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

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2012 Pharmacist Renewal Notices on Horizon

The 2012 renewal notices will be mailed to you in late February. The South Carolina Department of Labor, Licensing, and 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 that includes a **user ID** and a **password,** which 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, 2012, in order to avoid a penalty. If you do not renew online, please document the date the application is mailed. The Board of Pharmacy recommends the paper renewal be sent via **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, 2012, 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, 2012, 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). Of the 15 hours, six 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.

DEA Announcement: Carisoprodol (Soma) Changed to Schedule IV Status on January 11, 2012

By South Carolina Department of Health and Environmental Control (DHEC) – Bureau of Drug Control

On December 12, 2011, Drug Enforcement Administration (DEA) published a final rule making carisoprodol (Soma®) a Schedule IV controlled substance with an effective date of January 11, 2012. This means that several things must occur:

1. On or before January 11, 2012, every registered/licensed location possessing carisoprodol must have taken an inventory of the stocks on hand. All future controlled substance inventories must include carisoprodol.
2. Any location possessing carisoprodol that was not currently registered with DEA must have applied for a DEA registration prior to January 11, 2012. If they did apply, they may continue their activities until DEA acts on the application.

   Alternatively, those locations not wishing to seek DEA registration must have removed all carisoprodol from their possession prior to January 11, 2012.
3. All **current** prescriptions for carisoprodol must be treated as controlled substance prescriptions on and after January 11, 2012. **DHEC strongly recommends that pharmacists contact the practitioner who issued the original prescription for clarification on whether the prescription is to be continued. Contact with the practitioner will allow the opportunity for the pharmacist to confirm that the practitioner is aware of the drug's reclassification as Schedule IV and confirm his or her authorization for dosing, refills, etc. Documentation of the practitioner's authorization should be in the form of a new prescription communicated to the pharmacist by way of a written, faxed, or oral prescription.**
4. All **new** prescriptions received on or after January 11, 2012, are to be treated as Schedule IV controlled substances.
5. Commercial containers of carisoprodol must bear the Schedule IV designation on or after June 11, 2012. Until then, current stock not bearing the Schedule IV designation may be sold and dispensed, but the products are to be handled as you would a Schedule IV controlled substance.

For more information, please review the *Federal Register* publication at *www.gpo.gov/fdsys/pkg/FR-2011-12-12/pdf/2011-31542.pdf.*

Forms of carisoprodol included in this action:

- Generic (Brand) Dosage Forms Carisoprodol (Soma) 250 mg tabs, 350 mg tabs
- Carisoprodol + Aspirin (Soma Compound) 200 mg + 325 mg tabs

Nondispensing Hospital-Owned Physician Practices

At its November 17, 2011 meeting, the South Carolina Board of Pharmacy was asked to clarify its position regarding

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FDA Recommends Use of Sterile Needle and Syringe for Administration of Inactivated Influenza Vaccines

Food and Drug Administration (FDA) recommends that health care providers use a sterile needle and syringe to administer inactivated influenza vaccines. The recommendation was released in response to questions regarding the use of jet injector devices to administer inactivated influenza vaccines. FDA advises that "inactivated influenza vaccines that are approved by FDA have information in their labeling stating how the vaccines should be administered, such as, by intramuscular (IM) or intradermal (ID) administration." Further, FDA clarifies its October 21, 2011 communication "to inform the public that inactivated influenza vaccines labeled for IM injection are intended for administration using a sterile needle and syringe. There is one inactivated influenza vaccine labeled for ID administration, this vaccine is supplied in its own pre-filled syringe. The live attenuated influenza vaccine is given through the nose as a spray; the sprayer is not a jet injector." FDA also notes the following:

- Currently, there is only one vaccine, Measles, Mumps, and Rubella (MMR), that is approved and specifically labeled for administration by jet injector.
- Safety and effectiveness information that would support labeling inactivated influenza vaccines for delivery by jet injector have not been submitted to FDA.
- At this time, there are no inactivated influenza vaccines that are approved and specifically labeled by FDA for administration by jet injector.

