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North Dakota State Board of Pharmacy News

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Steve Irsfeld Appointed to Board

Steve Irsfeld, RPh, was appointed to serve on the North Dakota State Board of Pharmacy by Governor Jack Dalrymple on May 8, 2014. Steve will fill the vacant seat caused by the expiring term of Bonnie Thom, RPh.

Steve resides in Dickinson, ND, where he owns and operates Irsfeld Pharmacy. Steve is a 1988 graduate of the North Dakota State University (NDSU) College of Pharmacy, Nursing, and Allied Sciences. The Irsfeld family has a deep lineage in North Dakota pharmacy. Steve's father, James Irsfeld, RPh, served on the Board as a member from 1980-1990. Steve's daughter, Molly Irsfeld, PharmD, graduated in May from the NDSU College of Pharmacy, Nursing, and Allied Sciences.

The Board welcomes Steve, and it thanks Bonnie for her 10 years of service to the profession of pharmacy by serving on the Board.

New Rule on the Use of the PDMP in Certain Circumstances

The Board took comments and made modifications during the North Dakota Pharmacists Association Annual Convention in Fargo, ND, on the pending 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 on the Board's website. Please remember that pharmacy technicians and technicians-in-training 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 is set to be 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. over-utilization, 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 NARxCHECK will be an approved tool.
   a. The National Association of Boards of Pharmacy Foundation's NARxCHECK service is a risk assessment tool for health care providers and pharmacists that accesses patient prescription information from prescription drug monitoring program (PDMP) databases, analyzes the data, and provides a risk-based score that includes PDMP data and graphical analysis to assist in prescribing and dispensing decisions.

National Pharmacy

(Applicability of the contents of articles in the National Pharmacy Comp
and can only be ascertained by examini

New Educational Video for Pharmacists Addresses Prescription Drug Abuse

The National Association of Boards of Pharmacy® (NABP®) and the Anti-Diversion Industry Working Group (ADIWG), a consortium of pharmaceutical manufacturers and distributors of controlled substances (CS), have released an educational video for pharmacists to help them identify the warning signs of prescription drug abuse and diversion when dispensing CS prescriptions. The video, entitled "Red Flags," encourages pharmacists to help combat this national problem by exercising their professional judgment to ensure that the prescriptions they dispense were written for a legitimate medical purpose, and to act upon any unusual behavior they observe.

Drug Enforcement Administration and various state pharmacy boards have described "red flags" as circumstances surrounding the presentation of a CS prescription that should raise reasonable suspicion about the validity of that prescription. The video highlights a number of these potential warning signs, some of which are not easy to spot, by weaving personal narratives with interactions between pharmacists and customers.

The video is available in the Pharmacists section of the AWAR$_X$E® Prescription Drug Safety website at *www.AWARERX.ORG/pharmacists*.

Root Causes: A Roadmap to Action

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 Error Reporting Program Report online at* www.ismp.org. *E-mail: ismpinfo@ismp.org.*

Errors are almost never caused by the failure of a **single** element in the system. More often, there are **multiple** underlying system failures that lead to an error, many of which can be identified when the involved health care providers take the time to uncover them.

Consider the following error: A doctor sent a hand-written order for car**bam**azepine 400 mg twice daily for an adult patient with a history of seizures.

The pharmacist entered the medication into the profile of a four-year-old child with the same last name as the adult patient for whom the medication had been prescribed.

The pharmacist failed to notice that the patient was a child, as age was not in a prominent location on the order entry screen. The nurse failed to recognize that the dose was too high and administered 400 mg of car**bam**azepine to the child. She also never thought to question why the pharmacy would send oral tablets for a four-year-old child, considering that the drug is available in chewable tablets and as a liquid suspension.

The nurse **assumed** that the child was receiving the medication because he had a history of seizures. However, the nurse did not check the patient's medical record. In fact, the child did **not** have a history of seizures.

The parents had a very limited understanding of English, so they were unable to intervene to correct the erroneous seizure history.

The error was finally detected after the child became lethargic and developed nausea and vomiting. At the time of discovery, the child's car**bam**azepine level was 18 mcg/mL; levels greater than 12 in pediatric patients are supratherapeutic.[i]

It may be discouraging to see how many things go wrong when a medication error reaches a patient. However, a thorough root cause analysis (RCA) can uncover the latent failures and produce an action plan to avoid future errors.

ISMP, through a generous grant from the National Association of Boards of Pharmacy Foundation™, has developed the *Root Cause Analysis Workbook for Community/Ambulatory Pharmacy.* The workbook is designed to assist community pharmacy personnel in completing RCA for a sentinel event that may have occurred in their pharmacy. The RCA workbook uses a specific set of steps and associated tools to identify the primary causes of the **sentinel event.**

The goal of the RCA is to create an action plan framework, including risk-reduction strategies, communication and implementation strategies, and measurement of effectiveness.

RCA for **sentinel events** is required in the Center for Pharmacy Practice Accreditation's standards developed by NABP, American Pharmacists Association, and American Society of Health-System Pharmacists Association, as well as by several boards of pharmacy in conjunction with their continuous quality improvement regulations.

This ISMP RCA workbook is suitable for use in community pharmacy, mail-order pharmacy, or other ambulatory pharmacy practice settings that need to investigate a **sentinel event.** For more information and to access the **free** workbook, visit *www.ismp.org/tools/rca/.*

[i] *http://pediatrics.aappublications.org/content/113/2/406.abstract*

FDA Withdraws Approval of Some High Dose Acetaminophen Products

Food and Drug Administration (FDA) is withdrawing approval of 108 abbreviated new drug applications (ANDAs) for prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit. For the 108 ANDAs, the manufacturers asked to withdraw their applications, as announced in the March 27, 2014 *Federal Register* notice. A second *Federal Register* notice addresses the applications of six manufacturers who have discontinued marketing their products, but who have not withdrawn their applications. The notice also announces FDA's intention to begin the process of withdrawing approval of those applications.

