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[OAR Docket #16-672; filed 7-7-16]

**TITLE 310. OKLAHOMA STATE
DEPARTMENT OF HEALTH
CHAPTER 15. CLINICAL TRIALS ON THE
USE OF CANNABIDIOL**

[OAR Docket #16-704]

RULEMAKING ACTION:

PERMANENT final adoption

RULES:

- Subchapter 1. Purpose and Definitions [NEW]
- 310:15-1-1. Purpose [NEW]
- 310:15-1-2. Definitions [NEW]
- Subchapter 3. Physician Application and Reporting [NEW]
- 310:15-3-1. Physician application [NEW]
- 310:15-3-2. Physician reporting [NEW]

AUTHORITY:

Oklahoma State Board of Health; Title 63 O.S. Section 1-104 and Title 63 O.S. §§ 2-801 through 2-805

SUBMISSION OF PROPOSED RULES TO GOVERNOR AND CABINET SECRETARY:

September 9, 2015

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December 18, 2015

APPROVED BY GOVERNOR'S DECLARATION:

Approved by Governor's declaration on June 9, 2016

FINAL ADOPTION:

June 9, 2016

EFFECTIVE:

September 11, 2016

SUPERSEDED EMERGENCY ACTIONS:

Superseded rules:

- Subchapter 1. Purpose and Definitions [NEW]
- 310:15-1-1. Purpose [NEW]
- 310:15-1-2. Definitions [NEW]
- Subchapter 3. Physician Application and Reporting [NEW]
- 310:15-3-1. Physician application [NEW]
- 310:15-3-2. Physician reporting [NEW]

Gubernatorial approval:

January 13, 2016

Register publication:

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Docket number:

16-229

INCORPORATIONS BY REFERENCE:

"n/a"

ANALYSIS:

These rules implement the agency's requirements from House Bill Number 2154, from the 1st Session of the 55th Oklahoma Legislature (2015) known as "Katie and Cayman's Law" and codified at 63 O.S. §§ 2-801 through 2-805. The proposed regulations set forth the Department's requirements for the necessary approvals of clinical trials on subjects under the age of 18 for the use of Cannabidiol in treating certain types of seizures as required by the House Bill. Cannabidiol" means a non-psychoactive cannabinoid found in the plant Cannabis sativa L. or any other preparation thereof, that has a

tetrahydrocannabinol concentration of not more than three-tenths of one percent (0.3%) and that is delivered to the patient in the form of a liquid [63 O.S. § 2-801]

CONTACT PERSON:

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PURSUANT TO THE ACTIONS DESCRIBED HEREIN, THE FOLLOWING RULES ARE CONSIDERED FINALLY ADOPTED AS SET FORTH IN 75 O.S., SECTIONS 250.3(5) AND 308(E), WITH AN EFFECTIVE DATE OF SEPTEMBER 11, 2016:

SUBCHAPTER 1. PURPOSE AND DEFINITIONS

310:15-1-1. Purpose

The rules in this Chapter implement the Commissioner of Health's authorities established in Enrolled House Bill Number 2154, from the 1st Session of the 55th Oklahoma Legislature (2015) known as "Katie and Cayman's Law" and codified at 63 O.S. §§ 2-801 through 2-805.

310:15-1-2. Definitions

The following words and terms, when used in this Chapter, shall have the following meaning, unless the context clearly indicates otherwise.

"Clinical Trial" means a trial at an academic medical center of the use of cannabidiol at an academic medical center on patients eighteen (18) years of age or younger pursuant to the requirements of Katie and Cayman's Law, codified at 63 O.S. §§ 2-801 through 2-805.

"O.S." means Oklahoma Statute.

"Severe forms of epilepsy" means refractory epilepsy that is not adequately treated by traditional medical therapies, including Lennox-Gastaut Syndrome and Dravet Syndrome, also known as Severe Myoclonic Epilepsy of Infancy.

