



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 against **pharmacists** between the dates of April 17, 2014 and July 16, 2014:

Alsleben, Jerel L., License #111515. Mr Alsleben was the pharmacist-in-charge (PIC) of a pharmacy in which multiple violations related to the dispensing of controlled substances (CS) occurred. CS were dispensed to residents of long-term care facilities even though the pharmacy had not received legally valid prescriptions. The purported prescriptions received by the pharmacy did not contain some of the information required by federal and state law, such as a quantity; the prescriber's full name, signature, and address; and the date on which the prescription was written. Mr Alsleben admitted that he personally dispensed CS without receiving legally valid prescriptions. Consequently, the Board adopted a stipulation and consent order at its April 30, 2014 meeting that reprimanded Mr Alsleben and required him to pay a civil penalty in the amount of \$2,500.

Hmielewski, Trevor T., License #120466. Dr Hmielewski admitted that, as a PIC, he allowed an individual to work as a pharmacy technician for two months prior to the date on which that individual was first registered as a pharmacy technician. Consequently, the Board adopted a stipulation and consent order at its April 30, 2014 meeting that reprimanded Dr Hmielewski and required him to pay a civil penalty in the amount of \$250.

Parry, David M., License #111803. Mr Parry was the owner of a pharmacy in which multiple violations related to the dispensing of CS occurred. CS were dispensed to residents of long-term care facilities even though the pharmacy had not received legally valid prescriptions. The purported prescriptions received by the pharmacy did not contain some of the information required by federal and state law, such as a quantity; the prescriber's full name, signature, and address; and the date on which the prescription was written. Mr Parry admitted that he personally dispensed CS without receiving legally valid prescriptions. Some of the purported prescriptions were actually refill requests for Schedule II CS that were faxed to the pharmacy by a long-term care facility. That facility had never obtained prescriptions or orders from the prescribers in question. The pharmacy dispensed CS based on these refill requests without obtaining a valid prescription. In addition, biennial inventories were not completed for the pharmacy in a timely manner. An audit of the pharmacy conducted by Board surveyors revealed significant shortages of several Schedule II CS. Mr Parry also admitted

that he was not completing certification and quality assurance checks for filled prescriptions. Consequently, the Board adopted a stipulation and consent order at its April 30, 2014 meeting that reprimanded Mr Parry and required him to pay a civil penalty in the amount of \$10,000.

The Board took the following disciplinary actions against a **pharmacy** between the dates of April 17, 2014 and July 16, 2014:

Walgreens Pharmacy #2805, License #259859. Representatives of this pharmacy admitted that, when a patient presented at the drive-thru to pick up a filled prescription, he was also given two other prescriptions that had been filled for a different patient. While records indicated that the patient was counseled, it was unclear whether the patient actually was counseled because none of the pharmacists on duty recalled counseling the patient. This Walgreens pharmacy did not utilize a refusal log to document when patients refused consultation and the pharmacy's system for indicating whether a consultation occurred did not meet Board standards. Consequently, the Board adopted a stipulation and consent order at its April 30, 2014 meeting that reprimanded the pharmacy and required payment of a civil penalty in the amount of \$2,000.

2014 Legislation Concerning the Practice of Pharmacy

During the 2014 Minnesota State Legislative Session, many changes were made to the statutes that will have an impact on the practice of pharmacy. Other changes will have an impact on the Board, but will not have a direct impact on licensees and registrants. The following is a summary of one of the most significant changes. The next several editions of this *Newsletter* will summarize other changes. Additional information can be found on the Board's website. The Board strongly advises licensees and registrants to review documents provided on its website that are related to the changes made in statutes this year. These changes have already gone into effect. You may also contact Board staff if you have questions about changes in the statutes.

Changes to the Definition of 'Practice of Pharmacy'

The following changes were made to the definition of "practice of pharmacy:"

- ◆ In the past, this definition did not specifically state that pharmacists could perform laboratory tests that are waived under the federal Clinical Laboratory Improvement Act of 1988. The Board interpreted the old definition to allow pharmacists to

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New Educational Video for Pharmacists Addresses Prescription Drug Abuse

The National Association of Boards of Pharmacy® (NABP®) and the Anti-Diversion Industry Working Group (ADIWG), a consortium of pharmaceutical manufacturers and distributors of controlled substances (CS), have released an educational video for pharmacists to help them identify the warning signs of prescription drug abuse and diversion when dispensing CS prescriptions. The video, entitled “Red Flags,” encourages pharmacists to help combat this national problem by exercising their professional judgment to ensure that the prescriptions they dispense were written for a legitimate medical purpose, and to act upon any unusual behavior they observe.

