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Alabama State Board of Pharmacy News

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Board Hires Director of Professional Affairs

The Alabama State Board of Pharmacy would like to welcome the newest addition to its staff, Dr Susan Alverson. Susan has taken the position of director of professional affairs, and her job will be to work with the developers of the Board's new database and to oversee the conversion from the current system. She will also be responsible for working with sterile compounding pharmacies in Alabama to ensure compliance with United States Pharmacopeia Chapter <797>.

Susan earned both her master of science and doctorate degrees in public administration from the University of Southern California; her master of science in hospital pharmacy from Virginia Commonwealth University, Medical College of Virginia; and her bachelor of science degree in pharmacy from the University of Wisconsin.

Prior to joining the staff of the Board, Susan was the associate dean for student/alumni affairs and director of continuing education (CE) at Samford University, McWhorter School of Pharmacy in Birmingham, AL, from January 2, 1993 to July 31, 2012.

Database Conversion

In May of this year, the Board ended its contract with the company that had been providing the data support system for all office functions, its e-mail, and its Web support for the past three years. The Board also began a new contract with GL Solutions, which is a company that works solely with government offices. The Board researched this decision and found strong support from other boards of pharmacy as well as non-pharmacy groups that served as licensing and inspection offices. The changeover was, of course, a challenging task for everyone involved. It meant new screens, different methods of organizing data, and the inevitable "new way of doing things." Overall, the process was successful. As you can imagine, there are items that did not convert well, and the Board has spent the last six weeks tweaking and revamping. Fortunately, all data converted is intact, though it may have a new look for the Board.

One issue with this changeover is that the new data management company does not manage e-mail or Web sites. Consequently, the Board also changed to a new support system for both of these services and has had to engage in developing interfaces with the two new partners providing the data management and e-mail/Web support services. For that reason, you may have found the Board's Web site down for a few days in May, and one or two functions on the Web site are still in development. The license verification function is now working, as is the change of status function. One of the Board's next steps will be to change the appearance of the Web site. Everyone with whom the Board has spoken has commented that the Board should eliminate the rolling news screen. That will be the first change you will see; hopefully, you will be able to read an article without having to wait for it to roll around again to finish the story.

Technician Re-Registration for Fall of 2013

A number of methods have been used over the years for technician re-registration. Some have been more efficient and successful for all concerned than others. For the re-registration of 2013, the Board is putting a new system into place, which it hopes will go smoothly for those re-registering, as well as for the Board's office staff who are attempting to manage the influx of registrations. The Board has over 40,000 technicians on file and it can expect between 10,000 and 15,000 of them to re-register before December 31, 2013. In previous years, the Board has accepted paper applications for re-registration; that requires staff at the Board office to manually enter the information that is submitted and is definitely time consuming. The Board has also required submission of documentation of CE hours with re-registration. The CE documentation and the re-registration information do not always arrive together. This requires staff to pull and match information about the person registering at least twice, and sometimes more frequently. The process is very labor intensive and keeps the Board office from providing a timely turnaround for those registering.

Fifty-Year Pharmacist Licensees

The Alabama Pharmacy Association proposed that pharmacists who have been licensed in the state of Alabama for a minimum of 50 years shall pay a reduced fee for re-registration. This required a change to Alabama state regulations for Rules 680-X-3-.02 and 680-X-2-.34. The proposed amendments were discussed at the Board meeting on June 18, 2013. The Board agreed with the proposal and its wording, and based on comments received by the Board through the deadline, the Board voted to accept these amendments as proposed. The rule amendments will become effective approximately August 22, 2013. Since pharmacists renew in "even" numbered calendar years, this will affect the 2014-2015 renewals. Since 2006, the rules have read as shown below. The section with strikethroughs

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Pharmacists Likely to Recommend OTC Medications, CHPA Reports

Patients most often seek a pharmacist's advice on treating coughs, headaches, migraines, and allergies, and 98% of pharmacists recommend or have no reservations recommending over-the-counter (OTC) products to treat such ailments, according to a recent survey. The Consumer Healthcare Products Association's (CHPA) report, "Understanding Trust in OTC Medicines: Consumers and Healthcare Provider Perspectives," presents the results of the survey, which was developed to better understand what drives consumer and health care provider trust in OTC products. The survey, developed and conducted by Nielsen and IMS, included over 1,100 consumer respondents, and over 500 health care provider respondents, composed of pharmacists, pediatricians, nurse practitioners, and primary care providers.

