



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

Continuing Pharmacy Education Monitoring Service

Effective January 1, 2011, the Alabama State Board of Pharmacy will no longer approve continuing education (CE) programs on a case-by-case basis. Only programs approved by the Accreditation Council for Pharmacy Education (ACPE) can be used to satisfy the requirements of the Board. This action was taken at the Board of Pharmacy meeting on September 22, 2010.

In addition, only pharmacists will be allowed credit for programs specifically designated with a “P” in the program code and technicians will be allowed credit for programs specifically designated with a “T” in the program code. Some programs will be available for pharmacists and technicians and will carry both a “P” and “T” in the code.

Inside this *Newsletter*, you will find an article outlining a new service to be provided by National Association of Boards of Pharmacy® (NABP®) and ACPE, which in 2012 will allow the Alabama State Board of Pharmacy to verify its licensees’ and registrants’ compliance with CE requirements. It will also allow pharmacists and technicians to easily track their ACPE-accredited CE.

Electronic Prescriptions Received Via Fax

As of this date, the Drug Enforcement Administration (DEA) has not certified any transmitting or receiving system as meeting their criteria, therefore any electronically signed prescription for a controlled substance would not satisfy federal law requirements. Furthermore, DEA has no allowance for electronic signatures on controlled substances that are received via the pharmacy’s fax machine or brought in by the patient.

So how do you handle electronic prescriptions for controlled substances (EPCS) that have been received or prescriptions for controlled substances with an electronic signature that are brought in by a patient? Pharmacists may call the prescriber to verify the prescription and then treat it as a verbal order. Many hospitals, clinics, administrators, and prescribers have affirmed to pharmacists that they are legally transmitting EPCS but according to federal regulatory requirements this cannot be correct.

The Board suggests that pharmacists visit the DEA’s EPCS site at www.deadiversion.usdoj.gov/ecommm/e_rx/index.html. This site includes a brief description of the EPCS rule and has useful

links to the rule itself as well as question and answer sections for pharmacists and for prescribers.

Surescripts Publishes Guidance for Electronic Prescriptions

Surescripts has released a guidance document that “attempts to set the measurement standard against which electronic prescriptions can be assessed for accuracy and completeness.”

The document offers guidance to prescribers and their staffs, and e-prescribing and electronic medical record software vendors, and can serve as a resource for community pharmacists, their staffs, and their local prescribers. The document provides key principles and best practices for the writing of prescription orders – particularly, new electronic prescriptions – to help ensure that electronic prescriptions convey to the pharmacist and the patient the clinician’s therapeutic intent in an accurate, understandable, complete, unambiguous, and efficient manner. The document, *Guidelines for Creating High-Quality Electronic Prescriptions In The Ambulatory Healthcare Setting*, is available for download at www.sdpha.org/download/file/Surescripts.pdf.

Rule 680-X-2-.16 Practical Training Programs Standards

Effective April 4, 2011, the Alabama State Board of Pharmacy Rule 680-X-2-.16 was amended in part as follows:

- ◆ Four hundred traditional hours of the minimum total requirement may become attainable after completing the requirements of the second professional year.
- ◆ An extern/intern must be employed a minimum of four hours a week; however, no less than one hour will be accepted for a particular day and no more than 40 hours of externship/internship may be allowed for credit in any one calendar week.
- ◆ Externs/interns shall submit to the school of pharmacy he or she is attending adequate documentation demonstrating compliance with the requirements of this section. The applicable school of pharmacy, upon request by the Board, shall furnish the referenced documentation demonstrating compliance.

Every pharmacist licensed with this Board should have received a copy of this rule in its entirety either by first class mail or e-mail. If you did not and wish to obtain a copy, please e-mail Mitzi Ellenburg at mellenburg@albp.com.

