

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

RULEMAKING ACTION:

Notice of proposed PERMANENT rulemaking

PROPOSED RULES:

Subchapter 1. Purpose and Definitions

310:15-1-2. Definitions. [AMENDED]

Subchapter 3. Physician Application and Reporting

310:15-3-1. Physician application. [AMENDED]

SUMMARY:

These proposed regulations, if adopted, will implement the agency's requirements from House Bill Number 2835, from the 2nd Session of the 55th Oklahoma Legislature (2016), codified at 63 O.S. §§ 2-801 through 2-805. The proposed regulations would remove the age limitation for clinical trials on the use of cannabidiol as required by the House Bill.

AUTHORITY:

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

COMMENT PERIOD:

October 3, 2016, through November 3, 2016. Interested persons may informally discuss the proposed rules with the contact person identified below; or may, through November 3, 2016, submit written comment to the contact person identified below; or may, at the hearing, ask to present written or oral views.

PUBLIC HEARING:

Pursuant to 75 O.S. § 303 (A), the public hearing for the proposed rulemaking in this chapter shall be on November 3, 2016, at the Oklahoma State Department of Health, 1000 Northeast Tenth Street, Oklahoma City, OK 73117-1207, in room 1102 beginning at 10:00 a.m. Those wishing to present oral comments should be present at that time to register to speak. The hearing will close at the conclusion of those registering to speak. Interested persons may attend for the purpose of submitting data, views or concerns, orally or in writing, about the rule proposal described and summarized in this Notice.

REQUESTS FOR COMMENTS FROM BUSINESS ENTITIES:

Business entities affected by these proposed rules are requested to provide the agency with information, in dollar amounts if possible, on the increase in the level of direct costs such as fees, and indirect costs such as reporting, recordkeeping, equipment, construction, labor, professional services, revenue loss, or other costs expected to be incurred by a particular entity due to compliance with the proposed rule. Business entities may submit this information in writing through November 3, 2016, to the contact person identified below.

COPIES OF PROPOSED RULES:

The proposed rules may be obtained for review from the contract person identified below or via the agency website at www.health.ok.gov.

RULE IMPACT STATEMENT:

Pursuant to 75 O.S., §303(D), a rule impact statement is available through the contact person identified.

CONTACT PERSON:

Donald D. Maisch, General Counsel, Oklahoma State Department of Health, 1000 N.E. 10th Street, Oklahoma City, OK 73117-1207; phone (405) 271-6017, e-mail: donm@health.ok.gov.

INITIAL RULE IMPACT STATEMENT

(This document may be revised based on comment received during the public comment period.)

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

1. **DESCRIPTION:** *(a brief description of the purpose of the proposed rule [75 O.S. §303.D.2(a)])*
These proposed regulations, if adopted, will implement the agency's requirements from House Bill Number 2835, from the 2nd Session of the 55th Oklahoma Legislature (2016), codified at 63 O.S. §§ 2-801 through 2-805. The proposed regulations would remove the age limitation for clinical trials on the use of cannabidiol as required by the House Bill.
2. **DESCRIPTION OF PERSONS AFFECTED AND COST IMPACT RESPONSE:** *(a description of the classes of persons who most likely will be affected by the proposed rule, including classes that will bear the costs of the proposed rule, and any information on cost impacts received by the agency from any private or public entities [75 O.S. §303.D.2(b)])* Those classes of persons potentially affected are physicians and patients that will be wanting to develop clinical trials for the use of Cannabidiol, as well as the educational facilities where the trials will occur. The costs of compliance of these rules will be to the physicians and the hospitals where the trials will occur. Since there is no fee associated with the filing for the approval, the only cost to the physician and the hospital will be the time needed to fill out and collect the appropriate paperwork.
3. **DESCRIPTION OF PERSONS BENEFITING, VALUE OF BENEFIT AND EXPECTED HEALTH OUTCOMES:** *(a description of the classes of persons who will benefit from the proposed rule [75 O.S. §303.D.2(c)])* The potential benefit will be to the patients who receive the Cannabidiol treatment in the lessening or ceasing of certain seizure events. Additional benefit will be to the physicians and hospitals in determining whether Cannabidiol treatment is effective concerning such seizure events. The Department will track and determine potential benefits through the receipt of reports from any of the approved trials.
4. **ECONOMIC IMPACT, COST OF COMPLIANCE AND FEE CHANGES:** *(a description of the probable economic impact of the proposed rule upon affected classes of persons or political subdivisions, including a listing of all fee changes and, whenever possible, a separate justification for each fee change [75 O.S. §303.D.2(d)])*

While the cost to the physicians or hospitals is unknown at the present time, it is assumed that there will be minimal costs to the physician or hospital if the proposed rules are adopted. Necessary time and equipment will need to be obtained to fill out the forms necessary to obtain approval and to conduct the needed clinical trial.

