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News

State of Ohio Board of Pharmacy

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Reminder: Board Rules Require Licensees to Report Theft or Loss of Significant Drugs

Dear Ohio Pharmacist,

Maintaining drug security is one of the most important responsibilities you have as a pharmacist. Despite safeguards and policies to promote drug security, theft or loss can still occur. When it does, it is mandatory to notify the State of Ohio Board of Pharmacy in accordance with Ohio rules.

Rule 4729-9-15 of the Ohio Administrative Code (OAC) requires a licensee (pharmacist, terminal/wholesale distributor) to notify the Board of any theft or significant loss of dangerous drugs (controlled and non-controlled prescription drugs) immediately upon discovery of a theft or significant loss. This includes dangerous drugs in transit that were either shipped from or to the prescriber, terminal distributor of dangerous drugs (TDDD), or wholesale distributor of dangerous drugs.

Theft or significant loss should be reported by telephone immediately upon discovery. You may call the Board's main line at 614/466-4143 and ask to speak with the compliance department or contact your assigned compliance specialist or agent.

If a controlled substance (CS) is involved, Drug Enforcement Administration (DEA) must also be notified online using DEA Form 106. This form must also be submitted to the Board within 30 days following the discovery of a CS theft or significant loss. The form may be emailed to DEA106Reporting@pharmacy.ohio.gov or faxed to 614/752-4836. Please note, the Board is conducting checks against data reported to DEA to ensure licensee compliance with this reporting requirement.

To help answer any questions on reporting the theft or significant loss of drugs, the Board has developed a guidance document. The document, which includes a detailed explanation of what constitutes significant loss, can be accessed by visiting *www.pharmacy.ohio.gov/theft.*

On behalf of the Board, I would like to thank you for your important work in helping to deter and detect the diversion of dangerous drugs.

Sincerely,

Steven W. Schierholt, Esq
Executive Director
State of Ohio Board of Pharmacy

Senate Bill 319 – Ohio's Opiate Mid-Biennium Review

On January 4, 2017, Senate Bill 319 was signed by Governor John Kasich. This law includes the following provisions:

- **Ninety-Day Supply:** The law limits the authority of a pharmacist, pharmacy intern, or TDDD to dispense or sell an opioid analgesic pursuant to a prescription for a drug to be used on an outpatient basis. It prohibits dispensing or selling more than a 90-day supply of the drug, as determined according to the prescription's instructions for use of the drug, regardless of whether the prescription was issued for a greater amount. This provision takes effect on April 6, 2017.
- **Fourteen-Day Prescriptions for Opioid Analgesics:** The law generally prohibits a pharmacist, pharmacy intern, or terminal distributor from dispensing or selling an opioid analgesic pursuant to a prescription if the drug is to be used on an outpatient basis and more than 14 days have elapsed since the prescription was issued. This provision takes effect on April 6, 2017.
- **TDDD Requirements for CS:** All locations that possess CS are required to obtain licensure as a category III TDDD. Please be advised that this requirement takes effect on April 6, 2017. More information on this provision can be found by visiting *www.pharmacy.ohio.gov/TDDDcs.*

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National Pharmacy

The applicability of articles in the *National Pharmacy Compliance*
by examining the law of

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.

References:

1. Chaudhury H, Mahmood A, Valente M. The effect of environmental design on reducing nursing errors and increasing efficiency in acute care settings: a review and analysis of the literature. *Environ Behav.* 2009;41(6):755-786.
2. Graves K. *Nurses' Decision Making Processes About Lighting During Medication Administration* [dissertation]. Denton: Texas Woman's University College of Nursing; 2014.
3. Grasha AF. Psychosocial factors, workload, and risk of medication errors. *US Pharm.* 2002;27(4):HS32-52.
4. United States Pharmacopeial Convention. Chapter <1066> Physical environments that promote safe medication use. *Revision Bulletin.* October 1, 2010;2-6. www.ismp.org/sc?id=1664.

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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- **Office-Based Opioid Treatment:** Effective August 4, 2017, all locations that treat more than 30 individuals for opioid dependence or addiction using a CS are required to obtain a license as a TDDD with an office-based opioid treatment classification. Please be advised that there are some exemptions to this requirement. More information on this provision can be found by visiting *www.pharmacy.ohio.gov/OBOT*.
- **Registration of Pharmacy Technicians:** The law requires the registration of pharmacy technicians by April 6, 2018. While the deadline for registration is not until next year, the Board plans to open the registration process well in advance to allow enough time for individuals to register. The opening date of technician registration is not known at this time, as the Board needs to finalize rules regarding the registration process. More information on this provision can be found by visiting *www.pharmacy.ohio.gov/technicians*.

Report Shows Continued Progress in Promoting Responsible Opioid Prescribing

Opioid prescribing in Ohio declined for the fourth consecutive year in 2016, according to a newly released report from the Board's Ohio Automated Rx Reporting System (OARRS). The report can be accessed at *www.pharmacy.ohio.gov/OARRS2016*.

Introduction of OARRS 2.0

After 10 years of faithful service, it is time for OARRS 1.0 to retire. In the coming months, OARRS will be upgraded to a brand new software platform. While this means lots of new and exciting features, it also means change. The Board staff and its software vendor, Appriss, Inc, are doing everything possible to make this transition smooth and seamless. You will receive multiple emails from Appriss and the Board along the way to ensure you are kept well-informed. Please read these communications carefully. If you have questions, please use the contact information provided in the email. Continue reading below for a timeline of events, followed by further details of what you may need to do during each event.

