



Minnesota Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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Disciplinary Activity

The Minnesota Board of Pharmacy took the following disciplinary actions concerning **pharmacists** between the dates of May 13, 2010 and September 15, 2010:

Kerwin, Thomas L. License #117646. The Board revoked the registration of Mr Kerwin after receiving a notice of license revocation from the Minnesota Department of Revenue indicating that he owes \$500 or more in delinquent taxes, penalties, or interest or has not filed a return.

Kriz, Thomas E. License #111357. Mr Kriz petitioned the Board for reinstatement of an unrestricted license. The Board had placed conditions and limitations on his license on July 16, 2008, based on respondent's involvement in an illegal online pharmacy operation. The Board granted his petition and issued an order of unconditional license at its July 14, 2010 meeting.

Mahlendorf, Laura L. License #118771. Ms Mahlendorf petitioned the Board to have limitations lifted from an order that the Board issued on January 10, 2007. That order was based on her diversion and unauthorized use of controlled substances. The Board granted her petition by removing the limitation that prevented her from being a "traveling" or "floater" pharmacist – provided that she can work for only one pharmacy employer. The Board also removed the limitations that prevented her from being a pharmacist-in-charge or a preceptor. The Board issued an amended order outlining these changes at its September 15, 2010 meeting.

Pobuda, Michel L. License #118034. Dr Pobuda admitted that, while she was pharmacist-in-charge of a community pharmacy, there were unaccounted for shortages of hydrocodone-containing controlled substance products. In addition, she admitted that she sometimes went into the pharmacy office and slept during episodes of migraine headaches, leaving technicians to work in the pharmacy unsupervised. She further admitted that on two occasions, while she was on duty, she was observed to have slurred speech, fluttering eye movements, and difficulty standing without supporting herself on the counter. At the Board's March 17, 2010 meeting it adopted an order reprimanding Dr Pobuda. The order also assessed a \$1,000 civil penalty, required Dr Pobuda to be evaluated by Health Professionals Services Program (HPSP), and required her to have her pharmacy supervisors make certain reports to the Board on a regular basis. Dr Pobuda

violated the terms of her disciplinary order by not entering into an agreement with HPSP. Consequently, at its September 15, 2010 meeting, the Board rescinded her previous disciplinary order and suspended her license to practice pharmacy for an indefinite period of time.

Swanson, Amy L. License #116161. Ms Swanson petitioned the Board for reinstatement of an unrestricted license. The Board had placed conditions and limitations on her license in September 2007 after she admitted to the theft of controlled substances from her employer and the unauthorized personal use of those drugs. The Board granted Ms Swanson's petition and issued an order of unconditional license at its September 15, 2010 meeting.

Schouweiler, Gregory J. License #112153. Mr Schouweiler admitted that he failed to certify prescriptions as required by Minnesota Rule 6800.3100, subpart 3; failed to complete quality assurance checks as required by Minnesota Rule 6800.3950, subpart 4; and dispensed clonazepam for a family member without a legally valid prescription. (The prescription was written for lorazepam and Mr Schouweiler substituted clonazepam without first obtaining permission from the prescriber to do so.) The Board issued a stipulation and consent order at its September 15, 2010 meeting that reprimanded Mr Schouweiler and assessed a civil penalty of \$500.

The Board considers the following **technicians** to have voluntarily surrendered their registrations between the dates of June 23, 2010 and September 15, 2010: **Dahl, Justin R.**, Registration #713202 and **Kurschner, Alyson C.**, Registration #705348. The Board revoked the registration of the following technician after receiving a notice of license revocation from the Minnesota Department of Revenue indicating that she owes \$500 or more in delinquent taxes, penalties, or interest or has not filed a return: **Haugen, Kristin L.**, Registration #716918.

Pharmacist Vaccinations NEW INFO HERE

The statutory definition of the "practice of pharmacy" was changed in 2003 to allow pharmacists to administer certain vaccines. It was amended in 2009 to allow pharmacists to administer influenza vaccines to children 10 years of age and older and all other vaccines to adults. Several of the major pharmacy chains that operate in Minnesota are now offering vaccinations to their patients. As a result of this increase in pharmacist vaccinations, the Board has been receiving questions about this issue. There are

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FDA Alert Regarding Administration of Oral Nimodipine Capsules

Food and Drug Administration (FDA) reminds health care providers that oral nimodipine capsules should be given only by mouth or through a feeding or nasogastric tube and should never be given by intravenous administration. FDA continues to receive reports of intravenous nimodipine use, with serious, sometimes fatal, consequences. Intravenous injection of nimodipine can result in death, cardiac arrest, severe falls in blood pressure, and other heart-related complications.

