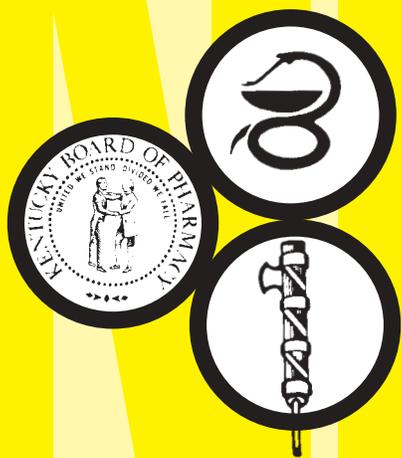


June 2003



NEWS

Kentucky Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

23 Millcreek Park
Frankfort, KY 40601-9230

Pharmacy Permit Renewals

All pharmacy permits expire on June 30, 2003. Pharmacy permit renewal packets for 2003-2004 were mailed to all pharmacies or corporate coordinators around the first week in May. Federal law prohibits manufacturers and wholesalers from delivering legend medications to persons or entities that do not have active licenses. Failure to have a current permit after the June 30, 2003 deadline may result in disciplinary action against the permit holder and/or pharmacist-in-charge.

Please be reminded that if your pharmacy has an address change, relocating within the current premises of the existing permit, or changing ownership, you must complete a new pharmacy permit application. A pharmacy application with a United States Post Office box address only will **not** be accepted and will be returned. There must be a physical address listed on the application. An inspection is required for a change in address and relocating within the existing premises. A change of ownership requires prior approval from the Kentucky Board of Pharmacy office. Pharmacists signing the pharmacy permit application to be a pharmacist-in-charge should make sure that they are not on record with the Board as being a pharmacist-in-charge for another pharmacy, unless previously approved by the Board. Once you are approved as a pharmacist-in-charge, the Board will issue a pharmacy permit identifying you as the pharmacist-in-charge. The pharmacy permit should be displayed conspicuously.

NCPDP/NABP Pharmacy Numbers

In 1979, the National Council for Prescription Drug Programs (NCPDP) in conjunction with the National Association of Boards of Pharmacy® (NABP®) implemented a pharmacy numbering system based on the need of the pharmaceutical industry to have an identification system for pharmacies. The purpose of the numbering system is to enable a pharmacy to be identified to third-

party processors by one standard number. Inquiries regarding NCPDP numbers should be directed to NCPDP in Scottsdale, AZ, at 480/477-1000.

News From the Impaired Pharmacists Committee

Submitted by Brian Fingerson

One of the joys of being a pharmacist is educating patients on treatment for various disease states. Helping the patient understand the “how” and “why” of his or her illness is rewarding. When the patient is prescribed a treatment regimen for his or her illness, we as pharmacists can help him or her understand the benefits of compliance with his or her treatment as well as the risks he or she may incur by not following treatment guidelines. Being compliant with one’s treatment for the disease of substance abuse disorder or addiction is every bit as important as being compliant with treatment for hypertension or diabetes.

The disease of addiction is said to be “cunning, baffling, and powerful” as well as a chronic, progressive, fatal disease. So I tell my patients with this disease that constant vigilance with what needs to be done daily is imperative. We have a treatment contract that must be followed in order to reinforce that importance. The benefits of proper treatment for this disease are great. The Board of Pharmacy and its Impaired Pharmacists Committee have seen these benefits firsthand. Should you desire more information or need help, please call Brian Fingerson at 502/222-9802 or by pager at 1-888/392-4621.

Electronic Signatures

Submitted by Philip Losch

Recently, the Board has had numerous inquiries about the acceptance of prescriptions with electronic signatures. This article will try to address some of the questions being asked. First, let it be very clear that there is no provi-

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sion for allowing electronic signatures on controlled substance prescriptions. Kentucky, like most other states, is awaiting Drug Enforcement Administration's (DEA) approval of electronic transmission criteria. Therefore, electronic transmission or Schedule II-V prescriptions are not allowed under current federal and state laws.

Historically, we have all observed the fact that all hard copy prescriptions must be signed by the practitioner. This is still the rule, but according to KRS Chapter 369, an electronic signature is acceptable for non-controlled prescriptions. An electronic signature entails more than a printed name on a prescription. The rules in KRS Chapter 369 are explicit and involve levels of security that must be observed. Therefore, the electronic signature must conform to the rules in KRS Chapter 369.

