



Virginia Board of Pharmacy

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Emergency Board of Medicine Regulations on Prescribing of Opioids

Emergency regulations promulgated by the Virginia Board of Medicine, addressing under what conditions physicians may prescribe opioids for acute and chronic pain and the prescribing of buprenorphine for the treatment of addiction, became effective March 15, 2017. Please note that a regulatory advisory panel of the Board of Medicine met again on May 15, 2017, to consider if amendments to the emergency regulations are necessary. The Board of Medicine will consider any such possible amendments at its Board meeting in June 2017.

Virginia Board of Pharmacy staff have received numerous inquiries from pharmacists regarding these regulations. Please note that the Board of Medicine's regulations do not place additional requirements on pharmacists. Pharmacists should continue to evaluate the validity of prescriptions by ensuring that the prescription was issued for a legitimate medical purpose. Further, while a pharmacist may refuse to dispense any prescription, a pharmacist may not require a patient to obtain naloxone when co-prescribed by the physician or recommended by the pharmacist under a standing order.

A summary of the current emergency regulations, as approved on March 15, 2017, is provided below.

Acute Pain

- ◆ Treatment with opioids for acute pain must be with short-acting opioids and for a seven-day supply or less (unless extenuating circumstances are clearly documented in the medical record).
- ◆ Treatment with opioids as part of treatment for a surgical procedure must be for a 14-day supply or less (unless extenuating circumstances are clearly documented in the medical record).
- ◆ An appropriate history and examination must be performed, including a check of the prescription monitoring program (PMP), in accordance with state law.

- ◆ Naloxone must be co-prescribed under certain conditions.

Chronic Pain

- ◆ An appropriate history and examination must be performed, as detailed in the regulations.
- ◆ The physician must discuss risks, benefits, proper storage, and disposal with the patient.
- ◆ Naloxone must be co-prescribed under certain conditions.
- ◆ Urine drug screen or serum medication levels shall be conducted at the initiation of chronic pain management and at least every three months for the first year of treatment and at least every six months thereafter.

Buprenorphine for Addiction

- ◆ Physicians engaged in office-based opioid addiction treatment with buprenorphine shall have obtained a Substance Abuse and Mental Health Services Administration waiver and the appropriate Drug Enforcement Administration (DEA) registration.
- ◆ Buprenorphine without naloxone, ie, the mono-product, shall only be prescribed when a patient is pregnant or when converting a patient from methadone (for a period not to exceed seven days).

Fatal Drug Overdose Data and Naloxone Dispensing

Preliminary data for 2016 from the Virginia Department of Health, Office of the Chief Medical Examiner reveals, "The total number of fatal drug overdoses statewide have been increasing each year. In 2013, fatal drug overdose became the number one method of unnatural death in the Commonwealth, surpassing both motor vehicle-related fatalities and gun-related fatalities. In 2014, fatal drug overdose became the leading cause of accidental death in Virginia. The number of all fatal overdoses in 2016 compared to 2015 increased by 38.1%." As of April 2017, data collection indicates there were 1,420 fatal drug overdoses in Virginia in 2016.

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DEA Changes Registration Renewal Process

As of January 2017, Drug Enforcement Administration (DEA) will no longer send its second renewal notification by mail. Instead, an electronic reminder to renew will be sent to the email address associated with the DEA registration.

In addition, DEA will retain its current policy and procedures with respect to renewal and reinstatement of registration. The policy is described below.

- ◆ If a renewal application is submitted in a timely manner prior to expiration, the registrant may continue operations, authorized by the registration, beyond the expiration date until final action is taken on the application.
- ◆ DEA allows the reinstatement of an expired registration for one calendar month after the expiration date. If the registration is not renewed within that calendar month, an application for a new DEA registration will be required.
- ◆ Regardless of whether a registration is reinstated within the calendar month after expiration, federal law prohibits the handling of controlled substances or List 1 chemicals for any period of time under an expired registration.

