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Virginia Board of Pharmacy News

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Required Reporting of Pediatric Immunizations to VIIS

Note: this information is provided on behalf of the Virginia Department of Health (VDH).

VDH recognizes pharmacy providers in administering vaccinations to individuals within their communities. This year, it is more important than ever to get vaccinated against influenza, considering the continued presence of the coronavirus disease 2019 (COVID-19) viral global pandemic that has already claimed more than 265,000 American lives. In addition to flu shots, it is also vital for parents to get their children caught up on any vaccinations they may have missed during the temporary stay-at-home order earlier this year, and for all Virginians to begin to ready themselves to get a COVID-19 vaccine when that becomes publicly available.

Effective September 22, 2020, emergency regulation 18 Virginia Administrative Code 110-20-271 requires pharmacists to report the administration of childhood vaccines to the Virginia Immunization Information System (VIIS). However, the administration of vaccines to adults should also be reported in the system. VIIS is a secured, confidential, reliable computerized registry maintained by the VDH Division of Immunization containing vaccine information from participating providers for individuals of all ages. To register for VIIS, visit the Virginia Electronic Registration for Immunization Programs website. VDH offers a variety of trainings to include hands-on, group, webinar, and online training modules. Once registered, you will be contacted by a VIIS trainer to schedule training.

Note: Some pharmacies are currently set up to submit vaccine administrations to VIIS under a parent or corporate account. However, in preparation for the COVID-19 vaccine, the registration should be updated so that every pharmacy location has an account in VIIS, and the reporting of administration is specific to that pharmacy location. Check in with the VIIS team today to ensure that your pharmacy's reporting is up to date by calling 866/375-9795.

Preceptors Allotted Continuing Education Credit

Of the 15 contact hours of continuing education (CE) required for annual renewal of a pharmacist license, at least three hours shall be obtained in courses or programs that are live or real-time interactive. Included in the three hours, a maximum of one hour may be awarded for serving as a preceptor for a pharmacy student or resident in an accredited school or program, or for a foreign-trained student obtaining hours of practical experience.

To document serving as a preceptor, a pharmacist should print out the attestation form located on the Virginia Board of Pharmacy's website, fill in the required information, and maintain this documentation with his or her records of CE for up to three years. If audited, the pharmacist shall produce this document as proof of completing one hour of live CE serving as a preceptor. Do not send this form to the Board outside of a request for audit. The form is not required to be signed by any other person.

Additional information on this subject is located in Guidance Document 110-4.

Fee Increases for Licensees

On October 14, 2020, regulations became effective to increase fees for all licensees. This is the first fee increase for the Board since 2002, when there were approximately 12,000 licensees. Since then, the Board has expanded to approximately 38,000 licensees and several new licensing categories have been added. The renewal fee for an active pharmacist license is $120, and the renewal fee for an inactive pharmacist license is $60, if paid before December 31, 2020. The renewal fee for a pharmacy technician is $35, if paid before December 31, 2020, and the renewal fee for a pharmacy permit is $350.

National Pharmacy Compliance News

December 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 Recommends Health Care Providers Discuss Naloxone With Patients Receiving Opioids, OUD Treatment

Recognizing the importance of discussing naloxone with patients receiving opioids or medications to treat opioid use disorder (OUD), Food and Drug Administration (FDA) recommends that health care providers include such discussions as a routine part of prescribing these medications. Further, the agency is requiring label changes to these medications to include this recommendation. The revised labels will encourage health care providers to discuss the availability of naloxone with patients and caregivers, both when beginning and renewing treatment. The labeling changes also suggest that providers prescribe naloxone to patients being prescribed opioids who are at increased risk of opioid overdose.

"Even during this global pandemic, we have continued to prioritize addressing the opioid crisis," said FDA Commissioner Stephen M. Hahn, MD, in a press release. "Today's action can help further raise awareness about this potentially life-saving treatment for individuals that may be at greater risk of an overdose and those in the community most likely to observe an overdose. We will use all available tools to address this crisis, and we know efforts to increase access to naloxone have the potential to put an important medicine for combatting opioid overdose and death in the hands of those who need it most – those at increased risk of opioid overdose and their friends and family."

The complete list of changes is available through an July 2020 Drug Safety Communication.

