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 7, 2005** at 2:00 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:

<u>4729-3-01</u> (*Definitions.*) To remove reference to the out-dated publication "The Internship Experience".

4729-5-01 (Definitions.) To define "originating pharmacy".

<u>4729-5-15</u> (*Prescriber.*) To remove language regarding the APN pilot program that is no longer applicable.

<u>4729-5-30</u> (*Manner of issuance of a prescription.*) To indicate, as in rule 4729-5-21, that a facsimile must have information regarding the origin of the prescription.

<u>4729-5-34</u> (*Successful completion of the "Test of Spoken English"*.) To add TOEFL-iBT as a board-approved equivalent to TSE.

<u>4729-7-01</u> (*Definitions.*) To update the name of the "Accreditation Council on Pharmaceutical Education".

<u>4729-7-02</u> (*Requirements for renewal of a pharmacist identification card.*) To remove language regarding continuing education reporting that is no longer applicable.

<u>4729-7-05</u> (*Procedure for approval as a provider of continuing pharmacy education.*) To update the name of the "Accreditation Council on Pharmaceutical Education".

<u>4729-9-02</u> (*Minimum standards for a pharmacy.*) Added the requirement for posting operating hours that was removed from rule 4729-9-11.

<u>4729-9-11</u> (*Security and control of dangerous drugs.*) Clarifies that a board-approved delivery system may be utilized when a pharmacy is closed.

<u>4729-9-15</u> (*Report of theft or loss of dangerous drugs, controlled substances, and drug documents.*) To clarify that a "terminal" means a terminal distributor of dangerous drugs, and adds reporting requirements of drugs lost in shipment or transit.

<u>4729-9-20</u> (*Drugs repackaged by a pharmacy.*) Removed unnecessary language.

<u>4729-9-25</u> (*Drugs compounded for direct administration by a prescriber.*) To allow pharmacists to compound limited quantities of drugs for use by prescribers.

<u>4729-17-01</u> (*Definitions.*) To allow hospitals to use passwords and personal identifiers as a form of positive identification under certain circumstances.

<u>4729-17-03</u> (*Security and control of drugs in an institutional facility.*) To clarify that positive identification is required to document drug transactions.

<u>4729-17-04</u> (*Records; institutional facility pharmacy.*) To clean up language on record retention and storage.

<u>4729-17-08</u> (*Minimum standards for an institutional facility pharmacy.*) Corrected language in the rule title.

<u>4729-17-09</u> (*Drug orders for patients of an institutional facility.*) To change out-dated language.

<u>4729-17-13</u> (*D.E.A. numbers for hospital employed physicians.*) To update the term "physicians" to "prescribers".

<u>4729-33-04</u> (*Recordkeeping.*) To correct the spelling of record keeping and to clarify that "positive identification" is required to document drug transactions.

<u>4729-35-01</u> (*Definitions.*) To allow drugs packaged by a pharmacy to be eligible for the drug repository program.

<u>4729-35-04</u> (*Eligible drugs.*) To state that, prior to donation, all pharmacy and patient identifiers must be removed from the drug packaging.

<u>4729-36-01</u> (*Definitions.*) To define terms used in new Chapter 4729-36 regarding charitable pharmacies.

<u>4729-36-02</u> (*Licensure of a charitable pharmacy.*) To indicate what is required to be submitted to the Board of Pharmacy when applying for licensure as a charitable pharmacy.

<u>4729-36-03</u> (*Requirements of a charitable pharmacy.*) To describe that a charitable pharmacy is considered to be a pharmacy and must follow all applicable laws, rules, and regulations.

<u>4729-36-04</u> (*Sample drug distribution to a charitable pharmacy.*) Describes who may give sample drugs to a charitable pharmacy.

<u>4729-36-05</u> (*Eligibility requirements for sample drugs received by a charitable pharmacy.*) Describes what sample drugs a charitable pharmacy may receive.

<u>4729-36-06</u> (*Dispensing a sample drug by a charitable pharmacy.*) Describes how a sample drug can be dispensed.

<u>4729-37-01</u> (*Definitions.*) To define terms used in new Chapter 4729-37 regarding the drug database program.

<u>4729-37-02</u> (*List of drugs to be reported.*) Provides a list of drugs that required entities must report to the Board of Pharmacy for the drug database.

<u>4729-37-03</u> (*Entities required to submit information.*) Describes those entities who must submit information to the Board of Pharmacy for the drug database.

<u>4729-37-04</u> (*Information required for submission.*) Lists the specific information that pharmacies and wholesalers must submit to the Board of Pharmacy for the drug database.

<u>4729-37-05</u> (*Electronic format required for the transmission of dispensing information.*) Specifies the format that pharmacies must use for information to be transmitted to the Board of Pharmacy for the drug database.

<u>4729-37-06</u> (*Electronic format required for the transmission of wholesale drug sales.*) Specifies the format that wholesalers must use for information to be transmitted to the Board of Pharmacy for the drug database.

<u>4729-37-07</u> (*Frequency requirements for submitting drug database information.*) Indicates that entities required to submit information to the Board of Pharmacy must do so twice a month.

<u>4729-37-08</u> (*Procedures for obtaining drug database information.*) Outlines how permitted entities may obtain information from the drug database.

<u>4729-37-09</u> (*Requesting an extension to the information storage requirements.*) Specifies how a government entity or law enforcement agency can request that database records be retained beyond two years.

<u>4729-37-10</u> (*Providing database statistics and law enforcement outcomes.*) Allows the Board of Pharmacy to present and provide database statistics and law enforcement outcomes based on request information in summary, statistical, or aggregate form.

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