



# Virginia Board of Pharmacy

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Perimeter Center • 9960 Mayland Dr, Suite 300 • Henrico, VA 23233

Phone: 804/367-4456 • [www.dhp.virginia.gov/pharmacy](http://www.dhp.virginia.gov/pharmacy)

## **Required CE for Pharmacists in 2017**

Pursuant to §54.1-3314.1(J) of the Code of Virginia and to address Virginia's opioid abuse crisis, which the state health commissioner recently declared a public health emergency, the Virginia Board of Pharmacy determined at its December full Board meeting that all pharmacists must obtain at least one hour of continuing education (CE) in 2017 in any of the following subject areas: proper opioid use, opioid overdose prevention, or naloxone administration. The one-hour minimum requirement is part of the required 15 hours of CE that must be obtained during 2017 and is not in addition to the required 15 hours. This is a one-time requirement; further action of the Board would be required to mandate CE in a specific topic in future years. This requirement applies only to pharmacists, not pharmacy technicians.

Please note that this requirement does not identify specific objectives that must be included in your selected CE program, nor has a list of approved CE programs been identified from which you must choose. The requirement is intended to be general to allow each pharmacist the flexibility in choosing an appropriate CE program that focuses on the proper use of opioids, opioid overdose prevention, or naloxone administration. The CE must be obtained between January 1 and December 31, 2017.

## **New Utilizations and Enhancements of PMP Information**

Drug overdose deaths and opioid-involved deaths continue to increase in the United States. In 2015, 801 Virginians died from an opioid overdose. In 2016, that number is expected to rise to over 1,000. The Virginia Prescription Monitoring Program (PMP) continues to serve as a valuable tool for prescribers and pharmacists in addressing the opioid abuse crisis. This article highlights recent changes in law that directly impact pharmacists reporting information to the PMP, how the information in the PMP database will be used to identify suspected prescriber/pharmacy shoppers, and upcoming integration of the PMP into electronic health

records (EHRs), which will assist prescribers and pharmacists in accessing the information.

## **Morphine Milligram Equivalent**

Calculating the total daily dose of opioids helps identify patients who may benefit from closer monitoring, reduction or tapering of opioids, and the prescribing/dispensing of naloxone or other measures to reduce risk of overdose. Patients prescribed higher opioid dosages are at a higher risk for overdose death. Morphine milligram equivalent (MME) is used to describe a comparison of opioid potency using morphine as the standard. The Centers for Disease Control and Prevention (CDC) recommends using extra precaution when increasing a patient's use of opioids to greater than 50 MME per day and to avoid or carefully justify increasing dosages to greater than 90 MME per day. Please note that CDC's suggested dosage thresholds are based on overdose risk when opioids are prescribed for pain and should not be used to guide dosing of medication-assisted treatment for opioid use disorder.

Daily MME is determined by taking a patient's total dosage of any narcotic in a 24-hour period and converting it to an equivalent amount of morphine using a standardized conversion table. For example, the conversion factor for hydromorphone is four. To calculate the MME for a patient taking 16 mg of hydromorphone per day, multiply the dose by the conversion factor for a total MME of 64. Note: Extra caution should be used in calculating and evaluating the MME of methadone and fentanyl. The conversion factor for methadone increases at higher doses, and fentanyl is dosed in mcg/hr instead of mg/day and its absorption is affected by heat and other factors.

To assist prescribers and dispensers in evaluating a patient's MME, the PMP report contains the calculated MME. The calculated MME is based on all **active** opioid prescriptions from all prescribers and dispensers for that particular patient as of the date the report is requested. Determination of whether a prescription is "active" is based on the days supply for each drug as reported to the PMP


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## FDA Issues Final Rule Amending List of Drug Products That May Not Be Compounded

Food and Drug Administration (FDA) issued a final rule amending FDA's list of drug products that may not be compounded under certain sections of the Federal Food, Drug, and Cosmetic Act (FD&C Act) that allow the marketing of unapproved compounded drugs. Drug products on the list may not be compounded because the drug products have been withdrawn or removed from the market for safety or effectiveness reasons, indicates FDA. The list may be found in the Code of Federal Regulations at Title 21, Section 216.24, at [www.ecfr.gov](http://www.ecfr.gov).

