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Minnesota Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

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Disciplinary Activity

The Minnesota Board of Pharmacy took no disciplinary actions concerning any licensees or registrants between the dates of June 21, 2012 and September 18, 2012.

Pharmacy License Categories

The Board adopted rule changes in September 2011 that substantially amended Minnesota Rules 6800.0350, which now read (with emphasis added):

6800.0350 **LICENSE CATEGORIES.**

A pharmacy must be licensed in one or more of the following categories:

A. community/outpatient;
B. hospital;
C. home health care;
D. long-term care;
E. nuclear;
F. central service;
G. nonsterile preparation compounding;
H. sterile preparation compounding;
I. veterinary; and
J. limited service.

Licensing of a pharmacy in more than one category shall not result in an increase in the license fee.

No pharmacy may engage in providing products or services in categories for which it is not licensed. A pharmacy must designate its category or categories on license renewal or application for an initial license. Effective July 1, 2012: an initial or renewed license issued by the board shall list each license category for which the pharmacy has received board approval; *a pharmacy must receive board approval before providing services in a license category not listed on its license; a pharmacy must notify the board if the pharmacy no longer provides services in a license category;* and the board shall issue a revised license without imposing an additional fee, if it approves a pharmacy's request to provide services in additional license categories or if a pharmacy no longer provides services in one or more license categories.

The board may establish special conditions for licensure, appropriate to the situation, before approving a license application for a pharmacy with a limited service license category. Such pharmacies must also apply for and receive any necessary variances, according to part 6800.9900, before an application for licensure is approved.

When applying for an initial pharmacy license or when renewing an existing pharmacy license, the applicant must indicate all licensing categories under which the pharmacy will be providing services, not just the primary category of service. Both a pharmacy and its pharmacist-in-charge could be subject to disciplinary action if the pharmacy provides services in a category not listed on the pharmacy's license. It is important for the Board to know the categories of service that will be provided by a pharmacy so that it can ensure that appropriate standards are being met. For example, the Board ensures that pharmacies that engage in sterile compounding meet all of the requirements of United States Pharmacopeia Chapter 797.

Controlled Substances

Responsibilities of Pharmacists Concerning Controlled Substance Prescriptions

Pharmacists have responsibilities concerning the filling of controlled substance prescriptions that can sometimes seem to be contradictory. On the one hand, Minnesota Rules 6800.2250 state that it is unprofessional conduct for a pharmacist to refuse to "compound or dispense prescription drug orders that may reasonably be expected to be compounded or dispensed in pharmacies by pharmacists." In addition, Minnesota Statutes §152.125 provide protection for physicians who prescribe narcotics for the treatment of intractable pain, thus indicating that the legislature finds the use of narcotics for such pain to be both important and legitimate.

On the other hand, the federal regulation 21 CFR 1306.04(a) states that (emphasis added):

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AHRQ Toolset Can Assist Pharmacies Using e-Prescribing

A toolset released by the Agency for Healthcare Research and Quality (AHRQ) can assist independent pharmacies with the implementation of e-prescribing and may also provide useful guidance to those pharmacies already using e-prescribing. The toolset for independent pharmacies consists of seven chapters that provide guidance on topics ranging from planning the implementation process and launching the system, to troubleshooting common problems and moving into more advanced pharmacy services, states AHRQ. Flyers for use in communicating the launch to patients, templates for communicating with providers about the launch, tools for assessing pharmacy workflow, and a spreadsheet to determine return-on-investment, among other tools, are also available to pharmacies. The toolset can be downloaded from the AHRQ Web site at *http://healthit.ahrq.gov/portal/server.pt/community/health_it_tools_and_resources/919/a_toolset_for_e-prescribing_implementation_in_independent_pharmacies/30595*.

FDA Database Provides Information on Pediatric Medications

A Food and Drug Administration (FDA) database provides information on pediatric medications, making it easier for both health care providers and caregivers to locate this information. The Pediatric Labeling Information Database is a one-stop resource, where providers and caregivers can search for information by the product's commercial or chemical name, or by the condition for which it was studied. The database was developed by FDA's Office of Pediatric Therapeutics (OPT), in collaboration with the Center for Drug Evaluation and Research. The OPT also provides a Safety Reporting page with information on products that have been tied to safety problems that specifically relate to children. Additional information and a link to the database is available in the Consumer Updates section of the FDA Web site at *www.fda.gov/ForConsumers/ConsumerUpdates/ucm305040.htm.*

Inattentional Blindness: What Captures Your Attention?

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 pharmacist enters a prescription for methotrexate daily into the pharmacy computer. A dose warning appears on the screen. The pharmacist reads the warning, bypasses it, and dispenses the medication as entered. The patient receives an overdose of the medication and dies.

This error, and many more, have happened because the person performing the task fails to see what should have been plainly visible, and later, they cannot explain the lapse.[1] People involved in these errors have been labeled as careless and negligent. But these types of accidents are common – even with intelligent, vigilant, and attentive people. The cause is usually rooted in inattentional blindness.[1]

Accidents happen when attention mistakenly filters away important information and the brain fills in the gaps with what is aptly referred to as a "grand illusion."[2] Thus, in the example above, the brain of the pharmacist filtered out important information on the computer screen, and filled in the gaps with erroneous information that led him to believe he had read the warning appropriately.