Pharmacists surveyed reported that they were more likely to recommend OTC products that demonstrated successful patient outcomes and consistent outcomes, and products known to be as efficacious as a prescription drug, and those containing ingredients known to be safe.

The survey also asked health care providers whether they recommended OTC products without, before, or in conjunction with recommending prescription drugs for certain symptoms. A majority of pharmacists surveyed, over 60%, recommend OTC medications to treat stomach symptoms and pain, without recommending a prescription treatment, and over 70% recommended OTC allergy, sinus, and flu medications without advising that a prescription drug is needed.

CHPA notes that with the expansion of patient self-care, OTC products will play an increasingly important role in health care. The potential for more prescription products to become OTC products in the new paradigm under consideration by Food and Drug Administration (FDA) could further impact this trend. As consumers are becoming more empowered in making health care decisions, they are also relying more on their pharmacist for medication advice. In fact, Nielsen and IMS findings show that multigenerational households, Hispanic households, and households who care for an adult outside of their home place a high value on pharmacist recommendations regarding selecting appropriate OTC medications, notes CHPA.

The full CHPA White Paper is available at *www.yourhealthathand.org/images/uploads/OTC_Trust_Survey_White_Paper.pdf.*

ISMP Study on Targeted Mandatory Patient Counseling

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition by visiting www.ismp.org. *ISMP is a federally certified patient safety organization, providing legal protection and confidentiality for submitted patient safety data and error reports. ISMP is also an FDA MedWatch partner. Call 1-800/FAIL-SAF(E) to report medication errors to the ISMP Medication Errors Reporting Program or report online at* www.ismp.org. *ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.*

In a recent study funded by a grant from Agency for Healthcare Research and Quality, ISMP evaluated the use of a combined checklist and patient information leaflet used during mandatory counseling sessions for consumers who pick up a filled prescription for 11 targeted medications:

- Opioid-containing analgesics
  - fentanyl patches
  - hydrocodone with acetaminophen
  - oxycodone with acetaminophen
- Anticoagulants
  - warfarin
  - enoxaparin
- Antidiabetic drugs (insulin analogs)
  - Humalog® (insulin lispro)
  - NovoLog® (insulin aspart)
  - Levemir® (insulin detemir)
  - Lantus® (insulin glargine)
  - Apidra® (insulin glulisine)
- Antineoplastic drug (non-oncologic use)
  - methotrexate

All 11 medications are on ISMP's list of high-alert medications dispensed from community pharmacies. Errors with high-alert medications may not be more frequent than errors with other medications; however, the consequences of errors with high-alert medications are often harmful. These 11 medications are also among the top 200 drugs dispensed in the United States, and many are used to treat chronic conditions, thus increasing the potential impact on public safety.

The medications were flagged in some manner to identify mandatory counseling opportunities. When a patient or patient representative picked up a flagged prescription, a pharmacist conducted a short counseling session (one to three minutes) that included the exchange of several key points on the checklist. At the end of the counseling session, the pharmacist provided the leaflet to the patient, along with a survey to complete and send back to ISMP.

Counseling sessions for these drugs were conducted for a consecutive period of four weeks, during which time, one trained ISMP staff member observed the counseling sessions for one day (six hours) to collect information on factors that facilitate or inhibit the counseling sessions. At the end of the four-week period of mandatory counseling, pharmacists at participating pharmacies were asked to complete a short mail-in survey regarding their perceived value of the process.

Results of the study showed that these consumer leaflets offer important safety tips for taking medication safely. Each leaflet begins with, "High-alert medicines have been proven to be safe and effective. But these medicines can cause serious injury if a mistake happens while taking them. This means that it is vitally important for you to know about this medicine and take it exactly as intended."