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Obtain Your NABP e-Profile ID Online Now, ID Required for ACPE-Accredited CPE

The new National Association of Boards of Pharmacy® (NABP®) CPE Monitor service, a collaborative effort between NABP, the Accreditation Council for Pharmacy Education (ACPE), and their providers, will allow pharmacists and technicians to easily track their ACPE-accredited continuing pharmacy education (CPE) credits beginning in the latter part of 2011. In addition, the service will provide a streamlined reporting and compliance verification process for participating state boards of pharmacy. When pharmacists and technicians complete an ACPE-accredited CPE program, their participation data will be sent electronically from the provider to ACPE, then to NABP for recording into the matching NABP e-Profile. Then, if the board of pharmacy participates in CPE Monitor, the pharmacists' or technicians' CPE credits will be automatically transmitted to the board, saving pharmacists and technicians the trouble and expense of documenting and submitting compliance with state-mandated CPE requirements for license renewal. This eliminates paper forms and the overall need to submit paper copies of CPE statements of credit to the board of pharmacy for CPE activities from ACPE-accredited providers.

For convenience, the NABP e-Profile will be available 24/7 for viewing a comprehensive list of the CPE activities completed. All information will be maintained in a highly secure environment. NABP does not distribute any personal information for commercial purposes without consent.

To prepare for the new process, pharmacists and technicians are encouraged to obtain their NABP e-Profile identification to ensure their e-Profile is properly set up. Beginning in the latter part of 2011, all pharmacists and technicians will be able to provide their NABP e-Profile ID, plus their birth date (mmdd) to receive credit for any accredited CPE activities from ACPE-accredited providers. Providers will ask CPE participants to provide the ID either when registering or when submitting participation data to the provider. Please note that CPE Monitor will not initially track CPE from non-ACPE-accredited providers. This feature will be added in Phase 2 of the CPE Monitor service, and, until then, pharmacists and technicians will need to submit non-ACPE-accredited CPE directly to their board of pharmacy when required to do so.

NABP and ACPE will work with CPE providers to ensure an adequate amount of time is allotted to implement this new service.

Pharmacists can obtain their ID by creating an NABP e-Profile using the portal in the Pharmacists section of the NABP Web site at www.nabp.net/pharmacists. Technicians can obtain their ID by creating an NABP e-Profile using the portal in the Technicians section of the NABP Web site at www.nabp.net/technicians. Visit www.MyCPEmonitor.net for more information.

FDA Asks Manufacturers to Limit Acetaminophen Strength

In the interest of patient safety, Food and Drug Administration (FDA) asked drug manufacturers to limit the strength of acetaminophen in prescription drug products – which are predominantly

combinations of acetaminophen and opioids – to 325 mg per tablet, capsule, or other dosage unit. In addition, FDA reports that the labels of all prescription drug products that contain acetaminophen will now include a boxed warning that highlights the potential for severe liver injury and a warning that highlights the potential for allergic reactions. FDA has taken these actions to reduce the risk of severe liver injury and allergic reactions associated with acetaminophen. FDA notes that over-the-counter products containing acetaminophen are not affected by this action.

While the maximum amount of acetaminophen in a prescription tablet, capsule, or other dosage unit will be limited to 325 mg, the total number of tablets or capsules that may be prescribed and the time intervals at which they may be prescribed will not change as a result of the lower amount of acetaminophen. Additional information for health care providers and patients is included in an FDA Drug Safety Communication available on the FDA Web site at www.fda.gov/Drugs/DrugSafety/ucm239821.htm.

Looking for Risk

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 a 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.

Health care organizations focused on improving patient safety must first identify, ascertain the causes of, and employ strategies to reduce risk. Everyone on staff in an organization has responsibility for risk assessment and, therefore, risk management.

This includes involving patients in their care and seeking their help to identify risk in the system. Assessing risk in an organization is important to understanding and prioritizing areas of highest risk and for discovering which improvements will have the greatest overall impact on patient safety.

