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North Dakota State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

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What is This?

The North Dakota State Board of Pharmacy in collaboration with the National Association of Boards of Pharmacy® will be sending out a quarterly pharmacy *Newsletter*. The Board envisions the *Newsletter* as a way to communicate with its licensees about current and changing pharmacy laws along with trending issues that our profession encounters.

Pharmacy Technician Certification

The North Dakota State Board of Pharmacy wants to make sure all North Dakota licensees and registrants are aware of the following requirements for North Dakota licensed pharmacy technicians.

Pharmacy Technician Certification Board (PTCB) certification is required and must be obtained before registration for new technicians. Current technicians who graduated from an American Society of Health-System Pharmacists-accredited program must obtain PTCB certification by March 1, 2014. The only exception to this requirement will be for those technicians registered before January 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*.

Pharmacist First Dose Review

In recent meetings, the North Dakota State Board of Pharmacy has been discussing requiring first dose review by a pharmacist. Through telepharmacy, the long-term vision has been to put the tools in place to allow all of its North Dakota hospitals to take advantage of pharmacist first dose review for every order, except where the practitioner is directly involved with the administration or in direct supervision of that administration. At the Board's September meeting it was pointed out that the Board now has four providers of hospital telepharmacy services in the state.

1. ePharmacist Direct.
2. Altru Health Systems – providing telepharmacy services to a couple of their affiliate hospitals in northeast North Dakota.
3. Avera McKenna out of Sioux Falls, SD, providing telepharmacy services to McKenzie County Healthcare Systems Pharmacy in Watford City, ND.
4. Sanford Health Systems to involve Cardinal Health's R_xe-source Center Pharmacy Resources to provide coverage in their affiliate hospitals.

The Board believes this gives hospitals four good options to work with to establish pharmacist first dose review. The Board will continue to have discussions about the issue before drafting a rule.

Transfer Between Pharmacies for Schedule III, IV, and V Controlled Substances for Refill Purposes

North Dakota law allows pharmacy technicians to transfer prescriptions to and from other pharmacies. However, federal law (CFR Section 1306.25(b)(1) states when transferring controlled substance prescriptions, the communication must be directly between two licensed pharmacists. Federal law also excludes interns from transferring controlled substance prescriptions. Federal law trumps the North Dakota law in this case. As a reminder, when there is a difference between state law and federal law the stricter of the two always applies.

Soma and Propofol Among Additions to Schedule IV Controlled Substances

During the 2011 North Dakota Legislative session SB 2119 was enacted in law. This legislation added previously non-scheduled substances Soma® and propofol to the list of substances as a Schedule IV substance. The law took effect on August 1, 2011.

Currently, there is a pending Drug Enforcement Administration (DEA) rule that will add Soma on the federal list of controlled substances but no official action has been taken. What this means for you is all prescriptions for products containing Soma are held to the same state rules and laws as other controlled substances.

North Dakota Legislature Passes Bill to Expand Scope of Practice for Pharmacists Providing Immunizations

The legislature overwhelmingly supported SB 2035 related to pharmacist administered immunizations and vaccinations. It removed the 18 or older age restriction for pharmacists in providing immunizations. This legislation lowers the age restrictions to at least 11 years of age for all immunizations and vaccinations. It also provides for the administration of influenza vaccination by injection or by "live" for an individual who is at least five years of age.

The state's legislature clearly indicated that improving the immunization rate is a goal for North Dakota and pharmacists are at the forefront to providing this service across the state. The Board believes it is essential for its pharmacists to capitalize on this opportunity and show what a crucial part of the health care team we are.

As a reminder, when any immunization is given all providers are required to report it to the North Dakota Immunization Information System administered by the North Dakota Department of Health.

