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Naloxone Dispensing Reporting to CSMP Required

As you are already aware, pharmacies in West Virginia can dispense naloxone without a prescription from a doctor under the pharmacy's own authority per the statewide naloxone protocol. One component of that protocol, and the state statutes enabling it, is that all dispensing of naloxone, by the prescriber's prescription or by the pharmacy alone under the protocol, must be reported to the Controlled Substances Monitoring Program (CSMP). As stated in the September 2016 *West Virginia Board of Pharmacy Newsletter,* "You must work with your software provider to include naloxone as a reportable item when reporting all [controlled substances (CS)] dispensed. Although naloxone is not a CS, the law requires all dispensings of it to be reported to the CSMP database." The law went into effect June 10, 2016 (passed March 12, 2016; in effect 90 days from passage). Therefore, all dispensings of naloxone from that date forward need to be reflected in the CSMP. The West Virginia Board of Pharmacy is tasked with reporting this information to the West Virginia Legislature's Legislative Oversight Commission on Health and Human Resources Accountability in a de-identified report, so please help the Board provide accurate data by meeting your end of the requirement for reporting.

Welcome to Newly Appointed Board Member

Sam Kapourales was appointed as a "new" Board member by Governor Earl Ray Tomblin to fill a five-year term ending June 30, 2021. Mr Kapourales is no stranger to the Board, having served numerous terms over the years, including serving as its president for many years. He assumed the seat vacated by George Karos, whose term expired June 30, 2016. Of course, it goes without saying that gratitude is owed to Mr Karos for his many years of service, also having served as a past president of the Board. Good luck to Mr Kapourales as he returns to the Board, and good luck to Mr Karos in his future endeavors.

Current Status of USP Chapters <795>, <797>, and <800>: Information for Pharmacies Doing Any Type of Compounding

The following text is reprinted from the United States Pharmacopeial Convention (USP).

May 2016 Update on Revisions to USP General Chapter <797> Pharmaceutical Compounding – Sterile Preparations

> USP proposed revisions to USP General Chapter <797> and sought public comments from September 25, 2015 to January 31, 2016. During this public comment process, the USP Compounding Expert Committee received more than 8,000 comments from over 2,500 stakeholders. The Expert Committee has been reviewing the comments and met face-to-face on April 11, 2016 to discuss the comments received. USP [expected] the revision process to continue through the summer of 2016. The Expert Committee will review all of the public comments received and USP will be gathering additional information where needed. The USP Healthcare Quality Standards Head of Science, Shawn C. Becker, will host two roundtables to seek clarity on public comments related to allergen extracts and radiopharmaceuticals . . . Based on the Expert Committee's evaluation of the public comments and significance of further revisions to the chapter, General Chapter <797> may be proposed for another public comment period. USP does not yet have an anticipated date for publication. To stay in touch with the revision process and updates on USP General Chapter <797>, please register for free practitioner updates at *http://www.usp.org/HQS-Signup-Form.*

<795> Pharmaceutical Compounding—Nonsterile Preparations

> This General Chapter provides guidance on applying good compounding practices in the preparation of nonsterile compounded formulations for dispensing and/or administration to humans or animals. The latest revision which became official May 1, 2011 includes categories of compounding (simple, moderate, and complex); definitions for terms (e.g., beyond-use date, hazardous drug, stability); and criteria for compounding each drug preparation (e.g., suitable compounding environment, use of appropriate equipment).

What is the status of the General Chapter <800> and when will General Chapter <800> become official?

> General Chapter <800> was published on February 1, 2016 in the First Supplement to USP 39–NF 34. The USP Compounding Expert Committee approved a delayed official implementation date of July 1, 2018 to allow entities additional time to implement the standard. With the delayed official date, entities have more than two years to implement this new standard.

Revised Statutes and Rules for Prescribing by APRNs

During the West Virginia Legislature's 2016 Regular Legislative Session, changes were made to the advanced practice registered nurse (APRN) statutes, including their prescriptive authority. The West Virginia Board of Examiners for Registered Professional Nurses then wrote emergency rules, which are now in effect, to implement the new changes. Information extracted from the September 23, 2016 emergency rule pertaining to the prescriptive authority of advanced

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National Pharmacy

The applicability of articles in the *National Pharmacy Compliance*
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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 appropriate 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 Item Writer Volunteer Interest Form available at 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.

