



# 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 action concerning a **pharmacist** between the dates of April 11, 2013 and June 19, 2013.

**Hins, Dennis D., License #112063.** Mr Hins erroneously dispensed methadone to a patient. The drug actually prescribed was methotrexate. He admitted that he was not doing quality assurance as required by Minnesota Rules 6800.3950, Subp 4. He further admitted that he had not developed a quality assurance policy, despite having been instructed to do so during an earlier routine inspection. Consequently, the Board adopted a stipulation and consent order at its May 1, 2013 meeting, which reprimanded Mr Hins, required him to pay a civil penalty in the amount of \$2,500, and required him to complete a continuing education course focusing on error prevention.

The Board took the following disciplinary actions concerning **pharmacy technicians** between the dates of April 11, 2013 and June 19, 2013.

**Anderson, Michelle G., Registration #702905.** Ms Anderson admitted that she stole several bottles of prescription medications from her employer. As a result, she was charged with felony theft in December 2012. Consequently, at its May 1, 2013 meeting, the Board adopted a stipulation and consent order for the voluntary surrender of Ms Anderson's registration.

**Sannes, Paige M., Registration #726105.** From September 2010 through December 2011, Ms Sannes had multiple charges and convictions for alcohol-related offenses in North Dakota and Minnesota. As a result, her North Dakota registration as a pre-pharmacy intern was placed on conditional status in January 2012. The North Dakota State Board of Pharmacy revoked her registration in July 2012 for failure to submit required reports. Ms Sannes also pleaded guilty to shoplifting in July 2012. She failed to fully disclose her convictions when registering with the Minnesota Board as a pharmacy technician in August 2012. Consequently, at its May 1, 2013 meeting, the Board adopted an order that reprimanded Ms Sannes and required her to pay a \$250 civil penalty. In addition, Ms Sannes

was required to enroll in the Health Professionals Services Program (HPSP).

The Board took the following disciplinary action concerning a **pharmacy** between the dates of April 11, 2013 and June 19, 2013.

**AlixRx, License #263885.** Representatives of AlixRx admitted that personnel of the pharmacy compounded sterile products without proper training and that on at least one occasion, pharmacy technicians were working without proper supervision because the pharmacy was out of compliance with the allowed technician-to-pharmacist ratio. Consequently, the Board adopted an order at its May 1, 2013 meeting that reprimanded AlixRx and imposed a civil penalty of \$5,000.

## **Board to Hire Additional Pharmacists Soon**

During the 2013 Legislative Session, the Board was granted a \$210,000 increase in its appropriation for the purpose of hiring additional staff. Note that there was no need to request for fee increases. The number of licenses issued by the Board has increased at a greater than expected rate, so there will be sufficient new revenue to offset the increase in spending. The Board is awaiting final approval to create two new positions.

- ◆ Deputy director will be classified as a pharmacist senior, a classification that is at the same pay grade as the pharmacy surveyor classification, but which has different class specifications. The deputy director will report to the executive director and will be "second-in-command" when it comes to the Board's operations. The deputy will also focus on certain aspects of the complaint and disciplinary processes and will be assigned to work on some of the many policy issues that currently confront the Board. Additional education or experience working closely with pharmacy- and drug-related laws, rules, or policy will be preferred for this position.
- ◆ Pharmacy surveyor will be classified as a pharmacy surveyor. The individual filling this position will join with the existing pharmacy surveyors to inspect facilities; review inspection reports submitted by out-of-state facilities that are licensed by the Board; investigate complaints; provide consultation to licensees, registrants, and the public; and participate in the review of variances and policies, etc.

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## Pharmacists Likely to Recommend OTC Medications, CHPA Reports

Patients most often seek a pharmacist's advice on treating coughs, headaches, migraines, and allergies, and 98% of pharmacists recommend or have no reservations recommending over-the-counter (OTC) products to treat such ailments, according to a recent survey. The Consumer Healthcare Products Association's (CHPA) report, "Understanding Trust in OTC Medicines: Consumers and Healthcare Provider Perspectives," presents the results of the survey, which was developed to better understand what drives consumer and health care provider trust in OTC products. The survey, developed and conducted by Nielsen and IMS, included over 1,100 consumer respondents, and over 500 health care provider respondents, composed of pharmacists, pediatricians, nurse practitioners, and primary care providers.

