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News



# State of Ohio Board of Pharmacy

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## **New Opioid Prescribing Guidelines for Management of Acute Pain to Prevent Drug Overdoses**

Dear Ohio Pharmacist,

With the support of clinicians, Ohio has made some promising progress in key areas in its fight against prescription opioid abuse. In recent years, both the number of opioid doses dispensed to Ohio patients and the number of “doctor shoppers” have decreased, according to data from the Ohio Automated Rx Reporting System (OARRS).

Still, there is more that we must do to save lives. Prescription opioids remain a significant contributor to unintentional drug overdose deaths in Ohio, and the number of overdose deaths increased each year from 2012 through 2014.

The Governor’s Cabinet Opiate Action Team developed opioid prescribing guidelines for emergency departments in 2012 and for management of chronic pain in 2013. It has released the *Ohio Guideline for the Management of Acute Pain Outside of Emergency Departments* for the management of acute pain expected to resolve within 12 weeks. Like the previous prescribing guidelines, these new guidelines are intended to supplement – not replace – clinical judgment.

Please visit [www.opioidprescribing.ohio.gov](http://www.opioidprescribing.ohio.gov) for copies of all three opioid prescribing guidelines, as well as tools and resources, including a letter for patients that explains a safer approach to treating their acute pain following these guidelines.

These new prescribing guidelines for the outpatient management of acute pain have been endorsed by numerous organizations including, but not limited to, the Ohio State Medical Association, Ohio Osteopathic Association, Ohio Academy of Family Physicians, Ohio Physical Therapy Association, Ohio Hospital Association, Ohio Public Health Association, State Medical Board of Ohio, Ohio State Dental Board, Ohio Board of Nursing, and State of Ohio Board of Pharmacy.

Thank you for your continued support in Ohio’s fight against prescription opioid abuse.

Sincerely,

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

## **It Is Okay to Say No – You Might Just Save a Life**

### **Board Announces New OARRS Rules for Pharmacists**

On February 1, 2016, updates to Rule 4729-5-20 of the Ohio Administrative Code (OAC) went into effect. These updates include new requirements on when a pharmacist is required to review patient information in OARRS. The new rule states in part:

- (D) Prior to dispensing an outpatient prescription for a reported drug . . . at a minimum, a pharmacist shall request and review an OARRS report covering at least a one year time period, including a border state’s information when the pharmacist is practicing in a county bordering another state if that state’s information is available, in any of the following circumstances:
- (1) A patient adds a different or new reported drug to their therapy that was not previously included;
  - (2) An OARRS report has not been reviewed for that patient during the preceding twelve months, as indicated in the patient profile;
  - (3) A prescriber is located outside the usual pharmacy geographic area;
  - (4) A patient is from outside the usual pharmacy geographic area;
  - (5) A pharmacist has reason to believe the patient has received prescriptions for reported drugs from more than one prescriber in the preceding 3 months, unless the prescriptions are from prescribers who practice at the same physical location; or
  - (6) Patient is exhibiting signs of potential abuse or diversion. This includes, but is not limited to, over-utilization, early refills . . . or an unfamiliar patient requesting a reported drug by specific name, street name, color, or identifying marks.

To assist you in the implementation of this updated rule, the Board has put together a one-page fact sheet and pocket card that provides the circumstances in which a pharmacist will have to query OARRS.

In addition, the Board has created a one-page sheet designed to assist pharmacists in talking with a patient in situations where they may need to refuse to fill a prescription. Entitled “Sometimes We Just Have to Say No,” the fact sheet provides an

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## **Discontinue Use of Chen Shwezin Sterile Drug Products, FDA Warns**

In October 2015, the United States Food and Drug Administration (FDA) issued a statement alerting health care providers and patients not to use drug products intended to be sterile that were made and distributed by Chen Shwezin, Inc, dba Park Compounding Pharmacy of Westlake Village, CA, because of lack of sterility assurance. Following an FDA inspection during which investigators observed unsanitary conditions, including poor sterile production practices, FDA recommended that Park Compounding Pharmacy cease sterile operations and recall all of its non-expired sterile drug products. However, the company had refused to recall its products, according to an FDA safety alert.

At this time, FDA has not received reports of any adverse events associated with the use of products from Park Compounding Pharmacy. FDA recommends that health care providers check their medical supplies, quarantine any sterile drug products from Park Compounding Pharmacy, and not administer them to patients.

More information is available in the FDA safety alert, available at [www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm465582.htm](http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm465582.htm).

## **Seven Persistent Safety Gaffes in Community/Ambulatory Settings That Need to Be Resolved!**



*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: [isminfo@ismp.org](mailto:isminfo@ismp.org).*

This is the final article of a three-part series on seven persistent safety gaffes of 2014.

