



Common Sense Initiative

Mike DeWine, Governor
Jon Husted, Lt. Governor

Carrie Kuruc, Director

MEMORANDUM

TO: Ali Simon, State of Ohio Board of Pharmacy

FROM: Ethan Wittkorn, Regulatory Policy Advocate

DATE: November 18, 2020

RE: CSI Review – Medical Marijuana (OAC 3796:7-1-01, 3796:7-2-01, 3796:7-2-04, 3796:7-3-01, 3796:8-1-01, 3796:8-2-03, 3796:8-2-04, and 3796:8-2-06)

On behalf of Lt. Governor Jon Husted, and pursuant to the authority granted to the Common Sense Initiative (CSI) Office under Ohio Revised Code (ORC) section 107.54, the CSI Office has reviewed the abovementioned administrative rule package and associated Business Impact Analysis (BIA). This memo represents the CSI Office's comments to the Board as provided for in ORC 107.54.

Analysis

This State of Ohio Board of Pharmacy (Board) rule package consists of six amended rules, one rescinded rule, and one new rule. This rule package was submitted to the CSI Office on May 8, 2020 and the public comment period was open through May 25, 2020. Unless otherwise noted below, this recommendation reflects the version of the proposed rules filed with the CSI Office on May 8, 2020.

This rule package proposes regulations for Ohio's medical marijuana industry and its patients. Rules in this package outline the registration process for patients, purchase processes, fee structures for patients and caregivers, forms of medical marijuana including those that may be attractive to children, and portion, dosing, and unit requirements of marijuana sold at dispensaries. One new rule is proposed to establish a 90-day supply maximum for all approved medical marijuana forms, replacing an existing version of the rule. Additionally, amendments to the rules proposed to standardize terms, remove passports as viable forms of identification, remove requirements that terminally ill patients be recertified every six months, update terminology, add a requirement that packaging contain a symbol denoting it contains marijuana, and add flexibility to allow products' THC and CBD levels to be within 10 percent of target amounts.

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117

CSIPublicComments@governor.ohio.gov

During the period of early stakeholder outreach, the Board posted the proposed rules on the Ohio Medical Marijuana Control Program website to solicit comments. The Board also contacted representatives of dispensaries and members of the Ohio Medical Marijuana Advisory Committee regarding changes to the 90-day patient supply calculations. Based on stakeholder feedback, the Board made changes to the proposed rules that included the removal of plant material tiers from rules on marijuana quantities available for purchase, widening THC and CBD target ranges from 5% to 10%, and establishing 45-day fill periods.

During the CSI public comment period, the Board received several comments on the proposed rules. Comments led to changes reinstating a passport along with two supporting documents as acceptable proof of Ohio residency and changes granting the Board flexibility to include additional programs that determine indigent status. The Board also removed requirements of target CBD on applications for a product identifier, moved labeling requirements for the use of a universal symbol to a different rule (OAC 3796:6-3-09) to avoid confusion, removed the phrase “cookie or other confection” from the rules to avoid confusion with allowable edibles, and increased single portion doses for oral administration in OAC 3796:8-2-06 to 55mg. Additional changes increased THC variances from 5% to 10%.

Stakeholders also raised concerns about the proposed language to reduce the allowable whole day unit of plant material from 2.83 grams to 2.52 grams. They cited the potential costs that such a change would place on their businesses, some suggesting that implementation costs could approach \$270,000 due to required equipment updates and packaging changes. The Ohio Medical Cannabis Industry Association (OMCIA) proposed that the Board address the adverse impact caused by the reduction in the allowable whole day unit by increasing the 90-day limit from the current eight-ounces to nine ounces (and therefore keep the whole day unit at 2.83 grams). The OMCIA said that this change would resolve the existing mathematical discrepancies while preventing stakeholders from incurring adverse impacts.

The Board declined to adopt stakeholders’ suggestions and argued that packaging costs could be controlled by packaging products in different unit sizes and that one-time costs to processors could be offset by allowing time to implement changes and deplete their current inventory.

Impacted communities include medical marijuana patients, caregivers, dispensaries, cultivators, and processors. Adverse impacts of the rules beyond those stated above include annual examinations by a physician for a patient to receive a medical marijuana recommendation, a \$50 registration fee for patients and a \$25 registration fee for caregivers, reporting of necessary documents, and packaging modifications to meet new size and labeling requirements. The Board states that costs associated

with compliance to the rules includes an estimated one-time expenditure for staff training and packaging costs to comply with updated packaging standards, as well as costs associated with training dispensary staff on the new one-day supply calculations. However, some stakeholders dispute the Board's characterization of the financial impact of the changes, as noted above.

Recommendation

The Board is statutorily obligated under ORC 3796.04 to specify by rule a maximum 90-day supply of medical marijuana a person can possess. Given the adverse impact the adjustment of the whole day unit that makes up that 90-day supply will have on packaging costs for regulated entities, CSI recommends that the Board continue to engage stakeholders to find an agreeable effective date for the proposed change. The Board should consider the amount of time necessary for stakeholders to use remaining labels and to sell remaining inventory in packaging allowed under current rules.