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Minnesota Board of Pharmacy News

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Disciplinary Activity

At its October and December meetings, the Minnesota Board of Pharmacy took disciplinary action against the following **pharmacists** and **technicians** in cases related to practicing or working without a current license or registration.

Armstrong, Diane C., Registration #726928. Failed to renew registration for calendar year 2014 in a timely manner; worked for approximately one month without an active registration; reprimand.

Blaney, Sheri L., Registration #704030. Failed to renew registration for calendar year 2014 in a timely manner; worked for approximately five weeks without an active registration; reprimand and $20 civil penalty.

Ferguson, Shandon L., Registration #716030. Failed to renew registration for calendar year 2014 in a timely manner; worked for approximately 10 weeks without an active registration; reprimand and $60 civil penalty.

Harris, Katherine Y., License #116972. While serving as a pharmacist-in-charge (PIC), allowed a technician to work without an active registration for a period of approximately 14 months; reprimand and $750 civil penalty.

Ikeri, Julian C., Registration #727912. Failed to renew registration for calendar year 2014 in a timely manner; worked for approximately nine weeks without an active registration; reprimand and $50 civil penalty.

McKeever, Gary J., Registration #728190. Failed to renew registration for calendar year 2014 in a timely manner; worked for approximately six weeks without an active registration; reprimand and $40 civil penalty.

Thompson, Craig A., License #116268. While serving as a PIC, allowed a technician to work without an active registration for a period of approximately one month; reprimand.

Thrall, Sarah A., Registration #727071. Worked for approximately eight weeks before she was first registered as a pharmacy technician; reprimand and $100 civil penalty.

Willgohs, Nathaniel B., License #115987. Failed to renew license by February 28, 2014; worked for approximately three weeks without an active license; reprimand and $150 civil penalty.

The Board took the following administrative disciplinary action against a **pharmacist** on November 3, 2014.

Arnold, Jennifer L., License #119190. On October 16, 2014, in the Second Judicial District Court (Ramsey County), licensee was found to be mentally ill, a danger to herself and others, and was civilly committed under Minnesota Statutes Chapter 253B. Pursuant to Minnesota Statutes Section 151.071, Subdivision 2(11), her license was automatically suspended due to the civil commitment.

The Board took the following disciplinary actions against a **pharmacy** at its October meeting.

The Compounding Shop Pharmacy, License #263643. The Board received documents from this Florida-based pharmacy that indicated that it had shipped repackaged bevacizumab (Avastin®) to Minnesota clinics for office use (ie, it did not receive prescriptions for individual patients and was therefore engaged in drug manufacturing and wholesale drug distribution without being licensed by the Board as either a wholesaler or manufacturer). Licensee did not admit to wrongdoing or violation of any statutes or rules that the Board is empowered to enforce but, to avoid the expense of further litigation, agreed that the Board could impose disciplinary action. Consequently, the Board adopted a stipulation and consent order that reprimanded the pharmacy and required payment of a civil penalty in the amount of $10,000.

The Board took the following disciplinary actions against **technicians** at its October and December meetings.

Findell, Gabrielle L., Registration #726346. Ms Findell admitted to her employer that she diverted controlled substances (CS) for personal use. The Board initiated a contested case against Ms Findell, who failed to appear at a prehearing conference before an administrative law judge. Consequently, the Board adopted Findings of Fact, Conclusions, and Final Order that suspended Ms Findell's registration for an indefinite period of time.

Hanson, Kendra A., Registration #726632. Ms Hanson admitted that she diverted hydrocodone-containing products from the pharmacy at which she worked and consumed them while on duty. She subsequently pleaded guilty to felony fifth-degree possession of a CS. The Board initiated a contested case against Ms Hanson, who failed to appear at a prehearing conference before an administrative law judge. Consequently, the Board adopted Findings of Fact, Conclusions, and Final Order that suspended Ms Hanson's registration for an indefinite period of time.

