this act, a cancer clinical trial shall be conducted under the auspices of an independent peer-reviewed protocol that has been reviewed and approved by: (1) One of the National Institutes of Health; or (2) a National Cancer Institute affiliated cooperative group; or (3) the federal Food and Drug Administration as part of an investigational new drug or device exemption; or (4) the federal Department of Defense or Veterans Affairs. Nothing in sections 8 to 14, inclusive, of 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.

Sec. 10. (NEW) In order to be eligible for coverage of routine patient care costs, as defined in section 11 of 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 five business days of 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 8 to 14, inclusive, of 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. (NEW) (a) For purposes of sections 8 to 14, inclusive, of this act, "routine patient care costs" means: (1) Coverage for 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 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; and (2) coverage for routine patient care costs incurred for drugs provided to the insured person, in accordance with section 38a-518b of the general statutes, 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. 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 nonhealth 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. (NEW) (a) Providers, hospitals and institutions that provide routine patient care services as set forth in subsection (a) of section 11 of this act as part of a cancer clinical trial that meets the requirements of sections 8 to 14, inclusive, of 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 11 of 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 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 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 11 of 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 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. (NEW) (a) 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 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 14 of 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 five business days of receiving such request and any other reasonable supporting materials requested by the insurer or health plan pursuant to section 10 of this act, except that an insurer or health care center that utilizes independent experts to review such requests shall respond within ten business days. Requests for coverage of phase III clinical trials for the prevention of cancer pursuant to section 8 of this act shall be approved or denied within fourteen business days.

(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 of the general statutes. 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 of the general statutes, to implement the provisions of this section.

Sec. 14. (NEW) (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 8 to 14, inclusive, of this act. If the department finds that such coverage is substantially equivalent to the requirements of sections 8 to 14, inclusive, of this act, the insurer or health care center shall be exempt from the provisions of sections 8 to 14, inclusive, of 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 8 to 14, inclusive, of this act shall abide by the requirements of sections 8 to 14, inclusive, of this act until the insurer or health care center has received such certification by the department.

Approved July 6, 2001