September 2000

Kentucky Board of Pharmacy

23 Mill Creek Park
Frankfort, KY40601-9230

Charlene L. Sizemore Retires

The following resolution was adopted on June 14, 2000.

Resolution of the Kentucky Board of Pharmacy

Whereas, **Charlene Lee Sizemore**, wife of Adolph and mother of Scott, Katherine, and Elizabeth, accepted a position as administrative secretary to the Kentucky Board of Pharmacy on December 16, 1968; and

Whereas, Charlene Sizemore, for her commitment and dedication to the goals and responsibilities of the Kentucky Board of Pharmacy, was promoted to Executive Secretary on November 11, 1988; and

Whereas, Charlene Sizemore has assisted in the issuance of 5,486 licenses to pharmacists seeking to practice the profession of pharmacy in the Commonwealth of Kentucky and 4,867 intern certificates to pharmacy students and pharmacist candidates seeking a license to practice the profession of pharmacy in the Commonwealth of Kentucky; and

Whereas, Charlene Sizemore has assisted 198 board members serving on 33 consecutive boards of the Kentucky Board of Pharmacy; and

Whereas, Charlene Sizemore has assisted 16 pharmacy and drug inspectors: **Earl Becknell**, **Rodney Bleidt**, **George Brazelton**, **Katie Busroe**, **William Cole**, **Ed Crews**, **Jim Fethe**, **Mike Lewis**, **Phil Losch**, **Paul Mahan**, **Jeff Osman**, **Julio Polio**, **Richard Ross**, **Maxine Snively**, **Craig Wells**, and **Jeff Wells**; and

Whereas, Charlene Sizemore has served with distinction under **Executive Director John H. Voige** (1968-1985), **Executive Director Richard L. Ross** (1985-1992), **Interim Executive Director Julio Polio** (1992), **Executive Director Ralph E. Bouvette** (1993-1996), and **Executive Director Michael A. Moné** (1996-2000); and

Whereas, Charlene Sizemore and her husband and children have survived her service to the above named Executive Directors and Interim Executive Director; and

Whereas, Charlene Sizemore through her dedication and service to the Kentucky Board of Pharmacy and kind aspects of character has come to be respected and loved by those with whom she has served and assisted; and

Whereas, Charlene Sizemore has declared her intention to conclude her service to the Citizens of the Commonwealth and Kentucky Board of Pharmacy, effective July 31, 2000;

Therefore, Be It Resolved that the Kentucky Board of Pharmacy shall with great sadness, but equal best wishes for her future fortunes, accept the aforesaid resignation; and

Therefore, Be It Further Resolved that the Kentucky Board of Pharmacy through the adoption of this Resolution acknowledges and expresses its profound appreciation for the service of Charlene Sizemore to the Citizens of the Commonwealth and Kentucky Board of Pharmacy.

Adopted this 14th day of June 2000, for and on behalf of the Kentucky Board of Pharmacy. **David L. Jaquith**, president.

DEA Policy on Schedule II Controlled Substances

The Board of Pharmacy and the Drug Control Branch recently received information from the Drug Enforcement Administration (DEA) addressing information that may be changed on a Schedule II controlled substance prescription. According to DEA, a pharmacist is permitted to telephone the prescribing practitioner and obtain directions for use, drug strength, dosage form, and drug quantity.

The pharmacist is **never** permitted to make changes to the patient's name, the controlled substance prescribed (except for generic substitution permitted by state law), or the prescriber's signature. These types of changes challenge the necessity of the original prescription and would require a new prescription from the prescribing practitioner.

The pharmacist should document the conversation held with the prescribing practitioner, indicating the date, time,

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and any additional comments of the prescriber on the back of the original hard copy prescription.

This information is based solely upon a DEA Policy Statement, and it is advisable to proceed with caution until there is certainty regarding the application of Kentucky Controlled Substance laws to a Schedule II controlled substance prescription.

Should you have questions or comments regarding DEA's policy, contact Drug Control at 502/564-7985 or DEA at 502/582-5908.

Board Modifies Disease State Record Keeping Requirements

At its March 22, 2000, meeting the Board unanimously approved a motion that: "The Board refrain from citing permit holders and pharmacists for failing to document chronic disease states on patient profiles where the disease state is not known."

In the past, the standard for pharmacy and drug inspectors was that all patients with medications for chronic medical conditions should have a corresponding diagnosis included in the patient record. These circumstances often required the pharmacist to make an "educated guess" as to the appropriate disease state in situations of medications with multiple possible uses. Physicians seldom include diagnoses on prescriptions, except where required by law, and patients often have no idea for what conditions a particular medication was prescribed.