Additional information is available on the DEA website at www.deadiversion.usdoj.gov/drugreg/index.html.

ISMP Medication Safety Self Assessment for Community/Ambulatory Pharmacy

 *This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition by visiting www.ismp.org. ISMP provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Errors Reporting Program Report online at www.ismp.org. Email: ismpinfo@ismp.org.*

Pharmacists in community and ambulatory settings can now access a newly revised tool that will help them review and improve their medication safety practices. The 2017 Institute for Safe Medication Practices (ISMP) Medication Safety Self Assessment® for Community/Ambulatory Pharmacy is designed to help pharmacies evaluate their current systems, proactively identify opportunities for improvement, and track their efforts over time.

An advisory panel of experts helped ISMP update items from the 2001 community/ambulatory self-assessment as well as add items to address new practices and processes, including the pharmacist's evolving role in immunization administration. New research findings about error prevention and emerging technologies previously not widely adopted are also covered.

The self-assessment contains items that address the use of medications in the clinical setting, many of which are on the

ISMP list of high-alert medications. Many of the items included represent system improvements and safeguards that ISMP has recommended in response to analysis of medication errors reported to the ISMP Medication Errors Reporting Program, problems identified during on-site consultations with health care organizations, and guidelines in medical literature.

The self-assessment is divided into 10 key elements that most significantly influence safe medication use. Each element is defined by one or more core characteristics of a safe pharmacy system that further define a safe medication use system. Each core characteristic contains individual self-assessment items to help evaluate success with achieving each core characteristic.

ISMP recommends that each pharmacy site convene its own team of staff members (ie, pharmacist(s), technician(s), and student pharmacist(s)) to complete this comprehensive assessment and use the information as part of its ongoing safety and quality improvement efforts. An online form has been provided to help participants organize and score their responses. **Important:** The self-assessment should be completed in its entirety by staff and managers who work within the pharmacy, not by off-site managers on behalf of the pharmacy.

When the self-assessment is completed, respondents can generate reports showing how their pharmacy answered each item and how they scored on each as a percentage of the maximum possible score. The pharmacy can then use its scores to identify and prioritize opportunities for its safety plan of action.

ISMP is not a regulatory or standards-setting organization. As such, the self-assessment characteristics represent ideal practices and are not purported to represent a minimum standard of practice. Some of the self-assessment criteria represent innovative practices and system enhancements that are not widely available in pharmacies today. However, the value of these practices in reducing errors is grounded in expert analysis of medication errors, scientific research, or strong evidence of their ability to reduce errors.

To view, download, and print the PDF of the assessment, which includes the introduction, instructions for use, self-assessment items, and definitions, visit <https://www.ismp.org/Survey/NewMssacap/Index.asp>.

CDC Publishes Resource to Foster Use of JCPP Pharmacists' Patient Care Process

A publication intended to encourage the use of the Joint Commission of Pharmacy Practitioners (JCPP) Pharmacists' Patient Care Process was released by the Centers for Disease Control and Prevention's (CDC's) Division for Heart Disease and Stroke Prevention. In *Using the Pharmacists' Patient Care Process to Manage High Blood Pressure: A Resource Guide for Pharmacists*, CDC calls on pharmacists and other health care providers to implement the Pharmacists' Patient Care Process model to reduce heart disease and stroke in the United States. Pharmacists can have a positive effect on population health by providing patient care services and participating in collaborative practice agreements and continuing education (CE) programs, notes the CDC publication. The publication is available at www.cdc.gov/dhbsp/pubs/docs/pharmacist-resource-guide.pdf.

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

The National Association of Boards of Pharmacy® (NABP®) is a member of JCPP and endorses the Pharmacists' Patient Care Process. In its September 2015 newsletter (page 167), NABP discusses integrating the JCPP Pharmacists' Patient Care Process to improve medication outcomes and promote consistency in patient care service delivery. Additional information about JCPP is available at <https://jcphp.net>.

