August 2010

News

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

Published to promote compliance of pharmacy and drug law

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Board Elections

At the June 2010 meeting, the South Carolina Department of Labor, Licensing, and Regulation – Board of Pharmacy members elected Mr James Robert "Bobby" Bradham, RPh, of Charleston, SC, as its new chairman. Mr Bradham is the pharmacist representative serving the First Congressional District. Mr Joseph D. "Dan" Bushardt, of Lake City, SC, representing the Sixth Congressional District, was elected as vice-chairman. Each will serve a one-year term from July 1, 2010 until June 30, 2011.

Immunization Law Passes

The South Carolina Code of Laws has been amended to allow pharmacists to administer **influenza vaccines** without a prescription effective July 1, 2010. Please review Section 40-43-190 to be aware of the requirements and limitations. **Only a pharmacist** can administer the influenza vaccine and **the pharmacist must use** the protocol which will be provided by the Board of Medical Examiners.

Ms Jennifer Baker and Mr James Sterrett were approved by the Board of Pharmacy as the two pharmacists on the committee outlined in Section 40-43-200 to assist the Board of Medical Examiners in establishing the protocol required in Section 40-43-190.

The South Carolina Board of Pharmacy has revised Policy and Procedure 138 to provide guidance for other vaccines that will require a written prescription or a protocol for a practitioner's patients.

Whereas, the primary purpose of **Act No. 224** is to promote, preserve, and protect the public health and safety and to prepare for the threat of pandemic influenza by expanding access to influenza vaccines.

Protocol for Pharmacists to Administer Influenza Vaccines and Certain Medications Without Order of Practitioner

SECTION 1. Chapter 43, Title 40 of the 1976 Code is amended by adding:

Section 40-43-190. (A)(1) The Board of Medical Examiners shall issue a written protocol for the administration of influenza vaccines by pharmacists without an order of a practitioner. The administration of influenza vaccines as authorized in this section must not be to persons under the age of eighteen years.

(2) The written protocol must further authorize pharmacists to administer without an order of a practitioner those medications necessary in the treatment of adverse events. These medications must be used only in the treatment of adverse events and must be limited to those delineated within the written protocol.

(3) The written protocol must be issued no later than January 1, 2011.

(B) The written protocol must provide that:

(1) A pharmacist seeking authorization to administer influenza vaccines as authorized in this section shall successfully complete a course of training accredited by the Accreditation Council for Pharmacy Education or a similar health authority or professional body approved by the Board of Pharmacy and the Board of Medical Examiners. Training must comply with current Centers for Disease Control guidelines and must include study materials, hands-on training, and techniques for administering influenza vaccines and must provide instruction and experiential training in the following content areas:

(a) mechanisms of action for influenza vaccines, contraindications, drug

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FDA Updates 'Medicines in My Home' Patient Education Resources

Food and Drug Administration (FDA) has updated the Medicines in My Home (MIMH) section of the agency's Web site with new resources and materials for patients. MIMH resources teach patients from adolescence through adulthood how to choose over-the-counter (OTC) medicines and how to use them safely. An interactive video teaches users how to understand the drug facts label and make sound medicine decisions. Downloadable documents provide information on caffeine use, choosing appropriate OTC medications, and other related topics. The MIMH Web page can be accessed at *www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingOver-the-CounterMedicines/ucm092139.htm.*

DEA Releases e-Prescription for Controlled Substances Interim Final Rule

The Drug Enforcement Administration (DEA) Interim Final Rule on electronic prescriptions for controlled substances was published in the *Federal Register* on March 31, 2010, and was scheduled to go into effect June 1, 2010, subject to Congressional review. The regulations would allow prescribers the option to write prescriptions for controlled substances electronically, and allow pharmacies to receive, dispense, and archive these electronic prescriptions. The regulations are an addition to existing rules, and include stipulations to ensure that a closed system of controls on controlled substances dispensing is maintained. The regulations have the potential to reduce prescription forgery and reduce the number of prescription errors, and should also reduce paperwork and help integrate prescription records into other medical records.

Confirmation Bias

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.*

Although pharmaceutical companies and regulatory agencies have been working on design changes to improve the situation, ISMP still associates many medication errors with confusion over "look-alike" or "sound-alike" product names. Since patients receive the wrong drug, these sometimes result in serious harm. A common cause of name mix-ups is what human factors experts call "confirmation bias." Confirmation bias refers to a type of selective thinking whereby individuals select what is familiar to them or what they expect to see, rather than what is actually there.