Proposed Rule to Require Electronic Submission of DEA Form 106

A proposed rule requiring accurate electronic submission of DEA Form 106 was published by Drug Enforcement Administration (DEA) in the *Federal Register* on July 29, 2020. The form, used by DEA registrants to report thefts or significant losses of controlled substances (CS), would also need to be submitted within a 15-day time period under the proposed rule. DEA registrants who experience theft or loss of CS would still be required to notify the DEA Field Division Office in their area, in writing, within one business day of discovery. According to the announcement published in the *Federal Register,* this requirement will impact the remaining 0.5% of DEA Form 106 responses that are reported by paper.

Inappropriate FentaNYL Patch Prescriptions at Discharge for Opioid-Naïve, Elderly Patients

This column was prepared by the Institute for Safe Medication Practices (ISMP), an ECRI affiliate. Have you experienced a medication error or close call? Report such incidents in confidence to ISMP's National Medication Errors Reporting Program online at www.ismp.org *or by email to ismpinfo@ismp.org to activate an alert system that reaches manufacturers, the medical community, and FDA. To read more about the risk-reduction strategies that you can put into practice today, subscribe to the ISMP Medication Safety Alert!® newsletters at* www.ismp.org.

ISMP recently heard from a long-term care (LTC) pharmacy about an increase in the prescribing of transdermal fenta**NYL** patches for elderly patients. In most cases, the pharmacists reviewing the patients' orders determined that the fenta**NYL** patches had been inappropriately prescribed for opioid-naïve patients, sometimes to treat acute pain rather than chronic pain. One of the more common underlying causes appears to be a knowledge deficit about the dangers of prescribing this opioid analgesic to opioid-naïve patients. Several of the events began in a hospital, with opioid-naïve patients receiving prescriptions for fenta**NYL** patches after treatment in an emergency department (ED) or upon discharge and transfer to a LTC facility. Prescribing a fenta**NYL** patch to elderly, opioid-naïve patients can result in fatal or life-threatening respiratory depression and overdose.

In one event, an 88-year-old resident from a LTC facility fell and was taken to a local hospital ED, where multiple rib fractures were diagnosed. Upon discharge

from the ED, the resident was prescribed a fenta**NYL** patch, 25 mcg/hour, every 72 hours. At the LTC facility, a consultant pharmacist reviewed the medication orders and the resident's medication history. The pharmacist determined that the resident had not received a prescription for opioids in the past year, revealing he was opioid-naïve. The consultant pharmacist contacted the prescribing ED physician to discuss the order for the fenta**NYL** patch. The ED physician reported that the resident had received "three small IV push doses" of fenta**NYL** in the ED, mistakenly believing this meant the resident was opioid-tolerant.

Additionally, the ED physician had prescribed the fenta**NYL** patch because the resident had a documented allergy to codeine. The ED physician mistakenly believed the fenta**NYL** patch was the only viable option. The consultant pharmacist clarified that the LTC records indicated that the resident had experienced mild nausea and an upset stomach while taking **HYDRO**codone and acetaminophen when he was younger, which is not an allergy but rather a mild intolerance. The ED physician changed the resident's analgesic to oral oxy**CODONE** 5 mg as needed every four to six hours.

Reliance on product labeling and practitioner education alone will not prevent life-threatening errors with fenta**NYL** patches. Yes, health care practitioners should be educated about safe prescribing, and their competency should be verified as a prerequisite to prescribing. But there will always be those who are unaware of the risks they take prescribing fenta**NYL** patches to opioid-naïve patients to treat acute pain. Thus, system safeguards must be established to avoid the risk of harm.

Fenta**NYL** patches should only be prescribed for patients who are opioid-tolerant with persistent, moderate-to-severe chronic pain that requires around-the-clock, long-term opioid administration. In 2018, ISMP called for the elimination of prescribing fenta**NYL** patches for opioid-naïve patients and/or patients with acute pain in our *Targeted Medication Safety Best Practices for Hospitals*. In 2020, this best practice was incorporated into a new best practice (No.15) to verify and document the patient's opioid status and type of pain before prescribing and dispensing extended-release opioids.