North Dakota State Board of Pharmacy Policy On What a Pharmacist May Change On a Controlled Substance Prescription

Schedule II

- Pharmacist may add or change the patient's address, upon verification.
- Pharmacist may add or change the dosage form, drug strength, drug quantity, directions for use, or issue date after consultation with and

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2011-2012 Influenza Vaccines Approved by FDA

Food and Drug Administration (FDA) announced that it has approved the 2011-2012 influenza vaccine formulation for all six manufacturers licensed to produce and distribute influenza vaccine for the United States. The vaccine formulation protects against the three virus strains that surveillance indicates will be most common during the upcoming season and includes the same virus strains used for the 2010-2011 influenza season. The Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) recommends that everyone six months of age and older receive an annual influenza vaccination. Details about the new vaccines are available in an FDA news release at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm263319.htm,* and information about the ACIP recommendations are available on the CDC Web site at *www.cdc.gov/media/pressrel/2010/r100224.htm.*

Another TEAspoon – mL Mix-Up

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.*

A few weeks ago ISMP heard from a mother whose child was accidentally given an overdose of an antibiotic. A pharmacist accidentally provided instructions on the prescription label for her child to receive 3.5 **TEA**spoonfuls of a liquid antibiotic for 10 days instead of 3.5 **mL.** The medication was dispensed in a 60 mL bottle. The child was given 3.5 **TEA**spoonfuls each day for three days. By the fourth day only one **TEA**spoonful (5 mL) was left in the bottle, so the mother called the pharmacy and learned that the dosage amount on the label was incorrect. The child experienced bouts of diarrhea and a yeast and fungal infection in the vaginal area.

Mix-ups between teaspoons and mL are common and have been happening for many years. ISMP first mentioned the problem in its June 28, 2000 newsletter article, "Oral liquid medications may be more vulnerable to errors than previously recognized" *(www.ismp.org/Newsletters/acutecare/articles/20000628_2.asp).* ISMP has received more than 50 similar errors in recent years, most resulting in patient harm. It is time to standardize to a single way of measuring liquid medications, using the metric system with volumes expressed in mL. If we all used the metric measurement when prescribing, dispensing, and administering medications, these types of mix-ups would no longer happen.

In response to ongoing errors, in June 2009, ISMP called for elimination of **TEA**spoonful and other non-metric measurements to prevent errors *(www.ismp.org/pressroom/PR20090603.pdf).* In May 2011, FDA published a guidance suggesting ways for manufacturers to improve the labeling of over-the-counter (OTC) liquid drug products to minimize the risk of accidental overdoses *(www.fda.gov/Drugs/DrugSafety/MedicationErrors/ucm253715.htm).* Unfortunately, the guidance still mentions both **TEA**spoon and **TABLE**spoon. The Consumer Healthcare Products Association has also published guidelines *(www.chpa-info.org/scienceregulatory/Voluntary_Codes.aspx#volumetricmeasure)* to improve the format for volume measures within the dosing directions for OTC products. The abbreviation "mL" is recommended for use on accompanying dosing devices that measure OTC oral liquid drug products so they match the dosing directions in labeling for children. The group has also told companies to avoid directions that mention tablespoon, cubic centimeters (cc), dram, fluid ounce (Fl Oz), and dropper(ful), and to use mL as the sole unit of measure in the dosing directions or, alternatively, mL **and** the **"TEA**spoonful" equivalent (eg, 5 mL (1 **TEA**spoon)).

While these are excellent moves to improve safety, ISMP would like to see the complete elimination of **TEA**spoonful amounts and the abbreviation "tsp." Doses expressed using mL alone would be the best way to eliminate the risk of mix-ups. The ISMP board fully supports this initiative and is currently in the process of approving a formal ISMP position on this issue. ISMP hopes the health care industry will also support this initiative.

'Know Your Dose' Campaign Aims to Prevent Acetaminophen Overdose

The Acetaminophen Awareness Coalition, has launched *www.KnowYourDose.org,* a Web site aimed to educate consumers about the dangers of acetaminophen overdose and how to ensure that the correct, safe dosage is administered. "Know Your Dose" stresses to patients the importance of checking the labels of both prescription and over-the-counter medications for the amount of acetaminophen contained in order to ensure that they do not exceed recommended maximum dosage levels. Health care providers may order a free Know Your Dose kit that includes materials to help educate patients about safely using medications containing acetaminophen. The kit includes posters, information cards for patients, and a display holder for use in distributing the cards. Members of the Acetaminophen Awareness Coalition include Alliance for Aging Research, American Academy of Nurse Practitioners, American Academy of Physician Assistants, American Pain Foundation, American Pharmacists Association, CHPA Educational Foundation, National Association of Boards of Pharmacy® (NABP®), National Association of Chain Drug Stores, National Community Pharmacists Association, National Consumers League, and the National Council on Patient Information and Education. The campaign was developed under advisement from the American Academy of Pediatrics, CDC, and FDA.

