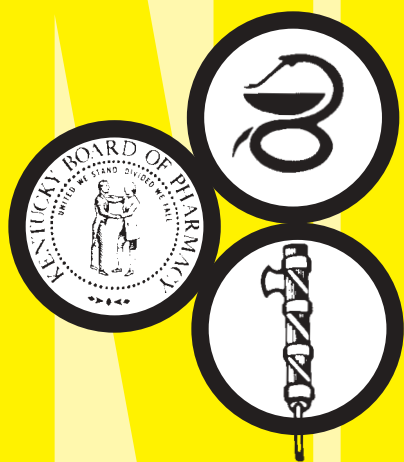


March 2004



Kentucky Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

23 Millcreek Park
Frankfort, KY 40601-9230

Kentucky Pharmacy Mourns Loss of Robert L. Barnett, Jr

The profession of pharmacy lost a true leader with the death of Robert L. Barnett, Jr, on January 20, 2004. Mr Barnett served as the executive director of the Kentucky Pharmacists Association for 12 years.

Through his leadership and dedication to the practice of pharmacy, Mr Barnett helped lay the foundation for pharmacy in the 20th and 21st centuries. Our condolences to his family.

Michael A. Moné

Michael A. Moné, RPh, JD, of Versailles, KY, resigned as executive director of the Kentucky Board of Pharmacy on January 7, 2004. Mr Moné will be pursuing other interests and opportunities in pharmacy. The Board thanks Mr Moné for his many contributions and service to the Board, pharmacists, and citizens of the Commonwealth of Kentucky.

The Board named Jeffrey L. Osman, PharmD, as the interim executive director until the position is filled.

Pharmacist Recovery Network

Submitted by Brian Fingerson

I have been asked to briefly deal with the question of what may happen to you professionally if you should get pulled over while driving under the influence (DUI). This question has been discussed and debated within the health care profession on many occasions. DUI incidents do come to the attention of the Board on an occasion. When they do, Pharmacist Recovery Network is usually consulted. If the DUI is an isolated incident, ie, there are no other alcohol- or drug-related citations within a five-year period, any review and/or investigation may stop at that point, unless there is a formal citizen complaint. If, however, there are other instances of problems with alcohol and/or drugs that have been identified, the person may be asked to meet with the Recovery Committee and/or submit themselves to an evaluation by an addictions professional. Then, dependent upon the results of that evaluation, further action may be required through the Recovery Committee and possibly the Board.

Protection of the public is the foremost concern along with getting help for the professional with a problem. Should you or someone you know need confidential help, please contact Brian Fingerson at 502/749-8385 or kyprn@insightbb.com.

Opening, Closing, or Moving a Pharmacy

Pharmacists, pharmacy owners, and consultant pharmacists are reminded that when opening, closing, or moving a pharmacy including special limited medical gas pharmacies, there are proper procedures to follow. Please refer to the Kentucky Practice Act for instructions or feel free to contact the Board office.

2004 Pharmacist License Renewals

License renewals for 2004 were mailed to all Kentucky Board of Pharmacy-licensed pharmacists in early January. Pharmacists continuing to practice after the February 28, 2004 licensure expiration deadline without a renewed license and a signed pocket card are in violation of the statute. Pharmacists should have proof of general pharmacy continuing education completed and certified by December 31, 2003, at their primary place of practice available for review by the pharmacy and drug inspectors.

Pharmacy Permit Renewals

Pharmacy permits expire on June 30, 2004. Renewal applications will be mailed out in early May to all pharmacies or corporate coordinators in order to allow time for processing. Failure to submit your renewal application by June 15, 2004, may result in unnecessary interruption of deliveries to your pharmacy. All incomplete applications will be returned. An incomplete application may include: (1) failure of the pharmacist-in-charge and/or owner to sign the application; (2) failure to enclose the proper fee; and (3) failure to provide ownership information and other required information.

Pharmaceutical Compounding – Sterile Preparations

Submitted by Philip C. Losch

As of January 1, 2004, United States Pharmacopoeia (USP) Chapter 797 was introduced and became mandatory within the Commonwealth of Kentucky under current statutes. This chapter provides procedures and requirements for compounding sterile preparations.

