



West Virginia Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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Board Officers Remain the Same

At its regular West Virginia Board of Pharmacy meeting in June 2016, the Board had to elect its officers for the new fiscal year, which started July 1, 2016. Given that six of the seven members had just started their terms in December 2015, the Board voted to keep the officers the same as had just been elected in January 2016. Thus, Mr Dennis Lewis was elected president, Mr JJ Bernabei was chosen to be vice president, and Mrs Vicky Skaff was elected as the secretary/treasurer. Mrs Skaff and Mr Chuck Jones remain as the two Complaint Committee members, and Mrs Kimberly Knuckles remains in the position as the Board's representative to the Continuing Pharmacy Education Committee.

Using Common Sense When Dispensing Controlled Substances for Chronic Pain Conditions

Contributed by Board Member JJ Bernabei

If you are a pharmacist, you will be using your skills and judgment on a daily basis concerning the dispensing of pain medication for chronic pain conditions. Not unlike the changing level of pain a patient can experience, your evaluation and ultimate actions of dispensing may also vary. The pharmacist must first attempt to place himself or herself in a place of familiarity with the physician and the patient. When this triangle of care is solidly in place, your dispensing decisions have clarity. Although the Board does not require each dispensing pharmacy to have a controlled substance (CS) dispensing policy, the Board does demand that pharmacists dispense CS with justifiable reasoning that is consistent. If it does not seem reasonable, your judgment will tell you not to fill the prescription in question and you should not follow through with dispensing the prescription.

West Virginia law mandates that all pharmacists dispensing CS in the state have access to the Controlled Substances Monitoring Program (CSMP) reporting database. The law does not mandate its use by pharmacists, but better allows for pharmacists to use their judgment for when or when not to access the database. You can access the database frequently. There are workflow integrations of this reporting program now in beta testing in the state. Until the time when this information is automatically available, pharmacists must be diligent in their dispensing practices.

Remember the primary function of the CSMP is to serve as a treatment tool to reduce drug diversion by reducing the amount of controlled dosage units in our community. This is done in part by identifying individuals who are getting CS from multiple pharmacies and prescribers. By reducing instances of doctor shopping and reducing fills of controlled prescriptions as a result of doctor shopping, we in turn reduce the amount of dosage units diverted in our communities. With the help of the reporting program and accessing it when your judgment dictates, you can feel confident you are dispensing the medication in good faith and for legitimate purposes. By developing a CS policy to provide for consistency in your pharmacy, you further sharpen your ability to have

a strong triangle of care in place when the dispensing of CS must occur. You are not required to access the CSMP database, but you are required to exhibit sound, reasonable judgment and will ultimately be held to a reasonable dispensing standard.

Naloxone Protocol Is Now Official

The Board, with input from the West Virginia Department of Health and Human Resources Bureau for Public Health, finalized and posted the naloxone protocol for pharmacists to furnish naloxone without a prescription from a doctor. In essence, per the protocol, pharmacists are the prescriber and the dispenser. The protocol and required trifold brochures are available from the Board's website at http://wvbop.com/index.php?option=com_content&view=article&id=127&Itemid=125.

The protocol is shown below.

West Virginia Board of Pharmacy Protocol for Pharmacist or [I]nterns Furnishing Opioid Antagonist Naloxone Hydrochloride Developed in Consultation with the DHHR Bureau for Public Health

A pharmacist or intern furnishing an opioid antagonist, naloxone hydrochloride, pursuant to West Virginia Code § 16-46-3a shall satisfy the requirements of this protocol.

- (a) As used in this protocol:
 - (1) "Recipient" means the person to whom naloxone hydrochloride is furnished.
- (b) West Virginia Code § 16-46-3a provides that a pharmacist or pharmacy intern under the supervision of a pharmacist may dispense an opioid antagonist without a prescription pursuant to a protocol developed by the Board of Pharmacy in consultation with the Bureau for Public Health. As set forth in subsection (b) of section 16-46-3a[.]

A pharmacist or intern or pharmacy intern who dispenses [naloxone hydrochloride] without a prescription under this [protocol] shall provide patient counseling to the individual for whom the opioid antagonist is dispensed regarding, but not limited to, the following topics: (1) The proper administration of the opioid antagonist; (2) the importance of contacting emergency services as soon as practicable either before or after administering the opioid antagonist; and (3) the risks associated with failure to contact emergency services following administration of an opioid antagonist. The patient counseling described in this section is mandatory and the person receiving the opioid antagonist may not opt out.