The above explanation is not to be confused with authorization of refills transmitted between two fax machines. Many pharmacies are now requesting authorization of refills by faxing a request to the practitioner and receiving this request back with a signed note from the practitioner or his or her designee. The Board views this as medical information transferred between medical professionals and it then becomes the pharmacist's responsibility to ascertain the validity of the information. Once appropriate due diligence is completed, this information can then be reduced into the writing of a new prescription. And, if this transmission involves a controlled substance, the pharmacist must sign the prescription as with any other telephoned controlled prescription. The issue of electronic signatures does not apply to faxed prescription refill requests.

In all cases it is the responsibility of the pharmacist to verify and validate any prescription prior to dispensing. No system is fail proof or foolproof. Therefore, appropriate due diligence must always be done. The advent of electronic prescribing is upon us. The Board has embraced this concept with much favor, but the laws on a federal level have not kept pace with the technology being developed. It is anticipated that many changes lie ahead, and that the Board will monitor these issues closely.

House Bill 459: Out-of-State Practitioner Bill

House Bill 459 (HB-459) was officially signed into law on March 12, 2003, and will take effect beginning June 12, 2003. HB-459 amends the KRS 217:015 definition of "practitioner" to also include "health care professionals who are residents of and actively practicing in a state other than Kentucky and who are licensed and have prescriptive authority under the professional licensing laws of another state, unless the person's Kentucky license has been revoked, suspended, restricted, or probated in which case the terms of the Kentucky license shall prevail."

Thus, this law allows pharmacists to dispense prescriptions written by out-of-state practitioners as long as they have an active license in another state and their license has not been revoked, suspended, or probated in Kentucky. With regard to this change, one must recognize that prescriptions for controlled substances written by out-of-state advanced registered nurse practitioners (ARNPs) and physician assistants (PAs) are not valid in the Commonwealth of Kentucky, regardless of ARNP and PA prescriptive privileges in another state. If there are any further questions or clarifications requested regarding HB-459, feel free to contact the Kentucky Board of Pharmacy.

The Young Pharmacy Practitioner's Perspective

Submitted by: J.D. Hammond

As I reflect on my final clerkship here at the Board of Pharmacy, I would have to say it has been a great rotation to prepare me for the practice of pharmacy. I have reviewed numerous cases, participated in many pharmacy inspections, read many laws, and now better understand that which constitutes "unprofessional conduct" when licensed as a pharmacist in the Commonwealth of Kentucky. Although many feel knowing "what to do" is the most important concept that reflects competency, truly defining moments in one's profession may often come when making the crucial decision not to fill a prescription order (eg, based on drug-disease interactions, drug allergy, etc) or provide an alternative means to optimally, yet legally, meet a patient's prescription requests.

As for some pointers that may help pharmacists across the state when it comes to Board inspections of your pharmacy, I offer the following suggestions:

- ◆ Electronic signatures on controlled substances (CII-CV) are not considered valid by Drug Enforcement Administration (DEA) at this time. Although these signatures are technically legal on non-controlled substances, due diligence should be exercised to determine the validity of these prescriptions.
- ◆ Always review your continuing education (CE) and do a few extra hours – 15 hours is all that is required and it must be completed by December 31 of each year; however, there is a substantial monetary penalty if CE requirements are not met. So, once again, double-count your CE and do a little extra.
- ◆ DEA 222 Forms should always be filled out completely and this includes recording the received dates on **each** line for each drug ordered once it is received.
- ◆ Quarterly inspections must be performed and documented for all medical gas pharmacies.

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- ◆ An inventory of all controlled substances in possession is required at least every two (2) years.

Attention Pharmacists: New Therapeutic Equivalence Regulation

201 KAR 2:280. Prescription dispensing for formulary compliance is a new regulation authorizing a pharmacist to dispense a therapeutic alternative drug product with the ordering practitioner's approval via a pre-printed check box on the prescription, or if in the practitioner's own handwriting as defined by the regulation. This regulation is summarized below and can be found on the Kentucky Board of Pharmacy Web site at www.state.ky.us/boards/pharmacy/.

Section 1. Dispensing

- (1) A pharmacist may dispense a therapeutic equivalent drug product under the following conditions:
 - (a) The ordering practitioner has indicated "formulary compliance approval" on the prescription, in one of the following ways:
 1. In the practitioner's own handwriting; **or**
 2. By checking a "formulary compliance approval" box on a pre-printed form;
 - (b) The pharmacist receives a formulary change as a consequence of the patient's third-party plan; **and**
 - (c) The product designated as "preferred" by the third-party formulary is in the same therapeutic class as the prescribed drug.
- (2) The pharmacist, within twenty-four (24) hours of the formulary compliance substitution, shall notify the ordering practitioner, in an original writing or by facsimile:
 - (a) That the pharmacist engaged in formulary compliance; **and**
 - (b) The therapeutic equivalent drug product that was dispensed.

