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North Dakota State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

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Findings of the Continuing Education Audit of Registered Pharmacy Technicians

- Sixty-three pharmacy technicians randomly audited
- Eight pharmacy technicians did not respond with continuing education (CE) hours
- Five pharmacy technicians did not have adequate CE hours

Those not is compliance received suspensions and will be receiving disciplinary actions according to NDAC 61-02-07.1-10.

The North Dakota State Board of Pharmacy will be next randomly auditing pharmacists and will look to audit pharmacy technicians again this year.

Refills of Schedule III-V Prescriptions

Often a point of confusion is whether you may partial refill a Schedule III-V prescription past five total fills. Drug Enforcement Administration's *Pharmacist's Manual* states that a pharmacist may partially dispense a prescription for Schedules III-V controlled substances provided that each partial filling is recorded in the same manner as a refilling, the total quantity dispensed in all partial fillings does not exceed the total quantity prescribed, and no dispensing occurs beyond six months from the date on which the prescription was issued.

Students Graduating and Seeking Licensure

The Board will have around 50 graduating pharmacy students who have applied to take the law test and practical test to become licensed in North Dakota. This is 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 North Dakota State University College of Pharmacy, Nursing, and Allied Sciences or the North Dakota Pharmacists Association (NDPhA) to help get the word out to the students.

Actions Taken by Board Against Pharmacies

The Board has recently taken action against three out-of-state pharmacies that were shipping tramadol prescriptions into North Dakota. Investigations showed these pharmacies were filling prescriptions that did not have a valid patient-practitioner relationship. The pharmacies were also cited for a failure to report the prescriptions for tramadol to the Prescription Drug Monitoring Program (PDMP).

These pharmacies were filling prescriptions where the medical diagnosis was determined by the patient filling out a questionnaire. The physicians were from all across the United States and very clearly did not have a valid patient-practitioner relationship with the patients, all who lived in North Dakota. The North Dakota Attorney General's office will be spearheading prosecutions against the physicians involved. This is the first action taken by the North Dakota State Board of Pharmacy for a failure to report to the PDMP.

Direct Access to the North Dakota Prescription Drug Monitoring Program

All North Dakota licensed pharmacists can and should get direct access to the North Dakota PDMP. Direct access will allow pharmacists to receive online real-time patient profiles of all controlled substances and tramadol prescriptions dispensed to the North Dakota resident. Pharmacists are allowed to authorize delegates to run reports under their direction.

Apply for 24/7 online access to your patient's controlled substance and tramadol history with the North Dakota PDMP. Apply today at *www.nodakpharmacy.com/directaccess.asp*.

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

Prescription Drug Monitoring Program: Important Error Information

North Datota's PDMP software vendor, Health Information Designs (HID), provides all submitters of data with an upload error report. When creating an account, you are required to submit an e-mail address and a fax number. You can specify if you wish to receive your upload error report by either of these methods. If you are not receiving the upload error reports you may be missing some vital information and compliance with the program. Please read on!

A single claim may be rejected, or if a certain percentage of claims are rejected in an individual file, the entire file may be rejected. The Board tracks four types of errors:

- **Minor** – Incorrect data in non-vital field
- **Serious** – Record can be loaded with missing or inappropriate data
- **Fatal** – Record cannot be loaded
- **Duplicate** – Record is not loaded but an error is logged in the error report

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DEA Provides Information Regarding Carisoprodol Prescriptions

A Drug Enforcement Administration (DEA) announcement provides information regarding the scheduling of carisoprodol, effective as of January 11, 2012. The DEA Final Rule making the drug a Schedule IV controlled substance was published December 12, 2011, and states that effective January 11, 2012, all prescriptions for drugs containing carisoprodol shall comply with DEA regulations. Specifically, a pharmacy may only fill or refill a prescription for a drug containing carisoprodol if all of the following requirements are met:

- the prescription was issued for a legitimate medical purpose by a DEA-registered practitioner acting in the usual course of professional practice (21 CFR §1306.04);
- the prescription contains all the information required by 21 CFR §1306.05; and
- the number of refills authorized by the prescribing practitioner is five or less (21 USC §829(b)).

