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News

Ohio State Board of Pharmacy

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Moving Forward, Working Together

I am honored to have the opportunity to serve as the new executive director of the Ohio State Board of Pharmacy. As this article serves as my introduction to the pharmacist community, I wanted to provide you with my vision of the day-to-day operations of your Board.

First, I am committed to ongoing improvement of all services offered. My staff and I will strive to continuously learn, develop, and improve. Whether it is the Ohio Automated Rx Reporting System (OARRS), licensing, or compliance, my door is always open to hear your suggestions of how we can work better, faster, and smarter.

Clear and consistent regulation is another important focus. As regulators of the pharmacy profession, it is our goal to ensure all Ohio laws and rules are applied consistently. I am currently working with staff to identify best practices to ensure that all inspections are consistent no matter where you are in the state. This also means ensuring that you have access to prompt, courteous, and consistent customer service whenever you have any questions or concerns.

Finally, as a regulatory entity, the protection of the public is our number one goal. As you know, Ohio is in the grips of a drug overdose epidemic largely driven by the abuse and misuse of opioid pain medications. Now more than ever, the pharmacy community plays a vital role in preventing the diversion of these powerful drugs for non-medical purposes. You are gatekeepers to ensure that all prescriptions have a legitimate medical purpose and to identify and report potential fraudulent activity. As such, the Board will continue to support the efforts of Ohio pharmacists to use your clinical judgment to determine what is in the best interest of your patients.

One of the best tools we have at our disposal to protect our citizens is OARRS. OARRS provides a wealth of information to help pharmacists and prescribers make informed decisions about the health and safety of their patients. As such, I envision a system that is continuously improving to meet the needs of its users in order to reduce the rampant abuse and misuse of opioid pain relievers plaguing our communities.

I realize there have been a number of changes at the Board over the past year. Often, change is difficult. However, I want to emphasize that the future of this Board will always involve the feedback and expertise of the pharmacy community. In fostering this collaborative exchange, we can continue to make Ohio one of the best states for the practice of pharmacy in the country.

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

Ohio Law Permits Pharmacists to Dispense an Emergency Supply of Medication Without a Prescription

Recently, several incidents have come to the Board's attention where patients with a chronic condition were unable to obtain an emergency supply of medication at the pharmacy. In such instances when a prescription is expired or a primary care physician is unavailable, being left untreated could endanger the life of a patient.

In the event that you are presented with a similar situation, Ohio Revised Code 4729.281 permits a pharmacist to dispense a drug, other than a Schedule II controlled substance (CS), without a written or oral prescription from a licensed health professional if they meet all of the following conditions.

(A)(1) The pharmacy at which the pharmacist works has a record of a prescription for the drug in the name of the patient who is requesting it, but the prescription does not provide for a refill or the time permitted by rules adopted by the state board of pharmacy for providing refills has elapsed.

(2) The pharmacist is unable to obtain authorization to refill the prescription from the health

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DEA Finalizes Rule on CS Prescription Drug Disposal

In September 2014, Drug Enforcement Administration (DEA) published its final rule, titled the Disposal of Controlled Substances, that allows some DEA registrants to modify their registration to become authorized collectors. Under the new rule, some DEA registrants, including retail pharmacies, hospitals/clinics with an on-site pharmacy, manufacturers, distributors, reverse distributors, and narcotic treatment programs, may modify their registration with DEA to become authorized collectors. The final rule implements the Secure and Responsible Drug Disposal Act of 2010, which authorized DEA to develop and implement regulations that would allow authorized entities other than law enforcement to collect unused and unwanted prescription drugs, including controlled substances (CS), for disposal purposes. Proper disposal of unused prescription medication is a key method of preventing and reducing prescription drug abuse. The final rule took effect on October 9, 2014.