Henderson, Jason W., Registration #726503. Mr Henderson's employment at a pharmacy was terminated after he admitted to diverting hydrocodone-containing CS. He was subsequently charged with felony fifth-degree possession of a CS. The Board initiated a contested case against Mr Henderson, who failed to appear at a prehearing conference before an administrative law judge. Consequently, the Board adopted Findings of Fact, Conclusions, and Final Order that suspended Mr Henderson's registration for an indefinite period of time.

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DEA Finalizes Rule on CS Prescription Drug Disposal

In September 2014, Drug Enforcement Administration (DEA) published its final rule, titled the Disposal of Controlled Substances, that allows some DEA registrants to modify their registration to become authorized collectors. Under the new rule, some DEA registrants, including retail pharmacies, hospitals/clinics with an on-site pharmacy, manufacturers, distributors, reverse distributors, and narcotic treatment programs, may modify their registration with DEA to become authorized collectors. The final rule implements the Secure and Responsible Drug Disposal Act of 2010, which authorized DEA to develop and implement regulations that would allow authorized entities other than law enforcement to collect unused and unwanted prescription drugs, including controlled substances (CS), for disposal purposes. Proper disposal of unused prescription medication is a key method of preventing and reducing prescription drug abuse. The final rule took effect on October 9, 2014.

The full rule is available on the *Federal Register* website at *www.federalregister.gov/articles/2014/09/09/2014-20926/disposal-of-controlled-substances.*

System-Based Causes of Vaccine Errors

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.*

Immunizations are widely recognized as one of the most successful and cost-effective health interventions ever introduced worldwide. However, errors with vaccines can result in an unintended and unrecognized source of vulnerability. While the immediate impact of a vaccine-related error on a patient may not be serious, such errors may render the vaccine ineffective or reduce its effectiveness, leaving patients unprotected against serious diseases such as hepatitis A, hepatitis B, diphtheria, tetanus, measles, cervical cancer, and many others. In September 2012, ISMP (in cooperation with the California Department of Public Health) established the ISMP National Vaccine Errors Reporting Program (VERP) to collect data about the type of vaccine errors occurring and the reasons they occur. In ISMP's November 28, 2013 newsletter *(www.ismp.org/sc?id=307),* ISMP provided a summary analysis of error reports submitted to the ISMP VERP during its first year. The vaccinations that are most frequently associated with errors included *Haemophilus influenzae* type b conjugate (Hib); diphtheria and tetanus toxoids, acellular pertussis adsorbed, and inactivated poliovirus (DTaP-IPV); tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis adsorbed (Tdap); diphtheria, tetanus toxoid, and acellular pertussis adsorbed (DTaP); hepatitis A (HepA); hepatitis B (HepB); human papillomavirus quadrivalent (types 6, 11, 16, and 18), recombinant (HPV4); zoster; and measles, mumps, rubella, and varicella (MMRV). The most common contributing factors associated with the reported vaccine errors included mistakes in choosing age-dependent formulations of vaccines intended to prevent the same diseases; unfamiliarity with the vaccine, particularly its dose, dosing schedule, age specifications, route of administration, and the vaccine's various components (eg, combination vaccines, diluents, and powder); failure to check or verify the patient's age, health record, or state registry; similar vaccine names and abbreviations; similar and confusing vaccine labeling and packaging; unsafe storage conditions (eg, stored near other similar vaccines or unwanted temperature fluctuations); and expiration dates not noticed or misunderstood.

Practice Recommendations. Involve the patient or parent(s)/caregiver(s) in a vaccine verification process by:

1) Documenting the vaccine name, formulation (pediatric or adult, if applicable), lot number, and expiration date on the patient's vaccine record **prior** to preparation/administration of the vaccine,
2) Bringing the vial and syringe or the prefilled syringe along with the immunization record into the exam room,
3) Asking the patient or parent/caregiver to simultaneously verify the information on the immunization record while a health care provider reads the information on the label aloud,
4) Asking the patient or parent/caregiver if the verified vaccine is what he or she expected to be administered (based on an immunization schedule provided to the patient or parent/caregiver previously),
5) Preparing and administering the vaccine immediately after verification, and
6) Documenting the vaccine on the patient's medical record.