The full text of the notice is available on the DEA Web site at *www.deadiversion.usdoj.gov/drugs_concern/carisoprodol/index.html.*

Pfizer Recalls Several Lots of Two Oral Contraceptive Products

Pfizer Inc recalled 14 lots of Lo/Ovral®-28 (norgestrel and ethinyl estradiol) tablets and 14 lots of norgestrel and ethinyl estradiol tablets (generic) due to potential for inexact count and out-of-sequence tablets. A Pfizer investigation found that some blister packs of the affected products may contain an inexact count of inert or active ingredient tablets and that the tablets may be out of sequence. As a result of this packaging error, the daily regimen for these oral contraceptives may be incorrect and could leave women without adequate contraception, and at risk for unintended pregnancy. Food and Drug Administration (FDA) advises that patients who have the affected product should notify their physician and return the product to the pharmacy. A Pfizer press release includes a list of the affected products with the National Drug Code (NDC) number, lot number, and expiration date for each, and is available at *www.fda.gov/Safety/Recalls/ucm289770.htm.*

Changes in Medication Appearance Should Prompt Investigation by Pharmacists and Patients

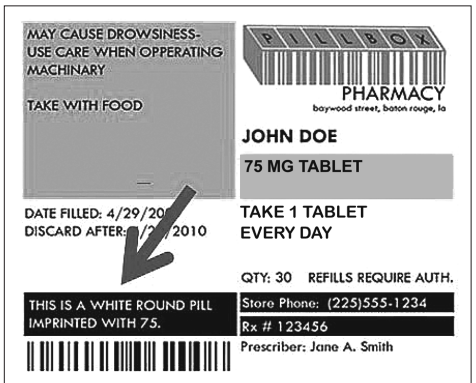
This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies 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.*

As the numbers of generic products continue to increase, it seems that both patients and practitioners have become desensitized to changes in medication appearance. So much so that patients may not question a change or, when they do, practitioners may simply reassure them that it was due to a change in manufacturer without actively investigating the reason. It is not uncommon for ISMP to receive reports from both practitioners and consumers where a change in medication appearance was not fully investigated and subsequently contributed to an error.

In one case, a man shared an account of what his 86-year-old father experienced over the course of nine days after his prescription for minoxidil was mistakenly refilled with another medication. He had been taking minoxidil 2.5 mg for years at a dose of 5 mg (2 tablets) twice daily. Due to failing vision, he did not realize that his minoxidil tablets looked different. His daughter noticed the change, but was unconcerned since the tablets had previously changed appearance. The pharmacy was contacted about the change and a staff member explained that it was a different generic for minoxidil, and that the pills could be exchanged for those that he usually received. There was no mention of a mistake being made when the medication was exchanged. He was taken to the hospital the following day, when he could barely walk.

After this incident was explained to hospital staff, they contacted the pharmacy. It was then revealed that he was given methotrexate by mistake because the bottles were stored next to each other. By this time, the man had taken 36 methotrexate 2.5 mg tablets, his white blood cell and platelet counts were extremely low, and he was in critical condition. We later learned that he passed away during that hospital visit.

Your pharmacy may be providing an important patient safety tool on the prescription label that may be overlooked by patients and their caregivers: a description of the shape, color, and imprint code of the medication that should be inside. This information can help ensure accuracy since it's based on the NDC number. Teach patients to look for this description and question any differences. In addition, the patient needs to know if the medication name on the pharmacy generated label is the medication he or she was expecting to receive. Even if the generic manufacturer is different each time the prescription is renewed, the description on the label should match the NDC number and thus the product inside.



With so much information on prescription labels such as patient and doctor name, drug name, instructions, and warnings – this added information can easily be missed. But it's important, so look for it and put it to use!