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FDA Calls for Review of Opioids Policy, Announces Action Plan

As part of a broad national campaign to address opioid abuse, dependence, and overdose, Food and Drug Administration (FDA) Deputy Commissioner for Medical Products and Tobacco, Dr Robert Califf, along with other FDA leaders, developed a comprehensive action plan to reassess the agency's approach to opioid medications. The objective of the plan is to "focus on policies aimed at reversing the epidemic, while providing patients in pain access to effective relief," indicates the FDA news release. FDA's plan is to:

- ◆ Re-examine the risk-benefit paradigm for opioids and ensure that the agency considers their wider public health effects;
- ◆ Convene an expert advisory committee before approving any new drug application for an opioid that does not have abuse-deterrent properties;
- ◆ Assemble and consult with the Pediatric Advisory Committee regarding a framework for pediatric opioid labeling before any new labeling is approved;
- ◆ Develop changes to immediate-release (IR) opioid labeling, including additional warnings and safety information that incorporate elements similar to the extended-release/long-acting (ER/LA) opioid analgesics labeling that is currently required;
- ◆ Update Risk Evaluation and Mitigation Strategy requirements for opioids after considering advisory committee recommendations and review of existing requirements;
- ◆ Expand access to, and encourage the development of, abuse-deterrent formulations of opioid products;
- ◆ Improve access to naloxone and medication-assisted treatment options for patients with opioid use disorders; and
- ◆ Support better pain management options, including alternative treatments.

FDA will also seek guidance from outside experts in the fields of pain management and drug abuse. The National Academies of Sciences, Engineering, and Medicine has been asked by FDA to help develop a framework for opioid review, approval, and monitoring that balances individual need for pain control with considerations of the broader public health consequences of opioid misuse and abuse. The news release is available on FDA's website at www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm484765.htm.

More Selected Medication Safety Risks to Manage in 2016



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.

Manufacturer Drug Labeling, Packaging, Nomenclature – Per Liter Electrolyte Content on Various Sizes of Manufacturers' IV Bags

The way electrolyte concentrations are expressed on intravenous (IV) bags in volumes less than or greater than one liter has tripped up many practitioners over the years. Concentrations are listed per liter, not per container volume. For example, a 250 mL 0.9% sodium chloride injection container label lists the sodium chloride content as 154 mEq/1,000 mL, rather than 38.5 mEq/250 mL. Commercially available parenteral nutrition products available in containers greater than one liter also express the electrolyte ingredients "per liter."

An error occurred while a pharmacist was preparing a bag of 3% sodium chloride after the pharmacy unexpectedly ran out of the commercially available bags. The pharmacist mistakenly set the proportion up as $154 \text{ mEq}/0.9\% = x/3\%$ and calculated that he needed 513 mEq of sodium chloride, when he actually only needed 256-257 mEq of sodium chloride for a 500 mL bag ($77 \text{ mEq}/0.9\% = x/3\%$).

For single- and multiple-dose injectables, the United States Pharmacopeial Convention (USP) requires the strength per total volume as the primary, prominent display on the label, followed in close proximity by the strength per mL enclosed in parentheses. This should apply to large volume parenterals as well. Until it does, pharmacists who calculate electrolyte quantities should seek out an independent double check. Sufficient quantities of commercially available products should be used whenever possible. For products that routinely require admixture, an instruction sheet should be available to guide the process.

Patient Education – Discharging Patients Who Do Not Understand Their Discharge Medications

Despite the importance of teaching patients about the medications to take after discharge, studies suggest health care providers are not successfully preparing patients for the transition home. Between 30% and 70% of patients make a medication error in the immediate weeks following hospitalization,¹⁻⁵ and the Centers for Medicare & Medicaid Services reports an average national hospital readmission rate of 17.5% to 19.5%.⁶ The discharge process is often rushed and interrupted, making it difficult to ensure patients know what medications to take, the correct doses, and how to take them after discharge. Immediately prior to discharge is not an ideal time for education either, as patients may be overwhelmed with the amount of information being provided at once.

Medication errors that occur during the first few weeks after discharge from the hospital can cause significant harm. In fact, one study showed that almost a quarter of all post-discharge errors were considered serious or life-threatening, and that



most of these errors happened within the first 14 days after discharge.⁵ The highest predictors of post-discharge errors included low health literacy and low subjective numeracy (self-reported measure of the ability to perform mathematical tasks and the preference for numerical versus prose information (ie, ordinary words)).⁴

Perhaps this risk is best addressed with a redesigned discharge process that facilitates the most effective means of teaching patients about their medications, initiating education earlier in the hospital stay, and providing post-discharge support.

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USP Publishes Chapter on Handling Hazardous Drugs in Health Care Settings

A new general chapter, <800> *Hazardous Drugs—Handling in Healthcare Settings*, has been published as part of a suite of health care quality standards included in the *United States Pharmacopeia – National Formulary (USP–NF)* by USP to help prevent and/or limit hazardous drug exposures in health care. The standard applies to all health care personnel, such as physicians, nurses, veterinarians, pharmacists, and technicians, and all health care facilities where hazardous drugs are handled or manipulated, including their storage and distribution. Health care facilities have more than two years to conform to the new requirements and have until July 1, 2018, to implement the new standard, indicates a USP press release, which is available at www.usp.org in the News section. General Chapter <800> is available in both the First Supplement to *USP 39–NF 34* and the *USP Compounding Compendium*.

FDA Provides Training Video on Keeping Medications Safe in Emergency Situations

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. In the February 2016 Drug Info Rounds video, “Emergency Preparedness – Keeping Medications Safe,”

pharmacists discuss educating patients about having a plan in place for emergency medication and medical supplies and the resources available for pharmacists to use when advising their patients. 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. All Drug Info Rounds videos can be viewed on the FDA website at www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm.

