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North Dakota State Board of Pharmacy News

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PTCB 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, who graduated from an American Society of Health-System Pharmacists-accredited program, and must be obtained by current technicians by March 1, 2014. 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.***

Address Changes

Please ensure that your address, e-mail, and work information are promptly updated with the Board upon any change as required by law. The Board has an easy process available on its Web site to make any changes necessary to your records. It will be important to maintain a regularly maintained e-mail address as this is increasingly becoming the way to communicate important changes and updates from the Board.

Reprinting and Verifying Licenses

Take note that you have the capability to verify any Board license or registration on the Board's Web site. License verification printouts to provide for various entities can be accomplished in this way.

The Board's Web site also allows you to reprint your license or registration at any time. This technology is useful in ensuring all licenses are properly posted at your facility.

Administrative Guidelines for Repackaging of Prescriptions

Repackaging by provider pharmacies or consultant pharmacists for patients in long-term care facilities who receive medications in packaging that does not conform to the medication distribution system, chosen by the facility, is appropriate under these guidelines:

1. Medication is delivered to the facility or the repackaging pharmacy so storage and handling under United States Pharmacopeia guidelines is assured.
2. The dispensing pharmacy provides the manufacturer's original lot number and expiration date.
   a. If no lot number is provided, an alternate number will be assigned by the repackaging pharmacy. If there is a recall of medication dispensed without the original lot number, the recall will affect all of the named drug.
   b. The repackaging pharmacy will assign an expiration date not more than six months from the date of dispensing by the original pharmacy, or the original expiration date, whichever is shortest.
3. A log must be kept by the repackaging pharmacy containing the following information:
   a. Patient's name
   b. Name, address, and phone number of original dispensing pharmacy
   c. The prescription number of the original dispensing pharmacy
   d. Date of dispensing by the original dispensing pharmacy
   e. Expiration date assigned by the original dispensing pharmacy, if available
   f. The manufacturer's lot number or the number assigned by the original dispensing pharmacy, if available
   g. The name of the product and identification of the manufacturer
   h. The quantity of product received and repackaged
   i. The prescription number assigned by the repackaging pharmacy
   j. Lot number assigned by the repackaging pharmacy or indication that the manufacturer's original lot number was used
4. The repackaging pharmacy is responsible for storage of the unused portion of the prescription until redistribution to the facility.
5. Charges for repackaging can be borne by the original dispensing pharmacy or the facility, but cannot be included by the consultant or repackager as part of another service. These charges must be billed separately to avoid the appearance of kickbacks. Medicaid does not allow repackaging charges directly to the department by the pharmacy. The patient may not be charged separately, as the distribution system is a requirement of the nursing facility and should be included in their rate. The cost is allowable by Medicaid on the facility cost report.
6. The repackaging pharmacist is the final decision maker as to whether the repackaging will be done, and the product utilized by the patient.

Scheduling of Tramadol

North Dakota House Bill 1070 passed the North Dakota House and Senate and was signed by Governor Jack Dalrymple. This bill

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FDA Issues New Guidelines for Sleep Aids Containing Zolpidem

Food and Drug Administration (FDA) has issued new dosing recommendations for sleep aids containing zolpidem. The new recommendations are based upon new data that shows that when taken at night, blood levels of zolpidem remain high enough in the morning to impair activities that require alertness, such as driving. The new guidelines halve the dosage for women because the new data showed that their bodies take longer to eliminate the drug.

FDA urges drug manufacturers and health care providers to follow the new dosing instructions, which apply to brand name and generic drugs containing zolpidem:

- Ambien®, Edluar™, and Zolpimist®: 5 mg for women, 5 mg or 10 mg for men
- Ambien CR®: 6.25 mg for women, 6.25 mg or 12.5 mg for men

Additionally, manufacturers of these drugs have been instructed to follow the new guidelines and print new patient information drug labels containing the new recommendations.

The recommended doses of Intermezzo®, a lower dose zolpidem product approved for middle-of-the-night awakenings, are not changing. At the time of Intermezzo's approval in November 2011, the label already recommended a lower dosage for women than for men. Additional details are available in an FDA Drug Safety Communication, available at *www.fda.gov/Drugs/DrugSafety/ucm334033.htm.*

What is the National Medication Error Rate? What Standards Are Available for Benchmarking?

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 national or other regional medication error rate does not exist. It is not possible to establish a national medication error rate or set a benchmark for medication error rates. Each pharmacy organization is different. The rates that are tracked are a measure of the number of **reports** at a given organization, not the actual number of **events** or the quality of the care given. Most systems for measuring medication errors rely on voluntary reporting of errors and near-miss events. Studies have shown that even in good systems, voluntary reporting only captures the "tip of the iceberg." For this reason, counting **reported** errors yields limited information about how safe a pharmacy actually is. It is very possible that a pharmacy organization with a good reporting system, and thus what appears to be a high error "rate," may have a safer system.

