STATE OF OHIO BOARD OF PHARMACY

**Hearing Summary Report**

**Hearing Date:** 11/16/2018

**Today's Date:** 12/16/2018

**Rule Number(s):**

Rule Number
4729-5-08 (Rescind)
4729-5-11 (Rescind)
4729-5-23 (Rescind)
4729-9-10 (Rescind)
4729-10-01 (Rescind)
4729-10-02 (Rescind)
4729-10-03 (Rescind)
4729-10-04 (Rescind)
4729:1-3-05 (New)
4729:2-3-01 (New)
4729:2-3-02 (New)
4729:3-3-04 (Amend)
4729:3-4-01 (Amend)
4729:3-4-02 (Amend)
4729:5-1-01 (New)
4729:5-2-01 (New)
4729:5-2-03 (New)
4729:5-2-04 (New)
4729:5-3-01 (Amend)
4729:5-3-04 (New)
4729:5-3-07 (New)
4729:5-3-08 (New)
4729:5-3-09 (New)
4729:5-3-10 (New)
4729:5-4-01 (New)
4729:5-8-01 (New)
4729:5-8-02 (New)
4729:5-8-03 (New)

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

- CVS Health
- Blaire Pharmacy Consulting – Scottsdale, Arizona
- Ohio Veterinary Medical Association (OVMA)

**Consolidated Summary of Comments Received**

- CVS Health (4729:2-3-01):
  - Suggested adding to the pharmacy intern scope of practice the duties that may be performed by a certified pharmacy technician.

- CVS Health (4729:3-3-04)
  - Remove the requirement for a prescriber to be on-site to provide supervision of a certified pharmacy technician to stock an automated dispensing unit.
  - Requested clarification to define positive identification in the rule.

- Blaire Pharmacy Consulting (4729:5-1-01)
  - Allow for a pharmacist to use professional judgement to extend the beyond-use date of a compounded drug.

- OVMA (4729:5-2-01)
  - Concerned that the Board has the option to deny a person from being a responsible person on a license if they are "addicted to or abusing alcohol or drugs."
  - Requested clarification for disciplinary actions relating to "inappropriate prescribing." Claim that there will be confusion because the word disciplinary action is not defined.

- OVMA (4729:5-4-01)
  - Concerned that the Board has the option to impose discipline on a license for knowingly employing someone who is "addicted to or abusing alcohol or drugs."

- OVMA (4729:5-3-08)
  - Requests exemption from having to include information on website for consumers to contact the Board of Pharmacy or the DEA when offering to sell drugs online. Claims that such information would be a "burden" and it would cause "confusion."

**Incorporated Comments into Rule(s)**

- Blaire Pharmacy Consulting (4729:5-1-01)
  - Allow for a pharmacist to use professional judgement to extend the beyond-use date of a compounded drug. **This rule was modified to not limit a beyond-use date to what is required by national standards. However, other compounding regulations for pharmacies still require adherence to these standards. It should be noted that the standards do allow for extension of beyond-use date with the appropriate sterility testing.**

- OVMA (4729:5-3-08)
  - Requests exemption from having to include information on website for consumers to contact the Board of Pharmacy or the DEA when offering to sell drugs online. Claims that such information would be a "burden" and it would cause "confusion." **Rule was modified to clarify that only entities that offer drug sales online would be required to include this information. Thus, limiting the burden on veterinarians and other prescribers who do not offer such services online.**

- OVMA (4729:5-2-01)
  - Concerned that the Board has the option to deny a person from being a responsible person on a license if they are "addicted to or abusing alcohol or drugs." **Provided a definition (4729:5-1-01) of addicted to or abusing alcohol or drugs that**

**comes from the definition of addiction in ORC 5119.01. It clarifies the Board may discipline a licensee who knowingly employs an individual who is currently or actively addicted to drugs or alcohol.**

- Requested clarification for disciplinary actions relating to "inappropriate prescribing." Claim that there will be confusion because the word disciplinary action is not defined. **Provided a definition (4729:5-1-01) for disciplinary actions that mirrors what Boards are required to report to the National Practitioner Data Bank (NPDB) https://www.npdb.hrsa.gov/resources/NPDBGuidebook.pdf.**

- OVMA (4729:5-4-01)
  - Concerned that the Board has the option to impose discipline on a license for knowingly employing someone who has access to prescription drugs who is "addicted to or abusing alcohol or drugs." **Provided a definition (4729:5-1-01) of addicted to or abusing alcohol or drugs that comes from the definition of addiction in ORC 5119.01. It clarifies the Board may discipline a licensee who knowingly employs an individual who is currently or actively addicted to drugs or alcohol.**

**UPDATED – Additional Comments Incorporated into Rule(s)**

- CVS Health (4729:3-3-04)
  - Remove the requirement for a prescriber to be on-site to provide supervision of a certified pharmacy technician to stock an automated dispensing unit. **This provision was removed from the draft rule.**
  - Requested clarification to define positive identification in the rule. **The definition of positive identification was added to the rule.**

- CVS Health (4729:2-3-01):
  - Suggested adding to the pharmacy intern scope of practice the duties that may be performed by a certified pharmacy technician. **Added to pharmacy intern scope of duties as outlined in the comment.**