FDA recommends that all approved vaccines, including influenza, be administered in accordance with their approved labeling, and FDA advises that if a vaccine has been approved for administration with a jet injector, information specifically addressing vaccine use with a jet injector will appear in the vaccine labeling. Additional background information is available in the communication posted on the FDA Web site at *www.fda.gov/BiologicsBloodVaccines/Vaccines/QuestionsaboutVaccines/ucm276773.htm.*

The Centers for Disease Control and Prevention continues to encourage people to get vaccinated throughout the flu season, which can begin as early as October and last as late as May. For information about the flu vaccine visit *www.cdc.gov/flu.*

'Tell Back' Works Best to Confirm Patient Understanding

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.*

In the past few years, multiple studies have demonstrated that patients often leave medical encounters with a poor understanding of their health conditions and recommended treatment. One recent study on this subject demonstrates the low level of understanding patients have about follow-up care and medication therapy upon discharge from the emergency department (Engel KG et al. Patient Comprehension of Emergency Department Care and Instructions: Are Patients Aware of When They Do Not Understand? Ann Emerg Med. Available on the journal Web site).

Given the importance of patient understanding of medical information, there are surprisingly few studies that point out how to approach this task. However, a study published in 2008 offers some insight into what approach to assessing understanding of medical information patients most prefer and perceive to be the most effective (Kemp EC, et al. Patients Prefer the Method of "Tell Back-Collaborative Inquiry" to Assess Understanding of Medical Information. J Am Board Fam Med 2008;21(1):24-30). Researchers tested three types of inquiry about the patient's understanding:

- Yes-No
- Tell Back-Directive
- Tell Back-Collaborative

The Yes-No approach asked closed-ended questions to assess patient understanding. (Example: "I've given you a lot of information. Do you understand?") The Tell Back-Directive method used open-ended questions that were physician-centered and paternalistic in that it was clear authority and control still remained with the physician. (Example: "It's really important that you do this exactly the way I explained. What do you understand?") The Tell Back-Collaborative approach used open-ended questions that were patient centered, making it clear that power and responsibility were shared between the health care provider and patient. (Example: I imagine you are really worried about your blood pressure. I've given you a lot of information. It would be helpful to me to hear your understanding about your clot and its treatment.)

Patients showed a significant preference for the Tell Back-Collaborative inquiry over other tested approaches. Because of the potential for embarrassment if patient misunderstandings are exposed, one might anticipate health care providers' reluctance to put patients "on the spot" with open-ended questions. But a collaborative approach to Tell Back allows the patient to save face for misunderstandings by acknowledging the large amount of information being provided. Patients might also view the request for Tell Back as evidence of the health care provider's care and concern for them personally, or evidence of the provider's attention to detail and competence. So, when counseling patients about their medications, instead of asking "Do you have any questions?" or "Do you understand?" ask them to restate their understanding of the information you provided in their own words within a shame-free, blame-free environment.

DEA Clarifications on Certification Process for Audits of EPCS Software

Drug Enforcement Administration (DEA) emphasizes that third-party audits of software applications for Electronic Prescriptions for Controlled Substances (EPCS) must encompass all applicable requirements in DEA regulations, including security, and must address "processing integrity" as set forth in the regulations. Further, DEA recommends that where questions or gaps may arise in reviewing a particular applica-

tion, federal guidelines set forth in National Institute of Standards and Technology Special Publication 800 – 53A should be consulted. DEA has also announced the first DEA-approved certification process for EPCS. Certifying organizations with a certification process approved by DEA pursuant to the regulations are posted on DEA's Web site at *www.deadiversion.usdoj.gov/ecomm/e_rx/thirdparty.htm#approved*. Detailed background information is provided in the Federal Register Notice, available for download at *www.gpo.gov/fdsys/pkg/FR-2011-10-19/pdf/2011-26738.pdf*.