Inattentional blindness is more likely to occur if part of your attention is diverted to secondary tasks, like answering the phone while entering prescriptions into the computer, or even thinking about your dinner plans while transcribing an order.

Low workload causes boredom and reduces the mental attention given to tasks, as does carrying out highly practiced tasks, such as counting out medication. We spend a large majority of our waking life functioning with the equivalent of an automatic pilot, with occasional conscious checks to ensure tasks are being carried out properly. This makes us particularly prone to inattentional blindness.

Our past experiences also teach us what is relevant. Errors occur when new or unusual circumstances happen in highly familiar situations. The pharmacist who did not notice important information on a computer warning had rarely encountered a clinically significant computer alert. The pharmacist had subconsciously learned that there was nothing important to see when reading alerts. Nothing had ever happened, so attention was automatically filtered away from the details to conserve mental processing.

Conspicuity is the degree to which an object or piece of information "jumps out" and captures your attention. The best way to achieve this effect is through use of contrast, color, or shape to call attention to differences in packaging or text.

It is difficult to reduce the risk of inattentional blindness, as it is an involuntary and unnoticed consequence of our adaptive ability to defend against information overload. Error-reduction strategies such as education, training, and rules are of little value. Instead, efforts should center on increasing conspicuity of critical information, and decreasing diversions of attention and secondary tasks when carrying out complex tasks.

1. Green M. "Inattentional blindness" and conspicuity. Visual Expert. 2004. Accessed at *www.visualexpert.com/Resources/inattentionalblindness.html,* March 1, 2012.
2. Angier N. Blind to change, even as it stares us in the face. The New York Times. April 1, 2008.

Know Your Dose Game Teaches Safe Acetaminophen Use

As part of the Know Your Dose campaign, the Acetaminophen Awareness Coalition has developed an interactive educational game to teach safe use of acetaminophen. The game not only answers some of the most common questions surrounding the safe use of acetaminophen, it gives an engaging face to the issue. The game, available on the

Know Your Dose Web site at *www.knowyourdose.org/game,* invites consumers to follow three characters through a typical day of aches and pains while helping the characters learn how to take medicine that contains acetaminophen safely.

Contraception Products Sold Online With No Prescription Required, Endangering Public Health

Health care providers should help to educate patients about the risks of prescription contraceptive products marketed online as "no prescription" and "over-the-counter" products, pharmaceutical security researchers conclude. A study by these researchers found that Google searches returned results for prescription contraceptive products such as injections, oral contraceptives, and patches, as well as intrauterine devices (IUDs). All of these products were marketed as available without a prescription and researchers found that sellers provided links to YouTube videos with IUD instructions. The researchers also found that these products were being promoted on social media channels, including Facebook, Twitter, SlideShare, and Flickr. Researchers Bryan A. Liang, MD, JD, PhD, Tim K. Mackey, MAS, and Kimberly M. Lovett, MD, conclude that such online contraceptive sales represent patient safety risks and also suggest that policy makers should "employ legal strategies to address these systemic risks." The study, "Suspect Online Sellers and Contraceptive Access," is available in the May 25, 2012 issue of *Contraception.*

New FDA Drug Info Rounds 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, available at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm313768.htm,* pharmacists discuss the Accelerated Approval Program and how FDA helps make new, potentially lifesaving drugs available more quickly. Drug Info Rounds is developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research, Office of Communications, and Division of Drug Information.

FDA Resources Help Raise Awareness About Health Fraud Scams

To help raise consumer awareness about health fraud scams, FDA provides numerous educational resources in the Health Fraud Scams section of its Web site. Educating consumers on how to avoid such scams, FDA videos present information on various types of fraudulent products such as fake diet, sexual enhancement, and body building products. Consumers can also access information about specific products that are the subject of FDA warning letters, recalls, public notifications, and safety alerts. FDA news releases related to health fraud are also accessible through this section of the Web site.

NABP Accepting Award Nominations for 109th Annual Meeting

The National Association of Boards of Pharmacy® (NABP®) is currently accepting nominations for the Association's 2013 awards that will be presented during the 109th Annual Meeting, to be held May 18-21, 2013, at the Hyatt Regency St Louis at the Arch in St Louis, MO.

Nominations are currently being accepted for the following awards: 2013 Lester E. Hosto Distinguished Service Award (DSA), 2013 NABP Honorary President, 2013 Fred T. Mahaffey Award, and 2013 John F. Atkinson Service Award.

Nominations for these awards must be received at NABP Headquarters no later than December 31, 2012. New this year, individuals wanting to submit a nomination will be asked to fill out and complete a nomination form, which may be accessed by visiting the Meetings section on the NABP Web site at *www.nabp.net/meetings.* Criteria for award nominees will also be posted to the Web site. Nomination forms should be sent to the NABP Executive Director/Secretary Carmen A. Catizone at NABP Headquarters, 1600 Feehanville Dr, Mount Prospect, IL 60056. Directions for electronic submission will be available on the online form. The NABP Executive Committee will review the nominations and select the award recipients.