The final rule adds 24 types of drugs to the withdrawn or removed list; modifies the withdrawn or removed list to allow one type of drug product to be compounded under certain circumstances; and clarifies that the withdrawn or removed list applies to sections 503A and 503B of the FD&C Act. The final rule is available at [www.gpo.gov/fdsys/pkg/FR-2016-10-07/pdf/2016-24333.pdf](http://www.gpo.gov/fdsys/pkg/FR-2016-10-07/pdf/2016-24333.pdf). FDA provides more information online at [www.fda.gov/Drugs/DrugSafety/ucm524320.htm](http://www.fda.gov/Drugs/DrugSafety/ucm524320.htm).

## Selected Medication Risks to Manage in 2017

 *This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition by visiting [www.ismp.org](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).*

Some medication safety risks are painfully apparent in an organization, while many others lie dormant in the system until an error or adverse event draws attention to them. ISMP thought it would be useful to describe selected medication safety risks for organizations to manage in 2017 that might otherwise fall off the radar screen.

### Environmental Factors, Workflow, and Staffing Patterns – Poor Quality Lighting

Lighting is a crucial aspect of the physical environment that has been linked to medication safety.<sup>1</sup> Poor quality lighting has often impaired the highly visual tasks associated with medication use, thus leading to medication errors. Examples include tubing misconnections due to low lighting in a patient's room, infusion pumps that have been misprogrammed because of dim backlighting on the screens, and product selection errors in the pharmacy and patient care units caused by low lighting under a pharmacy hood or shadows around an automated dispensing cabinet (ADC).

Despite existing guidelines for lighting in health care, it has been a challenge to implement optimal lighting conditions for prescribing, dispensing, and administering medications. Recent literature reviews found that little system-wide action has been

taken to increase staff awareness of the problem or improve the lighting.<sup>1,2</sup> This is largely because the tasks associated with medication use are varied and carried out under diverse physical conditions and in differing locations, and because there are differences in an individual's light requirements based on visual acuity and age. With an ever-increasing population of older health care providers, eye fatigue from computer work and task complexity, small font sizes on medication labels, poor background contrast, and glare or shadows have taken their toll on visual accuracy.<sup>1,2</sup>

Proper illumination improves both the accuracy and efficiency of medication-related tasks. Fluorescent cool white lamps or compact fluorescent lamps should be used in areas where critical tasks are performed, including on mobile medication carts, near ADCs, and in patients' rooms for nighttime administration of medications.<sup>3,4</sup> Administration of medications at night under low lighting to avoid disturbing the patient is an unsafe practice and should be avoided. Adjustable 50-watt high-intensity task lights are recommended when difficult-to-read prescriptions and product labels are encountered.<sup>4</sup> Illumination levels for computer order entry areas should be at least 75 foot-candles (fc), while 100-150 fc are needed when interpreting handwritten orders.<sup>4</sup> Medication preparation areas, medication verification areas, and patient counseling areas should have illumination levels between 90-150 fc.<sup>4</sup> Medication rooms should provide illumination at 100 fc.<sup>4</sup> Lighting levels should be increased if the workforce has an average age above 45 years. A magnifying glass and task light together can also significantly improve accuracy<sup>3</sup> and should be used on mobile medication carts (including those used with bar code medication verification systems)<sup>4</sup> and near ADCs.

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3. Grasha AF. Psychosocial factors, workload, and risk of medication errors. *US Pharm.* 2002;27(4):HS32-52.
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### DEA to Decrease Manufacturing Amount of Opioid Controlled Substances in 2017

Drug Enforcement Administration (DEA) is reducing the amount of almost every Schedule II opiate and opioid medication that may be manufactured in 2017 by 25% or more. Other medicines were reduced by more, such as hydrocodone, which will be 66% of last year's level, indicates the DEA news release. DEA notes that demand for these opioid medicines has declined based on sales data from IMS Health, a company that provides insurance companies with data on prescriptions written and prescription medications sold in the United States.

The aggregate production quota (APQ) established by the final order is the total amount of a controlled substance (CS) necessary to meet the estimated medical, scientific, research, industrial, and export needs for the year and for the maintenance

News to a particular state or jurisdiction can only be ascertained such state or jurisdiction.

of reserve stocks. The 2017 APQ has been reduced for oxycodone, hydrocodone, fentanyl, hydromorphone, morphine, and other such medications. Much of this reduction is attributed to the elimination of a 25% buffer that was added to the APQ annually in 2013 through 2016 to guard against shortages. The purpose of quotas is to provide an adequate and uninterrupted supply for legitimate medical need of the types of Schedule I and II CS that have a potential for abuse, while limiting the amounts available to prevent diversion.

