PROPOSED RULE

19 CSR 30-95.060 Infused Products Manufacturing Facility

PURPOSE: Under Article XIV of the Missouri Constitution, the Department of Health and Senior Services has the authority to regulate and control Medical Marijuana Facilities. This rule explains what regulations apply only to Infused Products Manufacturing Facilities.

(1) Infused Products Manufacturing Facility Licenses.
   (A) The number of manufacturing facility licenses will be limited to eighty-six (86) unless the department determines the limit must be increased in order to meet the demand for medical marijuana by qualifying patients.
   (B) A facility license will be issued for a single facility in a single location. Combinations of licenses at the same location must be approved pursuant to 19 CSR 30-95.040(4)(C).

(2) Manufacturing Facility Requirements. In addition to the requirements for manufacturing facilities in 19 CSR 30-95.040, manufacturing facilities shall also comply with the following.
   (A) Facilities must ensure all facility employees are trained in at least the following.
       1. The use of security measures and controls that have been adopted by the facility for the prevention of diversion, inversion, theft, or loss of marijuana;
       2. Proper use of the statewide track and trace system;
       3. Procedures for responding to an emergency, including severe weather, fire, natural disasters, and unauthorized intrusions;
       4. The differences between the types of infused products manufactured at that facility and their methods of production; and
       5. The facility’s safety and sanitation procedures.
   (B) Facilities must develop, implement, and maintain an odor control plan, which shall address odor mitigation practices including, but not limited to, engineering controls, such as system design and operational processes, which shall be reviewed and certified by a professional engineer or a certified industrial hygienist as sufficient to effectively mitigate odors for all odor sources.
   (C) Manufacturing facilities shall not transfer medical marijuana from the facility, except to a testing facility, until the medical marijuana has been tested by a testing facility, according to the provisions of 19 CSR 30-95.070, and the manufacturing facility has received verification from the testing facility that the medical marijuana passed all required testing.
   (D) Manufacturing facilities may only transport medical marijuana:
       1. That the facility manufactured;
       2. To a dispensary, testing, or other manufacturing facility;
       3. If the facility complies with the requirements of 19 CSR 30-95.100(2).
   (E) Manufacturing facilities that produce ingestible medical marijuana-infused products shall comply with the applicable food safety standards set forth in 19 CSR 20-1.025, 1.040, and 1.050,
as applicable. Such facilities are prohibited from producing frozen desserts, as defined by 19 CSR 20-1.030, or acidified foods, as defined by 19 CSR 20-1.042.

(F) Manufacturing facilities shall store all medical marijuana—
   1. At the approved location of the facility; or
   2. In offsite warehouses that comply with the security requirements of 19 CSR 30-95.040(4)(H), the location requirements of 19 CSR 30-95.040(4)(B), and that have been approved pursuant to 19 CSR 30-95.040(3)(C).

(G) Manufacturing facilities that use volatile solvents shall install air-handling systems and other controls designed to minimize the risks of explosions and fires. These controls should include systems to prevent ignition; plans for safe storage, use, and disposal of solvents; and policies for continuous staff monitoring of all processes involving volatile solvents.

**AUTHORITY:** Sections 1.3.(1)(b), 1.3.(2), and 1.3.(3) of Article XIV, Mo. Const. Original rule filed May 24, 2019. Emergency rule filed May 24, 2019, effective June 3, 2019, expires February 27, 2020.

**PUBLIC COST:** This proposed rule will cost state agencies or political subdivisions less than five hundred dollars ($500) in the aggregate.

**PRIVATE COST:** This proposed rule has an estimated cost to private entities of at least $4,300,000 in the aggregate.

**NOTICE TO SUBMIT COMMENTS:** Anyone may file a statement in support of or in opposition to this proposed rule with Lyndall Fraker, PO Box 570, Jefferson City, MO 65102 or via email at MMPublicComment@health.mo.gov. To be considered, comments must be received within thirty (30) days after publication of this notice in the Missouri Register. No public hearing is scheduled.