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Minnesota Board of Pharmacy News

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University Park Plaza • 2829 University Ave SE, Suite 530 • Minneapolis, MN 55414-3251
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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.

Prescription Monitoring Program Update

The Board's Prescription Monitoring Program (PMP) migrated to the American Society for Automation in Pharmacy (ASAP) 4.2 data reporting format standard on September 1. The previous ASAP 4.0 format will continue to be accepted until November 30, 2016. Dispensers (pharmacies) must be submitting all files in ASAP 4.2 no later than November 30, 2016. Dispensers licensed by the Board must report all Schedule II-V controlled substances (CS) and butalbital and gabapentin prescriptions on a daily basis. If no CS or butalbital or gabapentin prescriptions are dispensed on any given day, the dispenser is required to submit a "zero report" at the end of the day or on the following day, regardless of whether or not the pharmacy was open for business.

With the migration to ASAP 4.2, several additional fields of data are being collected. A complete list of data reporting specifications can be found in the *Uploader/Dispensers Implementation Guide for ASAP 4.2,* which can be found on the Minnesota PMP website under "PMP Data Uploaders."

Edit definitions have also been updated with new edits and/or levels of severity. These too may be found in the *Uploader/Dispensers Implementation Guide for ASAP 4.2.* As a reminder, fatal errors (eg, missing patient first or last name) will always be rejected by the database, whereas serious errors (eg, invalid prescriber Drug Enforcement Administration number) may upload depending on the percentage of errors in the entire batch of prescriptions that is submitted. Error reports listing all prescription errors are communicated to the uploader or pharmacy, depending on the contact information provided in the uploader account. It is important for pharmacies and/or uploaders to review error reports, recognize edit definitions and levels of severity, and make the necessary corrections to the prescription(s) with errors not only in the pharmacy's computer system but also in the PMP database. Errors must be corrected in the PMP within seven days of sending the error report. PMP staff audit pharmacies in the interest of data integrity and work with pharmacists-in-charge to strengthen data quality when necessary. In order for the PMP to be effective, the data submitted by pharmacies must be accurate.

Questions regarding this information should be directed to the Minnesota PMP staff at minnesota.pmp@state.mn.us. Technical questions regarding uploading data or error resolution can be directed to the PMP's vendor, Health Information Designs, at mnpdm-info@hidinc.com.

Serving Minnesota Health Care Programs Enrollees

Pharmacies and pharmacists that are enrolled as providers for Minnesota Health Care Programs (MHCP), including Medical Assistance (MA) and MinnesotaCare, are required to follow certain requirements in statutes and rules that pertain to those programs. The MHCP provider agreements that pharmacies and pharmacists enter into with the Minnesota Department of Human Services (DHS) reiterate that fact. It is important that MHCP statutes and rules be followed. Failure to follow them can result in a recoupment of payments by DHS. In addition, it is unprofessional conduct for a pharmacist or pharmacy to violate any "law, rule, regulation, or ordinance of the state or any of its political subdivisions, including the Board of Pharmacy, or the United States government, or any agency thereof relating to the practice of pharmacy." Consequently, violation of MHCP statutes and rules is grounds for the Board to take disciplinary action against the licenses of pharmacists or pharmacies.

There are many instances when the requirements for serving MHCP enrollees differ from the requirements associated with serving patients with private insurance. MHCP requirements apply to both enrollees in fee-for-service (often referred to as "straight MA") and managed care (plans administered by contracted managed care organizations). Board staff have worked with DHS Pharmacy Program staff to provide the following information concerning specific MHCP requirements. Questions concerning these requirements should be addressed to the DHS Provider Call Center (651/431-2700 or 1-800/366-5411). Here are some important issues:

Accepting Payment From the Recipient for a Prescription Subject to Abuse or Overuse. Pharmacies may not accept cash payment for prescriptions for drugs subject to abuse and overuse without authorization from DHS for the specific prescription. DHS defines drugs subject to abuse and overuse as gabapentin and CS, with the exception of phentermine. If an MHCP enrollee asks to pay cash for a gabapentin or CS prescription, the pharmacy may not accept the payment. The pharmacist should work with the prescriber to identify a covered option or ask the prescriber to call the MHCP provider help desk for authorization for the recipient to pay cash. The MHCP pharmacy benefit is comprehensive and should be sufficient

continued on page 4

National Vaccine Safety Surveillance Program Available for Reporting Adverse Events

The Vaccine Adverse Event Reporting System (VAERS) eSubmitter program, a national vaccine safety surveillance program cosponsored by the Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA), is available for the reporting of any clinically significant adverse event that occurs after the administration of any vaccine licensed in the United States. VAERS information is analyzed by CDC and FDA to identify new safety concerns. VAERS reports can be filed by anyone, including health care providers, manufacturers, state immunization programs, and vaccine recipients. Vaccine recipients are encouraged to seek help from their health care provider when filling out the VAERS form. Health care providers can find information about submitting a report on the VAERS website at *https://vaers.hhs.gov/professionals/index*.

