

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 1, 2010**, 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:

4729-1-07 (*Definitions; personal information systems.*) To create a new rule pursuant to the passage of House Bill 648 of the 127th General Assembly that includes definitions pertinent to the new rules in Chapter 4729-1 regarding confidential personal information.

4729-1-08 (*Procedures for accessing confidential personal information.*) To create a new rule pursuant to the passage of House Bill 648 of the 127th General Assembly regarding the procedures required for accessing confidential personal information.

4729-1-09 (*Valid reasons for accessing confidential personal information.*) To create a new rule pursuant to the passage of House Bill 648 of the 127th General Assembly regarding valid reasons for accessing confidential personal information.

4729-1-10 (*Confidentiality statutes, regulations, and rules.*) To create a new rule pursuant to the passage of House Bill 648 of the 127th General Assembly regarding current confidentiality statutes, regulations, and rules.

4729-1-11 (*Restricting and logging access to confidential personal information in computerized personal information systems.*) To create a new rule pursuant to the passage of House Bill 648 of the 127th General Assembly regarding restricting and logging access to confidential personal information.

4729-3-02 (*Registration as a pharmacy intern.*) To remove the reference to the Test of Spoken English since it is no longer provided and add language that the only acceptable test is the Test of Spoken English as a Foreign Language Internet-based test.

4729-3-03 (*Application for registration as a pharmacy intern.*) To remove the reference to the Test of Spoken English since it is no longer provided and add language that the only acceptable test is the Test of Spoken English as a Foreign Language Internet-based test.

4729-5-04 (*Violations as evidence for denial of a pharmacist or intern license.*) To add language to clarify that the Board of Pharmacy may consider as evidence any discipline issued by any professional licensing board.

4729-5-06 (*Pharmacist and pharmacy intern change of address and/or employment.*) To add language to clarify that a pharmacist or pharmacy intern must notify the Board of Pharmacy of a change in either their residential address or mailing address.

4729-5-19 (*Serial numbering of prescriptions.*) To require that a new serial number must be assigned to a prescription when additional dispensings are authorized by a prescriber.

4729-5-21 (*Manner of processing a prescription.*) To add language stating that a pharmacy computer system meeting the DEA requirements for electronic prescribing shall be considered approved by the Board of Pharmacy.

4729-5-24 (*Prescription copy.*) To add language that limits the transfer of all prescription copies to one time.

4729-5-30 (*Manner of issuance of a prescription.*) To add language stating that an electronic prescription transmission system meeting the DEA requirements for electronic prescribing shall be considered approved by the Board of Pharmacy.

4729-5-31 (*Criteria for licensure by exam.*) To remove the reference to the Test of Spoken English since it is no longer provided and add language that the only acceptable test is the Test of Spoken English as a Foreign Language Internet-based test.

4729-5-32(*Criteria for licensure by reciprocity.*) To remove the reference to the Test of Spoken English since it is no longer provided and add language that the only acceptable test is the Test of Spoken English as a Foreign Language Internet-based test.

4729-5-34 (*Successful completion of the "Test of Spoken English as a Foreign Language Internet-based test".*) To remove the reference to the Test of Spoken English since it is no longer provided and add language that the only acceptable test is the Test of Spoken English as a Foreign Language Internet-based test.

4729-5-37 (*Protocols for the administration of immunizations.*) To add a reference to rule 4729-5-38 of the Administrative Code for the purpose of identifying the immunizations a pharmacist may administer.

4729-9-07 (*Procedure for discontinuing business as a wholesale or a terminal distributor of dangerous drugs.*) To add language to clarify that an inventory shall also identify the strength and dosage form of a controlled substance that is transferred or disposed of.

4729-9-11 (*Security and control of dangerous drugs.*) To correct or update references to various sections and paragraphs of the Administrative Code.

4729-9-15 (*Report of theft or loss of dangerous drugs, controlled substances, and drug documents.*) To cite the specific references made to the Code of Federal Regulations in the proper form.

4729-9-16 (*Minimum requirements for wholesalers.*) To change from two years to three years as the minimum period of time that drug wholesalers shall maintain drug records.

4729-9-19 (*Violations as evidence for denial of terminal, wholesale, or manufacturer license.*) To add language to clarify that the Board of Pharmacy may consider as evidence any discipline issued by any professional licensing board.

4729-9-25 (*Drugs compounded for direct administration by a prescriber.*) To add language to update the information regarding the United States Pharmacopoeia/National Formulary beyond use dates for sterile compounds.

4729-17-01 (*Definitions; institutional facility.*) To correct the name of the Ohio Department of Mental Retardation and Developmental Disabilities to the new name of Ohio Department of Developmental Disabilities.

4729-17-02 (*Pharmacist-in-charge of an institutional facility.*) To add language that is similar to that used in rule 4729-5-11 of the Administrative Code which clarifies the process required to be considered the responsible person for more than one pharmacy.

4729-17-03 (*Security and control of drugs in an institutional facility.*) To clarify that a licensed health care professional that is authorized to administer a specific drug may also access that drug from emergency or contingency drug stock.

4729-17-05 (*Controlled substance record keeping.*) To add language to clarify that the health care professional responsible for the controlled substance shift counts and reconciliation must be licensed.

4729-17-09 (*Drug orders for patients of an institutional facility.*) To remove unnecessary language regarding drug orders and route of administration.

4729-31-03 (*Labeling.*) To add language to clarify that the name of the patient and the prescriber means full name.

4729-35-09 (*Handling fee.*) To set the maximum amount a drug repository can charge for a handling fee is twenty dollars and that the total fees collected shall not exceed the programs restocking and dispensing costs.

4729-36-04 (*Sample drug distribution to a charitable pharmacy.*) To add language to clarify that a prescriber that is exempt from licensure as Terminal Distributor of Dangerous Drugs may also donate drugs to a charitable pharmacy.

4729-37-04 (*Information required for submission.*) To add language to clarify that a patient address means the residential address.

4729-37-07 (*Frequency requirements for submitting drug database information.*) To remove language that referenced specific time periods that have expired and are no longer applicable.

The Board also reviewed the following rules and proposed that no changes be made: 4729-5-11, 4729-5-13, 4729-5-14, 4729-5-16, 4729-5-35, 4729-5-36, 4729-9-01, 4729-9-03, 4729-9-12, 4729-9-18, 4729-9-20, 4729-17-04, 4729-17-08, 4729-17-10, 4729-17-11, 4729-17-13, 4729-36-01, 4729-36-02, , 4729-36-03, 4729-36-05, 4629-36-06, 4729-37-01, 4729-37-02, 4729-37-03, 4729-37-05, 4729-37-06, 4729-37-08, 4729-37-09, 4729-37-10.

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