



Minnesota Board of Pharmacy

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Disciplinary Activity

The Minnesota Board of Pharmacy took the following disciplinary actions concerning **pharmacists** between the dates of December 22, 2010 and March 22, 2011:

Gilberts, Mark E., License #115330. Mr Gilberts admitted that he diverted controlled substances from his employer for his personal use, preparing fraudulent prescriptions to cover up the diversion. He also admitted that he consumed alcohol while on duty. Consequently, at its January 5, 2011 meeting, the Board adopted an order suspending Mr Gilberts' license for an indefinite period of time. He may not petition for reinstatement of his license until he can demonstrate 12 months of uninterrupted sobriety and participation in chemical dependency rehabilitation.

Jensen, James C., License #111475. Mr Jensen admitted that he diverted controlled substances from his employer for his personal use, preparing fraudulent prescriptions to cover up the diversion. He also admitted that he allowed a patient to return a controlled substance to the pharmacy at which he worked, ostensibly for destruction, but that he actually consumed the drug himself. Consequently, at its February 25, 2011 meeting, the Board adopted an order accepting the voluntary surrender of Mr Jensen's license.

McEachran, Michael W., License #115045. Mr McEachran acknowledged inappropriately using hydrocodone-containing controlled substances. He further admitted being unable to reach a participation agreement with the Health Professionals Services Program (HPSP), resulting in that program reporting him to the Board. Consequently, at its February 25, 2011 meeting, the Board issued an order that requires Mr McEachran to participate in HPSP and prohibits him from being a preceptor.

Melhus, Jacquelyn L., License #111261. Ms Melhus admitted that she diverted controlled substances from her employer for her personal use. She denied being chemically dependent but acknowledged that she has been treated for depression. At the Board's January 5, 2011 meeting it adopted an order accepting the voluntary surrender of Ms Melhus' license. She may not petition for reinstatement of her license for at least 12 months, at which time she must demonstrate that she is capable of practicing pharmacy in a fit and competent manner and that she has had stable mental health for at least 12 months prior to the date of her petition.

Mrozla, Donald L., License #112525. Mr Mrozla admitted that he diverted controlled substances from his employer for his personal use and acknowledged that he has been diagnosed with depression. At the Board's January 5, 2011 meeting it adopted an order that indefinitely suspends Mr Mrozla's license. He may not petition for reinstatement of his license until he can demonstrate 12 months of both uninterrupted sobriety and stable mental health.

Pobuda, Michel L., License #118034. At the Board's March 17, 2010 meeting, it adopted an order reprimanding Dr Pobuda for irregularities that occurred while she was the pharmacist-in-charge at a pharmacy. The order also assessed a \$1,000 civil penalty, required Dr Pobuda to be evaluated by 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 that 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. Dr Pobuda subsequently petitioned the Board to reinstate her license. She admitted that she diverted controlled substances from her employer for her personal use but noted that she had successfully completed chemical dependency treatment and was participating in aftercare. At its January 5, 2011 meeting, the Board issued a new order that suspended Dr Pobuda's license but stayed the suspension on condition that she participate in the HPSP. The following limitations were also established: (1) she may not be a preceptor or pharmacist-in-charge; (2) she may not have access to controlled substances; (3) she may not be employed as a pharmacist without the approval of the Board's executive director; and (4) she may not be involved in dispensing prescriptions unless she is supervised by another licensed pharmacist. The Board also assessed a civil penalty of \$1,500.

Wachtl, Jason R., License #119029. Dr Wachtl admitted that he diverted controlled substances from his employer for his personal use, preparing fraudulent prescriptions to cover up the diversion. Consequently, at its February 25, 2011 meeting, the Board issued an order reprimanding Dr Wachtl and requiring him to successfully complete HPSP monitoring. The order also established the following limitations: (1) he may not serve as a preceptor or as a pharmacist-in-charge; and (2) he may not work alone in any setting where he would have access to controlled substances.