### **6) Compounded Pain Creams: High Profit Margin and Danger**

Some compounding pharmacies have been heavily marketing compounded pain creams directly to consumers via unsolicited calls, suggesting that the creams are more effective and safer than oral or injectable pain medications. Many of the creams contain drugs that can cause central nervous system depression or adverse cardiac effects, and most have not been

FDA-approved for use in combination with each other or for topical use. Patients are charged per ingredient, with many creams containing numerous, expensive medications. Toxicity from the creams has been reported to poison control centers, including cases of accidental child exposures and intentional use for multiple family members. Patients are often unaware of the dangers with using the creams, which include unsafe packaging in containers without child-resistant closures. ISMP is specifically concerned about some statements that may be unproven, such as the products' safe use with children. Compounded pain creams need prominent warnings on labels that describe the potential for toxicity, and physicians and pharmacists who prescribe and dispense the creams must provide patients with instructions about possible adverse effects, safe storage, and proper use. ISMP believes regulatory or licensing oversight is necessary.

### **7) Clear Care: Still Causing Severe Eye Injuries Five Years Later**

Since early 2010, ISMP has received scores of reports of painful eye injuries from patients using CLEAR CARE® Cleaning & Disinfecting Solution for contact lenses by Alcon (formerly CIBA VISION), a Novartis company, and similar store-brand products. Hundreds more can be found on Internet listservs. Located on store shelves near other lens disinfectants and solutions, these disinfecting products differ from other commonly used solutions in that they must be used with a special lens case in order to neutralize the 3% hydrogen peroxide component of the solution over at least six hours before putting the lenses back into the eyes. However, many patients have inadvertently used the solution to soak their lenses in a standard lens case, or thought the solution was saline and instilled it directly into their eyes. This has caused severe eye burning, leading many to seek out emergency medical care for corneal burns. In 2012, Alcon made a label enhancement to warn customers to use the special lens case, but the label change has been ineffective. Neither the company nor FDA's Medical Devices division have been persuaded to make effective label improvements before permanent eye injury or blindness occurs. If the labeling and packaging cannot be improved to reduce the harm being reported, perhaps these products should be pulled from the market or available only behind the pharmacy counter.

### **Risk of Dose Confusion and Medication Errors With Avycaz, FDA Cautions**

Confusion about the drug strength displayed on the vial and carton labels has led to some dosing errors with the intravenous antibacterial drug Avycaz™ (ceftazidime and avibactam), warned FDA in September 2015. The agency explained that Avycaz was initially approved with the vial and carton labels displaying the individual strengths of the two active ingredients (2 g/0.5 g); however, the product is dosed based on the sum of the active ingredients (2.5 g). To prevent medication errors, FDA revised the labels to indicate that each



vial contains Avycaz 2.5 g, equivalent to ceftazidime 2 g and avibactam 0.5 g, according to an FDA safety alert.

As of September 2015, FDA had received reports of three medication error cases related to confusion on how the strength was displayed on the Avycaz vial and carton labels. Two cases stated that the errors occurred during preparation of the dose in the pharmacy. The third case described concern about the potential for confusion because the strength displayed for Avycaz differs from how the strength is displayed for other beta-lactam/beta-lactamase drugs. Based on the information provided in the reports, FDA is aware that at least one of the patients received a higher-than-intended dose of Avycaz. As of September 2015, no adverse events were reported.

More details are included in the FDA safety alert, available at [www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm463595.htm](http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm463595.htm).

## **US Compounding, Inc, Recalls All Lots of Sterile Compounded Products**

In September 2015, US Compounding, Inc, of Conway, AR, issued a voluntary recall of all lots of sterile products aseptically compounded and packaged by the company, and that remain within expiry, because of a lack of sterility assurance. The affected sterile products were distributed nationwide to patients, providers, hospitals, and clinics between March 14, 2015, and September 9, 2015. The recall does not apply to any nonsterile compounded medications prepared by US Compounding. Providers are advised to discontinue use of the products, quarantine any unused product, and contact US Compounding to arrange the return of any unused sterile compounded products using the information provided in the FDA press release, available at [www.fda.gov/Safety/Recalls/ucm464071.htm](http://www.fda.gov/Safety/Recalls/ucm464071.htm).

The company issued this recall out of an abundance of caution. Providers who have dispensed any sterile product distributed by US Compounding should contact patients to whom product was dispensed and notify them of this recall. A list of all sterile compounded products that have been recalled is provided on FDA's website at [www.fda.gov/Safety/Recalls/ucm464072.htm](http://www.fda.gov/Safety/Recalls/ucm464072.htm).