The full rule is available on the *Federal Register* website at *www.federalregister.gov/articles/2014/09/09/2014-20926/disposal-of-controlled-substances.*

System-Based Causes of Vaccine Errors

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.*

Immunizations are widely recognized as one of the most successful and cost-effective health interventions ever introduced worldwide. However, errors with vaccines can result in an unintended and unrecognized source of vulnerability. While the immediate impact of a vaccine-related error on a patient may not be serious, such errors may render the vaccine ineffective or reduce its effectiveness, leaving patients unprotected against serious diseases such as hepatitis A, hepatitis B, diphtheria, tetanus, measles, cervical cancer, and many others. In September 2012, ISMP (in cooperation with the California Department of Public Health) established the ISMP National Vaccine Errors Reporting Program (VERP) to collect data about the type of vaccine errors occurring and the reasons they occur. In ISMP's November 28, 2013 newsletter *(www.ismp.org/sc?id=307),* ISMP provided a summary analysis of error reports submitted to the ISMP VERP during its first year. The vaccinations that are most frequently associated with errors included *Haemophilus influenzae* type b conjugate (Hib); diphtheria and tetanus toxoids, acellular pertussis adsorbed, and inactivated poliovirus (DTaP-IPV); tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis adsorbed (Tdap); diphtheria, tetanus toxoid, and acellular pertussis adsorbed (DTaP); hepatitis A (HepA); hepatitis B (HepB); human papillomavirus quadrivalent (types 6, 11, 16, and 18), recombinant (HPV4); zoster; and measles, mumps, rubella, and varicella (MMRV). The most common contributing factors associated with the reported vaccine errors included mistakes in choosing age-dependent formulations of vaccines intended to prevent the same diseases; unfamiliarity with the vaccine, particularly its dose, dosing schedule, age specifications, route of administration, and the vaccine's various components (eg, combination vaccines, diluents, and powder); failure to check or verify the patient's age, health record, or state registry; similar vaccine names and abbreviations; similar and confusing vaccine labeling and packaging; unsafe storage conditions (eg, stored near other similar vaccines or unwanted temperature fluctuations); and expiration dates not noticed or misunderstood.

Practice Recommendations. Involve the patient or parent(s)/caregiver(s) in a vaccine verification process by:

1) Documenting the vaccine name, formulation (pediatric or adult, if applicable), lot number, and expiration date on the patient's vaccine record **prior** to preparation/administration of the vaccine,
2) Bringing the vial and syringe or the prefilled syringe along with the immunization record into the exam room,
3) Asking the patient or parent/caregiver to simultaneously verify the information on the immunization record while a health care provider reads the information on the label aloud,
4) Asking the patient or parent/caregiver if the verified vaccine is what he or she expected to be administered (based on an immunization schedule provided to the patient or parent/caregiver previously),
5) Preparing and administering the vaccine immediately after verification, and
6) Documenting the vaccine on the patient's medical record.

FDA Warns of Growing Network of Rogue Wholesale Drug Distributors

Through a new educational program called Know Your Source, Food and Drug Administration (FDA) is warning pharmacists and other health care providers to watch for counterfeit and unapproved drugs. Aimed at protecting patients from unsafe and ineffective drugs, the program advises providers to only purchase drugs from wholesale drug distributors licensed in their state. Further, FDA offers tips to providers to protect patients, including being wary of offers too good to be true, and ensuring that all drugs received are FDA-approved medications.

Another way that pharmacies can be assured of the legitimacy of a wholesale distributor is to look for the National Association of Boards of Pharmacy® (NABP®) Verified-Accredited Wholesale Distributors® (VAWD®) Seal. Those wholesale distributors that achieve VAWD accreditation are in compliance with state and federal laws, as well as NABP's VAWD criteria. Wholesale distributors that display the VAWD Seal as part of their accreditation have undergone a criteria compliance review, including a rigorous

review of their operating policies and procedures, licensure verification, survey of facility and operations, background checks, and screening through the NABP Clearinghouse. Accredited facilities are reviewed annually and undergo a site survey every three years. Created in 2004, the accreditation program plays a pivotal role in preventing counterfeit drugs from entering the United States drug supply.