The Board, in its discussions of this motion, made clear that it continues to require the documentation of known disease states as required of 201 KAR 2:210. It further clarified known disease states as those obtained by direct communication with a licensed practitioner, or his staff, and those indicated on a prescription order, either as a de facto diagnosis on the prescription or as a part of the "sig" portion of the prescription. An example of which might be: "Take one tablet daily for high blood pressure." In any of the aforementioned situations, the pharmacist is required to document the disease state in the patient profile.

The Board believes it is in the best interest of the citizens of the Commonwealth of Kentucky for pharmacists to strive to document all disease states but recognizes through this motion that a pharmacist is not required to document a professional guess. (*Submitted by David L. Jaquith, President.*)

Compliance Reminders

Prescriptions Written by Out-of-State Physician Assistants and Nurse Practitioners for Controlled Substances: This issue, involving principles of jurisdiction, was partially addressed in the Board of Pharmacy June 2000 *Newsletter*. In the Commonwealth, Advanced Registered Nurse Practitioners (ARNPs) and Physician Assistants (PAs) are **not** authorized to prescribe controlled substances; therefore, any controlled substance prescription a Kentucky pharmacist receives as a basis for dispensing that controlled substance, though presumptively valid in another state, would not be valid in Kentucky.

Pharmacy Compounding

After reviewing federal law and long discussions, the Board, during its May 17, 2000, meeting determined that it is a violation of current statutes and regulations for a retail pharmacy to compound a product and sell it to a licensed physician's office for administration to patients.

The Food and Drug Administration (FDA) Modernization Act of 1997, which went into effect in November 1998, contained a section addressing pharmacy compounding. The intent of this Act was to clarify the difference between compounding and manufacturing. After defining a compounded product, the Act exempts them from the new drug requirements of the Federal Food, Drug, and Cosmetic Act (FDCA). Compounding pharmacies are exempt from the "new drug" provisions of this Act if the following requirements for a compounded product are met: (1) It must be prescribed by a licensed physician; (2) It must be for an individual patient; (3) It must be an unsolicited prescription; (4) It may not copy commercially available products regularly or in inordinate amounts; (5) It may not be something that has been withdrawn from the market because it was found to be unsafe or ineffective, or on a list of substances that FDA determined were difficult to compound; and (6) The bulk drugs used must be on an FDA-compiled list, from a registered manufacturer, and accompanied by a certificate of analysis.

Board Office Has Relocated

By the time you receive this *Newsletter*, the Kentucky Board of Pharmacy will officially have moved. The new address will be:

Kentucky Board of Pharmacy
23 Millcreek Park
Frankfort, KY 40601-9230.

Kentucky Pharmacists Recovery Network

It began in Kentucky in 1986. A group of pharmacists was assembled at the Kentucky Pharmacists Association headquarters and charged with the task of finding ways to help pharmacists who may have the disease of alcoholism and/or addiction. From that meeting came a loosely knit organization that was named "P**h**armacists H**e**lping Fe**l**low **P**harmacists (HELP). This group met on an irregular basis for several years. HELP set up a continuing education program on substance abuse issues and calls began to come from pharmacists who were experiencing problems due to their inappropriate use of alcohol or drugs.

In 1998, with the help of numerous people, legislation was passed to assist in funding a program to further aid those in need who have this disease that so adversely affects the profession of pharmacy. In January 2000, Impaired Pharma-

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cists Committee, a committee appointed by the Board of Pharmacy, met for the first time. The Committee consists of members from various geographic areas of the Commonwealth. The Committee's task is to be an additional source of information for the Board when it comes time for them to act upon the license of a pharmacist who is petitioning for the reinstatement of a license that has been suspended, or a pharmacist who is ready to lose their pharmacist's license due to impairment of their ability to practice.

Brian Fingerson is the contact pharmacist for any questions or problems a pharmacist may have regarding chemical impairment or substance abuse issues within the profession of pharmacy. Brian is also the list-keeper for an informal group of pharmacists in recovery called Kentucky Pharmacists Recovery Network (KYPRN). It is part of the larger PRN network through the American Pharmaceutical Association (APhA). Brian can be contacted at 502/222-9802, or via digital pager number 502/478-0213 or 1-888/392-4621.

Pain Management and Palliative Care Helpline

Effective symptom management is a critical component to obtaining comfort and peace during the last stages of life. The *Journey's End* Project, an initiative based at the Kentucky Hospital Research and Education foundation, is offering a helping hand. A toll-free line has been established to provide an opportunity for Kentucky physicians, pharmacists, physician assistants, and nurse practitioners to strategize treatment options with physicians when having difficulty managing pain and other symptoms associated with care for the terminally ill. The helpline is being staffed by physicians who have special training in pain management and palliative care, also known as comfort care. Clinicians can call 1-888/733-6700, twenty-four hours a day, seven days a week and expect a timely response.

