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News

SC Department of Labor, Licensing, & Regulation – Board of Pharmacy

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Upcoming Board of Pharmacy Vacancy

The next South Carolina Department of Labor, Licensing, and Regulation – Board of Pharmacy member term begins July 1, 2011, and ends June 30, 2017. Any pharmacist interested in running as a candidate must:

- reside in the First Congressional District;
- be licensed and actively practicing pharmacy in South Carolina; and
- before December 1, 2010, submit to the Board office a biography and petition bearing signatures of at least 15 pharmacists practicing in the First Congressional District.

After receiving biographies and petitions, the Board administrator will:

- prepare and mail ballots by January 15, 2011, to all pharmacists who certified on their last renewal application that they reside in the First Congressional District; and
- certify as true and valid all ballots postmarked before February 15, 2011, and received by the Board office before February 25, 2011.

Before March 1, 2011, the Board will certify in writing to the governor the names of the three candidates receiving the most votes in the election along with the name of the person whom the nominee replaces on the Board. The new member, when appointed by the governor, will take office on July 1 of that year.

If you are interested in becoming a candidate for this position or have any questions, please contact the Board office.

Immunization Update

2010 Act 224 has changed the laws concerning the administration of influenza vaccines by pharmacists in pharmacy settings. As a result, both prescribers and pharmacists must review existing practices and conform them to the new law. Advice concerning immunization practice given by licensing boards and attorneys prior to Act 224 may no longer be reliable.

Some questions concerning the application of Act 224 cannot be answered until the protocol established by the Joint Pharmacist Administered Influenza Vaccines Committee is issued by the Board of Medical Examiners. The authority of prescribers to order and pharmacists to administer vaccines based upon a patient-specific prescription is not affected by Act 224 and remains acceptable practice under both the Pharmacy Practice Act and the Medical Practice Act. (Note that medical doctors treating patients in South Carolina are required by their own practice act to establish a physician-patient relationship before prescribing any drug. §40-47-113.)

After the protocol is issued by the Board of Medical Examiners, pharmacists will be specifically authorized by law to administer the influenza vaccine without a prescription so long as the patient is over 18 years old, the pharmacist has appropriate training, and the pharmacist follows the South Carolina protocol.

Questions associated with the use of physician-issued protocols or standing orders are complex and include considerations outside the scope of the Pharmacy Practice Act. The South Carolina Medical Practice Act states specifically that the practice of "prescribing drugs to individuals the licensee has never personally examined" is unprofessional conduct. Other prescribers also have both licensing and civil liability issues which must be addressed individually. Because of the complexity of the law and the variations among physician-issued protocols and standing orders, professionals with concerns about its use should consult their attorneys and/or professional liability insurers for guidance.

The pharmacy profession and the Board of Pharmacy are actively participating in the Joint Pharmacist Administered Influenza Vaccines Committee and will distribute the proposed protocol for comment as soon as it is available. The Joint Pharmacist Administered Influenza Vaccines Committee has met and is anticipating presenting the proposed protocol to the Board of Medical Examiners at its November 2010 meeting. In this transition period, the Board encourages a conservative approach to immunization practice.

Subpoenas

The Pharmacy Practice Act sets specific standards for pharmacy practice to protect patient information. Before "patient information or the nature of professional pharmacy services rendered" may be divulged or revealed to "unauthorized persons" without the patient's express consent, the Act requires either the order or the direction of a court. (S.C. Code Ann. §40-43-86(DD)(3)) The Pharmacy Practice Act predates the Health Insurance Portability and Accountability Act (HIPAA) and its associated Privacy Rule (45 CFR Part 164, Subpart E), which sets general standards for all professional practices governing the disclosure of personal health information without patient authorization. The Board of Pharmacy's last interpretation of §40-43-86(DD)(3) also predates the HIPAA Privacy Rule. At that time, the Board concluded that

Continued on page 4

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*.

Continued from page 1

only a directive issued by the tribunal itself, either in the form of an order or a court-issued subpoena, would comply with state law. While the Board recognized that attorneys generally are authorized, as officers of the court, to issue subpoenas, the Board was concerned that the language of the statute indicated a need for heightened protection of patient privacy that was not addressed in the general rules governing the issuance of subpoenas.

As courts and practitioners have become more accustomed to the HIPAA practice whereby the courts authorize the use of attorney-issued subpoenas meeting specific standards for patient protection, the South Carolina Board of Pharmacy has found it appropriate to revisit the associated issues so as to reduce the burden upon the pharmacy profession and upon the court system. Under HIPAA, a "covered entity" such as a pharmacy may lawfully disclose protected health information without the written authorization of an individual if the party requesting the information meets the requirements of 45 CFR §164.512(e) (2010). The HIPAA Privacy Rule, like the Pharmacy Practice Act, specifically authorizes a covered entity to disclose protected health information in the course of a judicial or administrative proceeding in response to a court order. (45 CFR §164.512(e)(1)(i)–(ii)) The HIPAA Privacy Rule, however, also addresses the use of a subpoena as a directive from the court. When the requesting party seeks the information using an attorney-issued subpoena unaccompanied by a court order, that party must meet the notification requirements of the HIPAA Privacy Rule. Such a subpoena must provide the pharmacy, as a covered entity, with "satisfactory assurance . . . that reasonable efforts have been made . . . to ensure that the individual who is the subject of the protected health information that has been requested has been given notice of the request." (45 CFR §164.512(e)(1)(ii)(A))

The requesting party must provide the pharmacy with "a written statement and accompanying documentation" demonstrating all of the following: (1) that the requesting party has made "a good faith attempt to provide written notice to the individual" (or, alternatively, to mail a notice to the individual's last known address if the individual's location is unknown), (2) that the notice included "sufficient information about the litigation or proceeding" to enable the individual to raise an objection to the court or administrative tribunal, and (3) that the time for the individual to object has elapsed without any objections being filed or without any objections going unresolved. (45 CFR §164.512(e)(1)(iii))

A subpoena, issued by an attorney as an officer of the court, in compliance with these specific HIPAA requirements is appropriately characterized as a direction of the court. Producing patient information or the nature of professional pharmacy services in response to such a direction is not unprofessional conduct as defined in §40-43-86(DD)(3).

Tips from the Compliance Department

- Nurse practitioners and physician assistants must be licensed in the state of South Carolina in order to have prescriptive authority.
- Reminder: you **cannot** have a blanket authorization from a licensed practitioner for therapeutic or non-therapeutic substitution for a brand-name product. If a prescription is written as a brand name and substitution is permitted, it must be AB rated. Please refer to the **Drug Product Selection Act** Title 39 Chapter 24.
- **Cargo theft** has increased greatly with the current economic trend. The Board is concerned about the safety and security of the supply chain and distribution of legend drugs in South Carolina. The stolen legend drugs are usually not stored properly, therefore, they are deemed adulterated. Many of the stolen legend drugs reappear into the United States drug supply as counterfeit, contaminated, and/or misbranded. Pharmacists-in-charge of pharmacies may register with **RxPatrol®** free of charge to track and/or verify cargo theft. Please be sure to watch Food and Drug Administration (FDA) recalls, FDA alerts, and the South Carolina Pharmacy Association's *Small Doses* regarding pharmaceutical theft information. As the saying goes, "If it is too good of a deal, then it is probably too good to be true."

The *South Carolina Board of Pharmacy News* is published by the South Carolina Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

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