Additional information about the VAWD program is available in the Programs section of the NABP website. Know Your Source is available at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm389121.htm*.

PTCB Implements Changes to CE Requirements

In 2015, the Pharmacy Technician Certification Board (PTCB) will implement two changes in recertification requirements for certified pharmacy technicians (CPhTs) in accordance with its certification program changes announced in 2013. First, any continuing education (CE) hours earned by a CPhT will need to be pharmacy technician-specific in order to qualify toward recertification. Second, PTCB will reduce the number of allowable "in-service" CE hours from 10 to five. PTCB's certification program changes are intended to support and advance improved patient care and safety throughout pharmacy practice, a PTCB press release indicates. The changes are the result of a PTCB initiative that began with a 2011 summit on future directions for pharmacy technicians.

Additional information can be accessed on the PTCB website at *www.ptcb.org*.

Security Guidelines Available as Rate of Pharmacy Robberies Still a Concern

Nationally, pharmacy robberies dipped slightly from 745 in 2012, to 713 in 2013, according to a report compiled by *Drug Topics* using DEA statistics. The 10 states that had the most robberies are in stark contrast to other states that had no robberies (South Dakota, North Dakota, and Alaska) or as few as one or two (such as Montana and Illinois), reports *Drug Topics*. However, fueled by the prescription drug abuse epidemic, pharmacy robberies still pose a threat to the safety of personnel and customers. The report lists the top 10 states that had the most pharmacy thefts in 2013. Arizona experienced the most pharmacy robberies in 2013 with 77 incidents, and Indiana took second place with 71 robberies. The report, titled "Top 10 states for pharmacy robberies," may be found at *http://drugtopics.modernmedicine.com/drug-topics/content/tags/arizona/top-10-states-pharmacy-robberies?page=full.*

NABP partnered with DEA to create an educational pamphlet identifying key strategies pharmacists can take to secure their stores against robberies, which can be downloaded at *www.deadiversion.usdoj.gov/pubs/brochures/pharmtheft.pdf*. In addition, some boards of pharmacy have identified best practices for preventing pharmacy theft, and have supported these practices through regulations or recommendations for their licensees. For example, the New Jersey State Board of Pharmacy's *Pharmacy Security Best Practices* document recommends that all Schedule II and III CS be stored in a "safe or substantially constructed steel cabinet that is locked at all times," with only licensed pharmacists having access. Additional recommendations include annual pharmacist-in-charge self-assessments and interfacing with prescribers and customers, among others. The best practices document can be downloaded from the New Jersey Consumer Affairs website at *www.njconsumeraffairs.gov/press/05012013.pdf.*

Private organizations have also developed resources to assist pharmacies in improving security. One such resource is the RxPATROL program, which works with law enforcement, the pharmacy community, and security professionals to maintain a database containing detailed information about pharmacy robberies and other losses. In addition, the RxPATROL website, *www.rxpatrol.com*, provides training videos and a pharmacy security checklist.

Further, NABP members directed the Association to convene a task force to review strategies that states have taken to prevent theft and drug diversion. The Task Force to Examine Strategies for Preventing and Reacting to Pharmacy Robberies and Thefts met on October 22-23, 2014, to discuss these issues.

Assured Brand Naproxen Tablets Recalled Due to Packaging Error

In October 2014, Contract Packaging Resources of Greensboro, NC, a drug repackaging company, issued a voluntary recall of nearly 12,000 boxes of Assured brand naproxen sodium tablets because some cartons contain bottles of 200 mg ibuprofen softgels instead, a press release posted to the FDA website indicates. The packaging error affected boxes of Assured brand naproxen sodium tablets 220 mg, 15 count (Lot Number FH4102A), which were distributed to and sold at Dollar Tree stores and on the Dollar Tree website. Contract Packaging Resources is contacting customers to arrange for replacement of all recalled products. Adverse reactions or quality problems experienced with the use of this product may be reported to FDA's MedWatch Adverse Event Reporting Program.

