



# Massachusetts Board of Registration in Pharmacy

*Published to promote compliance of pharmacy and drug law*

239 Causeway Street, 5<sup>th</sup> Floor • Boston, MA 02114 • [www.mass.gov/dph/boards/pharmacy](http://www.mass.gov/dph/boards/pharmacy)

## **Naloxone Standing Orders**

Now that all pharmacies licensed by the Massachusetts Board of Registration in Pharmacy must maintain a naloxone standing order and a sufficient supply to meet the needs of the community, naloxone may be dispensed to any person at risk for an opioid-related overdose or to family members, friends, or others in a position to assist a person at risk for an opioid-related overdose.

Patient-specific prescriptions from practitioners may still be honored.

Here are some helpful notes to be aware of:

- ◆ Standing orders must be renewed every two years.
- ◆ Label the naloxone rescue kits with the expiration date of the drug.
- ◆ The phrase “Naloxone Rescue Kit” may be used to create a patient profile and prescription label.
- ◆ With the purchaser’s permission, contact his or her insurance company to verify coverage.
- ◆ Distribute the administration pamphlet at the time of dispensing. The pamphlet may be downloaded at [www.mass.gov/eohhs/docs/dph/quality/boards/pharmacy/naloxone-pamphlet.pdf](http://www.mass.gov/eohhs/docs/dph/quality/boards/pharmacy/naloxone-pamphlet.pdf).
- ◆ By January 15, the number of naloxone units dispensed under the standing order for the previous calendar year must be reported to [naloxonestandingorders@massmail.state.ma.us](mailto:naloxonestandingorders@massmail.state.ma.us).
- ◆ See Policy 2017-03 for full details at <https://www.mass.gov/files/documents/2017/10/12/policy-2017-03.pdf>.

## **Inspection Tools**

Located on the Board’s website are the tools used by pharmacy investigators during inspections. Whether your facility is a wholesale distributor, sterile compounder, complex sterile compounder, or typical retail pharmacy, the tools may be found at <https://www.mass.gov/lists/pharmacy-practice-resources>.

Managers of record (MORs) are encouraged to perform self-inspections utilizing these tools prior to taking on the managerial role, and periodically thereafter, to ensure

compliance. Sharing this information with staff, including interns, will help them understand what is expected in terms of compliance.

Attached to the end of the United States Pharmacopeia (USP) Chapter <795> and USP Chapter <797> inspection tools are checklists itemizing the documents that will be requested during Board inspections. Preparing for inspection by having these documents readily available can help expedite the process.

## **Prescription Monitoring Program**

Pharmacists are on the front lines to help identify concerning activity that may suggest inappropriate prescribing or potential abuse/misuse of prescribed medications.

### **What Can a Pharmacist Do?**

- ◆ Register for and routinely use the online Massachusetts Prescription Awareness Tool.
- ◆ Look for suspicious things such as overlapping prescriptions, excessively high morphine milligram equivalents, and dangerous drug combinations.
- ◆ Be aware of certain patient behaviors, including paying in cash, refusing to provide a photo ID at pick up, or picking up prescriptions for multiple patients.
- ◆ For patients who concern you and your staff, talk to the patients themselves and/or their prescribers.
- ◆ Call local police if you suspect criminal behavior.
- ◆ Visit the Massachusetts Prescription Monitoring Program (PMP) website to register and obtain more information: <https://www.mass.gov/prescription-monitoring-program-pmp>.

### **Data Submission to the PMP**

The accuracy and timeliness of pharmacies’ prescription data submissions are the backbone of the PMP. Timely reporting can prevent a prescriber from writing a potentially harmful prescription. When in doubt, refer to the Data Submission Dispenser Guide, available at [www.mass.gov/eohhs/docs/dph/quality/drugcontrol/pmp/pmp-dispenser-guide.pdf](http://www.mass.gov/eohhs/docs/dph/quality/drugcontrol/pmp/pmp-dispenser-guide.pdf). The law requires you to report all Schedule II through V controlled substances (CS), as well as gabapentin,

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# National Pharmacy Compliance News

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**NABPF**  
National Association of Boards  
of Pharmacy Foundation

The applicability of articles in the *National Pharmacy Compliance News* to a particular state or jurisdiction can only be ascertained by examining the law of such state or jurisdiction.