'Script Your Future' Provides Tools and Outreach to Encourage Medication Adherence

United States Surgeon General Regina Benjamin called upon pharmacists, physicians, nurses, and other health care providers to talk with their patients about the importance of taking medications as directed to help prevent serious health complications at the recent launch of the national campaign, "Script Your Future." Benjamin also "encouraged patients with chronic conditions to speak with their health care professionals about their medication" as noted in a press release. A survey released by the National Consumer League, the organization that developed Script Your Future, indicates that "patients who do not always take their medication as directed are less likely to have received a full explanation of the consequences of their condition, and are less convinced of the importance of adherence." The Script Your Future campaign is targeting six regional areas with outreach activities and advertising, and more information is available at *www.ScriptYourFuture.org*. The campaign brings together "stakeholders in health care, business, and government to offer practical tools for patients to help them better adhere to their medication, and to help health care professionals better communicate with patients." More information about the campaign is available in a press release at *www.prnewswire.com/news-releases/us-surgeon-general-joins-baltimore-launch-of-the-national-script-your-future-campaign-to-highlight-importance-of-taking-medication-as-directed-133077423.html*.

FDA Releases 'Use Medicines Wisely' Video

FDA Office of Women's Health has released a new public service announcement (PSA) video titled, "Use Medicines Wisely," to help raise awareness about safe medication use. As stated in an FDA news release, "Millions of people benefit from FDA approved medications and are living longer productive lives. However, when medications are used incorrectly, they can cause serious injuries, even death. Many of these injuries can be prevented."

The video shows simple steps women can take to use medications wisely. Viewers are reminded to:

- Make a list of the medications they take
- Keep their medication list with them at all times
- Know the name of each medication, why they are taking it, how much to take, and when to take it
- Talk with their doctor, nurse, or pharmacist to find out how to safely use their medications

In addition to the video, a medications record-keeper, fact sheets, and other safe medication use resources are available on the FDA Web site.

Training Video Provides Tips on Preventing Pharmacy Robbery

Rx Pattern Analysis Tracking Robberies and Other Losses (RxPATROL) has released a training video discussing pharmacy robbery and how to prevent it. The video features a pharmacist and law enforcement liaison as they tour a pharmacy, evaluating security measures and discussing additional steps that can be taken to prevent robbery. RxPATROL is an initiative designed to collect, collate, analyze, and disseminate pharmacy theft intelligence to law enforcement throughout the nation. RxPATROL is designed to gather and disseminate critical information to help protect pharmacists, guard against potential robberies, and assist law enforcement in their efforts to successfully apprehend and prosecute those involved in controlled substance pharmacy crime. The training video can be accessed on the RxPATROL Web site at *http://rxpatrol.org/TrainingVideos.aspx*.

Nearly 20 Products Marketed as Natural Supplements Contain Sibutramine, FDA Warns

FDA has posted public warnings regarding 19 products, frequently marketed as natural supplements, and found to contain sibutramine, a controlled substance that was removed from the US market in October 2010 for safety reasons. These products pose a threat to consumers because sibutramine is known to substantially increase blood pressure and/or pulse rate in some patients and may present a significant risk for patients with a history of coronary artery disease, congestive heart failure, arrhythmias, or stroke. These products may also interact in life threatening ways with other medications a consumer may be taking. FDA warnings included products marketed as "Slender Slim 11," "Dream Body Slimming Capsule," "Acai Berry Soft Gel ABC," and 16 other product names. The products included in the warnings are being sold on Web sites and in some retail stores. FDA advises consumers not to purchase or use the products listed in the warnings. Consumers who have purchased any of these products should stop use immediately. And if consumers have experienced any negative side effects from using these products, they should consult a health care provider as soon as possible. The complete list of warnings is available on the FDA Web site at *www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/MedicationHealthFraud/ucm234592.htm*.

2012 Survey of Pharmacy Law Now Available

Serving as a convenient reference source for individuals seeking an overview of the state laws and regulations that govern pharmacy practice, the updated 2012 *Survey of Pharmacy Law* is now available and can be purchased online for $195 by visiting the NABP Web site at *www.nabp.net/publications*.

