Report of the Joint Committee on Administrative Rules

November 2023

November 14, 2023

Dean Plocher, Speaker
House of Representatives
State Capitol Building
Jefferson City, MO 65101

Caleb Rowden, President Pro Tem
Missouri Senate
State Capitol Building
Jefferson City, MO 65101

Dear Mister Speaker and Mister President Pro Tempore:

The Joint Committee on Administrative Rules has met, taken testimony, deliberated and concluded its review of the rules promulgated in 19 CSR 100 and the Department of Health and Senior Services, Division of Cannabis Regulation's guidance documents and waivers. The below listed committee members are pleased to submit the attached report:

Chair, Senator Nick Schroer	Vice-Chair, Representative Alex Riley
Senator John Rizzo	Representative Ben Baker
Senator Holly Thompson Rehder	Representative Peter Merideth
Senator Curtis Trent	Representative Louis Riggs
Senator Barbara Washington	Representative David Tyson Smith

Introduction

The Joint Committee on Administrative Rules (JCAR or "The Committee") may "review all rules promulgated by a state agency after January 1, 1976" and "to take such actions as it deems necessary, including holding hearings."[1] The Committee held a hearing on October 18, 2023. They invited the Department of Health and Senior Services, Division of Cannabis Regulation ("DCR"), members of the cannabis industry, and the public to present testimony regarding the implementation of the rules promulgated by the DCR in 19 CSR 100 and subsequent guidance documents, variances, and waivers issued by the DCR to determine if these guidance documents, variances, and waivers complied with rulemaking procedures in Missouri.

Properly promulgated rules in Missouri have the force of law. Section 536.010.6 defines "rule" as "each agency statement of general applicability that implements, interprets, or prescribes law or policy, or that describes the organization, procedure, or practice requirements of any agency."[2] Section 536.021 and other sections of Chapter 536 mandate the procedure for proposing, adopting, amending, or rescinding rules. That procedure includes filing the proposed rule or amendment with the Secretary of State and with the Joint Committee on Administrative Rules, an opportunity for public comment, and filing a final order of rulemaking the Joint Committee on Administrative Rules, and if the Committee does not take action, filing the final order with the Secretary of State. The final rules are published by the Secretary of State in the *Code of State Regulations*.

This system of rule promulgation serves many purposes. It allows public notice and input on the policies the agency is adopting. It gives the Legislature an opportunity to provide oversight to the Executive Branch's implementation of policy – serving as part of our system of checks and balances. It protects both consumers and regulated industries by ensuring that all statements of general applicability that have the force of law are found in one place and citizens do not have to check numerous websites or publications to know what to expect from their government regulators.

Additionally, if an agency enforces a statement of general applicability that was not promulgated as a rule, it costs the state resources, in both time and money. Section 9 of 536.021 states that:

> If it is found in a contested case by an administrative or judicial fact finder that a state agency's action was based upon a statement of general applicability which should have been adopted as a rule, as required by sections 536.010 to 536.050, and that agency was put on notice in writing of such deficiency prior to the administrative or judicial hearing on such matter, then the administrative or judicial fact finder shall award the prevailing nonstate agency party its reasonable attorney's fees incurred prior to the award, not to exceed the amount in controversy in the original action.

[1] RSMo §536.037.3

[2] There are thirteen exceptions to this general definition, none of which are applicable here.

The citizens of Missouri passed Amendment 3 in November of 2022. It mandated that the Department of Health and Senior Services promulgate rules to govern the newly legalized recreational cannabis industry and make certain modifications to the previously regulated medical cannabis industry. On January 20, 2023, DCR filed nineteen (19) proposed rules to fulfill this mandate. Pursuant to Chapter 536, DCR gathered public comment. On April 14, 2023, DCR filed final orders of rulemaking with JCAR. JCAR held a hearing on the rules on May 4, 2023. As a result of that hearing, DCR filed amended orders on six (6) rules. JCAR waived its thirty day review period and all nineteen (19) rules went into effect on July 30, 2023.

Subsequently, DCR has published numerous guidance documents that purport to explain how the DCR interprets the promulgated rules.[3] The DCR contends that it needs to be able to publish these types of guidance documents because it is answering questions from licensees.

[3] https://health.mo.gov/safety/cannabis/facility-comms-guidance.php

Summary of Public Testimony

On October 18, 2023, the Joint Committee on Administrative Rules held a hearing to discuss the rules in 19 CSR 100. Specifically, JCAR was concerned that several statements issued by the Department and referred to as "Guidance," "Variances," or "Waivers":

- are statements of general applicability that, pursuant to Chapter 536 should have been promulgated as rules; and
- are statements of general applicability that expanded on or contradicted the promulgated rules that were previously reviewed by the Committee.