Sterile compounding differs from non-sterile compounding primarily by requiring a test for sterility, requiring cleaner facilities, specific training and testing of personnel, air quality evaluation and maintenance, and sound knowledge of sterilization and solution stability principles and practices. In other words, USP Chapter 797 has many new major implications for pharmacies in Kentucky that are preparing sterile products.

The intent of USP 797 is to prevent harm and fatality to patients that could result from microbial contamination, large content errors in strength, or incorrect ingredients in compounded sterile products (CSPs). This new chapter applies to health care institutions, pharmacies, and other facilities in which CSPs are prepared, stored, and dispensed.

This chapter in USP is over 20 pages in length and is too complex to summarize in this brief article. Therefore, this information is being presented to encourage those that are compounding CSPs to become more familiar with these new requirements. Issues such as environmental classification will be necessary. Under the old guidelines, only the laminar hood was certified. Now, the environment (clean room) will need to meet specific standards as defined by the risk level that applies. New criteria for person-

Continued on page 4

Continued from page 1

nel cleaning and gowning are outlined. No longer will a standard lab jacket meet the requirements of USP 797.

Personnel training, verification of accuracy, equipment checks, and quality assurance are also addressed in this new chapter. Lines of responsibility are explained and all persons involved with the CSPs will be held accountable. Since this information will be news to many sterile compounders in Kentucky, the Board is requesting that they become more informed and address any issues of noncompliance. The Board recognizes that many changes may be necessary for compliance, and that some of these changes cannot happen overnight. But, a plan of action should be immediately developed by those persons responsible for compounding sterile preparations in their pharmacies.

Newsletter Comments

Each Board *Newsletter* contains information important to all Kentucky licensed pharmacists. We urge you to read, share, and file each *Newsletter* for future reference.

For a little history, the *Newsletter*'s masthead, designed by the National Association of Boards of Pharmacy®, is composed of three symbols, each representing a facet of the publication's purpose. The "Bowl of Hygeia" represents the profession of pharmacy, combined with Fasces, the Roman symbol of authority, and the seal of the Kentucky Board of Pharmacy. Together the three emblems characterize the legal and professional duties entrusted by the citizens of Kentucky to the Board of Pharmacy.

Grounds for Acting Against License

KRS 315.121 (3) states:

Any licensee, permit holder, or certificate holder entering an "Alford" plea, pleading nolo contendere, or who is found guilty of a violation prescribed in subsection (1)(c) [conviction of a felony], [conviction of an act involving moral turpitude or gross immorality] or [conviction of a violation of the pharmacy or drug laws, rules, or administrative regulations of this state, any other state, or the federal government] of this section shall within thirty (30) days notify the Board of that plea or conviction. Failure to do so shall be grounds for suspension or revocation of the license, certificate, or permit.

Board Inspectors

If you have ever said, "Oh no! Here comes the Board inspector!" please reconsider your thinking.

True, the inspectors do enforce the laws, rules, and regulations that govern the practice of pharmacy. But in legal and practical issues, the inspectors are the best friends you have. They are knowledgeable about what you must do to practice legally, and they will help you correct issues that could adversely affect you in a court of law or before the Board. Do not be afraid to ask them questions. The inspectors can help clarify your questions about the law or rules and regulations. They will readily provide you with an explanation that will show you how to handle the situation. The inspectors are professionals and deserve your respect for their services. Also, the Board office will be glad to address any questions and/or concerns you may have.

Notification to the Board Office

Pharmacists-in-charge (PICs) and/or pharmacists are required to notify the Board **in writing** if any of the following occur:

1. Change in the PIC or staff pharmacist;
2. Change of employment;
3. Change in schedule of hours for the pharmacy;
4. Change of mailing address; and
5. Change in name. Changes of name must be accompanied by a copy of the legal document that authorized the name change (eg, marriage or decree).

Numbers 1, 2, and 3 shall be submitted within fourteen (14) calendar days of changes pursuant to 201 KAR 2:205.

Page 4 – March 2004

The *Kentucky Board of Pharmacy News* is published by the Kentucky Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote voluntary compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

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Park Ridge, Illinois 60068
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