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Minnesota Board of Pharmacy News

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Disciplinary Actions

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

Governor Dayton Makes Appointments to Board

On January 4, 2017, Governor Mark Dayton announced the reappointment of Rabih Nahas and Andy Behm to the Board. Mr Nahas was first appointed to the Board on February 12, 2013. Mr Nahas, of Orono, MN, is a licensed pharmacist with over 27 years of experience in hospital pharmacy. He is currently a clinical pharmacist at Abbott Northwestern Hospital in Minneapolis, MN. He earned his bachelor of science degree in pharmacy from Drake University.

Dr Behm, of Edina, MN, was first appointed to a newly created pharmacist member position on January 15, 2016. Because of the need to stagger the terms of Board members, the first term for his position was set by the governor to expire in January 2017. Dr Behm received his doctor of pharmacy degree from the University of Minnesota in 2000 and has practiced in community, hospital, managed care, hospice/home care, and long-term care settings. He completed a residency in geriatric pharmacy at the Minneapolis Veterans Affairs Health Care System and is a certified geriatric practitioner. He has worked for Express Scripts since 2001, where he currently serves as vice president in the Office of Clinical Evaluation and Policy.

E-Prescribing and Facsimile Prescriptions

At its March 15, 2017 meeting, the Board addressed the issue of prescriptions that begin as **true** electronic prescriptions but that are ultimately converted and sent to a pharmacy as a facsimile. Minnesota Statutes §62J.497 requires prescribers and dispensers to use the National Council for Prescription Drug Programs SCRIPT Standard for the communication of a prescription or prescription-related information. A true electronic prescription involves use of that standard to transmit prescription data through an intermediary, an e-prescribing network that acts like a switch to route the prescription to the correct pharmacy. The transmission of prescriptions by facsimile does not meet that standard, not even when the prescription is generated within an electronic medical record (EMR) system and then transmitted by facsimile **directly** to a pharmacy's fax machine. Consequently, most prescriptions transmitted by facsimile are not true electronic prescriptions.

Minnesota Statutes §151.01, Subdivision 16a defines the word "prescription" and includes the following language (emphasis added): "**A prescription** written or printed on paper that is given to the patient or an agent of the patient or **that is transmitted by fax must contain the practitioner's manual signature.** An electronic prescription must contain the practitioner's electronic signature." Normally, most prescriptions received by facsimile must be **manually** signed by the prescriber (ie, there must be a "pen-to-paper" signature) before they are faxed. A notation on a paper or facsimile prescription such as "electronically signed by the prescriber" is not a valid signature, and the prescription is not legally valid – unless it is also manually signed. This is true even if the facsimile prescription was generated from within an EMR. Normally, a prescription generated within an EMR must either be: 1) electronically signed and transmitted as a true e-prescription through an intermediary network; 2) printed out on paper, manually signed, and given to the patient; or 3) printed out on paper, manually signed, and faxed to the pharmacy.

Sometimes, the intention of the prescriber is to generate a prescription within an EMR and transmit it as a true e-prescription. However, if the intermediary is unable to complete the transmission of the prescription to the pharmacy, it may convert the intended e-prescription into a facsimile and send that to the pharmacy instead. In that case, the facsimile is electronically signed, not manually signed. It is this situation that the Board discussed at its March 15, 2017 meeting. In the past, when this situation occurred, pharmacists had to call prescribers (because, as mentioned above, faxed

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DEA Changes Registration Renewal Process

As of January 2017, Drug Enforcement Administration (DEA) will no longer send its second renewal notification by mail. Instead, an electronic reminder to renew will be sent to the email address associated with the DEA registration.

In addition, DEA will retain its current policy and procedures with respect to renewal and reinstatement of registration. The policy is described below.

- If a renewal application is submitted in a timely manner prior to expiration, the registrant may continue operations, authorized by the registration, beyond the expiration date until final action is taken on the application.
- DEA allows the reinstatement of an expired registration for one calendar month after the expiration date. If the registration is not renewed within that calendar month, an application for a new DEA registration will be required.
- Regardless of whether a registration is reinstated within the calendar month after expiration, federal law prohibits the handling of controlled substances or List 1 chemicals for any period of time under an expired registration.

