



Minnesota Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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

Disciplinary Actions

Because of space limitations, information on disciplinary actions is no longer being included in the *Minnesota Board of Pharmacy Newsletter*. A document that provides information about recent Minnesota Board of Pharmacy disciplinary actions can be found on the [Board's website](#) under the "Resources/FAQs" menu item.

Governor Dayton Makes Appointments to Board

On January 15, 2016, Governor Mark Dayton announced the reappointment of Joseph Stanek and the appointments of James Bialke, Andrew Behm, Samantha Jaworski, and Mary Voelker Phipps to the Board. Mr Bialke and Ms Jaworski were appointed as public members, while Drs Behm, Stanek, and Phipps are pharmacist members. Their terms began on January 20, 2016. With these appointments, the Board has a full complement of nine members: six pharmacist members and three public members.

Dr Stanek was first appointed to the Board on August 6, 2015, to fill out the remaining portion of a term that expired on January 4, 2016. He replaced Kay Hanson, who had retired from the practice of pharmacy and was required to resign from the Board. This new appointment is for a full, four-year term that will expire in January 2020. Dr Stanek has over 18 years of hospital pharmacy/sterile product production experience. Former positions include pharmacy technician, staff pharmacist, clinical pharmacist, clinical coordinator, and director of pharmacy. He currently serves as program development manager for the Fairview Compounding Pharmacy. Dr Stanek received both bachelor of science in pharmacy and doctor of pharmacy degrees from Midwestern University.

Dr Behm, of Edina, MN, was appointed to a newly created pharmacist member position. Because of the need to stagger the terms of Board members, the first term of this position was set by the governor to expire in January 2017. Subsequent terms will be for the normal four-year period that members of health licensing boards serve. Dr Behm received his doctor of pharmacy degree from the University of Minnesota in 2000 and has practiced in the community, hospital, managed care, hospice/home care, and long-term care settings. He completed a residency in geriatric pharmacy at the Minneapolis Veterans Affairs Health Care System and is a certified geriatric practitioner. He has worked for Express Scripts since 2001, where he currently serves as vice president in the Office of Clinical Evaluation and Policy.

Mr Bialke, of Minneapolis, MN, was appointed to fill the remaining portion of the term of Justin Barnes, which expires on January 1, 2018. Mr Barnes accepted a position with a pharmaceutical manufacturer that is licensed by the Board, so he

could no longer continue as a public member. The Board thanks Mr Barnes for his service to the Board and to the public. Mr Bialke spent 28 years working for unions that represent both licensed and non-licensed health care workers in a variety of settings. Among other positions, he served as chief of staff at Service Employees International Union Healthcare Minnesota and as executive director of the Minnesota Nurses Association. He received a bachelor of arts degree in economics from the University of Minnesota and a master of arts in industrial relations from the University of Minnesota, Carlson School of Management.

Ms Jaworski, of Andover, MN, was appointed to a newly created public member position. Because of the need to stagger the terms of Board members, the first term of this position was set by the governor to expire in January 2019. Subsequent terms will be for the normal four-year period that members of health licensing boards serve. Ms Jaworski graduated from the University of Minnesota Duluth (UMD) in May 2009 with two degrees: a bachelor of science in biochemistry and molecular biology and a bachelor of arts with a major in chemistry and a minor in French. She subsequently received a master of science in chemistry from UMD in September 2012. She has worked for Legend Technical Services in St Paul, MN, since December 2012, where she is the organic department manager.

Dr Phipps, of St Cloud, MN, received a bachelor of science in pharmacy degree from the University of Minnesota in 1980 and a doctor of pharmacy degree from the University of Kentucky in 1982. She has experience practicing in community, clinical, hospital, and infusion pharmacy settings. Dr Phipps also has experience in academia, having served as an assistant clinical professor and assistant dean for the Drake University College of Pharmacy and Health Sciences. She has worked for CentraCare Health since 1999, first as director of pharmacy for the St Cloud Hospital and now as system director of pharmacy. She oversees pharmacy services at St Cloud Hospital and in five critical access hospitals across central Minnesota, as well as an infusion pharmacy and four clinic-based community pharmacies. Prior to starting with CentraCare 17 years ago, she worked in various positions at Mercy Medical Center and Drake University in Des Moines, IA.

