

NOTICE OF PUBLIC HEARING

State of Ohio
STATE BOARD OF PHARMACY
77 S. High Street, Room 1702
Columbus, Ohio 43215-6126

Acting under the authority of the Ohio Revised Code Sections 119.03 to 119.13, 3715.69, 3719.28, and 4729.26, the State Board of Pharmacy hereby announces a public hearing will be held on Monday, **November 3, 2008**, at 1:30 p.m. in Room South A, 31st Floor, Vern Riffe Center for Government and the Arts, 77 South High Street, Columbus, Ohio.

This is a statement of the agency's intention to consider adopting proposed new and amended rules as follows:

4729-3-02 (*Registration as a pharmacy intern.*) To add language pursuant to the passage of House Bill 104 regarding the criminal records check requirement for pharmacy interns seeking an initial license in Ohio.

4729-5-08 (*Pharmacy intern professional functions.*) To add language that lists another administrative code reference regarding the proper procedure for an intern to receive an oral prescription.

4729-5-10 (*Prescription pick-up station.*) To change language allowing a site that is appropriately licensed pursuant to Chapter 4729. to be considered as a pick-up station instead of limiting it just to a site licensed as a terminal distributor of dangerous drugs.

4729-5-11 (*Responsible person.*) To change language to allow a change of responsible person notification to be sent to the board by regular mail instead of certified mail.

4729-5-12 (*Criminal records check for pharmacists and pharmacy interns*) To create a new rule pursuant to the passage of House Bill 104 regarding the procedure required for a criminal records check for pharmacists and pharmacy interns seeking an initial license in Ohio.

4729-5-19 (*Serial numbering of prescriptions.*) To remove language that restricts a refill authorization to be transmitted by oral means only.

4729-5-29 (*Confidentiality of patient records.*) To add language pursuant to the passage of Senate Bill 175 to allow the Medical Board to have access to drug records when enforcing Chapter 4730. of the Revised Code regarding physician assistants.

4729-5-30 (*Manner of issuance of a prescription.*) To add language that references Medical Board rule 4730-2-07 regarding the requirement for a physician assistant to place his/her certificate to prescribe number on a prescription.

4729-5-31 (*Criteria for licensure by examination.*) To remove duplicated language and to add language pursuant to the passage of House Bill 104 regarding the criminal records check requirement for pharmacists seeking an initial license in Ohio.

4729-5-32 (*Criteria for licensure by reciprocity.*) To add language pursuant to the passage of House Bill 104 regarding the criminal records check requirement for pharmacists seeking an initial license in Ohio.

4729-7-01 (*Definitions.*) To remove the unused definition "Evidence of approved C.E.U.s" and to place the remaining definitions in alphabetical order.

4729-7-06 (*Criteria for in-state approved providers of continuing pharmacy education.*) To make the required notification to the pharmacy board time periods uniform at fourteen days and to clarify what needs to be included in the notification.

4729-9-01 (*Definitions.*) To add language pursuant to the passage of House Bill 283 regarding the exemption for expired drugs when donated to a school of pharmacy.

4729-9-02 (*Minimum standards for a pharmacy.*) To add language to clarify that all pharmacists working in a pharmacy must be able to access all current federal and state laws, regulations and rules governing the legal distribution of drugs. To add language referencing section 4729.55 of the Revised Code that states a pharmacy must be appropriately staffed to operate in a safe and effective manner. Also, to add language regarding the use of nametags that includes job title for pharmacy employees who may have contact with patients or the general public.

4729-9-08 (*Change in description of terminal or wholesale dangerous drug facility.*) To add language that identifies the board's long standing procedure that a change in license category requires a new application, fee, and license.

4729-9-12 (*Verification of license as a distributor of dangerous drugs or exempt status of a prescriber.*) To add language pursuant to the passage of House Bill 283 regarding the new license exemptions for sole shareholders and dentists.

4729-9-14 (*Records of controlled substances.*) To add language regarding the proper destruction procedures and record keeping requirements for controlled substances.

4729-9-16 (*Minimum requirements for wholesalers.*) To add language that requires the owner(s) or officers of a new wholesale distributor of dangerous drugs to submit to a criminal drug records check as a condition of licensure.

4729-9-17 (*Storage of adulterated drugs.*) To add language that references the proper record keeping requirements for the destruction of drugs other than controlled substances. To add language pursuant to the passage of House Bill 283 referencing the Revised Code sections that allow the donation of drugs to a school of pharmacy.

4729-9-20 (*Drugs repackaged or relabeled by a pharmacy.*) To add new language that requires documenting the positive identification of the pharmacist responsible for the creation of a barcode label that is used to identify a drug and the positive identification of the pharmacist responsible for affixing the barcode label to a drug product.

4729-9-21 (*Drugs compounded by a pharmacy.*) To change language to the correct number of final digits in a terminal distributor of dangerous drug license from six to seven.

4729-9-22 (*Records of dangerous drugs.*) To add language that indicates the rule reference that requires certain drug transactions must be documented with positive identification. To add language that identifies the proper record keeping requirements when destroying dangerous drugs other than controlled substances. Also, to add language that indicates the proper procedure for providing records to the Board of Pharmacy.

4729-9-24 (*Retail and wholesale sales of dangerous drugs on-line.*) To make technical language changes to clarify the rule.

4729-13-01 (*Definitions.*) To add definitions for "Controlled substance" and "Dangerous drug" and to place the definitions in alphabetical order.