Additional information is available on the DEA website at *www.deadiversion.usdoj.gov/drugreg/index.html.*

ISMP Medication Safety Self Assessment for Community/Ambulatory Pharmacy

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.*

Pharmacists in community and ambulatory settings can now access a newly revised tool that will help them review and improve their medication safety practices. The 2017 Institute for Safe Medication Practices (ISMP) Medication Safety Self Assessment® for Community/Ambulatory Pharmacy is designed to help pharmacies evaluate their current systems, proactively identify opportunities for improvement, and track their efforts over time.

An advisory panel of experts helped ISMP update items from the 2001 community/ambulatory self-assessment as well as add items to address new practices and processes, including the pharmacist's evolving role in immunization administration. New research findings about error prevention and emerging technologies previously not widely adopted are also covered.

The self-assessment contains items that address the use of medications in the clinical setting, many of which are on the ISMP list of high-alert medications. Many of the items included represent system improvements and safeguards that ISMP has recommended in response to analysis of medication errors reported to the ISMP Medication Errors Reporting Program, problems identified during on-site consultations with health care organizations, and guidelines in medical literature.

The self-assessment is divided into 10 key elements that most significantly influence safe medication use. Each element is defined by one or more core characteristics of a safe pharmacy system that further define a safe medication use system. Each core characteristic contains individual self-assessment items to help evaluate success with achieving each core characteristic.

ISMP recommends that each pharmacy site convene its own team of staff members (ie, pharmacist(s), technician(s), and student pharmacist(s)) to complete this comprehensive assessment and use the information as part of its ongoing safety and quality improvement efforts. An online form has been provided to help participants organize and score their responses. **Important:** The self-assessment should be completed in its entirety by staff and managers who work within the pharmacy, not by off-site managers on behalf of the pharmacy.

When the self-assessment is completed, respondents can generate reports showing how their pharmacy answered each item and how they scored on each as a percentage of the maximum possible score. The pharmacy can then use its scores to identify and prioritize opportunities for its safety plan of action.

ISMP is not a regulatory or standards-setting organization. As such, the self-assessment characteristics represent ideal practices and are not purported to represent a minimum standard of practice. Some of the self-assessment criteria represent innovative practices and system enhancements that are not widely available in pharmacies today. However, the value of these practices in reducing errors is grounded in expert analysis of medication errors, scientific research, or strong evidence of their ability to reduce errors.

To view, download, and print the PDF of the assessment, which includes the introduction, instructions for use, self-assessment items, and definitions, visit *https://www.ismp.org/Survey/NewMssacap/Index.asp.*

CDC Publishes Resource to Foster Use of JCPP Pharmacists' Patient Care Process

A publication intended to encourage the use of the Joint Commission of Pharmacy Practitioners (JCPP) Pharmacists' Patient Care Process was released by the Centers for Disease Control and Prevention's (CDC's) Division for Heart Disease and Stroke Prevention. In *Using the Pharmacists' Patient Care Process to Manage High Blood Pressure: A Resource Guide for Pharmacists,* CDC calls on pharmacists and other health care providers to implement the Pharmacists' Patient Care Process model to reduce heart disease and stroke in the United States. Pharmacists can have a positive effect on population health by providing patient care services and participating in collaborative practice agreements and continuing education (CE) programs, notes the CDC publication. The publication is available at *www.cdc.gov/dhdsp/pubs/docs/pharmacist-resource-guide.pdf.*

The National Association of Boards of Pharmacy® (NABP®) is a member of JCPP and endorses the Pharmacists' Patient Care Process. In its September 2015 newsletter (page 167), NABP discusses integrating the JCPP Pharmacists' Patient Care Process to improve medication outcomes and promote consistency in patient care service delivery. Additional information about JCPP is available at *https://jcpp.net.*

FDA Issues Final Guidance on Repackaging Drugs by Pharmacies and Registered Outsourcing Facilities

In January 2017, Food and Drug Administration (FDA) issued a final guidance for industry titled, "Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities." This guidance describes the conditions under which FDA does not intend to take action for violations of certain provisions of the Federal Food, Drug, and Cosmetic Act when a state-licensed pharmacy, a federal facility, or an outsourcing facility repackages certain human drug products. The guidance is available at *www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM434174.pdf.*

