

Hearing Summary Report

Note: Email completed form to jcarr1@jcarr.state.oh.us.

Hearing Date: 3/29/2017

Today's Date: 4/5/2017

Agency: State of Ohio Board of Pharmacy

Rule Number(s): 4729-9-14; 4729-9-22; 4729-9-30; 4729-18-01, 02, 03 and 04

If no comments at the hearing, please check the box.

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

1. Levi Tkach – Graff and McGovern, LPA

2. Healthcare Distribution Alliance (HDA)

3. Click here to enter text.

4. Click here to enter text.

5. Click here to enter text.

6. Click here to enter text.

7. Click here to enter text.

8. Click here to enter text.

9. Click here to enter text.

10. Click here to enter text.

11. Click here to enter text.

12. Click here to enter text.

13. Click here to enter text.

14. Click here to enter text.

15. Click here to enter text.

16. Click here to enter text.

Hearing Summary Report

Consolidated Summary of Comments Received

Please review all comments received and complete a consolidated summary paragraph of the comments and indicate the rule number(s).

Graff and McGovern:

Rule 4729-18-02:

Licensure should not apply to anyone who does not store or dispense medications from their offices.

Extension should be granted for licensure requirement and a grandfather provision should be included.

Extension will also allow physicians to get specialty board certification.

Permit responsible persons to serve at two locations and request a board approved exemption for three or more locations.

Ambiguity regarding 15 hours' requirement. Physicians need to know whether this means treating patients or a combo of treating patients and performing other tasks (charting, etc.).

How often will the 15 hours be calculated? Averaging the 15 hours per week on a monthly or quarterly basis will improve the administrative efficiency of this part of the rule.

The rules should be revised to promote consistent standards for owners and responsible persons.

No justification for precluding the simultaneous ownership of a pain management clinic and office based opioid treatment facility. Often the physician and staff working in PMCs possess the greatest level of expertise in identifying, diagnosing and treating addiction. Request removal of this provision.

Rule 4729-18-03:

Rules relating to criminal background checks should reflect the culture of addiction treatment. Often the most qualified individuals to treat addiction are the individuals who understand the severity of addiction. Rules should be modified to recognize rehabilitation.

HDA:

Rule 4729-9-30

Our members have reviewed the language and would like to suggest that the Board clarifies the

Hearing Summary Report

definition to add that a broker should only include purchases from pharmacies or other wholesalers, and not manufacturers. If manufacturers are included, it will pull in every wholesaler that facilitates a drop shipment.

Hearing Summary Report

Incorporated Comments into Rule(s)

Indicate how comments received during the hearing process were incorporated into the rule(s). If no comments were incorporated, explain why not.

Graff and McGovern:

Rule 4729-18-02:

Comment: Licensure should not apply to anyone who does not store or dispense medications from their offices. Extension should be granted for licensure requirement and a grandfather provision should be included. Extension will also allow physicians to get specialty board certification.

Response: The Board did not amend the rules to address these comments as the licensing requirement is included in statute (ORC 4729.553).

Comment: Permit responsible persons to serve at two locations and request a board approved exemption for three or more locations.

Response: The Board permits a responsible person from serving at two locations in the rule. Therefore, no change to the rule is necessary.

Comment: Ambiguity regarding 15 hours' requirement. Physicians need to know whether this means treating patients or a combo of treating patients and performing other tasks (charting, etc.). How often will the 15 hours be calculated? Averaging the 15 hours per week on a monthly or quarterly basis will improve the administrative efficiency of this part of the rule.

Response: The rule states physically present on a weekly basis. This includes treating patients as well as performing other tasks. The Board did not make any changes as it may clarify such questions in guidance documents.

Comment: The rules should be revised to promote consistent standards for owners and responsible persons.

Response: The responsible person requirements are consistent across all licenses issued by the Board. Therefore, the Board felt that it was maintaining consistency and did not feel the need to change the rule.

Hearing Summary Report

Comment: No justification for precluding the simultaneous ownership of a pain management clinic and office based opioid treatment facility. Often the physician and staff working in PMCs possess the greatest level of expertise in identifying, diagnosing and treating addiction. Request removal of this provision.

Response: The Board did not change this rule, as it does not have a blanket preclusion on the ownership of both facilities. Rather an applicant must request approval by the Board.

Rule 4729-18-03:

Comment: Rules relating to criminal background checks should reflect the culture of addiction treatment. Often the most qualified individuals to treat addiction are the individuals who understand the severity of addiction. Rules should be modified to recognize rehabilitation.

Response: The Board did not change this rule because the criminal records check provisions in the rule are provided in statute.

HDA:

Rule 4729-9-30:

Comment: Our members have reviewed the language and would like to suggest that the Board clarifies the definition to add that a broker should only include purchases from pharmacies or other wholesalers, and not manufacturers. If manufacturers are included, it will pull in every wholesaler that facilitates a drop shipment.

Response: The recommended language by the HDA would conflict with an existing rule (OAC 4729-9-28) that governs the licensure of virtual wholesalers. The Board requested further clarification on 3/28/2017 but has yet to receive any further feedback. Therefore, the Board decided to retain the rule as is.

--