Many errors often occur when pharmacists or technicians, due to familiarity with certain products, see the name of the product they think it is rather than what it actually is. For instance, if a pharmacist reads a poorly written drug name, he or she is most likely to see a name that is most familiar to him or her, overlooking any disconfirming evidence. Another example of this is if a pharmacy technician chooses a medication container based on a mental picture of the item, whether it is a characteristic of the drug label, the shape, size, or color of the container, or the location of the item on a shelf.

Although various compilations of look-alike name pairs are available for posting (see *www.ismp.org/Tools/confuseddrugnames.pdf* for ISMP's List of Confused Drug names, which has recently been updated), these lists have only limited usefulness since it is impossible for practitioners to memorize them in order to know when to check on questionable prescriptions. Also, when confirmation bias occurs, there is never a reason for the practitioner to question the order to begin with.

In many cases, hospital or pharmacy computer systems can be used to reduce the risk of confirmation bias and resulting name mix-ups. Many systems have a "formulary note" field that can be easily adapted to display important information prominently on the computer screen. Similar to a road sign warning about a dangerous intersection ahead, this feature can be used to alert the person inputting the medication when a look-alike or sound-alike danger is present. For example, when Norvasc® is entered into the computer, a formulary note screen appears, alerting the pharmacist that Norvasc often looks like Navane® when handwritten. The pharmacist will then take the necessary steps to confirm the prescription if necessary.

In addition, physically separating drugs with look-alike labels and packaging helps to reduce this confirmation bias as does implementing bar-coding technology for the verification process of drug selection. Employing a simple system that compares computer-generated National Drug Codes (NDC) on prescription labels and NDC codes on manufacturers' containers to verify that the appropriate drug has been selected and dispensed also helps reduce confirmation bias.

It is human nature for people to associate items by certain characteristics. It is very important for the health care community and regulators to recognize the role that confirmation bias may play in medication errors and to work together to address associated problems.

FDA-TRACK Provides Public Access to Agency's Performance Data

The new FDA-TRACK will provide access to updated information about FDA programs, projects, and core responsibilities. The system is part of the FDA transparency initiative and its objectives are represented in the TRACK name which stands for transparency, results, accountability, credibility, and knowledge-sharing. This agency-wide system will track performance measurement data reported from over 100 FDA program offices. Common measures, key center director measures, program measures, and key projects are the measurement areas currently in use, and more information about these areas is available in the FDA-TRACK announcement available at *www.fda.gov/AboutFDA/WhatWeDo/track/default.htm*. FDA-TRACK will continue to be updated and the latest information can be found on the following Web pages: Cross-Agency FDA-TRACK Program Areas available at *www.fda.gov/AboutFDA/WhatWeDo/track/ucm206441.htm*, Center FDA-TRACK Program Areas available at *www.fda.gov/*

AboutFDA/WhatWeDo/track/ucm195008.htm, and Dashboards available at *www.fda.gov/AboutFDA/WhatWeDo/track/ucm195011.htm*. Public feedback on FDA-Track and its measures can be submitted by e-mail to FDATRACK@fda.hhs.gov.

Survey Suggests Majority of Patients Seek Pharmacist Advice About OTC Medications

When selecting OTC medications, 82% of pharmacy customers base their decision on a pharmacist's recommendation, according to a survey of over 1,000 pharmacists conducted by the American Pharmacists Association (APhA). Survey results also indicate which products, among 76 categories presented to pharmacists, are most often recommended. The survey results are published in the Pharmacy Today Over-the-Counter Supplement available at *www.imirus.com/tmp/2536/2501/1001/pm2536.pdf*. An APhA news release, available at *www.pharmacist.com/AM/Template.cfm?Section=News_Releases2&Template=/CM/ContentDisplay.cfm&ContentID=23117*, indicates that 90% of patients seek help identifying the most appropriate product and 80% seek counsel regarding using an OTC product with their prescription medications.