Timeline

- Now – Create new data upload accounts.
- March 15, 2017 – Begin sending dispensing reports to the Appriss Prescription Monitoring Program (PMP) Clearinghouse.
- April 25, 2017 – OARRS 2.0 goes live.

Create New Data Upload Accounts

Those responsible for uploading dispensing information to OARRS should have already received communication regarding creating their new data upload accounts. If your vendor or home office reports for you, please check with them to ensure this information was received. The PMP Clearinghouse began accepting registrations for Ohio data uploaders on January 31 of this year. Data upload accounts from OARRS 1.0 will not be transferred to the PMP Clearinghouse. If you submit dispensing data to the Appriss PMP Clearinghouse for another state, you do not need to register for a new account. You simply need to create a folder for Ohio in your existing PMP Clearinghouse account.

If you need technical assistance related to the PMP Clearinghouse, please contact the Appriss help desk at 844/464-4767 or create a support request at *https://apprisspmpclearinghouse.zendesk.com/hc/en-us/requests/new*. Technical assistance is available 24 hours a day, 365 days a year.

Begin Sending Dispensing Reports to the Appriss PMP Clearinghouse

Effective March 15, 2017, OARRS 1.0 will no longer accept dispensing uploads. All dispensing data uploads will be required to be sent to the Appriss PMP Clearinghouse. The PMP Clearinghouse will provide the records to both OARRS 2.0 for testing as well as to OARRS 1.0 until the date OARRS 2.0 goes live. Again, please direct any technical support issues to the Appriss help desk using the information above.

OARRS 2.0 Goes Live

The target date for OARRS 2.0 to go live is April 25, 2017. The Board is still working out the details on this process. Please stay tuned for future updates.

CS Inventory Disposal

Effective February 1, 2017, Rule 4729-9-06 will no longer require approval from the Board prior to the disposal of a licensee's CS inventory. Instead, the rule will require adherence to all DEA disposal requirements set forth in 21 Code of Federal Regulations (CFR) §1317 and all record-keeping requirements set forth in 21 CFR §1304. A complete copy of the new rule along with frequently asked questions can be found by visiting *www.pharmacy.ohio.gov/InventoryDisposal*.

Please be advised that the new CS inventory disposal rule also applies to emergency medical service organizations.

February 2017 Rules Updates

Several changes to Board rules take effect during the month of February. For summaries and full text of each rule, please visit *www.pharmacy.ohio.gov/Feb2017Rules*.

Fiscal Year 2016 Annual Report

The Board has published its annual report for fiscal year 2016. The report highlights the Board's efforts to

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combat Ohio's drug overdose epidemic, along with individual updates for the Board's different departments.

To view the full report, visit *www.pharmacy.ohio.gov/2016Report*.

New Requirements for Notification of Change of Responsible Person

Rule 4729-5-11 states that when there is a change of responsible person for a location licensed as a terminal distributor, the Board shall be notified of the change within **10 days** of the effective date of the appointment of the new responsible person. The Board encourages all licensees to comply to this rule, as failure to do so could result in disciplinary action.

Reporting Gabapentin Products to OARRS

Effective December 1, 2016, Rule 4729-37-12 requires certain entities to submit the specified dispensing, personal furnishing, or wholesale sale information on all products containing gabapentin to OARRS.

For questions regarding reporting of products containing gabapentin, please visit *www.pharmacy.ohio.gov/gabapentin*. If you need additional information, the most expedient way to have your questions answered is to contact OARRS at *https://www.ohiopmp.gov/Portal/Contact.aspx*.

Board Resolution: Responsible Person Requirements

Pursuant to Rule 4729-5-11, the Board is required to adopt a resolution providing the credential types or qualifications required for the responsible person of each classification/business type of terminal and wholesale distributor license. Only individuals who meet the credentials specified may be the responsible person for that classification type.

The resolution can be accessed at *www.pharmacy.ohio.gov/requirements*.

Terminal Distributor Requirements for Prescribers and Compounded Drugs

Effective April 1, 2017, all prescribers who possess compounded drugs or engage in the compounding of dangerous drugs (ie, prescription drugs) must obtain a license as a TDDD (Ohio Revised Code 4729.541). More information on this provision can be found at *www.pharmacy.ohio.gov/prescribercompound*.

On or after April 1, 2017, any facility possessing compounded drugs or engaging in drug compounding without being properly licensed as a terminal distributor will be in violation of Ohio law. In addition, a facility that is not licensed as a terminal distributor will not be able to purchase any compounded medications or drugs used for the purpose of compounding from any wholesaler or pharmacy.

Physician Assistant Prescribing of Buprenorphine Products for Office-Based Treatment of Opioid Addiction

The Substance Abuse and Mental Health Services Administration recently announced that physician assistants (PAs) can train and apply to become Drug Addiction Treatment Act of 2000 (DATA 2000)-waived practitioners. PAs who have completed the required training and seek to become DATA 2000-waived for up to 30 patients will be able to apply to do so beginning in early 2017.

Beginning in January 2017, buprenorphine products will be listed on the Ohio Physician Assistant Formulary as "may prescribe" for office-based treatment of opioid addiction. The PA formulary may be accessed at *http://med.ohio.gov/Applications/PhysicianAssistant-PA.aspx*.

Changes to CTP Number for PAs

Please be advised that the State Medical Board of Ohio no longer issues separate Certificate to Prescribe (CTP) numbers for PAs. Instead, a PA's authority to prescribe is now designated by his or her license number with an "RX" at the end (for example, 50.xxxxxxxRX). The "RX" at the end of a PA license number meets the requirements for the CTP pursuant to Rule 4729-5-30 of the OAC.

The *State of Ohio Board of Pharmacy News* is published by the State of Ohio 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.

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