Obtain Your NABP e-Profile ID Online Now, ID Required for ACPE-Accredited CPE

The new National Association of Boards of Pharmacy® (NABP®) CPE Monitor service, a collaborative effort between NABP, the Accreditation Council for Pharmacy Education (ACPE), and their providers, will allow pharmacists and technicians to easily track their ACPE-accredited continuing pharmacy education (CPE) credits beginning in the latter part of 2011. In addition, the service will provide a streamlined reporting and compliance verification process for participating state boards of pharmacy. When pharmacists and technicians complete an ACPE-accredited CPE program, their participation data will be sent electronically from the provider to ACPE, then to NABP for recording into the matching NABP e-Profile. Then, if the board of pharmacy participates in CPE Monitor, the pharmacists' or technicians' CPE credits will be automatically transmitted to the board, saving pharmacists and technicians the trouble and expense of documenting and submitting compliance with state-mandated CPE requirements for license renewal. This eliminates paper forms and the overall need to submit paper copies of CPE statements of credit to the board of pharmacy for CPE activities from ACPE-accredited providers.

For convenience, the NABP e-Profile will be available 24/7 for viewing a comprehensive list of the CPE activities completed. All information will be maintained in a highly secure environment. NABP does not distribute any personal information for commercial purposes without consent.

To prepare for the new process, pharmacists and technicians are encouraged to obtain their NABP e-Profile identification to ensure their e-Profile is properly set up. Beginning in the latter part of 2011, all pharmacists and technicians will be able to provide their NABP e-Profile ID, plus their birthdate (mmdd) to receive credit for any accredited CPE activities from ACPE-accredited providers. Providers will ask CPE participants to provide the ID either when registering or when submitting participation data to the provider. Please note that CPE Monitor will not initially track CPE from non-ACPE-accredited providers. This feature will be added in Phase 2 of the CPE Monitor service, and, until then, pharmacists and technicians will need to submit non-ACPE-accredited CPE directly to their board of pharmacy when required to do so.

NABP and ACPE will work with CPE providers to ensure an adequate amount of time is allotted to implement this new service.

Pharmacists can obtain their ID by creating an NABP e-Profile using the portal in the Pharmacists section of the NABP Web site at www.nabp.net/pharmacists. Technicians can obtain their ID by creating an NABP e-Profile using the portal in the Technicians section of the NABP Web site at www.nabp.net/technicians. Visit www.MyCPEmonitor.net for more information.

FDA Asks Manufacturers to Limit Acetaminophen Strength

In the interest of patient safety, Food and Drug Administration (FDA) asked drug manufacturers to limit the strength of acetaminophen in prescription drug products – which are predominantly

combinations of acetaminophen and opioids – to 325 mg per tablet, capsule, or other dosage unit. In addition, FDA reports that the labels of all prescription drug products that contain acetaminophen will now include a boxed warning that highlights the potential for severe liver injury and a warning that highlights the potential for allergic reactions. FDA has taken these actions to reduce the risk of severe liver injury and allergic reactions associated with acetaminophen. FDA notes that over-the-counter products containing acetaminophen are not affected by this action.

While the maximum amount of acetaminophen in a prescription tablet, capsule, or other dosage unit will be limited to 325 mg, the total number of tablets or capsules that may be prescribed and the time intervals at which they may be prescribed will not change as a result of the lower amount of acetaminophen. Additional information for health care providers and patients is included in an FDA Drug Safety Communication available on the FDA Web site at www.fda.gov/Drugs/DrugSafety/ucm239821.htm.

Looking for Risk

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 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.

Health care organizations focused on improving patient safety must first identify, ascertain the causes of, and employ strategies to reduce risk. Everyone on staff in an organization has responsibility for risk assessment and, therefore, risk management.

This includes involving patients in their care and seeking their help to identify risk in the system. Assessing risk in an organization is important to understanding and prioritizing areas of highest risk and for discovering which improvements will have the greatest overall impact on patient safety.

FMEA

The Failure Mode and Effects Analysis (FMEA) process is a “systematic method of identifying and preventing product and process problems before they occur.” FMEA is the tool that has the potential to be an integral part of any risk assessment and, therefore, the risk management process.



Compliance News to a particular state or jurisdiction should not be assumed as representing the law of such state or jurisdiction.)

FMEAs focus on identifying and removing defects, enhancing safety, and increasing customer satisfaction.

AROC

Assessing Risk and Opportunities for Change (AROC) is designed to help community pharmacy personnel identify potential medication safety risks and prevent errors. Pharmacists can use these materials and tools to pinpoint specific areas of weakness in their medication delivery systems and to provide a starting point for successful organizational improvements.