FDA Reminder: Purchasing Unapproved Injectable Cancer Medications Threatens Patient Safety

FDA is reminding health care providers to obtain and use only FDA-approved injectable cancer medications purchased directly from the manufacturer or from wholesale distributors licensed in the United States. FDA explains that "current shortages of injectable cancer medications may present an opportunity for unscrupulous individuals to introduce non-FDA approved products into the drug supply, which could result in

serious harm to patients." FDA reports that the agency is aware of promotions and sales of unapproved injectable cancer medications directly to clinics in the US and that the medications were likely administered to patients. Examples of products include unapproved versions of FDA-approved medications such as Faslodex® (fulvestrant), Neupogen® (filgrastim), Rituxan® (rituximab), and Herceptin® (trastuzumab). FDA stresses the risks to patients when such unapproved medications are used. The agency outlines several steps health care providers should take to ensure patient safety:

1. Obtain and use only FDA-approved injectable cancer medications purchased directly from the manufacturer or from wholesale distributors licensed in the US. An FDA Web page, *www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm281446.htm,* provides the online resource for each state for verifying that a wholesale distributor is appropriately licensed.
2. Determine if the medication you have received is FDA-approved by checking the Orange Book or searching the Drugs@FDA database.
3. Question whether a price sounds too good to be true. Deep discounts may be offered because the product is stolen, counterfeit, or unapproved.
4. Carefully inspect the product and packaging and be alert for signs that the product is not FDA approved, such as if the packaging looks different or the dosing recommendations are unfamiliar.

FDA also notes that if a health care provider receives multiple complaints about the same product, such as a new side effect or lack of therapeutic effect, these may signal a product quality issue.

FDA reminds health care providers that in certain circumstances the agency may authorize limited importation of medications that are in short supply. Such medications are imported from approved international sources and distributed in the US through a controlled network, and would not be sold in direct-to-clinic solicitations. If FDA has arranged for limited importation of the foreign version of a medication, information on obtaining that medication will be available in the Drug Shortages section of the FDA Web site, *www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050792.htm.*

Additional details are provided in an FDA Drug Safety Communication, available at *www.fda.gov/downloads/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/UCM287717.pdf.*

Insulin Pens Should Not Be Used for Multiple Patients, Stresses CDC

Centers for Disease Control and Prevention (CDC) issued a notice, reminding health care providers that insulin pens are intended for use by a single patient, and should never be used on more than one patient. CDC indicates that the agency has become "increasingly aware of reports of improper use of insulin pens, which places individuals at risk of infection with pathogens including hepatitis viruses and human immunodeficiency virus (HIV)." The notice explains that regurgitation of blood into the insulin cartridge can occur after injection, creating a risk of bloodborne pathogen transmission if the pen is used for more than one person, even when the needle is changed. CDC provides the following recommendations to help protect patient safety:

- Insulin pens containing multiple doses of insulin are meant for use on a single person only, and should never be used for more than one person, even when the needle is changed.
- Insulin pens should be clearly labeled with the person's name or other identifying information to ensure that the correct pen is used only on the correct individual.
- Hospitals and other facilities should review their policies and educate their staff regarding safe use of insulin pens and similar devices.
- If reuse is identified, exposed persons should be promptly notified and offered appropriate follow-up including bloodborne pathogen testing.

The notice may be downloaded from the CDC Web site at *www.cdc.gov/injectionsafety/PDF/Clinical-Reminder-insulin-pen.pdf.*

US Public Health Service Report Supports Maximizing the Scope of the Pharmacist as Part of Health Care Team

Presenting an evidence-based discussion of the comprehensive patient care services that pharmacists currently provide, a new government report calls for expanded support for such pharmacist-delivered patient care models. The report, *Improving Patient and Health System Outcomes through Advanced Pharmacy Practice,* prepared by the Office of the Chief Pharmacist, US Public Health Service (PHS), is organized into four focus points as follows:

- Focus point 1 discusses how pharmacists are integrated in many practice settings as health care providers, such as through collaborative practice agreements, and provides data showing interprofessional support for such models.
- Focus points 2 and 3 support recognition of pharmacists as health care providers and compensation models that will allow pharmacists to continue to improve patient and health care system outcomes.
- Focus point 4 presents a review of numerous peer-reviewed studies that demonstrate favorable outcomes from pharmacist-delivered care.

