

State of Ohio Board of Pharmacy - Hearing Summary Report

Hearing Date: 3/11/2022

Today's Date: 6/15/2022

Rule Number(s):

Rule Number	Туре	Tagline
3796:8-2-02	Amend	Establishment of additional forms or methods of administration.
3796:8-2-05	Amend	Assignment of a product identifier.
3796:8-3-01	Amend	Product identifier fee.
3796:6-3-01	Amend	Dispensary operations generally.
3796:6-3-02	Amend	Dispensary premises generally.
3796:6-3-03	Amend	Hours of operation.
3796:6-3-05	Amend	Medical marijuana dispensary designated representative.
3796:6-3-06	Amend	Receipt of medical marijuana by a dispensary.
3796:6-3-08	Amend	Dispensing of medical marijuana.
3796:6-3-11	Rescind	Duty to report.
3796:6-3-11	New	Duty to report.
3796:6-3-12	Amend	Dispensing error reporting.
3796:6-3-13	Amend	Review of dispensing errors.
3796:6-3-14	Amend	Destruction and disposal of medical marijuana.
3796:6-3-15	Amend	Dispensary patient and caregiver educational materials.
3796:6-3-16	Amend	Monitoring, surveillance, and security requirements.
3796:6-3-17	Amend	Record keeping requirements.
3796:6-3-18	Rescind	Confidentiality of patient records.
3796:6-3-18	New	Release of records related to patient transactions maintained by dispensaries.
3796:6-3-19	Amend	Employee training requirements.
3796:6-3-20	Amend	Medical marijuana dispensary internal inventory control system.
3796:6-3-21	Amend	Recall procedures.
3796:6-3-22	Amend	Prohibitions.
3796:6-3-23	Amend	Dispensary access.
3796:7-2-02	Amend	Caregiver eligibility.
3796:7-2-03	Amend	Procedure for caregiver registration.
3796:7-2-07	Amend	Duty to report.
3796:7-2-08	Amend	Grounds for discipline.
3796:7-2-09	Amend	Suspension of a patient or caregiver registration without a hearing.
3796:7-2-10	Rescind	Confidentiality of patient records at hearing.
3796:7-2-10	New	Confidentiality of patient-identifying information at adjudication hearings.
3796:7-2-11	New	Release of registered patient information maintained by the state board of pharmacy.
3796:7-2-12	New	Suspension of Access to Patient Information.
3796:6-4-02	Amend	Compliance and inspection of medical marijuana dispensaries.

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3796:6-4-03	Amend	Grounds for discipline.
3796:6-4-05	Amend	Suspension of a dispensary employee license without a hearing.
3796:6-4-06	Amend	Suspension of a dispensary provisional license or certificate of operation without a hearing.
3796:6-4-07	Amend	Failure to properly store medical marijuana.
3796:6-4-09	Amend	Interagency cooperation.
3796:6-5-01	Amend	Medical marijuana dispensary fee structure.

<u>List organizations or individuals giving or submitting testimony before, during or after public hearing and indicate the rule number(s) in question.</u>

• GTI Ohio, LLC

Consolidated Summary of Comments Received

- 3796:6-3-01: Instead of requiring a separate security badge for every employee for each dispensary location, GTI recommends requiring one badge per employee for all licensed facilities that employee is required to have access to where each approved location can be disclosed on the license.
- 3796:6-3-05: GTI recommends maintaining the original provision that provides a process for unforeseen circumstances (situation of death, incapacity, or termination of an employee).
- 3796:6-3-08: GTI recommends the Board allow the ability to offer online payment to streamline curbside pickup at dispensary locations.
- 3796:6-3-08: GTI recommends the Board consider allowing licensed employees to conduct home delivery under a strict regulatory structure.
- 3796:6-3-17: GTI recommends a technical language change to clarify that the third-party service providers have their own employees that physically secure the records, therefore the records are not only accessible to authorized dispensary employees.
- 3796:6-3-20: GTI recommends technical two technical language changes to ensure the Board attains necessary financial information and certifications, but removes duplicative processes that may create unnecessary costs.
- 3796:6-3-22: GTI recommends the Board revise the language in OAC 3796:6-3-22(A) and (B) to clarify that educational events at dispensaries with physicians holding CTRs are permitted if approved by the Board pursuant to these rules.
- 3796:6-3-22: GTI recommends drive-through windows and the home delivery of medical marijuana be permitted.
- 3796:6-3-23: GTI asks the Board to accommodate the existing practice that allows reasonable use of dispensary photographs, subject to Board approval.
- 3796:6-5-01: GTI asks for the removal of the \$100 fee per advertisement submission.