Drug Enforcement Administration and various state pharmacy boards have described “red flags” as circumstances surrounding the presentation of a CS prescription that should raise reasonable suspicion about the validity of that prescription. The video highlights a number of these potential warning signs, some of which are not easy to spot, by weaving personal narratives with interactions between pharmacists and customers.

The video is available in the Pharmacists section of the AWARE_xE® Prescription Drug Safety website at www.AWARERX.ORG/pharmacists.

Root Causes: A Roadmap to Action

 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 Error Reporting Program Report online at www.ismp.org. E-mail: ismpinfo@ismp.org.

Errors are almost never caused by the failure of a **single** element in the system. More often, there are **multiple** underlying system failures that lead to an error, many of which can be identified when the involved health care providers take the time to uncover them.

Consider the following error: A doctor sent a hand-written order for carbamazepine 400 mg twice daily for an adult patient with a history of seizures.

The pharmacist entered the medication into the profile of a four-year-old child with the same last name as the adult patient for whom the medication had been prescribed.

The pharmacist failed to notice that the patient was a child, as age was not in a prominent location on the order entry screen. The nurse failed to recognize that the dose was too high and administered 400 mg of carbamazepine to the child. She also never thought to question why the pharmacy would send oral tablets for a four-year-old child, considering that the drug is available in chewable tablets and as a liquid suspension.

The nurse **assumed** that the child was receiving the medication because he had a history of seizures. However, the nurse did not check the patient’s medical record. In fact, the child did **not** have a history of seizures.

The parents had a very limited understanding of English, so they were unable to intervene to correct the erroneous seizure history.

The error was finally detected after the child became lethargic and developed nausea and vomiting. At the time of discovery, the child’s carbamazepine level was 18 mcg/mL; levels greater than 12 in pediatric patients are supratherapeutic.¹

It may be discouraging to see how many things go wrong when a medication error reaches a patient. However, a thorough root cause analysis (RCA) can uncover the latent failures and produce an action plan to avoid future errors.

ISMP, through a generous grant from the National Association of Boards of Pharmacy Foundation™, has developed the *Root Cause Analysis Workbook for Community/Ambulatory Pharmacy*. The workbook is designed to assist community pharmacy personnel in completing RCA for a sentinel event that may have occurred in their pharmacy. The RCA workbook uses a specific set of steps and associated tools to identify the primary causes of the **sentinel event**.

The goal of the RCA is to create an action plan framework, including risk-reduction strategies, communication and implementation strategies, and measurement of effectiveness.

RCA for **sentinel events** is required in the Center for Pharmacy Practice Accreditation’s standards developed by NABP, American Pharmacists Association, and American Society of Health-System Pharmacists Association, as well as by several boards of pharmacy in conjunction with their continuous quality improvement regulations.

This ISMP RCA workbook is suitable for use in community pharmacy, mail-order pharmacy, or other ambulatory pharmacy practice settings that need to investigate a **sentinel event**. For more information and to access the **free** workbook, visit www.ismp.org/tools/rca/.

¹<http://pediatrics.aappublications.org/content/113/2/406.abstract>



FDA Withdraws Approval of Some High Dose Acetaminophen Products

Food and Drug Administration (FDA) is withdrawing approval of 108 abbreviated new drug applications (ANDAs) for prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit. For the 108 ANDAs, the manufacturers asked to withdraw their applications, as announced in the March 27, 2014 *Federal Register* notice. A second *Federal Register* notice addresses the applications of six manufacturers who have discontinued marketing their products, but who have not withdrawn their applications. The notice also announces FDA's intention to begin the process of withdrawing approval of those applications.

In light of these announcements, and to protect patients from inadvertent acetaminophen overdose, NABP advises that pharmacies no longer dispense combination drugs containing more than 325 mg of acetaminophen per dosage unit. NABP also advises that pharmacists consult with prescribers to discuss alternative products with lower acetaminophen doses.

FDA asked manufacturers to voluntarily withdraw these products from the market to reduce the risk of severe liver injury from inadvertent acetaminophen overdose. In January 2014, FDA recommended that providers consider prescribing acetaminophen products containing 325 mg or less per dose. The original announcement may be found in the Drug Safety and Availability section of FDA's website at www.fda.gov/Drugs/DrugSafety.

