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Minnesota Board of Pharmacy News

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2015 Legislation Concerning the Practice of Pharmacy

During the 2015 Minnesota State Legislative Session, several changes were made to Minnesota Statutes that will have an impact on the practice of pharmacy. This edition of the *Newsletter* highlights key changes. A document that provides information on additional 2015 legislative changes can be found on the Minnesota Board of Pharmacy website under the Current Issues tab. Another document that provides information about recent Board disciplinary actions can be found there as well. The changes took effect on July 1, 2015. However, as noted below, the Board will allow pharmacists and pharmacies some additional time to come into compliance with changes related to immunizations.

Changes Related to Immunizations

Currently, pharmacists can administer influenza vaccines to individuals 10 years of age and older, and all other vaccines to individuals 18 years of age and older. Effective July 1, 2015, pharmacists will be allowed to administer "influenza vaccines to all eligible individuals six years of age and older and all other vaccines to patients 13 years of age and older." Please note that the following requirements still apply.

A pharmacist must ensure equal access to immunizations for children (defined as individuals through 18 years of age) enrolled in a Minnesota Health Care Program (MHCP). This can be done by enrolling in the Minnesota Vaccines for Children (MnVFC) program. The MnVFC program will provide enrolled pharmacies with vaccines to be given to children who are in an MHCP, uninsured, or American Indian or Alaskan Native. For children enrolled in an MHCP, the pharmacy can bill the MHCP for the vaccine administration fee. More information on the MnVFC program can be found on the Minnesota Vaccines for Children Program page. If a pharmacist is not enrolled in the MnVFC program and is providing vaccines to privately insured children or to children who are cash customers, **a pharmacist must also provide the same vaccines to MHCP-enrolled children free of charge.** The pharmacy cannot charge MHCP-enrolled children for the cost of the vaccine or for an administration fee. Additionally, the pharmacy cannot bill the MHCP for the vaccine administration fee if they are not enrolled in the MnVFC program.

Currently, pharmacists must report the administration of vaccines to the patient's primary physician or clinic or to the Minnesota Immunization Information Connection (MIIC). The new statutory language requires pharmacists to report the administration of all vaccine doses to MIIC. Reporting separately to the patient's primary physician is not required. In addition, pharmacists will be required to utilize MIIC to "assess the immunization status of individuals **prior to** the administration of vaccines, except when administering influenza vaccines to individuals age nine and older."

The Board will exercise enforcement discretion and not require pharmacies and pharmacists to immediately begin following the new provisions related to MIIC on July 1, 2015. The Board urges all pharmacies to begin complying with the legislation as soon as possible, following the expectations outlined below.

Steps for Compliance With New MIIC Provisions

If your pharmacy is actively participating in MIIC, both to assess patient immunization status and to submit data for all administered vaccines, the Board expects that you will continue to use MIIC for these functions for all patients served.

If your pharmacy is not actively participating in MIIC, both to assess patient immunization status and to submit data for all administered vaccines, please complete the steps relevant to your participation status provided on the Participating in MIIC page. If you are unsure of your organization's MIIC participation status, please contact the MIIC Provider Help Desk at health.miichelp@state.mn.us.

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Counterfeit Botox Found in the United States, FDA Warns

On April 16, 2015, Food and Drug Administration (FDA) alerted health care providers that a counterfeit version of Botox® was found in the United States and may have been sold to doctors' offices and clinics throughout the country. The counterfeit products may be identified by a missing lot number on the vial, missing information on the carton (next to LOT, MFG, and EXP), and a displayed active ingredient as "Botulinum Toxin Type A" instead of "OnabotulinumtoxinA." The counterfeit products were sold by an unlicensed supplier who is not authorized to ship or distribute drug products in the US, according to an FDA Drug Safety Alert. The agency advises health care providers to confirm that the distributor from which they purchase Botox is authorized by Allergan, the drug's manufacturer. No adverse events related to this product have been reported to FDA.

Medical practices that purchase and administer counterfeit, illegal, and unapproved medications from unlicensed or foreign sources are putting patients' health at risk, as patients may not be getting proper treatment, warns FDA. Wholesale drug distributors must be licensed in the states where they conduct business. Suspicious Botox products may be reported to FDA's Office of Criminal Investigations. More information is available on the FDA website at *www.fda.gov/Drugs/DrugSafety/ucm443217.htm*.

One way 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. 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 an on-site survey every three years. Created in 2004, the accreditation program plays a pivotal role in preventing counterfeit drugs from entering the US drug supply.

Seven Persistent Safety Gaffes in Community/Ambulatory Settings That Need to Be Resolved!