Nimodipine is a medication intended to be given in a critical care setting to treat neurologic complications from subarachnoid hemorrhage and is only available as a capsule. Prescribing information warns against intravenous use of nimodipine and also provides clear instructions on how to remove the liquid contents from the capsules for nasogastric tube administration in patients who are unable to swallow. The instructions recommend that the syringe used for withdrawal of capsule contents be labeled with "Not for IV Use." FDA will continue working with the manufacturers of nimodipine and with outside groups to evaluate and implement additional ways to prevent medication errors with this product.

An FDA Drug Safety Communication providing additional information for health care providers and patients is available at www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm220386.htm.

FDA Approves Vaccines for the 2010-2011 Influenza Season

FDA approved vaccines for the 2010-2011 influenza season in the United States on July 30, 2010, and some manufacturers began shipping as early as mid-August. The seasonal influenza vaccine protects against three strains of influenza, including the 2009 H1N1 influenza virus, which caused the 2009 pandemic. Last year, two separate vaccines were needed to protect against seasonal flu and the 2009 H1N1 pandemic flu virus because the 2009 H1N1 virus emerged after production began on the seasonal vaccine, but this year, only one vaccine is necessary. The Centers for Disease Control and Prevention has published recommendations for annual influenza vaccination to include all people aged six months and older. The expanded recommendation is to take effect in the 2010-2011 influenza season. More information on the approved vaccine is available in an FDA news release available at www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm220718.htm.

FDA Alert Regarding Adverse Effects in Children After Unintentional Exposure to Evamist

FDA advises patients and health care providers of reports regarding adverse effects from Evamist® in children who may have been unintentionally exposed to the drug through skin contact with women using this product. Evamist contains estradiol, an estrogen hormone, and is a topical product, sprayed on the skin on the inside of the forearm between the elbow and the wrist. Children unintentionally exposed to Evamist may experience premature puberty. FDA is currently reviewing these reported adverse events and is working with the company to identify any factors that may contribute to unintended exposure and to evaluate ways to minimize the risk. FDA advises that patients should make sure that children are not exposed to Evamist and that children do not come into contact with any skin area where the drug was applied, and for

those who cannot avoid contact with children to wear a garment with long sleeves to cover the application site. Additional information for patients is provided in an FDA Drug Safety Communication available at www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm220185.htm.

Safeguards to Implement with 'High Alert' Medications



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 a FDA Med-Watch 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.

While most medications have a large margin of safety, a small number of drugs have a high risk of causing injury when they are misused. ISMP calls these "high-alert medications" to draw attention to this characteristic so that all involved in their use will treat them with the care and respect that they require. Errors may or may not be more common with these drugs than with the use of any others; however, the consequences of the errors are more devastating. For this reason, special considerations are required. These medications often need to be packaged differently, stored differently, prescribed differently, and administered differently than others. Examples of high-alert medications in community pharmacy include warfarin, insulin, methotrexate, and fentanyl patches. Whenever possible, "forcing functions" – methods that make it impossible for the drug to be given in a potentially lethal manner – should be developed and instituted. Forcing functions are procedures that create a "hard stop" during a process to help ensure that important information is provided before proceeding. For example, a pharmacy computer system that prevents overriding selected high-alert messages without a notation (eg, patient-specific indication must be entered if high-alert medication selected) is a forcing function.

An independent double-check of a high-alert medication is a procedure in which two pharmacists, alone and apart from each other, separately check each component of dispensing and verifying the high-alert medication, then compare results before giving it to the patient to self-administer. While technological solutions such as bar coding systems have great potential to detect human error, manual redundancies such as independent double checks still play an important role in error detection. Studies show that manual redundancies detect about 95% of errors. Independent double checks serve two purposes: to prevent a serious error from reaching a patient; and just as important, to bring attention to the systems that allow the introduction of human error. In retail pharmacies, with only one pharmacist per shift, the independent double check can be performed via a "will call" bag



check or by another pharmacist at the beginning of the next shift. If the medication has been dispensed, serious harm can be avoided or mitigated if the error is discovered within one or two doses.

The following information must be verified during the double-check process:

Comparison to prescriber's order:

- ◆ Is this the prescribed drug?
- ◆ Is this the prescribed dose/strength/rate and route of administration?
- ◆ Is this the right patient (use two patient identifiers)?
- ◆ Is this the prescribed frequency?

Additional cognitive checks:

- ◆ Does the drug's indication correspond to the patient's diagnosis?
- ◆ Is this the right drug formulation?
- ◆ Are dose calculations correct?
- ◆ Is the dosing formula (eg, mg/kg) used to derive the final dose correct?
- ◆ Is the prescribed dose/frequency/timing appropriate for this patient?
- ◆ Is the route of administration safe and proper for this patient?
- ◆ Has patient been educated on appropriate monitoring?

