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Virginia Board of Pharmacy News

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Mandatory E-Prescribing of Opioids Effective July 1, 2020

The Virginia Board of Pharmacy staff has received numerous inquiries regarding the new law that mandates e-prescribing of opioids effective July 1, 2020. Section 54.1-3408.02 of the Drug Control Act related to the transmission of prescriptions requires that any prescription for a controlled substance (CS) that contains an opioid shall be issued as an electronic prescription. The law includes a number of exceptions to this requirement, such as a prescription for an individual who is residing in a hospital, assisted living facility, nursing home, or residential health care facility, or someone who is receiving services from a hospice provider or outpatient dialysis center. The law also does not apply to prescriptions issued under research protocols or prescriptions issued by veterinarians for the treatment of an animal. Prescriptions issued to pharmacies located on federal property are also excluded from the requirement. Additionally, individual prescribers may apply to their licensing Board for a waiver of this requirement for no more than one year due to demonstrated economic hardship, technological limitations, or other exceptional circumstances.

Please note that while pharmacists must continue to ensure only valid prescriptions are dispensed, the law does not require the pharmacist to determine if a non-electronic prescription for an opioid is exempted from electronic transmission requirements or if the prescriber has been issued a waiver by his or her licensing Board. Specifically, §54.1-3410(E) states that a "dispenser [eg, pharmacist] who receives a non-electronic prescription for a controlled substance containing an opioid is not required to verify that one of the exceptions set forth in §54.1-3408.02 applies and may dispense such controlled substance pursuant to such prescription and applicable law."

Board Bids Farewell to Inspector Jackson

Pharmacy Inspector Donald "Don" Jackson retired from the Department of Health Professions (DHP) Enforcement Division at the end of March, after serving DHP in the southwest portion of the state for nearly 19 years. The Board extends its appreciation to Mr Jackson for his dedication to public service and the profession of pharmacy, and wishes him the best in the coming years.

HB 1506 Expands Pharmacist Clinical Services

House Bill (HB) 1506, signed by Governor Ralph Northam on April 6, 2020, went into effect on July 1, 2020. It allows pharmacists to initiate treatment, dispense, and administer certain drugs and devices to persons 18 years of age or older in accordance with statewide protocols to be developed by the Board in collaboration with the Board of Medicine and the Department of Health. The bill directs the Board to establish such protocols by November 1, 2020, and promulgate regulations to implement the provisions to be effective within 280 days of its enactment. A meeting of representatives from the Board, Board of Medicine, and Department of Health will convene this summer to provide recommendations regarding the development of the protocols and regulations. It is anticipated that the Board will adopt such protocols and regulations at its meeting scheduled for September 9, 2020. As authorized in the bill, the statewide protocols will specifically address pharmacist initiation, dispensing, and administration of the following drugs to persons 18 years of age or older:

- epinephrine,
- injectable or self-administered hormonal contraceptives,
- prescription prenatal vitamins,
- dietary fluoride supplements,

continued on page 4

National Pharmacy Compliance News

July 2020

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.*

continued from page 1

- naloxone or other opioid antagonist, and
- medications covered by the patient's insurance carrier when the patient's out-of-pocket cost is lower than the out-of-pocket cost to purchase the over-the-counter (OTC) equivalent of the same medication.

The bill also requires a work group consisting of representatives of the Board of Pharmacy, Board of Medicine, the Department of Health, schools of medicine and pharmacy located in the commonwealth, and other stakeholders to provide recommendations regarding the development of protocols for pharmacist initiation of treatment, dispensing, and administration to persons 18 years of age or older of:

1. vaccines;
2. drugs for tobacco cessation, including nicotine replacement therapy;
3. tuberculin purified protein derivative for tuberculosis testing;
4. drugs or devices for the treatment of conditions for which clinical decision making can be guided by a clinical test that is classified as waived under the federal Clinical Laboratory Improvement Amendments of 1988, including influenza virus, Helicobacter pylori bacteria, urinary tract infection, and group A Streptococcus bacteria;
5. drugs for the prevention of human immunodeficiency virus, including drugs for pre-exposure and post-exposure prophylaxis; and
6. drugs sold OTC for which the patient's health insurance provider requires a prescription.

It is anticipated that this larger work group will also meet in early fall to develop its findings and recommendations, which must be reported to the governor and the chairmen of the House Committee on Health, Welfare and Institutions and the Senate Committee on Education and Health by November 1, 2020.

Revised Naloxone Standing Order

On March 19, 2020, Virginia Health Commissioner M. Norman Oliver, MD, MA, issued a new statewide standing order for naloxone as the previously issued order was close to expiring. At that time, the Board emailed a copy of the signed standing order to all pharmacists with a current email address on file with the Board. To request an additional copy of the signed standing order, pharmacists may contact Board staff at pharmbd@dhp.virginia.gov. Please note that the link on the Virginia Department of Health website is to an unsigned version of the standing order.

Pursuant to the new standing order, the following individuals may dispense naloxone, to a person, to administer to another person believed to be experiencing, or about to experience, a life-threatening opioid overdose, and shall follow the Board's Guidance Document 110-44 when dispensing naloxone, as authorized in §54.1-3408 (X) and (Y):

- Pharmacists who maintain a current active license, practicing in a pharmacy located in Virginia that maintains a current active pharmacy permit; and
- Emergency medical services personnel, as defined in §32.1-111.1.