Pharmacists' Role

Pharmacists are often assumed to be the “guardians” in ensuring that medication errors do not occur. This expectation is unrealistic, because avoiding error is a health care team effort. It has, however been suggested that pharmacists should assume a leadership role in implementing safe medication use efforts in their organization.

Objectives for the pharmacist and other pharmacy staff who participate in the assessment process:

- ◆ Explain the important processes and sub-processes of medication use from prescription through administration.
- ◆ Participate in identifying failure modes and risk throughout the entire medication process, especially in information that should be available to the prescriber and nurse, as well as describing the steps in the process that occur after the medication order is transferred to the pharmacy.
- ◆ Offer possible causes for medication errors because of breakdowns in the prescription to administration process.
- ◆ Identify effects, as well as their severity and probability, when a system failure occurs.
- ◆ Offer suggestions, along with all team members, for actions that should be taken to prevent medication errors.

Pharmacists are an integral part of any medication safety assessment process. They not only offer information – as do the other disciplines in the organization – they can also expand their knowledge through participating in these risk assessments. Pharmacy participation should include frontline staff, pharmacists, pharmacy technicians, and pharmacy support staff. It is important to have multilevel involvement so that all system enhancements are discussed and identified.

To learn more about assessing risk in acute care pharmacy visit www.ismp.org/Tools/pathways.asp.

To learn more about assessing risk in community pharmacy visit www.ismp.org/communityRx/aroc/.

NABP Launches New and Improved NAPLEX/MPJE Application in March

In March 2011, NABP launched a new and improved application process for the North American Pharmacist Licensure Examination® (NAPLEX®) and the Multistate Pharmacy Jurisprudence Examination® (MPJE®). The online application was upgraded to be more user friendly, allowing candidates to perform more registration tasks and providing status information to examination candidates.

In addition to providing the basic features of registering for the NAPLEX, NAPLEX score transfer, and MPJE, the new application also allows candidates to make changes to, add to, or withdraw an application, eliminating the need for candidates to call NABP for this service. Changes that can be made to an application include registering for the MPJE in additional jurisdictions and adding NAPLEX score transfer requests until the time of the examination. Technological enhancements to the application allow for the elimination of the previous requirement that candidates submit score transfer requests five business days prior to sitting for the NAPLEX.

The new application also gives candidates who miss sitting for an examination or who do not cancel within two business days of their appointment the ability to submit resitting fees online rather than having to send a payment to NABP via mail. This expedites the receipt of the candidate's new Authorization to Test so that he or she may schedule another examination appointment more quickly.

An additional benefit to candidates is the ability to monitor the status of their profile. After submitting an application, candidates can log in to their profile and see if the application has been received; if eligibility has been requested, granted, denied, or expired; if Authorization to Test has been generated; if the application has been withdrawn or expired; and history of examinations taken.

The profiles of candidates who registered for the NAPLEX or MPJE before the new application was launched will need to create a user name and password through the new application so that they can view the historical data of their NAPLEX and MPJE registrations. Upon creating a new user account, the system will match the newly created account with applications previously submitted or currently in progress so that all the information will be viewable by the candidate.

The new application also allows users to update their profiles as needed and review past orders.

In addition, the score results for the NAPLEX and MPJE are also accessible when candidates log in to the application, provided that the board for which the candidate tested participates in the online score interface. Currently, 21 boards utilize this service.

Overall, candidates can expect a clearer and smoother registration process because both front and back-end functionality of the application has been streamlined and tightly integrated.

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, pharmacists discuss the role of FDA in responding to and mitigating drug shortages. Drug Info Rounds is developed with contributions from pharmacists in the FDA's Center for Drug Evaluation and Research, Office of Communications, and Division of Drug Information. FDA Drug Info Rounds training videos may be accessed on the FDA Web site at www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm.

Proposed Rule Changes

The Board has been working on a large package of proposed rule changes since 2008. The proposed changes involve definitions, applications for pharmacy licenses, pharmacy license categories, transfers of pharmacy ownership, pharmacy counseling areas, supervision of pharmacy areas, automated counting devices, closing a pharmacy, applications for pharmacist licensure, drug manufacturer and wholesaler licensure, registration of pharmacy technicians, training and educational requirements for pharmacy technicians, unprofessional conduct, continuous quality improvement programs, answering machines and electronic voice recording devices, compounding, prospective drug reviews, patient profiles, transfer of prescriptions between pharmacies, prepackaging and labeling, radiopharmaceutical labeling, veterinary prescription drug labels, interns and preceptors, consulting services to licensed nursing homes, emergency kits, pharmaceutical services policies, variances, and medical gas distributor registrations.

