



Alabama State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

111 Village St • Hoover, AL 35242 • Tel: 205/981-2280 • Fax: 205/981-2330

Fifty-Year Pharmacists

The Alabama State Board of Pharmacy wishes to congratulate the following Alabama pharmacists that have completed 50 years in the practice of pharmacy. Thank you for your service and dedication to the pharmacy profession.

W. T. Parnell Hughes	John Clyde Winn, Jr
Sidney Webb Armistead	John David Luther
David Scott Hardenbergh, Jr	Betty Jo Matthews
Gordon Clyde Boyd	Janella Jolley Gann
Rhea Moorman Black	Ralph Carmichael Moseley, Jr
Ronald Don Price	John Lewis Lott
Jackie C. Wear	Roger L. Johnson
Frederick Harold Alexander, Jr	James Vincent Jackson
Jerry Keith Stubbs	Mark D. Shelley
Gerald Lee Campbell	Otis Doyle Springer, Jr
Norma Clair Rains	Donald Phillip Maughan
Joseph Lee Owings	Thomas Raymond Parker, Jr
Jimmy Bruce Gann, Sr	Barbara F. Glaude
George Hunter Payne	Stephen Clay Lipscomb
Joseph Leon Centanni	Robert Horn Owen
William Martin Padgett	Ronald Dominguez
Charles Lionel Epp	Robert Charles Landis
Charles Edward Varni	A. Lamar Brooks
William Martin Beasley	Robert Douglas Kelley, Jr
Nancy B. Eubanks	James B. Hudson
Roy Ellis Sanderson	Ralph Craig Knapp
Richard Wayne Montgomery	Julian Franklin Skinner, Jr
Bobby Donald Maise	Celia Killingsworth Fuson

Herb Bobo, RPh, Retires

Herb Bobo, secretary of the Board, retired effective October 8, 2012. The Board members and Board staff wish to thank him for his many years of service and dedication to the Board and to the profession of pharmacy. The Board wishes him continued success with his future endeavors.

Mentors – Board of Pharmacy Wellness Program

The Board of Pharmacy’s Wellness Program is in the process of establishing a state-wide network of mentor-committee members who are interested in helping newly recovering pharmacists and pharmacy technicians. The only requirement is that you be willing to listen, give advice where needed, and be able to report to Dr Michael Garver, administrator of the Board Wellness Program, any concerns that you may have about whomever you are helping. No mentor needs to be in recovery (an ex addict or alcoholic). The Board is looking for individuals who have a genuine feel for helping people who need advice or just someone in their own profession to talk to about problems that arise out of business, and which may affect their sobriety.

If you are interested, please send your name and contact information to Dr Garver via e-mail at bopwellness@gmail.com.

Board Statement on Compounding Hydroxyprogesterone Caproate

On June 15, 2012, Food and Drug Administration (FDA) issued a statement indicating it will apply its normal enforcement policies for pharmacies compounding hydroxyprogesterone caproate. In line with FDA’s statement, licensees are reminded that 20 CSR 2220-2.200(9) provides:

Compounding of drug products that are commercially available in the marketplace or that are essentially copies of commercially available Federal [Food and] Drug Administration (FDA) approved drug products is **prohibited**. There shall be sufficient documentation within the prescription record



NIH Database Provides Information on Drugs Associated With Liver Injury

The National Institutes of Health (NIH) has launched a free searchable database with information on prescription and over-the-counter (OTC) drugs, herbals, and dietary supplements associated with liver injury. The LiverTox database, www.livertox.nih.gov, is a free resource for health care providers and researchers studying liver injury associated with these products. The database provides up-to-date, accurate, and easily accessed information on the diagnosis, cause, frequency, patterns, and management of liver injury attributable to prescription and nonprescription medications, herbals, and dietary supplements. The database currently contains information on 700 medications, and 300 more will be added.