When entering discharge and transfer orders, interactive alerts requiring confirmation that the patient is opioid-tolerant and experiencing chronic pain might help prevent inappropriate prescribing, as might hard stops if patients do not meet prescribing criteria. Consider creating a daily list of discharge prescriptions and transfer orders for fenta**NYL** patches generated from the order entry system, and requiring a hospital pharmacist to review them to verify that the patient is opioid-tolerant and has chronic pain.

Engage patients. Educate all patients prescribed a fenta**NYL** patch and their caregivers about how to use the patch safely.

SAMHSA Health Privacy Rule Revised to Better Integrate, Coordinate Care for Patients With SUD

A revised Substance Abuse and Mental Health Services Administration (SAMHSA) rule will make it easier for people diagnosed with substance use disorders (SUDs) to receive integrated and coordinated care. The revisions to the agency's Confidentiality of Substance Use Disorder Patient Records regulation, 42 CFR Part 2, advances the integration of health care for individuals with SUDs while maintaining critical privacy and confidentiality protections.

According to a US Department of Health and Human Services (HHS) press release, under Part 2, a federally assisted SUD program may only disclose patient identifying information with the individual's written consent, as part of a court order, or under a few limited exceptions. In addition, health care providers, with patients' consent, will be able to more easily conduct quality improvement, claims management, patient safety, training, and program integrity efforts.

The revised rule modifies several major sections of Part 2, including provisions related to records, consent requirements, and research, among others. For a list of changes in the final rule, visit the HHS Fact Sheet.

HHS Assistant Secretary for Mental Health and Substance Use Elinore F. McCance-Katz, MD, PhD, the head of SAMHSA, further stated, "Modernizing 42 CFR Part 2 will strengthen the nation's efforts to reduce opioid misuse and abuse and to support patients and their families confronting substance use disorders. The rule will make it easier for primary care clinicians to treat individuals with substance use disorders."

Governor Northam Appoints New Board Members

Governor Ralph Northam has appointed two new pharmacist members to the Board.

- **Sarah T. Melton, PharmD, RPh, BCPP, BCACP, CGP, FASCP,** of Bristol, VA, is a professor of pharmacy practice at the Gatton College of Pharmacy in Johnson City, TN.
- **R. Dale St Clair, Jr, PharmD, RPh,** of Goochland, VA, is the vice president, East Region for Remedi SeniorCare. Dr Melton and Dr St Clair replace the positions previously held by Cindy Warriner and Rebecca Thornbury.

Board Election Results

Congratulations to Kristopher Ratliff and Cheryl Nelson who were recently elected to serve as chairman and vice chairman of the Board, respectively. Additionally, the Board extends its appreciation to Cindy Warriner and Kris Ratliff for their dedication and leadership while serving as chairman and vice chairman, respectively, during the past year.

Statewide Protocols for Prescribing of Certain Drugs by Pharmacists

House Bill (HB) 1506, which went into effect on July 1, 2020, allows a pharmacist to initiate treatment with and dispense and administer certain drugs and devices to persons 18 years of age or older in accordance with a statewide protocol. The bill required the statewide protocols to be developed by the Board of Pharmacy in collaboration with the Virginia Board of Medicine and the VDH, and directed the Board of Pharmacy to promulgate emergency regulations to implement the protocols.

At its September 9, 2020, full Board meeting, the Board voted to adopt the proposed statewide protocols recommended by the Protocol Workgroup. Once the emergency regulations become effective, which is anticipated in January 2021, the statewide protocols will be posted on the Board's website, and pharmacists may begin initiating treatment in accordance with the protocols and regulations.

As authorized in the bill, the statewide protocols 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,
- 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 equivalent of the same medication.

Although the bill also provides for a dietary fluoride supplement protocol, the American Dental Association does not recommend the prescribing of dietary fluoride supplements for persons 18 years of age or older.

Additional information on this subject may be found in the agendas and minutes from the meetings held on August 4, August 17, September 9, and October 2, 2020.

Ban on Vaping Inhalation Products Containing Vitamin E Acetate

At its June meeting, the full Board approved an emergency regulation to ban vitamin E acetate from cannabidiol oil and tetrahydrocannabinolic acid oil products intended to be vaporized or inhaled. Inhalation of vitamin E acetate through vaping may lead to severe lung disease. This prohibition went into effect on August 6, 2020.

