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North Dakota State Board of Pharmacy News

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New Rule on the Use of the PDMP in Certain Circumstances Effective as of October 1, 2014

The North Dakota State Board of Pharmacy took comments and made modifications during the North Dakota Pharmacists Association Annual Convention in Fargo, ND, on the rule requiring use of the North Dakota Prescription Drug Monitoring Program (PDMP) in certain circumstances.

It is now time to get set up with a PDMP account to view patient reports if you do not have one. The application process is very easy to complete online at the Board's website. Please remember that pharmacy technicians, technicians-in-training, and interns may sign up and look up reports as delegates under the pharmacist's discretion. The Board recommends that you utilize the PDMP and determine the policies and procedures for its use in your practice to meet the standards set in the rule. Below is the language of the rule that became effective in October 2014.

61-12-01-04. Required use for Certain Dispensing Situations.

1. Prior to dispensing a prescription each dispenser licensed by a regulatory agency in the state of North Dakota who dispenses a controlled substance to a patient, for the treatment of pain or anxiety shall, at a minimum, request and review a Prescription Drug Monitoring Report covering at least a one year time period and/or another state's report, where applicable and available, if the dispenser becomes aware of a person currently:
   a. Receiving reported drugs from multiple prescribers;
   b. Receiving reported drugs for more than twelve consecutive weeks;
   c. Abusing or misusing reported drugs (i.e. overutilization, early refills, appears overly sedated or intoxicated upon presenting a prescription for a reported drug, or an unfamiliar patient requesting a reported drug by specific name, street name, color, or identifying marks);
   d. Requesting the dispensing of a reported drug from a prescription issued by a prescriber with whom the dispenser is unfamiliar (i.e. the prescriber is located out-of-state or the prescriber is outside the usual pharmacy geographic prescriber care area); or,
   e. Presenting a prescription for reported drugs when the patient resides outside the usual pharmacy geographic patient population.
2. After obtaining an initial Prescription Drug Monitoring Report on a patient, a dispenser shall use professional judgment based on prevailing standards of practice in deciding the frequency of requesting and reviewing further Prescription Drug Monitoring Reports and/or other state[s]' reports for that patient.
3. In the rare event a report is not immediately available; the dispenser shall use professional judgment in determining whether it is appropriate and in the patient's best interest to dispense the prescription prior to receiving and reviewing a report.
4. For the purpose of compliance with Section 1, a report could be obtained through a PDMP integration with software or also a Board approved aggregate tool, for which the NAR$_X$CHECK will be an approved tool.

License Renewal for Pharmacists and Pharmacy Technicians

The license renewal process for pharmacists and pharmacy technicians will be available in mid-December. A notice will be e-mailed to all licensees and registrants when it is available. In accordance with North Dakota law, be sure to keep your contact information current with the Board to ensure that you receive notifications. You may update your address, employment, and Pharmacy Technician Certification Board (PTCB) certification (for technicians) on the Board's website at any time.

Pharmacy technicians, please remember that you will have to continue to provide a current PTCB certification number and expiration date on renewal of your registration. The only exception to this requirement will be for those technicians registered on or before August 1, 1995, who will continue to be grandfathered.

Information about the certification test and how to apply to take it can be found at *www.ptcb.org*.

Counseling on New and Refilled Prescriptions

As a reminder, North Dakota law requires that a pharmacist counsel on **all prescriptions.** Violations of this law were noted often on inspections and in some recent complaints. The law reads as follows:

43-15-31.2. Prescription drug information required.

With each prescription dispensed, the licensed pharmacist or the licensed intern pharmacist, in addition to labeling the prescription in accordance with law, must explain to the patient or the patient's agent the directions for use and a warning of the potential harmful effect of combining any form of alcoholic beverage with the medication and any additional information, in writing if necessary, to assure the proper utilization of the medication or device prescribed. For those prescriptions delivered outside the confines of the pharmacy, the explanation must be by telephone or

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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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in writing, provided that this does not apply to those prescriptions for patients in hospitals or institutions where the medication is to be administered by a nurse or other individual licensed to administer medications, or to those prescriptions for patients who are to be discharged from a hospital or institution.

Counseling is a safeguard that gives a pharmacist the opportunity to make a visual verification that everything is correct before delivery to the patient. It allows the pharmacist to check one last time for any discrepancies between the actual prescription and the prescription product dispensed before it actually goes to the patient for ingestion. It ensures that the patient understands how to take the medication properly.

There are many reasons why a pharmacist is required to counsel patients. It not only allows a safety check, it educates the patient and opens the lines of communication to address any concern the patient may have. Patients usually have a basic understanding of their drug therapy and can alert you to changes in their health. Gathering this information leads to better patient care, improved outcomes, a reduction in dispensing errors, and the general well-being of the patient. The lack of counseling or failure to properly counsel leads to unnecessary errors and possibly limits therapy outcomes.

Compounding Rules NDAC 61-02-01-03 to Be Effective January 1, 2015

The April 2012 compounding rules will become effective on January 1, 2015. The Board gave pharmacies over two years to prepare their facilities to meet the standard within the rules. Please note that these rules are very similar to United States Pharmacopeia Chapters <795> and <797>.

Please conduct a thorough review of the rules, found on pages 11 through 22 of the Board law book, to ensure you are fully compliant with the new standards, which will be inspected for compliance once effective. It is best to look at the rules to identify what levels of compounding your pharmacy conducts and determine the procedures and documentation that needs to be followed.

Policy and Procedure Manual

Each pharmacy must have and maintain a policy and procedure manual as set forward in the recent rule promulgated by the Board. Please ensure that your pharmacy has a manual created and regularly updated that encompasses all activities of the pharmacy operation. The context of the rule is as follows.

61-02-01-19. Policy and Procedure Manual Required.

1. Each Pharmacy must have a written or electronic and easily accessible policy and procedure manual to address all aspects of the pharmacies operations. The policy and procedure manual must be available for inspection. The policy and procedure manual must set forth in detail the objectives and operational guidelines of the pharmacy. The policy and procedure manual must be reviewed and revised or reaffirmed on an annual basis.
   a. Inspection Procedures including
      i. Location of Controlled substance records including
         1. Location of current biennial inventory
         2. Wholesale records of receipt and sale of controlled substances
         3. DEA 222 forms, both paper and electronic, executed or not.
         4. Information for running reports from the pharmacy computer system relative to dispensing of specific controlled substances
         5. Power of attorney forms if granted and termination forms if executed
      ii. Location of most recent inspection forms by the board of pharmacy, accreditation agencies or the FDA, if applicable

Board Meetings Set for 2015

- ♦ January 5-7 – Wingate Inn, Fargo
- ♦ March 19
- ♦ May 26-29 – Wingate Inn, Fargo
- ♦ July 16
- ♦ September 17
- ♦ November 19

The meetings are typically held at the Board's office in Bismarck, ND, unless otherwise specified. The public may attend Board meetings. All the information regarding the meetings, including the time, place, and agenda, is found at the Board's website.

The *North Dakota State Board of Pharmacy News* is published by the North Dakota State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation™ (NABPF™) 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 NABPF or the Board unless expressly so stated.

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