The *Journey's End* Project is a three-year initiative designed to provide a better quality of life for Kentucky's dying population. It is made possible through a generous grant from the Robert Wood Foundation with additional funding support from Kentucky organizations and individuals. Other project partners include Kentucky Hospital Association, Kentucky Medical Association, Kentucky Nurses Association, Kentucky Association of Health Care Facilities, and Kentucky Association of Hospices.

201 KAR 2:230. Special limited pharmacy - central refill pharmacy.

Section 1. Definition. "Central refill pharmacy" means a pharmacy located in the Commonwealth that provides packaging, labeling, and delivery of a refill prescription product to another pharmacy in the Commonwealth for the purpose of refilling a valid prescription.

Section 2. The central refill pharmacy shall:

(1) Either: (a) Have a written contract with the pharmacy which has custody of the original prescription authorization for refill dispensing; or (b) Be under common ownership with that pharmacy;

(2) Prepare the label for the refill prescription product which clearly identifies the name and address of the pharmacy preparing the product for refill dispensing and the name and address of the pharmacy that will receive the prepared product for dispensing to the patient;

(3) In addition to its obligation to maintain complete and accurate records of drug products received and otherwise disposed of, maintain complete and accurate records of the preparation of the refilled prescription product, including the name of the:

(a) Pharmacist who verified the accuracy of the refilled prescription product;

(b) Pharmacy preparing the refilled prescription product; and

(c) Pharmacy to which the prepared refill prescription product is delivered;

(4) Provide the originating pharmacy with written information that describes how a patient may contact the central refill pharmacy if the patient has any questions about the preparation of the prescription refill; and

(5) Be responsible for ensuring that the order has been properly prepared and verified by a pharmacist.

Section 3. The pharmacy to which a prepared prescription refill product is delivered shall:

(1) In addition to its obligation to maintain complete and accurate records of drug products received and otherwise disposed of, maintain complete and accurate records of the receipt and dispensing of the centrally refilled prescription product, including the name of the:

(a) Pharmacist who verified the accuracy of the refilled prescription product prior to its dispensing; and

(b) Pharmacy preparing the refilled prescription product;

(2) Be responsible for ensuring that the refill has been properly prepared, packaged and labeled;

(3) Provide the patient with written information that described how a patient might contact either:

(a) The central refill pharmacy if the patient has any questions about the preparation of the prescription refill; or

(b) the dispensing pharmacy if the patient has

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any questions about the use of the medication; and

(4) Be responsible for adherence to the requirements of 201 KAR 2:210. (eff. 06-12-2000)

Provider Tax Expires

Please be advised that the 15 cents per prescription provider tax expired July 1, 2000.

CLIA Waiver Information

The Board office has received a number of questions regarding Clinical Laboratory Improvement Amendments (CLIA) waivers. In 1998, congress passed a public law regulating clinical laboratory procedures. This law applies to labs, physician offices, and pharmacies that perform testing of materials derived from the human body for purposes of diagnosis, prevention, treatment, or health assessment. Pharmacies performing lab testing must adhere to strict Occupational Safety and Health Administration (OSHA) guidelines regarding blood borne pathogen exposure including:

1. Appropriate handling and disposal of blood borne and otherwise potentially infectious material;
2. Training of all persons likely to perform test; and
3. Written plan defining what to do in event of an exposure.

To obtain a Clinical Laboratory Application (HCFA Form 116), please contact Jeff Miniard at the Cabinet for Health Services, Division of Licensing and Regulation, 275 E Main St, Frankfort, KY 40621. You may also contact them by telephone at 502/564-2800. the cost of the Certificate of Waiver is $150 and is valid for a period of two years.

Dichloralphenazone is a Schedule IV Controlled Substance

The Board office was recently notified by the Drug Control Branch that dichloralphenazone is a Schedule IV controlled substance since it contains chloral hydrate. It has been erroneously treated as a non-controlled substance, when in fact should have been treated as a Schedule IV controlled substance. In the near future, the Drug Enforcement Administration (DEA) will publish a clarification in the Federal Register.

Kentucky law states that any material, compound, mixture, or preparation containing chloral hydrate is a Schedule IV controlled substance (KRS 218A.110 (1); therefore any product containing dichloralphenazone is also a Schedule IV controlled substance. Pharmacists are being advised to inventory all dichloralphenazone products, make the appropriate adjustments to their computer, and begin notifying practitioners that any prescription for a dichloralphenazone product must be written on a Kentucky security prescription blank. If you have questions or comments, please contact the Drug Control Branch at 502/564-7985 or DEA at 502/582-5908.

Newsletter Comments

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

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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Permit No. 5744