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.*

ISMP has been reflecting on the strength and resolve of many across the nation who have demonstrated an unparalleled commitment to keeping patients safe. Despite the many safety accomplishments in 2014, ISMP cannot help but mull over persistent medication safety gaffes that continue to be unresolved. ISMP would like to share seven persistent safety gaffes of 2014, in three parts, with NABP *National Pharmacy Compliance News* readers with the hope that they will join ISMP in bringing attention to these crucial issues and the compelling need for their resolution. Part one of the three-part series is below.

1) Patient Counseling: Still Only a Veiled "Offer" in Many States

The effectiveness of patient counseling in a community pharmacy to detect and prevent medication errors, and its link to improved medication adherence and positive clinical outcomes have been well documented in the literature. Yet, studies have placed patient counseling rates at only eight percent to 42%. An increase in the frequency and quality of patient counseling has been linked to state-specific regulations that require patient counseling for new prescriptions coupled with strict enforcement surveillance. States that require an "offer" to counsel have very low patient counseling rates. Patients often fail to recognize an offer to counsel when simply asked, "Do you have any questions?" or told to "Please sign here." They may not even know what to ask. This means that, with few exceptions, pharmacies in states that require only an offer to counsel will likely dispense a powerful opioid such as fentanyl transdermal patches and allow the patient or caregiver to walk out of the pharmacy without even a brief discussion about safe use and disposal. ISMP has long promoted mandatory patient counseling in community pharmacies for prescriptions for targeted high-alert medications.

For a list of high alert community medications, please visit *www.ismp.org/communityRx/tools/ambulatoryhighalert.asp.* ISMP hopes you will use this list to determine which medications require mandatory patient education in order to reduce the risk of errors and minimize harm.

2) Patients Impacted by Dispensing Errors: Callous Response From Pharmacists

When patients report dispensing errors to ISMP, they are usually more upset about the response they received when contacting the pharmacist or pharmacy manager than the actual error itself. All too often, consumers tell ISMP that pharmacy staff have responded in a callous manner when confronted with the possibility of a dispensing error, demonstrating a lack of empathy and concern for the adverse effects the patient might have experienced. While pharmacy staff may want to be more responsive to patients who report errors, they are often following corporate policies that are focused on legal concerns. As patients are continually encouraged to be active participants in their health care, they want and deserve honest disclosure of errors, and knowledge that there is an action plan to reduce the risk of it happening again.

Flurbiprofen-Containing Topical Medication May Be Dangerous to Pets, Cautions FDA

People who use topical medications containing flurbiprofen, a nonsteroidal anti-inflammatory drug (NSAID), should take care to prevent their pets from being exposed to the drug, recommended FDA in an April 2015 Safety Alert. The warning is in response to reports of cats in two separate households that became ill or died after their owners used topical medications containing flurbiprofen to treat

muscle, joint, or other pain. Two cats in one household developed kidney failure and recovered with veterinary care. Two cats in a second household developed symptoms that included reluctance to eat, lethargy, vomiting, melena, anemia, and dilute urine, and subsequently died despite veterinary care. A third cat in the second household also died after the owner stopped using the medication. Necropsies on the three cats found evidence that were consistent with NSAID toxicity. The pet owners had applied the drug to their own neck or feet, and not directly to the pet, and it is not known exactly how the cats became exposed to the medication, the Safety Alert notes.

Health care providers who prescribe or dispense topical pain medications containing flurbiprofen should advise patients with pets to take steps to prevent exposure of the pets to the medication. Additional information is available in the FDA Safety Alert available at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm443386.htm*.

New FDA Drug Info Rounds Videos Available

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. The latest Drug Info Rounds videos are as follows.

- In "NDC Directory," pharmacists demonstrate how to use this quick, easy, online resource.
- In "FAERS," pharmacists discuss the FDA Adverse Event Reporting System (FAERS) and review three ways FAERS data is made available to the public.

Drug Info Rounds is developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research, Office of Communications, Division of Drug Information. These videos and previous Drug Info Rounds resources are available on the FDA website at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm*.

Mucinex Cold, Sinus, and Flu Medications Recalled Due to Possible Labeling Error

In April 2015, RB (formerly Reckitt Benckiser) of Parsippany, NJ, issued a voluntary recall of certain lots of liquid Mucinex® due to a potential error involving the over-the-counter medications' drug facts labels. While the front label of the recalled lots correctly lists the name of the product as well as the active ingredients, some bottles may not have the correct corresponding drug facts label on the back. The recall was initiated after a confirmed report from a retailer. The recalled medications include:

- MUCINEX FAST-MAX Night-Time Cold & Flu;
- MUCINEX FAST-MAX Cold & Sinus;
- MUCINEX FAST-MAX Severe Congestion & Cough; and
- MUCINEX FAST-MAX Cold, Flu & Sore Throat.