Electronic or written comments may be submitted at any time for this final guidance following the instructions provided in the *Federal Register,* which can be found at *www.federalregister.gov/documents/2017/01/13/2017-00723/repackaging-of-certain-human-drug-products-by-pharmacies-and-outsourcing-facilities-final-guidance.*

CriticalPoint Launches QP503A Certification Program for Sterile Compounding in 2017

In 2017, CriticalPoint, LLC, launched its QP503A certification program for sterile compounding personnel. Specifically, CriticalPoint is offering the QP503A Certification and the QP503A Master Certification, which may be earned after obtaining the basic QP503A Certification. Participants will gain vital knowledge and skills to successfully plan, develop, and operate a 503A pharmacy sterile compounding operation.

The QP503A Certification involves a didactic program of home study, live training, and practicum activities accompanied by required objective personnel and cognitive testing. The QP503A Master Certification requires participants to demonstrate their ability to apply their QP503A Certification training in actual work settings and produce measurable changes in sterile compounding processes resulting in improved patient safety.

Additional details about these programs and the certification requirements are available online at *www.criticalpoint.info/wp-content/uploads/CriticalPoint-QP503A-Certification.pdf.*

PTCB Suspends Implementation of Planned 2020 Accredited Education Requirement for Pharmacy Technicians

The Pharmacy Technician Certification Board (PTCB) is suspending the implementation of the accredited education requirement for pharmacy technicians. In 2013, PTCB announced that the requirement would take effect in 2020, but PTCB has "determined that additional deliberation and research are needed to address stakeholder input, develop supporting policy, and conduct further study of technician roles," said Larry Wagenknecht, BPharm, chair of the PTCB Board of Governors, and chief executive officer of the Michigan Pharmacists Association, in a news release. The role of pharmacy technicians is evolving, and PTCB is taking steps to support the pharmacy community.

PTCB recently completed a job analysis study to collect data on current roles and responsibilities of pharmacy technicians across all practice settings to update PTCB's Pharmacy Technician Certification Exam and is in the process of developing advanced certification programs. In addition, PTCB hosted an invitational conference in February 2017 where pharmacy leaders and stakeholders examined entry-level standards and provided information to help determine future plans for implementing PTCB program changes.

PTCB's news release is available at *www.ptcb.org* in the News Room section.

ASOP Global Spreads Awareness About Illegal Online Drug Sellers and Counterfeit Medications

Alliance for Safe Online Pharmacies (ASOP Global) partnered with several nonprofit organizations, including NABP, to launch a campaign to raise awareness of illegal online drug sellers and counterfeit medications. The campaign encourages dialogue among health care providers and patients regarding where patients purchase their medications, especially if patients are buying them online.

After offering the CE course "Internet Drug Sellers: What Providers Need to Know" to over 1,000 health care providers, ASOP Global found that less than 10% of providers reported they were "very aware" counterfeit prescription drugs are being sold on the internet and only 1.4% said they regularly discuss the risks of illegal internet drug sellers with patients. ASOP Global Executive Director Libby Baney said, "After completing the course, however, there was a ten-fold increase in the expected frequency in which providers planned to discuss the risks associated with buying prescription medicines online with their patients and what they can do to avoid physical and financial harm."

For more information about the campaign, visit *www.BuySafeRx.pharmacy.*

New Interactive Map Tracks Pharmacist Vaccination Laws

A new resource – an interactive 50-state map tracking pharmacist vaccination laws between 1990 and 2016 – was published by The Policy Surveillance Program, A LawAtlas Project. The map, which is available at *http://lawatlas.org/datasets/pharmacist-vaccination,* explores laws that give pharmacists authority to administer vaccines and establish requirements for third-party vaccination authorization, patient age restrictions, and specific vaccination practice requirements, such as training, reporting, record keeping, notification, malpractice insurance, and emergency exceptions. The Policy Surveillance Program is administered by Temple University Beasley School of Law.

