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.

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 6/7/82

John D. Rockefeller IV
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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 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)

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

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Chapter 16-5A
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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 _____ day of _____, 19___, and filed on the _____ day of _____, 19___, in the Secretary of State's office.

1.04. Effective Date - These legislative rules became effective on the _____ day of _____, 19___.

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.

2.02. Enforcement - The enforcement of these legislative rules is vested with the director of the West Virginia department of health or his lawful designee.

Section 3. Definitions

3.01. West Virginia Department of Health - means the public corporation created and empowered by the West Virginia Legislature to develop and to implement a coordinated and comprehensive continuum of health services in the state.

3.02. Director - means the chief executive officer and administrative head of the West Virginia department of health or his lawful designee.

3.03. Marihuana - means marihuana, tetrahydrocannabinols or a chemical derivative of tetrahydrocannabinol.

3.04. Practitioners - means a physician licensed to prescribe and to administer drugs which are subject to the controlled substance act.

Section 4. Controlled Substances Therapeutic Research Program Established.

4.01. In accordance with Chapter 16, Article 5A, Section 7 of the Code of West Virginia, 1931, as amended, there is established a controlled substances therapeutic research program for the benefit of cancer chemotherapy patients who are certified to the patient qualification review board, as hereinafter described, by a qualified practioner as being involved in a life-threatening or sense-threatening situation and who are not responding to conventional controlled substances or where the conventional controlled substances administered have proven to be effective, but where the patient has incurred severe side effects.

4.02. Such controlled substances therapeutic research program shall be

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 Opthalmology; 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 marihuana 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

patient. Such Research Order for Medication is identical to a prescription order. A standard prescription blank may be used, but it must contain a statement that informed patient consent has been obtained.

6.01.13. The quantity of delta 9-THC dispensed is limited to 25 capsules (5mg strength) for each single prescription.

6.01.14. The director shall apply to contract with the National Institute on Drug Abuse or any federally registered distributor or manufacturer for receipt of marihunana pursuant to and in accordance with regulations promulgated by the National Institute on Drug Abuse, the Food and Drug Administration and pursuant to the provisions of these rules and regulations.

6.01.15. The director may cause such analyzed marihuana to be transferred to a certified licensed pharmacy for distribution to a certified patient upon the written prescription of a certified practioner pursuant to the provisions of these rules and regulations.

6.01.16. The physician shall advise the patient as to the effects and possible side effects of the drug (delta 9-THC) prior to the initial administration thereof.

6.01.17. The director shall provide each registered physician and registered pharmacy with a copy of the Group C Guidelines for the use of Delta 9-Tetraydrocannabinol NSC 134454 for Nausea and Vomiting Induced by Antineplastic Chemotherapy, September 1980, Investigational Drug Branch Cancer Therapy Evaluation Program, Bethesda, Maryland.

6.01.18. Delta 9-THC (marihuana) shall be provided to each qualified patient pursuant to these rules and regulations at no cost.

Section 7. Participating Pharmacy Qualifications.

7.01. The patient qualification review board shall review and certify licensed pharmacies for participation in the controlled substances therapeutic research program.

7.02. Each licensed pharmacy 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.

7.03. The patient qualification review board shall limit the certification of pharmacies to those pharmacies that are affiliated with hospitals providing chemotherapy services. Furthermore, such hospital pharmacies shall be open during the regular business hours of the hospital with a registered pharmacist on duty during the hours of such operation.

7.04. The hospital pharmacy shall comply with all federal and state laws, rules and regulations relating to the security and dispensing of Schedule I controlled substances. Furthermore, such participating hospital pharmacies shall be inspected by the director of the West Virginia Department of Health or his lawful designee at least annually to insure compliance with applicable security regulations. Furthermore, such participating hospital pharmacies may be inspected by agencies of the federal government as necessary, to insure compliance with security and dispensing regulations.

7.05. The patient qualification review board shall issue a certificate of registry to each hospital pharmacy 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 hospital pharmacies, desiring a public hearing shall do so in the manner prescribed in

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

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.