More information is available on the FDA website at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm419769.htm.*

Martin Avenue Pharmacy Issues Voluntary Recall for All Sterile Compounded Preparations

Martin Avenue Pharmacy, Inc, of Naperville, IL, issued a voluntary recall for all in-date compounded sterile preparations due to a lack of sterility assurance in August 2014. Following a recent FDA inspection that revealed "quality control procedures that present a risk to sterility assurance," the company issued the recall out of an abundance of caution, indicates a news release posted to the FDA website. Martin Avenue Pharmacy supplied compounded sterile preparations to offices of licensed medical professionals and individuals in multiple states including Illinois, Wisconsin, Ohio, Michigan, Florida, Alabama, and Texas until August 20, 2014. A full list of recalled products is available on the Martin Avenue Pharmacy website (registration required). FDA urges consumers and health care providers to report adverse events or side effects related to the use of these products to FDA's MedWatch Safety Information Adverse Event Reporting Program.

More information is available on the FDA website at *www.fda.gov/Safety/Recalls/ucm412431.htm*.

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care professional who issued the prescription or another health professional responsible for the patient's care.

(3) In the exercise of the pharmacist's professional judgment:

(a) The drug is essential to sustain the life of the patient or continue therapy for a chronic condition of the patient.

(b) Failure to dispense or sell the drug to the patient could result in harm to the health of the patient.

(4) The amount of the drug that is dispensed or sold does not exceed a seventy-two hour supply as provided in the prescription.

(B) A pharmacist who dispenses or sells a drug shall do all of the following:

(1) For one year after the date of dispensing or sale, maintain a record in accordance with this chapter of the drug dispensed or sold, including the name and address of the patient and the individual receiving the drug, if the individual receiving the drug is not the patient, the amount dispensed or sold, and the original prescription number;

(2) Notify the health professional who issued the prescription described in (A)(1) of this section or another health professional responsible for the patient's care not later than seventy-two hours after the drug is sold or dispensed;

(3) If applicable, obtain authorization for additional dispensing from one of the health professionals described in (B)(2) of this section.

(C) A pharmacist who dispenses or sells a drug under this section may do so once for each prescription described in (A)(1) of this section.

The Board is committed to helping pharmacists act in the best interest of their patients. Should you have any questions regarding emergency dispensing without a prescription or any other issue, please do not hesitate to contact the Board.

Reminders From OARRS

OARRS Prescription Reporting: Per Rules 4729-37-03 and 4729-37-07 of the Ohio Administrative Code (OAC), all dispensing of CS to outpatients must be reported to the OARRS database on a daily basis. Compliance with reporting is monitored, and repeated occurrences of late reporting are handled on an individual basis. Courtesy reminder emails are sent to late pharmacies only when there is contact information on the account. Check your data upload accounts to verify that the contact information is correct and current. OARRS suggests having more than one contact on each account and using an email address that is frequently monitored.

OARRS Wholesale Reporting: Did your pharmacy transfer a controlled medication to another pharmacy or sell a controlled product to a prescriber? Those transactions/occasional sales must be recorded in OARRS as a wholesale transfer. To do so, you must register for a wholesale account in OARRS and report the transaction using the "Pharmacy Rx – Manual Rx Entry" option. Reporting is monthly and due by the 15th of the month following the month of the transaction. As long as you transfer less than 5% of your total quantity of controlled medications, you do not need to apply for a wholesale license.

Do You Have Your OARRS Account Yet? Still actively practicing pharmacy? If you have not done so already, be sure to create your own OARRS account. This will be required as a condition of renewing your pharmacist license. As a reminder, Rule 4729-5-20 of the OAC outlines the minimum conditions under which you must run an OARRS report on a current patient.