FDA Issues Final Guidance on Repackaging Drugs by Pharmacies and Registered Outsourcing Facilities

In January 2017, Food and Drug Administration (FDA) issued a final guidance for industry titled, "Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities." This guidance describes the conditions under which FDA does not intend to take action for violations of certain provisions of the Federal Food, Drug, and Cosmetic Act when a state-licensed pharmacy, a federal facility, or an outsourcing facility repackages certain human drug products. The guidance is available at www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM434174.pdf.

Electronic or written comments may be submitted at any time for this final guidance following the instructions provided in the *Federal Register*, which can be found at www.federalregister.gov/documents/2017/01/13/2017-00723/repackaging-of-certain-human-drug-products-by-pharmacies-and-outsourcing-facilities-final-guidance.

CriticalPoint Launches QP503A Certification Program for Sterile Compounding in 2017

In 2017, CriticalPoint, LLC, launched its QP503A certification program for sterile compounding personnel. Specifically, CriticalPoint is offering the QP503A Certification and the QP503A Master Certification, which may be earned after obtaining the basic QP503A Certification. Participants will gain vital knowledge and skills to successfully plan, develop, and operate a 503A pharmacy sterile compounding operation.

The QP503A Certification involves a didactic program of home study, live training, and practicum activities accompanied by required objective personnel and cognitive testing. The QP503A Master Certification requires participants to demonstrate their ability to apply their QP503A Certification training in actual work settings and produce measurable changes in sterile compounding processes resulting in improved patient safety.

Additional details about these programs and the certification requirements are available online at www.criticalpoint.info/wp-content/uploads/CriticalPoint-QP503A-Certification.pdf.

PTCB Suspends Implementation of Planned 2020 Accredited Education Requirement for Pharmacy Technicians

The Pharmacy Technician Certification Board (PTCB) is suspending the implementation of the accredited education requirement for pharmacy technicians. In 2013, PTCB announced that the requirement would take effect in 2020, but PTCB has "determined that additional deliberation and research are needed

to address stakeholder input, develop supporting policy, and conduct further study of technician roles," said Larry Wagenknecht, BPharm, chair of the PTCB Board of Governors, and chief executive officer of the Michigan Pharmacists Association, in a news release. The role of pharmacy technicians is evolving, and PTCB is taking steps to support the pharmacy community.

PTCB recently completed a job analysis study to collect data on current roles and responsibilities of pharmacy technicians across all practice settings to update PTCB's Pharmacy Technician Certification Exam and is in the process of developing advanced certification programs. In addition, PTCB hosted an invitational conference in February 2017 where pharmacy leaders and stakeholders examined entry-level standards and provided information to help determine future plans for implementing PTCB program changes.

PTCB's news release is available at www.ptcb.org in the News Room section.

ASOP Global Spreads Awareness About Illegal Online Drug Sellers and Counterfeit Medications

Alliance for Safe Online Pharmacies (ASOP Global) partnered with several nonprofit organizations, including NABP, to launch a campaign to raise awareness of illegal online drug sellers and counterfeit medications. The campaign encourages dialogue among health care providers and patients regarding where patients purchase their medications, especially if patients are buying them online.

After offering the CE course "Internet Drug Sellers: What Providers Need to Know" to over 1,000 health care providers, ASOP Global found that less than 10% of providers reported they were "very aware" counterfeit prescription drugs are being sold on the internet and only 1.4% said they regularly discuss the risks of illegal internet drug sellers with patients. ASOP Global Executive Director Libby Baney said, "After completing the course, however, there was a ten-fold increase in the expected frequency in which providers planned to discuss the risks associated with buying prescription medicines online with their patients and what they can do to avoid physical and financial harm."

For more information about the campaign, visit www.BuySafeRx.pharmacy.