4729-13-04 (*Record keeping.*) To correct the spelling of “record keeping” in the title. To remove language that is unnecessary. Also, to add language that references the proper record keeping requirements when destroying dangerous drugs that are not controlled substances.

4729-13-06 (*Responsible person for approved laboratories.*) To change language to allow a change of responsible person notification to be sent to the board by regular mail instead of certified mail and to add language to allow the notification to be sent also by verified facsimile transmission.

4729-14-01 (*Definitions.*) To add definitions for “Controlled substance” and “Dangerous drug” and to place the definitions in alphabetical order.

4729-14-06 (*Responsible person for an approved animal shelter.*) To change language to allow a change of responsible person notification to be sent to the board by regular mail instead of certified mail and to add language to allow the notification to be sent also by verified facsimile transmission.

4729-15-02 (*Responsibility for nuclear pharmacy.*) To change language to allow a change of responsible person notification to be sent to the board by regular mail instead of certified mail and to add language to allow the notification to be sent also by verified facsimile transmission.

4729-15-04 (*Labeling of radiopharmaceuticals.*) To add language requiring that a radiopharmaceutical label must include the telephone number of the nuclear pharmacy.

4729-17-02 (*Responsible person for an institutional pharmacy.*) To change the term “pharmacist-in-charge” where appropriate to the term “responsible person.” To change language to allow a change of responsible person notification to be sent to the board by regular mail instead of certified mail and to add language to allow the notification to be sent also by verified facsimile transmission. To change language to clarify who must file the change of responsible person notice and who must complete the controlled substance inventory when there is a change in responsible person.

4729-17-03 (*Security and control of drugs in an institutional facility.*) To change the term “pharmacist-in-charge” where appropriate to the term “responsible person.”

4729-17-04 (*Records; Institutional pharmacy.*) To change the term “pharmacist-in-charge” where appropriate to the term “responsible person.”

4729-17-08 (*Minimum standards for an institutional pharmacy.*) To add language to clarify that all pharmacists working in a pharmacy must be able to access all current federal and state laws, regulations and rules governing the legal distribution of drugs. To add language referencing section 4729.55 of the Revised Code that states a pharmacy must be appropriately staffed to operate in a safe and effective manner. Also, to add language regarding the use of nametags that includes job title for pharmacy employees that may have contact with patients or the general public.

4729-17-10 (*Labeling of prescriptions for patients of an institutional facility.*) To change language to the correct number of final digits in a terminal distributor of dangerous drug license from six to seven.

4729-31-01 (*Definitions.*) To place the definitions in alphabetical order.

4729-31-02 (*Prescriptions for sterile products.*) To remove the “if other than oral” exemption and clarify that a drug order for a sterile product must include the route of administration.

4729-31-03 (*Labeling.*) To add language requiring that a drug label must include the telephone number of the fluid therapy pharmacy.

4729-33-01 (*Definitions.*) To place the definitions in alphabetical order.

4729-33-02 (*Licensure.*) To clarify that a formal mutual aid agreement needs to be in writing. To change language to allow a change of responsible person notification to be sent to the board by regular mail instead of certified mail and to add language to allow the notification to be sent also by verified facsimile transmission.

4729-33-04 (*Record keeping.*) To make technical language changes to clarify the rule.

4729-33-05 (*Posting up.*) To make technical language changes and to clarify that a mutual aid agreement needs to be in writing.

4729-35-05 (*Eligibility requirements to receive drugs.*) To change one of the eligibility requirements to receive a repository program drug from not having active third party coverage for a drug prescribed to not having a reasonable financial means to pay for a drug prescribed.

4729-35-07 (*Recipient form.*) To remove language requiring a recipient form to be signed each time a drug is dispensed and to change language so that a form just needs to be signed prior to receiving drugs from a drug repository program. Also, to remove the drug dispensing record keeping requirements from this rule and more appropriately address these requirements in rule 4729-35-08 titled "Record keeping."

4729-35-08 (*Record keeping.*) To add language that describes the prescriber and pharmacist record keeping requirements when dispensing a drug repository program drug.

4729-37-07 (*Frequency requirements for submitting drug database information.*) To make a technical change by removing language that was supposed to be changed during the last rule review period, but was accidentally missed.

4729-37-11 (*Corrections to the drug database.*) To create a new rule that describes the appropriate procedure for making corrections to drug dispensing or wholesale drug sale information in the drug database.

The Board also reviewed the following rules and proposed that no changes be made:

4729-7-07, 4729-7-08, 4729-13-02, 4729-13-03, 4729-13-05, 4729-14-02, 4729-14-03, 4729-14-04, 4729-14-05, 4729-15-05, 4729-29-01, 4729-29-03, 4729-29-04, 4729-29-06, 4729-29-07, 4729-31-04, 4729-33-03, 4729-35-01, 4729-35-02, 4729-35-03, 4729-35-04, 4729-35-06, 4729-35-09.

The full text of the proposed rules are available at the office of the State Board of Pharmacy in printed form without charge to any person affected by such proposals. The proposed rules are also on the Board's website at www.pharmacy.ohio.gov and on the Register of Ohio website at www.registerofohio.state.oh.us.

On the date and at the time and place designated in this notice, any person affected by the proposed actions of the State Board of Pharmacy may appear and be heard in person, by his/her attorney, or both; may present his/her position, arguments, or contentions orally or in writing; offer witnesses; and, present evidence tending to show that any proposal, if adopted or effectuated, will be unreasonable or unlawful.

William T. Winsley, M.S., R.Ph.
Executive Director