Board Continues to Pursue Adoption of Work Condition Rules

As noted in the last edition of this *Newsletter*, the Board has been working to adopt a new rule (6800.2160) to address pharmacy work conditions that have a direct impact on the safety of the public. The Board heard public comments concerning this proposed rule at its December 16, 2015 meeting. In addition, as of the date of that

continued on page 4



FDA Approves Naloxone Nasal Spray to Prevent Opioid Overdose Deaths

Food and Drug Administration (FDA) has approved Narcan® Nasal Spray (also known as naloxone), a life-saving medication that can stop or reverse the effects of an opioid overdose. Prior to this approval, naloxone was only approved in injectable forms, most commonly delivered by syringe or auto-injector, explains FDA in a news release.

Narcan Nasal Spray does not require assembly and delivers a consistent, measured dose when used as directed. This prescription product can be used on adults or children and is easily administered by anyone, even those without medical training. The drug is sprayed into one nostril while the patient is lying on his or her back, which can be repeated if necessary. However, it is important to note that it is not a substitute for immediate medical care, and the person administering Narcan Nasal Spray should seek further immediate medical attention on the patient's behalf. The use of Narcan Nasal Spray in patients who are opioid dependent may result in severe opioid withdrawal characterized by body aches, diarrhea, increased heart rate (tachycardia), fever, runny nose, sneezing, goose bumps (piloerection), sweating, yawning, nausea or vomiting, nervousness, restlessness or irritability, shivering or trembling, abdominal cramps, weakness, and increased blood pressure. Narcan Nasal Spray is distributed by Adapt Pharma, Inc, of Radnor, PA. The FDA news release is available at www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm473505.htm.

Selected Medication Safety Risks to Manage in 2016



This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization 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 provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Errors Reporting Program Report online at www.ismp.org. Email: ismpinfo@ismp.org.

It is a nearly impossible task to list all the risks associated with medication use that could lead to harmful medication

errors. So where do health care professionals start to improve medication safety? Most people frequently resort to playing “whack-a-mole,” addressing risks only after they pop up and become visible after an adverse event.

Listed below are two serious medication safety risks that might fall off the radar screen unless an adverse event happens to draw attention to them. Additional serious risks will be published in future issues of the National Association of Boards of Pharmacy® *National Pharmacy Compliance News*.
Patient Information – Placing Orders on the Wrong Patient's Electronic Health Record

A potentially hidden vulnerability that can lead to serious errors is placing orders on the wrong patient's electronic health record. A recent study published in the *Journal of the American Medical Informatics Association* identified and quantified close calls that would have resulted in wrong-patient errors. According to this study, about 14 wrong-patient electronic orders are placed every day in a large hospital system with approximately 1,500 beds, or about 68 wrong-patient errors per 100,000 medication orders. By this measure, one in 37 hospitalized patients will have an order placed for them that was intended for another patient.¹

These errors are sometimes due to juxtaposition but more often caused by interruptions and having more than one patient's electronic health record open.

Multiple studies have demonstrated ways to reduce these events. Requiring verification of the patient's identity has reduced errors by 16% to 30%, and requiring re-entry of the patient's identification has reduced errors by 41%.^{1,2} Prompting clinicians for an indication when certain medications are ordered without an indication on the patient's problem list has intercepted errors at a rate of 0.25 per 1,000 alerts.³ In one study, most emergency department (ED) staff (81%) felt a room number watermark on the patient's electronic health record would eliminate most wrong-patient orders in the ED.⁴

Communication About Drug Therapy – Confusing the Available Concentration as the Patient's Dose on Electronic Records

Another risk deals with how home medications appear on computer screens. For example, a physician accidentally ordered 100 units of Lantus® (insulin glargine) instead of the correct dose of six units because the list of medications used at home displayed the concentration right next to the drug name on the first line, and the patient's dose below it on the second line: “Insulin glargine (Lantus) 100 units/mL,” followed on the next line with “6 units subcutaneous daily every evening.”

Now that insulin is available in 100 units/mL, 200 units/mL, 300 units/mL, and 500 units/mL concentrations, the risk



of receiving an overdose of insulin is high if the presentation of the order lists the product's concentration before the patient's dose. ISMP's recommendation is to list the drug name, patient-specific dose, and directions for use on the first line of the electronic medication administration record and patient medication lists, and the available concentration and any directions on how to measure the patient's dose below it.

