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News

Massachusetts Board of Registration in Pharmacy

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Acute Use Medications for Inpatient Hospice Facilities

In March 2020, a circular letter was jointly issued from the Massachusetts Board of Registration in Pharmacy and the Bureau of Health Care Safety and Quality outlining a process through which an inpatient hospice facility's pharmacy provider may store certain non-patient-specific medications at the facility. With this change, hospice inpatient facilities (as defined in 105 Code of Massachusetts Regulations 141.000) will now have the ability to treat patient symptoms that are not life-threatening, but require medication management in a timely manner to provide prompt palliative care. A list of medications that may be stored, as well as details on the requirement to store them in an automated dispensing device (ADD), is also included in the circular letter.

The pharmacy must reconcile all medications dispensed through the ADD with prescriptions in the same manner as emergency medication kits used by long-term care facilities. The contents of the ADD, until dispensed for administration pursuant to a prescriber's prescription or order, remain the property of the pharmacy.

Each unit of medication supplied by the pharmacy provider must be tamper evident/resistant, in an individually packaged, single dose form. Supplies accessed from the ADD should only be enough to treat the patient until the pharmacy can fill and deliver the full prescription.

Pharmacies must obtain a machine-specific controlled substance registration (CSR) from the Board for each ADD used to store and secure these acute use medications, and must also determine whether a machine-specific Drug Enforcement Administration (DEA) number is required. Other requirements for ADD use and security are found in policy 2019-02: Automated Dispensing Device Use.

Automated Dispensing Devices in Licensed Health Care Facilities

An ADD is defined as a mechanical system designed for use in health care facilities allowing for computer-controlled storage and dispensing of drugs and devices to licensed health care professionals near the point of care. These systems are also known as automated dispensing machines and automated dispensing cabinets.

The use of an ADD in a Massachusetts-licensed health care facility is permitted only if the facility's licensure allows it to store and dispense medications. For instance, if there is not an on-site pharmacy, prior approval for use and placement of the ADD must be obtained from the agency that licenses that facility.

Medications must be provided in unit-of-use packaging for a single dose or a specific person and remain the property of the pharmacy until dispensed pursuant to a patient-specific prescription or order. Any losses must be reported to the pharmacy's licensing body (ie, Board of Pharmacy or Drug Control Program).

If the ADD is to be used for routine medication dispensing, the pharmacy must obtain a machine-specific DEA number (if applicable) and CSR prior to use and installation. ADDs for routine medication dispensing may only be loaded by a certified pharmacy technician or pharmacy intern while being supervised by a Massachusetts-licensed pharmacist. If the ADD is only to be used for emergency medication kits or hospice kits, it may be loaded by a certified pharmacy technician, pharmacy intern, pharmacist, or licensed nurse. See the Board policy 2019-02: Automated Dispensing Device Use for more details.

Insurance Quantity Restrictions

There have been several reports lately of patients not receiving the full quantity of medications indicated on their prescriptions because of insurance restrictions. For example, insurance coverage for a medication may limit the monthly number of tablets to 30. If the prescription is for 20 mg tablets, and the patient takes two tablets daily, this may create an access issue for the patient in 15 days. To avoid this, pharmacists should call the provider to change to 40 mg tablets, discuss a prior authorization, or explore other options.

Shared Pharmacy Services

With the recent approval of policy 2019-01: Shared Pharmacy Service Models including Central Fill, Central and Remote Processing, and Telepharmacy, pharmacies and

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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 Releases MOU on Human Drug Compounding Regulation and Oversight

Acknowledging the vital role states play in reducing the risks associated with compounded drugs, Food and Drug Administration (FDA) has made available a Final Standard Memorandum of Understanding (MOU) Addressing Certain Distributions of Compounded Human Drug Products, intended to be entered into between the agency and the states. The release of the MOU is required as part of its submission to the Office of Management and Budget for review and clearance under the Paperwork Reduction Act of 1995. The MOU was developed in close consultation with the National Association of Boards of Pharmacy® (NABP®), as described in the Federal Food, Drug, and Cosmetic Act. The agency also engaged with states, pharmacies, associations, pharmacists, and other stakeholders.

Among the issues addressed in the MOU is the definition of the statutory term "inordinate amounts," which refers to compounded drugs that are distributed interstate. In addition, the MOU includes the risk-based oversight model from the 2018 revised draft MOU. States that sign the document agree to identify pharmacy compounders that distribute inordinate amounts (greater than 50%) of compounded drug products interstate, as well as report certain information to FDA about those compounders. FDA also provided clarity in the MOU on state investigations of complaints associated with compounded drugs distributed out of state. States that enter into the MOU will investigate complaints about drugs compounded at a pharmacy within their state and distributed outside of the state and advise FDA when they receive reports of serious adverse drug experiences or serious product quality issues, like drug contamination.