Board to Require Registration of Pharmacy Technician Trainees

HB 1304, which became effective in July 2020, amends the eligibility requirement for pharmacy technicians, defines "pharmacy technician trainee," and sets out requirements for registration as a pharmacy technician trainee. The bill also requires the Board to convene a workgroup of stakeholders to develop recommendations related to the addition of duties that a pharmacy technician registered by the Board may perform. The provisions of the bill pertaining to accreditation of pharmacy technician training programs has a delayed enactment of July 1, 2022.

At its September 9, 2020, full Board meeting, the Board adopted emergency regulations requiring the registration of pharmacy technician trainees. To be registered as a pharmacy technician trainee, a person will need to submit an application and fee to the Board prior to performing the duties of a pharmacy technician. The registration will be valid for no more than two years provided the trainee is enrolled in a pharmacy technician training program and actively progressing toward completion. The regulations also require the pharmacy technician trainee to be directly supervised by a pharmacist who holds a current active license and assumes full responsibility for the supervision of the trainee. The emergency regulations requiring registration of pharmacy technician trainees are anticipated to take effect in January 2021. The application for obtaining the registration will be posted on the Board's website at that time, and trainees currently performing the duties of a pharmacy technician must submit an application for compliance.

Scam Alert

The Virginia Department of Health Professions (DHP) has been made aware that some licensees have received fraudulent communications from individuals claiming to be from one of its licensing boards, such as the Board of Pharmacy or another agency, such as Drug Enforcement Administration (DEA). The communications, often by phone, may threaten arrest or license suspension, demand personal information, or require the payment of fines. Please be aware that phone calls may "spoof" DHP or the Board and may appear to be from the Board's number. If you need to verify the identity of a DHP investigator or inspector, call 804/367-4691 or email enfcomplaints@dhp.virginia.gov. DHP will never demand that you provide personally identifiable information, such as a Social Security number, date of birth, or bank or credit card account numbers over the phone. These types of licensing scams are a problem nationwide.

If you believe that you are the recipient of a fraudulent communication claiming to be from DHP, notify DHP at 804/367-4691, or email enfcomplaints@dhp.virginia.gov, and report the communication to local law enforcement or the Virginia State Police. The Federal Trade Commission (FTC) also accepts reports about "imposter scams" through the FTC Complaint Assistant, or at 1-877/382-4357. These reports are used to aid ongoing investigations. DEA has also warned of imposters posing as DEA agents. Information and reporting of these scams can be found on the DEA website.

Pharmacies Encouraged to Register as COVID-19 Testing Site

VDH maintains an external-facing testing site locator, which is intended to help provide information of known locations of various COVID-19 test sampling sites and does not constitute official endorsement by VDH. Pharmacies that are performing one-time community or routine COVID-19 testing may visit this website to request its event and location to be added to the testing locator. Refer to the COVID-19 testing resource document for additional information regarding pharmacies performing COVID-19 tests.

Emergency Waivers Amended

The Board has amended an emergency waiver that allowed pharmacists and pharmacy technicians not licensed in Virginia, but currently licensed in another state or holding national certification as a pharmacy technician, to practice in an affected area of the commonwealth or perform certain central/remote order processing functions on behalf of an out-of-state pharmacy during the declared state of emergency. Beginning January 1, 2021, pharmacists and pharmacy technicians may not practice in Virginia unless they are properly licensed or registered with the Board.

Additionally, the Board amended an emergency waiver that allowed a pharmacy technician trainee who is currently enrolled in a Board-approved pharmacy technician training program and whose nine-month allowance for performing duties restricted to a pharmacy technician is about to expire or has recently expired to continue performing pharmacy technician duties during the declared emergency. Beginning January 1, 2021, the trainee whose nine-month allowance has expired must obtain registration from the Board as a pharmacy technician prior to resuming duties of a pharmacy technician.

Refer to the emergency provisions during the COVID-19 declared emergency for information regarding all Board-approved emergency waivers.

The *Virginia Board of Pharmacy News* is published by theVirginia Board of Pharmacy and the National Association of Boards of Pharmacy Foundation® (NABPF®) to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of NABPF or the Board unless expressly so stated.

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