



West Virginia Board of Pharmacy

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House Bill 4208: Hydrocodone, Tramadol, and Buprenorphine With Naloxone

House Bill 4208 passed during the 2014 Regular Legislative Session, and becomes effective on June 6, 2014. It updates several things in the West Virginia Controlled Substances Act, including adding a number of synthetic cannabinoids to Schedule I, and cleaning up some differences between the state and federal schedules (like moving buprenorphine to Schedule III in the state code to match the federal). Three other highlights include the following.

Hydrocodone in Combination: For hydrocodone in combination as a Schedule III drug, the new language added to West Virginia Code §60A-2-208(e) provides in relevant part:

... Provided, That a prescription for this product may not be filled for more than a one month supply or filled or refilled more than three months after the date of the original prescription. Such prescription may not be refilled more than twice . . .

In short, this means that for Schedule III hydrocodone prescriptions, (a) the orders expire 90 days from the date written; (b) they cannot be filled at any one time for more than a 30-day supply; and (c) they can only be refilled a maximum of two times, regardless.

So, the question arises of how to apply this new law to current prescriptions already on file on June 6, when the statute becomes effective. Given that the statute does not contain any exceptions for them, then all existing prescriptions will be affected. So, if a given prescription is more than 90 days old, it would be expired. Similarly, if you have a prescription with five refills that has already been refilled twice or more, it would be against the new statute to dispense any further refills on it. Still further, if it is written for more than a 30-day supply, you would be limited to a 30-day supply, regardless. To take it further, let us say a prescriber writes for a 15-day supply with three refills; you could only dispense the original and two refills even though the prescriber only wrote for a total of a 60-day supply, and could have written for 90. In summary, you are limited by each of the three parameters, whichever ones apply; in this last example, no more than two refills regardless of the smaller quantity. Likewise, if the prescriber writes for a single 90-day supply, or for a 45-day supply with one refill, you can only dispense a 30-day supply, and would have to speak with the prescriber to change

the prescriptions to 30-day supplies with two refills if you want to be able to give the full 90 days of therapy under one prescription. To the extent pharmacists can, in between all of their other duties, it might be worth being proactive to let affected patients and prescribers know to smooth the transition.

Tramadol Added to Schedule IV: The bill also adds any substance containing tramadol hydrochloride to Schedule IV in West Virginia Code §60A-2-210(f)(3). As such, beginning June 6, tramadol must be treated as a Schedule IV drug for all purposes, including record keeping, storage, dispensing, and reporting. Please let your dispensing software vendors or in-house programmers know that it needs to be added to your dispensing reports to the West Virginia Controlled Substances Monitoring Program database.

Buprenorphine with Naloxone Restrictions Removed: The bill also struck the language in West Virginia Code §60A-3-308(e) that was added in 2012 to limit the prescribing and dispensing of a combination of buprenorphine and naloxone to the form of sublingual film. By deleting this subsection in its entirety, a prescriber is free to write for, and a dispenser is free to dispense, Suboxone® or Zubsolv® tablets or any other generic equivalent, or the film, whichever is appropriate dependent on how the prescription is written (brand medically necessary, patient substitution issues, etc). In other words, as of June 6, the restrictions limiting prescribing to the film are simply removed from the law in West Virginia.

Frequently Asked Questions on CPE Hours Given Recent Changes

Q. By when must I complete the new required three continuing pharmacy education (CPE) hours for best practices prescribing and dispensing for pain (drug diversion CPE)?

A. The statute and rules require the drug diversion CPE to be completed every reporting period. So, if you are up for renewal on July 1, 2014, then you must have completed the three hours as required for your renewal this time around. If you are up for renewal July 1, 2015, you must have completed it for your reporting period for your July 1, 2013 through June 30, 2015, license period. However, if you are a newly licensed pharmacist, you must complete this requirement during your first year of practice, regardless of when you come up for renewal.

continued on page 4



New USP Webpage Answers Common Questions About USP Chapters <795> and <797>

In response to questions concerning United States Pharmacopeia-National Formulary (USP-NF) General Chapters <795> and <797>, USP has created a new frequently asked questions (FAQs) page on its website. The FAQs answer questions related to the Revision Bulletin for Chapter <795> that was issued on November 22, 2013, and became official on January 1, 2014. Among other topics, the FAQs address common questions regarding beyond-use dating and the differences between testing stability with strength (potency) or stability-inducing methods. The FAQs can be accessed at www.usp.org/support-home/frequently-asked-questions/compounding. Question four on the page includes a link to a USP article, "Strength and Stability Testing for Compounded Preparations."

