SENATE. . . . . No. 2121

The Commonwealth of Massachusetts

SENATE, September 21, 2001.

The committee on Ways and Means, to whom was committed the House Bill providing for insurance coverage of certain clinical trials (House, No. 4376), reports recommending that the same ought to pass, with an amendment, striking out all after the enacting clause and inserting in place thereof a new text, Senate, No. 2121.

For the committee,

MARK C. MONTIGNY.

The Commonwealth of Massachusetts

In the Year Two Thousand and One.

AN ACT PROVIDING FOR INSURANCE COVERAGE OF CERTAIN CLINICAL TRIALS.

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

SECTION 1. Chapter 118E of the General Laws, as appearing in the 2000 Official Edition, is hereby amended by inserting after section 10C the following new section:—

Section 10D. The division shall provide coverage for patient care services furnished pursuant to qualified clinical trials as defined in, and subject to the requirements and limitations of, section 110L of chapter 175.

SECTION 2. Chapter 175 of the General Laws, as so appearing, is hereby amended by inserting after section 110K the following new section:—

Section 110L.

(a) Any policy, contract, agreement, plan or certificate of insurance issued, delivered, or renewed within the commonwealth shall cover and reimburse for patient care services provided pursuant to a qualified clinical trial to the same extent as they would be covered and reimbursed if the patient did not receive care in a qualified clinical trial.

(b) A "qualified clinical trial" means a clinical trial that meets the following conditions:

(1) The clinical trial is intended to treat cancer in a patient who has been so diagnosed.

(2) The clinical trial has been peer-reviewed and is approved by one of the United States National Institutes of Health, a Cooperative Group or Center of the National Institutes of Health, a qualified nongovernmental research entity identified in guidelines issued by the National Institutes of Health for center support grants, the United States Food and Drug Administration pursuant

to an investigational new drug exemption, the United States Departments of Defense or Veterans Affairs, or, with respect to Phase II, III and IV clinical trials only, a qualified institutional review board.

(3) (1) The facility and personnel conducting the clinical trial are capable of doing so by virtue of their experience and training and treat a sufficient volume of patients to maintain that expertise.

(2) With respect to phase I clinical trials, the facility shall be an academic medical center or an affiliated facility, and the clinicians conducting the trial shall have staff privileges at said academic medical center.

(4) The patient meets the patient selection criteria enunciated in the study protocol for participation in the clinical trial.

(5) The patient has provided his or her informed consent for participation in the clinical trial, in a manner that is consistent with current legal and ethical standards.

(6) The available clinical or pre-clinical data provide a reasonable expectation that the patient's participation in the clinical trial will provide a medical benefit that is commensurate with the risks of participation in the clinical trial.

(7) The clinical trial does not unjustifiably duplicate existing studies.

(8) The clinical trial must have a therapeutic intent and must, to some extent, assess the effect of the intervention on the patient.

(c) An institutional review board shall qualify under paragraph (b)(2) only if it: (1) meets all the federal requirements for the operation of institutional review board as identified in the Code of Federal Regulations; (2) is not disqualified to oversee clinical research by the National Institutes of Health or the Food and Drug Administration for noncompliance with federal law; and (3) has taken corrective action to rectify any noncompliance issue raised by the National Institutes of Health or the Food and Drug Administration within the past three years and has passed all subsequent National Institutes of Health or Food and Drug Administration inspections, audits or examinations.

(d) This section does not apply to any policy, contract, agreement, plan or certificate of insurance paid for, or providing supplemental coverage, under Title XVIII or XIX of the Social Security Act.

(e) Coverage under this section shall be subject to all other terms and conditions of the policy, contract, agreement, plan or certificate of insurance, including, but not limited to, provisions requiring the use of participating providers and provisions related to utilization review. Payment to health care providers under this section shall be subject to the terms and conditions of the applicable agreement between the provider and the carrier, including, but not limited to, provisions relating to utilization review, audits and the financial liability of covered persons.

(f) Coverage of services, when required by this section, shall not create any legal presumption that the carrier has recommended, directed or required the patient's participation in the trial.

(g) In this section, the following terms shall have the following meanings:

(1) "Cooperative Group" means a formal network of facilities that collaborate on research projects and have an established peer review program approved by the National Institutes of Health operating within the group. The term includes (1) a National Cancer Institute sanctioned Clinical Cooperative Group and (2) the National Cancer Institute Community Clinical Oncology Program.

(2) "Patient care service" means a health care item or service that is furnished to an individual enrolled in a qualified clinical trial, which is consistent with the usual and customary standard of care for someone with the patient's diagnosis, is consistent with the study protocol for the clinical trial, and would be covered if the patient did not participate in the clinical trial. The term does not include:

i. An investigational drug or device; provided, however that a drug or device that has been approved for use in the qualified clinical trial, whether or not the Food and Drug Administration has approved the drug or device for use in treating the patient's particular condition, shall be a patient care service to the extent that the drug or device is not paid for by the manufacturer, distributor, or provider of the drug or device.

ii. Non-healthcare services that a patient may be required to receive as a result of being enrolled in the clinical trial.

iii. Costs associated with managing the research associated with the clinical trial.

iv. Costs that would not be covered for non-investigational treatments.

v. Any item, service or cost that is reimbursed or otherwise furnished by the sponsor of the clinical trial.

vi. The costs of services which are inconsistent with widely accepted and established national or regional standards of care.

vii. The costs of services which are provided primarily to meet the needs of the trial, including, but not limited to, tests, measurements and other services which are typically covered but which are being provided at a greater frequency, intensity or duration.

viii. Services or costs that are not covered under the patient's contract with the health plan.

SECTION 3. Chapter 176A of the General Laws, as so appearing, is hereby amended by inserting after section 8V the following new section:—

Section 8W.

Any contract between a subscriber and the corporation under an individual or group hospital service plan which shall be delivered or issued or renewed within the commonwealth shall provide for coverage of patient care services furnished pursuant to qualified clinical trials as defined in, and subject to the requirements and limitations of, section 110L of chapter 175.

SECTION 4. Chapter 176B of the General Laws, as so appearing, is hereby amended by inserting after section 4V the following section:-

Section 4W.

Any subscription certificate under an individual or group medical service agreement that shall be delivered, issued or renewed within the commonwealth shall provide for the coverage of patient care services furnished pursuant to qualified clinical trials as defined in, and subject to the requirements and limitations of, section 110L of chapter 175.

SECTION 5. Chapter 176G of the General Laws, as so appearing, is hereby amended by inserting after section 4N, added by chapter 355 of the Acts of 2000, the following new section:—

Section 4O.

Any individual or group health maintenance contract shall provide for the coverage of patient care services furnished pursuant to qualified clinical trials as defined in, and subject to the requirements and limitations of, section 110L of chapter 175.

SECTION 6. This act shall apply to all policies, contracts, plans and certificates of insurance issued or delivered within commonwealth on or after January 1, 2002, and to all policies, contracts, agreements, plans and certificates of insurance in effect before that date upon renewal on or after January 1, 2002.