FDA Warns of Growing Network of Rogue Wholesale Drug Distributors

Through a new educational program called Know Your Source, Food and Drug Administration (FDA) is warning pharmacists and other health care providers to watch for counterfeit and unapproved drugs. Aimed at protecting patients from unsafe and ineffective drugs, the program advises providers to only purchase drugs from wholesale drug distributors licensed in their state. Further, FDA offers tips to providers to protect patients, including being wary of offers too good to be true, and ensuring that all drugs received are FDA-approved medications.

Another way that pharmacies can be assured of the legitimacy of a wholesale distributor is to look for the National Association of Boards of Pharmacy® (NABP®) Verified-Accredited Wholesale Distributors® (VAWD®) Seal. Those wholesale distributors that achieve VAWD accreditation are in compliance with state and federal laws, as well as NABP's VAWD criteria. Wholesale distributors that display the VAWD Seal as part of their accreditation have undergone a criteria compliance review, including a rigorous

review of their operating policies and procedures, licensure verification, survey of facility and operations, background checks, and screening through the NABP Clearinghouse. Accredited facilities are reviewed annually and undergo a site survey every three years. Created in 2004, the accreditation program plays a pivotal role in preventing counterfeit drugs from entering the United States drug supply.

Additional information about the VAWD program is available in the Programs section of the NABP website. Know Your Source is available at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm389121.htm*.

PTCB Implements Changes to CE Requirements

In 2015, the Pharmacy Technician Certification Board (PTCB) will implement two changes in recertification requirements for certified pharmacy technicians (CPhTs) in accordance with its certification program changes announced in 2013. First, any continuing education (CE) hours earned by a CPhT will need to be pharmacy technician-specific in order to qualify toward recertification. Second, PTCB will reduce the number of allowable "in-service" CE hours from 10 to five. PTCB's certification program changes are intended to support and advance improved patient care and safety throughout pharmacy practice, a PTCB press release indicates. The changes are the result of a PTCB initiative that began with a 2011 summit on future directions for pharmacy technicians.

Additional information can be accessed on the PTCB website at *www.ptcb.org*.

Security Guidelines Available as Rate of Pharmacy Robberies Still a Concern

Nationally, pharmacy robberies dipped slightly from 745 in 2012, to 713 in 2013, according to a report compiled by *Drug Topics* using DEA statistics. The 10 states that had the most robberies are in stark contrast to other states that had no robberies (South Dakota, North Dakota, and Alaska) or as few as one or two (such as Montana and Illinois), reports *Drug Topics*. However, fueled by the prescription drug abuse epidemic, pharmacy robberies still pose a threat to the safety of personnel and customers. The report lists the top 10 states that had the most pharmacy thefts in 2013. Arizona experienced the most pharmacy robberies in 2013 with 77 incidents, and Indiana took second place with 71 robberies. The report, titled "Top 10 states for pharmacy robberies," may be found at *http://drugtopics.modernmedicine.com/drug-topics/content/tags/arizona/top-10-states-pharmacy-robberies?page=full.*

NABP partnered with DEA to create an educational pamphlet identifying key strategies pharmacists can take to secure their stores against robberies, which can be downloaded at *www.deadiversion.usdoj.gov/pubs/brochures/pharmtheft.pdf*. In addition, some boards of pharmacy have identified best practices for preventing pharmacy theft, and have supported these practices through regulations or recommendations for their licensees. For example, the New Jersey State Board of Pharmacy's *Pharmacy Security Best Practices* document recommends that all Schedule II and III CS be stored in a "safe or substantially constructed steel cabinet that is locked at all times," with only licensed pharmacists having access. Additional recommendations include annual pharmacist-in-charge self-assessments and interfacing with prescribers and customers, among others. The best practices document can be downloaded from the New Jersey Consumer Affairs website at *www.njconsumeraffairs.gov/press/05012013.pdf.*

Private organizations have also developed resources to assist pharmacies in improving security. One such resource is the RxPATROL program, which works with law enforcement, the pharmacy community, and security professionals to maintain a database containing detailed information about pharmacy robberies and other losses. In addition, the RxPATROL website, *www.rxpatrol.com*, provides training videos and a pharmacy security checklist.