ASCO/FDA Program Provides Information on Expanded Access for IND Applications

Developed in partnership with FDA, the American Society of Clinical Oncology (ASCO) offers an online interactive educational program to help providers understand FDA regulations regarding expanded access programs for individual-patient investigational new drug (IND) applications. The program provides an introduction from the viewpoint of various involved stakeholders, including physicians, FDA, industry, and patients and may assist pharmacists in providing patient counsel regarding expanded access.

This interactive module consists of:

- ◆ A thorough explanation of all expanded access programs available
- ◆ Links to key references and resources that are relevant to the slide content
- ◆ Selected virtual meeting presentations from ASCO Annual Meetings
- ◆ Helpful resources to use with patients

The program is available at <http://university.asco.org/ExpandedAccess> and participants may earn a certificate of participation or completion.

Rise in Prescription Pain Pill Abuse Documented in Latest SAMHSA Data

Abuse of prescription pain medications continues to rise, according to the latest data from the Substance Abuse and Mental Health Services Administration (SAMHSA). The agency's Treatment Episode Data Set showed that the proportion of substance abuse treatment admis-

sions for individuals aged 12 and older rose 400% from 1998 to 2008. SAMHSA data also showed an increase in emergency room visits involving the non-medical use of a prescription narcotic pain reliever, which have tripled in proportion since 1998. SAMHSA Administrator Pamela S. Hyde, JD, stressed that the non-medical use of prescription pain relievers is now the second most prevalent form of illicit drug use. Hyde emphasized the importance of raising awareness about this public health threat and educating the public on the "critical importance of properly using, storing, and disposing of these powerful drugs" as reported in a SAMHSA press release available at www.samhsa.gov/newsroom/advisories/1007140544.aspx.

USP Recommends Patient-Centered Standards for Prescription Labels

To address the problem of patient misinterpretation of medication instructions, the United States Pharmacopeial Convention (USP) Health Literacy and Prescription Container Labeling Advisory Panel developed and recently released recommendations for standardizing the format, appearance, content, and language of prescription labels. The panel, on which the National Association of Boards of Pharmacy® (NABP®) participated, developed the patient-centered recommendations in response to a call for such standards from the Institute of Medicine. More details about the panel's recommendations are available in a USP press release at <http://vocuspr.vocus.com/vocuspr30/ViewAttachment.aspx?EID=2WSh2u7neSpIu2bXW1HJ5VQ48HGFAOGH1NdNBeuPwJE%3d>.

Seven Pharmacy Organizations Respond to AMA Scope of Pharmacy Practice Document

Seven national pharmacy organizations, including NABP, collaborated on the analysis and responded to the AMA Scope of Practice Data Series: Pharmacists, a document published by the American Medical Association (AMA) that describes the scope of the practice of pharmacy as viewed by the AMA authors. The pharmacy organizations identified significant opportunities for enhanced understanding by the AMA of contemporary pharmacy practice and urged the AMA to correct the identified issues noted in the document. AMA responded that meaningful dialogue will be pursued to examine ways pharmacists and physicians can collaboratively address the health care needs of patients. Collaborating on the pharmacy organizations' review and response were the American Pharmacists Association (APhA), American Association of Colleges of Pharmacy, American College of Clinical Pharmacy, Accreditation Council for Pharmacy Education, American Society of Consultant Pharmacists, National Alliance of State Pharmacy Associations, and NABP. The letter and materials sent to AMA are available at the following links from the APhA Web site:

- ◆ Recommendations: AMA Scope of Practice Data Series: Pharmacists, www.pharmacist.com/AM/Template.cfm?Section=Home2&CONTENTID=23148&TEMPLATE=/CM/ContentDisplay.cfm.
- ◆ Response Letter: AMA Scope of Practice Data Series: Pharmacists, www.pharmacist.com/AM/Template.cfm?Section=Home2&TEMPLATE=/CM/ContentDisplay.cfm&CONTENTID=23149.
- ◆ Scope of Contemporary Pharmacy Practice, www.pharmacist.com/AM/Template.cfm?Section=Home2&TEMPLATE=/CM/ContentDisplay.cfm&CONTENTID=23150.

several sections of law and one section of rules that pharmacists who participate in immunization programs need to know:

Minnesota Statutes §151.01, Subd. 27(5) states that pharmacists may participate “in administration of influenza vaccines to all eligible individuals ten years of age and older and all other vaccines to patients 18 years of age and older under standing orders from a physician licensed under chapter 147 or by written protocol with a physician provided that:

- (i) the pharmacist is trained in a program approved by the American Council of Pharmaceutical Education [Accreditation Council for Pharmacy Education] for the administration of immunizations or graduated from a college of pharmacy in 2001 or thereafter; and
- (ii) the pharmacist reports the administration of the immunization to the patient's primary physician or clinic.”