Additional details may be found in the DEA news release available at [www.dea.gov/divisions/hq/2016/hq100416.shtml](http://www.dea.gov/divisions/hq/2016/hq100416.shtml) and in the final order available at <https://www.gpo.gov/fdsys/pkg/FR-2016-10-05/pdf/2016-23988.pdf>.

### **New CDC Brochure Offers Pharmacists Tips for Addressing Prescription Opioid Abuse and Overdose**

Centers for Disease Control and Prevention (CDC) released a brochure encouraging pharmacists, who are an essential part of the health care team, to help prevent opioid abuse and overdose. The brochure, “Pharmacists: On the Front Lines,” offers tips for communicating with patients who are receiving opioid therapy. In addition, the brochure offers tips on how to identify forged prescriptions and urges pharmacists to maintain collaborative working relationships with prescribers to improve patient outcomes. The brochure is available at [www.cdc.gov/drugoverdose/pdf/pharmacists\\_brochure-a.pdf](http://www.cdc.gov/drugoverdose/pdf/pharmacists_brochure-a.pdf).

### **FDA Requires Boxed Warnings and Patient-Focused Medication Guides Indicating Serious Risks Related to Combined Use of Certain Opioid Medications and Benzodiazepines**

FDA is requiring class-wide drug labeling changes to inform health care providers and patients of the serious risks associated with the combined use of certain opioid medications and benzodiazepines. Specifically, after an extensive review of the latest scientific evidence, FDA is requiring boxed warnings and patient-focused Medication Guides for prescription opioid analgesics, opioid-containing cough products, and benzodiazepines that provide information about the serious risks associated with using these medications at the same time. Risks include extreme sleepiness, respiratory depression, coma, and death.

FDA’s news release indicates the changes are part of the agency’s Opioids Action Plan, which focuses on policies aimed at reversing the prescription opioid abuse epidemic while providing patients in pain with access to effective and appropriate pain management. The public health crisis is evident through the significant rise of preventable overdose and death associated with the concurrent use of two drug classes, indicates FDA Commissioner Robert Califf, MD, in the press release, available at [www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm518697.htm](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm518697.htm).

### **FDA’s Division of Drug Information Offers CE Webinars for Students and Clinicians**

FDA’s Center for Drug Evaluation and Research (CDER), Office of Communications, Division of Drug Information presents a series of continuing education (CE) webinars

targeted toward students and health care providers who wish to learn more about FDA and drug regulation. The webinars are presented by FDA staff and allow participants to interact with staff. Previous webinar topics have included an overview of drug shortages and prescription drug promotion. The webinars and presentation slides can be accessed on FDA’s website at [www.fda.gov/DDIWebinars](http://www.fda.gov/DDIWebinars).

### **FDA Approves Labeling Changes for All Prescription Testosterone Products**

In October 2016, FDA approved class-wide labeling changes for all prescription testosterone products regarding the risks associated with abuse and dependence of the drug. The changes include adding a new warning as well as updating the Abuse and Dependence section to include new safety information from published literature and case reports regarding the risks associated with abuse and dependence of testosterone and other anabolic androgenic steroids (AAS). The Anabolic Steroids Control Act of 1990 placed AAS, including testosterone, in Schedule III of the Controlled Substances Act.

Prescription testosterone products are FDA-approved as hormone replacement therapy for men who have low testosterone due to certain medical conditions. However, testosterone and other AAS are abused by adults and adolescents, including athletes and body builders, notes FDA. FDA indicates the new warning will “alert prescribers to the abuse potential of testosterone and the serious adverse outcomes, especially those related to heart and mental health that have been reported in association with testosterone/AAS abuse.” In addition, new labeling information in the Warning and Precautions section advises prescribers of the importance of measuring serum testosterone concentration if abuse is suspected.

FDA explains that abuse of testosterone, usually at doses higher than those typically prescribed and usually in conjunction with other AAS, is associated with serious safety risks affecting the heart, brain, liver, mental health, and endocrine system. Reported serious adverse outcomes include heart attack, heart failure, stroke, depression, hostility, aggression, liver toxicity, and male infertility. Individuals abusing high doses of testosterone have also reported withdrawal symptoms, such as depression, fatigue, irritability, loss of appetite, decreased libido, and insomnia. The FDA announcement is available at [www.fda.gov/Drugs/DrugSafety/ucm526206.htm](http://www.fda.gov/Drugs/DrugSafety/ucm526206.htm).