California PMP Data Shows Frequency of Doctor Shopping

Early data collected from California's prescription monitoring program (PMP), the Controlled Substances Utilization Review and Evaluation System (CURES), correlates the frequency of patient "doctor shopping," or obtaining multiple prescriptions from various providers, with the number of prescriptions patients receive for additional controlled substances, as reported in *Medical News Today*. The research analysis, presented at the American Academy of Pain Medicine 26th Annual Meeting, showed that patients prescribed a single additional class of a controlled substance, such as benzodiazepines, had a two-fold likelihood of doctor shopping for multiple opioid prescriptions. A 13-fold increase in doctor shopping was seen when more than one additional drug class was involved. Researchers at the University of California, Davis, conducted the analysis using de-identified CURES data, and also found that patients involved in doctor shopping were involved in more than one episode about 50% of the time.

Highest Dose of Zocor Increases Risk of Muscle Injury, FDA Warns

FDA has informed health care practitioners that there is an increased risk of muscle injury in patients taking the highest approved dose of the cholesterol-lowering medication, Zocor® (simvastatin) 80 mg. This information is based on review of data from a large clinical trial and other sources, and FDA is currently reviewing additional data to better understand the relationship between high-dose simvastatin use and muscle injury. More information is included in an FDA Drug Safety Communication at *www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm204882.htm*.

New OxyContin Formulation to Help Prevent Abuse of the Drug

FDA has approved a new formulation of the controlled-release drug OxyContin® which is designed to decrease the likelihood that this medication will be misused or abused, and result in overdose. FDA explains that the new formulation adds in new tamper-resistant features aimed at preserving the controlled release of the active ingredient, oxycodone. The old formulation allowed tampering with the tablet, via cutting, chewing, breaking, or dissolving, which resulted in dangerously high levels of oxycodone being released at once. In accordance with FDA requirements, Purdue Pharma L.P. will conduct a post-marketing study to determine the impact of the new formulation, and the manufacturers will follow a Risk Evaluation and Mitigation Strategy (REMS) for this product. The REMS will include the issuance of a Medication Guide to all patients who use the product. More information is provided on the FDA OxyContin Question and Answer Web page at *www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm207196.htm*.

Use of e-Prescribing Grows Dramatically

The number of electronic prescriptions increased 181% from 2008 to 2009, according to the 2009 National Progress Report on E-Prescribing, published by Surescripts, operator of the largest e-prescription network that connects prescribers' e-prescribing software to pharmacies. Over 190 million e-prescriptions were routed in 2009, compared with 68 million in 2008, and 29 million in 2007. Correlating with those increases, 156,000 prescribers were using e-prescriptions by the end of 2009 compared with 74,000 at the end of 2008, a 109% increase. The report also indicates that 85% of community pharmacies in the United States are connected and able to receive e-prescriptions from prescribers.

Study Shows e-Prescribing Reduces Prescriber Errors

Prescribers using e-prescribing were seven times less likely to make errors than those writing their prescriptions by hand, according to a new study published in the *Journal of General Internal Medicine*. The study, conducted by researchers at Weill Cornell Medical College, focused on 12 community practices and compared the prescriptions of 15 providers using e-prescribing and 15 providers writing prescriptions by hand. The researchers found that two in five handwritten prescriptions contained errors such as incomplete directions, prescribing a medication but omitting the quantity, and prescribing incorrect dosages. Further, comparing handwritten prescriptions and e-prescriptions one year from the start of the study, researchers found that errors dropped from 42.5 % to 6.6% for the providers using e-prescriptions. Errors associated with the handwritten prescriptions in the study increased from 37.3% to 38.4% a Weill Cornell Medical College press release providing more information about the study is available at *http://weill.cornell.edu/news/releases/wcmc/wcmc_2010/02_26_10.shtml*.

Counterfeit Drug Investigation Leads to Two Arrests

Two individuals have been arrested and face charges related to illegally importing counterfeit weight-loss medication. FDA issued a series of alerts, from 2008 to 2010, about tainted weight-loss pills and counterfeit drugs, and an undercover investigation identified one of the defendants as the alleged trafficker of these tainted and counterfeit drugs. This investigation was a joint effort by FDA Office of Criminal Investigations, US Immigration and Customs Enforcement, and US Postal Inspection Service. More information about the investigation and arrests is available in a US Attorney's Office Press Release at *www.fda.gov/ICECI/CriminalInvestigations/ucm206314.htm*.