If mislabeled, consumers who purchase these products may be unaware of the side effects and potential risks associated with active ingredients such as acetaminophen, dextromethorphan, guaifenesin, phenylephrine, and/or diphenhydramine. RB is recalling these products as a precautionary measure to ensure consumers have all relevant facts and warnings; the company asks consumers to dispose of any unused product.

Additional information about the recall, including the lot numbers and expiration dates for the recalled medications and guidelines for safe disposal, is available on the FDA website at *www.fda.gov/Safety/Recalls/ucm444028.htm*.

Pharmacists Are Performing More Patient Care Activities, National Survey Indicates

Pharmacists are performing more patient care activities in a variety of health care settings and are spending less time in traditional dispensing roles, indicates the *2014 National Pharmacist Workforce Survey*. Specifically, the report found that 60% of pharmacists provided medication therapy management, and 53% performed immunizations in 2014, indicates a press release from the American Association of Colleges of Pharmacy (AACP). The survey was created using a random sample of 5,200 individuals selected from a list of 7,000 licensed pharmacists in the US. Response rate to the survey was 48%.

Additional details, including the full results of the survey and an executive summary, are available through the Resources section of the AACP website, *www.aacp.org*.

Potentially Lethal Drug Sold Globally as Diet Supplement, Warns INTERPOL

INTERPOL has issued a global alert for a drug known as 2.4-dinitrophenol (DNP), an illicit and potentially lethal drug sold as a dieting and body building aid. The "Orange Notice" warning about DNP was published in May 2015, following the death of a woman in the United Kingdom and the serious illness of a man in France. In the 1930s, DNP was used to boost metabolism and encourage weight loss, but it was taken out of circulation due to several deaths. Sold as a plain yellow powder, capsules, or cream, DNP is often illegally manufactured and sold via the Internet; unsafe manufacturing of the drug and potential contamination may be magnifying the dangers of taking the drug, notes INTERPOL.

Additional information is available on the INTERPOL website at *www.interpol.int/News-and-media/News/2015/N2015-050*.

HHS Announces New Interactive Training on Safe Opioid Use

The Department of Health and Human Services (HHS) has announced a new, interactive training course that teaches health care providers how to talk to patients about safely using opioids to manage chronic pain. The course, "Pathways to Safer Opioid Use," also teaches implementation strategies for meeting the opioid-related recommendations from the National Action Plan for Adverse Drug Event Prevention. Adverse drug events (ADEs) are the largest contributor to hospital-related complications and account for more than 3.5 million physician office visits each year, according to HHS. The training, which is offered at no cost, includes self-guided interactive videos with decision points to help users learn how to apply health literacy strategies to help patients understand and act on information to prevent opioid-related ADEs; identify individual risk factors, opioid medications, and interactions that place individuals with chronic pain at increased risk for opioid-related ADEs; recognize the importance of a multidisciplinary team-based approach to treating patients with chronic pain; and demonstrate the ability to combine the principles of the Health Literate Care Model and the biopsychosocial model.

Additional information, including a link to the National Action Plan for Adverse Drug Event Prevention, is available on the course website at *http://health.gov/hcq/training.asp#pathways*.

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The Minnesota Department of Health will be hosting a webinar in September on how to participate in MIIC. The Board expects all immunizing pharmacies to be actively using MIIC for assessment and to be manually submitting data and/or be registered for electronic data exchange no later than January 1, 2016.

Changes Related to Technicians

As noted in the January 2015 edition of the Board's *Newsletter,* 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 had 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 technician-to-pharmacists from 2:1 to 3:1. However, the Board also directed staff to work on a repeal of language that allows one additional technician to work in a pharmacy so long as at least one technician is certified. Had the Board's proposed language been adopted by the legislature, the overall ratio would have changed from 2:1 + 1 to 3:1.

During the legislative session, representatives of the PPAJTF and other organizations sought to have the technician-to-pharmacist ratio changed to 4:1, which the Board found unacceptable. Ultimately, a compromise was reached, as described below.

The definition of the term "pharmacy technician" was amended to "a person not licensed as a pharmacist or registered as a pharmacy 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." In addition, Minnesota Statutes §151.102, Subdivision 1 was amended to read:

> A pharmacy technician may assist a pharmacist in the practice of pharmacy by performing tasks that are not reserved to, and do not require the professional judgment of, a licensed pharmacist. A pharmacy technician works under the personal and direct supervision of the pharmacist. A pharmacist may supervise up to three technicians. A pharmacist is responsible for all the work performed by the technicians who are under the supervision of the pharmacist. A pharmacy may exceed the ratio of pharmacy technicians to pharmacists permitted in this subdivision or in rule by a total of one technician at any given time in the pharmacy, provided at least one technician in the pharmacy holds a valid certification from the Pharmacy Technician Certification Board or from another national certification body for pharmacy technicians that requires passage of a nationally recognized, psychometrically valid certification examination for certification as determined by the Board of Pharmacy. The Board of Pharmacy may, by rule, set ratios of technicians to pharmacists greater than three to one for the functions specified in rule.