FDA Requires Class-Wide Labeling Changes for IR Opioid Analgesics

FDA is requiring class-wide safety labeling changes for IR opioid pain medications, which will include a new boxed warning about the serious risks of misuse, abuse, addiction, overdose, and death. The announcement is part of the agency’s effort to educate prescribers and patients about the potential risks related to opioid use. FDA is also requiring several safety labeling changes across all prescription opioid products to include additional information on the risk of these medications. The new requirements are part of a plan to reassess the agency’s approach to opioid medications. The plan is focused on reversing the epidemic of abuse and overdose while still providing patients in pain access to effective relief, indicates the FDA news release at www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm491739.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery.

Further, FDA is requiring updated labeling for all opioids (both IR and ER/LA products) to include safety information about potentially harmful drug interactions with other medicines that can result in a serious central nervous system condition called serotonin syndrome. In addition, updated labeling will include information about opioid effects on the endocrine system, including a rare but serious disorder of the adrenal glands (adrenal insufficiency) and decreased sex hormone levels (androgen deficiency). More information about these risks is available in FDA’s Drug Safety Communication announcement, available at www.fda.gov/Drugs/DrugSafety/ucm489676.htm.

FDA Issues Alert Regarding All Unexpired Sterile Drug Products Produced by Medaus Pharmacy

On April 1, 2016, FDA alerted health care providers and patients not to use products marketed as sterile from Medaus Pharmacy in Birmingham, AL. Insanitary conditions, including poor sterile production practices, were identified by FDA investigators during a recent inspection at Medaus’ facility. The affected products were distributed nationwide and internationally. The alert applies to all unexpired drug products that are intended to be sterile. Health care providers should check their medical supplies, quarantine any drug products marketed as sterile from Medaus, and not administer them, indicates the FDA Safety Alert, available at www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsForHumanMedicalProducts/ucm493871.htm.

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Further, subsection (d) provides: "All pharmacists or pharmacy interns who dispense an opioid antagonist under this section shall provide educational materials to any person receiving such an opioid antagonist on opiate-related overdose prevention and treatment programs, as well as materials on administering the opioid antagonist." Following is the protocol developed to meet these requirements. The law clearly requires only a protocol issued by the Board in consultation with the Bureau for Public Health for pharmacists to dispense Naloxone without any prescription from any practitioner. However, although not required, a pharmacy may choose to have a prescribing practitioner sign the protocol set forth in subsection (c) below to treat it as a standing order.

(c) Protocol for Pharmacist or Interns Furnishing Naloxone Hydrochloride.

- (1) Before providing naloxone hydrochloride, the pharmacist or intern shall screen the potential recipient by asking whether the person to whom the naloxone hydrochloride would be administered has a known hypersensitivity to naloxone. (If the recipient answers yes, the pharmacist or intern may not provide naloxone. If the recipient responds no, the pharmacist or intern may continue.)
- (2) When naloxone hydrochloride is furnished:
 - (A) The pharmacist or intern shall provide the recipient with appropriate counseling and information on the product furnished, including dosing, effectiveness, adverse effects, storage conditions, [shelf life], and safety. The recipient is not permitted to waive the required consultation.
 - (B) The pharmacist or intern shall provide the recipient with the number to talk with someone about available substance abuse treatment and recovery services near them, 1-844-HELP-4-WV, if the recipient indicates interest in addiction treatment or recovery services at this time.
 - (C) The pharmacist or intern shall answer any questions the recipient may have regarding naloxone hydrochloride.
- (3) Product Selection: A pharmacist or intern may supply naloxone hydrochloride in any [Food and Drug Administration]-approved product form.

- (4) The dispensing shall be documented and labelled as a prescription dispensed per this protocol.
- (5) Fact Sheet: The pharmacist or intern shall provide the recipient a copy of the current Naloxone Administration Tri-fold "I Have Narcan", and the Naloxone Tri-fold [Brochure] concerning recognition of signs of an overdose and other information, both created and maintained by the West Virginia Department of Health & Human Resources, Bureau for Public Health, Office of Emergency Medical Services: <http://www.wvoems.org/medical-direction/naloxone-information>.
- (6) Privacy: All pharmacist or interns furnishing naloxone hydrochloride in a pharmacy or health care facility shall operate under the pharmacy or facility's policies and procedures to ensure that recipient confidentiality and privacy are maintained.
- (7) Although not required, a pharmacy may choose to have a prescribing practitioner sign the protocol to treat it as a standing order.

There are some real and practical issues. First, the price will often make access to naloxone prohibitive without a prescription benefit to pay for it. Second, while pharmacists with their own National Provider Identifier number may write the prescription and bill directly for this item, some insurance carriers may not recognize a pharmacist as a provider. So, pharmacists may seek and obtain a standing order from a physician and issue prescriptions in the physician's name for billing. Finally, it must be remembered that the dispensing of all opioid antagonists must be reported to the CSMP database. You must work with your software provider to include naloxone as a reportable item when reporting all CS dispensed. Although naloxone is not a CS, the law requires all dispensings of it to be reported to the CSMP database.

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