This applies also to the following individuals who have completed a training program in accordance with the policies and procedures of their employer or governing entity:

- Law enforcement officers, as defined in §9.1-101;
- Employees of the Department of Corrections designated as probation and parole officers or as correctional officers, as defined in §53.1-1;
- Employees of regional jails;
- Firefighters;
- Employees of local health departments and contractors, or Medical Reserve Corps volunteers acting on behalf of the local health department;
- Employees of local community services boards;
- Persons acting on behalf of a harm reduction site approved by the Department of Health; and
- Individuals acting on behalf of the American Red Cross of Virginia as disaster health services volunteers.

The individuals now included on the commissioner's standing order may opt to dispense under the commissioner's standing order, in accordance with policies and protocols of their employer or governing entity and Board protocols, in lieu of obtaining a standing order from another prescriber. However, except for pharmacists, persons authorized to dispense under this standing order shall only dispense formulations for intranasal administration or an auto-injector formulation. A controlled substances registration for naloxone dispensing from the Board is no longer required for the dispensing of non-injectable forms of naloxone.

Changes to Pharmacy Technician Eligibility Requirements

HB 1304 and Senate Bill (SB) 830 identically amend the eligibility criteria for registration as a pharmacy technician to include a requirement that the individual has:

1. successfully completed a training program that is an accredited training program approved by the Board, including one operated through the Department of Education's Career and Technical Education program or through a federal agency or branch of the military; and

continued on page 5

continued from page 4

2. successfully passed a national certification examination administered by the Pharmacy Technician Certification Board or the National Healthcareer Association, eg, Exam for the Certification of Pharmacy Technicians.

This section of the bills has a delayed enactment of July 1, 2022, and therefore, completion of an accredited training program will not be required until that time. The bills also define the term "pharmacy technician trainee" and require persons enrolled in a pharmacy technician training program who are performing duties restricted to a pharmacy technician to be registered with the Board. This requirement will become effective once the regulations are final, which will likely occur in January 2021.

The bills also require the Board to convene a work group to develop recommendations related to the addition of duties and tasks that a pharmacy technician registered by the Board may perform. It is anticipated that the work group will meet in 2021 to develop its recommendations, which must be reported to the secretary of Health and Human Resources and the chairmen of the House Committee on Health, Welfare and Institutions and the Senate Committee on Education and Health by November 1, 2021.

SB 976 Changes to Pharmaceutical Processors

Several bills were passed during the 2020 General Assembly Session that impact pharmaceutical processors and cannabis products. Specifically, SB 976 included several significant changes. The bill replaces the definitions of "cannabidiol oil" and "THC-A oil" with a newly defined term of "cannabis oil," which means any formulation of processed cannabis plant extract or a dilution of the resin of the cannabis plant that contains at least five milligrams of cannabidiol or tetrahydrocannabinolic acid (THC-A) and no more than 10 milligrams of tetrahydrocannabinol (THC) per dose. The previous 5% THC cap for these products was stricken. The bill also creates a new licensing category for a "cannabis dispensing facility," which must be owned, at least in part, by a pharmaceutical processor and may dispense cannabis oil produced by a pharmaceutical processor under the personal supervision of a pharmacist. Each pharmaceutical processor may apply for up to five cannabis dispensing facility permits to be located in the same health service area as the processor. It is anticipated that the Board will adopt regulations for these facilities at its September Board meeting, which will likely become effective in January 2021. Lastly, the bill allows the practitioner to employ use of telemedicine consistent with federal requirements for the prescribing of Schedule II through V CS. Guidance on this issue may be forthcoming to assist licensees with compliance. Please access SB 976 to review additional statutory changes included in the bill.

Third Pharmaceutical Processor Permit Issued

Green Leaf Medical of Virginia, Inc, located in Richmond, VA, received a permit as a pharmaceutical processor on May 12, 2020. This is the third pharmaceutical processor permit issued in Virginia. Earlier this year, the Board issued permits to Dharma Pharmaceuticals in Bristol, VA, and Columbia Care in Portsmouth, VA. It is anticipated that medicinal cannabis oil products will be available in Virginia in July 2020. Additional information regarding pharmaceutical processors may be accessed at *www.dhp.virginia.gov/Pharmacy/PharmaceuticalProcessing/default.htm.*

Virtual Inspections Amid COVID-19

In an effort to provide for business continuity during the coronavirus disease 2019 (COVID-19) pandemic, the Board inspectors are conducting virtual inspections for new locations, change of location, and remodels. In most instances, this process eliminates the need for an inspector to physically inspect on site at the facility. Prior to the virtual inspection, the inspector will provide the pharmacist-in-charge (PIC) with a list of photographs that must be submitted to the inspector, along with a floor plan of the facility, with the locations and zones of each motion sensor clearly marked on the diagram. If it is an inspection for a new facility location, the square footage is confirmed. The virtual inspection is then conducted with the PIC or pharmacist on duty via FaceTime or Google Hangouts. During the virtual inspection, alarm tests are conducted and verified with the monitoring entity via speakerphone. Virtual inspections also allow for validation of other physical requirements such as locking mechanisms on doors, refrigeration and freezer temperatures, clinical references, and running water.

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