105 CMR 724.000: IMPLEMENTATION OF M.G.L. c. 94D; THE CONTROLLED SUBSTANCES THERAPEUTIC RESEARCH ACT

Section

724.001: Purpose and Scope

(A) The purpose of 105 CMR 724.000 is to set forth the requirements for the therapeutic research program in M.G. L. c. 94D.

(B) 105 CMR 724.000 establishes standards and criteria for a therapeutic research program to conduct research and monitor experimentation in the use of marijuana as a therapeutic modality for patients certified to participate in the program.

724.002: Definitions

For the purpose of 105 CMR 724.000, the following definitions apply unless the context or subject matter requires a different meaning.

Commissioner means the Commissioner of Public Health.

Department means the Department of Public Health.

Marijuana means the plant *Cannabis sativa L.*, tetrahydrocannabinol, or a chemical derivative or synthesis of tetrahydrocannabinol.

Patient means a person who has been certified by a physician as eligible for the therapeutic research program in accordance with the provisions of 105 CMR 724.000.

Physician means a person licensed in accordance with the provisions of M.G.L. c. 112, § 2.

Program means the therapeutic research program approved by the Department to conduct research and monitor experimentation in the use of marijuana as a therapeutic modality in alleviating the nausea and ill-effects of cancer chemotherapy and radiation therapy, in decreasing intraocular pressure in patients with glaucoma, and in decreasing airway resistance in patients with asthma.

724.003: Requirements for the Therapeutic Research Program

(A) Patient Eligibility. Eligibility for the therapeutic research program shall be limited to patients who experience the nausea and ill-effects of cancer chemotherapy and radiation therapy; glaucoma patients who experience intraocular pressure from glaucoma; and patients with asthma who experience severe respiratory problems or discomfort.

(B) Supply. The Department shall contract with the National Institute on Drug Abuse, the National Cancer Institute or other manufacturer, distributor or analytical laboratory for the receipt of a supply of analyzed marijuana in accordance with all applicable state and federal laws.

(C) Approval of Institutional Review Board. Prior to the implementation of any study protocol pursuant to the therapeutic research program, the protocol shall undergo the review and approval of an Institutional Review Board in accordance with the provisions of 45 CFR part 46 and 21 CFR part 56, as most recently amended.

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(D) Location of Use. A patient may not use the marijuana provided by the program in the presence of persons under the age of 18, in a moving vehicle, or in a public place, or in any manner inconsistent with the requirements of the program.

(E) Record-Keeping. The therapeutic research program established pursuant to 105 CMR 724.000 shall meet all record-keeping requirements of 21 CFR part 312, as most recently amended.

(F) Reporting.

(1) The Department shall file an annual report of the activities of the program with the Governor and General Court.

(2) The therapeutic research program shall meet all the reporting requirements found in 21 CFR part 312 and 105 CMR 700.009, as most recently amended.

724.004: Certification of Patients for Eligibility in the Therapeutic Research Program

(A) A physician may certify the following types of patients for eligibility to participate in the program:

(1) patients who experience the nausea and ill-effects of cancer chemotherapy and radiation therapy;

(2) glaucoma patients who require the decreasing of intraocular pressure; and

(3) patients with asthma who require the decreasing of airway resistance.

(B) Prior to the participation of a patient in the program, a physician must certify that a patient is eligible for the program by providing the Department with the following information:

(1) that the patient is threatened by loss of life or sight; or, for patients with asthma, that the patient experiences severe respiratory problems or discomfort;

(2) that the patient is not responding to or has incurred severe side effects from the administration of conventional controlled substances;

(3) that the administration of marijuana may have beneficial therapeutic effects upon the patient; and,

(4) that the patient has given in writing his or her informed consent based upon information about the nature, duration, and purpose of the research, the method and means by which it is to be conducted, the inconveniences and hazards reasonably to be expected, and the effects upon the patient's health or person which may reasonably be expected to come from his or her participation.

(C) A physician who intends to certify a patient for eligibility to participate in the program shall obtain the written informed consent of said patient on a form provided by the Department.

(D) A physician who certifies a patient for eligibility to participate in the program shall submit the criteria for such patient's eligibility to the Department on the certification form provided by the Department.

(E) The Department may request additional information from a physician who certifies a patient for eligibility to participate in the program if it deems it necessary.

724.005: Certification and Review of Patients for Participation in the Therapeutic Research Program

(A) The Department shall convene a panel of three physicians appointed by the Commissioner for the purpose of reviewing all certification forms submitted by physicians to the Department for compliance with 105 CMR 724.000

(B) The panel shall conduct a timely review and inform the physician who submitted the certification form of its decision to approve or deny certification of the patient's participation in the program.

(C) All certification forms shall be kept on file at the Department and a copy included in the patient's medical record.

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(D) The records of the Department which are maintained pursuant to the therapeutic research program shall not be deemed to be public records within the meaning of M.G.L. c. 4, § 7.

724.006: Guidelines

(A) The Department shall establish guidelines for the therapeutic research program which shall include, but not be limited to, the criteria for submission of study protocols and the criteria for patient participation in a study protocol.

(B) The Department shall have oversight over any study protocol which is instituted pursuant to 105 CMR 724.000.

724.007: Severability

The provisions of 105 CMR 724.000 are severable. If any provision herein is declared unconstitutional or invalid by a court of competent jurisdiction, the validity of the remaining provisions shall not be so affected.

REGULATORY AUTHORITY:

105 CMR 724.000: M.G.L. c. 94C, § 34; c. 94D.

NON-TEXT PAGE