### **Latest FDA Drug Info Rounds Training Videos Available**

Drug Info Rounds, a series of online videos by FDA, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. In the latest Drug Info Rounds video, “Extortion Scam,” pharmacists discuss steps a potential victim could take if they receive a call from individuals posing as FDA and DEA agents. Drug Info Rounds is developed with contributions from pharmacists in FDA’s CDER, Office of Communications, Division of Drug Information. All Drug Info Rounds videos can be viewed on the FDA website at [www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm](http://www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm).

by the dispenser. Pharmacists are encouraged to utilize the PMP report, taking the calculated MME into consideration, to determine if further consultation with the prescriber and/or patient is necessary and if the offering of naloxone for the patient or caregiver to have on hand in the event of an overdose is appropriate. CDC has published a brochure to assist pharmacists in addressing opioid abuse and overdose, which may be accessed at [https://www.cdc.gov/drugoverdose/pdf/pharmacists\\_brochure-a.pdf](https://www.cdc.gov/drugoverdose/pdf/pharmacists_brochure-a.pdf). Additional information from CDC on calculating the total daily dose of opioids may be viewed at <https://stacks.cdc.gov/view/cdc/38481>, and information regarding the guideline for prescribing opioids for chronic pain may be accessed at <https://www.cdc.gov/drugoverdose/prescribing/guideline.html>.

### Identifying Suspected Prescriber/Pharmacy Shoppers

In addition to providing the MME to patients and dispensers, the PMP will begin sending unsolicited reports to prescribers regarding any patients identified with more than nine prescriptions in Schedules II-IV from three prescribers and three pharmacies within a 60-day period. The criteria used to identify these patients was recommended by a special PMP Advisory Committee consisting of representatives from the Board of Pharmacy and Virginia Board of Medicine. A pop-up window will also appear when prescribers or dispensers view the PMP report online for these individuals that identifies these patients as a “suspected prescriber/pharmacy shopper.” Pharmacists are encouraged to consider this information and consult with the prescriber and/or patient as necessary. Mitigating circumstances may exist to justify the circumstances; however, pharmacists should exercise professional judgment in determining the validity and appropriateness of the prescription. Documenting actions taken by the pharmacist and any mitigating circumstances is strongly recommended.

### PMP Reporting Reminder

In accordance with §54.1-2521(C), as of January 1, 2017, a pharmacy must report to the PMP “**within 24 hours or the dispenser’s next business day, whichever comes later.**” This change was mandated by the law that passed in March 2016, but had a delayed effective date of January 1, 2017. Additionally, please note that only the patient’s actual first name and actual last name should be placed in those fields. Adding other information in these fields may prevent the patient from being found and the patient’s prescriptions from appearing on the PMP report.

### Grant to Integrate PMP With EHRs

Governor Terry McAuliffe announced on January 26, 2017, that the PMP has been awarded a grant to help integrate use of its data in doctors’ and pharmacists’ regular workflow. The \$3.1 million grant from Purdue Pharma L.P. will allow the Virginia Department of Health Professions to connect the state PMP with EHRs used by Virginia doctors and pharmacies. Integrating the PMP with EHRs – through “NarxCare” technology developed by Kentucky-

based Appriss, Inc – will make the step of checking the PMP easier for prescribers and pharmacists by integrating the PMP query into the existing workflow. The goal is to improve the performance, access, and usability of the PMP data for 18,000 prescribers and 400 pharmacies in the Commonwealth of Virginia by the end of 2017. This is an additional step in Virginia’s fight against the epidemic of opioid addiction and overdose. More information can be found at <https://governor.virginia.gov/newsroom/newsarticle?articleId=19145#sthash.B6PtUPWg.dpuf>.

### USP Chapter <800>

United States Pharmacopeia (USP) Chapter <800> Hazardous Drugs—Handling in Healthcare Settings was created to protect all workers, patients, and the general public who may be accessing facilities where hazardous drugs are prepared. The chapter describes the practice and quality standards for handling hazardous drugs in health care settings and defines the processes necessary for minimizing the exposure to hazardous drugs. Initially, the chapter was published for public comment in March 2014. Many revisions were made after review of comments, and the chapter was republished in December 2014 for further public comment. The final version was published on February 1, 2016, and an erratum was published on May 26, 2016. Chapter <800> has a delayed implementation date of July 1, 2018, to allow facilities sufficient time to implement new standards to comply with the chapter. At the December 2016 full Board meeting, implementation in enforcement of this chapter was thoroughly discussed. A request to delay enforcement of the chapter was denied; however, the Board agreed to form a workgroup to develop guidance for its licensees to assist in understanding how to comply with Chapter <800>. Additionally, the Board determined that inspectors should begin inspecting for compliance in 2017 in an effort to assist pharmacists in identifying areas that do not comply with the new standards. No sanctions will be imposed prior to the effective date of the chapter, July 1, 2018. Pharmacists are strongly encouraged to review USP Chapter <800> and begin implementing any necessary changes. The Board is aware of training opportunities through USP, which may be accessed by visiting the “Find Training” section at [https://uspharmacopeia.csod.com/LMS/catalog/Welcome.aspx?tab\\_page\\_id=-67&tab\\_id=20000495](https://uspharmacopeia.csod.com/LMS/catalog/Welcome.aspx?tab_page_id=-67&tab_id=20000495).