Methylene Blue and Linezolid May Interact With Certain Psychiatric Medications

FDA has issued two safety communications regarding adverse drug reactions in patients taking certain psychiatric medications, and also given methylene blue or linezolid (Zyvox®). Specifically, FDA has received reports of serious central nervous system reactions in patients taking serotonergic psychiatric medications who are also given methylene blue, a product commonly used in diagnostic procedures. FDA explains that "[a]lthough the exact mechanism of this drug interaction is unknown, methylene blue inhibits the action of monoamine oxidase A – an enzyme responsible for breaking down serotonin in the brain. It is believed that when methylene blue is given to patients taking seroto-

nergic psychiatric medications, high levels of serotonin can build up in the brain, causing toxicity. This is referred to as Serotonin Syndrome. Signs and symptoms of Serotonin Syndrome include mental changes (confusion, hyperactivity, memory problems), muscle twitching, excessive sweating, shivering or shaking, diarrhea, trouble with coordination, and/or fever." FDA has published a list of the serotonergic psychiatric medications that can interact with methylene blue, available at *www.fda.gov/Drugs/DrugSafety/ucm263190.htm#table,* and advises that "Methylene blue should generally not be given to patients taking serotonergic drugs." Exceptions and more information for health care providers and patients are available in an FDA Drug Safety Communication available at *www.fda.gov/Drugs/DrugSafety/ucm263190.htm.*

Similar reports of interactions between certain serotonergic psychiatric medications and the antibacterial drug, linezolid (Zyvox) have also been reported to FDA. FDA has published a list of the serotonergic psychiatric medications that can interact with linezolid, available at *www.fda.gov/Drugs/DrugSafety/ucm265305.htm#table,* and advises that "Linezolid should generally not be given to patients taking serotonergic drugs." Exceptions and more information about the linezolid interaction for health care providers and for patients are available in an FDA Drug Safety Communication available at *www.fda.gov/Drugs/DrugSafety/ucm265305.htm.*

NABP Looking For Item Writers to Develop New Questions for NAPLEX, MPJE, FPGEE, and PCOA

NABP is seeking individuals to serve as item writers for the North American Pharmacist Licensure Examination® (NAPLEX®), Multistate Pharmacy Jurisprudence Examination® (MPJE®), the Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®), and the Pharmacy Curriculum Outcomes Assessment® (PCOA®).

Pharmacists in all areas of practice and faculty from schools and colleges of pharmacy are encouraged to apply. To be considered as an item writer for the NAPLEX and MPJE, pharmacists must have at least two years of pharmacy practice experience.

Item writers will be selected based on the specific needs of the programs. Those who are chosen will be asked to attend a workshop at NABP Headquarters with travel, lodging, and ancillary expenses paid by NABP.

Attendees will receive detailed instructions and training materials describing the item-writing process and content-related requirements for their designated examination. Item writers will then be asked to develop new test items that will be considered for inclusion in NABP licensure and certification and assessment examination programs.

The NAPLEX is an examination consisting of 185 selected-response and constructed-response test questions, the majority of which are asked in a scenario-based format, that covers important information about the knowledge, judgment, and skills an entry-level pharmacist is expected to demonstrate. The three competency areas of the examination are:

- Assess pharmacotherapy to ensure safe and effective therapeutic outcomes
- Assess safe and accurate preparation and dispensing of medications
- Assess, recommend, and provide health care information that promotes public health

The MPJE is a computer-based examination that consists of 90 select-response items. It combines federal and state-specific questions that test the pharmacy jurisprudence knowledge of prospective pharmacists on the following areas:

- Legal aspects of pharmacy practice, including responsibilities with regard to the distribution and dispensing of pharmaceuticals and for the care of patients
- Licensure, registration, certification, and operational requirements
- Regulatory structure and terms of the laws and rules that regulate or affect pharmacists, pharmacies, manufacturers, and distributors

The FPGEE is a comprehensive examination consisting of 250 multiple-choice questions that measures four major pharmacy content areas:

- Basic biomedical sciences
- Pharmaceutical sciences
- Social/behavioral/administrative pharmacy sciences
- Clinical sciences

The PCOA is a 220-question, multiple-choice assessment that is administered to pharmacy students in all four professional years. The assessment follows a blueprint that reflects actual curriculum hours established through a national sample of PharmD programs in the US and is broken down into the following four areas:

- Basic biomedical sciences
- Pharmaceutical sciences
- Social, behavioral, and administrative pharmacy sciences
- Clinical sciences

Interested individuals should mail or fax a letter of interest indicating their current practice/educational setting, specialties/certifications, and years of experience, along with a resume or curriculum vitae via mail to NABP Executive Director/Secretary Carmen A. Catizone at 1600 Feehanville Drive, Mount Prospect, IL 60056; via e-mail at exec-office@nabp.net; or via fax at 847/391-4502.