To help states to better investigate these issues, FDA has also announced an agreement with NABP to make an information sharing network available to the states. Through this network, states will be able to obtain information from pharmacies in their states and transmit that information to FDA.

"We anticipate the final MOU, once signed, will help to facilitate increased collaboration between the FDA and the states that sign it," said Janet Woodcock, MD, Director, Center for Drug Evaluation and Research, in an FDA Voices article. "Working together, we can help promote quality compounding practices and better address emerging public health concerns that may affect patients."

FDA Clarifies Compounding Rules, Offers Flexibility to Help Ease Drug Shortages During COVID-19 Pandemic

FDA noted it will use discretion in enforcing certain standards related to 503A and 503B compounding in an effort to ease drug shortages during the coronavirus disease 2019 (COVID-19) pandemic. During an American Pharmacists Association (APhA) webinar on April 30, 2020, the agency clarified it will "look to 503B compounders to grapple with drug shortages" and "turn to 503A compounders to fill in the gaps."

In addition, the agency clarified that medications on the FDA drug shortage list are effectively considered "not commercially available," which frees 503A and 503B compounding facilities from limits on compounding drugs that are "essentially a copy" of a product already available on the market. FDA also does not intend to take action if a 503A facility fills orders for a compounded drug that is essentially a copy of an approved drug that has been discontinued and is no longer marketed.

In April 2020, FDA issued a temporary guidance that granted flexibility for pharmacists to compound certain necessary medications under 503A for nonspecific patients hospitalized due to COVID-19. In addition, a temporary guidance was issued that granted enforcement flexibility for 503B outsourcing compounding facilities for drugs in shortage for patients hospitalized during the COVID-19 public health emergency. The guidance documents stipulate the conditions compounders must meet and are available at *https://www.fda.gov/media/137125/download.*

More information on these compounding rule clarifications is available in a May 5, 2020 press release on the APhA website.

CMS Allows Pharmacies to Temporarily Enroll as Clinical Diagnostic Laboratories for COVID-19 Testing

Centers for Medicare & Medicaid Services (CMS) has released a document detailing a process that allows pharmacies to temporarily enroll as independent clinical diagnostic laboratories. This process will allow those

facilities to seek Medicare reimbursement for COVID-19 tests, making it easier for them to provide that service during the pandemic.

"Up until this point in time, most pharmacies could only offer this as a cash service because they were not considered providers through CMS, and really a lot of the third-party payers really didn't have an interest in a fee-for-service type model," said Michael E. Klepser, PharmD, FCCP, pharmacy professor at Ferris State University, in an interview with *Bloomberg Law.* "The fact that CMS is saying we're now authorizing or allowing pharmacists to get reimbursed for these is a great door opening at the federal level and that's a huge, huge thing."

Chain pharmacies such as CVS, Walgreens, and Rite Aid are offering drive-through testing at many pharmacies throughout the country.

FDA Issues Updated Guidance for Compounding Pharmacies Experiencing PPE Shortages

FDA has issued an update for its guidance to pharmacy compounders that may experience shortages of personal protective equipment (PPE) during the COVID-19 pandemic. As compounders typically utilize PPE when performing sterile compounding, the updated guidance clarifies that the drugs can be compounded under the policy in a segregated compounding area that is not in a cleanroom. This policy has been adopted to ensure patients continue to have access to medicines they need during the pandemic, and to reduce the risks of compounding when standard PPE is not available.

In addition to FDA guidance, United States Pharmacopeial Convention has previously issued an informational document for compounders regarding garb and PPE shortages during the pandemic. The document includes recommendations for conserving garb and PPE and what steps might be considered in the case of shortages of garb and PPE used for both sterile and nonsterile compounding.

The updated guidance can be accessed through FDA's website by visiting *www.fda.gov/media/136841/download.*

HHS Expands Telehealth Access in Response to COVID-19

In an effort to prevent and respond to the COVID-19 pandemic, the US Department of Health and Human Services (HHS) has awarded $20 million to increase telehealth access and infrastructure for health care providers and families. The funds, which are awarded through the Health Resources and Services Administration (HRSA), will increase capability; capacity and access to telehealth and distant care services for providers, pregnant women, children, adolescents, and families; and assist telehealth providers with cross-state licensure.

"This new funding will help expand telehealth infrastructure that is already being used during the pandemic to provide essential care, especially to the most vulnerable, including pregnant women and children with special health care needs," said HHS Secretary Alex Azar in a press release. "This funding will also help clinicians use telehealth nationally by streamlining the process to obtain multi-state licensure."