Pharmacists surveyed reported that they were more likely to recommend OTC products that demonstrated successful patient outcomes and consistent outcomes, and products known to be as efficacious as a prescription drug, and those containing ingredients known to be safe.

The survey also asked health care providers whether they recommended OTC products without, before, or in conjunction with recommending prescription drugs for certain symptoms. A majority of pharmacists surveyed, over 60%, recommend OTC medications to treat stomach symptoms and pain, without recommending a prescription treatment, and over 70% recommended OTC allergy, sinus, and flu medications without advising that a prescription drug is needed.

CHPA notes that with the expansion of patient self-care, OTC products will play an increasingly important role in health care. The potential for more prescription products to become OTC products in the new paradigm under consideration by Food and Drug Administration (FDA) could further impact this trend. As consumers are becoming more empowered in making health care decisions, they are also relying more on their pharmacist for medication advice. In fact, Nielsen and IMS findings show that multigenerational households, Hispanic households, and households who care for an adult outside of their home place a high value on pharmacist recommendations regarding selecting appropriate OTC medications, notes CHPA.

The full CHPA White Paper is available at [www.yourhealthathand.org/images/uploads/OTC\\_Trust\\_Survey\\_White\\_Paper.pdf](http://www.yourhealthathand.org/images/uploads/OTC_Trust_Survey_White_Paper.pdf).

## ISMP Study on Targeted Mandatory Patient Counseling

 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](http://www.ismp.org). ISMP is a federally certified patient safety organization, providing legal protection and confidentiality for submitted patient safety data and error reports. ISMP is also an FDA MedWatch partner. Call 1-800/FAIL-SAF(E) to report medication errors to the ISMP Medication Errors Reporting Program or report online at [www.ismp.org](http://www.ismp.org). ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: [ismpinfo@ismp.org](mailto:ismpinfo@ismp.org).

In a recent study funded by a grant from Agency for Healthcare Research and Quality, ISMP evaluated the use of a combined checklist and patient information leaflet used during mandatory counseling sessions for consumers who pick up a filled prescription for 11 targeted medications:

- ◆ Opioid-containing analgesics
  - ◇ fentanyl patches
  - ◇ hydrocodone with acetaminophen
  - ◇ oxycodone with acetaminophen
- ◆ Anticoagulants
  - ◇ warfarin
  - ◇ enoxaparin
- ◆ Antidiabetic drugs (insulin analogs)
  - ◇ Humalog® (insulin lispro)
  - ◇ NovoLog® (insulin aspart)
  - ◇ Levemir® (insulin detemir)
  - ◇ Lantus® (insulin glargine)
  - ◇ Apidra® (insulin glulisine)
- ◆ Antineoplastic drug (non-oncologic use)
  - ◇ methotrexate

All 11 medications are on ISMP's list of high-alert medications dispensed from community pharmacies. Errors with high-alert medications may not be more frequent than errors with other medications; however, the consequences of errors with high-alert medications are often harmful. These 11 medications are also among the top 200 drugs dispensed in the United States, and many are used to treat chronic conditions, thus increasing the potential impact on public safety.

The medications were flagged in some manner to identify mandatory counseling opportunities. When a patient or patient representative picked up a flagged prescription, a pharmacist conducted a short counseling session (one to three minutes) that included the exchange of several key points on the checklist. At the end of the counseling session, the pharmacist provided the leaflet to the patient, along with a survey to complete and send back to ISMP.

Counseling sessions for these drugs were conducted for a consecutive period of four weeks, during which time, one trained ISMP staff member observed the counseling sessions for one day (six hours) to collect information on factors that facilitate or inhibit the counseling sessions. At the end of the four-week period of mandatory counseling, pharmacists at participating pharmacies were asked to complete a short mail-in survey regarding their perceived value of the process.

Results of the study showed that these consumer leaflets offer important safety tips for taking medication safely. Each leaflet begins with, "High-alert medicines have been proven to be safe and effective. But these medicines can cause serious injury if a mistake happens while taking them. This means that it is vitally important for you to know about this medicine and take it exactly as intended."

ISMP tested the readability, usability, and perceived value of the leaflets. Ninety-four percent of patients felt the leaflets provided great information or good information to know. Ninety-seven percent felt the information in the leaflets was provided in a way they could understand. Eighty-two percent of patients taking the drug for the first time and 48% of patients who had previously taken the medication reported learning something new. Overall, 85% of the patients felt they were less likely to make a mistake with the medication because they had read the leaflet.