Only You Can Prevent Look-Alike Sound-Alike Drug Names

 *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 Error Reporting Program. Report online at www.ismp.org. E-mail: ismpinfo@ismp.org.*

VESicare/Vesanoid Mix-Up. A prescriber's office sent an electronic prescription to the patient's pharmacy; the prescriber intended to prescribe **VESicare**® (solifenacin succinate) for overactive bladder but inadvertently selected **Vesanoid**® (tretinoin), which is used to induce remission of acute promyelocytic leukemia. The pharmacy technician entered the prescription for generic tretinoin; however, the pharmacy was unable to dispense the medication as the patient's pharmacy benefit manager required a prior authorization. The technician faxed a request and the prescriber's office replied back that VESicare was intended. Both of these products are available in 10 mg solid oral dosage forms, increasing the risk of confusion. Investigate strategies (eg, tall man letters) to differentiate these products on computer screens. Prescribers should include the indication for the drug with the prescription. As always, providing patient education, especially for new prescriptions, is a good strategy to intercept errors before they impact the patient.

Benazepril Confused With Benadryl. A pharmacist reported a mix-up between benazepril (**Lotensin**®) and **Benadryl**® (diphenhydramine). A patient faxed a request to the pharmacy to ask for her "benazpryl." The pharmacist who received the fax interpreted

it as Benadryl and placed a bottle of diphenhydramine in the bag for pick-up. Around this same time, the pharmacy went through a change in wholesaler and many manufacturers of generic products were changed. A few days later, a coworker of the patient picked up the medication (along with several others). The technician at the point-of-sale told the coworker that many of the manufacturers had changed recently and that some of the pills may look different. The patient received the diphenhydramine, filled her medication box with the capsules, and took diphenhydramine daily for three weeks before noticing she was unusually tired. When she brought the bottle back to the pharmacy, the error was recognized.

ISMP continues to receive reports of confused drug name pairs being involved in errors. ISMP wants to inform its readers of these drug name confusions so they may continue evaluating what measures they have in place to protect against these possible confusions.

Your Help Is Needed With Product Safety Testing. If you are a pharmacist, nurse, pharmacy technician, or other health care practitioner who is interested in furthering medication safety and error prevention, you can make a difference! Med-ERRS (a subsidiary of ISMP) is looking for assistance to help evaluate medication labels, drug packaging, and proposed drug names prior to submission by pharmaceutical and biotech companies for approval by Food and Drug Administration (FDA). The process is fun, simple, and easy. A small honorarium is paid. For more information or to sign up, visit www.med-errs.com and click on "Become a Reviewer."

FDA Issues Alert on Acetaminophen Products

In light of all the recent news alerts and warnings about the use of acetaminophen and acetaminophen-containing products, FDA issued a recommendation of importance to pharmacists, prescribers, and patients.

FDA recommends that health care providers consider prescribing combination drug products that contain 325 mg or less of acetaminophen. FDA also recommends that when a pharmacist receives a prescription for a combination product with more than 325 mg of acetaminophen per dosage unit that he or she contacts the prescriber to discuss a product with a lower dose of acetaminophen. A two-tablet or two-capsule dose may still be prescribed, if appropriate. In that case, the total dose of acetaminophen would be 650 mg (the amount in two 325 mg dosage units). When making individual dosing determinations, health care providers should always consider the amounts of both the acetaminophen and the opioid components in the prescription combination drug product.

FDA, in its MedWatch Safety Alert, reports that, "There are no available data to show that taking more than 325 mg of acetaminophen per dosage unit provides additional benefit that outweighs the added risks for liver injury. Further, limiting the amount of acetaminophen per dosage unit will reduce the risk of severe liver injury from inadvertent acetaminophen overdose, which can lead to liver failure, liver transplant, and death."