## **FDA Investigates the Risks of Using Pain Medicine Tramadol in Young Patients**

As of September 2015, FDA is investigating the use of the pain medicine tramadol in young patients because of the rare but serious risk of slowed or difficult breathing. This risk may be increased in patients treated with tramadol for pain after surgery to remove their tonsils and/or adenoids. Tramadol is not FDA-approved for use in patients aged 17 years or younger; however, data show it is being used "off-label" in the pediatric population, according to the safety alert on FDA's website, available at [www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm463499.htm](http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm463499.htm).

FDA is evaluating all available information and will communicate final conclusions and recommendations to the public

when the review is complete. Health care providers are encouraged to report adverse events or side effects related to the use of these products to FDA's MedWatch Safety Information and Adverse Event Reporting Program.

## **Decreased Potency Reported in Drugs Stored in Becton-Dickinson Syringes**

In September 2015, FDA expanded its alert regarding compounded or repackaged drugs stored in Becton-Dickinson (BD) general use syringes to include certain additional syringe sizes including 1 mL, 10 mL, 20 mL, and 30 mL BD syringes, and BD oral syringes. FDA's original alert applied to compounded or repackaged drugs that have been stored in 3 mL and 5 mL BD syringes. The agency expanded the alert based on BD reports that an interaction with the rubber stopper in certain lots of these syringes can cause some drugs stored in these syringes to lose potency if filled and not used immediately. BD reports that the following drugs in particular can be affected by the stoppers, but it does not know whether other drugs can be affected: fentanyl, rocuronium, neostigmine, morphine, midazolam, methadone, atropine, hydromorphone, cisatracurium, and remifentanyl. This safety alert does not pertain to BD prefilled, prefillable, heparin flush, saline flush, or insulin syringes, indicates BD in an alert notice. Further, BD's alert notice also has a search tool to assist customers in determining if their lots are affected. FDA advises hospital pharmacies and staff to contact any outsourcers to determine if affected lots of BD syringes were used for compounded or repackaged products. Hospital pharmacies and staff should not administer compounded or repackaged drugs that have been stored in any of these syringes unless there is no suitable alternative available. Adverse reactions may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting program.

More details are included in the FDA Safety Alert, available at [www.fda.gov/Drugs/DrugSafety/ucm458952.htm](http://www.fda.gov/Drugs/DrugSafety/ucm458952.htm).

## **MediStat Pharmacy Issues Recall of Sterile Drug Products**

MediStat Pharmacy, a 503B outsourcing facility in Foley, AL, has initiated a national recall of all sterile injectable products distributed between November 1, 2014, and September 3, 2015. The recall is based on the identification of various pathogens within the compounding environment. Health care providers should check their medical supplies, quarantine any drug products marketed as sterile from MediStat, and not administer them to patients. FDA has received reports of several adverse events that are potentially associated with the drug products made by MediStat. MediStat voluntarily ceased sterile compounding operations in September 2015. FDA asks health care providers and patients to report adverse reactions or quality problems experienced with the use of these products to the FDA's MedWatch Adverse Event Reporting program.

More details are included in an FDA press release, available at [www.fda.gov/Safety/Recalls/ucm461939.htm](http://www.fda.gov/Safety/Recalls/ucm461939.htm).

overview of when prescriptions are not considered valid, explains a pharmacist's corresponding responsibility under the law, and provides a phone number where patients and families can locate an addiction services provider.

These resources may be accessed at [www.pharmacy.ohio.gov/OARRSRules](http://www.pharmacy.ohio.gov/OARRSRules).

The Board would like to remind all pharmacists that a corresponding responsibility rests with the pharmacist who dispenses any prescription. An order purporting to be a prescription issued not in the usual course of bona fide treatment of a patient is not a prescription, and the person knowingly dispensing such a purported prescription, as well as the person issuing it, shall be subject to the penalties of law. Pharmacists should always use their professional judgment when making a determination about the legitimacy of a prescription (OAC 4729-5-20(G), 4729-5-30(A), and 4729-5-21(A)).

### **Changes to Continuing Education Rules**

Effective January 15, 2016, the Board implemented the following rule changes related to continuing education (CE) requirements.

#### **Patient/Medication Safety**

Effective January 15, 2016, pharmacists are now required to complete 0.2 continuing education units (CEUs) of patient or medication safety CE per CE reporting cycle. Patient- or medication safety-related CE is defined as any [Accreditation Council for Pharmacy Education \(ACPE\)](#) program as identified by ACPE numbering convention "05" that deals with the prevention of health care errors and the elimination or mitigation of patient injury caused by health care errors.