Further, NABP members directed the Association to convene a task force to review strategies that states have taken to prevent theft and drug diversion. The Task Force to Examine Strategies for Preventing and Reacting to Pharmacy Robberies and Thefts met on October 22-23, 2014, to discuss these issues.

Assured Brand Naproxen Tablets Recalled Due to Packaging Error

In October 2014, Contract Packaging Resources of Greensboro, NC, a drug repackaging company, issued a voluntary recall of nearly 12,000 boxes of Assured brand naproxen sodium tablets because some cartons contain bottles of 200 mg ibuprofen softgels instead, a press release posted to the FDA website indicates. The packaging error affected boxes of Assured brand naproxen sodium tablets 220 mg, 15 count (Lot Number FH4102A), which were distributed to and sold at Dollar Tree stores and on the Dollar Tree website. Contract Packaging Resources is contacting customers to arrange for replacement of all recalled products. Adverse reactions or quality problems experienced with the use of this product may be reported to FDA's MedWatch Adverse Event Reporting Program.

More information is available on the FDA website at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm419769.htm.*

Martin Avenue Pharmacy Issues Voluntary Recall for All Sterile Compounded Preparations

Martin Avenue Pharmacy, Inc, of Naperville, IL, issued a voluntary recall for all in-date compounded sterile preparations due to a lack of sterility assurance in August 2014. Following a recent FDA inspection that revealed "quality control procedures that present a risk to sterility assurance," the company issued the recall out of an abundance of caution, indicates a news release posted to the FDA website. Martin Avenue Pharmacy supplied compounded sterile preparations to offices of licensed medical professionals and individuals in multiple states including Illinois, Wisconsin, Ohio, Michigan, Florida, Alabama, and Texas until August 20, 2014. A full list of recalled products is available on the Martin Avenue Pharmacy website (registration required). FDA urges consumers and health care providers to report adverse events or side effects related to the use of these products to FDA's MedWatch Safety Information Adverse Event Reporting Program.

More information is available on the FDA website at *www.fda.gov/Safety/Recalls/ucm412431.htm*.

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Lopez, Ricardo D., Registration #723189. Mr Lopez admitted to his employer that he diverted approximately 1,500 tablets of alprazolam and hydrocodone-containing products. He was subsequently convicted in a Minnesota District Court of felony theft. The Board initiated a contested case against Mr Lopez, who failed to appear at a prehearing conference before an administrative law judge. Consequently, the Board adopted Findings of Fact, Conclusions, and Final Order that suspended Mr Lopez's registration for an indefinite period of time.

Merrick, Anthony J., Registration #721263. Mr Merrick was terminated by his employer for suspected diversion of CS and admitted theft of shoe insoles. The Board initiated a contested case against Mr Merrick, who failed to appear at a prehearing conference before an administrative law judge. Consequently, the Board adopted Findings of Fact, Conclusions, and Final Order that suspended Mr Merrick's registration for an indefinite period of time.

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. Ms Sannes also pleaded guilty to shoplifting in July 2012. She failed to fully disclose her convictions when registering with the 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 Minnesota Health Professionals Services Program (HPSP). However, Ms Sannes violated that order by failing to enroll in HPSP. The Board initiated a contested case against Ms Sannes, who failed to appear at a prehearing conference before an administrative law judge. Consequently, the Board adopted Findings of Fact, Conclusions, and Final Order that suspended Ms Sannes' registration for an indefinite period of time.

Small, Jeffrey L., Registration #723194. Mr Small admitted to his employer that he diverted approximately 4,300 tablets of a hydrocodone-containing CS and sold them for profit. He was subsequently convicted in a Minnesota court of felony theft. The Board initiated a contested case against Mr Small, who failed to appear at a prehearing conference before an administrative law judge. Consequently, the Board adopted Findings of Fact, Conclusions, and Final Order that suspended Mr Small's registration for an indefinite period of time.

