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North Carolina Board of Pharmacy News

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Item 2288 – Keep Current on Board News Electronically

The North Carolina Board of Pharmacy's website, *www.ncbop.org,* is a great resource for practicing pharmacists and the general public. News items and alerts are added regularly. The FAQ sections provide ready responses to many day-to-day issues encountered by pharmacists. Pharmacists should make a review of the Board website a regular part of their practice.

Beginning in August 2014, Board staff has begun sending a monthly electronic mail message to all licensed pharmacists highlighting new content on the Board's website.

The Board also has a Twitter account, @NCBOPNews, that publishes new website content as it is added. Website visitors will find a convenient link at the top of the home page to begin following the Twitter feed.

Finally, the Board's monthly meetings are now being live-streamed via YouTube. Visit *www.ncbop.org/calendar.htm* to access a calendar of 2014-2015 Board meeting dates. Meetings begin at 9 AM.

To watch live, at the start of the meeting visit *https://www.youtube.com,* and in the search box at the top, type in the month, year, and "NC Board of Pharmacy meeting." For example, to view the July meeting, you would search for "July 2014 NC Board of Pharmacy meeting." If you have trouble finding the meeting, please send an e-mail to cparham@ncbop.org or to tbuedel@ncbop.org.

As always, Board staff is available by phone and e-mail to answer your questions and provide guidance, but these electronic sources and references are a terrific means of staying abreast of the most current Board news.

Item 2289 – DEA Places All Hydrocodone-Containing Products into Schedule II Effective October 6, 2014

On August 22, 2014, the federal Drug Enforcement Administration (DEA) issued a final rule placing all hydrocodone-containing drug products into Schedule II. The rule is effective October 6, 2014. Hydrocodone-only products were already Schedule II controlled substances (CS). This rule places all hydrocodone combination products into Schedule II. The full text of the rule, including DEA's response to various concerns raised about the rescheduling, may be found at: *www.ncbop.org/PDF/DEAHydrocodoneCombinationProductReschedule082214.pdf.*

Some questions likely to arise:

1. **When is the rule effective?** The rule is effective October 6, 2014.
2. **Why did the Board pass the rule?** The Board did not pass this rule. It is a federal rule passed by DEA. DEA's explanation of the rule is found in the document linked above.
3. **What do I need to do with my inventory of hydrocodone-containing products?** Per requirements in the federal Controlled Substances Act, each DEA registrant pharmacy must conduct an inventory of all hydrocodone-containing products on October 6, 2014. Pharmacies must maintain that inventory with all other CS inventory records.
4. **What do I do about prescriptions for hydrocodone-containing products issued prior to October 6?** DEA's rule speaks directly to this issue: "Any prescriptions for [hydrocodone-containing products] that are issued before October 6, 2014, and authorized for refilling, may be dispensed in accordance with [the rules governing Schedule III prescriptions] if such dispensing occurs before April 8, 2015." In other words, any refills authorized on a pre-October 6, 2014 prescription for hydrocodone-containing products may be dispensed in accordance with the "no more than five refills within 6 months" requirement for Schedule III products, but no refills of such prescriptions may occur after April 8, 2015.
5. **When do I have to start ordering hydrocodone-containing products using DEA Form 222 or the**

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DEA Reschedules Hydrocodone Combination Products as Schedule II

Drug Enforcement Administration (DEA) has published its final rule rescheduling hydrocodone combination products from Schedule III to Schedule II in the *Federal Register.* The change imposes Schedule II regulatory controls and sanctions on anyone handling hydrocodone combination products, effective October 6, 2014. DEA first published the proposed rules in March 2014 in response to a Food and Drug Administration (FDA) recommendation. DEA received almost 600 public comments regarding the proposed rules after they were published, with a small majority of the commenters supporting the change, DEA notes in a press release, which is available at *www.justice.gov/dea/divisions/hq/2014/hq082114.shtml.*