**Note:** Pharmacists who are required to report CE in 2016 must ensure that they have completed 0.2 CEUs of patient or medication safety CE prior to the reporting deadline of September 15, 2016. This also applies to pharmacists who are currently certified by a Board-approved, pharmacy practice-specific specialty certification program. If you have already completed 0.2 CEUs of patient or medication safety CE prior to January 15, 2016, and during the CEU reporting dates, then you have satisfied the requirement of the rule.

#### **Pharmacy Jurisprudence**

Effective January 15, 2016, pharmacists have two options to meet the current requirement that they obtain 0.3 CEUs of pharmacy jurisprudence per CE reporting cycle. These two options are:

- (1) [ACPE](#) law programs as identified by ACPE numbering convention "03;" or
- (2) If provided by an in-state provider of CE, Board-approved continuing pharmacy education (CPE) programs that deal with current laws, rules, and regulations dealing with the practice of pharmacy and the recent changes that have occurred to those laws, rules, and regulations. A list of Board-approved courses can be accessed from the Board's CE website at [www.pharmacy.ohio.gov/Licensing/CE.aspx](http://www.pharmacy.ohio.gov/Licensing/CE.aspx).

**Note:** ACPE law programs successfully completed prior to January 15, 2016, and during the CEU reporting dates will count towards meeting jurisprudence requirements. For additional information, including a copy of the updated rules, please visit [www.pharmacy.ohio.gov/cechange](http://www.pharmacy.ohio.gov/cechange).

### **Annual Board of Pharmacy Law CE Test**

The Board is pleased to offer the annual Jurisprudence Quiz. The quiz can be accessed by visiting [www.pharmacy.ohio.gov/2015quiz](http://www.pharmacy.ohio.gov/2015quiz). This year's law CE quiz contains questions on content from both the 2015 quarterly *Newsletters* and the guidance documents developed to provide greater depth and breadth of information on the new rules. Guidance documents are available at <http://pharmacy.ohio.gov/Pubs/Special.aspx>.

For your convenience, when a question comes from a guidance document, the Board is attaching a link to that guidance document. The Board knows this is a change from prior years' CE quizzes.

Guidance documents contain a significant amount of information and go into much more detail than what can be provided in the *Newsletter*. The information is important for your daily practice as a pharmacist.

Like last year, the test is taken online and graded as soon as you submit your test. You may preprint the exam, but you will have only one opportunity to actually take and submit the test for grading. A 75% correct score is needed to pass. After successful completion, you will have the ability to immediately print your certificate, and a copy of it 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®.

There is no charge for this CE. Yes, it is free.

Please do not mail any quizzes to the Board office. The Board will neither hand-process exams nor mail a certificate to you. The entire process must be completed online.

### **OARRS Data Entry**

The content of a patient's OARRS report is only as accurate as what the pharmacy reports. Each line item of the report contributes to a bigger picture of the patient's prescription history. When there are errors in the data, the picture may end up distorted. OAC 4729-37-04 outlines the elements required for an OARRS submission. The two largest areas where reporting errors occur are the prescriber name and the days supply.

Entering the wrong doctor may result in refill requests being sent to the wrong doctor (and thus a Health Insurance Portability and Accountability Act violation) and potentially a delay in patient therapy due to waiting for an authorization that will never be returned. Prescribers are able to run a Practice Insight Report, which tells them the names of patients for whom the prescriber's name has been entered on a prescription. (They only get the name, no details of the specific prescription.) When a name shows up that the prescriber does not know, a chain reaction is initiated to determine if this was an honest data entry error or if fraudulent activity is occurring. The Board has received numerous calls from prescribers upset with pharmacies over entering the wrong prescriber (same name, but a different prescriber). By entering the prescriber's Drug Enforcement Administration number taken off of the prescription rather than entering the prescriber name, this type of error can be eliminated.

Entering the correct days supply of a medication is another area where errors commonly occur. For opioid prescriptions, a smaller days supply drives the prescription to a higher morphine equivalent dose (MED). Pharmacies tend to assume maximum usage on prescriptions with a dosing range, eg, prescriptions with instructions of one to two tablets every four to six hours. While this is understandable, basic math errors are not. Prescribers use the MED as a factor in their dosing guidelines.

The Board will address repeat errors in reporting on an individual basis.

### **New Rules Effective January 15, 2016**

A number of new and amended rules recently went into effect. These rules can be accessed by visiting [www.pharmacy.ohio.gov/jan2016rules](http://www.pharmacy.ohio.gov/jan2016rules).