FMEA

The Failure Mode and Effects Analysis (FMEA) process is a “systematic method of identifying and preventing product and process problems before they occur.” FMEA is the tool that has the potential to be an integral part of any risk assessment and, therefore, the risk management process.



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

FMEAs focus on identifying and removing defects, enhancing safety, and increasing customer satisfaction.

AROC

Assessing Risk and Opportunities for Change (AROC) is designed to help community pharmacy personnel identify potential medication safety risks and prevent errors. Pharmacists can use these materials and tools to pinpoint specific areas of weakness in their medication delivery systems and to provide a starting point for successful organizational improvements.

Pharmacists' Role

Pharmacists are often assumed to be the “guardians” in ensuring that medication errors do not occur. This expectation is unrealistic, because avoiding error is a health care team effort. It has, however been suggested that pharmacists should assume a leadership role in implementing safe medication use efforts in their organization.

Objectives for the pharmacist and other pharmacy staff who participate in the assessment process:

- ◆ Explain the important processes and sub-processes of medication use from prescription through administration.
- ◆ Participate in identifying failure modes and risk throughout the entire medication process, especially in information that should be available to the prescriber and nurse, as well as describing the steps in the process that occur after the medication order is transferred to the pharmacy.
- ◆ Offer possible causes for medication errors because of breakdowns in the prescription to administration process.
- ◆ Identify effects, as well as their severity and probability, when a system failure occurs.
- ◆ Offer suggestions, along with all team members, for actions that should be taken to prevent medication errors.

Pharmacists are an integral part of any medication safety assessment process. They not only offer information – as do the other disciplines in the organization – they can also expand their knowledge through participating in these risk assessments. Pharmacy participation should include frontline staff, pharmacists, pharmacy technicians, and pharmacy support staff. It is important to have multilevel involvement so that all system enhancements are discussed and identified.

To learn more about assessing risk in acute care pharmacy visit www.ismp.org/Tools/pathways.asp.

To learn more about assessing risk in community pharmacy visit www.ismp.org/communityRx/aroc/.

NABP Launches New and Improved NAPLEX/MPJE Application in March

In March 2011, NABP launched a new and improved application process for the North American Pharmacist Licensure Examination® (NAPLEX®) and the Multistate Pharmacy Jurisprudence Examination® (MPJE®). The online application was upgraded to be more user friendly, allowing candidates to perform more registration tasks and providing status information to examination candidates.

In addition to providing the basic features of registering for the NAPLEX, NAPLEX score transfer, and MPJE, the new application also allows candidates to make changes to, add to, or withdraw an application, eliminating the need for candidates to call NABP for this service. Changes that can be made to an application include registering for the MPJE in additional jurisdictions and adding NAPLEX score transfer requests until the time of the examination. Technological enhancements to the application allow for the elimination of the previous requirement that candidates submit score transfer requests five business days prior to sitting for the NAPLEX.

The new application also gives candidates who miss sitting for an examination or who do not cancel within two business days of their appointment the ability to submit resitting fees online rather than having to send a payment to NABP via mail. This expedites the receipt of the candidate's new Authorization to Test so that he or she may schedule another examination appointment more quickly.

An additional benefit to candidates is the ability to monitor the status of their profile. After submitting an application, candidates can log in to their profile and see if the application has been received; if eligibility has been requested, granted, denied, or expired; if Authorization to Test has been generated; if the application has been withdrawn or expired; and history of examinations taken.

The profiles of candidates who registered for the NAPLEX or MPJE before the new application was launched will need to create a user name and password through the new application so that they can view the historical data of their NAPLEX and MPJE registrations. Upon creating a new user account, the system will match the newly created account with applications previously submitted or currently in progress so that all the information will be viewable by the candidate.

The new application also allows users to update their profiles as needed and review past orders.

In addition, the score results for the NAPLEX and MPJE are also accessible when candidates log in to the application, provided that the board for which the candidate tested participates in the online score interface. Currently, 25 boards utilize this service.

