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Alabama State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

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

The Alabama State Board of Pharmacy **will not** present its annual Law Seminar. The Board is sorry for any inconvenience this may cause.

Changes to Schedule II Prescriptions

On August 25, 2010, the Alabama State Board of Pharmacy adopted the following policy (#20100825) permitting the same changes to Schedule II prescriptions, after oral consultation with the prescriber, as are permitted by Drug Enforcement Administration (DEA) (*www.deadiversion.usdoj.gov/faq/general.htm*) on Schedule III through V prescriptions.

Question: What changes may a pharmacist make to a prescription written for a controlled substance in schedule II?

Answer: On November 19, 2007, DEA published in the Federal Register (FR) the Final Rule entitled *Issuance of Multiple Prescriptions for Schedule II Controlled Substances* (72 FR 64921). In the preamble to that Rule, DEA stated that "the essential elements of the [schedule II] prescription written by the practitioner (such as the name of the controlled substance, strength, dosage form, and quantity prescribed) . . . may not be modified orally."

The instructions contained in the Rule's preamble are in opposition to DEA's previous policy which permitted the same changes a pharmacist may make to schedules III-V controlled substance prescriptions after oral consultation with the prescriber. DEA recognizes the resultant confusion regarding this conflict and plans to resolve this matter through a future rulemaking. Until that time, pharmacists are instructed to adhere to state regulations or policy regarding those changes that a pharmacist may make to a schedule II prescription after oral consultation with the prescriber.

Question: What changes may a pharmacist make to a prescription written for a controlled substance in schedules III-V?

Answer: The pharmacist may add or change the patient's address upon verification. The pharmacist may add or change the dosage form, drug strength, drug quantity, directions for use, or issue date only after consultation with and agreement of the prescribing practitioner. Such consultations and corresponding changes should be noted by the pharmacist on the prescription. Pharmacists and practitioners must comply with any state/local laws, regulations, or policies prohibiting any of these changes to controlled substance prescriptions.

The pharmacist is never permitted to make changes to the patient's name, controlled substance prescribed (except for generic substitution permitted by state law) or the prescriber's signature.

Use of Telecommunications Relay Services in Alabama

On September 22, 2010, the Alabama State Board of Pharmacy adopted the following policy (#20100922) to permit the use of Telecommunications Relay Services (TRS) in Alabama.

Pharmacists who are deaf or hard of hearing are allowed to use TRS to receive oral prescriptions and/or for other purposes as long as such pharmacist ensures that in his or her professional judgment he or she can practice pharmacy with reasonable skill and safety to patients by utilizing TRS.

The use of TRS by deaf or hard of hearing pharmacists as set forth above does not violate *Code of Alabama* (1975), §34-23-70(h).

This policy shall supersede any prior statements by the Board with respect to the use of TRS.

Continuing Education Approval

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

New Rules Effective September 1, 2010

680-X-2-.24 Precursor Drugs

(1) LISTED PRECURSOR CHEMICALS:

All substances listed as precursor chemicals in any regulation set forth in the Code of Federal Regulations shall be considered and designated as a precursor chemical with the exception of those precursor chemicals designated or deleted as such under federal law to which the Board objects, after notice, in the manner provided in Code of Alabama (1975), § 20-2-181(c), all precursor chemicals listed in any federal regulation shall be considered and designated as precursor chemicals pursuant to the provisions of Code of Alabama (1975), § 20-2-180, et seq.

(2) LICENSE.

(a) Beginning in 2011 and every two years thereafter, any individual, corporation, partnership, association or other entity who is a manufacturer, wholesaler, retailer or other person who sells, transfers,

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FDA Alert Regarding Administration of Oral Nimodipine Capsules

Food and Drug Administration (FDA) reminds health care providers that oral nimodipine capsules should be given only by mouth or through a feeding or nasogastric tube and should never be given by intravenous administration. FDA continues to receive reports of intravenous nimodipine use, with serious, sometimes fatal, consequences. Intravenous injection of nimodipine can result in death, cardiac arrest, severe falls in blood pressure, and other heart-related complications.