Improper and Unsafe Vaccine Storage

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.*

Few issues are more important than proper storage and handling of vaccines, because their ability to prevent disease is dependent on these factors. To maintain stability, most vaccines must be stored in a refrigerator or freezer, and many also require protection from light. Excessive heat or cold – even a single exposure in some instances – can reduce vaccine potency. These temperature excursions are often due to improper refrigeration or freezer units, inadequate thermostat controls, and refrigeration/freezer units with inadequate space to allow good air circulation and even temperatures.

Improper and unsafe storage can also result in serious errors caused by selecting the wrong vaccines, diluents, and other medications with look-alike names and/or labeling and packaging. Storing vaccines close to each other has led to dispensing and administering the wrong vaccine or wrong form of vaccine (eg, adult versus pediatric). Storing vaccines too close to non-biologic medications in a refrigerator or freezer has also led to serious adverse outcomes, particularly when the mix-up involved a vaccine and a high-alert medication. For example, vials of insulin have frequently been mistaken as influenza vaccine, and various neuromuscular blocking agents have been used to reconstitute vaccines or were mistaken as influenza or hepatitis B vaccines.

Store vaccines in their own dedicated refrigeration and freezer units. Regular temperature monitoring is necessary, and technology is available to assist with alarmed, continuous monitoring devices that can alert staff via email and pager if a unit is out of specified range. Separate vaccine vials and syringes into bins or other containers according to vaccine type and formulation, keeping diluents with the appropr iate vaccines. Never store different vaccines in the same containers. Do not store vaccines with similar labels, names, abbreviations, or overlapping components immediately next to each other or on the same shelf. Separate the storage areas of pediatric and adult formulations of vaccines. Label the specific locations where vaccines are stored to facilitate correct age-specific selection and to remind staff to combine the contents of vials. ISMP's March 26, 2015 newsletter[1] contains additional strategies, as does a Vaccine Storage & Handling Toolkit available from CDC.[2]

References

1. ISMP. Recommendations for practitioners to prevent vaccine errors. Part 2: analysis of ISMP vaccine errors reporting program (VERP). *ISMP Medication Safety Alert!* 2015;20(6):1-6.
2. CDC. Vaccine storage & handling toolkit. www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf. June 2016.

Coalition Reports Impact of Educational Efforts on Safe Acetaminophen Use

The Acetaminophen Awareness Coalition reports that progress has been made to increase consumer awareness about the safe use of acetaminophen. The coalition also notes a decline in unintentional overdoses. The National Poison Data System's 2015 report indicates unintentional acetaminophen exposures, including dosing errors and accidental misuse, have decreased through 2013 after a peak in 2009. In addition, a nationwide survey indicates the number of consumers who understand that exceeding the recommended daily dose of acetaminophen may lead to liver damage has increased to 87% in 2013 from 78% in 2010. The survey also reports the number of consumers who think it is important to check the medicine label for the maximum daily dose increased to 98% in 2013 from 93% in 2010.

Developed in 2011, the Know Your Dose campaign encourages pharmacists and other health care providers to talk to their patients about medicine safety and acetaminophen use. The Know Your Dose campaign offers a list of helpful health tips to share with patients, including the following:

(1) Read and follow the label.

(2) Know which medicines contain acetaminophen.

(3) Take only one medicine at a time that contains acetaminophen.
(4) Ask a health care provider or pharmacist about dosing instructions or medicines that contain acetaminophen.

Pharmacists may download or order free educational materials, including posters, flyers, and talking points, to give their patients on the Know Your Dose website, *www.knowyourdose.org*.

FDA Offers Webinars on Online Drug Information Resources for Students and Clinicians

FDA's Division of Drug Information in the Center for Drug Evaluation and Research presents a series of CE webinars targeted toward students and health care providers who wish to learn more about FDA and drug regulation. The webinars are presented by FDA staff and allow participants to interact with staff. Previous webinar topics have included an overview of FDA's expanded access program and the pregnancy and lactation labeling rule. The webinars and presentation slides can be accessed on FDA's website at *www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/PharmacyStudentExperientialProgramCDER/ucm228391.htm*.

