



# State of Ohio Board of Pharmacy

*Published to promote compliance of pharmacy and drug law*

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## **New OARRS Reporting Rule Takes Effect in December**

Dear Ohio Pharmacist,

As we head toward the end of the calendar year, the State of Ohio Board of Pharmacy would like to remind you of a new Ohio Automated Rx Reporting System (OARRS) reporting rule going into effect soon.

Effective December 1, 2016, Rule 4729-37-12 requires pharmacies, wholesalers, and prescribers to report the specified dispensing, personal furnishing, or wholesale sale information on all products containing gabapentin to OARRS. This requirement is the result of increased reports of the abuse of gabapentin. For example, the drug was found in the systems of 44 unintentional drug overdose decedents in 2014.

Unlike the rules requiring pharmacists to request and review an OARRS report prior to dispensing controlled substances (CS) (Ohio Administrative Code (OAC) 4729-5-20), there is no requirement to request and review an OARRS report prior to dispensing a product containing gabapentin. However, pharmacists are encouraged to run a report prior to dispensing this drug if they suspect abuse or diversion.

Additional information on reporting procedures and some frequently asked questions can be found by visiting [www.pharmacy.ohio.gov/gabapentin](http://www.pharmacy.ohio.gov/gabapentin). As always, if you have any questions that are not addressed in the guidance document, please feel free to contact the Board directly.

On behalf of the Board, I want to once again thank you for the tremendous work you do each day for patients. Without the hard work of health care professionals like you, we would not be able to continue the fight against drug abuse.

Sincerely,

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

## **Naloxone Guidance for Hospitals**

Hospitals treating individuals who suffer from nonfatal opioid-related overdoses have an important opportunity to provide naloxone upon discharge. Providing naloxone can be an effective tool to prevent a fatal overdose, as data indicate that a risk factor for a fatal overdose includes individuals discharged from emergency medical care following opioid intoxication or poisoning.

The Board has developed a guidance document for hospitals seeking to provide naloxone to at-risk individuals upon discharge. To review the guidance, please visit [www.pharmacy.ohio.gov/hospitalnaloxone](http://www.pharmacy.ohio.gov/hospitalnaloxone).

## **Final Roundtable Presentation**

Today's demands on pharmacists are great. Adding to this is the fact that drug diversion is at an all-time high, so the need to maintain supervision, accountability, and security over the pharmacy is critical. As such, the Board has set up a roundtable presentation on how to increase the security of drugs in your retail pharmacy, as well as tips for avoiding burglaries and robberies.

The roundtable will take place on **Wednesday, November 16 at the University of Toledo**. Registration begins at 8:30 AM, with the presentation running from about 9 AM to noon. For more information, please visit [www.pharmacy.ohio.gov/roundtables](http://www.pharmacy.ohio.gov/roundtables) or email Andrea Wagner at [andrea.wagner@pharmacy.ohio.gov](mailto:andrea.wagner@pharmacy.ohio.gov).

## **Immunizations by Pharmacists and Pharmacy Interns**

[Section 4729.41 of the Ohio Revised Code \(ORC\)](#) and [Rule 4729-5-38 of the OAC](#) authorizes a pharmacist or pharmacy intern working under the direct supervision of a pharmacist to administer the following immunizations:

- ◆ Any immunization recommended by the Centers for Disease Control and Prevention (CDC)'s Advisory Committee on Immunization Practices


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## **National Vaccine Safety Surveillance Program Available for Reporting Adverse Events**

The Vaccine Adverse Event Reporting System (VAERS) eSubmitter program, a national vaccine safety surveillance program cosponsored by the Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA), is available for the reporting of any clinically significant adverse event that occurs after the administration of any vaccine licensed in the United States. VAERS information is analyzed by CDC and FDA to identify new safety concerns. VAERS reports can be filed by anyone, including health care providers, manufacturers, state immunization programs, and vaccine recipients. Vaccine recipients are encouraged to seek help from their health care provider when filling out the VAERS form. Health care providers can find information about submitting a report on the VAERS website at <https://vaers.hhs.gov/professionals/index>.