Coalition Urges Consumers to ‘Double Check, Don’t Double Up’ on Acetaminophen

With the start of cold and flu season in October 2012, the Acetaminophen Awareness Coalition began urging consumers to double check their medicine labels to make sure they do not double up on medicines containing acetaminophen. The coalition’s “Double Check, Don’t Double Up” message is aimed to reach the more than 50 million Americans who use acetaminophen every week, encouraging them to take three simple steps to avoid acetaminophen overdose: (1) know if your medicine contains acetaminophen; (2) never take two medicines with acetaminophen at the same time; and (3) always read your medicine label. The coalition also wants to educate consumers that taking more acetaminophen than directed is an overdose and can lead to liver damage. Health care providers can join the effort by educating patients about safe use of acetaminophen, and can refer patients to the KnowYourDose.org Web site for more information. The Acetaminophen Awareness Coalition is made up of a diverse group of organizations representing health care providers and consumers who have joined forces through the Know Your Dose campaign to inform consumers about safe acetaminophen use and preventing liver damage that can result from unintentional overdose.

Root Cause Analysis



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.

To assist pharmacists in the process of minimizing the occurrence of medication errors, many state boards of pharmacy are contemplating or already requiring community pharmacies to have a continuous quality improvement program in place. Many of these state’s regulations include the requirement of root cause analysis (RCA) in the case of sentinel events. The Joint Commission defines a sentinel event as an “unexpected occurrence involving death or serious physical or psychological injury or

risk thereof,” and recommends completing an RCA for all sentinel events for health care organizations in which they accredit. It is anticipated that RCA for sentinel events may be required as part of an accreditation program for community/ambulatory pharmacies.

RCA is a process for identifying the basic or causal factors that underlie variation in performance, including the occurrence or risk of occurrence of a sentinel event. RCA focuses primarily on systems and processes, not individual performance. Finding and identifying root causes during an investigation adds considerable value by pointing out significant, underlying, fundamental conditions that increase the risk of adverse consequences. These analyses can be of enormous value in capturing both the big-picture perspective and the details of the error. They facilitate system evaluation, analysis of need for corrective action, and tracking and trending.

The RCA process starts by creating a team, holding a meeting, and stating the problem. The team gathers documentation (prescriptions, labels, computer reports, etc) and interviews staff involved in the error to determine the sequence of events.

The RCA team will review the documentation and review the sequence of events and continue asking themselves “Why did this happen?” until they arrive at each root cause.

The team must assume that any problem is preventable and caused by weak or vulnerable systems rather than individual incompetence. Even in the case of a person making a mistake, the team must ask “Why do our systems allow these types of mistakes to happen so easily?” or “What factors set this person up to make this error?”

The heart of the process is the analysis itself. Table 1 lists basic questions that should be answered during RCA.

Table 1. Basic Questions to Answer During RCA
1. What happened?
2. What normally happens?
3. What do policies/procedures require?
4. Why did it happen?
5. How was the organization managing the risk before the event?

It is important to answer “What normally happens?”(Question 2, in the above table). The difference between “What normally happens?” and “What do the policies and procedures require?” (Question 3) helps determine the reliability of processes and how often staff cut corners to get the work done.

RCA also includes a method to measure the effectiveness of these strategies over time. Targeting corrective measures at the identified root causes is the best way to ensure that similar problems do not occur in the future.

USP Releases Universal Standards for Prescription Labels

New United States Pharmacopeial Convention (USP) standards for a universal approach to the format, appearance, content, and instructions for medicines in containers dispensed by pharmacists have been released. “Wide variability in prescription container labels exists today across individual prescriptions, pharmacies, retail chains and states. The USP standards provide specific direction on how to organize labels in a ‘patient-centered’ manner that best reflects how most patients seek out and understand medication instructions,” as explained in a USP press release. Lack of universal standards for medication labeling can contribute to patients



Compliance News to a particular state or jurisdiction should not be assumed (regarding the law of such state or jurisdiction.)