Fresenius Kabi Recalls Sensorcaine-MPF (Bupivacaine HCl) Injection, USP

In April 2016, Fresenius Kabi USA recalled a single lot of Sensorcaine®-MPF (bupivacaine HCl) injection, USP, 0.75%, 7.5 mg/mL, 30 mL fill in a 30 mL vial, because of visible particulate matter characterized as glass observed by the company during inspection of reserve samples. The recalled product was shipped in the US to wholesaler and distributor outlets between March 4, 2016, and March 21, 2016, and has an expiration date of September 2019. The recall affects lot number 6111504, product code 470237, and National Drug Code number 63323-472-37. The product is supplied as 0.75% strength in a 30 mL single-dose flint molded vial and is packaged in units of 25. To date, Fresenius Kabi has not received any reports of adverse events regarding this recall, indicates the press release posted to the FDA website.

Health care facilities that have the affected lot are instructed to immediately discontinue distributing, dispensing, or using the lot and return all units to Fresenius Kabi. Distributors are instructed to immediately notify their customers who have been shipped or may have been shipped the recalled product. Adverse reactions or quality problems may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting program at *www.fda.gov/MedWatch*. Additional details are available on FDA's website at *www.fda.gov/Safety/Recalls/ucm497812.htm*.

Oral Liquid Docusate Sodium by PharmaTech Recalled Due to Contamination

In July 2016, FDA alerted health care providers that PharmaTech, LLC, of Davie, FL, voluntarily recalled all non-expired lots of Diocto Liquid, a docusate sodium solution distributed by Rugby Laboratories of Livonia, MI. The affected product was distributed nationwide in one-pint (473 mL) bottles with a Rugby label. FDA confirmed the product has been contaminated with *Burkholderia cepacia,* a bacteria linked to an outbreak in five states. The safety alert indicates FDA has received several adverse event reports of *B. cepacia* infections in patients, and some of these reports identify liquid docusate sodium products manufactured by companies other than PharmaTech. FDA and CDC continue to investigate the extent of this issue in order to identify other potentially contaminated liquid docusate sodium products. FDA joins CDC in recommending that clinicians not use any liquid docusate sodium product as a stool softener or for any other medical purpose. Adverse events or side effects may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program at *www.fda.gov/MedWatch*. More information may be found in the safety alert on FDA's website at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm511528.htm*.

NABP Seeks Pharmacists From Districts 1, 5, and 7 to Serve as Volunteer Item Writers

The National Association of Boards of Pharmacy® (NABP®) is seeking pharmacists who reside in states in the following districts to serve as volunteer item writers:

- **District 1:** Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont.
- **District 5:** Iowa, Minnesota, Nebraska, North Dakota, and South Dakota.
- **District 7:** Alaska, Idaho, Montana, Oregon, Washington, and Wyoming.

In an effort to secure more individuals representative of these areas of the country, NABP encourages pharmacists in all areas of practice as well as school and college of pharmacy faculty who reside in these states to apply.

NABP uses volunteer item writers to develop questions for the following examination programs: North American Pharmacist Licensure Examination® (NAPLEX®), Multistate Pharmacy Jurisprudence Examination® (MPJE®), Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®), Pharmacy Curriculum Outcomes Assessment® (PCOA®), and Pharmacist Assessment for Remediation Evaluation® (PARE®).

Interested individuals should complete the online interest form available in the Meetings section of the NABP website. Individuals who are selected will receive further information on opportunities to attend and participate in NABP-hosted workshops.

For more information about NABP item writing, visit the Meetings section of the NABP website at *www.nabp.pharmacy*, or contact CompAssess@nabp.pharmacy.

continued from page 1

to provide any medically necessary drug treatment for an enrollee in nearly all cases. The department will only authorize cash payment for truly exceptional circumstances. Enrollees do have the option to pay cash for phentermine and non-CS other than gabapentin so long as they sign the Advanced Recipient Notice of Non-covered Prescription Form and the pharmacist has explored covered alternatives with the recipient. If a patient's MHCP eligibility status is in question and the individual offers cash payment for his or her prescription, the pharmacy must verify eligibility through MN-ITS or the eligibility verification service (EVS).

Automatic Refills. Pharmacies may not enroll MHCP enrollees into prescription automatic refill programs. Prescription refills are not eligible for payment without an explicit request from a recipient or authorized caregiver. The pharmacy may not contact the recipient in an effort to initiate a refill unless it is part of a good faith clinical effort by the pharmacist to assess the recipient's medication regimen or to provide other clinical services such as medication therapy management.

Coupons and Vouchers. Pharmacies may not apply pharmaceutical manufacturer vouchers to prescriptions for MHCP enrollees. Pharmacies are also not allowed to offer cash, coupons, or gift cards to MHCP enrollees in exchange for transferring or filling prescriptions at a certain pharmacy.

