

State of Ohio Board of Pharmacy - Hearing Summary Report

Hearing Date: 6/13/2019

Today's Date: 7/10/2019

Rule Number(s):

| Rule Number | Description |
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| 4729:5-2-03 (Amend) | Change in description of a terminal distributor of dangerous drugs. |
| 4729:11-1-01 (New) | Definitions – home medical equipment. |
| 4729:11-2-01 (New) | Licensure, registration and renewal. |
| 4729:11-2-02 (New) | Designated representative. |
| 4729:11-2-03 (New) | Applications. |
| 4729:11-2-04 (New) | Recognized accrediting bodies. |
| 4729:11-2-05 (New) | Change in description of an HME services provider or discontinuation of a business. |
| 4729:11-3-01 (New) | Minimum standards for licensees. |
| 4729:11-3-02 (New) | Record keeping. |
| 4729:11-3-03 (New) | Inspections and corrective actions. |
| 4729:11-3-04 (New) | Continuing education. |
| 4729:11-3-05 (New) | Advertising and solicitation. |
| 4729:11-4-01 (New) | Disciplinary actions. |
| 4761:1-1-01 (Rescind) | Public hearings on adoption, amendment, or rescission of rules: methods of public notice. |
| 4761:1-1-02 (Rescind) | Notice of board meetings. |
| 4761:1-2-01 (Rescind) | Board organization. |
| 4761:1-2-02 (Rescind) | Personnel. |
| 4761:1-2-03 (Rescind) | Board records. |
| 4761:1-2-05 (Rescind) | Personal information systems. |
| 4761:1-3-01 (Rescind) | Definition of terms. |
| 4761:1-3-02 (Rescind) | Home medical equipment defined. |
| 4761:1-4-01 (Rescind) | Recognition of accrediting organizations. |
| 4761:1-5-01 (Rescind) | Qualifications for licensure. |
| 4761:1-5-02 (Rescind) | Application form requirements. |
| 4761:1-5-03 (Rescind) | Failure to file a complete application for a license. |
| 4761:1-6-01 (Rescind) | Qualifications to obtain a certificate of registration. |
| 4761:1-6-02 (Rescind) | Application form requirements to apply for a certificate of registration. |
| 4761:1-6-03 (Rescind) | License and certificate of registration issuance and display. |
| 4761:1-6-04 (Rescind) | Failure to file a complete application for a certificate of registration. |
| 4761:1-7-01 (Rescind) | Qualifications for license renewal. |
| 4761:1-7-02 (Rescind) | Qualifications for certificate of registration renewal. |
| 4761:1-7-03 (Rescind) | Lapsed license or certificate of registration reinstatement procedure. |
| 4761:1-8-01 (Rescind) | Fees. |
| 4761:1-8-02 (Rescind) | Late fees. |
| 4761:1-8-03 (Rescind) | Inspection fees. |
| 4761:1-8-04 (Rescind) | License and certificate of registration replacement fees. |
| 4761:1-9-01 (Rescind) | Standards of practice for license holders. |
| 4761:1-9-02 (Rescind) | Standard for maintaining a facility. |
| 4761:1-9-03 (Rescind) | Standard for maintaining equipment. |
| 4761:1-9-04 (Rescind) | Client records. |
| 4761:1-9-05 (Rescind) | Personnel. |
| 4761:1-10-01 (Rescind) | Filing of complaints. |
| 4761:1-10-02 (Rescind) | Authority of board investigators. |

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| 4761:1-10-03 (Rescind) | Licensees and certificate holders must comply with investigations conducted by the board. |
| 4761:1-11-01 (Rescind) | Administrative procedure for refusal to issue or renew a license, suspend, or revoke a license or impose a fine or other disciplinary action. |
| 4761:1-11-02 (Rescind) | Board imposition of penalties. |
| 4761:1-11-03 (Rescind) | Filing a request with the Ohio attorney general's office for injunctive relief or civil penalties. |
| 4761:1-11-04 (Rescind) | Other disciplinary action. |
| 4761:1-12-01 (Rescind) | Representation; appearance; communication; applicability. |
| 4761:1-12-02 (Rescind) | Authority and duties of the board or hearing examiner. |
| 4761:1-12-03 (Rescind) | Filing. |
| 4761:1-12-04 (Rescind) | Motions. |
| 4761:1-12-05 (Rescind) | Service. |
| 4761:1-12-06 (Rescind) | Computation and extension of time. |
| 4761:1-12-07 (Rescind) | Exchange of documents and witness lists. |
| 4761:1-12-08 (Rescind) | Exhibits. |
| 4761:1-12-09 (Rescind) | Witnesses. |
| 4761:1-12-10 (Rescind) | Subpoenas for purposes of hearing. |
| 4761:1-12-11 (Rescind) | Expert testimony. |
| 4761:1-12-12 (Rescind) | Mileage reimbursement and witness fees. |
| 4761:1-12-13 (Rescind) | Depositions and transcripts of prior testimony. |
| 4761:1-12-14 (Rescind) | Continuance of hearing. |
| 4761:1-12-15 (Rescind) | Reports and recommendations. |
| 4761:1-12-16 (Rescind) | Transcripts. |
| 4761:1-12-17 (Rescind) | Prior action by the board. |
| 4761:1-13-01 (Rescind) | Continuing education standards. |
| 4761:1-14-01 (Rescind) | Inspection frequency. |
| 4761:1-14-02 (Rescind) | Inspection requirements. |
| 4761:1-15-01 (Rescind) | Advertising and solicitation. |
| 4761:1-15-02 (Rescind) | Signage. |
| 4761:1-15-03 (Rescind) | Transfer of authorization to new facility or new ownership. |
| 4761:1-15-04 (Rescind) | Requirement to provide board contact information to clients. |
| 4761:1-16-01 (Rescind) | Definitions for accessing confidential personal information. |
| 4761:1-16-02 (Rescind) | Procedures for accessing confidential personal information. |
| 4761:1-16-03 (Rescind) | Valid reasons for accessing confidential personal information. |
| 4761:1-16-04 (Rescind) | Confidentiality statutes. |
| 4761:1-16-05 (Rescind) | Restricting and logging access to confidential personal information in computerized information systems. |
| 4729:5-3-11 (New) | Transmission of outpatient prescriptions.* |
| 4729:5-5-15 (New) | Manner of issuance of a prescription.* |
| 4729:5-5-17 (New) | Drugs repackaged or relabeled by a pharmacy.* |
| 4729:5-5-18 (New) | Multi-Med dispensing by an outpatient pharmacy.* |
| 4729:5-5-03 (New) | Filing and storage of prescriptions.* |
| 4729:5-5-05 (New) | Prescription format requirements.* |
| 4729:5-5-07 (New) | Patient profiles.* |
| 4729:5-5-09 (New) | Patient counseling.* |
| 4729:5-5-10 (New) | Manner of processing a prescription.* |
| 4729:5-5-11 (New) | Prescription copy.* |
| 4729:5-5-12 (New) | Partial dispensing of schedule II controlled substances.* |
| 4729:5-5-13 (New) | Serial numbering of prescriptions.* |