HRSA's Maternal and Child Health Bureau awarded a total of $15 million to four recipients; each award supports a key area in maternal and child health, including pediatric care, maternal health care, state public health systems, and family engagement for children with special health care needs. HRSA's Federal Office of Rural Health Policy awarded a total of $5 million to two recipients through the Licensure Portability Grant Program, which will assist telehealth clinicians nationally on licensure and credentialing to meet emerging needs related to COVID-19.

Criminals Found Posing as CDC Representatives to Steal Money and Information

Centers for Disease Control and Prevention (CDC) is warning the general public of a new type of phone and phishing scam by criminals posing as CDC representatives, often requesting donations. According to CDC, most of these fraudulent activities are being conducted by phone, utilizing software to "spoof" phone calls to make them appear as if they are coming from phone numbers that may look familiar. CDC advises consumers to avoid answering calls from numbers they do not recognize, and to avoid sharing personal information over the phone. In addition, CDC notes that no federal agency will request donations from the general public. Suspicious phone calls may be reported to the Federal Communications Commission.

More information on the scams is available on the CDC website at *https://www.cdc.gov/media/phishing.html.*

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pharmacists can now take advantage of "sharing" services with other pharmacies and providing remote cognitive services.

Massachusetts-licensed pharmacists located anywhere in the country can verify prescriptions, conduct patient counseling, drug utilization review, and drug therapy monitoring utilizing telepharmacy technologies for any Massachusetts patient.

Please note that in Massachusetts, the scope of telepharmacy is limited to remote pharmacist clinical activities and verification of final patient-specific products. The practice of having a pharmacy technician fill and dispense a prescription without a pharmacist on site is **not currently permitted.** Please review the policy for more details.

Pharmacy Staffing and Personnel Reminders

As a reminder, the maximum ratio of pharmacist to support personnel is one to four only if:

a. at least one of the four is a certified pharmacy technician and one is a pharmacy intern;
b. at least two are certified pharmacy technicians; or
c. two are pharmacy interns.

Sales clerks, messengers, delivery personnel, secretaries, and any other persons who do not directly support the pharmacist in a professional capacity do not have to be counted in the ratio. Such personnel should be designated accordingly on posted work schedules.

Interns on rotations may be directly supervised in a four to one ratio by a licensed pharmacist **only if they are not** processing, verifying, and/or dispensing prescriptions or medication orders.

Please review the regulations and staffing advisory for more details on ratios and support personnel.

CE Requirements

It is a renewal year, so the Board would like to provide some helpful information regarding continuing education (CE) credits. Except for the year of graduation from pharmacy school, you are required to obtain at least 20 contact hours of CE credit each **calendar year.** Of those credits, there are specific requirements for live, law, immunization, and compounding.

The Accreditation Council for Pharmacy Education (ACPE) Universal Activity Number can help you figure out if a program "counts" for law, live, pharmacist, or technician CE credit, as well as provide other information. For instance, topic designator "03" would be counted for law credits. This ACPE link explains the designations in detail.

Be aware that the ACPE compounding topic designator "07" may not be specific enough to count for compounding credits in Massachusetts and should not be used as the **sole indicator** of acceptability. As long as the program title and learning objectives are specific to either sterile or complex nonsterile compounding, they would be accepted for that requirement, regardless of the ACPE designation.

If you are unclear as to whether your job duties would require you to obtain sterile or complex nonsterile compounding credits, please review the Board's policy on CE requirements.

Did You Know?

- E-prescribing is coming soon! This helpful circular letter provides a great overview, so review it and bookmark it for future reference.
- During the coronavirus disease 2019 (COVID-19) emergency period, pharmacies should continue to accept oral prescriptions for any controlled substances, including emergency Schedule II, as long as a follow-up prescription is requested to be sent within the increased timeframe of 15 business days. The prescriptions should indicate: "Issued to document an Oral Prescription." Schedule II prescriptions must also have the additional notation: "Authorization for Emergency Dispensing." Follow-up prescriptions may be issued by any DEA-approved method allowable during the emergency period. This includes sending via United States mail (postmarked within 15 days of the oral prescription), e-prescribing, faxing, or by taking a photograph or scan of the follow-up prescription and sending the photograph or scan to the pharmacy via secure email.
- During the COVID-19 emergency period, physicians may prescribe for themselves and family members, but prescribing must be for a legitimate medical purpose and in the usual course of professional practice. Please see the Board of Medicine's Policy 20-02 Interim Policy on Prescribing.
- Answers to many more COVID-19 questions can be found here.

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