In light of these announcements, and to protect patients from inadvertent acetaminophen overdose, NABP advises that pharmacies no longer dispense combination drugs containing more than 325 mg of acetaminophen per dosage unit. NABP also advises that pharmacists consult with prescribers to discuss alternative products with lower acetaminophen doses.

FDA asked manufacturers to voluntarily withdraw these products from the market to reduce the risk of severe liver injury from inadvertent acetaminophen overdose. In January 2014, FDA recommended that providers consider prescribing acetaminophen products containing 325 mg or less per dose. The original announcement may be found in the Drug Safety and Availability section of FDA's website at *www.fda.gov/Drugs/DrugSafety*.

NCPDP Recommends Standardized Metric Measurements on Oral Liquid Medication Labels

The National Council for Prescription Drug Programs (NCPDP) has issued new recommendations and guidance for standardizing the dosing designation used on prescription container labels of oral liquid medications dispensed by community pharmacies in order to reduce dosing errors. NCPDP notes that such errors have been "a source of concern for many years," and that dosing errors involving young children are of particular concern because they may be more susceptible to harm from measurement errors and overdoses. The paper outlines the following recommendations for the dosing designation on prescription container labels for oral liquid medications:

- The millimeter (mL) should be used as a standard unit of measurement.
- Dose amounts should always use leading zeros before decimal points for amounts less than one and should not use trailing zeros after a decimal point.
- Dosing devices with numeric graduations and units corresponding to the container label should be made easily and universally available. For example, a device should be included with each dispensed medication.

The white paper was developed following a meeting with stakeholders representing 27 participants, including NABP. In addition to its general recommendations, the white paper also issued calls to action for relevant stakeholders, including government agencies, standards organizations, pharmacists and pharmacy technicians, pharmacy leadership, and health care associations. The white paper, *NCPDP Recommendations and Guidance for Standardizing the Dosing Designations on Prescription Container Labels of Oral Liquid Medications,* is available for download from the NCPDP website at *http://ncpdp.org/Education/Whitepaper*.

USP Proposes New General Chapter Addressing Compounding of Hazardous Drugs

In an effort to protect health care providers and personnel who handle hazardous drugs, United States Pharmacopeial Convention (USP) has proposed new General Chapter <800> Hazardous Drugs–Handling in Healthcare Settings. The new proposed chapter addresses standards that apply to all personnel who compound hazardous drug preparations and all places where hazardous drugs are prepared, stored, transported, and administered. The new chapter also covers standards for receiving, storing, compounding, dispensing, administering, and disposing of nonsterile and sterile products and preparations. The proposed chapter applies to all personnel who are involved in handling hazardous drugs, including health care providers and staff, occupational health and safety specialists, and human resources. General Chapter <800> was published in the May/June issue of *Pharmacopeial Forum,* and may currently be viewed on the USP website at *www.usp.org/usp-nf*. Comments were accepted until July 31, 2014.

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Pharmacy Inspections

The Board inspectors are currently out conducting their yearly inspections. By the time you receive this *Newsletter,* many of you will have your pharmacy's inspection completed. The inspectors this year will be Judy Swisher, RPh; Bonnie Thom, RPh; and Howard Anderson, Jr, RPh. The focus of this year's inspection will include:

- Controlled substance (CS) audit,
- Counseling on all prescriptions (if inspector notices non-compliance, warning notices will be issued),
- Compounding regulations,
- First dose review in hospitals, and
- PDMP use and upcoming required use.

Please have your inspection form filled out and, if applicable, have your CS audit completed. The Board wants you to spend some quality time with the inspector while he or she is there and to ask any questions you or your staff may have.

Certificate to Administer Immunizations or Other Injectable Medications

The Board website allows pharmacists to obtain their immunization certification online. Pharmacists will be able to scan and upload the appropriate documents and view previously uploaded documents. Once completed and approved by the Board office, a certificate will be sent via e-mail.

The necessary documentation includes proof of your course certificate, current CPR certification, and documentation of six continuing education hours related to immunizations/injectables over the past two years. The certificate will still need to be renewed every two years. Obtaining this certificate will continue to be free when completed online.

As a reminder, the North Dakota Legislature approved legislation 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.

Our 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. Take a moment to ensure your certification is ready for the upcoming flu shot season.

Visit *www.nodakpharmacy.com/immunization* to apply or renew online.

Take Note

As a result of the changes in laws and rules in various states and increased collaboration between multiple regulatory entities, there have been multiple disciplinary actions against licenses of out-of-state pharmacies, especially surrounding those pharmacies conducting compounding in unsafe conditions.

With these recent actions, it is important that we as pharmacy professionals educate our patients in North Dakota, as well as fellow health care providers, about the importance of only obtaining prescription medications from North Dakota licensed entities. This includes pharmacies, wholesalers, and manufacturers. As a reference point, the Board has a very useful verification tool on its website for anyone to use to check the status of a license/registration/permit.

Tramadol Now a Federal Schedule IV CS

As of August 18, 2014, tramadol-containing products are Schedule IV CS by federal law. The Board introduced legislation to make tramadol-containing products a state CS during the last legislative session in North Dakota. Beginning August 18, tramadol-containing products will need to be handled just as any other federal Schedule IV CS.

Guidance Documents

The Board's website contains guidance documents that explain and clarify many of the frequently asked questions that the Board office receives. Please visit this website and take the time to read through any documents that may you may find helpful.

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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