## **Improper and Unsafe Vaccine Storage**

 *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](http://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](http://www.ismp.org). Email: [ismpinfo@ismp.org](mailto:ismpinfo@ismp.org).*

Few issues are more important than proper storage and handling of vaccines, because their ability to prevent disease is dependent on these factors. To maintain stability, most vaccines must be stored in a refrigerator or freezer, and many also require protection from light. Excessive heat or cold – even a single exposure in some instances – can reduce vaccine potency. These temperature excursions are often due to improper refrigeration or freezer units, inadequate thermostat controls, and refrigeration/freezer units with inadequate space to allow good air circulation and even temperatures.

Improper and unsafe storage can also result in serious errors caused by selecting the wrong vaccines, diluents, and other medications with look-alike names and/or labeling and packaging. Storing vaccines close to each other has led to dispensing and administering the wrong vaccine or wrong form of vaccine (eg, adult versus pediatric). Storing vaccines too close to non-biologic medications in a refrigerator or freezer has also led to serious adverse outcomes, particularly when the mix-up

involved a vaccine and a high-alert medication. For example, vials of insulin have frequently been mistaken as influenza vaccine, and various neuromuscular blocking agents have been used to reconstitute vaccines or were mistaken as influenza or hepatitis B vaccines.

Store vaccines in their own dedicated refrigeration and freezer units. Regular temperature monitoring is necessary, and technology is available to assist with alarmed, continuous monitoring devices that can alert staff via email and pager if a unit is out of specified range. Separate vaccine vials and syringes into bins or other containers according to vaccine type and formulation, keeping diluents with the appropriate vaccines. Never store different vaccines in the same containers. Do not store vaccines with similar labels, names, abbreviations, or overlapping components immediately next to each other or on the same shelf. Separate the storage areas of pediatric and adult formulations of vaccines. Label the specific locations where vaccines are stored to facilitate correct age-specific selection and to remind staff to combine the contents of vials. ISMP's March 26, 2015 newsletter<sup>1</sup> contains additional strategies, as does a Vaccine Storage & Handling Toolkit available from CDC.<sup>2</sup>

## **References**

1. ISMP. Recommendations for practitioners to prevent vaccine errors. Part 2: analysis of ISMP vaccine errors reporting program (VERP). *ISMP Medication Safety Alert!* 2015;20(6):1-6.
2. CDC. Vaccine storage & handling toolkit. [www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf](http://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf). June 2016.

## **Coalition Reports Impact of Educational Efforts on Safe Acetaminophen Use**

The Acetaminophen Awareness Coalition reports that progress has been made to increase consumer awareness about the safe use of acetaminophen. The coalition also notes a decline in unintentional overdoses. The National Poison Data System's 2015 report indicates unintentional acetaminophen exposures, including dosing errors and accidental misuse, have decreased through 2013 after a peak in 2009. In addition, a nationwide survey indicates the number of consumers who understand that exceeding the recommended daily dose of acetaminophen may lead to liver damage has increased to 87% in 2013 from 78% in 2010. The survey also reports the number of consumers who think it is important to check the medicine label for the maximum daily dose increased to 98% in 2013 from 93% in 2010.

Developed in 2011, the Know Your Dose campaign encourages pharmacists and other health care providers to talk to their patients about medicine safety and acetaminophen use. The Know Your Dose campaign offers a list of helpful health tips to share with patients, including the following:

- (1) Read and follow the label.
- (2) Know which medicines contain acetaminophen.



- (3) Take only one medicine at a time that contains acetaminophen.
- (4) Ask a health care provider or pharmacist about dosing instructions or medicines that contain acetaminophen.

Pharmacists may download or order free educational materials, including posters, flyers, and talking points, to give their patients on the Know Your Dose website, [www.knowyourdose.org](http://www.knowyourdose.org).

