April 2012

Minnesota Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

University Park Plaza • 2829 University Ave SE, Suite 530 • Minneapolis, MN 55414-3251
www.pharmacy.state.mn.us

Disciplinary Activity

The Minnesota Board of Pharmacy took the following disciplinary actions concerning **pharmacists** between the dates of December 21, 2011 and March 19, 2012:

Keaveny, Katherine A., License #113573. Ms Keaveny admitted diverting controlled substances from her employer in Indiana and giving them to other individuals. The Indiana Board of Pharmacy subsequently revoked her license to practice pharmacy and the Illinois State Board of Pharmacy placed her license in a "refuse to renew" status. Ms Keaveny was charged in Indiana with felony theft and with felony possession of a controlled substance with the intent to distribute. Her criminal case in Indiana was resolved with a stay of imposition and probation. Consequently, at its February 22, 2012 meeting, the Board issued a stipulation and consent order that suspends Ms Keaveny's license to practice pharmacy. She may not petition for a reinstatement of her license for a minimum of three years.

Lundholm, Mandy E., License #119378. Dr Lundholm admitted to the diversion of controlled substances from her employer, which she used to self-medicate headache pain. She had not received valid prescriptions from a practitioner for those controlled substances. Consequently, at its January 11, 2012 meeting, the Board issued a stipulation and consent order suspending Dr Lundholm's license. The suspension was stayed on condition that she successfully complete the Health Professionals Services Program, abstain from the use of mood-altering chemicals except those expressly prescribed for her, undergo a neuropsychological evaluation, and comply with any recommendations the evaluator might have. Dr Lundholm will not be allowed to work in a pharmacy without being supervised by another licensed pharmacist, may not be the pharmacist-in-charge of a pharmacy, and may not act as a preceptor.

Yang, Chao, License #116552. Dr Yang admitted that he failed to renew his pharmacist license in a timely manner and that he worked without a valid license from March 1, 2010 until March 21, 2011. Consequently, the Board adopted a stipulation and consent order at its January 11, 2012 meeting, reprimanding Dr Yang and assessing a civil penalty of $1,275.

The Board considers the following **pharmacy technicians** to have voluntarily surrendered their registrations between December 21, 2011 and March 19, 2012: **Dahl, Sharon L., Registration #712791; Ludwig, Chad W., Registration #716920; Prueher, Michelle M., Registration #707418; and Wendling, Bonnie J., Registration #702668.**

Additional Rule Changes

The Board adopted a large package of rule changes on September 13, 2011. Many of those changes were outlined in the October 2011 edition of this *Newsletter.* The following are other changes that were adopted:

Prescriptions and Chart Orders

The definition of "prescription" was changed to read:

> A prescription drug order that is written or printed on paper, an oral order reduced to writing by a pharmacist, or an electronic order. To be valid a prescription must be issued for an individual patient by a practitioner within the scope and usual course of the practitioner's practice, and must contain the date of issue, name and address of the patient, name and quantity of the drug prescribed, directions for use, the name and address of the practitioner, and a telephone number at which the practitioner can be reached. A prescription written or printed on paper that is given to the patient or an agent of the patient, or transmitted facsimile-to-facsimile must contain the practitioner's manual signature. An electronic prescription must contain the practitioner's electronic signature.

Please note that prescriptions must now contain a telephone number for the prescriber. In addition, this change clarifies that all paper prescriptions given to a patient and all prescriptions that are printed out and sent from one facsimile machine to another must be manually signed by the prescriber.

True electronic prescriptions are transmitted from the prescriber's computer to the pharmacy's computer over a secure network. Prescriptions transmitted by facsimile are not true electronic prescriptions. For drugs that are not controlled substances, electronic prescriptions may be electronically signed by the prescriber. Electronic controlled substance prescriptions are **not** currently legal in Minnesota. However, the Board anticipates that

Continued on page 4

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

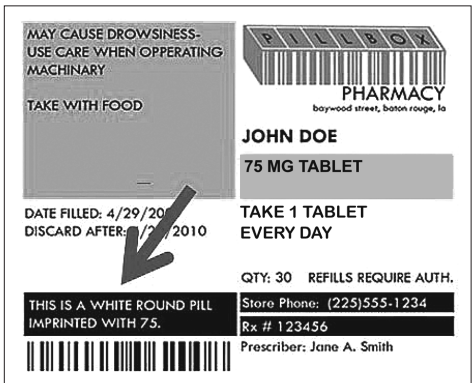
This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies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

Continued from page 1

the legislature will change the law so that electronic controlled substance prescriptions that are transmitted in accordance with the rules of the United States Drug Enforcement Administration will be legal effective August 1, 2012. The Board will post a notice on its Web site to confirm this after legislation is signed into law by Governor Mark Dayton.