## **FDA Draft Guidance Addresses Delayed Enforcement of DSCSA Requirements for Product Identifiers**

Food and Drug Administration (FDA) issued a draft guidance for industry that informs manufacturers and other supply chain stakeholders that although manufacturers are to begin including a product identifier on prescription drug packages and cases on November 27, 2017, FDA is delaying enforcement of those requirements until November 2018 to provide manufacturers additional time and avoid supply disruptions. The compliance policy outlined in the June 2017 draft guidance, *Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy*, applies solely to products without a product identifier that are introduced into commerce by a manufacturer between November 27, 2017, and November 26, 2018. While manufacturers work to meet product identifier requirements, they must comply with other Drug Supply Chain Security Act (DSCSA) requirements. The draft guidance can be accessed from FDA's website at [www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm565358.htm](http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm565358.htm).

## **Amount of Prescribed Opioids Remains High, Reports CDC**

The amount of opioids prescribed remains approximately three times as high as in 1999, despite reductions in each year after 2010 through 2015. Centers for Disease Control and Prevention (CDC) researchers analyzed retail prescription data to assess opioid prescribing in the United States from 2006 to 2015 and county-level prescribing patterns in 2010 and 2015. According to a CDC report, results of the study showed higher amounts of opioids were prescribed in counties that had a greater percentage of non-Hispanic white residents, a higher prevalence of diabetes and arthritis, micropolitan status (ie, town/city; nonmetro), and higher unemployment and Medicaid enrollment rates. The researchers conclude that health care providers should carefully weigh the benefits and risks when prescribing opioids outside of end-of-life care, follow evidence-based guidelines (eg, CDC's *Guideline for Prescribing Opioids for Chronic Pain*), and consider non-opioid therapy for chronic pain treatment.

Additionally, the researchers conclude that state and local jurisdictions can use these findings along with

prescription drug monitoring program (PDMP) data to identify prescribing patterns that place patients at risk for opioid use disorder and overdose and to target interventions with prescribers based on opioid prescribing guidelines. The July 7, 2017 *Morbidity and Mortality Weekly Report*, "Vital Signs: Changes in Opioid Prescribing in the United States, 2006–2015," can be accessed on the CDC website at [www.cdc.gov/mmwr/index.html](http://www.cdc.gov/mmwr/index.html) in the Weekly Report section.

## **AMA Opioid Task Force Encourages Co-Prescribing Naloxone to At-Risk Patients**

The American Medical Association (AMA) Opioid Task Force encourages physicians to consider co-prescribing naloxone when it is clinically appropriate to do so. The AMA Opioid Task Force offers several questions for determining whether to co-prescribe naloxone to a patient or a patient's family member or close friend, which may be found in the August 2017 document, "AMA Opioid Task Force naloxone recommendations," available on the AMA opioid microsite at <https://www.end-opioid-epidemic.org>.

The Naloxone section of the AMA opioid microsite also offers physicians multiple resources on co-prescribing naloxone in their practice and community. To help end the opioid epidemic, the AMA Opioid Task Force made several recommendations for physicians, including registering and using state PDMPs, training and education on evidence-based treatment, and promoting safe storage and disposal of opioids and medications.

## **Opioid Addiction Medications Should Not Be Withheld From Patients Taking Benzodiazepines or CNS Depressants**

Opioid addiction medications – buprenorphine and methadone – should not be withheld from patients taking benzodiazepines or other drugs that depress the central nervous system (CNS), advises FDA. The combined use of these drugs increases the risk of serious side effects; however, the harm caused by untreated opioid addiction usually outweighs these risks. Careful medication management by health care providers can reduce these risks, notes a safety alert. FDA is requiring this information to be added to the buprenorphine and methadone drug labels along with detailed recommendations for

minimizing the use of medication-assisted treatment drugs and benzodiazepines together.