The announcement is available on the *Federal Register* website at *https://federalregister.gov/articles/2014/08/22/2014-19922/schedules-of-controlled-substances-rescheduling-of-hydrocodone-combination-products-from-schedule.*

The mL-Only Standard for Liquid Dosing Gathers Steam

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization 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 provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Errors Reporting Program Report online at* www.ismp.org. *E-mail: ismpinfo@ismp.org.*

ISMP first reported on the confusion of teaspoonfuls and milliliters (mL) in its newsletter in 2000, and in 2009, issued a call for practitioners to move to sole use of the metric system for measuring over-the-counter and prescription oral liquid doses, but mix-ups have continued to result in the serious injury of children and adults. Use of the metric system alone when prescribing, dispensing, and administering medications would prevent mix-ups because there would only be one method used to communicate and measure doses.

The health care industry is beginning to acknowledge the risk of confusion when using non-metric measurements, especially with oral liquid medications. The National Council for Prescription Drug Programs (NCPDP) just released a white paper entitled *NCPDP Recommendations and Guidance for Standardizing the Dosing Designations on Prescription Container Labels of Oral Liquid Medications,* which is available at *www.ismp.org/sc?id=337.* The white paper supports mL as the standard unit of liquid measure used on prescription container labels for oral liquid medications. It also calls for dosing devices with numeric graduations, and for units that correspond to the container labeling to be easily and universally available, such as including a device each time oral liquid prescription medications are dispensed. NCPDP also reiterates that dose amounts should always use leading zeroes before the decimal point for amounts less than one, and should not use trailing zeroes after a decimal point on labels for oral liquid medications.

The white paper comes as welcome news and is well-aligned with the *ISMP 2014-15 Targeted Medication Safety Best Practices for Hospitals,* Best Practice 5, which calls for organizations to use oral liquid dosing devices (oral syringes/cups/droppers) that only display the metric scale. The white paper also comes at a time when the Centers for Disease Control and Prevention, ISMP, the Consumer Healthcare Products Association, the United States FDA, the US Metric Association, and the American Academy of Pediatrics have initiatives in place that will help guide health care organizations to commit to metric measurements.

ISMP recommends the following actions to help prevent errors:

- Use only metric units, not teaspoon or other non-metric measurements, for all patient instructions, including those listed in prescribing and pharmacy computer systems. This should cover directions incorporated into computer system mnemonics, speed codes, or any defaults used to generate prescriptions and prescription labels.
- Take steps to ensure patients have an appropriate device to measure oral liquid volumes in milliliters.
- Coach patients on how to use and clean measuring devices; use the "teach back" approach and ask patients or caregivers to demonstrate their understanding.

DEA Classifies Tramadol a Controlled Substance

Under a final rule published in the *Federal Register*, the pain reliever tramadol is now classified as a Schedule IV controlled substance. As of August 18, 2014, DEA requires manufacturers to print the "C-IV" designation on all labels that contain 2-[(dimethylamino)methyl]-1-(3-methoxyphenyl) cyclohexanol (tramadol), including its salts, isomers, and salts of isomers. The agency notes that every "DEA registrant who possesses any quantity of tramadol on the effective date of this final rule must take an inventory of all stocks of tramadol on hand as of August 18, 2014, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11 (a) and (d)." In addition, all "prescriptions for tramadol

or products containing tramadol must comply with 21 U.S.C. 829, and be issued in accordance with 21 CFR part 1306 and subpart C of 21 CFR part 1311 as of August 18, 2014."

The announcement is available on the *Federal Register* website at *www.federalregister.gov/articles/2014/07/02/2014-15548/schedules-of-controlled-substances-placement-of-tramadol-into-schedule-iv*.

FDA Lowers Recommended Starting Dose for Lunesta Due to Risk of Morning Impairment

FDA has lowered the recommended starting dose of the sleep drug Lunesta® (eszopiclone) from 2 mg to 1 mg. Patients who are currently taking 2 mg and 3 mg doses of eszopiclone should contact their health care provider to ask for instructions on how to continue to take their medication safely at a dose that is best for them, FDA advises. The dose change came after findings from a study of 91 healthy adults found that the medication was associated with impairment to driving skills, memory, and coordination for as long as 11 hours after the drug is taken, FDA notes.