For more information, please contact the NABP Executive Office via e-mail at exec-office@nabp.net.

NABP Looking for Exam and Assessment Item Writers

NABP is seeking individuals to serve as item writers for the North American Pharmacist Licensure Examination®, the Multistate Pharmacy Jurisprudence Examination®, the Foreign Pharmacy Graduate Equivalency Examination®, the Pharmacy Curriculum Outcomes Assessment®, and the Pharmacist Assessment for Remediation Evaluation℠. Pharmacists in all areas of practice, and faculty from schools and colleges of pharmacy are encouraged to apply. Interested individuals should e-mail, fax, or mail a letter of interest indicating their current practice/educational setting, specialties/certifications, and years of experience, along with a résumé or curriculum vitae:

- via e-mail at exec-office@nabp.net;
- via fax at 847/391-4502; or
- via mail to NABP Executive Director/Secretary Carmen A. Catizone at 1600 Feehanville Drive, Mount Prospect, IL 60056.

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. Additional information may also be found in the August 2012 *NABP Newsletter*.

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> *A prescription for a controlled substance* to be effective *must be issued for a legitimate medical purpose* by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but *a corresponding responsibility rests with the pharmacist who fills the prescription*. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and *the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.*

Refusing to fill a prescription for a controlled substance when the patient truly has a legitimate medical need for the drug might be considered unprofessional conduct. However, filling a controlled substance prescription when there are clear indications that something is amiss might be a violation of the corresponding responsibility language found in the federal regulations. As an example, a pharmacist may be confronted by a patient who repeatedly requests that a controlled substance prescription be refilled early. Even if the pharmacist receives permission from the prescriber to refill the prescription early, the pharmacist might still be held responsible for inappropriately refilling the prescription. In other words, "the physician said it was OK," might not be an adequate defense, depending on all of the circumstances involved. Pharmacists are allowed to refuse to fill a controlled substance prescription if they have **legitimate reasons** for doing so, regardless of the wishes of the patient or the directions of the prescriber.

Given these considerations, pharmacists must exercise sound professional judgment when deciding whether or not to fill prescriptions for controlled substances. Patients with legitimate medical needs deserve to have access to controlled substances that can relieve pains or other distressing symptoms. However, when pharmacists question the legitimacy of a controlled substance prescription, they would be well-advised to discuss their concerns with the prescriber and, as appropriate, with the patient. These discussions should be documented in the patient's profile or on the prescription, regardless of whether or not the pharmacist decides to fill the prescription.

The Minnesota Prescription Monitoring Program

Unfortunately, some individuals attempt to obtain controlled substances through fraudulent means, such as engaging in "doctor shopping," which involves obtaining prescriptions from multiple prescribers and having them filled at multiple pharmacies. The individual usually does this within a short period of time and without notifying the prescribers and pharmacies about recently filled controlled substance prescriptions. The Board operates the Minnesota Prescription Monitoring Program (PMP), the purpose of which is to promote public health and welfare by detecting the diversion, abuse, and misuse of controlled substances.

The PMP collects data, submitted electronically by dispensers on a daily basis, concerning Schedule II, III, and IV controlled substance prescriptions dispensed for residents of Minnesota. Pharmacists, prescribers, and certain other individuals are eligible to register as users of the PMP. Information about applying for access to the PMP database can be obtained at *http://pmp.pharmacy.state.mn.us/pharmacist-rxsentry-access-form*. Once registered as a user, a pharmacist can log in to the PMP database and submit a query that will provide information concerning the controlled substance prescriptions dispensed to a patient during the past 12-month period of time. Pharmacists are not required to register as users of the PMP or to use it before dispensing controlled substance prescriptions. However, the Board does recommend that pharmacists use the PMP when they have reason to believe that an individual may be abusing controlled substances.

Pharmacy Technician Training Requirement

Effective **January 1, 2014,** the Board will not renew the registration of a pharmacy technician who was **initially** registered after **January 1, 2013,** or who was initially registered prior to that date but did not maintain continuous registration, unless the individual has completed a pharmacy technician training program. There are several types of training that will be acceptable, one of which is an employer-based program that includes a minimum of 240 hours in a one-year period of both theoretical and practical instruction. Standards for employer-based training programs were adopted by the Board at the June 20, 2012 meeting and were published in the July 2012 edition of this *Newsletter.*

The Board subsequently received a request from *Pharmacist's Letter* to allow one of their programs, Pharmacy Technicians University (PTU), to be used as part of an employer-based program for technician training. The Board approved that request at its August 1, 2012 meeting. Consequently, pharmacies may use PTU as the didactic or written portion of an employer-based training program but must also ensure that technicians complete practical, experiential training.

Technicians who initially register after January 1, 2013, are responsible for completing the required training in the allotted amount of time. Those who do not complete the training will not be permitted to renew their registrations and will therefore not be allowed to continue working as technicians. It is the responsibility of the pharmacist-in-charge to ensure that all individuals working in a pharmacy who are required to be registered or licensed have current licenses and registrations.

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.

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