INITIAL RULE IMPACT STATEMENT

TITLE 442. OKLAHOMA MEDICAL MARIJUANA AUTHORITY

CHAPTER 10. MEDICAL MARIJUANA REGULATIONS

1. DESCRIPTION:

The amendments establish Oklahoma Medical Marijuana Authority as an independent entity as required under SB 1543. The rules adjust references from OAC 442:10-1-1 to OAC 442: Appendix E, replacing: Oklahoma State Department of Health with Oklahoma Medical Marijuana Authority, Department with Authority, and Commissioner with Executive Director. New requirements that commercial growers are prohibited from being within 1,000 feet of a school are adjusted in OAC 442:10-9-3(e)(5). The definition of "public school" is amended to include technology centers in OAC 442:10-1-4. Language establishing a moratorium on processing and issuing new medical marijuana business licenses for growers, processors and dispensaries beginning August 1, 2022 is added to OAC 442:10-5-3(h). New packaging standards allowing transparent packaging and requiring the use of an exit package and specific package warning labels are added to OAC 442:10-7-1(d). Enhanced penalties for unlawful diversion of product by businesses and patients is added to OAC 442:10-2-9, OAC 442:10-4-6, OAC 442:10-5-6.1, and OAC 442:10, Appendix C. The requirement that medical marijuana commercial grow licensees who operate an outdoor medical marijuana facility register with the Oklahoma Department of Agriculture, Food, and Forestry as an environmentally sensitive crop owner is added to OAC 442:10-5-1.1. The requirement that commercial grower licenses to post signage at the site of the commercial grow operation is added to OAC 442:10-6-1. Amendments to OAC 442:10-4-2(e)(2), OAC 442:10-5-2(e) and OAC 442:10-9-2(e) govern material changes that affect a licensee's qualifications for licensure and clarifies that licensees cannot operate under the conditions of a material change until approved in writing by the Authority. Amendments to OAC 442:10-5-2(e)(2)(A)(iv) requires commercial licensees carry a physical copy of the written location change approval while transporting medical marijuana products from location to location. Amendments to OAC 442:10-5-8 remove references to the Medical Marijuana Advisory Council and renumber the subsequent food safety standards for processors section to conform, adjusting internal citations throughout.

Clarification regarding the transporter license issued to qualifying applicants and the application for individual transporter agent licenses is added to OAC442:10-3-1(a). The language regarding "chain of custody" is removed in OAC 442:10-3-6(e) to clarify inventory manifests. OAC 442:10-5-2(k) is amended to reference violations outlined in Appendix C. OAC 442:10-5-6(b)(3)(A) clarifies record retention for both commercial licensees and patient licensees involved in each transaction. OAC 442:10-5-12(c) clarifies the mandatory requirement to use the OMMA provided system for verification of licensees and transactions. OAC 442:10-7-1(g) is amended to require all storage receptacles be labeled with product batch numbers when in use.

Amendments to OAC 442:10-8-1 include clarifying and clean up language. OAC 442:10-8-1(d) allows growers to transfer medical marijuana from harvest batches to processors for decontamination or remediation prior to testing only if the remediated and decontaminated medical marijuana is returned to the originating licensed commercial grower and successfully passes all tests prior to transfer or sale. Provisions regarding the embargo of medical marijuana in OAC 442:10-8-1(g) are amended to no longer conflict with the provisions of 63 O.S. § 427.24. OAC 442:10-8-1(i) removes chemical residue from the list of required tests for production batch samples, requires heavy metal limits be applied to the product from that is submitted at testing, defines a list of terpenoids that must be included in tests for harvest batch and production batch samples, removes the requirement for a continual process of physical inspection, requires harvest batch and production batch samples that are remediated or decontaminated be fully tested and successfully pass all analyses required under this subsection and Appendix F, establishes testing requirements for noninfused pre-rolls, kief, infused pre-rolls, and shake and trim. Amendments to OAC 442:10-8-2 clarify that laboratory accreditation must be specific to the procedure used in the laboratory and

allows a medical laboratory director to delegate in writing the duties and responsibilities to a designee that meets all requirements of a laboratory director, requires all deviations from the written procedure be reviewed and approved in writing by the laboratory director, removes the requirement that any non-routine repair must be reported to and reviewed by the quality assurance laboratory, and provides clarification regarding required staff competency documentation. Amendments to OAC 442:10-8-3 require tamper-proof seals affixed to samples at the time of collection, requires samples be collected in the final form for transfer or sale of harvest batches or production batches, requires copies of the sample field log be maintained by both the laboratory and the commercial licensee from which the samples are being collected, and adds the state inventory tracking system tag number, the sample tag number, and the source package tag number to the list of required items on all COAs. Amendments to OAC 442:10-9-6(c) allow commercial licensees to transport their own waste to a licensed medical marijuana waste disposal facility.

2. DESCRIPTION OF PERSONS AFFECTED AND COST IMPACT RESPONSE:

Primary persons affected by the proposed rules are licensed businesses, though the Agency expects negligible impact. Agency has worked to minimize cost impacts by limiting amendments, both in number and in scope.

3. DESCRIPTION OF PERSONS BENEFITING, VALUE OF BENEFIT AND EXPECTED HEALTH OUTCOMES:

Licensed businesses and patients will benefit from the proposed changes. Businesses will primarily benefit from significantly enhanced clarity throughout, as well as several amendments that are in response to feedback received from the industry. Patients will benefit from additional protections with regards to testing.

4. ECONOMIC IMPACT, COST OF COMPLIANCE AND FEE CHANGES:

The proposed permanent rules are not expected to have an economic impact, cost of compliance, or fee changes.

5. COST AND BENEFITS OF IMPLEMENTATION AND ENFORCEMENT TO THE AGENCY.

The benefits to the Agency are overall clarity of rules for streamlined enforcement, greater transparency within the stream of commerce for regulatory oversight, and enhanced processes for licensed laboratories. There are no expected costs of implementation and enforcement.

6. IMPACT ON POLITICAL SUBDIVISIONS:

There is not expected to be an impact on political subdivisions.

7. ADVERSE EFFECT ON SMALL BUSINESS:

There are no expected adverse effects on small businesses.

8. EFFORTS TO MINIMIZE COSTS OF RULE:

The agency has made efforts to minimize costs by gathering input from the industry on amendments that would benefit both agency and industry, as well as limiting the number and scope of amendments.

9. EFFECT ON PUBLIC HEALTH AND SAFETY:

These proposed permanent rules will preserve the Agency's core functions to protect the health and

safety of all licensees.

10. DETRIMENTAL EFFECTS ON PUBLIC HEALTH AND SAFETY WITHOUT ADOPTION:

There are no identifiable detrimental effects on public health and safety.

11. PREPARATION AND MODIFICATION DATES:

This rule impact statement was prepared on October 25, 2022.