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News

West Virginia Board of Pharmacy

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Clarification on One Point of CARA

In July 2016, the Comprehensive Addiction and Recovery Act of 2016 (CARA) was signed into law. This article focuses on Section 702 of the Act, partial fills of Schedule II controlled substances (CS), and West Virginia law. Section 702 contains new language that allows for partial filling of Schedule II drugs if, among other things, it is not prohibited by state law and the partial fill is requested by the patient or the practitioner who wrote the prescription. Importantly, CARA made a change that allows for the remaining portions of a partially filled prescription in Schedule II to be provided no later than 30 days after the date on which the prescription is written, except for an emergency situation, in which the remaining portion must be filled within 72 hours. However, we must focus on West Virginia, which is more restrictive, and therefore controls.

West Virginia Code §30-5-27 states that partial fills are legally permissible, but in subsection (b), it specifically restricts Schedule II partial fills as follows:

> The partial filling of a prescription for a controlled substance listed in Schedule II is permissible if the pharmacist is unable to supply or the patient requests less than the full quantity called for in the prescription. **The remaining portion of the prescription may be filled within seventy-two hours of the first partial filling:** Provided, That if the remaining portion is not or cannot be filled within the seventy-two hour period, the pharmacist shall notify the prescribing individual practitioner. **Further quantity may not be supplied beyond seventy-two hours without a new prescription.** (Emphasis added)

This language is reiterated in the West Virginia Board of Pharmacy's Rules at West Virginia Code of State Rules §15-2-7.11. Therefore, despite the permissiveness of CARA to provide the remainder of a partial fill of a Schedule II drug for up to 30 days from the date the prescription is written, West Virginia law still contains the restriction of the 72-hour rule, which says the remainder must be filled within 72 hours of the original partial fill or it is forfeited by the patient.

Next, the language of the two provisions read together brings up an interesting situation that may occur: what if a patient comes in more than 30 days after a prescription is written for a Schedule II CS and asks for a partial fill? Under both CARA and West Virginia law, the partial fill is permissible, but what about the remainder? In this case, CARA is tighter and the remainder would be forfeited, as CARA states that the remaining portions of a partially filled prescription in Schedule II must be provided no later than 30 days after the date on which the prescription is written. So, watch out for this unique situation where the two separate rules collide and CARA actually prohibits filling the remainder.

CSMP Update

The Board continues to improve and update the Controlled Substances Monitoring Program (CSMP). The number of active CSMP users has more than doubled in the last two years, and utilization of the CSMP continues to grow. Utilization by all types of users has risen to well over a million queries annually. The morphine equivalent daily dose/morphine milligram equivalent reporting function began July 28, 2016, giving practitioners a tool to assess the level of their patients' opioid medications. There have also been several ad hoc reports added to the system to better assess a number of activities. Since June 2016, the Board has been collecting dispensing data for opioid antagonists. The Board is also in the process of soliciting bids for a new CSMP vendor contract, which will begin on July 1, 2017.

Overall dosage unit dispensing numbers have declined over the last several years. The top 12 products by number of doses dispensed are listed in Figure 1. The Schedule II opioid hydrocodone has seen the most significant drop in numbers in West Virginia in past years, with a decrease of over 12 million doses from 2014 to 2015, and almost 40 million since 2011. Tramadol, a Schedule IV analgesic, seems to be a safer replacement for the much stronger hydrocodone, seeing an increase of 34 million doses over the same time.

Figure 1: West Virginia Controlled Substance Doses (in Millions)

	Year					
Drug Products	**2011**	**2012**	**2013**	**2014**	**2015**	**2016**
Hydrocodone	99.61	94.75	82.78	76.19	63.83	60.15
Oxycodone	40.3	43.99	42.79	42.76	40.59	36.18
Tramadol	0.95	9.81	10.83	21.08	35.53	35.68
Codeine	4.07	3.58	3.11	3.22	4.37	4.56
Alprazolam	42.28	40.22	37.78	36.84	35.25	32.14
Clonazepam	17.41	17.53	17.36	18.11	18.01	17.39
Lorazepam	17.17	16.85	16.46	16.34	15.69	15.83
Diazepam	11.36	10.88	10.22	9.97	9.5	8.83
Zolpidem	10.73	10.51	9.72	6.98	8.98	8.22
Amphetamine	7.86	6.87	6.99	7.27	7.46	7.82
Buprenorphine	3.52	4.58	4.72	5.61	6.26	7.12
Methylphenidate	2.13	4.13	4.62	4.5	4.46	4.74

