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COMMISSIONER OF INSURANCE

Bulletin 2002-13

To: **Commercial Health Insurers, Blue Cross and Blue Shield of Massachusetts, Inc. and Health Maintenance Organizations**

From: **Commissioner Julianne M. Bowler** Julianne M Bowler

Re: **Insurance Coverage of Qualified Clinical Trials**

Date: **September 13, 2002**

This Bulletin is to inform carriers of the enactment of 2002 Mass. Acts 257 (Chapter 257), An Act Providing Insurance Coverage of Certain Clinical Trials, which adds the following Massachusetts health insurance statutes:. M.G.L. c. 175, § 110L, c. 176A, § 8X, c. 176B, § 4X, and c. 176G, § 4P. Chapter 257, which was enacted on August 12, 2002, will apply to all policies, contracts, agreements or certificates issued or delivered within the Commonwealth on or after January 1, 2003 and for those in existence before that date, as of the renewal date on or after January 1, 2003. The provisions of these sections do not apply to Medicare Supplement plans or to self-funded health benefit plans administered under the Employee Retirement Income Security Act of 1974 (ERISA) or contracts purchased by a subscriber that is a church or qualified church-controlled organization, as defined in 26 U.S.C. section 3121(w)(3)(A) and (B).

Chapter 257 requires that insured policies, contracts, agreements, plans and certificates of coverage provide coverage for patient care service furnished pursuant to qualified clinical trials to the same extent as they would be covered and reimbursed if the patient did not receive care in a qualified clinical trial. The term "patient care service" is defined as 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.

Chapter 257 further defines a clinical trial to be a "qualified clinical trial" if it meets the following conditions:

(1) the clinical trial is to treat cancer;
(2) the clinical trial has been peer reviewed and approved by one of the following:
  (i) United States National Institutes of Health;
  (ii) a cooperative group or center of the National Institutes of Health;
  (iii) a qualified nongovernmental research entity identified in guidelines issued by the National Institutes of Health for center support grants;
  (iv) the United States Food and Drug Administration pursuant to an investigational new drug exemption;
  (v) the United States Departments of Defense or Veterans Affairs; or
  (vi) with respect to Phase II, III and IV clinical trials only, a qualified institutional review board.
(3) 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 experience;

(4) 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;
(5) the patient meets the patient selection criteria enunciated in the study protocol for participation in the clinical trial;
(6) the patient has provided informed consent for participation in the clinical trial in a manner that is consistent with current legal and ethical standards;
(7) 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;
(8) the clinical trial does not unjustifiably duplicate existing studies; and
(9) the clinical trial must have a therapeutic intent and must, to some extent, assume the effect of the intervention on the patient.

Chapter 257 indicates that coverage for qualified clinical trials shall be subject to all the other terms and conditions of the policy, including, but not limited to, requiring the use of participating providers, provisions related to utilization review and the applicable agreement between the provider and the carrier.

Any questions regarding this bulletin should be addressed to Kevin Beagan, Director, Health Unit of the State Rating Bureau at (617) 521-7347.