Submission of Correct Days Supply. Pharmacy claims must be submitted with a days supply that is consistent with the prescriber's instructions. Some pharmacies have been manipulating the days supply submitted on prescription claims in an effort to bypass maximum dose claim edits. For example, if DHS has a limit of three tablets per day and the prescriber wrote for #80 tablets with directions of one tablet four times a day, some pharmacies are submitting the prescription as a 27-day supply rather than a 20-day supply so the claim will bypass the three-day limit. This is not acceptable and has the potential to contribute to patient harm since many quantity-per-day limits are set for safety reasons. If the patient has a medical need for a quantity that exceeds the maximum allowed quantity or maximum dose per day, the pharmacy should work with the prescriber to submit a prior authorization request.

Dispensing Over-the-Counter (OTC) Drugs in the Correct Package Quantity. In most cases, OTC drugs should be dispensed in the manufacturer's original package quantity. The pharmacy may dispense the OTC drugs in a prescription vial, compliance packaging, or the manufacturer's original container. Smaller quantities may be dispensed if the patient needs less than the package contents for the entire course of therapy. For example, a pharmacy may dispense two bisacodyl tablets if only two tablets are needed for a scheduled bowel preparation. For as needed (prn) OTCs such as acetaminophen or preventative OTCs such as calcium supplements, pharmacies must dispense the entire quantity contained in the manufacturer's package. Please watch the DHS website for upcoming changes regarding OTCs for pharmacies dispensing to nursing homes using unit dose or automated machine delivery.

340B Contract Pharmacies. Only 340B covered entities and pharmacies under common ownership of the 340B entity are allowed to "carve" MHCP in to their 340B operation. All other contract pharmacies must carve MHCP out of 340B and dispense only non-340B product to MHCP enrollees. A list of bank identification number/processor control number combinations for MHCP managed care plans are available on the DHS website to facilitate the mandatory carve-out.

Prior Authorization Forms. When submitting a form requesting prior authorization, the pharmacy must fill out the form completely. Incomplete requests will be denied or delayed. Some medications can never be covered even with prior authorization due to limitations in state or federal law. Examples of medications that are never covered include medications for fertility, erectile dysfunction, weight loss, hair loss, or cosmetic purposes. Investigational drugs not yet approved by Food and Drug Administration are also not covered.

Available DHS Resources: MHCP-enrolled pharmacies must ensure that pharmacy staff can verify eligibility through MN-ITS or EVS and have access to the available resources on the DHS website:

- MHCP Provider Manual – Pharmacy Services and Medication Therapy Management Services chapters.
- MHCP National Drug Code search.
- MHCP Prescription Drug Information site, which includes the Preferred Drug List, Prior Authorization Criteria and Regimen Review Sheets, State Maximum Allowable Cost Research Request Form, and other necessary forms.

Retirements and New Staff

The Board's office manager, Patricia Eggers, recently retired after 39 years of exemplary service to the Board and the citizens of the state. Ms Eggers was hired in June 1977 as office staff and was promoted to office manager when her predecessor retired. In recognition of her years of service to the profession, the Board declared her to be an honorary pharmacist at its July 2016 meeting. Her last day with the Board was August 15. The Board and its staff wish her a long and happy retirement.

The Board hired Lamar Niemczycki to replace Ms Eggers. Ms Niemczycki started with the Board on August 1. She was previously employed as a financial counseling supervisor at the Hennepin County Medical Center. Ms Niemczycki has Lean Six Sigma White Belt and team supervisor certifications from the Management and Strategy Institute.

Pharmacy Surveyor Les Kotek also recently retired, after ably serving the Board and public for 23 years. Mr Kotek received both bachelor of science and master of science in pharmacy degrees from the University of Minnesota. He had extensive experience in hospital pharmacy prior to accepting his position as a pharmacy surveyor. The Board and its staff wish him a long and happy retirement. As of the date this *Newsletter* was prepared, the Board had not yet hired a replacement, but was in the process of doing so.

In Memoriam

William Appel, pharmacist and former member of the Board, passed away on April 8, 2016. Mr Appel was born in Minneapolis, MN, on October 8, 1924, and graduated from the University of Minnesota College of Pharmacy in 1949. He was first licensed by the Board on July 19, 1949. After serving in the Navy as a lieutenant, he joined Appel Pharmacy, founded by his father in 1915. His career in pharmacy spanned more than 60 years. Mr Appel served as the American Pharmacists Association president from 1976 to 1977 and as treasurer from 1979 to 1981. He also served as vice president of the Minnesota Pharmacists Association from 1969 to 1970. He was appointed to the Board in April 1961 and served until January 1966. He was president of the Board in 1965. Mr Appel was married for 65 years to Louise (Altman) Appel. She preceded him in death. He is survived by his four children.

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Cody Wiberg, PharmD, MS - State News Editor

Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor

Amy Suhajda - Communications Manager