The National Coordinating Council for Medication Error Reporting and Prevention published a statement refuting the use of medication error rates. The statement, which is posted on the council's Web site (*www.nccmerp.org*), states the "Use of medication error rates to compare health care organizations is of no value." The council has taken this position for the following reasons:

- Differences in **culture** among health care organizations can lead to significant differences in the level of reporting of medication errors.
- Differences in the **definition** of a medication error among health care organizations can lead to significant differences in the reporting and classification of medication errors.
- Differences in the **patient populations** served by various health care organizations can lead to significant differences in the number and severity of medication errors occurring among organizations.
- Differences in the **type(s) of reporting and detection systems** for medication errors among health care organizations can lead to significant differences in the number of medication errors recorded.

According to the statement, the council believes that there are no acceptable incidence rates for medication errors. The goal of every health care organization should be to continually improve systems to prevent harm to patients due to medication errors. Pharmacies should monitor actual and potential medication errors that occur within their organization, and investigate the root cause of errors with the goal of identifying ways to improve the medication-use system to prevent future errors and potential patient harm. The value of medication error reporting and other data gathering strategies is to provide the information that allows an organization to identify weaknesses in its medication-use system and to apply lessons learned to improve the system. The sheer number of error reports is less important than the quality of the information collected in the reports, the organization's analysis of the information, and its actions to improve the system to prevent harm to patients.

It is more important to create the open environment that encourages the reporting of errors and near errors than to develop less meaningful comparative error rates.

ISMP Launches Program to Track Vaccine Errors

ISMP has launched a National Vaccine Error Reporting Program (VERP) that allows health care providers to confidentially report vaccine administration errors and near misses. Health care providers from all practice settings, including pharmacies and physicians' offices, are encouraged to report all mistakes related to vaccines, regardless of whether any harm resulted from the incident. The program will help ISMP "better quantify the sources of errors and advocate for vaccine name, labeling, device, information, and other needed product changes to ensure patient safety," stated Michael Cohen, ISMP president. The ISMP VERP was designed with the assistance of the California Department of Public Health and with input from experts in the field, indicates ISMP. Reports sent to the ISMP VERP will be shared with FDA and forwarded to the vaccine manufacturer when applicable. ISMP also plans to work with the Centers for Disease Control and Prevention on information received to address vaccine-related safety. VERP can be accessed at *http://verp.ismp.org/.*

Providers Should Ensure Only Diluted Forms of Acetic Acid Are Used, ISMP Warns

ISMP has issued a National Alert Network (NAN) notice advising that health care organizations should take immediate steps to ensure that only diluted acetic acid solutions are used in patient care. ISMP advises that the use and purchase of glacial acetic acid, the most concentrated form of acetic acid available, should be eliminated. Several cases of severe burns, scarring, and other permanent damage to skin or mucous membranes due to the inadvertent application of glacial acetic acid have been reported to the National Medication Errors Reporting Program operated by ISMP. ISMP provides the following steps for preventing further such events:

- Remove glacial acetic acid, which has no use in its current form in clinical medicine, from the pharmacy and replace with vinegar (5% solution) or commercially available diluted acetic acid 0.25% (for irrigation) or 2% (for otic use).
- Restrict purchasing so that pharmacy staff is purchasing acetic acid for all procedural areas.
- Restrict choices for purchasing so that glacial acetic acid is not selected by mistake.
- Ensure the correct strength is ordered.
- Educate staff about the differences between glacial acetic acid and diluted forms of acetic acid.
- Order 5% as "vinegar," which reduces the potential for confusion with glacial acetic acid.
- Verify the product by requiring an independent double-check of acetic acid solutions before dispensing or applying the product.

Information on the cases reported and common reasons for the cases are included in the NAN alert, which is available on the ISMP Web site at *www.ismp.org/NAN/files/20130121.pdf.*

New FDA Training Video

FDA Drug Info Rounds, a series of online training videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better medication decisions. In the latest Drug Info Rounds video, pharmacists discuss how FDA Drug Safety Communications let health care providers, patients, and consumers know about newly observed potential risks of FDA-approved drugs. Drug Info Rounds videos are developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research, Office of Communications, and Division of Drug Information and are available on the FDA Web site at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm.*

Progress Made in Implementing Recommendations Intended to Prevent Acetaminophen Overdose