Health care providers should take several actions and precautions and should develop a treatment plan when buprenorphine or methadone is used in combination with benzodiazepines or other CNS depressants. Additional information may be found in an FDA Drug Safety Communication announcement at [www.fda.gov/Drugs/DrugSafety/ucm575307.htm](http://www.fda.gov/Drugs/DrugSafety/ucm575307.htm).

### **New Study Shows Substantial Variation in the Availability of Pharmacies Across the Country**

Despite the rising number of US pharmacies from 2007 to 2015, the availability of pharmacies varied significantly across local areas, indicates a new study. The study, *The availability of pharmacies in the United States: 2007–2015*, found that the number of community pharmacies increased 6.3% from 63,752 to 67,753 between 2007 and 2015. Although the number of pharmacies per capita remained at 2.11 per 10,000 individuals between 2007 and 2015, the researchers found substantial variation across counties. “Some counties have 13 pharmacies per capita, while others have none,” said Dima Qato, lead study author and assistant professor of pharmacy systems, outcomes and policy, in a University of Illinois at Chicago (UIC) news release.

In 2015, counties in the highest quintile had nearly three-fold more pharmacies than those in the lowest quintile. Counties in the lowest quintile are located in the Pacific West, Southwest, and Great Lakes regions, while counties with the highest tend to be located in the Northeast, Southeast, Northern Appalachia, and Plains states. The researchers conclude that future programs and policies should address the availability of pharmacies and ensure that pharmacy characteristics, including accommodations such as multilingual staffing and home delivery, align with local population needs.

To view the study, visit <https://doi.org/10.1371/journal.pone.0183172>. The UIC news release is available at <https://today.uic.edu/access-to-pharmacies-limited-to-some-patients>.

### **Consent Decree Entered Against Outsourcing Facility Isomeric Pharmacy Solutions**

Under a consent decree of permanent injunction entered in August 2017, Isomeric Pharmacy Solutions of Salt Lake City, UT, its owners, and chief operating officer are prohibited from manufacturing, processing, packing, holding, or distributing drugs until they

comply with the Federal Food, Drug, and Cosmetic Act (FD&C Act) and its regulations, in addition to other requirements. Isomeric manufactured and distributed purportedly sterile drug products, including injectable and ophthalmic drugs, that were adulterated because the drugs were made under insanitary conditions and in violation of current good manufacturing practice requirements under the FD&C Act, according to the complaint for permanent injunction. The complaint also alleges that Isomeric manufactured and distributed unapproved drugs and drugs that were misbranded because their labeling did not bear adequate directions for use. Isomeric initially registered as an outsourcing facility in July 2015 and reregistered in December 2015 and January 2017. Additional information is available in an FDA news release at [www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm570130.htm](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm570130.htm).

### **FDA Issues Warning on Alcohol Pads or Benzalkonium Chloride Antiseptic Towelettes Made by Foshan**

In September 2017, FDA alerted health care providers and patients to not use alcohol pads or benzalkonium chloride antiseptic towelettes made by Foshan Flying Medical Products Co, Ltd, located in China, due to lack of sterility assurance and other quality issues. These products are distributed by Total Resources International, of Walnut, CA, and Simple Diagnostics, Inc, of Williston Park, NY. The use of these alcohol pads and antiseptic towelettes could cause infections.

FDA placed all drug products made by Foshan on import alert on May 23, 2017, to stop these products from entering the US. However, FDA is concerned these products might still be in distribution in the US. FDA also sent Foshan a warning letter on August 1, 2017, for violations of current good manufacturing practice regulations. FDA initially contacted Foshan regarding a recall on May 25, 2017, and had several follow-up meetings with the company. Foshan has not taken action to remove its alcohol pads or antiseptic towelettes from the market. The safety alert posted to FDA's website may be found at [www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm574576.htm](http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm574576.htm).

Pharmacies and health care facilities that have alcohol pads and antiseptic towelettes labeled by Total Resources or Simple Diagnostics should immediately stop using them and discard the products. Adverse events or side effects related to the use of these products may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program at [www.fda.gov/MedWatch/report](http://www.fda.gov/MedWatch/report).