### **FDA Offers Webinars on Online Drug Information Resources for Students and Clinicians**

FDA's Division of Drug Information in the Center for Drug Evaluation and Research presents a series of 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 FDA's expanded access program and the pregnancy and lactation labeling rule. The webinars and presentation slides can be accessed on FDA's website at [www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/PharmacyStudentExperientialProgramCDER/ucm228391.htm](http://www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/PharmacyStudentExperientialProgramCDER/ucm228391.htm).

### **Fresenius Kabi Recalls Sensorcaine-MPF (Bupivacaine HCl) Injection, USP**

In April 2016, Fresenius Kabi USA recalled a single lot of Sensorcaine®-MPF (bupivacaine HCl) injection, USP, 0.75%, 7.5 mg/mL, 30 mL fill in a 30 mL vial, because of visible particulate matter characterized as glass observed by the company during inspection of reserve samples. The recalled product was shipped in the US to wholesaler and distributor outlets between March 4, 2016, and March 21, 2016, and has an expiration date of September 2019. The recall affects lot number 6111504, product code 470237, and National Drug Code number 63323-472-37. The product is supplied as 0.75% strength in a 30 mL single-dose flint molded vial and is packaged in units of 25. To date, Fresenius Kabi has not received any reports of adverse events regarding this recall, indicates the press release posted to the FDA website.

Health care facilities that have the affected lot are instructed to immediately discontinue distributing, dispensing, or using the lot and return all units to Fresenius Kabi. Distributors are instructed to immediately notify their customers who have been shipped or may have been shipped the recalled product. Adverse reactions or quality problems may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting program at [www.fda.gov/MedWatch](http://www.fda.gov/MedWatch). Additional details are available on FDA's website at [www.fda.gov/Safety/Recalls/ucm497812.htm](http://www.fda.gov/Safety/Recalls/ucm497812.htm).

### **Oral Liquid Docusate Sodium by PharmaTech Recalled Due to Contamination**

In July 2016, FDA alerted health care providers that PharmaTech, LLC, of Davie, FL, voluntarily recalled all non-expired lots of Diocto Liquid, a docusate sodium solution

distributed by Rugby Laboratories of Livonia, MI. The affected product was distributed nationwide in one-pint (473 mL) bottles with a Rugby label. FDA confirmed the product has been contaminated with *Burkholderia cepacia*, a bacteria linked to an outbreak in five states. The safety alert indicates FDA has received several adverse event reports of *B. cepacia* infections in patients, and some of these reports identify liquid docusate sodium products manufactured by companies other than PharmaTech. FDA and CDC continue to investigate the extent of this issue in order to identify other potentially contaminated liquid docusate sodium products. FDA joins CDC in recommending that clinicians not use any liquid docusate sodium product as a stool softener or for any other medical purpose. Adverse events or side effects may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program at [www.fda.gov/MedWatch](http://www.fda.gov/MedWatch). More information may be found in the safety alert on FDA's website at [www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm511528.htm](http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm511528.htm).

### **NABP Seeks Pharmacists From Districts 1, 5, and 7 to Serve as Volunteer Item Writers**

The National Association of Boards of Pharmacy® (NABP®) is seeking pharmacists who reside in states in the following districts to serve as volunteer item writers:

- ◆ **District 1:** Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont.
- ◆ **District 5:** Iowa, Minnesota, Nebraska, North Dakota, and South Dakota.
- ◆ **District 7:** Alaska, Idaho, Montana, Oregon, Washington, and Wyoming.

In an effort to secure more individuals representative of these areas of the country, NABP encourages pharmacists in all areas of practice as well as school and college of pharmacy faculty who reside in these states to apply.

NABP uses volunteer item writers to develop questions for the following examination programs: North American Pharmacist Licensure Examination® (NAPLEX®), Multistate Pharmacy Jurisprudence Examination® (MPJE®), Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®), Pharmacy Curriculum Outcomes Assessment® (PCOA®), and Pharmacist Assessment for Remediation Evaluation® (PARE®).