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practice nurse practitioners is set forth below. The full text can be found on the West Virginia Secretary of State's website at *https://apps.sos.wv.gov/adlaw/csr/ruleview.aspx?document=10105.*

§19-8-5. Drugs Excluded from Prescriptive Authority; Prescriptive Authority Requirements.

5.1. The advanced practice registered nurse shall not prescribe from the following categories of drugs:

5.1.a. Schedules I and II of the Uniform Controlled Substances Act;

5.1.b. Antineoplastics;

5.1.c. Radio-pharmaceuticals; or

5.1.d. General anesthetics.

~~5.1.e. MAO Inhibitors, except when in a collaborative agreement with a psychiatrist.~~

5.2. Drugs listed under Schedule III ~~and benzodiazepines~~ are limited to a 30 day ~~72 hour~~ supply without refill.

~~5.3. The advanced practice registered nurse may prescribe drugs from Schedules IV through V in a quantity necessary for up to a 90 day supply, with only 1 refill, and shall provide that the prescription expires in 6 months, with the following exceptions:~~

~~5.3.a. Prescriptions for phenothiazines shall be limited to up to a 30 day supply and shall be non- refillable;~~

~~5.3.b. Prescriptions for non-controlled substances of antipsychotics, and sedatives prescribed by the advanced practice registered nurse shall not exceed the quantity necessary for a 90 day supply, shall provide for no more than 1 prescription refill and shall expire in 6 months.~~

~~5.4. Pursuant to a collaborative agreement as set forth in the law governing prescriptive authority the advanced practice registered nurse may prescribe an annual supply of any drug, with the exception of controlled substances, which is prescribed for the treatment of a chronic condition, other than chronic pain management.~~

~~5.5. The maximum dosage of any drug, including antidepressants, prescribed by the advanced practice registered nurse shall be consistent with the advanced practice registered nurse's area of practice.~~

5.3~~6~~. Each prescription and subsequent refills given by the advanced practice registered nurse shall be entered on the patient's chart.

~~5.7. Advanced practice registered nurse shall not prescribe other prescription drugs or refill for a period exceeding 6 months; provided, that this limitation shall not include contraceptives or those treating a chronic condition as defined in WV Code §30-7-15a and section 19-8-5.4 of this rule.~~

5.4~~8~~. An advanced practice registered nurse may administer local anesthetics.

5.5~~9~~. The advanced practice registered nurse who has been approved for limited prescriptive authority by the board may sign for, accept, and provide to patients samples of drugs received from a drug company representative.

5.6~~10~~. The prescription authorized by an advanced practice registered nurse shall comply with all applicable standards of care related to prescribing, state and federal laws and regulations; must be signed by the prescriber with the legal designation or the designated certification title of the prescriber and must include the prescriber's identification number assigned by the board or the prescriber's N~~n~~ational P~~p~~rovider I~~i~~dentifier (NPI) assigned by the National Plan and Provider Enumeration System pursuant to 45 CFR §162.408.

5.~~10~~6.a. All prescriptions shall include the following information:

5.~~10~~6.a.1. The name, title, address and phone number of the prescribing advanced practice registered nurse;

5.~~10~~6.a.2. The name and date of birth of the patient;

5.~~10~~6.a.3. The date of the prescription;

5.~~10~~6.a.4. The full name of the drug, the dosage, the route of administration and directions, for its use;

5.~~10~~6.5. The number of refills;

5.~~10~~6.a.6. The Drug Enforcement Agency number of the prescriber, when required by federal laws; and

5.~~10~~6.a.7. The prescriptive authority identification number issued by the board; or the prescriber's N~~n~~ational P~~p~~rovider I~~i~~dentifier (NPI) assigned by the National Plan and Provider Enumeration System pursuant to 45 CFR §162.408.

The *West Virginia Board of Pharmacy News* is published by the West Virginia 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.

West Virginia Board of Pharmacy
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