Nimodipine is a medication intended to be given in a critical care setting to treat neurologic complications from subarachnoid hemorrhage and is only available as a capsule. Prescribing information warns against intravenous use of nimodipine and also provides clear instructions on how to remove the liquid contents from the capsules for nasogastric tube administration in patients who are unable to swallow. The instructions recommend that the syringe used for withdrawal of capsule contents be labeled with "Not for IV Use." FDA will continue working with the manufacturers of nimodipine and with outside groups to evaluate and implement additional ways to prevent medication errors with this product.

An FDA Drug Safety Communication providing additional information for health care providers and patients is available at *www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm220386.htm.*

FDA Approves Vaccines for the 2010-2011 Influenza Season

FDA approved vaccines for the 2010-2011 influenza season in the United States on July 30, 2010, and some manufacturers began shipping as early as mid-August. The seasonal influenza vaccine protects against three strains of influenza, including the 2009 H1N1 influenza virus, which caused the 2009 pandemic. Last year, two separate vaccines were needed to protect against seasonal flu and the 2009 H1N1 pandemic flu virus because the 2009 H1N1 virus emerged after production began on the seasonal vaccine, but this year, only one vaccine is necessary. The Centers for Disease Control and Prevention has published recommendations for annual influenza vaccination to include all people aged six months and older. The expanded recommendation is to take effect in the 2010-2011 influenza season. More information on the approved vaccine is available in an FDA news release available at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm220718.htm.*

FDA Alert Regarding Adverse Effects in Children After Unintentional Exposure to Evamist

FDA advises patients and health care providers of reports regarding adverse effects from Evamist® in children who may have been unintentionally exposed to the drug through skin contact with women using this product. Evamist contains estradiol, an estrogen hormone, and is a topical product, sprayed on the skin on the inside of the forearm between the elbow and the wrist. Children unintentionally exposed to Evamist may experience premature puberty. FDA is currently reviewing these reported adverse events and is working with the company to identify any factors that may contribute to unintended exposure and to evaluate ways to minimize the risk. FDA advises that patients should make sure that children are not exposed to Evamist and that children do not come into contact with any skin area where the drug was applied, and for those who cannot avoid contact with children to wear a garment with long sleeves to cover the application site. Additional information for patients is provided in an FDA Drug Safety Communication available at *www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm220185.htm.*

Safeguards to Implement with 'High Alert' Medications

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.*

While most medications have a large margin of safety, a small number of drugs have a high risk of causing injury when they are misused. ISMP calls these "high-alert medications" to draw attention to this characteristic so that all involved in their use will treat them with the care and respect that they require. Errors may or may not be more common with these drugs than with the use of any others; however, the consequences of the errors are more devastating. For this reason, special considerations are required. These medications often need to be packaged differently, stored differently, prescribed differently, and administered differently than others. Examples of high-alert medications in community pharmacy include warfarin, insulin, methotrexate, and fentanyl patches. Whenever possible, "forcing functions" – methods that make it impossible for the drug to be given in a potentially lethal manner – should be developed and instituted. Forcing functions are procedures that create a "hard stop" during a process to help ensure that important information is provided before proceeding. For example, a pharmacy computer system that prevents overriding selected high-alert messages without a notation (eg, patient-specific indication must be entered if high-alert medication selected) is a forcing function.

An independent double-check of a high-alert medication is a procedure in which two pharmacists, alone and apart from each other, separately check each component of dispensing and verifying the high-alert medication, then compare results before giving it to the patient to self-administer. While technological solutions such as bar coding systems have great potential to detect human error, manual redundancies such as independent double checks still play an important role in error detection. Studies show that manual redundancies detect about 95% of errors. Independent double checks serve two purposes: to prevent a serious error from reaching a patient; and just as important, to bring attention to the systems that allow the introduction of human error. In retail pharmacies, with only one pharmacist per shift, the independent double check can be performed via a "will call" bag

check or by another pharmacist at the beginning of the next shift. If the medication has been dispensed, serious harm can be avoided or mitigated if the error is discovered within one or two doses.