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prescriptions must normally be manually signed). However, the prescriber is usually not aware that the conversion to a facsimile occurred and believes that a true e-prescription was transmitted. Prescribers are sometimes upset that the pharmacist has called to verify what the prescriber believes to be a valid e-prescription. To address this issue, the Board adopted the following policy:

- When a pharmacist receives a faxed prescription that is electronically but not manually signed, **and it is clear from the prescription** that it originated as a true electronic prescription that was converted to a facsimile, the pharmacist can fill the prescription without calling the prescriber to verify that the prescriber actually issued the prescription. Such converted prescriptions have statements such as: "This document originated as an electronic prescription, but due to a temporary network outage or because your practice is not enabled for true electronic prescribing, it has been converted to a computer-generated fax." They also have notifications that indicate that an intermediary has been used, such as "Delivered by Surescripts."
- All other faxed prescriptions must have been manually signed by the prescriber before being faxed. If it is not clear from the prescription that it originated as a true electronic prescription before being converted to a facsimile, the pharmacist must contact the prescriber to verify that the prescriber actually issued the prescription.

Important note: Drug Enforcement Administration (DEA) regulations prohibit intermediaries from converting an e-prescription for a controlled substance (CS) into a facsimile. If a CS e-prescription cannot be electronically delivered to the pharmacy computer, the intermediary must notify the prescriber. The prescriber can then print out and manually sign the prescription and send it to the pharmacy by facsimile. So, **all** faxed prescriptions for CS **must** be manually signed by the prescriber. But, remember that DEA regulations place restrictions on the faxing of Schedule II CS prescriptions. The following is taken from the DEA *Pharmacist's Manual:*

> In order to expedite the filling of a prescription, a prescriber may transmit a schedule II prescription to the pharmacy by facsimile. The original schedule II prescription must be presented to the pharmacist and verified against the facsimile at the time the controlled substance is actually dispensed. The pharmacist must make sure the original document is properly annotated and filed with the records that are required to be kept . . . DEA has granted three exceptions to the facsimile prescription requirements for schedule II controlled substances. The facsimile of a schedule II prescription may serve as the original prescription as follows:
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> 1. A practitioner prescribing a schedule II narcotic controlled substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion may transmit the prescription by facsimile. The pharmacy will consider the facsimile prescription a "written prescription" and no further documentation is required. All normal requirements of a legal prescription must be followed.
> 2. Practitioners prescribing schedule II controlled substances for residents of Long Term Care Facilities may transmit a prescription by facsimile to the dispensing pharmacy. The facsimile prescription serves as the original written prescription for the pharmacy. No further documentation is required.
> 3. A practitioner prescribing a schedule II narcotic controlled substance for a patient enrolled in a hospice care program certified and/or paid for by Medicare under Title XVIII or a hospice program which is licensed by the state, may transmit a prescription to the dispensing pharmacy by facsimile. The practitioner will note on the prescription that it is for a hospice patient. The facsimile serves as the original written prescription. No further documentation is required.

In Memoriam

Former Board Member Thomas Dickson passed away on March 5, 2017, after a long battle with cancer. Tom was first appointed to the Board by Governor Jesse Ventura in January 2001 and was reappointed by Governor Tim Pawlenty in April 2005. He served as the Board's vice president in 2003 and as president in 2004 and 2008. Tom also served as president of the Minnesota Society of Health-System Pharmacists, which awarded him the Hugh F. Kabat Award in 2015. That award is presented annually to an individual in recognition of leadership or innovation in Minnesota pharmacy practice.

Tom was born on April 3, 1950, in Duluth, MN, at St Luke's Hospital to Franklin H. Dickson, MD, and Anne (Portegys) Dickson. He grew up in Proctor, MN, and attended St Rose Grade School and Proctor Senior High School. Tom received a bachelor of arts degree in biology and chemistry from the University of Minnesota in Duluth, and a bachelor of science degree in pharmacy from the University of Minnesota in Minneapolis. From 1983-1999, he served as director of pharmacy and material management at St Luke's Hospital in Duluth. He most recently served as director of pharmacy at Community Memorial Hospital in Cloquet, MN, from 2003-2016. Prior to that, Tom served as director of pharmacy at Mercy Hospital in Moose Lake, MN, and as the president and owner of Shrem Corporation, a Duluth-based pharmacy and nursing home consulting service.

Tom was dedicated to the education of future health care providers and pharmacists. He was a clinical instructor for the University of Minnesota Duluth College of Pharmacy. Many pharmacy students rotated through Tom's pharmacy as part of their community hospital pharmacy education.

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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