misunderstanding dosage instructions and can lead to medication errors. Elements of the new USP standards, contained in General Chapter <17> Prescription Container Labeling, of the USP and the National Formulary, include:

- ◆ Emphasizing instructions and other information important to patients
- ◆ Improving readability
- ◆ Giving explicit instructions
- ◆ Including purpose for use
- ◆ Addressing limited English proficiency
- ◆ Addressing visual impairment

Descriptions of each standard including examples, as well as more information about the development of the standards, are provided in a USP press release, available at <http://us.vocuspr.com/Newsroom/ViewAttachment.aspx?SiteName=USPharm&Entity=PRAsset&AttachmentType=F&EntityID=109587&AttachmentID=5dc9eb96-5706-4e61-b0fa-ce9673fb3010>.

Enforcement of the standards will be the decision of individual state boards of pharmacy, which may choose to adopt it into their regulations, notes USP. The National Association of Boards of Pharmacy® (NABP®) member boards adopted Resolution 108-1-12 at the NABP 108th Annual Meeting stating that the Association should support state boards of pharmacy in efforts to require a standardized prescription label. NABP also convened a task force on this issue in December 2008. The resolution and the Report of the NABP Task Force on Uniform Prescription Labeling Requirements are available in the Members section of the NABP Web site.

New Law Increases Penalties on Medical Cargo Theft

New legislation signed into law by President Obama on October 5, 2012, increases penalties for medical product cargo theft, a significant problem that threatens patient safety when these stolen products are reintroduced into the legitimate supply chain. The Strengthening and Focusing Enforcement to Deter Organized Stealing and Enhance Safety Act of 2012 (SAFE DOSES Act) prohibits theft of medical products as well as trafficking, buying, selling, or distributing illegally obtained pre-retail medical products. The law “prescribes criminal and civil penalties for violations, including a civil penalty of up to the greater of 3 times the economic loss attributable to the violation or \$1 million.” According to the Coalition for Patient Safety and Medicine Integrity, “current federal criminal laws do not distinguish between stealing a load of insulin and stealing a truck full of paper clips.” By increasing the penalties for medical theft, the SAFE DOSES Act should help deter such theft. The text of the new law is available for download from the Government Printing Office Web site at www.gpo.gov/fdsys/pkg/BILLS-112hr4223enr/pdf/BILLS-112hr4223enr.pdf.

NABP Implements Action Plan to Assist States in Regulating Compounding Pharmacies

Supporting state board of pharmacy efforts to enforce compounding regulations, NABP is implementing a four-part action plan centered around inspection of nonresident compounding pharmacies and creating an information-sharing network of regulatory details on such pharmacies. Focusing on inspections of nonresident compounding pharmacies and sharing this data among boards of pharmacy nationwide was determined by NABP and its member state boards of pharmacy to be key to preventing future tragedies like the current meningitis outbreak.

NABP developed the action plan at a November 2012 meeting of board of pharmacy executive directors where the attendees expressed a strong

commitment to correcting system failures that allowed the meningitis outbreak to occur, and implementation began quickly thereafter. The Iowa Board of Pharmacy recently requested NABP to develop an inspection program for entities that are licensed by the state as nonresident pharmacies and dispensing compounded drugs in Iowa. Those in attendance expressed their support of this inspection initiative, which became a cornerstone of the four-part action plan.

In the first part of its action plan, NABP shared the list of nonresident compounding pharmacies provided by the Iowa Board with other NABP member boards of pharmacy and began coordinating the collection of information on these pharmacies. The boards’ collaboration on this data helped NABP identify the initial pharmacies to inspect. NABP believes that the list provided by Iowa represents a significant number of nonresident pharmacies dispensing compounded drugs across the country.

Implementing the inspection program is the second part of the action plan and is currently underway. Initial results will reveal whether the selected pharmacies are compounding pursuant to a prescription in compliance with state regulations, or instead are engaging in manufacturing. Entities that refuse inspection may be subject to disciplinary action by the Iowa Board and such actions will be shared with all of NABP’s member boards.

