

John D. Rockefeller IV
Governor



L. Clark Hansbarger, M.D.
Director

State of West Virginia

DEPARTMENT OF HEALTH
CHARLESTON 25305

Notice

Legislative Rule: Regulations for the Establishment of a
Controlled Substances Therapeutic Research
Program and the Certification of Patients,
Practitioners and Hospital Pharmacies

The above titled legislative rule was submitted to the Legislative
Rule Making Review Committee on June 3, 1982.

A handwritten signature in cursive script, appearing to read "L. Clark Hansbarger".

L. Clark Hansbarger, M.D.
Secretary
West Virginia Board of Health

June 3, 1982

Entered

FILED IN THE OFFICE OF
A. JAMES MANCHIN
SECRETARY OF STATE
THIS DATE 7/6/82

FILED IN THE OFFICE OF
A. JAMES MANCHIN
SECRETARY OF STATE
THIS DATE 6/7/82

John D. Rockefeller IV
Governor



L. Clark Hansbarger, M.D.
Director

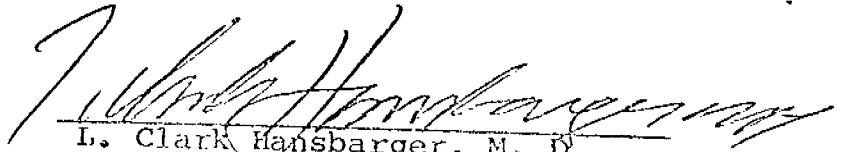
State of West Virginia

DEPARTMENT OF HEALTH
CHARLESTON 25305

Certification

Legislative Rule: Regulations for the Establishment of a Controlled Substances Therapeutic Research Program and the Certification of Patients, Practitioners and Hospital Pharmacies

The above titled legislative rule constitutes the official rule approved by the West Virginia Board of Health on January 22, 1982 and filed pursuant to law in the Office of the Secretary of State, State of West Virginia.


L. Clark Hansbarger, M. D.
Secretary
West Virginia Board of Health

June 3, 1982
Entered

FILED IN THE OFFICE OF
A. JAMES MANCHIN
SECRETARY OF STATE
THIS DATE 7/16/82

FILED IN THE OFFICE OF
A. JAMES MANCHIN
SECRETARY OF STATE
THIS DATE 6/7/82

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WEST VIRGINIA LEGISLATIVE RULES
BOARD OF HEALTH

Regulations for the Establishment of a Controlled Substances
Therapeutic Research Program and the Certification of Patients,
Practitioners and Hospital Pharmacies

Chapter 16-5A
Series I
(1983)

FILED IN THE OFFICE OF
A. JAMES MANCHIN
SECRETARY OF STATE
THIS DATE _____

Regulations for the Establishment of a Controlled Substances
Therapeutic Research Program and the Certifications of Patients,
Practitioners and Hospital Pharmacies

Chapter 16-5A
Series I
(1983)

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WEST VIRGINIA LEGISLATIVE RULES
BOARD OF HEALTH

Chapter 16-5A
Series I
(1983)

FILED IN THE OFFICE OF
A. JAMES MANCHIN
SECRETARY OF STATE
THIS DATE 7/16/82

Subject: Regulations for the Establishment of a Controlled Substances
Therapeutic Research Program and the Certification of Patients,
Practitioners and Hospital Pharmacies.

Section 1. General

1.01. Scope - The West Virginia Code, Chapter 16, Article 5A, Section 1, et sequentia, as amended mandates that the director of the state department of health execute and administer the diagnosis, treatment and care of persons suffering from cancer in accordance with the applicable laws, rules and regulations of the State of West Virginia. Chapter 16, Article 5A, Section 7, of the West Virginia Code of 1931, as amended further mandates the establishment of a controlled substances therapeutic research program.

1.02. Authority - These legislative rules are issued under the authority of and related to Chapter 16, Article 5A, Section 7(a), of the West Virginia Code of 1931, as amended.

1.03. Filing Date - These legislative rules were promulgated on the 29th day of October 1981, and filed on the 6th day of June 1982 in the Secretary of State's office.

1.04. Effective Date - These legislative rules became effective on the 16th day of July 1982 under the provisions of Chapter 29A, Article 3, Section 15 of the West Virginia Code of 1931, as amended.

Section 2. Application and Enforcement

2.01. Application - These legislative rules shall apply to all physicians, pharmacists, hospital pharmacies, health care facilities and patients that are qualified to participate in the hereinafter established controlled substances therapeutic research program.

conducted in accordance with all applicable federal and state laws and all applicable federal and state rules and regulations.

Section 5. Patient Qualification Review Board Established.

5.01. In accordance with Chapter 16, Article 5A, Section 8, of the West Virginia Code of 1931, as amended there is established a Patient Qualification Review Board.