Amy Moore, the Director of the Missouri Department of Health and Senior Services, Division of Cannabis Regulation, and Ben Terrell, Legislative Director, Missouri Department of Health and Senior Services, testified on behalf of DCR. DCR contended that the guidance documents issued, specifically the *Packaging, Labeling and Product Design Guide* published on their website at https://health.mo.gov/safety/cannabis/pdf/packaging-labeling-and-product-design-guide-072023.pdf in July 2023 are guidance and are meant to clarify the rules and answer questions that licensees have been asking DCR. They also emphasized that if a licensee were to be disciplined, that discipline would be based on the statutes or promulgated rules, not on the *Packaging, Labeling and Product Design Guide*. DCR also correctly contended that the rules themselves give them the ability to issue waivers to change the effective date of rules and waivers to institute alternative ways to meet the requirements for some rules.

Chris McHugh of Vertical Enterprise, LLC, who owns several licensed entities, testified regarding his experience with the Division of Cannabis Regulation's rules and guidance documents. He stated that DCR's Compliance Officers site the guidance documents and enforce them during their inspections.

Eric Walters, an attorney for several cannabis licensees, testified regarding his clients' experience with the Division of Cannabis Regulation's rules and guidance documents.

JCAR also received a letter from Lowell Pearson, attorney with Husch Blackwell, who represents several cannabis licensees regarding the DCR's guidance documents.

Findings

JCAR finds that the statutory process for the promulgation pursuant to Chapter 536 of any statement of general applicability by an agency is necessary to ensure the checks and balances of our government and to protect the rights of citizens of this State. When those rules are regarding cannabis regulation, that process is also necessary to protect consumers of cannabis products by ensuring that the products they purchase are being held to the promulgated safety standards. The rule promulgation process also protects the licensed industry by providing input into the rulemaking process, stability of the regulatory framework of the state, and predictability of the regulatory burden imposed on the industry. The general principal in our law is that an agency has no authority to issue a statement of general applicability that implements, interprets, or prescribes law or policy or that describes the organization, procedure, or practice requirements of any agency, outside of the formal rule promulgation process in Chapter 536 other than found in a regulation that allows waivers.

JCAR finds this situation is analogous to that reviewed by the Missouri Supreme Court in *Missouri Association of Nurse Anesthetists, Inc. v. State Board of Registration for the Healing Arts,* 343 S.W.3d 348 (2011). Just as the DCR has done in this case, in *Missouri Association of Nurse Anesthetists (MoANA),* the Board of Registration for the Healing Arts (the Board), issued a letter answering a licensee's question regarding whether a physician could delegate a certain procedure to advanced practice nurses (APNs). The letter stated, "Based on the information provided to the Board, it was their opinion that [APNs] currently do not have the appropriate training, skill or experience to perform these injections." No rulemaking procedures were followed in issuing this letter. The Missouri Association of Nurse Anesthetists, Dr. Glenn Kunkel, and a nurse sued for a declaratory judgement pursuant to section 527.120, RSMo. Separately, the Board also filed an administrative complaint seeking discipline against Dr. Kunkel alleging that he had improperly delegated the procedure discussed in the latter to an APN. The discipline cited the statute prohibiting improper delegation, not the letter.

The Court found that the statement in the letter issued by the Board constituted a statement of general applicability because it was not confined to a specific set of facts and had a future effect and potential impact on a physician wanting to delegate the specified procedure to an APN and it interpreted law and proscribed policy, and therefore it required promulgation. While the Court found that the letter was not a "rule" because it wasn't promulgated, they issued an injunction prohibiting the Board from enforcing the letter.

Similarly, in this case, the Department has issued a *Packaging, Labeling and Product Design Guide*, as well as other statements, which were not promulgated as a rule. The *Packaging, Labeling and Product Design Guide* contains numerous statements of general applicability, which interpret law and proscribe policy, as outlined below.

DCR relies on the case *United Pharmacal Co. of Missouri, Inc. v. Missouri Board of Pharmacy*, 159 S.W.3d 361 (2005). In that case a pharmacy sought a declaratory judgement under §536.050, RSMo as to whether the Board of Pharmacy's publishing of Frequently Asked Questions, with answers (FAQ), was a valid rule. The Board of Pharmacy issued a cease and

desist letter to United Pharmacal, demanding it end the practice addressed in the FAQ and citing statutory authority for that position.

The Court found that the FAQ was not a valid rule because it hadn't been promulgated and was void with no effect under §536.050. While the Court's analysis of the issue of whether the FAQ was a valid rule is instructive, the Court only determined that the FAQ was not a rule under Chapter 536 and therefore United Pharmacal was not entitled to relief under Chapter 536. It did not determine if the FAQ was a statement of general applicability that should have been promulgated as a rule.

