February 2013

News

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

Published to promote compliance of pharmacy and drug law

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2013 Pharmacist Renewal Notices on Horizon

The 2013 renewal notices will be mailed to you in late February. The South Carolina Department of Labor, Licensing, & Regulation – Board of Pharmacy has enhanced its online renewal system to make it easier and more convenient for you to renew your license. You will receive a renewal notice with a **user ID** and a **password** that will allow you to access the online renewal Web site. If you choose not to renew online, you can request a paper renewal form from the Board office and renew by mailing the completed form and proper fees to that office. Applications for renewal must be filed before March 31, 2013, in order to avoid a penalty. If you do not renew online, please document the date the application is mailed. The Board recommends the paper renewal be sent **certified mail with a return receipt requested.** Postage machines do not provide acceptable proof of mailing.

Applications submitted for renewal between April 1 and April 30, 2013, must include a penalty of $50 for late renewal in addition to evidence that the applicant meets the renewal requirements and has paid the appropriate fees. If you do not renew your license by April 30, 2013, it will be considered lapsed. You can be disciplined for unlicensed practice if you continue to work in South Carolina after that date.

Continuing Education for Pharmacist Renewals

To renew online, you must indicate you have completed the required 15 hours of continuing education (CE). Six of those hours must be live and 50% must be in drug therapy or patient management. **You cannot renew until you have completed the CE requirements.** After renewals are processed, a random CE audit will be conducted. If you are selected for the audit, please respond promptly. Disciplinary action will be taken if you cannot show you completed the CE requirements or if the required CE is dated **after** your renewal is received in the Board office.

CE Requirements for Registered Pharmacy Technicians and State Certified Pharmacy Technicians

- Ten hours of Accreditation Council for Pharmacy Education (ACPE)-accredited CE or continuing medical education (CME) Category I CE are required each registration year for renewal. Of the 10 hours, a minimum of four hours must be "live" hours. CE must be taken **before** renewing a registration each year.
- **There are no exemptions to the CE requirement for technicians.**
- Technicians may take CE that is designated for pharmacists (P) or technicians (T).
- Use the ACPE universal program number (UPN) to determine if CE is live (L), home (H), or combination (C). Example: Live CE will have an "L" in the UPN, eg, 430-000-092-021-L01.
- All CME Category I hours are live hours.
- Hours completed in excess of the requirements may be carried forward in the next registration year but may not be carried forward for more than one registration year. It is the responsibility of the technician to keep up with excess hours that can be forwarded to the next registration year.

ACPE-approved Web sites for CE hours:

- *www.rxschool.com*
- *www.powerpak.com*
- *www.continuingeducation.com/pharmtech*
- *www.techlectures.com*
- *www.freece.com*
- *www.scrx.org*
- *www.acpe-accredit.org*
- *www.SCSHP.com*
- *www.sccp.sc.edu*

College health-related fields are not acceptable in lieu of the required CE hours.

Compliance Tips

An **out-of-state or United States government prescription** is **not required** to meet the South Carolina law prescription format requiring two lines with "Dispense as Written" on left and "Substitution Permitted" on right. The Board staff has received several calls concerning this issue, which may be the result of a third-party payer or a chain's auditor raising this issue. If there is not an indication on the prescription as to whether substitution is permissible, the practitioner must be contacted and documented on the prescription. Puerto Rico, Guam, and the Virgin Islands prescriptions are considered out-of-state prescriptions.

> **SECTION 39-24-60.** Out of state and United States government prescriptions. This chapter shall not be construed to prevent registered pharmacists from filling, as otherwise provided by law, prescriptions originating outside the boundaries of this State and official United States government prescriptions issued by authorized governmental officials.

Nurse practitioner (NP), certified nurse midwife (CNM), clinical nurse specialist (CNS), and physician assistant (PA)

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NIH Database Provides Information on Drugs Associated With Liver Injury

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

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

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

Root Cause Analysis

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition by visiting www.ismp.org. *ISMP is a federally certified patient safety organization, providing legal protection and confidentiality for submitted patient safety data and error reports. ISMP is also an FDA MedWatch partner. Call 1-800/FAIL-SAF(E) to report medication errors to the ISMP Medication Errors Reporting Program or report online at* www.ismp.org. *ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.*

To assist pharmacists in the process of minimizing the occurrence of medication errors, many state boards of pharmacy are contemplating or already requiring community pharmacies to have a continuous quality improvement program in place. Many of these state's regulations include the requirement of root cause analysis (RCA) in the case of sentinel events. The Joint Commission defines a sentinel event as an "unexpected occurrence involving death or serious physical or psychological injury or risk thereof," and recommends completing an RCA for all sentinel events for health care organizations in which they accredit. It is anticipated that RCA for sentinel events may be required as part of an accreditation program for community/ambulatory pharmacies.

