

## Summary Information on Emergency Rule Changes to OAC 475 Regarding Medical Marijuana

There have been questions regarding the recent emergency rule changes to Oklahoma Administrative Code (OAC) 475, specifically those affecting Medical Marijuana Registrants. The rules can be found in their entirety on the OBN website at <https://www.ok.gov/obn/dd/>, under the “Rules and Regulations” tab at the left side of the page. Each emergency rule has an accompanying impact statement that can provide clarity. The impact statements can also be located under the “Rules and Regulations” tab.

For some time, Oklahoma Statute has tasked the Oklahoma Bureau of Narcotics (OBN) with registering and regulating manufacturers, processors, and distributors of controlled dangerous substances (CDS), as well as those allowed to prescribe, administer, and dispense CDS. Some examples of registrants are drug manufacturers, doctors, and laboratories authorized to test CDS. The rules require all registrants to have effective controls and procedures to guard against theft and diversion. OBN works closely with other regulatory bodies such as the Oklahoma Board of Medical Licensure and Supervision, the Oklahoma Board of Osteopathic Examiners, the Oklahoma Board of Pharmacy, and many others. OBN maintains ongoing efforts to keep OAC 475 in harmony with statute, rules from other agencies, and meet changing needs.

There is a very specific process to change administrative rules. From time to time, rules need to be changed prior to the normal rule change schedule. Emergency rules fill this gap. While the process can be quite complex, a simplified version is that the emergency rule is drafted to meet the need(s). The proposed rule changes are then sent to the Governor’s Office for approval or denial. In this case, emergency rules were submitted to the Governor’s Office on December 12<sup>th</sup>, 2018. Emergency rules must be submitted during the next legislative session for conversion to “permanent” rules. This permanent rule process involves posting the rules, a 30-day public comment period, a public hearing, as well as other requirements.

OBN recognizes the medical marijuana industry has several unique needs. Many of the rules prior to the emergency rules, particularly those that specified security protocols and incorporated federal code, would have been difficult, if not impossible, for the medical marijuana industry. Where possible, rule changes were adopted to utilize and accept Oklahoma Medical Marijuana Authority (OMMA) requirements for reporting to avoid duplication of effort by the commercial entity. Following are some key points regarding the recent emergency rule changes.

### Authority

- Every person who manufactures, distributes, dispenses, prescribes, administers, or uses for scientific purposes any controlled dangerous substance within this state shall obtain a registration issued by the Director of OBN in accordance with rules promulgated by the Director. *See* 63 O.S. §2-302(A).
- Marijuana is a Schedule I Controlled Dangerous Substance. *See* 63 O.S. §2-304(C)(12).
- *Gregg v. Oklahoma ex rel. Okla. Dep't of Health*, No. CV-2018-1416 (Clev. Cty. Aug. 21, 2018) (Tupper, J.) Eighteen plaintiffs challenged 21 separate regulations promulgated by the Oklahoma Board of Health, including:
  - OAC 310:681-1-5, which recognized that OBN's registration requirements continue to apply to marijuana; and

- OAC 310:681-5-10, which recognized that OBN's waste and disposal laws continue to apply to marijuana.
- The Court held:
  - that the *State Question does not explicitly repeal other portions of Oklahoma statutes that already regulated medical marijuana*, and food and drug products more generally, including the Oklahoma Public Code, 63 O.S. Section 1-101 et seq., as well as the Uniform Controlled Dangerous Substances Act, Title 63 O.S. 2-101 et seq. Therefore, the Court needs to *read 788 in harmony, to the extent possible, with preexisting statutes* (emphasis added).
- The Court also held that "nothing in the State Question explicitly or implicitly declared that marijuana is no longer a controlled dangerous substance. It is."

### Notice to Registrants

- OAC 475 only applies to those required to register with OBN. In the case of medical marijuana, it only applies to commercial entities, NOT patients.
- Upon completion of the registration process, each registrant receives a notice letter that states, "You should familiarize yourself with OBNDD Registration Statutes and Rules in Title 63 and 475, which you can find on our website at [www.ok.gov/obnidd](http://www.ok.gov/obnidd) on the left menu under RULES AND REGULATIONS".

### Emergency Rule Changes

- Chapter 10
  - The rule changes provide manufacturers with the ability to conduct chemical analysis of Schedule I medical marijuana, which in turn will provide a benefit to those consuming medical marijuana. The public's health and safety will also benefit by providing an avenue to see any schedule limitations that have been placed on an OBNDD registration such as Schedule I medical marijuana.
- Chapter 20
  - 20-1-3
    - This section references a Code of Federal Regulations (CFR) that requires CDS to be stored in a secured steel cabinet or vault. The change applies to medical marijuana retailers and allows medical marijuana retail storage facilities to use a separate set of requirements, more in line with the needs of the industry.
  - 20-1-4
    - This section references a CFR that regulates CDS in a manufacturing area. This change allows medical marijuana facilities to use a separate set of requirements, more in line with the needs of the industry.

- 20-1-5
  - This change adopts OMMA rules for transit requirements.
  - This change adopts criminal history requirements of 63 O.S. § 420A for medical marijuana registrants, which only prohibits registrants from having a felony conviction within the previous two years or a violent felony conviction in the previous five years. The criminal history requirements remain unchanged for other registrants, which prohibits those registrants or employees from having a conviction or deferred sentence for any felony, or a conviction or deferred sentence for a misdemeanor or felony relating to CDS.
- Chapter 25
  - The rule amendments provide the same requirements set forth in the rules of OMMA for maintenance of records, reports, and inventory tracking (*see* OAC 310:681-5-6). The rule amendments also allow qualitative and quantitative analysis to be conducted on samples for quality control, consumer information, and product safety. The previous rule prohibited release of quantitative analysis results on CDS. Samples no longer have to be anonymous.
- Chapter 30
  - The rule amendment provides that labeling for Schedule I medical marijuana shall be in accordance with rules promulgated by the OMMA (*see* OAC 310:681-7-1).
- Chapter 35
  - This rule change provides that disposal for Schedule I medical marijuana shall be in accordance with the Uniform Controlled Dangerous Substances Act and the rules of the Oklahoma Department of Environmental Quality. Transfers of Schedule I medical marijuana **will not** require the use of forms in accordance with the CFR, but will require Schedule I medical marijuana registrants to comply with transfer rules promulgated by OMMA.
- Chapter 40
  - The rule amendment provides that Schedule I medical marijuana registrants are subject to administrative inspections that shall include, but not be limited to, inspecting, copying, and verifying the correctness of records, reports, or other documents required to be kept pursuant to OMMA (*see* OAC 310:681-5-6) and applicable state statutes and rules. This rule adopts the OMMA format for records to reduce duplication on the part of medical marijuana registrants. All registrants are subject to administrative inspection.