Section 2. The pharmacist may make adjustments in the quantity and directions to provide for an equivalent dose of the preferred formulary therapeutic alternative.

Kentucky Board of Pharmacy's Web Site

The Kentucky Board of Pharmacy's Web site contains the Practice Act, forms for registration, and other pertinent information, which we hope will be useful to pharmacists. The Board's Web site address is www.state.ky.us/boards/pharmacy/.

Medication Errors – Consumer Complaints

The Board of Pharmacy office receives consumer complaints on a monthly basis regarding medication errors. The Board exists for the protection of the public and, therefore, responds to each complaint. Sometimes the complaint may seem trivial to the pharmacist, but certainly not to the complainant who took the time to report it. When a patient telephones or visits your pharmacy questioning why his or her medication looks different, is a different color, or has a different wording on the label, the **pharmacist** (not the store manager, clerk, or technician) must take the time to verify that the prescription was filled accurately. When medication error occurrences are brought to your attention, do not rely solely upon the computer record when assuring the patient that he or she has received the correct medication. The pharmacist should review the original prescription, patient's profile, dispensing log, and verify the dosage form's color, shape, and markings with the patient or caregiver.

The Board recognizes that on a daily basis, pharmacists spend many hours in their individual pharmacies dispensing prescriptions without error. It also recognizes that pharmacists will, occasionally, commit a medication error. The majority of the time, the matter is resolved appropriately and the Board office never hears about it. Recent medication error complaints suggest that pharmacists had a clear opportunity to listen to patients at the store level and correct errors before situations worthy of filing a complaint with the Board occurred. Granted, some complaints are without merit, but your diligence in investing a few minutes of your time on each complaint may prevent a serious health consequence. Patients place a great amount of trust and respect in their pharmacists to accurately dispense prescriptions. A conscientious effort by you today may save a great deal of aggravation tomorrow. The primary promise pharmacists make to the public in return for their privilege to practice the profession is the promise to dispense the prescribed drug correctly.

Kentucky Board Nominations

Pursuant to KRS 315.150, the Kentucky Pharmacists Association (KPhA) has the statutory responsibility to select and submit to Governor Paul E. Patton the names of qualified pharmacist candidates to serve on the Board of Pharmacy. Candidates must have at least five years' experience in pharmacy practice and be a Kentucky resident in good standing with the Board.

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KPhA has announced an opening for nominations of individuals to be considered for the 2004 candidate list. Nominees need not be members of the Association.

A cover letter highlighting the talents or experiences that a potential candidate would bring to the Board and the candidate's resume should be forwarded to KPhA, 1228 US 127 S, Frankfort, KY 40601.

Service to the Board can be a unique and rewarding experience. The decisions made are at many times difficult and often times unpopular. However, the opportunity to leave a lasting impression on the profession is unmatched. Many pharmacists quickly remark that they better understand how to regulate the profession, but few attempt to enter the batter's box, and fewer attempt to step up to the plate. If you believe that you possess talents beneficial to our profession, challenge yourself to serve on the Board.

Pharmacy Closures

It seems that today, as many pharmacy owners contemplate mergers or buy-outs, there is a strong tendency or desire to maintain a high level of secrecy in order to protect the seller or buyer. Although negotiations are waged over many months, actual transfer decisions appear to be effective virtually overnight, leaving in their wake anxious employees and the number one priority, the patients. Pharmacy regulation 201 KAR 2:106, as originally drafted, was designed to protect the rights of patients and guarantee them the

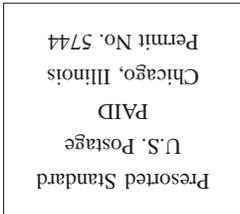
opportunity to make informed choices in the face of uninterrupted, preferred pharmacy care.

The perfect solution would be the appeasement of both needs. While it is understandable that circumstances may not always allow for this, be forewarned that Board sympathies must favor the patients. And, by the way of reminder, please be advised that all "pharmacy"-related signage, outside or within, must be removed from vacated premises. Should that responsibility be the permit holder's or the landlord's? The Board's first recourse is the professional it has direct jurisdiction over – you, who in turn must deal with the former landlord in a reasonable time frame. Check your previous locations!

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