In January 2011, FDA asked manufacturers of prescription combination drug products containing acetaminophen to limit the amount of acetaminophen to no more than 325 mg in each tablet or capsule by January 14, 2014. FDA requested this action to protect consumers from the risk of severe liver damage that

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can result from taking too much acetaminophen. More than half of manufacturers have voluntarily complied with FDA's request. However, some prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit remain available. In the near future, FDA intends to institute proceedings to withdraw approval of prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit that remain on the market.

Boards of pharmacy have received inquiries from pharmacists about remaining stock of the higher dose acetaminophen and what procedures should be followed. The FDA recommendation notes that pharmacists are advised to contact prescribers and request a change in the prescription. If the prescriber is not willing to make the change in the prescription, unfortunately, there is no clear cut recommendation at this point as to whether to dispense the higher dose acetaminophen product. It would appear that the higher dose acetaminophen-containing products will be regarded by FDA as unapproved and delisted from FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations*, commonly known as the "Orange Book." Until this occurs, pharmacists must make a judgment regarding continuing to dispense the higher dose acetaminophen containing products in light of the FDA recommendation and concern for patient safety.

Some Rohto Eye Drops Products Recalled

The Mentholatum Company of Orchard Park, NY, has issued a voluntary recall of some Rohto® eye drop products due to a manufacturing review at the production facility in Vietnam involving sterility controls. The recall has been issued at the retail level and includes Rohto Arctic, Rohto Ice, Rohto Hydra, Rohto Relief, and Rohto Cool eye drops that were manufactured in Vietnam. Products made in other facilities are not affected by the recall. To date, there has been no evidence indicating the recalled products do not meet specifications, according to a press release.

The recalled products are sold over the counter at pharmacies and retail stores throughout the United States, and can be identified by the words "Made in Vietnam" on the side carton panel under the company name and address information as well as on the back label of the bottle. Lot numbers for the recalled products contain the letter "V." Distributors and retailers are being notified by letter to stop distributing the products and to follow the recall instructions provided by the company. Questions about the recall can be directed to The Mentholatum Company at 877/636-2677, Monday through Friday, 9 AM to 5 PM Eastern Time. FDA urges consumers and health care providers to report any adverse events or side effects related to the use of these products to FDA's MedWatch Safety Information and Adverse Event Reporting Program. More information is available at www.fda.gov/Safety/Recalls/ucm382076.htm.

FDA Provides Compounding Law Implementation Information

FDA has provided implementation information on Title I of the recently passed Drug Quality and Security Act – known as the Compounding Quality Act – through its website.

Of note, FDA specifies that compounding entities may register as an outsourcing facility, which, under certain conditions, may be exempt from the Federal Food, Drug, and Cosmetic Act's (FD&C Act) approval and labeling requirements. Drugs produced by compounders that are not registered as outsourcing facilities must meet the conditions of Section 503A of the FD&C Act, which was amended by the new law, to qualify for certain exemptions.

The document adds, "If a compounded drug does not qualify for exemptions under either section 503A or 503B of the [FD&C Act], the compounded drug would be subject to all of the requirements of the [FD&C Act] that are applicable to drugs made by conventional manufacturers, including the new drug approval and adequate directions for use requirements." FDA also notes it will provide additional information about how the agency will interpret certain provisions of Section 503A at a later date.

The implementation information may be viewed at www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm375804.htm.

New e-LTP Fees Effective July 1, 2014

Supporting ongoing efforts to protect the integrity of its licensure transfer programs and to support the expansion of new technologies that are being implemented to enhance the program, the National Association of Boards of Pharmacy® (NABP®) is adjusting the fees for the Electronic Licensure Transfer Program® (e-LTP™).

Beginning July 1, 2014, the e-LTP fees will be adjusted as follows:

- ◆ The preliminary application and first state transfer fee will increase from \$350 to \$375
- ◆ Each additional state transfer will increase from \$50 to \$75
- ◆ Change of states will increase from \$50 to \$75
- ◆ Time extensions will increase from \$50 to \$75

The fees for e-LTP were last adjusted in 2010. More information about e-LTP is available in the Programs section of the NABP website at www.nabp.net. Additional questions about the fee adjustment may be directed to Neal Watson, licensure programs manager, at 847/391-4406, or at nwatson@nabp.net.