Interested individuals should complete the online interest form available in the Meetings section of the NABP website. Individuals who are selected will receive further information on opportunities to attend and participate in NABP-hosted workshops.

For more information about NABP item writing, visit the Meetings section of the NABP website at [www.nabp.pharmacy](http://www.nabp.pharmacy), or contact [CompAssess@nabp.pharmacy](mailto:CompAssess@nabp.pharmacy).

(ACIP) and any immunization specified in rules adopted by the Board to individuals 13 years old or older without a prescription.

- ◆ Any immunization recommended by the ACIP and any immunization specified in rules adopted by the Board to individuals between the ages of seven and 13 if there is a prescription for the immunization.
- ◆ Flu shots to individuals starting at seven years old without a prescription.

**You must be able to document that you meet the training criteria for each immunization that you will be administering.** Prior to administering an immunization listed in Rule 4729-5-38 of the OAC, paragraph (C) of Rule 4729-5-36 requires a pharmacist or pharmacy intern to complete additional coursework if his or her current certification does not include training on that particular immunization.

For more information, please visit [www.pharmacy.ohio.gov/HB394](http://www.pharmacy.ohio.gov/HB394).

### **New Requirements for Change in Description of Terminal or Wholesale Facility**

Rule 4729-9-08 of the OAC states that any change in the ownership, business or trade name, category, or address of a terminal or wholesale distributor of dangerous drugs requires a new application, required fee, and license. The new application and required fee shall be submitted within **30 days** of any change in the ownership, business or trade name, category, or address. The Board encourages all licensees to comply to this rule, as failure to do so could result in disciplinary action.

### **Avoiding Gaps in OARRS Reporting**

Pharmacists and prescribers rely on information from the OARRS database as one tool in their decision-making process to prescribe or dispense CS medications. Having information as current and complete as possible is important for optimizing patient care.

Rule 4729-37-07 of the OAC addresses the frequency requirements for submitting drug database information. Prescription data or a “zero report” must be submitted to the Board on a daily basis. This includes weekends and holidays. Every date must have either prescription data or a “zero report” to cover that day.

OARRS can only build a report based on the information provided by the pharmacies. Incomplete data yields an incomplete report.

### **Supplying Stock Medications to Prescribers or Another Pharmacy**

A prescriber wants to purchase product from the pharmacy to be used in his or her office. A pharmacy wants to purchase a bottle of medication from another

pharmacy, either within the same chain or another chain. This is permitted under the Drug Supply Chain Security Act (DSCSA), but only for a patient-specific need. How should the pharmacy accomplish this?

For Schedule II CS, the **only** legal way is for the purchaser (prescriber or other pharmacy) to complete his or her own Drug Enforcement Administration (DEA) Form 222 and provide it to the selling pharmacy. The selling pharmacy must comply with all rules regarding processing the DEA Form 222.

For all other dangerous drugs, both controlled and non-controlled, the pharmacy may sell product to the prescriber or other pharmacy by using an itemized invoice detailing precisely how much and what medications are being sold. Please note that per DSCSA, dispensers do not need to provide the transaction history, transaction information, or transaction statement when transferring to fulfill a specific patient need.

Under no circumstance should you fill a prescription labeled with “office use” as if it were for a patient. Prescriptions and the prescription numbering sequences are for unique, individual patients. Prescription numbers are **not** to be used as an office accounting system.

**Do not forget the OARRS component of this transaction.** Remember that all sales of CS (and gabapentin after December 1, 2016) from your pharmacy DEA registration to another DEA registrant (either a pharmacy or a prescriber) must be reported as a wholesale transaction in OARRS. This will require the pharmacy to establish an OARRS wholesale account. A “wholesale handbook” is posted on the OARRS website under the Documents tab. Please also be aware that Rule 4729-9-10 of the OAC states that occasional wholesale sales shall not exceed 5% of the total value of dangerous drugs purchased by the pharmacy during the same calendar year. In addition, the total amount of CS sold pursuant to this rule shall not exceed the allowable amount as specified in Title 21 Code of Federal Regulations §1307.11 (March 16, 2016). Any sales that exceed this limit will require the pharmacy to obtain a wholesale distributor license.