ISMP tested the readability, usability, and perceived value of the leaflets. Ninety-four percent of patients felt the leaflets provided great information or good information to know. Ninety-seven percent felt the information in the leaflets was provided in a way they could understand. Eighty-two percent of patients taking the drug for the first time and 48% of patients who had previously taken the medication reported learning something new. Overall, 85% of the patients felt they were less likely to make a mistake with the medication because they had read the leaflet.

The leaflets are available for download and can be reproduced for free distribution to consumers at *www.ismp.org/AHRQ/default.asp?link=ha.*

Generic Drug Substitution Requires Pharmacist Attention to State Laws and Regulations

While 40 years ago, most states forbade prescription drug substitution, almost all states now have drug product selection laws that allow, encourage, or mandate pharmacists to substitute generics for brand-name

drugs. These laws vary widely from state to state and pharmacists are therefore encouraged to review their state's substitution laws to ensure that they understand and comply with the state's requirements.

FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations* publication, commonly known as the *Orange Book,* is generally considered the primary source for identifying suitable generic alternatives for a brand-name drug, and while not mandated by FDA regulations, the majority of states use the *Orange Book's* determinations of therapeutic equivalence to legally guide pharmacists in substituting generics.

State laws on generic substitution vary widely. A few states, such as Kentucky or Minnesota, follow a "negative formulary" approach, in which substitution is permitted for all drugs except those that appear on a particular list. Other states, including Massachusetts and Wisconsin, use a "positive formulary" approach, in which substitution is limited to the drugs on a particular list.

States also differ as to whether their substitution laws are permissive, thereby allowing a pharmacist to substitute a generic version of a brand-name drug, provided all prescription requirements are met, or mandatory, thereby requiring substitution. Prescription requirements may include such factors as the availability of a cheaper, therapeutically equivalent drug, the prescriber's specification that a brand-name drug be dispensed, or requiring the patient's or prescriber's consent. As reported in the 2013 NABP *Survey of Pharmacy Law*, 14 boards of pharmacy indicate that generic substitution falls into the "mandatory" category, while 38 boards indicate that their substitution laws are "permissive." Oklahoma law states that "[I]t is unlawful for a pharmacist to substitute without the authority of the prescriber or purchaser."

Other regulatory variations include states specifying the acceptable means for the prescriber to designate that substitution is not authorized, and states requiring patient consent prior to substitution.

The full article on this subject, which also reviews considerations regarding the accuracy of therapeutic equivalent determinations, is available in the June-July 2013 *NABP Newsletter,* which may be accessed in the Publications section of *www.nabp.net.*

NHF Provides Standards of Care for Pharmacies Serving Hemophilia Patients

For pharmacies that offer blood-clotting medications, organizations such as the National Hemophilia Foundation (NHF) emphasize the importance of being able to meet the specialized needs of their patients with bleeding disorders.

NHF's Medical and Scientific Advisory Council (MASAC) issued a standards-of-care recommendation in 2008 to assist pharmacies providing clotting factor concentrates for home use to patients with bleeding disorders. MASAC's guidelines are intended to be minimum standards of care and are divided into six areas:

As a brief overview of the MASAC guidelines, pharmacists wishing to meet the standards should:

1. Have a basic knowledge of bleeding disorders and experience with and knowledge of the full range of clotting factor concentrates, ancillary supplies, and hazardous waste disposal.

Pharmacies wishing to meet MASAC standards:

2. Should be able to provide a full range of available concentrates in all available assays and vial sizes, along with all necessary ancillary supplies, and hazardous waste disposal assistance as well as access to nursing services.
3. Should support reliable access to clotting factor for appropriate home treatment, by filling prescription orders within 48 hours, in the quantities prescribed, with expiration dates commensurate with the individual patient's needs.
4. Should be reliably open during regular business hours; provide 24-hour emergency access; and have an emergency action plan that allows patients to receive factor within 12 hours "in case of emergent need," with a goal of three hours "where logistically possible."
5. Should deliver products to the patient's desired location, meeting federal medication shipping standards, and providing an emergency number for patients to call in case of a problem with a delivery.
6. Should maintain patients' treatment prescription information along with maintaining records in compliance with state and federal requirements and be able to track the clotting factor products from manufacturer to patient, and participate in a recall information system.