SUBCHAPTER 3. PHYSICIAN APPLICATION AND REPORTING

310:15-3-1. Physician application

Any physician, who has been designated a principal investigator of a clinical trial concerning *Lennox-Gastaut Syndrome*, also known as *Severe Myoclonic Epilepsy of Infancy*; any other severe form of epilepsy not adequately treated by traditional medical therapies (63 O.S. § 2-101 (23)), or any other form of refractory epilepsy that is not adequately treated by traditional medical therapies (63 O.S. § 2-801 (5)) on individuals eighteen (18) years of age or younger, and who requests approval from the Commissioner of Health, or designee shall:

- (1) Submit an application on a form provided by the Commissioner of Health, which shall include the name, address and other contact information for the principal investigator;

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- (2) Submit a statement from either the Oklahoma State Board of Medical Licensure or the Oklahoma State Board of Osteopathic Examiners that the physician is licensed and in good standing with said licensure board;
- (3) Submit a copy of the documents from the United States Food and Drug Administration naming the physician as the principal investigator;
- (4) Submit a copy of the license obtained by the United States Drug Enforcement Administration;
- (5) Submit and maintain a current Oklahoma State Bureau of Narcotics and Dangerous Drugs Control registration;
- (6) Demonstrate registration with the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control;
- (7) Submit the names, addresses and other contact information of any subinvestigators who will be assisting the principal investigator and include with the submission:
- (A) A copy of the license obtained by the United States Drug Enforcement Administration; and
- (B) Information demonstrating registration of the subinvestigator with the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control;
- (8) Submit the following information concerning the clinical trial to be performed:
- (A) Name, address and contact information of the academic medical center where the clinical trial will occur;
- (B) Statement from Institutional Review Board (IRB) of the academic medical center where the clinical trial will occur, concurring with the requirements for said clinical trial;
- (C) Statement from the United States Food and Drug Administration allowing cannabidiol to be used as a investigation new drug on qualified patients with severe forms of epilepsy;
- (D) Name, address and other contact information of the source of the cannabidiol to be used for the study. The submission of the information of the source of the cannabidiol shall include:
- (i) Information that the cannabidiol was manufactured at a facility in the United States or in a foreign country that was approved by the United States Food and Drug Administration; and
- (ii) Information that the cannabidiol has been tested on animals to:
- (I) demonstrate preliminary effectiveness; and
- (II) ensure the cannabidiol is safe to administer to humans;
- (E) Submit a statement that the clinical trial will be performed at the highest standards of clinical research; and
- (F) Submit a statement that the clinical trial will conclude no later than December 31, 2017;
- (9) Submit a statement that the principal investigator and all subinvestigators shall adhere to the rules and regulations established by the relevant Institutional Review Board for the clinical trial; and

- (10) Submit an attestation by the principal investigator as to the accuracy and completeness of the information provided in the application.

310:15-3-2. Physician reporting

(a) Any physician approved by the Commissioner of Health or designee to perform a clinical trial, pursuant to this Chapter shall submit annual reports, and a final report, to the Commissioner of Health. The report shall include:

- (1) Data from the clinical trial; and
- (2) Summary of findings from the clinical trial.

(b) Any physician, approved by the Commissioner of Health or designee to perform a clinical trial pursuant to this Chapter shall immediately report to the Commissioner of Health and to the Director of the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control any adverse outcomes or injuries to any subjects participating in the clinical trial.

[OAR Docket #16-704; filed 7-11-16]

TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH CHAPTER 257. FOOD SERVICE ESTABLISHMENTS

[OAR Docket #16-705]

RULEMAKING ACTION:

PERMANENT final adoption

RULES:

Subchapter 1. Purpose and Definitions [AMENDED]
Subchapter 3. Management and Personnel [AMENDED]
Subchapter 5. Food [AMENDED]
Subchapter 7. Equipment, Utensils and Linens [AMENDED]
Subchapter 9. Water, Plumbing and Waste [AMENDED]
Subchapter 11. Physical Facilities [AMENDED]
Subchapter 13. Poisonous or Toxic Materials [AMENDED]
Subchapter 15. Compliance and Enforcement [AMENDED]
Subchapter 17. Mobile Pushcarts, Mobile Food Service Establishments, and Mobile Retail Food Service Establishments [AMENDED]
Appendix A. Tables [NEW]

AUTHORITY:

Oklahoma State Board of Health; Title 63 O.S. Section 1-104 and Title 63 O.S. §§ 1-106.3 and 1-1118.

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