### **Reporting DEA Registration Number Suffixes by Hospitals**

Effective October 1, 2016, Rule 4729-17-13 requires all hospitals to submit electronically to the Board an initial list of the internal codes that are used as a suffix to the hospital DEA registration number within 30 days. Furthermore, the rule requires that all additions, deletions, or changes to the list be submitted to the Board within five business days of any such addition, deletion, or change.

For more information, please visit [www.pharmacy.ohio.gov/reporting](http://www.pharmacy.ohio.gov/reporting).

## **Board Resolution: Transfers Between Terminal Distributor Locations**

Pursuant to [Section 4729.51 of the ORC](#), a licensed terminal distributor of dangerous drugs having more than one licensed location may transfer or deliver dangerous drugs from one licensed location to another licensed location owned by that terminal distributor if the license issued for each location is in effect at the time of the transfer or delivery. Such transfer or delivery includes either of the following:

- (1) Intracompany sales, which include any transaction or transfer between any division, subsidiary, parent, affiliate, or related company under the common ownership and control.
- (2) The sale, purchase, or transfer of a drug or an offer to sell, purchase, or transfer a drug among hospitals or other health care entities that are under common control. Common control means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, by contract, or otherwise.

## **Storage of Records Outside of the Pharmacy Department**

Effective August 15, 2016, any designated area outside the prescription department at the location licensed as a terminal distributor of dangerous drugs intending to be used for the storage of dangerous drugs, DEA CS order forms, exempt narcotics, hypodermics, poisons, records relating to the distribution of dangerous drugs except where the Board has granted permission for such records to be stored at a secure off-site location pursuant to rules 4729-9-14 and 4729-9-22 of the OAC, and every other item or product that requires the personal supervision or sale by a pharmacist shall meet the following requirements:

- ◆ The designated area shall be secured by either a physical barrier with suitable locks and/or an electronic barrier to detect unauthorized entry. Such a barrier, before being put into use, must be approved by the Board.
- ◆ No item, product, record, or equipment that must be accessible to anyone other than a pharmacist may be stored in the designated area, unless authorized by the Board.

- ◆ Authorized personnel may have access if there is on-site supervision by a pharmacist.

The Board has issued a resolution that extends this requirement until February 1, 2017. Pharmacies must ensure that they meet this requirement by February 1, 2017, and should begin the process of securing their on-site records storage now to allow time for approval by their local compliance agent or specialist.

If a pharmacy cannot meet the February 1, 2017 deadline, it can receive a six-month extension (no later than August 1, 2017) if it submits a plan to the Board indicating how it will meet the requirements of the rule.

For more information on this rule, please visit [www.pharmacy.ohio.gov/storage](http://www.pharmacy.ohio.gov/storage).

## **Rules on Pharmacist Consult Agreements With Physicians**

On March 23, 2016, [Ohio House Bill 188 \(131<sup>st</sup> General Assembly\)](#) went into effect. This law makes the following modifications to pharmacist consult agreements with physicians ([ORC 4729.39](#)):

- ◆ Authorizes one or more pharmacists practicing under a consult agreement with one or more physicians to (1) manage a patient's drug therapy for specified diagnoses or diseases and (2) order and evaluate blood and urine tests.
- ◆ Creates a single process for establishing a consult agreement, in place of separate processes that were based on whether the patient's drug therapy was being managed within or outside a hospital or long-term care facility.
- ◆ Grants certain immunities from civil liability to pharmacists and physicians practicing under consult agreements.

New rules regarding consult agreements went into effect **August 18, 2016**. A copy of the rules can be accessed by visiting [www.pharmacy.ohio.gov/consult](http://www.pharmacy.ohio.gov/consult).

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