The full article on this topic is available in the June-July 2013 *NABP Newsletter,* accessible in the Publications section of *www.nabp.net.* NABP notes that each state needs to review the standards recommended by MASAC to determine whether they coincide with existing state board of pharmacy requirements. NABP recognizes the unique patient needs of hemophiliacs, but also the responsibility of state boards of pharmacy to set required standards for medication dispensing and use. NABP is working with NHF to help the boards of pharmacy gain a better understanding of the medication needs of patients to help achieve uniformity in related regulations.

NABPLAW Online Now Includes Guam, Puerto Rico, and the Virgin Islands

The complete pharmacy acts and regulations of Guam, Puerto Rico, and the Virgin Islands are now included in **NABP***LAW*® Online, the comprehensive national data bank of state pharmacy laws and regulations provided by NABP. **NABP***LAW* Online's powerful search capabilities allow users to research subjects one state at a time or across all 50 states and included jurisdictions. More information about **NABP***LAW* Online and a link to the online subscription order form are available in the Programs section of the NABP Web site at *www.nabp.net/programs/member-services/nabplaw/.*

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will be deleted from the rule; the section that is underlined will be added to the rule.

680-X-3-.02. Registration and Reregistration Fee.

"Effective January 1, 2006 for" will be deleted from paragraphs (a); (b); and (c) and paragraph (d) will read as follows:

(d) ~~Effective January 1, 2006 for~~ Eeach pharmacist registration or reregistration to dispense controlled substances listed in Schedule II through V, the registrant shall pay a fee of one hundred dollars ($100) to be renewed in even-numbered years. Upon verification of fifty (50) years of licensure in this state the renewal fee shall be no more than twenty-five dollars ($25.00).

680-X-2-.34 Fees for Applicants for Pharmacist License and Biennial License Renewal.

Paragraph (3) will change as follows while paragraphs (1); (2); (4); and (5) will remain unchanged:

(3) The fee for biennial renewal of a pharmacist license will be $100.00. Upon verification of fifty (50) years of licensure in this state the renewal fee shall be no more than twenty-five dollars ($25.00).

Sterile Product Pharmacies

It is not news to any pharmacist, or to most of the public, that there have been issues with some products compounded by pharmacies that prepare sterile products. Though the vast majority of pharmacies prepare products that serve the well-being of the patient, a small number of pharmacies have bypassed standards and prepared contaminated sterile products. The damage caused by these products has touched people in numerous states and related stories have headlined the national news.

While the federal legislature, pharmacy activists, and Food and Drug Administration debate appropriate oversight for compounding pharmacies, the states maintain the responsibility for inspection and licensing of all pharmacies within their states. Alabama has approximately 200 pharmacies that are registered as sterile compounding businesses. This includes institutional and retail settings, pharmacies that prepare one or two sterile products per day, plus pharmacies that service 1,000-plus bed hospitals, and pharmacies that ship to purchasers in multiple states. Compounding ranges from low-risk to high-risk and hazardous products. In Alabama, the Board wants to be sure that all of these pharmacies in all categories are complying with standards written by the United States Pharmacopeial Convention and adopted by the state of Alabama.

To assist in implementation of this monitoring, the Board hired Dr Susan Alverson in May of this year to commit to inspection of all registered sterile product pharmacies. Dr Alverson obtained her pharmacy degree from the University of Wisconsin and did graduate work at the Medical College of Virginia and at the University of Southern California. She has worked in sterile compounding in the hospital setting and in private home health. She has taught sterile compounding at the McWhorter School of Pharmacy, Samford University since 1993. She and the Board inspectors have been reviewing inspection standards for Alabama pharmacies and have recently begun inspections. If you are a sterile compounding pharmacy, you will likely see Dr Alverson within the next few months.

There will be a topic heading added to the Board Web site at *www.albop.com*. You will be able to view the inspection form and the list of documents that will be required for those inspections. Now would be the time to collect those in one place.

Reminder

Please notify the Board, in writing, of any change of address or employment.

Do You Know a Pharmacist or Technician Who Needs Help?

Call the Alabama State Board of Pharmacy Wellness Program help-line at 205/981-2273 or 251/866-5585. The Board Wellness Program e-mail address is bopwellness@gmail.com. All communications are confidential.

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