RADM Scott Giberson, chief professional officer, PHS Pharmacists, and the primary author of the report, stated that "one of the most evidence-based and cost-effective decisions we can make as a nation is to maximize the expertise and scope of pharmacists, and minimize expansion barriers to successful health care delivery models." The report may be downloaded from the US PHS Web site at *www.usphs.gov/corpslinks/pharmacy/comms/pdf/2011AdvancedPharmacyPracticeReporttotheUSSG.pdf.*

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An entire batch (daily upload) may be rejected if:

- **All** records have fatal or serious errors
- More than 10% of the records have fatal errors
- More than 20% of the records have serious errors

For more information on errors or correcting them, check out the *Dispenser's Implementation Guide* at *https://www.nodakpharmacy.com/pdfs/dataSubmissionMethods.pdf* under Upload Reports and Edit Definitions. Contact your software vendor or HID technical support for assistance in reporting if you need help understanding your error reports or if you need to access your account's login information where you can check your account settings to make sure you are receiving the error reports and have correct contact information listed.

Contact HID at 1-866/792-3149 or ndpdminfo@hidinc.com.

Rule Hearing Held at the NDPhA Convention

The Board held a rule hearing at the NDPhA convention in Jamestown, ND, on April 14. The hearing was held in front of a full room of pharmacists and technicians. There were five potential rule changes that were discussed including:

- 61-02-07.1 to codify the current Board policy on education and certification requirements for pharmacy technician registration.
- 61-04-06-02 and -03 to bring the rule into compliance with Senate Bill 2122, adopted in the 2011 legislative session related to "brand medically necessary" requirements.
- 61-05 Radiopharmaceutical Services, to revise this 1983 rule to bring it into accordance with current radiopharmaceutical standards of practice and radiological health rules of the Department of Health.
- 61-07 Hospital Pharmacy, to establish a requirement for protection of hospital patients by requiring a pharmacist to review all medication orders, before administration to the patient, except where the practitioner is directly involved in the administration or in "stat" orders.
- 61-09 Prescription Drug Inventory of Ambulance Services, to allow the option of the ambulance service's medical director to obtain and maintain the drugs for the ambulance service.

The full text of the proposed changes in each of the rules along with the consideration of comments from the rule hearing is available on the Board's Web site, *www.nodakpharmacy.com*, under Proposed Laws and Rules.

Prescription Drug Repository Program

The Prescription Drug Repository Program has been operational since 2007. The purpose of the program is to collect and distribute unused medications so that pharmacies and physicians can dispense them to those who need them. A drug donated, or dispensed under the program, must be in the original, unopened package, except drugs packaged in single-unit doses, or punch cards may be accepted and dispensed if the outside packaging has been opened and the single-unit dose package is unopened.

Those who choose to volunteer to participate in the dispensing of the donated drugs are defined as either a practitioner or pharmacy that has elected to participate in the program and accept legend drugs, devices, and supplies from donors for the program. Those who receive the donations will be able to post the availability of the medications on the Board's Web site, where both patients and practitioners can access the information. Pharmacies and practitioners must register with the Board of Pharmacy as participants.

Before being dispensed to an eligible individual, the legend drugs, devices, and supplies donated under the program must be inspected by a pharmacist to determine that they are not adulterated or misbranded. The participating pharmacist or practitioner must keep a record of the source of the donation for two years.

Because this is a volunteer program, the dispenser of donated legend drugs, devices, or supplies may not submit a claim or otherwise seek reimbursement from any public or private third-party payer for the cost of donated legend drugs, devices, or supplies dispensed to any eligible individual under the program. You may charge a small fee of up to 2.5 times the Medicaid fee of $4.60 to cover your costs.

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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