Please note, applications are accepted on a continuous basis and kept on file for a period of five years. For more information about item writing, contact NABP at custserv@nabp.net.

Clarification Regarding Pradaxa Storage and Handling Requirements

An FDA alert released in March 2011 details important storage and handling guidelines for Pradaxa® (dabigatran etexilate mesylate) capsules, as reported in the third quarter NABP *National Pharmacy Compliance News.* As a point of clarification, the FDA-approved Pradaxa label states that once opened, the product must be used within 30 days. FDA is currently reviewing data that indicate no significant loss of potency up to 60 days after the bottle is opened as long as Pradaxa is stored in the original bottle and the handling requirements are met. An FDA Drug Safety Communication available at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm249005.htm* provides more details, and the manufacturer's Pradaxa safety information is available at *www.pradaxa.com* by clicking on the link for "Important Storage & Handling Information" at the top of the page.

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agreement of the prescribing practitioner. Such consultation and corresponding changes should be noted by the pharmacist on the prescription.

- Pharmacist may add the DEA number of the practitioner.

** The pharmacist is **not** permitted to make changes to the patient's name, the controlled substance prescribed (except for generic substitution), or the prescriber's signature.

Schedules III-V

- Pharmacist may add or change the patient's address, upon verification.
- Pharmacist may add or change the dosage form, drug strength, drug quantity, directions for use, or issue date after consultation with and agreement of the prescribing practitioner. Such consultation and corresponding changes should be noted by the pharmacist on the prescription.
- Pharmacist may add the DEA number of the practitioner.

The important tenets of any changes to a controlled substance prescription should be:

- Take care of the patient.
- Verify the identity of each patient receiving a controlled substance.
- Verify that the prescriber's intentions for the care of his or her patient are being fulfilled.

North Dakota Pharmaceutical Compounding Standards

The Board would like to highlight part of the North Dakota State Board of Pharmacy Rule 61-02-01-03 regarding compounding standards.

The minimum standards and technical equipment to be considered as adequate shall include:

- A logbook or record system to track each compounded prescription and component used.

Board compliance officers have found this to be part of the standards that are not being followed in all practice settings. If you are not in compliance with this, your pharmacy needs to set up a policy to implement it. The Board finds it imperative that pharmacies can track and duplicate the method of preparation along with recording the individuals who did the compounding.

Helpful Hints for Using Your PDMP Direct Access Account

The automatic setting for looking up your patient is on "Fastest: Last Name = and First Name Begins" on your prescription drug monitoring program (PDMP) access account, which means you will enter the full last name and the first few letters of the first name. Select "Begins with" and enter the first few letters of the last name and the first few letters of the first name. Enter in the date of birth, select the Within drop-down box, and change it from Exact Match to 1 Year. Skip straight down to the Dispensed time frame from and to fields. By entering in the zip code and other information you may be limiting your search to pull back only the accounts that fall within the parameter of information you are selecting.

	Name Selection
Recipient	Begins with
	Sounds like
	Fastest: Last Name = and First Name Begins
***Last Name**	
***First Name**	

Why should you do this? If you have a patient that goes by the name of David or Dave McRuggles and you enter in D-a-v-i-d instead of D-a-v you are only going to get the accounts back under David and not Dave. Occasionally, the Board will find the rare misspelling of a last name and by entering in m-c instead of McRuggles you can catch an error where someone entering the script may have entered a space in between the C and R or left out a G. The Board chooses the Within 1 Year parameter to catch any typos for the date of birth, which generally would only be off by one number. If you find a misspelling of an account, want patient accounts linked together, or find a patient with several last names or nick names, please contact Kathy at 701/328-9537 with any information about accounts that should be linked together or if you find an error so that the Board can correct it for future health care professionals also using the system.

Pharmacists and Technicians

Renew your license online by **March 1,** at *www.nodakpharmacy.com.*

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, 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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