### Naloxone Protocol Recently Amended

During the December 2016 full Board meeting, the Board reviewed two amendments to the naloxone prescribing and dispensing protocol. These amendments arose from the declaration by the Virginia health commissioner of a public health emergency as a result of the opioid abuse crisis.

The first amendment to the protocol accepted by the Board was to include the statewide standing order as an acceptable authorization for the dispensing of naloxone. In order to hasten the delivery of life-saving naloxone to patients, family members, and caregivers, Health Commissioner

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Marissa Levine issued a statewide standing order authorizing pharmacists to dispense the specified naloxone formulations to any person seeking to obtain naloxone.

The second amendment to the protocol was to address the delivery of dispensed naloxone to an alternate delivery site, such as a local health department, wherein a pharmacist may not be on site to counsel the patient as required by the protocol. The amendment allows the counseling to be provided by a physician, nurse practitioner, physician assistant, or nurse or by an approved trainer of the REVIVE! training program at the alternate delivery site. Patients may not waive the counseling unless the person authorized to provide the counseling is able to verify the patient's successful completion of the REVIVE! training program. Viewing the patient's certificate of completion issued by the REVIVE! training program is an acceptable method for verifying completion of the program.

To access the Board-approved protocol, visit <http://www.dhp.virginia.gov/pharmacy/guidelines/110-44.docx>.

## **Guidance Documents Recently Amended**

A guidance document is defined as “. . . any document developed by a state agency or staff that provides information or guidance of general applicability to the staff or public to interpret or implement statutes or the agency's rules or regulations . . .” There are approximately 40 guidance documents currently approved by the Board. The Board amended two guidance documents at the December 2016 full Board meeting: Guidance Documents 110-38 and 110-1.

### **Guidance Document 110-38: Requirement for Non-resident Pharmacies to Submit Current Inspection Report**

Pursuant to §54.1-3434.1 of the Code of Virginia, as a prerequisite to obtaining an initial nonresident pharmacy registration or renewing such registration, the nonresident pharmacy must submit a copy of a current inspection report resulting from an inspection conducted by the regulatory or licensing agency of the jurisdiction in which it is located that indicates compliance with Virginia law, including USP and the National Formulary (USP-NF) standards for performing compounding. Because an “opening” inspection of a new

pharmacy is generally performed prior to the pharmacy beginning operations, the inspection does not indicate if the pharmacy performs compounding in compliance with USP-NF standards. Thus, the Board voted to amend the guidance document in the following manner: an “opening” inspection report for a newly opened pharmacy or a new location for an existing pharmacy indicating compliance with the requirements of statute, including compliance with USP-NF standards for pharmacies **performing nonsterile compounding**, may satisfy the requirements for obtaining initial registration as a nonresident pharmacy. However, an “operational” inspection report shall be provided during the subsequent renewal of the registration. An “opening” inspection report for a newly opened pharmacy or a new location for an existing pharmacy **performing sterile compounding** shall not satisfy the requirements for obtaining initial registration or renewal as a nonresident pharmacy. Submission of an “operational” inspection report indicating compliance with USP-NF standards for sterile compounding shall be required for consideration for obtaining initial registration or renewal as a nonresident pharmacy.

### **Guidance Document 110-1: Categories of Facility Licensure**

Guidance Document 110-1 lists the categories of facility licenses issued by the Board and provides a description of each license. The document was recently amended to include the new categories of an outsourcing facility, nonresident outsourcing facility, nonresident medical equipment supplier, and practitioner of the healing arts to sell controlled substances facility.

All guidance documents may be accessed at [http://www.dhp.virginia.gov/pharmacy/pharmacy\\_guidelines.htm](http://www.dhp.virginia.gov/pharmacy/pharmacy_guidelines.htm).