The following information must be verified during the double-check process:

Comparison to prescriber's order:

- Is this the prescribed drug?
- Is this the prescribed dose/strength/rate and route of administration?
- Is this the right patient (use two patient identifiers)?
- Is this the prescribed frequency?

Additional cognitive checks:

- Does the drug's indication correspond to the patient's diagnosis?
- Is this the right drug formulation?
- Are dose calculations correct?
- Is the dosing formula (eg, mg/kg) used to derive the final dose correct?
- Is the prescribed dose/frequency/timing appropriate for this patient?
- Is the route of administration safe and proper for this patient?
- Has patient been educated on appropriate monitoring?

ASCO/FDA Program Provides Information on Expanded Access for IND Applications

Developed in partnership with FDA, the American Society of Clinical Oncology (ASCO) offers an online interactive educational program to help providers understand FDA regulations regarding expanded access programs for individual-patient investigational new drug (IND) applications. The program provides an introduction from the viewpoint of various involved stakeholders, including physicians, FDA, industry, and patients and may assist pharmacists in providing patient counsel regarding expanded access.

This interactive module consists of:

- A thorough explanation of all expanded access programs available
- Links to key references and resources that are relevant to the slide content
- Selected virtual meeting presentations from ASCO Annual Meetings
- Helpful resources to use with patients

The program is available at *http://university.asco.org/Expanded Access* and participants may earn a certificate of participation or completion.

Rise in Prescription Pain Pill Abuse Documented in Latest SAMHSA Data

Abuse of prescription pain medications continues to rise, according to the latest data from the Substance Abuse and Mental Health Services Administration (SAMHSA). The agency's Treatment Episode Data Set showed that the proportion of substance abuse treatment admissions for individuals aged 12 and older rose 400% from 1998 to 2008. SAMHSA data also showed an increase in emergency room visits involving the non-medical use of a prescription narcotic pain reliever, which have tripled in proportion since 1998. SAMHSA Administrator Pamela S. Hyde, JD, stressed that the non-medical use of prescription pain relievers is now the second most prevalent form of illicit drug use. Hyde emphasized the importance of raising awareness about this public health threat and educating the public on the "critical importance of properly using, storing, and disposing of these powerful drugs" as reported in a SAMHSA press release available at *www.samhsa.gov/newsroom/advisories/1007140544.aspx*.

USP Recommends Patient-Centered Standards for Prescription Labels

To address the problem of patient misinterpretation of medication instructions, the United States Pharmacopeial Convention (USP) Health Literacy and Prescription Container Labeling Advisory Panel developed and recently released recommendations for standardizing the format, appearance, content, and language of prescription labels. The panel, on which the National Association of Boards of Pharmacy® (NABP®) participated, developed the patient-centered recommendations in response to a call for such standards from the Institute of Medicine. More details about the panel's recommendations are available in a USP press release at *http://vocuspr.vocus.com/vocuspr30/ViewAttachment.aspx?EID=2WSh2u7neSpIu2bXW1HJ5VQ48HGFAOGH1NdNBeuPwJE%3d*.

Seven Pharmacy Organizations Respond to AMA Scope of Pharmacy Practice Document

Seven national pharmacy organizations, including NABP, collaborated on the analysis and responded to the AMA Scope of Practice Data Series: Pharmacists, a document published by the American Medical Association (AMA) that describes the scope of the practice of pharmacy as viewed by the AMA authors. The pharmacy organizations identified significant opportunities for enhanced understanding by the AMA of contemporary pharmacy practice and urged the AMA to correct the identified issues noted in the document. AMA responded that meaningful dialogue will be pursued to examine ways pharmacists and physicians can collaboratively address the health care needs of patients. Collaborating on the pharmacy organizations' review and response were the American Pharmacists Association (APhA), American Association of Colleges of Pharmacy, American College of Clinical Pharmacy, Accreditation Council for Pharmacy Education, American Society of Consultant Pharmacists, National Alliance of State Pharmacy Associations, and NABP. The letter and materials sent to AMA are available at the following links from the APhA Web site:

- Recommendations: AMA Scope of Practice Data Series: Pharmacists, *www.pharmacist.com/AM/Template.cfm?Section=Home2&CONTENTID=23148&TEMPLATE=/CM/ContentDisplay.cfm*.
- Response Letter: AMA Scope of Practice Data Series: Pharmacists, *www.pharmacist.com/AM/Template.cfm?Section=Home2&TEMPLATE=/CM/ContentDisplay.cfm&CONTENTID=23149*.
- Scope of Contemporary Pharmacy Practice, *www.pharmacist.com/AM/Template.cfm?Section=Home2&TEMPLATE=/CM/ContentDisplay.cfm&CONTENTID=23150*.

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manufactures, purchases for resale or otherwise furnishes any listed precursor chemicals as defined or designated by any federal or state law or rule must obtain a license. The license shall be issued only after the filing of an application with the Alabama State Board of Pharmacy and Board approval. The application shall contain information as required by and in conformity with any applicable federal or state laws or rule.

(b) A biennial license fee in the amount of $500.00 shall be paid by all licensees to the Alabama State Board of Pharmacy.

(3) PERMIT.

(a) A permit must be obtained from the Alabama State Board of Pharmacy each time any individual, corporation, partnership, association or other entity having a legitimate need for using any listed precursor chemical as defined or designated by law or rule of the Alabama State Board of Pharmacy obtains such chemical(s). The permit shall be issued only after the filing of an application with the Alabama State Board of Pharmacy and the Board's approval of that application. The application shall contain information as required by and conform with the requirements of all applicable laws or rules of the Alabama State Board of Pharmacy.

(b) A permit fee in the amount of $35.00 shall be paid to the Alabama State Board of Pharmacy each time any individual, corporation, partnership, association or other entity obtains any listed precursor chemical. Amended: Filed July 5, 2010; Effective September 1, 2010.

680-X-2-.40 Non-Disciplinary Penalty for Late Renewal of License or Permit

(1) In the event an application for renewal any type of Pharmacy Permit, Pharmacist or Assistant License, Wholesaler, Manufacturer, Distributor Permit or Retail Oxygen Permit and the appropriate renewal fee is not received in the Board's office by December 31 of any even numbered year, but is received in the Board's office no later than January 31 of the following year, a non-disciplinary administrative penalty of fifty percent (50%) of the prevailing renewal fee must be paid by January 31 of the following year in order to renew. This penalty shall be in addition to the prevailing renewal fee.

This Rule is adopted pursuant to the Board's authority set forth in Code of Alabama (1975), § 34-23-33(b) and is in lieu of formal disciplinary proceedings. Filed July 5, 2010; Effective September 1, 2010.

680-X-3-.03 Time and Method of Payment; Renewal and Non-Disciplinary Penalty for Late Renewal of Controlled Substances Permit

(1) Registration fees shall be paid at the time the application or renewal furnished by the Alabama State Board of Pharmacy for registration is submitted for filing. Payment shall be made payable to the Alabama State Board of Pharmacy and shall be due October 1 of each even-numbered year and delinquent after the last day of December of each even-numbered year. If the application for renewal and appropriate renewal fee is not received in the Board's office by December 31 of any even numbered year but is received in the Board's office no later than January 31 of the following year, a non-disciplinary administrative penalty of fifty percent (50%) of the prevailing renewal fee must be paid by January 31 of the following year in order to renew. This penalty shall be in addition to the prevailing renewal fee.

This Rule is adopted pursuant to the Board's authority set forth in Code of Alabama (1975), § 34-23-33(b) and is in lieu of formal disciplinary proceedings. Amended Filed: July 5, 2010; Effective September 1, 2010.

Renewal Deadline for 2011-2012 is December 31, 2010

Online renewals for every license and permit **except** technicians are available on the Board Web Site at *www.albop.com* at the **same cost** as a mail-in renewal.

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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 Feehanville Drive
Mount Prospect, Illinois 60056

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