References

1. Adelman JS, Kalkut GE, Schechter CB, et al. Understanding and preventing wrong-patient electronic orders: a randomized controlled trial. *J Am Med Inform Assoc.* 2013; 20(2):305-310.
2. Green RA, Hripcsak G, Salmasian H, et al. Intercepting wrong-patient orders in computerized provider order entry system. *Ann Emerg Med.* 2015; 65(6):679-686.
3. Galanter W, Falck S, Burns M, Laragh M, Lambert BL. Indication-based prescribing prevents wrong-patient medication errors in computerized provider order entry (CPOE). *J Am Med Inform Assoc.* 2013; 20(3):477-481.
4. Yamamoto LG. Reducing emergency department charting and ordering errors with a room number watermark on the electronic medical record display. *Hawaii J Med Public Health.* 2014; 73(10):322-328.

FDA Provides Training Videos on MedWatch Resources and Breakthrough Therapy

FDA Drug Info Rounds, a series of online videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. In the January 2016 Drug Info Rounds video, "MedWatch Tips and Tools," pharmacists discuss reporting adverse events to FDA's MedWatch Safety Information and Adverse Event Reporting Program and the resources available for health care professionals to report safety information. In the December 2015 Drug Info Rounds video, "Breakthrough Therapy," pharmacists discuss the breakthrough therapy designation program, which is intended to expedite the development and review of drugs for serious or life-threatening conditions. Drug Info Rounds is developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research (CDER), Office of Communications, Division of Drug Information. All Drug Info Rounds videos can be viewed on the FDA website at www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm.

Reading Medicine Labels Helps Reduce Acetaminophen Overdoses

The Acetaminophen Awareness Coalition (AAC) reminds pharmacists and other health care providers to encourage patients to properly read medicine labels to avoid unintentional acetaminophen overdoses. The coalition also encourages pharmacists and other health care providers to talk to their patients about medicine safety and acetaminophen use.

AAC's "Know Your Dose" campaign reminds patients to take these four steps to avoid acetaminophen overdose:

- (1) Always read and follow the medicine label.
- (2) Know if their medicines contain acetaminophen.
- (3) Take only one medicine at a time that contains acetaminophen.
- (4) Ask their health care provider about any questions.

Additionally, pharmacists may download or order free educational materials, including posters, flyers, and talking points, to give their patients on the Know Your Dose website at www.knowyourdose.org.

Over-the-Counter Children's Medicine Recalled Due to Incorrect Dose Markings

In January 2016, Perrigo Company voluntarily recalled two lots of children's guaifenesin grape liquid cough medicine (100 mg/5 mL) and three lots of children's guaifenesin DM cherry liquid cough medicine (100 mg guaifenesin and 5 mg dextromethorphan HBr/5 mL) sold in 4 oz bottles. The recall was initiated because some packages contain an oral dosing cup with incorrect dose markings. The affected products were sold by distributors nationwide and distributed through retail stores. The recalled lots and store brands are available in the Perrigo press release posted on the company's website, www.perrigo.com, under "Investors." To date, the company has not received reports of overdose. Distributors and retailers that have the affected lots should stop distribution and return the product using the information provided in the press release.

Adverse reactions or quality problems may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program at www.fda.gov/MedWatch.

FDA Offers Webinars on Online Drug Information Resources for Students and Clinicians

FDA's Division of Drug Information, CDER, presents a series of continuing education webinars targeted toward students and health care providers who wish to learn more about FDA and drug regulation. The webinars are presented by FDA staff and allow participants to interact with staff. Past topics have included "Introduction to FDA's MedWatch Adverse Reporting Program" and "An Overview of the FDA's Breakthrough Therapy Designation Program." Upcoming webinars, previous webinars, and presentation slides can be accessed on FDA's website at www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/PharmacyStudentExperientialProgramCDER/ucm228391.htm.

meeting, the Board had received written comments from approximately 80 individuals, businesses, health care systems, and trade or professional associations. After considering all of the written and verbal comments, the Board voted unanimously to accept recommendations made by the executive director to modify the proposed language. The Board further directed the executive director to take the additional actions necessary to adopt the rules. The modified language is as follows.