Pharmacists & Technicians:
Don't Miss Out on Valuable CPE Credit.
Set Up Your NABP e-Profile and Register for CPE Monitor Today!

Continuing pharmacy education (CPE) providers who are accredited by the Accreditation Council for Pharmacy Education (ACPE) have integrated CPE Monitor® into their systems and are requiring pharmacists and pharmacy technicians to provide an NABP e-Profile ID number and date of birth (MMDD) in order to process ACPE-accredited CPE credit.

Visit www.MyCPEmonitor.net to set up your NABP e-Profile and register for CPE Monitor and avoid possible delays in your CPE reporting.

CPE Monitor is a national collaborative service from NABP, ACPE, and ACPE providers that will allow licensees to track their completed CPE credit electronically.

continued from page 1

Q. Do I still need to complete the “End of Life Care” CPE that was mandatory for all first-time license renewals?

A. No, the end-of-life CPE requirement was deleted from the law. The statute now requires the drug diversion CPE each reporting period. So, you will have to get three hours of this CPE every two years going forward as part of your 30 hours, but end-of-life care is no longer required.

Q. I am registered as a consultant pharmacist (and/or immunizing pharmacist) and a registered pharmacist. Can the CPE hours I have completed for my consultant license (and/or immunizing pharmacist permit) be applied towards the 30 hours needed to renew my pharmacist license?

A. Yes, the hours can count toward your 30 required total CPE hours. The same is also true for the new best practices prescribing and dispensing for pain hours (drug diversion CPE).

Pharmacy Technician Registration and Pharmacy Technician Trainee Training Changes

As you are aware, the Pharmacy Practice Act revisions done in the 2013 Regular Legislative Session require anyone registering as a pharmacy technician (PT) beginning July 1, 2014, to have either graduated from an approved formal PT education and training program, or have completed an approved pharmacy-based, on-the-job PT training program; and then successfully passed a national PT certification exam. Of course, those already registered and in good standing as a PT as of June 30, 2014, are grandfathered in and can simply continue to renew their registrations as before. As for the national examinations, the West Virginia Board of Pharmacy still accepts either the Pharmacy Technician Certification Board or the National Healthcare Association Certified Pharmacy Technician certifications granted upon passing the Pharmacy Technician Certification Exam (PTCE) or the Exam for the Certification of Pharmacy Technicians (ExCPT), respectively. A pharmacy technician trainee (PTT) in a formal education setting will need to make sure his or her program is approved by the Board, provide proof of completion, pass the national exam, and otherwise fulfill the requirements set out in the Board’s application process.

Regarding PTTs trying to get registered through a pharmacy-based, on-the-job PT training program, questions have arisen about what happens to one who is already working toward

registration but not finished with the current 2,080-hour pharmacy-based PT training program and tested on the old Board-provided PT examination prior to July 1. First, the Board voted to shorten the on-the-job, pharmacy-based PT training required from 2,080 hours down to 960 hours. Second, rather than giving two years to complete it, the Board voted to allow nine months to complete the training, and then three months to successfully pass a national examination. In addition, the Board agreed to give credit for hours already earned in a 2,080-hour program toward the 960 hours, with the understanding that the rules still require a supervising pharmacist to certify that full training has been completed (including content, not just number of hours).

Further, while those in a training program would not have to start over at zero hours, the Board also agreed that they would have until the end of their original 2,080-hour, two-year period, or the full nine months, starting July 1, 2014, whichever occurs first, to complete the training they are in. So, just because an affected PTT may reach 960 hours shortly after (or already have 960 hours as of) July 1, they would not be limited to three more months to pass the exam or get out of the pharmacy. They would have a full nine months starting July 1, 2014, within which to finish their training, or until the end of their original two-year, 2,080-hour training, whichever occurs first. The key is that the supervising pharmacist must certify them as being fully trained under the pharmacy’s PT training program, from which date of certification they will have three months to pass the PTCE or ExCPT. If they are ready the minute they reach 960 hours, then fine. If, however, they are not, then the Board will not penalize them because they started under the old law and finished under the new law. They will still have to get a national certification, but they will have the remainder of their two-year, 2,080-hour training period, or the nine months starting July 1, to finish training.

Page 4 – June 2014

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