More information is available in an FDA news release at *www.fda.gov/newsevents/newsroom/pressannouncements/ucm397453.htm*.

Lidocaine Should Not Be Used to Treat Teething Pain in Children, FDA Warns

FDA is recommending that prescription oral viscous lidocaine 2% solution should not be used to treat infants and children with teething pain, and is now requiring a new boxed warning to be added to the drug label to highlight this information. Oral viscous lidocaine solution is not approved to treat teething pain, and use in infants and young children can cause serious harm, including death, indicates FDA in a June 2014 Safety Announcement. FDA advises health care providers not to prescribe or recommend this product for teething pain. FDA is also requiring the "Warnings" and "Dosage and Administration" sections of the drug label to describe the risk of severe adverse events and to include additional instructions for dosing when the drug is prescribed for approved uses.

In 2014, FDA reviewed 22 case reports of serious adverse reactions, including deaths, in infants and young children who were either given lidocaine for treatment of mouth pain, or who accidentally ingested the medication.

More information is available in the safety announcement on FDA's website at *www.fda.gov/Drugs/DrugSafety/ucm402240.htm*.

FDA Reiterates Warning Against Using NuVision Pharmacy Products

Health care providers should not use or distribute compounded drugs marketed as sterile produced by Downing Labs, LLC, of Dallas, TX, also known as NuVision Pharmacy, warns FDA. Inspection results issued on July 16, 2014, indicate that FDA observed unsanitary conditions resulting in a lack of sterility assurance of sterile drug products produced by the company, which may put patients at risk, FDA notes in the safety announcement. "The inspection revealed sterility failures in 19 lots of drug products intended to be sterile, endotoxin failures in three lots of drug products, and inadequate or no investigation of these failures," states FDA in the announcement.

In 2013, the agency issued several similar warnings following NuVision's refusal to recall all sterile products. In April 2013, NuVision recalled methylcobalamin injection and lyophilized injection products, citing concerns about sterility in the wake of adverse event reports. Health care providers and consumers may report adverse events or quality problems associated with NuVision products to FDA's MedWatch Safety Information and Adverse Event Reporting Program.

Additional information is available in the safety announcement, available on FDA's website at *www.fda.gov/Drugs/DrugSafety/ucm405940.htm*.

JCPP Releases New Patient-Care Document to Promote Consistency

The Joint Commission of Pharmacy Practitioners (JCPP) has released a resource document aimed at promoting consistency in the pharmacists' process of patient care service delivery. "Pharmacists' Patient Care Process" was developed by examining key source documents on pharmaceutical care and medication therapy management. The document describes the process in five parts: collect, assess, plan, implement, and follow-up.

JCPP brings together the chief executive officers and elected officers of national pharmacy associations, including the National Association of Boards of Pharmacy®, to create a forum for discussion and opportunity for collaborative work on issues and priorities of pharmacy practice.

The document can be downloaded online at *www.pharmacist.com/sites/default/files/JCPP_Pharmacists_Patient_Care_Process.pdf*.

CPE Credit Offered for FDA Course on Misleading Prescription Drug Promotion

To raise awareness about the risks associated with false or misleading prescription medication marketing, FDA, in partnership with Medscape, is offering an online, one-hour continuing education course through its Bad Ad Program. Pharmacists may receive continuing pharmacy education (CPE) credit by taking this course. Learning objectives, faculty information, and other information is available on the course's website at *www.sigmatech.com/BadAd*. There is no registration fee for the course. Upon completion, pharmacists will receive one Accreditation Council for Pharmacy Education-accredited CPE hour (0.1 continuing education unit).

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Controlled Substance Ordering System? October 6, 2014.