The leaflets are available for download and can be reproduced for free distribution to consumers at [www.ismp.org/AHRQ/default.asp?link=ha](http://www.ismp.org/AHRQ/default.asp?link=ha).

## Generic Drug Substitution Requires Pharmacist Attention to State Laws and Regulations

While 40 years ago, most states forbade prescription drug substitution, almost all states now have drug product selection laws that allow,



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encourage, or mandate pharmacists to substitute generics for brand-name drugs. These laws vary widely from state to state and pharmacists are therefore encouraged to review their state's substitution laws to ensure that they understand and comply with the state's requirements.

FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations* publication, commonly known as the *Orange Book*, is generally considered the primary source for identifying suitable generic alternatives for a brand-name drug, and while not mandated by FDA regulations, the majority of states use the *Orange Book's* determinations of therapeutic equivalence to legally guide pharmacists in substituting generics.

State laws on generic substitution vary widely. A few states, such as Kentucky or Minnesota, follow a "negative formulary" approach, in which substitution is permitted for all drugs except those that appear on a particular list. Other states, including Massachusetts and Wisconsin, use a "positive formulary" approach, in which substitution is limited to the drugs on a particular list.

States also differ as to whether their substitution laws are permissive, thereby allowing a pharmacist to substitute a generic version of a brand-name drug, provided all prescription requirements are met, or mandatory, thereby requiring substitution. Prescription requirements may include such factors as the availability of a cheaper, therapeutically equivalent drug, the prescriber's specification that a brand-name drug be dispensed, or requiring the patient's or prescriber's consent. As reported in the 2013 NABP *Survey of Pharmacy Law*, 14 boards of pharmacy indicate that generic substitution falls into the "mandatory" category, while 38 boards indicate that their substitution laws are "permissive." Oklahoma law states that "[I]t is unlawful for a pharmacist to substitute without the authority of the prescriber or purchaser."

Other regulatory variations include states specifying the acceptable means for the prescriber to designate that substitution is not authorized, and states requiring patient consent prior to substitution.

The full article on this subject, which also reviews considerations regarding the accuracy of therapeutic equivalent determinations, will be available in the forthcoming June-July 2013 *NABP Newsletter*, which will be accessible in the Publications section of [www.nabp.net](http://www.nabp.net).

## **NHF Provides Standards of Care for Pharmacies Serving Hemophilia Patients**

For pharmacies that offer blood-clotting medications, organizations such as the National Hemophilia Foundation (NHF) emphasize the importance of being able to meet the specialized needs of their patients with bleeding disorders.

NHF's Medical and Scientific Advisory Council (MASAC) issued a standards-of-care recommendation in 2008 to assist pharmacies providing clotting factor concentrates for home use to patients with bleeding disorders. MASAC's guidelines are intended to be minimum standards of care and are divided into six areas:

As a brief overview of the MASAC guidelines, pharmacists wishing to meet the standards should:

1. Have a basic knowledge of bleeding disorders; experience with and knowledge of the full range of clotting factor concentrates, ancillary supplies, and hazardous waste disposal; and the background to communicate relevant trends or issues to the patient.

Pharmacies wishing to meet MASAC standards:

2. Should be able to provide a full range of available concentrates in all available assays and vial sizes, along with all necessary ancil-

lary supplies, and hazardous waste disposal assistance as well as access to nursing services.

3. Should support reliable access to clotting factor for appropriate home treatment, by filling prescription orders exactly as written within 48 hours, in the quantities prescribed, with expiration dates commensurate with the individual patient's needs.
4. Should be reliably open during regular business hours; provide 24-hour emergency access; and have an emergency action plan that allows patients to receive factor within 12 hours "in case of emergent need," with a goal of three hours "where logistically possible."
5. Should deliver products to the patient's desired location, meeting federal medication shipping standards, and providing an emergency number for patients to call in case of a problem with a delivery.
6. Should maintain patients' treatment prescription information along with maintaining records in compliance with state and federal requirements; be able to track the clotting factor products from manufacturer to patient, and participate in a recall information system; and regularly review insurance payment information with patients, and provide unit cost information to help patients manage medication costs.

The full article regarding standards of care for hemophilia patients, including information on state implementation of such standards, will be available in the forthcoming June-July 2013 *NABP Newsletter*, which will be accessible in the Publications section of [www.nabp.net](http://www.nabp.net).