Minnesota Statutes §145.58 states that “The commissioner of health shall enroll a licensed pharmacy or individual pharmacist as a program-registered provider in the pediatric vaccine administration program under section 13631 of the federal Omnibus Budget Reconciliation Act of 1993, Public Law 103-66, based on the program's infrastructure capacity to enroll the additional pharmacy providers in the program.”

Minnesota Statutes §145.987 states that “Pharmacies and pharmacists providing immunizations to children under private insurance or fee-for-service arrangements prior to June 1, 2009, that are not enrolled in the pediatric vaccine administration program under section 13631 of the federal Omnibus Budget Reconciliation Act of 1993, Public Law 103-66, must discontinue immunization services to children under private insurance or fee-for-service arrangements after December 31, 2009.”

Minnesota Rules 9505.0195, Subp. 10, which is enforced by the Department of Human Services (DHS), states, in part, that a Minnesota Health Care Program (MHCP) “provider shall render to recipients services of the same scope and quality as would be provided to the general public.”

Pharmacists involved in administering vaccines must remain in compliance with these statutes and rules. Pharmacists are not allowed to administer influenza vaccines to individuals under the age of 19 unless they are enrolled in the Minnesota Vaccines for Children (MnVFC) Program. A pharmacy is not enrolled in that program until it has submitted an application, has had a site visit, and has had the application approved. For information about enrolling in the MnVFC, pharmacists should contact the Minnesota Department of Health (MDH). Information about the MnVFC is also available on the MDH Web site at www.health.state.mn.us/divs/idepc/immunize/mnvfc/lowcostimz.html.

Pharmacists may administer any vaccine to individuals 19 years of age and older. (Even though the law states that all other vaccines can be administered to persons 18 years of age and older, the Board has learned from MDH that the MnVFC program covers individuals up through 18 years of age.) Pharmacists must provide influenza vaccinations to children who are MHCP recipients if they offer such vaccinations to any other children. DHS has informed the Board that pharmacists who do not follow that rule are at risk of losing their MHCP enrolled provider status. Note that pharmacists can only bill DHS (or the health plans under contract to DHS) for the cost of adult influenza, varicella, and zoster vaccines. There is no reimbursement for the cost of other vaccines because providers

are expected to access them through the contract DHS has with MDH, which involves enrolling in the MnVFC. Pharmacies can bill for an administration fee when administering the vaccines that they are allowed to administer to MHCP recipients. Pharmacists may not charge MHCP recipients for the cost of vaccinations.

Unless they graduated from a pharmacy school in 2001 or later, pharmacists should have proof that they have completed an Accreditation Council for Pharmacy Education (ACPE)-accredited program for the administration of vaccines. The Board recommends that even those pharmacists who graduated in 2001 or later complete ACPE-approved immunization training. Programs not accredited by ACPE are not acceptable. Pharmacists may administer vaccinations under the direction of a licensed **physician** only – either by protocol or standing orders. Pharmacists should have a signed copy of their standing orders or protocol available for review by Board surveyors. Pharmacists must report vaccinations they give to the patient's primary physician or clinic and should keep records proving that they have done so.

Since pharmacists are most likely to administer influenza vaccinations, the Board strongly recommends a review of the MDH Flu Guide, available on MDH's Web site at www.health.state.mn.us/divs/idepc/diseases/flu/hcp/vaccine/fluguide.pdf. Additional information for health professionals about influenza is available at www.health.state.mn.us/divs/idepc/diseases/flu/hcp.

Important Notice – Electronic Licensing Surcharge

Beginning October 1, 2010, license and registration fees will include an electronic licensing surcharge. The Minnesota Office of Enterprise Technology (OET) sponsored (and the Minnesota Legislature passed) legislation requiring a 10% surcharge on all business, commercial, professional, or occupational licenses and registrations issued by certain state agencies, including the Board of Pharmacy. (Note that there is a minimum \$5 surcharge.) The additional money that licensees and registrants will have to pay will be transferred to OET, which will use it to implement one portion of a state electronic licensing system. The surcharge will be in place through June 15, 2015.

Please note that the Board has been informed that it will have to pay to either link its existing “back office” electronic licensing system to the system being developed by OET or to migrate to back office software developed by a vendor under contract to OET. Depending on the costs involved, the Board may have to request permission from the Legislature to further increase fees.