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interactions, and monitoring after vaccine administration;

(b) standards for adult immunization practices;

(c) basic immunology and vaccine protection;

(d) vaccine-preventable diseases;

(e) recommended immunization schedules;

(f) vaccine storage management;

(g) biohazard waste disposal and sterile techniques;

(h) informed consent;

(i) physiology and techniques for vaccine administration;

(j) prevaccine and postvaccine assessment and counseling;

(k) immunization record management;

(l) management of adverse events, including identification, appropriate response, emergency procedures, documentation, and reporting;

(m) understanding of vaccine coverage by federal, state, and local entities;

(n) needle stick management.

(2) A pharmacist administering an influenza vaccine without an order of a practitioner pursuant to this section shall:

(a) obtain the signed written consent of the person being vaccinated or that person's guardian;

(b) maintain a copy of the vaccine administration in that person's record and provide a copy to the person or the person's guardian;

(c) notify that person's designated physician or primary care provider of any influenza vaccine administered;

(d) report administration of an influenza vaccine to any statewide immunization registry established by the Department of Health and Environmental Control as the department may require;

(e) maintain a current copy of the written protocol at each location at which a pharmacist administers an influenza vaccine pursuant to this section.

(3) A pharmacist may not delegate the administration of influenza vaccines to a pharmacy technician as defined in Section 40-43-30 or any other person who is not a pharmacist.

(4) A pharmacist administering influenza vaccines shall, as part of the current continuing education requirements pursuant to Section 40-43-130, complete no less than one hour of continuing education each license year regarding administration of influenza vaccines.

(C) Informed consent must be documented in accordance with the written protocol for influenza vaccine administration issued pursuant to this section.

(D) All records required by this section must be maintained in the pharmacy for a period of at least six years.

Section 40-43-200. (A) There is created a Joint Pharmacist Administered Influenza Vaccines Committee as a committee to the Board of Medical Examiners which consists of seven members with experience regarding influenza vaccines. The committee is comprised of two physicians selected by the Board of Medical Examiners, two pharmacists selected by the Board of Pharmacy, and two advanced practice nurse practitioners selected by the Board of Nursing. One member of the Department of Health and Environmental Control designated by the Commissioner of the Department also shall serve on the committee. Members of the committee may not be compensated for their service on the board and may not receive mileage, per diem, and subsistence as otherwise authorized by law for members of state boards, committees, and commissions.

(B) The committee shall meet at least once annually and at other times as may be necessary. Five members constitute a quorum for all meetings. At its initial meeting, and at the beginning of each year thereafter, the committee shall elect from its membership a chairperson to serve for a one year term.

(C) The committee shall assist and advise the Board of Medical Examiners in establishing a written protocol for the purpose of authorizing pharmacists to administer influenza vaccines without an order of

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a practitioner as authorized by Section 40-43-190 and shall provide a suggested written protocol to the board no later than four months after the passage of this act.

Policy and Procedure #138

The South Carolina Board of Pharmacy, alarmed by the many deaths of South Carolina citizens due to a lack of immunizations and recognizing that pharmacists are easily accessible to all South Carolina citizens, and bearing in mind that pharmacists are authorized by South Carolina law to administer drugs,

1. Encourages South Carolina pharmacists to participate in immunization programs by making available and administering immunizations to the public at permitted pharmacy locations; and
2. Reminds pharmacists that such immunization programs shall meet the following requirements:
   - ♦ Administering pharmacists shall have completed an immunization training program, reviewed by Centers for Disease Control and Prevention, and resulting in certification as an immunizing pharmacist.
   - ♦ Administering pharmacists shall be currently certified in CPR.
   - ♦ Administering pharmacists shall have written policies and procedures for aftercare of immunized patients.
   - ♦ Administering pharmacists shall have an order or protocol from a licensed practitioner or such order or protocol from the South Carolina Department of Health and Environmental Control.
   - ♦ This policy and procedure applies to immunizations in South Carolina not addressed by any other statute.

This statement does not address every legal issue, which might arise in the context of immunization programs, including but not limited to, professional insurance coverage.

Electronic Prescriptions for Controlled Substances

Connie L. Overton, Diversion Group Supervisor, DEA

On June 1, 2010, the application of Electronic Prescriptions for Controlled Substances came into effect. Drug Enforcement Administration (DEA), in conjunction with other federal agencies, was instrumental in the development of this rule. The rule revises DEA regulations to provide practitioners with the option of writing prescriptions for controlled substances electronically. The regulations also permit pharmacies to receive, dispense, and archive these electronic prescriptions. These regulations are an addition to, not a replacement of, the existing rules. The regulations provide pharmacies, hospitals, and practitioners with the ability to use modern technology for controlled substance prescriptions while maintaining the closed system of controls on controlled substances.