Compelling progress has been made by stakeholders seeking to address the public health issue of acetaminophen overdose, indicates a white paper published by the National Council for Prescription Drug Programs (NCPDP). In 2011, NCPDP made recommendations that the health care industry take actions to support the safe use of acetaminophen, including recommending that pharmacies produce prescription labels with the complete spelling of acetaminophen and eliminating use of abbreviations such as "acet" or "APAP." Previous to that, in July 2010, the National Association of Boards of Pharmacy® (NABP®) recommended that "state boards of pharmacy prohibit the use of the abbreviation 'APAP' on prescription labels, and require that 'acetaminophen' be spelled out to assist in preventing the well-recognized danger of acetaminophen induced hepatotoxicity." The recommendation was based on established policy and a letter, sent by FDA to state boards of pharmacy, regarding the pharmacist's role in educating patients about acetaminophen induced hepatotoxicity caused by unintentional overdose. The recommendation was also consistent with the report of the NABP Task Force on Uniform Prescription Labeling Requirements, which made recommendations to encourage use of prescription labels that are organized in a patient-centered manner. NCPDP reports that pharmacy retailers "estimated to collectively represent more than half of the prescriptions dispensed in 2011, have either implemented or committed to a phased implementation" of the recommendation to use the complete spelling of acetaminophen on prescription labels. "This update to our white paper provides additional guidance for those industry stakeholders who have not yet implemented the new pharmacy labeling practices for acetaminophen-containing medicines," states Lee Ann Stember, president, NCPDP. The updated white paper is accompanied by a bulletin (PDF), available at *www.ncpdp.org/pdf/wp/NCPDPAcetaminophenInfoBulletin_PharmacyStakeholders.pdf,* developed for pharmacists that summarizes some of NCPDP's key recommendations regarding acetaminophen. In addition, the white paper, available for download at *www.ncpdp.org/ind_WP.aspx,* includes a list of resources for pharmacists to use in educating staff and pharmacy staff to use in educating patients (see Appendix D of the white paper). More information is available in an NCPDP news release available at *www.ncpdp.org/press/013113_NCPDP_Acetaminophen%20WP_FINAL.pdf.*

Pharmacists Rated High for Honesty and Ethical Standards in Gallup's 2012 Poll

Pharmacists ranked as the second most trusted profession in the 2012 Gallup Poll that asked consumers to rate 22 professions according to their honesty and ethical standards. Pharmacists were ranked as very high or high in this category by 75% of those surveyed, with nurses ranking first at 85%, and medical doctors third at 70%. Additional information on the results of the 2012 poll is available on the Gallup Web site at *www.gallup.com/poll/159035/congress-retains-low-honesty-rating.aspx*.

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included revisions to Schedule I through V controlled substances (CS) based on federal Drug Enforcement Administration scheduling changes. This year, the bill included scheduling of multiple spiced cannabinoids and substances marked as bath salts as Schedule I CS.

The other important revision within this bill is the addition of tramadol and tramadol-containing products as Schedule IV substances. An initial inventory should have been taken after the date of scheduling, and the handling of prescriptions for tramadol-containing products should conform to the requirements set forward in state law. As a reminder, North Dakota law does allow electronic prescribing of CS outside of the stricter federal standards. Since tramadol, at this time, is only a state CS, the electronic prescribing of prescriptions for tramadol is not subject to federal regulations.

Direct Access to Prescription Drug Monitoring Program

The Board strongly recommends to North Dakota-licensed pharmacists to obtain direct access to the North Dakota Prescription Drug Monitoring Program (ND PDMP). Direct access will allow pharmacists to receive online real-time patient profiles of all CS, including tramadol prescriptions dispensed to the North Dakota resident. Pharmacists are allowed and encouraged to authorize delegates to run reports under their direction.

Apply for 24/7 online access to your patient's CS history with the ND PDMP. Apply today at *www.nodakpharmacy.com/directaccess.asp.*

For questions or assistance, please contact Kathy Zahn at 701/328-9537 or ndbophpdmp@btinet.net.

Students Graduating and Taking Test

The Board has over 50 graduating pharmacy students who have applied to take the law test and practical test to become licensed in North Dakota. This will again be one of the highest amounts of graduating students that have applied for the license in recent years.

The national trend of pharmacist employment has quickly changed from the shortage, just five years ago, to the current surplus of pharmacists, nationally. As always, if you are looking to hire a pharmacist, contact the college of pharmacy or the North Dakota Pharmacists Association to help get the word out to the students.

RxPATROL Tweets Crimes, Rewards, and Valuable Tips

Pharmacy staff, law enforcement officials, and loss prevention personnel can now follow updates about pharmacy robberies, burglaries, and potential threats in their area and nationwide at *http://twitter.com/rxpatrol.* The tweets provide safety and security tips for pharmacy staff that may help them better protect customers and their businesses.

Tweets contain specific information on robberies and burglaries including the exact location of the incident, description of the suspect, and any pertinent information that could lead to the capture of a suspect. All information is verified with local law enforcement before it is released. All tweets direct followers to the Rx Pattern Analysis Tracking Robberies & Other Losses (RxPATROL) database for additional information, including pictures and video of suspects.

Purdue Pharma L.P. developed RxPATROL in 2003 as a collaborative effort among industry, pharmacists, and law enforcement to collect, collate, analyze, and disseminate information on pharmacy theft in the US, and posts important crime-related information at *www.RxPATROL.org.* The program also issues alerts and updates via e-mail to registered users in the pharmacy and law enforcement communities. However, since many pharmacy staff members do not have Internet access during work hours but do have access to cell phones, RxPATROL is now using Twitter to instantly deliver pharmacy crime updates to followers via their cell phones.

Twitter can provide followers with timely pharmacy crime information, giving them access to information that is often not reported by the media. Twitter followers also receive notices for reward offers that are funded through Purdue Pharma L.P.'s partnership with Crime Stoppers and other local anti-crime organizations.

Please visit *www.rxpatrol.org* for more information and start following RxPATROL by visiting *http://twitter.com/rxpatrol.*

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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