Starr, Laurie A., Registration #703566. Ms Starr admitted to police that she had diverted alprazolam, clonazepam, and temazepam from her employer for a period of 13 years. She was subsequently convicted of felony theft. The Board initiated a contested case against Ms Starr, who failed to appear at a prehearing conference before an administrative law judge. Consequently, the Board adopted Findings of Fact, Conclusions, and Final Order that revoked Ms Starr's registration.

Waste, Dori G., Registration #711761. Ms Waste admitted to her employer that she had diverted hydrocodone-containing CS for personal use. The Board initiated a contested case against Ms Waste, who failed to appear at a prehearing conference before an administrative law judge. Consequently, the Board adopted Findings of Fact, Conclusions, and Final Order that suspended Ms Waste's registration for an indefinite period of time.

Pharmacy Technicians Renewals

Pharmacy technician registration renewals are actually **due on December 1** of each year. The Board then provides a 31-day grace period, with December 31 being the deadline for renewing pharmacy technician registrations. Any technicians who do not renew their registration by that date must pay a late fee when their registration is renewed, and are not allowed to work as technicians. The PIC of each Minnesota pharmacy is responsible for making sure that all of the pharmacy technicians employed in his or her pharmacy have current technician registrations posted.

Technicians and PICs should note that many of the disciplinary cases described in the previous article involved technicians who continued working after failing to renew their registrations by the deadline. Other cases involved PICs who allowed technicians to continue working without a current registration.

Legislative Initiatives for 2015

The Board will pursue passage of several bills during the 2015 Minnesota State Legislative Session. The following are initiatives that will have a direct impact on the licensees and registrants of the Board.

Change Related to Pharmacy Technicians

The Pharmacy Practice Act Joint Task Force (PPAJTF) approached the Board with proposals to make two changes in Chapter 151 that are related to pharmacy technicians: amending the definition of "pharmacy technician," and increasing the ratio of pharmacy technicians to pharmacists. (The PPAJTF has representatives from the Minnesota Pharmacists Association, the Minnesota Society of Health-System Pharmacists, the University of Minnesota College of Pharmacy, the National Association of Chain Drug Stores, the Minnesota College of Clinical Pharmacy, and Duluth Area Pharmacists.) At its December 10, 2014 meeting, the Board directed staff to prepare legislation that would:

- Change the definition of the term "pharmacy technician" to "a person not licensed as a pharmacist or a pharmacist intern, who has been trained in pharmacy tasks that do not require the professional judgment of a licensed pharmacist. A pharmacy technician may not perform tasks specifically reserved to a licensed pharmacist."
- Change the basic ratio of technicians to pharmacists from 2:1 to 3:1. However, language that allows one additional technician to work in a pharmacy so long as at least one technician is certified would be repealed. Consequently, the overall ratio would change from 2:1 + 1 to 3:1. The increased ratios of 3:1 that are already established in rule for certain tasks, such as unit dose packaging, compounding, and pre-packaging, will remain in place. If the basic ratio is changed in the statutes, the Board may consider amending the ratios found in the rules.

Change Related to Immunizations

The PPAJTF also approached the Board with a proposal to expand the ability of pharmacists to administer vaccinations by lowering the influenza vaccination age limit from 10 years old to six years old, and lowering the age limit for all other vaccinations from 18 years old to 10 years old. The Board directed staff to prepare legislation that would make these changes and that would require pharmacists to use the Minnesota Immunization Information Connection online database to assess immunization status and to report immunizations given. The Board also authorized staff to negotiate with the Minnesota Department of Health, which may not fully agree with these proposed changes.

The *Minnesota Board of Pharmacy News* is published by the Minnesota Board of Pharmacy and the National Association of Boards of Pharmacy Foundation™ (NABPF™) to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of NABPF or the Board unless expressly so stated.

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