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

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

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

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

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

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

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

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

USP Releases Universal Standards for Prescription Labels

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

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

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

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

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

New Law Increases Penalties on Medical Cargo Theft

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

NABP Implements Action Plan to Assist States in Regulating Compounding Pharmacies

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

NABP developed the action plan at a November 2012 meeting of board of pharmacy executive directors where the attendees expressed a strong commitment to correcting system failures that allowed the meningitis outbreak to occur, and implementation began quickly thereafter. The Iowa Board of Pharmacy recently requested NABP to develop an inspection program for entities that are licensed by the state as nonresident pharmacies and dispensing compounded drugs in Iowa. Those in attendance expressed their support of this inspection initiative, which became a cornerstone of the four-part action plan.

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

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

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

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

Continued from page 1

prescriptions must have the name, address, and phone number of the NP, CNM, CNS, or PA and the name, address, and phone number of their sponsoring practitioner. If you notify the NP, CNM, CNS, or PA of an omission on the prescription and it is not corrected, a copy of the prescription with an explanation should be sent to the South Carolina Board of Nursing for an NP, CNS, or CNM and to the South Carolina Board of Medical Examiners for a PA. **This applies to hard copy and electronic prescriptions.**

> **SECTION 40-33-34.** Performance of delegated medical acts; qualifications; protocols; prescriptive authorization; anesthesia care.
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> F) (1) Authorized prescriptions by a nurse practitioner, certified nurse-midwife, or clinical nurse specialist with prescriptive authority:
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> (a) must comply with all applicable state and federal laws; (d) must be signed by the NP, CNM, or CNS with the prescriber's identification number assigned by the board and all prescribing numbers required by law. The prescription form must include the name, address, and phone number of the NP, CNM, or CNS and physician and must comply with the provisions of Section 39-24-40. A prescription must designate a specific number of refills and may not include a nonspecific refill indication;
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> **SECTION 40-47-965.** Requirements for writing prescriptions for drugs, controlled substances, and medical devices. (A) If the written scope of practice guidelines authorizes the physician's assistant to prescribe drug therapy: (1) prescriptions for authorized drugs and devices shall comply with all applicable state and federal laws; (3) prescriptions must be signed by the physician assistant and must bear the physician assistant's identification number as assigned by the board and all prescribing numbers required by law. The preprinted prescription form shall include both the physician assistant's and physician's name, address, and phone number and shall comply with the provisions of Section 39-24-40.

Are You Ordering Your Prescription Drugs and Devices from Board Permitted Facilities?

Upon routine inspection, the Board has discovered some pharmacies, wholesalers, clinics, emergency medical services, and medical gas-durable medical equipment facilities are ordering from out-of-state wholesalers, manufacturers, and pharmacies that are not permitted in South Carolina. A South Carolina facility should request a copy of the supplier's South Carolina Non Dispensing Drug Outlet Permit or verify online that the facility, jobber, or broker has a current South Carolina permit. An in-state or out-of-state pharmacy that sells medications with the exception for "emergency medical reasons" according to Section 40-43-30(52)(e), shall be permitted as a wholesale distributor. Also, in order for a South Carolina pharmacy to sell to an out-of-state pharmacy, the South Carolina pharmacy may need to be permitted in the state to which it is selling the legend products.

Some of the medications received from wholesalers and pharmacies from other states that are not properly permitted in this state have been obtained illegally and may be misbranded or adulterated.

> **SECTION 40-43-30.** Definitions. (52) "Wholesale distributor" means a person engaged in wholesale distribution of prescription drugs or devices including, but not limited to, manufacturers; repackagers; own-label distributors; private-label distributors; jobbers; brokers; warehouses including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions.
>
> **"Wholesale distributor" does not include:**
>
> (e) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons. For purposes of this section, "emergency medical reasons" includes the transfer of legend drugs by a licensed pharmacy to another licensed pharmacy or a practitioner licensed to possess prescription drugs to alleviate a temporary shortage, except that the gross dollar value of the transfers may not exceed five percent of the total legend drug sales revenue of either the transferor or the transferee pharmacy during a consecutive twelve-month period.

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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