The *Survey,* produced in a CD format, consists of four sections including a state-by-state overview of organizational law, licensing law, drug law, and census data. Newly added this year, a question in Section 17, Wholesale Distributor Licensure Requirements, asks which state agency has regulatory authority over medical device distributors. In addition, a newly added question in Section 22, Electronic Transmission of Prescriptions: Computer-to-Computer, asks whether the state allows electronic prescribing of controlled substances.

Updates for the 2012 *Survey* were graciously provided by the state boards of pharmacy. In addition to the boards' support, NABP requested data from relevant health care associations for the *Survey's* prescribing authority and dispensing authority laws in Sections 24 and 25, and laws pertaining to the possession of non-controlled legend drugs and possession of controlled substances in Sections 26 and 27.

All final-year pharmacy students receive the *Survey* free of charge through the generous grant of Purdue Pharma L.P.

For more information on the *Survey,* please contact Customer Service via phone at 847/391-4406 or via e-mail at custserv@nabp.net.

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the permitting requirements of nondispensing hospital-owned physician practices. South Carolina Code Ann. §40-43-60(H) of the Board of Pharmacy Practice Act states:

> Nothing in this chapter shall be construed to require a permit of or to prevent a licensed practitioner as defined under Section 40-43-30(45) from possessing or administering drugs or devices, or compounding drugs used for administration in the regular course of professional practice.

At its meeting, the Board determined that, pursuant to §40-43-60(H), a nondispensing hospital-owned physician practice is not required to seek a permit to operate in South Carolina. Clinics, surgery centers, and all other off-site facilities that store and/or administer medications must have a nondispensing drug outlet permit. The intent was that the director of pharmacy still be responsible for the monitoring of hospital-owned physician practices.

Compliance Tips

Transferring Prescriptions

Upon routine inspections, staff is finding that transfer prescription documentation is not complete in many pharmacies. Please review §40-43-86(G) to ensure your pharmacy is documenting correctly as the receiving or transferring pharmacy. Examples of incomplete information include the address of pharmacy on each end, "transfer" not written on the face of the transferred prescription, the date and time of the transfer, and the manufacturer or brand name of drug dispensed at previous site. The Board has received many telephone calls from patients confused about their prescription because a different generic was substituted. If the documentation is not correct, it is not easy to trace where a medication error occurs if necessary.

Compounding Logs and Formulas

For all compounded medications, the formulas and logs can be maintained either electronically or manually. Formulas must include each ingredient, amounts, the mixing directions (methodology), equipment, the assigned control number, and the beyond use date.

Repackaging Logs

Please review §40-43-86(I) to ensure your pharmacy is documenting the required information on the repackaging logs as well as required information on the label of the repackaged drug. The **log** must include the identity of the repackager, the name of the drug, the lot number, the manufacturer, the facility control number, the expiration date, the quantity, and the initials of the pharmacist. The **label** must include name of drug, route of administration (if other than oral), the strength and volume, the control number and the expiration date, as well as special storage conditions, if required. As a reminder, the facility control number is different from the lot number.

Prescription Requirements

Please review §40-43-86(E)(1-8) and §40-43-86(H)(3) to ensure that prescriptions received meet the requirements according to statute. Upon routine inspections, staff has found that prescription formats and/or requirements are not being adhered to. All written prescriptions to include verbal call-ins, faxed prescriptions, and fax back refill authorizations must have two signature lines at the opposite ends of the bottom of the form. Under the line at the left side the words "Dispense As Written" must be clearly printed. Under the line on the right side, the words "Substitution Permitted" must be clearly printed. The practitioner must communicate the instructions to the pharmacist by signing on the appropriate line. No prescription is valid without the signature of the practitioner on one of these lines.

Note: If an electronic prescription is printed out and given to the patient, **it must possess an original handwritten signature.** Electronic prescriptions must note any generic substitution instructions on the electronic prescription order. The substitution format may follow the requirement provided for in §40-43-86(H)(3) or any other format that clearly indicates the generic substitution instructions.

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