Interstate Data Sharing – In March 2014, West Virginia successfully deployed its interface with the National Association of Boards of Pharmacy® PMP InterConnect® program. West Virginia is currently

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National Pharmacy

The applicability of articles in the *National Pharmacy Compliance*
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FDA Issues Final Rule Amending List of Drug Products That May Not Be Compounded

Food and Drug Administration (FDA) issued a final rule amending FDA's list of drug products that may not be compounded under certain sections of the Federal Food, Drug, and Cosmetic Act (FD&C Act) that allow the marketing of unapproved compounded drugs. Drug products on the list may not be compounded because the drug products have been withdrawn or removed from the market for safety or effectiveness reasons, indicates FDA. The list may be found in the Code of Federal Regulations at Title 21, Section 216.24, at *www.ecfr.gov.*

The final rule adds 24 types of drugs to the withdrawn or removed list; modifies the withdrawn or removed list to allow one type of drug product to be compounded under certain circumstances; and clarifies that the withdrawn or removed list applies to sections 503A and 503B of the FD&C Act. The final rule is available at *www.gpo.gov/fdsys/pkg/FR-2016-10-07/pdf/2016-24333.pdf.* FDA provides more information online at *www.fda.gov/Drugs/DrugSafety/ucm524320.htm.*

Selected Medication Risks to Manage in 2017

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.*

Some medication safety risks are painfully apparent in an organization, while many others lie dormant in the system until an error or adverse event draws attention to them. ISMP thought it would be useful to describe selected medication safety risks for organizations to manage in 2017 that might otherwise fall off the radar screen.

Environmental Factors, Workflow, and Staffing Patterns – Poor Quality Lighting

Lighting is a crucial aspect of the physical environment that has been linked to medication safety.[1] Poor quality lighting has often impaired the highly visual tasks associated with medication use, thus leading to medication errors. Examples include tubing misconnections due to low lighting in a patient's room, infusion pumps that have been misprogrammed because of dim backlighting on the screens, and product selection errors in the pharmacy and patient care units caused by low lighting under a pharmacy hood or shadows around an automated dispensing cabinet (ADC).

Despite existing guidelines for lighting in health care, it has been a challenge to implement optimal lighting conditions for prescribing, dispensing, and administering medications. Recent literature reviews found that little system-wide action has been taken to increase staff awareness of the problem or improve the lighting.[1,2] This is largely because the tasks associated with medication use are varied and carried out under diverse physical conditions and in differing locations, and because there are differences in an individual's light requirements based on visual acuity and age. With an ever-increasing population of older health care providers, eye fatigue from computer work and task complexity, small font sizes on medication labels, poor background contrast, and glare or shadows have taken their toll on visual accuracy.[1,2]

Proper illumination improves both the accuracy and efficiency of medication-related tasks. Fluorescent cool white lamps or compact fluorescent lamps should be used in areas where critical tasks are performed, including on mobile medication carts, near ADCs, and in patients' rooms for nighttime administration of medications.[3,4] Administration of medications at night under low lighting to avoid disturbing the patient is an unsafe practice and should be avoided. Adjustable 50-watt high-intensity task lights are recommended when difficult-to-read prescriptions and product labels are encountered.[4] Illumination levels for computer order entry areas should be at least 75 foot-candles (fc), while 100-150 fc are needed when interpreting handwritten orders.[4] Medication preparation areas, medication verification areas, and patient counseling areas should have illumination levels between 90-150 fc.[4] Medication rooms should provide illumination at 100 fc.[4] Lighting levels should be increased if the workforce has an average age above 45 years. A magnifying glass and task light together can also significantly improve accuracy[3] and should be used on mobile medication carts (including those used with bar code medication verification systems)[4] and near ADCs.

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DEA to Decrease Manufacturing Amount of Opioid Controlled Substances in 2017

Drug Enforcement Administration (DEA) is reducing the amount of almost every Schedule II opiate and opioid medication that may be manufactured in 2017 by 25% or more. Other medicines were reduced by more, such as hydrocodone, which will be 66% of last year's level, indicates the DEA news release. DEA notes that demand for these opioid medicines has declined based on sales data from IMS Health, a company that provides insurance companies with data on prescriptions written and prescription medications sold in the United States.

The aggregate production quota (APQ) established by the final order is the total amount of a controlled substance (CS) necessary to meet the estimated medical, scientific, research, industrial, and export needs for the year and for the maintenance

of reserve stocks. The 2017 APQ has been reduced for oxycodone, hydrocodone, fentanyl, hydromorphone, morphine, and other such medications. Much of this reduction is attributed to the elimination of a 25% buffer that was added to the APQ annually in 2013 through 2016 to guard against shortages. The purpose of quotas is to provide an adequate and uninterrupted supply for legitimate medical need of the types of Schedule I and II CS that have a potential for abuse, while limiting the amounts available to prevent diversion.