A rules hearing, with Administrative Law Judge Eric Lipman presiding, was held on March 3, 2011. The Board anticipates receiving Judge Lipman's report by the end of April 2011. The Board is considering a number of modifications to the proposed rule language in response to the comments that were submitted before, during, and after the hearing. Additional information about the proposed rule changes can be found on the Board's Web site at www.phcybrd.state.mn.us/rulemake2010.htm.

Board of Pharmacy Elects New Officers

At its meeting on January 5, 2011, the Board of Pharmacy elected pharmacist Stacey Jassey, of Maple Grove, MN, as Board president for calendar year 2011.

Pharmacist member James Koppen, of Pine City, MN, was elected as vice president.

Dr Jassey has over 23 years of experience in the pharmacy profession. She is a community clinical pharmacist for Walgreens where she also serves as one of the nationwide interpreters for Spanish speaking Walgreens patients. She is an assistant professor at the University of Minnesota College of Pharmacy. She received her bachelor of science and her doctor of pharmacy degrees from the University of Minnesota College of Pharmacy. She was appointed in 2008 by Governor Tim Pawlenty.

James Koppen served as the director of pharmacy at Pine Medical Center in Sandstone, MN, where he supervised all pharmacy operations including the upgrading of the medication delivery system and the launching of a medication safety program. Mr Koppen is a licensed pharmacist with over 39 years of experience in both retail and hospital pharmacy. He earned his bachelor of science degree in pharmacy from South Dakota State University, in Brookings, SD. He was appointed in 2009 by Governor Tim Pawlenty.

Cody Wiberg was elected to serve as Board secretary (executive director) for an additional year. In addition to electing officers, the Board designated Candice Fleming to be associate director for compliance and Pat Eggers to be assistant director for administrative affairs.

Pharmacist Interns and Preceptors

Approximately 160 pharmacy students will become eligible to work as pharmacy interns this summer. Many of these students will be seeking employment in order to obtain their required internship hours. Minnesota pharmacists who will be hiring pharmacy students as pharmacist interns over the summer must

be sure that students are registered with the Board of Pharmacy as interns and that the pharmacists under whose supervision the interns will be working are properly registered with the Board as pharmacist preceptors. Failure of students to properly register as interns or failure of pharmacists to properly register as preceptors will result in loss of intern hours for the student and the potential for disciplinary action involving the pharmacist.

Every year individuals are found to be working in Minnesota as interns based on intern registration in another state. Registration as an intern in another state does not allow a pharmacy student to work as an intern in Minnesota. A student of a college of pharmacy located in another state, who is employed in a Minnesota pharmacy as an intern, must be registered as an intern in Minnesota.

At its June 2009 meeting, the Board went on record as clarifying the interpretation of existing rules to mean that there is a 1:1 intern:preceptor ratio so that a preceptor may not have more than one assigned intern at any one time without requesting a variance from the Board. However, since the Board is in the process of adopting a rule change that would modify the ratio to 2:1, the Board also directed staff to automatically approve variance requests that ask for permission to use a 2:1 ratio.

The Board anticipates that the proposed rule to change the intern:preceptor ratio to 2:1 will be officially adopted by June 2011. However, a 1:1 ratio will remain in effect in regard to the supervision of interns that are performing compounding or dispensing duties. (Unless one or more interns is completing an experiential education rotation through an accredited college of pharmacy, in which case the supervisory ratio will be 2:1.) The language that the Board is proposing to adopt is as follows:

An intern performing tasks associated with dispensing or compounding shall be immediately and personally supervised by a licensed pharmacist stationed within the same work area who has the ability to control and is responsible for the actions of the intern. Except in the case of internship experience conducted as part of the experiential education program of an accredited college or school of pharmacy, a licensed pharmacist may not supervise more than one intern who is performing tasks associated with dispensing or compounding. In the case of an internship experience conducted as part of the experiential education program of an accredited college or school of pharmacy, a licensed pharmacist may supervise two interns who are performing tasks associated with dispensing or compounding. The ultimate responsibility for the actions of an intern performing tasks associated with dispensing or compounding shall remain with the licensed pharmacist who is supervising the intern.