Non-controlled substance prescriptions that are sent from a facsimile machine to a pharmacy's computer may be electronically signed. However, controlled substance prescriptions **cannot** be legally transmitted from a prescriber's facsimile machine to a pharmacy's computer. Whenever a controlled substance prescription is sent via facsimile, it must be printed out first and manually signed by the prescriber. Paper or facsimiled controlled substance prescriptions that contain "electronic signatures" such as the phrase "this prescription has been electronically signed by the prescriber" are not legally valid under federal laws and rules.

The Board also adopted a definition of the term "chart order," which means:

> A prescription drug order for a drug that is to be dispensed by a pharmacist, or by a pharmacist-intern under the direct supervision of a pharmacist, and administered by an authorized person only during the patient's stay in a hospital or long-term care facility. The chart order shall contain the name of the patient, another patient identifier such as a birth date or medical record number, the drug ordered, and any directions as the practitioner may prescribe concerning strength, dosage, frequency, and route of administration. The manual or electronic signature of the practitioner must be affixed to the chart order at the time it is written or at a later date in the case of verbal chart orders.

Limited Service Pharmacies

The Board adopted a definition of "limited service pharmacy," which reads:

> A pharmacy to which the board may assign a restricted license to perform a narrow range of the activities that constitute the practice of pharmacy.

There are currently several different scenarios for which a limited service pharmacy license might be appropriate. For example, the Board has received inquiries from pharmacists who want to open an office at which they will perform vaccinations and conduct medication therapy management. They do not intend to fill prescriptions at these offices and therefore do not need to purchase or store drugs. Issuing a limited service pharmacy license to such an office may help the pharmacists obtain reimbursement from third-party payers that require such services to be performed in a licensed pharmacy.

Public Notification of Pharmacy Closures

The Board now requires that the public be notified in advance of pharmacy closures. The Board added this requirement after receiving complaints from members of the public about not being notified of a pharmacy's pending closure. The following language was added to Minnesota Rules 6800.1010:

> Subp. 3. **Public notification.** A licensed pharmacy must provide the following public notification when closing a pharmacy: distribution, by at least one of the following means, of a notice that informs patients that the pharmacy will close on a specified date and that gives the name, address, and telephone number of the pharmacy to which prescription files will be transferred:
>
> A. publication of the notice in a local newspaper for one week prior to the date on which the pharmacy is to be closed;
>
> B. a direct mailing to patients who have had at least one prescription filled at that pharmacy during the six months preceding the date of closing, with the mailing designed to reach patients no later than one business day prior to the closing; and
>
> C. distribution of the notice to patients who are picking up prescriptions at least 30 days prior to the date on which the pharmacy will be closed.
>
> In the case of patients who are residents of long-term care facilities, the pharmacy shall provide a written notice to the patients, the caregivers of the patients, or the long-term care facilities in which the patients reside at least 30 days prior to the date on which the pharmacy will be closed.

Unprofessional Conduct

The Board added the following to the definition of "unprofessional conduct," found in Minnesota Rules 6800.2250:

> Engaging in any pharmacy practice which constitutes a danger to the health, welfare, or safety of a patient or the public, including but not limited to, practicing in a manner which substantially departs from the standard of care ordinarily exercised by a pharmacist and which harms or could harm a patient.

The Board has long expected pharmacists to practice in a manner that is consistent with generally accepted standards of care. The addition of this language to the rules emphasizes that expectation.

Remotely Engaging in Dispensing Activities: Clarification

An article in the last *Newsletter* concluded with the statement: "However, the Board cannot allow dispensing activities to be performed remotely from unlicensed places." This prohibition does not apply to prescription data entry, pharmacist review of such data entry, and prospective drug utilization review done by a pharmacist working within a hospital that has a licensed pharmacy on the premises.

The *Minnesota Board of Pharmacy News* is published by the Minnesota 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.

Cody Wiberg, PharmD, MS - State News Editor
Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor
Larissa Doucette - Communications Manager