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electronically at least every 24 hours or the next business day. Be sure to have a backup submission plan for vacations and sick days!

### **Quality Related Events and Serious Adverse Drug Events**

A **quality related event (QRE)** is the incorrect dispensing of a prescribed medication that is received by a patient. All Board-licensed pharmacies must establish and maintain a continuous quality improvement (CQI) program for the purpose of detecting, documenting, assessing, and preventing QREs. The regulation concerning CQI programs is available for download at <https://www.mass.gov/regulations/247-CMR-1500-continuous-quality-improvement-program>.

A designated person(s) must be responsible for monitoring CQI program compliance and provide ongoing staff education.

QREs must be brought to the attention of a pharmacist immediately upon discovery so that the patient, his or her representative, and the prescriber (if necessary) may be immediately notified. A plan for correcting the error and instructions for minimizing any negative effects on the patient must be implemented immediately. All communications must be documented either manually or electronically.

QREs must be investigated and analyzed, both individually and collectively, to assess causes and contributing factors such as system or process failures. This is also recommended for the purpose of analyzing and assessing “near misses.”

Policies and procedures should be developed requiring that incident reports be completed and submitted to a national database, such as the Institute for Safe Medication Practices Medication Errors Reporting Program or another patient safety organization. Institute a system to review QREs at least quarterly to identify trends and make improvements.

Additionally, any **serious adverse drug event** resulting in serious injury or death that was caused by a compounded preparation (sterile or nonsterile) or a dispensing error must be reported within seven business days of discovery using a Reporting of Serious Adverse Drug Events form, available at [www.mass.gov/eohhs/docs/dph/quality/boards/pharmacy/sade-reporting.pdf](http://www.mass.gov/eohhs/docs/dph/quality/boards/pharmacy/sade-reporting.pdf).

### **Manager of Record Changes**

Accepting an MOR position in a Massachusetts-licensed pharmacy is truly an important decision. At the Board, we find that most pharmacy managers accept the responsibility seriously and do a great job ensuring full compliance with Massachusetts regulations (247 Code of Massachusetts Regulations) and Drug Enforcement Administration regulations. Occasionally, the Board encounters a manager who either is unfamiliar with the expectations and requirements of the role or does not fully understand the level of accountability.

In August 2017, the Board adopted an advisory to help guide managers in their obligations. All MORs, whether new or well-seasoned in the role, should periodically review it: [www.mass.gov/eohhs/docs/dph/quality/boards/pharmacy/advisories/new-managers-record.pdf](http://www.mass.gov/eohhs/docs/dph/quality/boards/pharmacy/advisories/new-managers-record.pdf).

The main thing to remember is that someone needs to be responsible for the licensed facility at all times. Should the current MOR leave the position, even temporarily (30-100 days), the Board should be notified immediately with the name of an “interim manager.”

Prior to his or her absence, an MOR must perform a CS inventory that is signed by the MOR and the interim manager. If the MOR is unexpectedly not available, another registered pharmacist must perform the CS inventory with the interim manager.

If you are the outgoing manager, you should personally notify the Board (via email) as well. Everything in that pharmacy remains your responsibility until the Board has been informed otherwise.

Remember that the Board must be notified within 10 days of the start or termination of a specific MOR’s employment.

The Application for Change in Manager of a Pharmacy may be found at [www.mass.gov/eohhs/docs/dph/quality/boards/pharmacy/pharmacy-change-manager.pdf](http://www.mass.gov/eohhs/docs/dph/quality/boards/pharmacy/pharmacy-change-manager.pdf).

The Board now requires random MOR applicants to appear before the Board to answer questions from Board members. Make sure your continuing education credits are up to date!

### **Did You Know?**

- ◆ You can email the Board with practice questions at [pharmacy.admin@massmail.state.ma.us](mailto:pharmacy.admin@massmail.state.ma.us).
- ◆ Best practice recommendations may be found at <https://www.mass.gov/files/2017-08/pharmacy-best-practice.doc>.

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