5. **COST AND BENEFITS OF IMPLEMENTATION AND ENFORCEMENT TO THE AGENCY:** *(the probable costs and benefits to the agency and to any other agency of the implementation and enforcement of the proposed rule, the source of revenue to be used for implementation and enforcement of the proposed rule, and any anticipated effect on state revenues, including a projected net loss or gain in such revenues if it can be projected by the agency [75 O.S. §303.D.2(e)])*

The cost to implement the rule for the Oklahoma State Department of Health is unknown at the present time. If adopted the proposed rules would modify the requirements for physicians and hospitals wanting

to conduct clinical trials on the use of Cannabidiol as a treatment for certain type of seizures, expanding the individuals who may participate in a clinical trial to anyone at any age. These new requirements would increase the cost to the Oklahoma State Department of Health in receiving applications, reviewing applications and issuing approvals for the use of Cannabidiol in clinical trials.

The cost to the Department to implement the amendments will be approximately \$4,419.6 to cover the costs of rule drafting, adoption, publication, distribution, and education. The proposed rules will be implemented and enforced by existing Department personnel and will have no anticipated effect on state revenues.

6. **IMPACT ON POLITICAL SUBDIVISIONS:** *(a determination of whether implementation of the proposed rule will have an economic impact on any political subdivisions or require their cooperation in implementing or enforcing the rule [75 O.S. §303.D.2(f)])*

There will be no economic impact on any political subdivisions.

7. **ADVERSE EFFECT ON SMALL BUSINESS:** *(a determination of whether implementation of the proposed rule may have an adverse economic effect on small business as provided by the Oklahoma Small Business Regulatory Flexibility Act [75 O.S. §303.D.2(g)])¹²*

Since all trials must occur at a research hospital, there will be no impact on small business.

8. **EFFORTS TO MINIMIZE COSTS OF RULE:** *(an explanation of the measures the agency has taken to minimize compliance costs and a determination of whether there are less costly or nonregulatory methods or less intrusive methods for achieving the purpose of the proposed rule [75 O.S. §303.D.2(h)])*

There have been no effort to minimize compliance costs, as all the requirements contained in the proposed regulations are required by the implementing statutory requirements.

9. **EFFECT ON PUBLIC HEALTH AND SAFETY:** *(a determination of the effect of the proposed rule on the public health, safety and environment and, if the proposed rule is designed to reduce significant risks to the public health, safety and environment, an explanation of the nature of the risk and to what extent the proposed rule will reduce the risk [75 O.S. §303.D.2(i)])*

- Explain how this rule supports core public health functions, ensures delivery of essential public health services, and contributes to strategic planning goals and objectives.
- Hyperlinks to published articles on the internet supporting the statement of effects are acceptable.

10. **DETRIMENTAL EFFECTS ON PUBLIC HEALTH AND SAFETY WITHOUT ADOPTION:** *(a determination of any detrimental effect on the public health, safety and environment if the proposed rule is not implemented [75 O.S. §303.D.2(j)])*

It is unknown if there are any detrimental effects on public health and safety if these proposed rules are not adopted.

¹ 75 O.S. § 502. As used in the Oklahoma Small Business Regulatory Flexibility Act:

4. "Small business" means a for-profit enterprise consisting of fifty or fewer full-time or part-time employees.

² 75 O.S. § 504(B). If the proposed rules may have an adverse economic effect upon small business, the agency shall submit a copy of the proposed rules and a rule impact statement to the Small Business Regulatory Review Committee for its review and comment pursuant to the review and comment provisions of paragraph 2 of subsection A and paragraph 6 of subsection B of [Section 303](#) of this title.

11. This rule impact statement was prepared on July 1, 2016. Modifications made subsequent to the publication of the *Notice of Rulemaking Intent* were made on: none. (*the date the rule impact statement was prepared and if modified, the date modified* [75 O.S. §303.D.2(k)])

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

SUBCHAPTER 1. PURPOSE AND DEFINITIONS

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;
- (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.