New Interactive Map Tracks Pharmacist Vaccination Laws

A new resource – an interactive 50-state map tracking pharmacist vaccination laws between 1990 and 2016 – was published by The Policy Surveillance Program, A LawAtlas Project. The map, which is available at <http://lawatlas.org/datasets/pharmacist-vaccination>, explores laws that give pharmacists authority to administer vaccines and establish requirements for third-party vaccination authorization, patient age restrictions, and specific vaccination practice requirements, such as training, reporting, record keeping, notification, malpractice insurance, and emergency exceptions. The Policy Surveillance Program is administered by Temple University Beasley School of Law.

To address this public health emergency, as declared by Virginia Health Commissioner Marissa Levine in 2016, efforts continue to increase access to naloxone. Most recently, the 2017 General Assembly passed House Bill (HB) 1642 (<http://leg1.state.va.us/cgi-bin/legp504.exe?ses=171&typ=bil&val=hb1642>), which authorizes employees of the Department of Forensic Science, Office of the Chief Medical Examiner, and Department of General Services Division of Consolidated Laboratory Services to possess and administer naloxone in accordance with the Board of Pharmacy protocol. This will assist the safety of employees handling evidence associated with overdose victims. As a result of this legislation, the Board recently amended Guidance Document 110-44, Protocol for the Prescribing of Naloxone and Dispensing by Pharmacists and Distribution to Authorized Entities, to acknowledge these additional entities that may be distributed naloxone.

Additionally, the General Assembly passed HB 1453/Senate Bill 848 (<http://leg1.state.va.us/cgi-bin/legp504.exe?ses=171&typ=bil&val=sb848>), which continues the expansion of access to naloxone by allowing approved trainers of the REVIVE! training program to dispense naloxone at the conclusion of a training program offered throughout the community. The Board adopted a separate naloxone protocol for this provision, which is located in Guidance Document 110-45, available at www.dhp.virginia.gov/pharmacy/pharmacy_guidelines.htm.

Lastly, the Board encourages all pharmacists, pharmacy technicians, and pharmacy interns to ensure all pharmacy staff interfacing with patients are familiar with a patient's ability to request naloxone from a pharmacist under the statewide standing order. Staff are aware of some situations in which members of the public requested naloxone at pharmacies, but the pharmacy employee communicating with the patients was unaware of the allowance and the patients were unable to obtain the naloxone. For more information regarding the naloxone protocols and other related information, visit www.dhp.virginia.gov/pharmacy.

Discontinuation of the Virginia Pharmacy Technician Examination

On March 21, 2017, the Board elected to discontinue the administration of the Virginia Pharmacy Technician Examination as of September 1, 2017. Prior to September 1, 2017, students who have successfully completed a Board-approved pharmacy technician training program may choose to take either the Pharmacy Technician Certification Examination (PTCE), the Examination for the Certification of Pharmacy Technicians (ExCPT), or the Virginia Pharmacy Technician Examination. Beginning September 1, 2017, students who have successfully completed a Board-approved pharmacy technician training program must choose to take either the PTCE or ExCPT examination prior to submitting an application to the Board for pharmacy technician registration. Information regarding the PTCE examination may be

accessed on the Pharmacy Technician Certification Board website at www.ptcb.org. Information on the ExCPT examination may be found on the National Healthcareer Association website at www.nhanow.com. Information regarding the current registration process may also be accessed on the Board's website, under the Frequently Asked Questions section related to Pharmacy Technician Registration, available at www.dhp.virginia.gov/pharmacy/pharmacy_faq.htm.

PMP Reporting Guidelines for Gabapentin

As a result of legislation passed by the 2017 General Assembly (HB 2164) and signed into law by Governor Terry McAuliffe, the dispensing of gabapentin is now required to be reported to the Virginia PMP. An enactment clause within the legislation declares that an emergency exists; thus, the law became effective upon the signing of the legislation on February 23, 2017. Therefore, reporting of the dispensing of gabapentin is required to begin immediately.