Additional details may be found in the DEA news release available at *www.dea.gov/divisions/hq/2016/hq100416.shtml* and in the final order available at *https://www.gpo.gov/fdsys/pkg/FR-2016-10-05/pdf/2016-23988.pdf*.

New CDC Brochure Offers Pharmacists Tips for Addressing Prescription Opioid Abuse and Overdose

Centers for Disease Control and Prevention (CDC) released a brochure encouraging pharmacists, who are an essential part of the health care team, to help prevent opioid abuse and overdose. The brochure, "Pharmacists: On the Front Lines," offers tips for communicating with patients who are receiving opioid therapy. In addition, the brochure offers tips on how to identify forged prescriptions and urges pharmacists to maintain collaborative working relationships with prescribers to improve patient outcomes. The brochure is available at *www.cdc.gov/drugoverdose/pdf/pharmacists_brochure-a.pdf*.

FDA Requires Boxed Warnings and Patient-Focused Medication Guides Indicating Serious Risks Related to Combined Use of Certain Opioid Medications and Benzodiazepines

FDA is requiring class-wide drug labeling changes to inform health care providers and patients of the serious risks associated with the combined use of certain opioid medications and benzodiazepines. Specifically, after an extensive review of the latest scientific evidence, FDA is requiring boxed warnings and patient-focused Medication Guides for prescription opioid analgesics, opioid-containing cough products, and benzodiazepines that provide information about the serious risks associated with using these medications at the same time. Risks include extreme sleepiness, respiratory depression, coma, and death.

FDA's news release indicates the changes are part of the agency's Opioids Action Plan, which focuses on policies aimed at reversing the prescription opioid abuse epidemic while providing patients in pain with access to effective and appropriate pain management. The public health crisis is evident through the significant rise of preventable overdose and death associated with the concurrent use of two drug classes, indicates FDA Commissioner Robert Califf, MD, in the press release, available at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm518697.htm*.

FDA's Division of Drug Information Offers CE Webinars for Students and Clinicians

FDA's Center for Drug Evaluation and Research (CDER), Office of Communications, Division of Drug Information presents a series of continuing education (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 drug shortages and prescription drug promotion. The webinars and presentation slides can be accessed on FDA's website at *www.fda.gov/DDIWebinars*.

FDA Approves Labeling Changes for All Prescription Testosterone Products

In October 2016, FDA approved class-wide labeling changes for all prescription testosterone products regarding the risks associated with abuse and dependence of the drug. The changes include adding a new warning as well as updating the Abuse and Dependence section to include new safety information from published literature and case reports regarding the risks associated with abuse and dependence of testosterone and other anabolic androgenic steroids (AAS). The Anabolic Steroids Control Act of 1990 placed AAS, including testosterone, in Schedule III of the Controlled Substances Act.

Prescription testosterone products are FDA-approved as hormone replacement therapy for men who have low testosterone due to certain medical conditions. However, testosterone and other AAS are abused by adults and adolescents, including athletes and body builders, notes FDA. FDA indicates the new warning will "alert prescribers to the abuse potential of testosterone and the serious adverse outcomes, especially those related to heart and mental health that have been reported in association with testosterone/AAS abuse." In addition, new labeling information in the Warning and Precautions section advises prescribers of the importance of measuring serum testosterone concentration if abuse is suspected.

FDA explains that abuse of testosterone, usually at doses higher than those typically prescribed and usually in conjunction with other AAS, is associated with serious safety risks affecting the heart, brain, liver, mental health, and endocrine system. Reported serious adverse outcomes include heart attack, heart failure, stroke, depression, hostility, aggression, liver toxicity, and male infertility. Individuals abusing high doses of testosterone have also reported withdrawal symptoms, such as depression, fatigue, irritability, loss of appetite, decreased libido, and insomnia. The FDA announcement is available at *www.fda.gov/Drugs/DrugSafety/ucm526206.htm*.

Latest FDA Drug Info Rounds Training Videos Available

Drug Info Rounds, a series of online videos by FDA, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. In the latest Drug Info Rounds video, "Extortion Scam," pharmacists discuss steps a potential victim could take if they receive a call from individuals posing as FDA and DEA agents. Drug Info Rounds is developed with contributions from pharmacists in FDA's CDER, 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*.