NCPDP Recommends Standardized Metric Measurements on Oral Liquid Medication Labels

The National Council for Prescription Drug Programs (NCPDP) has issued new recommendations and guidance for standardizing the dosing designation used on prescription container labels of oral liquid medications dispensed by community pharmacies in order to reduce dosing errors. NCPDP notes that such errors have been "a source of concern for many years," and that dosing errors involving young children are of particular concern because they may be more susceptible to harm from measurement errors and overdoses. The paper outlines the following recommendations for the dosing designation on prescription container labels for oral liquid medications:

- ◆ The millimeter (mL) should be used as a standard unit of measurement.
- ◆ Dose amounts should always use leading zeros before decimal points for amounts less than one and should not use trailing zeros after a decimal point.

- ◆ Dosing devices with numeric graduations and units corresponding to the container label should be made easily and universally available. For example, a device should be included with each dispensed medication.

The white paper was developed following a meeting with stakeholders representing 27 participants, including NABP. In addition to its general recommendations, the white paper also issued calls to action for relevant stakeholders, including government agencies, standards organizations, pharmacists and pharmacy technicians, pharmacy leadership, and health care associations. The white paper, *NCPDP Recommendations and Guidance for Standardizing the Dosing Designations on Prescription Container Labels of Oral Liquid Medications*, is available for download from the NCPDP website at <http://ncdp.org/Education/Whitepaper>.

USP Proposes New General Chapter Addressing Compounding of Hazardous Drugs

In an effort to protect health care providers and personnel who handle hazardous drugs, United States Pharmacopeial Convention (USP) has proposed new General Chapter <800> Hazardous Drugs—Handling in Healthcare Settings. The new proposed chapter addresses standards that apply to all personnel who compound hazardous drug preparations and all places where hazardous drugs are prepared, stored, transported, and administered. The new chapter also covers standards for receiving, storing, compounding, dispensing, administering, and disposing of nonsterile and sterile products and preparations. The proposed chapter applies to all personnel who are involved in handling hazardous drugs, including health care providers and staff, occupational health and safety specialists, and human resources. General Chapter <800> was published in the May/June issue of *Pharmacopeial Forum*, and may currently be viewed on the USP website at www.usp.org/usp-nf. Comments were accepted until July 31, 2014.



Pharmacists & Technicians:
Don't Miss Out on Valuable CPE Credit.
Set Up Your NABP e-Profile and Register for CPE Monitor Today!

Continuing pharmacy education (CPE) providers who are accredited by the Accreditation Council for Pharmacy Education (ACPE) have integrated CPE Monitor[®] into their systems and are requiring pharmacists and pharmacy technicians to provide an NABP e-Profile ID number and date of birth (MMDD) in order to process ACPE-accredited CPE credit.

Visit www.MyCPEmonitor.net to set up your NABP e-Profile and register for CPE Monitor and avoid possible delays in your CPE reporting.

CPE Monitor is a national collaborative service from NABP, ACPE, and ACPE providers that will allow licensees to track their completed CPE credit electronically.

perform those tests, but received quite a few questions about that interpretation. The statutes now state that pharmacists may perform “laboratory tests that are waived under the federal Clinical Laboratory Improvement Act of 1988 . . . provided that a pharmacist may interpret the results of laboratory tests but may modify drug therapy only pursuant to a protocol or collaborative practice agreement.”

- ◆ The portion of this definition that allows pharmacists to provide immunizations has been modified. Pharmacists have been able to provide immunization pursuant to “standing orders” or a protocol issued by a physician for many years. The modifications made this session require the use of a protocol containing, at a minimum, certain information specified in the statutes. The protocol may now be issued by a physician, physician assistant, or advanced practice registered nurse (APRN). Standing orders are no longer permitted.