Persons who wish to prescribe or dispense controlled substances using electronic prescriptions must select software that meets the requirements of the rule. Application providers who make such electronic prescribing software or pharmacy software available may wish to carefully review the requirements of this rule if they wish their software to handle electronic prescriptions for controlled substances. As of June 1, 2010, only those electronic prescription applications and pharmacy applications that comply with all of DEA's requirements, as set forth in 21 CFR Part 1311, may be used by DEA-registered prescribing practitioners and DEA-registered pharmacies to sign and transmit controlled substance prescriptions electronically or electronically receive and archive controlled substance prescriptions and dispense controlled substances based on those prescriptions, respectively.

Persons may obtain additional information regarding the Office of Diversion Control Program by accessing the Web site at *www.DEAdiversion.usdoj.gov*. The local point of contact is Diversion Group Supervisor Connie Overton, 803/253-3441, connie.overton@usdoj.gov.

Note: SC Code Ann. Reg. 61-4 §506.1 requires that a pharmacist dispensing a controlled substance prescription place a manual and in cursive handwriting notation on the prescription indicating his or her identity. Therefore, a hard copy of any electronic prescription received by a pharmacy must be generated to satisfy this requirement.

Pharmacy Technician ALERT

Pharmacy technicians do not receive this *Newsletter*, therefore pharmacists are asked to assist in ensuring that pharmacy technicians are aware of several issues and concerns that will ultimately save the pharmacy technician wasted time, effort, and money.

1. Multiple pharmacy technician programs are recruiting students causing confusion. According to Section §40-43-82 of the SC Code of Laws, for a technician to become "state" certified, the individual must have completed a formal academic pharmacy technician training program approved by the Board. Currently, the only programs approved by South Carolina are those that are accredited by the American Society of Health-System Pharmacists (ASHP).

   Prior to enrolling in a program with the intention of obtaining a certified pharmacy technician credential, the program must be verified on the ASHP Web site. Many programs advertise for a pharmacy technician degree; however, the programs may not be approved by the Board.

   a. To verify the program, visit the ASHP Web site, *www.ashp.org.*
   b. Under Accreditation choose Technician Training Directory.

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c. The Pharmacy Technician Program Directory will give a list of programs by state.

d. Click the Name of Site to determine whether the program is "Accredited." Some programs have the status "Application Submitted."

e. If there are specific questions, contact Janet Teeters, ASHP, at 301/664-8656.

f. Some retail chains have their programs approved for only their employees and are listed under the state in which the corporate offices are located.

2. Certified pharmacy technicians must maintain their National Pharmacy Technician Certification and send a copy of their current Pharmacy Technician Certification Board certification with their registration renewal.

3. The Board of Pharmacy has approved a new form, Pharmacy Technician Certification of Clinical Experience, which must be completed after completion of an accredited pharmacy technician program. The form is on the Board of Pharmacy Web site under the Applications/ Forms tab.

Compounding Update

If a facility has a permit and is performing sterile or nonsterile compounding, the Board requests the facilities provide an e-mail address in order to facilitate communication regarding practice issues and guidelines available that impact the practice of pharmacy as it relates to sterile and nonsterile compounding. Please provide that information to sandersc@llr.sc.gov.

Pharmacists by virtue of their education are trained in the art and practice of pharmacy, which includes compounding. The level of training for personnel engaged in compounding practice and the types of equipment required vary according to the level of compounding. The Board anticipates that all pharmacists are able to provide to patients simple compounds, which **do not** require a change of dosage forms, use of specialized equipment, and use of bulk chemicals. Pharmacists are reminded that compounding logs are required for any compound, and good practice standards direct that references for stability and storage should be available to support storage and patient use. This process, if followed, would not cause patient harm or hardships to people in rural areas. Compounding that falls outside the guidelines above would suggest that the pharmacy evaluate special training and inspection by the Board for requirements associated with sterile or nonsterile compounding.

Pharmacists involved in sterile compounding know that this is a specialized area of practice. Several references are available including United States Pharmacopeia (USP) Chapter 797 and USP Chapter 795 as well as others. These references provide good recommendations for standards of practice. The Board encourages pharmacists involved in this area of practice to be familiar with current standards of practice.

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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