Generally, dispensing records submitted to the PMP must contain the DEA registration of the dispenser (pharmacy or physician licensed to dispense) and the prescriber. Because gabapentin is a Schedule VI drug, prescribers and dispensers are not required to maintain a DEA registration. In these situations, the dispensing data submitted to the PMP should contain the National Provider Identifier (NPI) issued by the Centers for Medicare & Medicaid Services (CMS) to the dispenser and/or prescriber. Please note that for veterinarians who prescribe gabapentin but do not maintain a DEA registration or NPI, dispensers should insert "1234567893" in the NPI field and "02" in the species code field.

Below is a summary of guidelines that should be followed to allow dispensing data for gabapentin prescriptions to be accurately reported to the PMP:

Scenario 1 – Pharmacy does not dispense drugs in Schedules II-V, eg, free clinic, but does dispense "drugs of concern" such as gabapentin. Pharmacy does not have a DEA registration, but has obtained an NPI to allow the pharmacy to submit data to the PMP.

Guideline 1 – Leave the pharmacy DEA registration field blank in the controlled substance (CS) report. Insert the pharmacy NPI number in the appropriate field of the CS report. Reference the PMP dispenser guide for additional details.

Scenario 2 – Prescriber does not prescribe drugs in Schedules II-V, but does prescribe "drugs of concern" such as gabapentin. Prescriber does not have a DEA registration, but does have an NPI.

Guideline 2 – Leave the prescriber DEA registration field blank in the CS report. Insert the prescriber NPI in the appropriate field of the CS report. Reference the PMP dispenser guide for additional details.

Scenario 3 – Prescriber is a veterinarian who does not prescribe drugs in Schedules II-V, but does prescribe “drugs of concern” such as gabapentin. Because CMS will not issue an NPI to a veterinarian, the prescriber does not have an NPI.

Guideline 3 – Leave the prescriber DEA registration field blank in the CS report. Insert “1234567893” in the prescriber NPI field and “02” in the species code field.

Healthcare Workforce Data Center – Survey and Workforce Trends

The Healthcare Workforce Data Center (HWDC) is part of the Virginia Department of Health Professions (DHP), and its role is to collect and measure data of Virginia’s health care workforce through regular assessments of over 60 professions and 350,000 practitioners licensed by the DHP. Most licensees are familiar with the HWDC through the survey that they are requested to complete upon renewal of a license or registration. These surveys are important because they provide a statewide look at the health care workforce in the pharmacy profession, as well as more detailed data regarding the trends in factors, including education, demographics, finances, current employment, and job turnover. The HWDC recently published the results of the 2016 survey for pharmacists and pharmacy technicians, which is available at www.dhp.virginia.gov/hwdc/findings.htm#Pharm.

The HWDC also provides the Virginia CareForce Snapshot, which is a compilation of the CareForce indicators for all professions statewide in a given HWDC survey year. It is accessible at <http://vahwdc.tumblr.com/VACareForceSnapshot>. The CareForce Snapshot, updated annually in spring, provides an interactive

guide to compare CareForce Indicators across professions. It is a quick and easy summary of the survey report published by the HWDC each year and includes all professions, but may also be limited to professions the viewer chooses to include on the report. There is also a Region CareForce version with geographic breakouts by Area Health Education Center regions for a more local perspective (<http://vahwdc.tumblr.com/RegionalCareforce>).

This year, the HWDC also developed the new Healthcare Occupational Roadmap, which will be used in high schools to encourage students to join health professions such as pharmacy technician, respiratory therapist, and dental hygienist. The Roadmap offers students an overview of professions that may not necessarily require a four-year college degree, along with the educational requirements for such professions. The Roadmap also offers information such as average salaries, growth potential, and future employment outlook. It is available at www.dhp.virginia.gov/Roadmap/OccupationalRoadmap.pdf.

For more information on the HWDC, the reports, or briefs available for viewing, please visit the HWDC website at www.dhp.virginia.gov/hwdc.

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