6. **I have stock bottles of hydrocodone-containing products that are labeled "C III." Do I need to relabel them?** No. Manufacturers must label all hydrocodone-containing products "C II" by October 6, 2014. Neither pharmacists nor manufacturers are required to relabel stock bottles distributed prior to October 6, 2014.
7. **Does this affect North Carolina's identification requirement for dispensing CS?** No. North Carolina's CS identification statute already requires that identification be obtained prior to dispensing any Schedule II CS, and for certain Schedule III CS. Hydrocodone-containing products were among the Schedule III CS for which identification had to be obtained. More information about the CS identification statute may be found at *www.ncbop.org/faqs/PhotoIDFAQ.pdf.*
8. **Will hydrocodone-containing product prescriptions have a six-month expiration date under North Carolina law?** Yes. More information concerning that statute, which went into effect October 1, 2013, may be found at *www.ncbop.org/faqs/Pharmacist/faq_SchIIControlledSub.htm.*

Item 2290 – Board Issues Guidance on the Permitting of 'Outsourcing Facilities'

Board staff has received inquiries concerning whether and under what circumstances a Section 503B outsourcing facility (as defined in the federal Drug Quality and Security Act (DQSA)) must also hold a pharmacy permit. The answer depends on the scope of services provided at the facility. The following guidance issued by the Board on July 15, 2014, details the circumstances under which Section 503B outsourcing facilities must obtain (or maintain) a pharmacy permit: *www.ncbop.org/PDF/GuidancePermittingOutsourcingFacilities071514.pdf.*

Item 2291 – FDA Issues Additional Guidance Concerning Implementation of the DQSA

On July 1, 2014, the federal Food and Drug Administration (FDA) released additional guidance concerning implementation of the DQSA, including (1) draft interim guidance concerning current Good Manufacturing Practice compliance for Section 503B outsourcing facilities; (2) a proposed rule revising FDA's list of drug products that may not be compounded because they have been withdrawn or removed from the market for lack of safety or efficacy; (3) final guidance to compounding pharmacies on Section 503A; and (4) notice of reopening the nomination process for lists of bulk drug substances that may be used to compound drug products. More information, including links to the various documents, may be found at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm403507.htm.*

Jack W. "Jay" Campbell IV, the Board's executive director, has written a two-part article overviewing the DQSA. The National Association of Boards of Pharmacy® published the article in its August and September *Newsletters,* which may be found at *www.nabp.net/system/rich/rich_files/rich_files/000/000/561/original/august2014nabpnewsletter.pdf* and *www.nabp.net/system/rich/rich_files/rich_files/000/000/556/original/september2014nabpnewsletter.pdf.*

Item 2292 – Board Publishes Proposed Amendments to Health Department Nurse Dispensing

The Board has published proposed amendments to allow health department nurses to dispense epinephrine auto-injectors to designated school personnel. The North Carolina General Assembly passed, and the governor signed into law, a statute requiring all public and charter schools in North Carolina to have on hand at least two epinephrine auto-injectors.

General guidance on the new statute may be found at *www.ncbop.org/faqs/Pharmacist/GuidanceEpinephrineAutoInjectorStatuteSept2014.pdf.*

Information on the rulemaking in process, including instructions for submitting comments, may be found at *www.ncbop.org/rulemakings.htm.* Please note that all comments are due to the Board by 9 AM on November 18, 2014.

Item 2293 – Leadership North Carolina Names Board's Associate Executive Director to Its 2014-2015 Class

Congratulations to Ellen Vick, the Board's associate executive director, on being selected as one of 55 civic and community leaders from across the state to form the 2014-2015 class for Leadership North Carolina.

The state's premiere leadership engagement program, Leadership North Carolina comprises key personnel from the government, business, nonprofit, and education sectors. Selected participants study five key areas: economic development, education, environment, government, and health and human services. Their goal is to use the knowledge gained to better their own organizations, their local communities, and North Carolina as a whole.

More information may be found at *http://leadershipnc.org/wp-content/uploads/2014/09/Leadership-North-Carolina-Class-XXII-Announcement-9-9-14.pdf.*

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