The third part of the action plan includes NABP collecting and maintaining data on the compounding pharmacies identified by the Iowa Board and by other boards of pharmacy. Initial data collected from the boards and the inspection reports will be stored in an NABP Pharmacy e-Profile, allowing the Association to disseminate pertinent public information among state boards. Ultimately, states will be able to submit inspection reports and other related information to NABP for inclusion in pharmacies’ e-Profiles. The network will be made available at no cost to boards for use in making licensure and registration determinations for pharmacies, and may also help to identify pharmacies whose operations are more akin to manufacturing than compounding.

As the final part of the action plan, NABP plans to schedule immediate and ongoing training of board of pharmacy inspectors and compliance officers via Webinar and field training opportunities. NABP will also continue cooperative efforts with Food and Drug Administration and legislators to address the regulatory quagmire that exists when traditional compounding is exceeded and manufacturing may be occurring.



Pharmacists & Technicians:
Don't Miss Out on Valuable CPE Credit.
Set Up Your NABP e-Profile and
Register for CPE Monitor Today!

CPE Monitor™ integration is underway. Most Accreditation Council for Pharmacy Education (ACPE)-accredited providers should now be requiring you to submit your NABP e-Profile ID, assigned when you set up your NABP e-Profile, along with your date of birth (MMDD), in order to obtain continuing pharmacy education (CPE) credit for any ACPE-accredited activity.

Visit www.MyCPEmonitor.net to set up your e-Profile, obtain your e-profile ID, and register for CPE Monitor and avoid possible delays in your CPE reporting.

CPE Monitor is a national collaborative service from NABP, ACPE, and ACPE providers that will allow licensees to track their completed CPE credit electronically.

of the pharmacy of the **specific medical need** for a particular variation of a commercially available compound.

Accordingly, licensees must have sufficient documentation of a **specific medical need** prior to compounding hydroxyprogesterone caproate in the future.

Meeting Dates for Calendar Year 2013

- ◆ January 15-16, 2013
- ◆ February 19-20, 2013
- ◆ March 19-20, 2013
- ◆ April 16-17, 2013
- ◆ May 14-15, 2013
- ◆ June 18-19, 2013
- ◆ July 16-17, 2013
- ◆ August 20-21, 2013
- ◆ September 17-18, 2013
- ◆ October 22-23, 2013
- ◆ November 19-20, 2013
- ◆ December 17-18, 2013

Tuesday meetings begin at 8 AM for administrative hearings.
Wednesday meetings begin:

- ◆ 7:30 AM: work session
- ◆ 9 AM: business meeting
- ◆ 11:30 AM: interview candidates for licensure

**Amendment to Rule 680-X-2-.16
Practical Training Programs Standards**

Paragraph (10) was completely deleted as indicated below and paragraph (11) was re-numbered to (10) for numbering purposes.

- ~~(10) The pharmacy intern shall be non-impaired.~~
- ~~(a) The pharmacy intern is subject to random drug screen testing and/or evaluations during the duration of their internship.~~

- ~~(b) A positive drug screen may be self-evident as proof of improper drug use. For the purposes of this chapter, a missed screen, a screen submitted beyond the mandated period, and/or any screen submitted indicating the sample provided is diluted, substituted, or in any way adulterated is considered to be a positive drug screen. All positive screens shall be reported to the Board of Pharmacy's Wellness Program.~~
- ~~(c) It is the responsibility of the School of Pharmacy to establish and maintain such screenings while interns are enrolled in school.~~

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.

Page 4 – February 2013

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Mitzi Ellenburg, Director of Operations - State News Editor
Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor
Larissa Doucette - Communications Manager

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National Association of Boards of Pharmacy Foundation, Inc
1600 Fehanhville Drive
Mount Prospect, Illinois 60056
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