Annual Law Continuing Education Test Now Available

The Board is pleased to offer the annual Jurisprudence Quiz. This no-cost quiz can be accessed by visiting *www.pharmacy.ohio.gov/quiz*. The questions in the quiz relate to the topics covered in the February, May, August, and November 2014 *Newsletters*. The test is taken online and is graded immediately upon submission. You may pre-print the exam, but you will have only one opportunity to take and submit the test for grading. A score of 75% is needed to pass. After successful completion, you will have the ability to immediately print your certificate, and a copy of your certificate will also be emailed to you. Be sure to keep this certificate to use if you are audited. The Board is not able to upload successful completion of the exam to CPE Monitor®. **Please note: Do not mail any quizzes to the Board office. The Board will neither hand-process exams nor mail a certificate to you.**

End of General Assembly Sees Passage of New Laws Impacting the Practice of Pharmacy

The conclusion of the 130th Ohio General Assembly in December saw a flurry of activity with the passage of several new laws impacting the practice of pharmacy, including:

- **House Bill (HB) 394 – Immunizations –** Regarding the authority of pharmacists and pharmacy interns to administer immunizations **(Effective: March 19, 2015).**

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- ◊ Authorizes a pharmacist to administer certain immunizations to individuals who are 13 years old or older.
- ◊ Authorizes a pharmacist to administer certain immunizations to individuals between seven and 13 years old if there is a prescription for the immunization.
- ◊ Authorizes a pharmacist to administer a flu shot to an individual who is seven years old or older without a prescription.
- ◊ Authorizes a pharmacy intern working under direct supervision to administer the same immunizations as a pharmacist.

♦ **HB 326 – Diabetic Shoe Fitters –** Exempts the following individuals from the requirement to be licensed by the Ohio State Board of Orthotics, Prosthetics, & Pedorthics: a licensed pharmacist, licensed pharmacist intern, registered wholesale distributor of dangerous drugs, or licensed terminal distributor of dangerous drugs who is acting within the respective scope of practice **(Effective: March 23, 2015).**

♦ **HB 367 – Buprenorphine –** Establishes requirements regarding CS containing buprenorphine used for the purpose of treating drug dependence or addiction **(Effective: March 23, 2015).**

- ◊ Prohibits a prescriber from personally furnishing more than a 72-hour supply of buprenorphine.

♦ **HB 341 – Mandatory OARRS Registration and Reports –** To prohibit an opioid or benzodiazepine from being prescribed without review of patient information in OARRS. A frequently asked questions document is available at *www.pharmacy.ohio.gov/341FAQ*.

♦ **Senate Bill 258 – Pharmacy Audits –** Establishes standards for the performance of pharmacy audits in Ohio and to authorize the continued use of certain analgesic CS in the practice of optometry **(Effective: March 19, 2015).**

- ◊ Allows optometrists to continue to administer and prescribe certain analgesic CS (including hydrocodone and tramadol) that are currently used in the practice of optometry.

To assist the pharmacy community, the Board will be sending out email updates with additional information on the implementation of these new laws. As these updates become available, they can also be accessed at *www.pharmacy.ohio.gov/Pubs/Special.aspx*.

Disciplinary Actions

Anyone having a question regarding the license status of a particular practitioner, nurse, pharmacist, pharmacy intern, or dangerous drug distributor in Ohio should contact the appropriate licensing board. The professional licensing agency websites listed below may include disciplinary actions for their respective licensees.

State Dental Board.....614/466-2580
www.dental.ohio.gov

State Medical Board.....614/466-3934
www.med.ohio.gov

State Nursing Board.....614/466-3947
www.nursing.ohio.gov

State Optometry Board.....614/466-5115
www.optometry.ohio.gov

State Pharmacy Board.....614/466-4143
www.pharmacy.ohio.gov

State Veterinary Medical Board.....614/644-5281
www.ovmlb.ohio.gov

Drug Enforcement Administration.....800/882-9539
www.deadiversion.usdoj.gov

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