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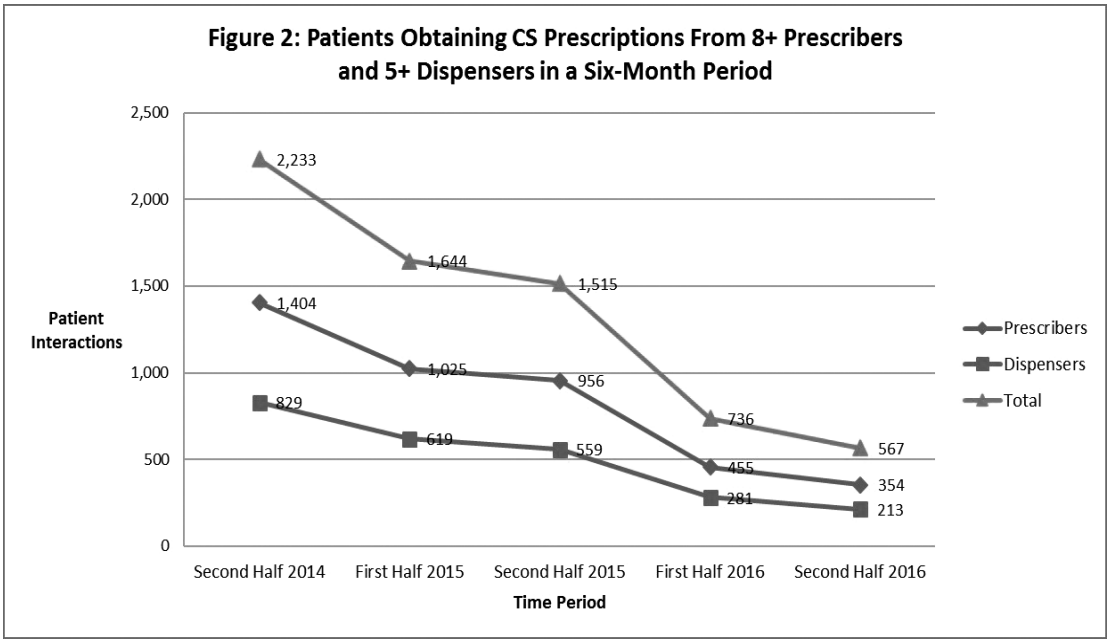

sharing prescription data with its border states Kentucky, Maryland, Ohio, and Virginia (Pennsylvania is anticipated in early 2017 once its system is fully functional). West Virginia is also sharing data with Arizona, Colorado, Connecticut, Indiana, Kansas, Massachusetts, Minnesota, Nevada, New Mexico, New York, and South Carolina. The Board is actively working toward connecting with a number of other states.

Advisory and Database Review Committees – Advisory and database review committees meet regularly and continue to monitor and assess prescription monitoring program (PMP) data to proactively address potential drug diversion activities and to find ways to reduce the state's drug overdose problem. The CSMP Database Review Committee reviewed 912 drug-related overdose deaths, sent out over 400 notifications to involved prescribers, and included 91 referrals to licensing boards, law enforcement officials, and federal and county prosecutors for further investigation. In 2015, West Virginia drug overdose deaths were a record high (731), but hydrocodone- and oxycodone-related deaths were down, being replaced by heroin.

One activity the committee regularly monitors is multiple provider episodes (MPEs). MPEs are defined as when a patient is obtaining CS prescriptions from multiple physicians and visiting multiple pharmacies to get them filled, all in a relatively short period of time. Every six months, notifications are sent out to doctors and pharmacists regarding their specific patients who are exhibiting MPE behavior (currently, eight different physicians and five different pharmacies in a six-month period). As a result, the number of individuals identified has dropped off significantly and continues to decline (see Figure 2).

Dispensing Error Fatal for Pet

At a recent Board meeting, a complaint investigation report was presented to the full Board for possible action to be taken against the involved pharmacy and pharmacy staff. The essence of the complaint was that a person had medication prescribed by a veterinarian for his or her pet. When the pet owner picked up the medication, he or she questioned the medication in the bottle as it appeared different than what had been administered to the pet in the past. The pharmacy technician advised the person that the medication was the same, only from a different manufacturer. The person took the medication and administered it to the pet. Unfortunately, the pet died five days later as it really was the wrong drug and it proved fatal. The technician should have alerted the pharmacist on duty, and a thorough review of the ordered medication compared with the dispensed medication should have caught this error before the medication left the pharmacy. Any time there is a question about the content of a prescription container, it would be wise for the pharmacist to verify the correctness of the dispensed product.

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