**Denotes additional hearing.*

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

- Walgreens
- Ohio Association of Medical Equipment Services
- Ohio Society for Respiratory Care

Consolidated Summary of Comments Received

- Rule 4729:11-3-01: The Ohio Association of Medical Equipment Services requested that language be added to clarify that FBI background checks are only required for new hires and will not be applied retroactively to current employees.
- Rule 4729:11-2-01: The Ohio Society for Respiratory Care has concerns regarding the qualifications of Board of Pharmacy inspection staff. They requested that the inspections be conducted by licensed respiratory therapists.

Walgreens

4729:5-5-03:

- Requested clarification that prescription scanning requirements only apply if the pharmacy is not maintaining hard copy records of prescriptions.
- Requested that the rule permits the notation of scanned prescriptions to be on either the front or back of the prescription (rule specified front).
- Asked to move paragraph (F) to paragraph (E)(7).

4729:5-5-07:

- Requested that a patient's phone number be an option field in the patient profile.
- Questioned why documenting medical devices is necessary in a patient profile.
- Requested that specialty type could be included in the profile in lieu of prescriber credential.

4729:5-5-10

- Requested that the agent of the prescriber not be a requirement of a faxed prescription.
- Requested prior removal of the approval of electronic prescription transmission systems from the rule.

4729:5-5-13

- Requested that record keeping provisions exclude prescriptions that were not dispensed by the pharmacy.

Incorporated Comments into Rule(s)

- Rule 4729:11-3-01: The Ohio Association of Medical Equipment Services requested that language be added to clarify that FBI background checks are only required for new hires and will not be applied retroactively to current employees. **The rule was refiled on 7/8/2019 to clarify this issue.**

Walgreens

4729:5-5-03:

- Requested clarification that prescription scanning requirements only apply if the pharmacy is not maintaining hard copy records of prescriptions. **Board approved change and rule will be refiled to incorporate comment.**
- Requested that the rule permits the notation of scanned prescriptions to be on either the front or back of the prescription (rule specified front). **Board approved change and rule will be refiled to incorporate comment.**
- Asked to move paragraph (F) to paragraph (E)(7). **Board approved change and rule will be refiled to incorporate comment.**

4729:5-5-07:

- Requested that a patient's phone number be an option field in the patient profile. **Board approved change and rule will be refiled to incorporate comment. However, the rule will remain in TBR status until August in order to address some additional issues that were not raised at the public hearing.**

4729:5-5-10

- Requested prior removal of the approval of electronic prescription transmission systems from the rule. **Board approved change and rule will be refiled to incorporate comment.**

Comments not Incorporated into Rule(s)

4729:5-5-10

- Requested that the agent of the prescriber not be a requirement of a faxed prescription. **This rule does not include the requirement for the agent to be listed on a faxed prescription. Regardless, the Board feels that this provision is necessary (it is a requirement of rule 4729:5-3-11) to ensure that the pharmacy has a point of contact at the prescriber office and to help with the investigation of fraudulent prescriptions.**

4729:5-5-13

- Requested that record keeping provisions exclude prescriptions that were not dispensed by the pharmacy. **This rule does not impact the record keeping requirements of outpatient pharmacies (the rule governing record keeping is 4729:5-5-04). However, even if a prescription is not dispensed it should be assigned a number if processed by a pharmacy. This is critical for investigating issues relating to prescription transfers where the original prescription information is collected by one pharmacy but transferred to another pharmacy for dispensing.**

4729:11-2-01

- The Board does not dictate in rule the qualifications of its compliance and inspection staff. The Board of Pharmacy requested that the both Ohio Association of Medical Equipment Services and Ohio Society for Respiratory Care offer annual training to Board staff and both associations have agreed to participate.