Overall, candidates can expect a clearer and smoother registration process because both front and back-end functionality of the application has been streamlined and tightly integrated.

New FDA Drug Info Rounds Training Video

FDA Drug Info Rounds, a series of online training videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better medication decisions. In the latest Drug Info Rounds video, pharmacists discuss the role of FDA in responding to and mitigating drug shortages. Drug Info Rounds is developed with contributions from pharmacists in the FDA's Center for Drug Evaluation and Research, Office of Communications, and Division of Drug Information. FDA Drug Info Rounds training videos may be accessed on the FDA Web site at www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm.

Extern/Intern Training Sites

Code of Alabama 1975, Title 34 Chapter 23, Practice of Pharmacy Act 205, §34-23-72, Internship training sites, reads in part:

Every site approved by the State Board of Pharmacy for intern training shall be managed so that the intern is provided with ample opportunity to meet the training requirements established by the board. The site must have in its employ, or have an arrangement with, a pharmacist who is registered as a preceptor. A site which meets these qualifications may be approved for internship training by the board.

If you are a preceptor or extern/intern, please verify that the facility is either registered as a pharmacy or has an agreement with the Board.

Bath Salts

On February 22, 2011, Dr Donald E. Williamson, state health officer, adopted an Emergency Rule, effective immediately to identify and control certain stimulants that pose a serious health threat and that have a great potential for abuse. These drugs create a methamphetamine-like high and can cause violent behavior in users. The chemical names he added were methylenedioxypropylamphetamine (MDPV) and mephedrone. MDPV is considered by DEA Office of Diversion Control to be a chemical analogue of the controlled substance cathinone. The substance mephedrone is considered by DEA to be a chemical analogue of the controlled substance methcathinone. Cathinone and methcathinone are listed in the DEA and the Alabama Controlled Substances List as Schedule I (f), Stimulants.

Five Synthetic Cannabinoids

On March 1, 2011, DEA placed five synthetic cannabinoids into Schedule I of the Federal Controlled Substances List, to be effective March 1, 2011. The five synthetic cannabinoids include:

- ◆ 1-pentyl-3-(1-naphthoyl)indole (JWH018)
- ◆ 1-butyl-3-(1-naphthoyl)indole (JWH073)
- ◆ 1-[2-(4-morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH200)
- ◆ 5-(1,1-dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (CP47,497)

- ◆ 5-(1,1-dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol(cannabicyclohexanol; CP47,497 C8 homologue).

The Comprehensive Crime Control Act of 1984 gives the Attorney General the authority to temporarily place a substance into Schedule I of the Controlled Substances Act for one year without regard to the requirements of 21 U.S.C. 811(b) if he or she finds that such action is necessary to avoid imminent hazard to the public safety. The Alabama State Committee of Public Health received this notice of federal control without objection and placed the five substances on the Alabama Controlled Substances List into Schedule I.

Disciplinary Actions Are Reportable to the Data Bank

The Alabama State Board of Pharmacy is required by federal law to report most disciplinary actions to the Healthcare Integrity and Protection Data Bank. The reportable actions are sent to NABP for filing with the data bank. To learn more, visit www.npdb-hipdb.hrsa.gov/.

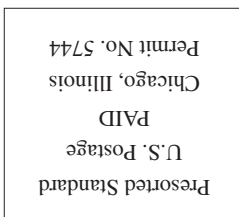
Do You Know a Pharmacist or Technician Who Needs Help?

Call the Committee on Rehabilitating Impaired Pharmacists help-line at the voicemail of Steve Moore at 205/975-8548. All calls are confidential.

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Herbert "Herb" Bobo - State News Editor
Carmen A. Catizone, MS, RPh, DPh - National News Editor
& Executive Editor
Larissa Doucette - Communications Manager



National Association of Boards of Pharmacy Foundation, Inc
1600 Fehherville Drive
Mount Prospect, Illinois 60056
ALABAMA STATE BOARD OF PHARMACY