Importantly, *MoANA* and *United Pharmacal* answered different questions. DCR is correct that *United Pharmacal* supports their position that these statements are not "rules" because DCR did not promulgate them as rules. However *MoANA*, stands for the position that an agency cannot issue statements of general applicability without going through the rule promulgation process. DCR relies on the fact that any discipline issued will cite the promulgated rule, not the guidance statement. The Board in the *MoANA* case made the same argument. The Court held that was irrelevant and the issuing of the statement was not legal because it was a statement of general applicability and should not have been issued outside of the rulemaking process. They pointed out that even if the Board said it was not disciplining a licensee based on the statement, the statement was in fact a statement of general applicability in that the statement was not confined to a specific set of facts and had a future effect and potential impact on a physician wanting to delegate the specified procedure to an APN and it interpreted law and proscribed policy. Similarly, the statements below by DCR interpret law and prescribe policy and have had a future effect and potential impact on a licensee wanting to engage in a particular proscribed activity. For example, their statement that "'Limited colors' means that the entire package must be limited to only one main color and any additional colors that are part of up to two logos" will have the effect of licensees designing packaging without shade or gradients of color.

While DCR is correct that "Not everything written or published by a state agency is an administrative rule," when the statement written or published is a statement of general applicability, it is a rule and must be promulgated as a rule. [4]

JCAR specifically finds that the following statements that appear in guidance statements published by DCR meet the definition of rule under §536.010(6) in that they are statements of general applicability that implement, interpret, or prescribe law or policy or describe the organization, procedure, or practice requirements of DCR. Additionally, JCAR finds, pursuant to *Missouri Association of Nurse Anesthetists, Inc. v. State Board of Registration for the Healing Arts,* 343 S.W.3d 348 (2011) the following are statements of general applicability in that they are not confined to a specific set of facts and have a future effect and potential impact on DCRs licensees and cannabis consumers. DCR does not have authority to issue the following statements outside of the rule promulgation process in Chapter 536 and these statements do not have any effect.

[4] *United Pharmacal Co. of Missouri, Inc. v. Missouri Board of Pharmacy*, 159 S.W.3d at 365.

- "Shape of a human includes figures such as an alien or robot."[5] This statement interprets 19 CSR 100-1.120(1)(B)1's which says in part that "no marijuana product or packaging may be designed using the shape or any part of the shape of a human. . ."

- "'Limited colors' means that the entire package must be limited only one main color and any additional colors that are part of up to two logos."[6] This interprets 19 CSR 100-1.120(1)(B)5.A. which says in part, "All marijuana product packaging design . . . may only utilize . . .A. limited colors. . ."

- "The primary color may not include patterns or additional shades/gradients of the package's chose primary color."[7] This interprets 19 CSR 100-1.120(1)(B)5.A. which states in part "All marijuana product packaging, design . . . may only utilize – A. Limited colors, including a primary color. . . ."

- "QR Code may not include a logo or image."[8] This interprets 19 CSR 100-1.120(1)(B)5.E. which states, "All marijuana product packaging, design . . . may only utilize – E. A QR code linking to a website where a purchaser can learn more about the product."

- "QR code may only be in black or white."[9] This interprets 19 CSR 100-1.120(1)(B)5.E. which states, "All marijuana product packaging, design . . . may only utilize – E. A QR code linking to a website where a purchaser can learn more about the product."

- "Each individual licensee must receive approval for each different final marijuana product SKU produced by the licensee."[10] This interprets 119 CSR 100-1.120(2) which states that "Prior to use, all marijuana product designs, packaging designs, and label designs must be submitted to the department for review of compliance with section (1) of this rule."

- The underlined portion of the statement "Licensees are required to list out all ingredients used in their final marijuana product, in descending order of predominance for each ingredient."[11] This interprets 19 CSR 100-1.120(1)(C)2.A. which states that "All active and other ingredients, which shall not include groupings of ingredients that obscure the actual ingredients, such as natural flavors or 'botanically derived terpenes' and shall include solvents used in the manufacturing process."

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[5] *Product Labeling and Design Guide* (July 2023), page 3.
[6] *Product Labeling and Design Guide* (July 2023), page 5.
[7] *Product Labeling and Design Guide* (July 2023), page 6.
[8] *Product Labeling and Design Guide* (July 2023), page 7.
[9] *Product Labeling and Design Guide* (July 2023), page 7.
[10] *Product Labeling and Design Guide* (July 2023), page 7.
[11] *Product Labeling and Design Guide* (July 2023), page 10.

- The requirement that in addition to a photo of the packaging, that 19 CSR 100-1.120(1)(B)6. requires licensees to upload separate pdfs of each logo or symbol, a pdf of the QR code, a certification of child resistant packaging, a package specification sheet, a packaging manufacturer's food grade statement or certificate of FDA compliance are required to be submitted to comply with "Item Approval Application Checklist" and obtain package approval. [12]

[12] "Item Approval Application Checklist" (September 8, 2023)

Recommendations

JCAR recommends:

1. This report will be forwarded to the House Budget Committee, the Senate Appropriations Committee, members of the House and Senate, and the Governor's Office. Copies will also be made available to the public upon request.

2. DCR should follow the requirements of Chapter 536 when issuing any statement of general applicability.

3. DCR should remove from its website or other publications any statements of general applicability that are not contained in properly promulgated rules.