In order to provide immunizations, a pharmacist must have completed a program approved by the Accreditation Council for Pharmacy Education specifically for the administration of immunizations or a program approved by the Board. Graduation from a college of pharmacy after 2001 is no longer sufficient. The Board will develop a list of colleges of pharmacy that provide approved immunization training. A pharmacist who completes immunization training at one of those colleges will not have to complete additional training. Pharmacists must comply with guidelines for vaccines and immunizations established by the federal Advisory Committee on Immunization Practices (ACIP), except that a pharmacist does not need to comply with those portions of the guidelines that establish immunization schedules when administering a vaccine pursuant to a valid, patient-specific order issued by a physician licensed under Chapter 147, a physician assistant authorized to prescribe drugs under Chapter 147A, or an advanced practice nurse authorized to prescribe drugs under Section 148.235, provided that the order is consistent with United States Food and Drug Administration (FDA)-approved labeling of the vaccine. This means that an immunization protocol **must** follow the immunization schedules established by ACIP. However, a pharmacist can administer a vaccine outside of those schedules as long as the administration is ordered for a specific patient by a physician, physician assistant, or APRN, and as long as the vaccine is being administered in a manner approved by FDA.

- ◆ Pharmacists have long been able to participate in “managing and modifying” therapy pursuant to a protocol between an individual pharmacist and the individual dentist, optometrist, physician, podiatrist, or veterinarian responsible for a patient’s care. Pharmacists may now participate in the “initiation, management, modification, and discontinuation of drug therapy according to a written protocol or collaborative practice agreement between: (i) one or more pharmacists and one or more dentists, optometrists, physicians, podiatrists, or veterinarians; or (ii) one or more pharmacists and one or more physician assistants authorized to prescribe, dispense, and administer under chapter 147A, or advanced practice nurses authorized to prescribe, dispense, and administer under section 148.235.”

When establishing protocols, there no longer needs to be a one-to-one relationship between a specific pharmacist and a specific practitioner. For example, the medical director of a clinic could establish a protocol for drug therapy management that covers all pharmacists and relevant practitioners employed by the clinic without having to list each individual by name. In addition, pharmacists

can now enter into drug therapy management protocols directly with physician assistants and APRNs.

Note that pharmacists can also enter into collaborative practice agreements with practitioners. While the term “collaborative practice agreement” has long been used by pharmacists, it actually had no legal meaning until the passage of these changes to the definition of the practice of pharmacy. The terms “protocol,” “collaborative practice,” and “collaborative practice agreement” are now defined in the statutes.

“Protocol” means: (1) a **specific** written plan that describes the nature and scope of activities that a pharmacist may engage in when initiating, managing, modifying, or discontinuing drug therapy as allowed in Subdivision 27, Clause (6); or (2) a **specific** written plan that authorizes a pharmacist to administer vaccines and that complies with Subdivision 27, Clause (5). A protocol is a detailed, written set of instructions to be followed by a pharmacist when initiating, managing, and modifying therapy. It is not a general or blanket authorization for a pharmacist to make unspecified changes to drug therapy.

“Collaborative practice” means patient care activities, consistent with Subdivision 27, engaged in by one or more pharmacists who have agreed to work in collaboration with one or more practitioners to initiate, manage, and modify drug therapy under specified conditions mutually agreed to by the pharmacists and practitioners. “Collaborative practice agreement” means a written and signed agreement between one or more pharmacists and one or more practitioners that allows the pharmacist or pharmacists to engage in collaborative practice. Unlike a protocol, a collaborative practice agreement does not have to consist of detailed, step-by-step instructions that must be followed by a pharmacist. Instead, a collaborative practice agreement can more broadly allow pharmacists to participate in initiating, managing, and modifying therapy. Note that collaborative practice agreements may include protocols but they do not have to include them.

In Memoriam

Paul Grussing, Former Executive Secretary

Dr Paul Grussing recently passed away at the age of 81. He was the executive secretary of the Board from July 1965 until November 6, 1973. He was born on April 7, 1933, to George and Anna Grussing and grew up in Clara City, MN. He attended Macalester College and graduated from the University of Minnesota (U of M) in 1954. He then served in the US Army in Frankfurt, Germany. After serving as the executive secretary of the Board, Paul returned to U of M and earned a PhD in 1978. He was a professor of pharmacy administration at the University of Illinois at Chicago for nearly 20 years, and was twice awarded the Rufus A. Lyman Award for the best paper published in the American Journal of Pharmaceutical Education. He and his wife, Ann Bangsund Grussing, retired in 1988 to a lakeside home that he designed in Pillager, MN. Paul was devoted to his friends, his church, his community, and his family. Ann preceded him in death in 2012. He is survived by his brother, Roger Grussing, of Pillager, his son, Jon Grussing, of London, England (along with Jon’s wife, Kate, and four children), and his daughter, Jane Lonnquist, of Edina, MN (along with Jane’s husband, John, and two children).

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