In regard to these statutory changes related to technicians, the following considerations should be kept in mind.

- Pharmacy technicians cannot perform tasks that require the professional judgment of a licensed pharmacist. Pharmacists and pharmacies should contact the Board office with questions about tasks that pharmacy technicians can perform. Minnesota Rules Chapter 6800 already contains provisions that reserve certain tasks to pharmacists or specifically prohibit technicians from performing certain duties. For situations not addressed in statutes or rules, the Board may have to make a determination as to whether a task requires the professional judgment of a pharmacist.
- The new base technician-to-pharmacist ratio, as of July 1, 2015, will be three to one. Provided that at least one technician who is on duty is certified, one additional technician can be on duty in the pharmacy. (The Board currently recognizes certification by the Pharmacy Technician Certification Board **or** the Institute for the Certification of Pharmacy Technicians/ National Healthcareer Association.) **Please note that having a certified technician on duty does not mean that there can be one additional technician per pharmacist on duty. Only one additional technician can be on duty in the pharmacy, regardless of how many pharmacists are on duty.** The Board has not changed any of the ratios that it has established in rule, all of which are 3:1. The change in statutory language does not change those ratios established by rule. As in the past, the Board expects the ratios to be strictly followed. The chart on the following page may be of assistance.

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No Certified Technicians on Duty Within the Pharmacy (3:1 Ratio)		At Least One Certified Technician on Duty Within the Pharmacy (3:1 Ratio Plus One Additional Technician **in Pharmacy, Not per Pharmacist)**	
Number of Pharmacists on Duty	Number of Technicians Allowed	Number of Pharmacists on Duty	Number of Technicians Allowed
1	3	1	4
2	6	2	7
3	9	3	10
4	12	4	13
5	15	5	16

Change Related to the Board

The Board currently has seven members: five pharmacists and two public members. The size of the Board will be increased by the addition of one pharmacist and one public member. Based on communications with the Minnesota Office of the Secretary of State (SOS), these new positions will most likely be posted by the SOS in early July. Application to serve as a Board member is made through the Open Commissions and Appointments area of the SOS website. The governor appoints Board members from among the individuals who apply. By law, pharmacists must be currently licensed by the Board and actively engaged in the practice of pharmacy, and must have had at least five consecutive years of practical experience as a pharmacist immediately preceding appointment.

The statutory definition of the term "public member" is "a person who is not, or never was, a member of the profession or occupation being licensed or regulated or the spouse of any such person, or a person who does not have or has never had, a material financial interest in either the providing of the professional service being licensed or regulated or an activity directly related to the profession or occupation being licensed or regulated." Consequently, no employee of a business licensed or otherwise regulated by the Board can be a public member of the Board.

Fee Increases

Licensing, registration, and other fees assessed by the Board will increase effective July 1, 2015, which is the beginning of the state's 2016 fiscal year. The Board's last fee increases occurred during fiscal year 2012. The Board has data on fees dating back to the 1950s. Up until 2002, the average length of time between fee increases was about three years. The Board then went 10 years before the last fee increases in 2012. Thus, the four-year interval since the last fee increases is on par with the historical interval between increases.

The Board's workload has dramatically increased over the past decade. The number of facilities licensed by the Board increased by 31%, and the number of individuals licensed increased by 49%. Due to several factors, the Board has seen the number of complaints that need to be processed triple since fiscal year 2008. The Board has also been tasked by the legislature to administer the Prescription Monitoring Program and to more stringently monitor nonresidential businesses that ship drugs into Minnesota. This increased workload has resulted in increased expenses. Space limitations do not allow for the new fees to be listed in this *Newsletter*. However, a document that provides additional information on 2015 legislative changes, including a complete list of the new fees, can be found on the Board's website under the Current Issues tab.

Note that the fee increases will be mostly offset by the elimination of the "electronic licensing" surcharge that the Board has been required to collect since 2010. (Surcharge revenue was transferred to another state agency known as MN-ITS and was not used by the Board to fund its operations.) The surcharge was 10% of the licensing fee, with a $5 minimum. As an example, pharmacists have been paying a $130 licensing fee plus a $13 surcharge, for a total of $143. The new license fee for pharmacists will be $145.

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