Incorporated Comments into Rule(s)

- 3796:6-3-22: The Board has incorporated the suggestion to explicitly allow for CTR physician visits upon prior approval of the Board in rule Ohio Adm.Code 3796:6-3-23.
- 3796:6-3-22: The Board has incorporated the suggestion related to drive-throughs and have removed that prohibition.

Comments not Incorporated into Rule(s)

• 3796:6-3-01: Section (J)(3) provides, "dispensary employee shall be issued a separate identification card for each dispensary employing that individual, unless the dispensaries employing the individual share common ownership and use identical cards for all

- dispensaries employing the individual." Thus, the rule allows for a single badge under certain circumstances. The Board does not regulate cultivator or processor facilities, and thus, does not have jurisdiction to permit the request for a single badge to allow access to those facilities.
- 3796:6-3-05: Elimination of the rule streamlines the process for replacing a designated representative. In practice, the Board works closely with dispensaries regarding changes of designated representative, without the need to issue a temporary certificate of authority. The changes to the rule incorporate current board practices regarding designated representative changes
- 3796:6-3-08: All sales of medical marijuana must occur under proper video surveillance, to
 ensure a registered patient or caregiver is the individual purchasing the product. To allow
 online payment would create a risk of diversion by allowing non-licensed individuals to
 purchase product.
- 3796:6-3-08: Home delivery is expressly prohibited and has been prohibited since the program's inception. Allowing delivery of medical marijuana would increase the risk of diversion from employees who are not under constant video surveillance. The Board has utilized video surveillance as evidence in administrative and criminal prosecutions. Additionally, the risk of criminal offenses against dispensary employees making deliveries would be increased if home delivery were allowed.
- 3796:6-3-17: There were no changes to Section (D), which is where this reference is made.
- 3796:6-3-20: The current rule requires a separate audit to be completed for each licensed dispensary. The amendment allows for an owner of multiple dispensaries to prepare a single audit containing required information for all dispensaries under common ownership. The rule requires both an audit and separate certified statement that includes an income statement, balance sheet, and cash flow statement. The comment does not provide any information as to what would be duplicative.
- 3796:6-3-22: The Board has not incorporated the prohibition related to delivery of medical
 marijuana. Delivery is expressly prohibited and has been prohibited since the program's
 inception. Allowing delivery of medical marijuana would increase the risk of diversion from
 employees who are not under constant video surveillance. The Board has utilized video
 surveillance as evidence in administrative and criminal prosecutions. Additionally, the risk
 of criminal offenses against dispensary employees would be increased if home delivery were
 allowed.
- 3796:6-3-23: The rule only prohibits (1) photographs of restricted dispensary areas and (2) photographs or recording that would identify patients or caregivers without their consent. To permit photographs of restricted areas would allow the photographing of security layouts such as video surveillance, location of vault, location of delivery area, etc. and would compromise the security of the facility.
- 3796:6-5-01: The Board is required to review and approve advertisements to ensure compliance with program regulations, including but not limited to, ensuring the advertisements are not false or misleading, attractive to children, or include health claims that are unsupported by substantial evidence or clinical data. The Board also routinely convenes a Health Claims Advisory Committee to research proposed health claims and make recommendations to the Board related to advertisements. The costs associated with advertisements are necessary to administer and maintain the MMCP.