6800.2150. PHARMACIST ON DUTY.

A- Subpart 1. **REQUIREMENT TO HAVE A PHARMACIST ON DUTY.** A pharmacy or satellite pharmacy shall have at least one licensed pharmacist on duty and physically present in the pharmacy at all times that the pharmacy is open for the transaction of business except that for brief absences of the pharmacist arising out of and in the course of pharmacy practice, are allowable;

B- Subp. 2. **LIMITING ACCESS TO PHARMACIES.** When a pharmacy is closed or there is no pharmacist on duty, other individuals shall not be allowed access to the pharmacy except as provided in part 6800.7530. ~~In pharmacies where there are two or more pharmacists on duty, the pharmacists shall stagger their breaks so that the pharmacy is not left without a pharmacist for a temporary period.~~

6800.2160 PHARMACY WORK CONDITIONS.

Subpart 1. **Limitation on continuous hours worked.** A pharmacy licensed under Minnesota Statutes §151.19, subd. 1, which is located within the state of Minnesota, shall not require a pharmacist, pharmacist-intern or pharmacy technician to work longer than 12 continuous hours per day, inclusive of the breaks required under subpart 2.

Subp. 2. **Requirements for breaks.** (a) A pharmacist, pharmacist-intern or pharmacy technician working longer than six continuous hours per day shall be allowed during that time period to take a 30 minute, uninterrupted break.

(b) A pharmacist, pharmacist-intern or pharmacy technician shall be allowed adequate time from work within each four consecutive hours of work to utilize the nearest convenient restroom.

(c) A pharmacy may, but is not required to, close when a pharmacist is on a meal break. If the pharmacy does not close, the pharmacist shall remain within the licensed pharmacy in order to be available for emergencies. If the licensed pharmacy comprises the entire establishment in which the dispensing area is located, the pharmacist shall remain in close proximity to the dispensing area. In addition, the following apply:

(1) pharmacy technicians, pharmacist-interns and other supportive staff authorized by the pharmacist on duty may continue to perform duties as delineated by that pharmacist while the pharmacist is on break;

(2) no duties reserved to pharmacists and pharmacist-interns under any part of this chapter, or that require the professional judgment of a pharmacist, may be performed by pharmacy technicians; and

(3) only prescriptions that have been certified by a pharmacist, as required by part 6800.3100,

may be dispensed while the pharmacist is on break; except that prescriptions that require counseling by a pharmacist, including all new prescriptions and those refill prescriptions for which a pharmacist has determined that counseling is necessary, may not be dispensed while the pharmacist is on break.

(d) In pharmacies staffed by two or more pharmacists, the pharmacists shall stagger their breaks so that at least one pharmacist remains on duty at all times that the pharmacy remains open for the transaction of business. Subp. 3. Exceptions for emergencies. Subp. 1 and subp. 2, paragraph (a) shall not apply in the event that an emergency necessitates that a pharmacist, intern or technician work longer than 12 continuous hours, work without taking required meal breaks, or have a break interrupted in order to minimize immediate health risks for patients.

As of the date on which this edition of the *Newsletter* was drafted, the Board was awaiting final feedback from the Office of Governor Mark Dayton, who must give his approval before the Board can adopt the proposed rule. The Board remains hopeful that the governor will give his approval. If he does, the Board will publish a *Notice of Hearing* in the *Minnesota State Register*. After waiting for at least the 30 days after publication of the *Notice*, the Board will hold a rules hearing before an administrative law judge. Interested individuals and organizations can submit comments during the 30-day period mentioned above, at the hearing, and for a short period of time after the hearing. After the end of these comment periods, the administrative law judge will issue a report to the Board. The full Board will review the report and, depending on its findings, may issue an order to adopt the rules and publish a *Notice of Adoption* in the *State Register*. The rule becomes effective five days after the publication of the *Notice*.

Interested individuals can find additional information about this rulemaking initiative on the Board's website on the [Rules page](#) (scroll to the bottom of the page to find the Rule-Making Docket). The Board continues to welcome written comments concerning this proposed rule. Also, the Board will take additional public testimony during its April 13, 2016 meeting. After hearing this testimony and considering any additional comments it receives, it is possible that the Board will make additional changes to the proposed rule.

Continuing Education

Minnesota-licensed pharmacists are reminded that continuing education (CE) reporting is due no later than October 1 of every even-numbered year. There are now approximately six months left during which pharmacists can complete and report their CE for the period from October 1, 2014, to September 30, 2016. Upon completion of at least the required 30 hours of CE, pharmacists can visit the Board's website (www.pharmacy.mn.gov), choose "Online Services" from the Quick Links menu, log in to the Board's system, and certify the completion of their CE. Alternatively, pharmacists can access a Certification of Completion of CE form on the Board's website by selecting "Forms" from the menu, filling out and signing the form, and sending it to the Board office.