5.02. The director shall appoint a Patient Qualification Review Board comprised of a physician licensed to practice medicine in West Virginia and certified by the American Board of Ophthalmology; a physician licensed to practice medicine in West Virginia and certified by the American Board of internal medicine and also certified in the subspecialty of medical oncology or hematology; and a physician licensed to practice medicine in West Virginia and certified by the American Board of Psychiatry.

5.03. Such appointed physicians shall serve at the will and pleasure of the director.

5.04. The patient qualification review board shall review all applicants for the controlled substances therapeutic research program and their licensed practitioners and certify their participation in the program. Furthermore, such review board shall additionally certify practitioners and licensed pharmacies for participation regarding the distribution of marijuana pursuant to Chapter 16, Article 5A, Section 9, of the West Virginia Code of 1931, as amended.

5.05. The patient qualification review board may include other disease groups for participation in the controlled substances therapeutic research program after pertinent medical data has been presented by a practitioner to both the director and the patient qualification review board.

5.06. Members of the patient qualification review board may be reimbursed for their attendance at meetings at the rate of forty dollars per day. Furthermore, such review board members may be reimbursed for mileage and travel expenses in accordance with the travel rules and regulations of the State of West Virginia and in a format prescribed by the West Virginia department of health. The director may reimburse these expenses from sources of funds available to the department of health.

Section 6. Drug Procurement - Physician Eligibility

6.01. A physician is eligible to prescribe delta-9-THC (marihuana) if he meets the following criteria.

6.01.01 The patient qualification review board shall review and certify physician practioners for participation in the controlled substances therapeutic research program.

6.01.02. Each physician desiring to participate in the controlled substances therapeutic research program shall apply to the patient qualification review board in a format prescribed by such board.

6.01.03. The physician shall document experience in cancer therapy.

6.01.04. The physician shall have a current drug enforcement administration controlled substances registration number.

6.01.05. The physician shall register with a registered pharmacy as hereinafter described and the National Cancer Institute.

6.01.06. The physician shall affirm that the patient has signed an informed consent form. A copy of such signed consent form shall be maintained by the patient qualification review board.

6.01.07. The physician shall limit drug usage to the purposes herein contained.

6.01.08. The physician shall report adverse drug reactions immediately to the Investigational Drug Bank, National Cancer Institute and to the patient qualification review board.

6.01.09. The patient qualification review board shall issue a certificate of registry to each physician meeting the requirements of these rules and regulations. The patient qualification review board may revoke such certificate of registry for good cause shown. Those affected persons desiring a public hearing shall do so in the manner prescribed in and by the West Virginia Rules of Procedures for Contested Case Hearings and Declaratory Rulings, West Virginia State Department of Health, Chapter 16, Series I, dated 1981, as may be amended and further identified as Rules of Procedure for Contested Case Hearings. The aforementioned rules of procedure are incorporated herein by reference.

6.01.10. Physicians wishing to participate in the controlled substances therapeutic research program shall register by completing and signing Federal Drug Administration Form 1573. Upon certification by the patient qualification review board such Federal Drug Administration Form 1573 shall be presented to a registered pharmacy which will submit the form to the National Cancer Institute for approval.

6.01.11. The National Cancer Institute will notify the applicant pharmacy of the physician's eligibility status and the physician will be notified by the registered pharmacy.

6.01.12. Once certified, registered and approved the prescribing physician shall complete a "Research Order for Medication". The Research Order for Medication will be presented to a registered pharmacy by the

and by the West Virginia Rules of Procedure for Contested Case Hearings and Declaratory Rulings, West Virginia State Department of Health, Chapter 16, Series I, dated 1981, as may be amended and further identified as Rules of Procedure for Contested Case Hearings. The aforementioned rules of procedure are incorporated herein by reference.

Section 8. Confidentiality and Report.

8.01. All records of the identity, diagnosis, prognosis or treatment of any patient which are maintained pursuant to the provision of these rules and regulations shall be confidential. The release of such information shall be effected by court order, subpoena duces tecum, or by the written verified authorization of the patient.

8.02. The proceedings of the patient qualification review board shall be closed to the public in accordance with the provisions of Chapter 6, Article 9A, Section 4, or the West Virginia Code of 1931, as amended unless specifically requested by the practitioner, the hospital pharmacy or the patient whose cases are under review and consideration. Such request for an open meeting shall be submitted in writing and made a part of the record.

8.03. Pursuant to the provision of Chapter 16, Article 5B, Section 10 of the West Virginia Code of 1931, as amended, the director in conjunction with the patient qualification review board shall annually report his findings and recommendations to the governor and the legislature regarding the effectiveness of the controlled substances therapeutic research program.

Section 9. Severability - If any provisions of these rules or the application thereof to any person or circumstance shall be held invalid, such invalidity shall not affect the provisions or application of these rules

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Sec. 9.

which can be given effect without the invalid provisions or application, and to this end the provisions of these rules are declared to be severable.