## **NABPLAW Online Now Includes Guam, Puerto Rico, and the Virgin Islands**

The complete pharmacy acts and regulations of Guam, Puerto Rico, and the Virgin Islands are now included in NABPLAW® Online, the comprehensive national data bank of state pharmacy laws and regulations provided by NABP. NABPLAW Online's powerful search capabilities allow users to research subjects one state at a time or across all 50 states and included jurisdictions. More information about NABPLAW Online and a link to the online subscription order form are available in the Programs section of the NABP Web site at [www.nabp.net/programs/member-services/nabplaw/](http://www.nabp.net/programs/member-services/nabplaw/).



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Creation of these positions is necessary because of the Board's increased workload. The number of licenses and registrations issued by the Board has increased substantially in recent years. Also, in response to the fungal meningitis outbreak linked to a Massachusetts compounding pharmacy, the legislature enacted statutes that will require much closer scrutiny of applications for out-of-state pharmacies, drug manufacturers, drug wholesalers, and medical gas distributors. The Board and its staff have also been asked to work on a variety of policy issues including synthetic designer drugs, prescription drug abuse, regulation of methadone treatment facilities, pharmaceutical waste, the "gray market" for pharmaceuticals, a complete revision of the Pharmacy Practice Act, and better regulation of compounding, drug shortages, and more.

Pharmacists who are interested in these positions should regularly check the Board's Web site for additional announcements. The plan is to have these positions filled by late summer or early fall.

### **Health Professionals Services Program**

The Board investigates at least a dozen complaints each year against pharmacists and technicians involved in the alleged diversion of controlled substances, the abuse of alcohol, or the inability to safely practice due to a mental illness. The Board takes such complaints seriously because, left untreated, substance abuse and other mental illnesses can put patients at risk. Fortunately, licensed and registered health professionals can get help before they become the subject of disciplinary action. Created in 1994 as an alternative to Board discipline, the state of Minnesota's HPSP offers a proactive way to get confidential help for illnesses.

HPSP evaluates professionals and, if necessary, enters into participation agreements with them. HPSP monitors treatment progress, work quality, and medications, along with attendance at support groups. Random urine screens (if alcohol or drug use is part of the illness), counseling, work limitations, or other stipulations that address both the professional's needs and public safety might also be required. Typically, agreements are for 36 months. A health professional who self-reports to HPSP and who fulfills the conditions of a participation agreement is not reported to the relevant licensing board.

To learn more about HPSP and how to refer someone who may have an illness, call 651/643-2120, visit its Web site at [www.hpsp.state.mn.us](http://www.hpsp.state.mn.us), or write for information at Energy Park Place, 1380 Energy Park Lane, Suite 202, St Paul, MN 55108.

### **Pharmacist Interns and Preceptors**

Approximately 165 University of Minnesota pharmacy students, plus students from colleges of pharmacy in surrounding states, 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 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.

### **In Memoriam**

#### **Lester Hackner – Former Board Member**

Lester Hackner recently passed away at the age of 85. He attended Johnson High School in Minneapolis, MN, and served in the United States Army during World War II. Lester graduated from the University of Minnesota College of Pharmacy in 1951. He worked for 37 years as a pharmacist at Gray's Drug, becoming a co-owner in 1976. Lester was actively involved in pharmacy-related organizations. He was a member of the Minnesota Pharmacists Association, the American Pharmacists Association (APhA), the National Association of Retail Drug-gists (now the National Community Pharmacists Association), and Phi Delta Chi. He served as president of the University of Minnesota Pharmacy Alumni Society and was on the Board of Directors for the Century Mortar Club. He was appointed to the Minnesota Board of Pharmacy in January of 1984 and served for four years. The Board recognizes and honors Lester's service to the public and to the profession, and offers its condolences to his family and friends.

#### **Louise Schmitz Kortz – Former Board Member**

Louise Schmitz Kortz also recently passed away, at the age of 99. She attended Central High School in Minneapolis and graduated from the University of Minnesota College of Pharmacy in 1936. Louise maintained an active pharmacist license for more than 50 years, and worked as a hospital pharmacist at St Barnabas in Minneapolis and St Mary's in Rochester, MN. She also worked for the APhA and in 1983 was chosen as honorary chair of the APhA Board of Directors. She was appointed to the Minnesota Board of Pharmacy in 1975 by Governor Wendell Anderson and served for four years. The Board recognizes and honors Louise's service to the public and to the profession, and offers its condolences to her family and friends.

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