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Important COVID-19 Information

Virginia Board of Pharmacy

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***Information highlighted below in yellow represents new information added since the last publication of this document. ***

In response to Governor Northam's declared state of emergency in Executive Order Amended Number Fifty-One (2020) regarding COVID-19 and as authorized in §54.1-3307.3 of the Code of Virginia, the Virginia Board of Pharmacy offers the following information and provisions for the duration of the declared emergency.

Amended as of 9/25/2020: Assistance from Pharmacists and Pharmacy Technicians Licensed in Other States; Central/Remote Order Processing (§54.1-3320, §54.1-3321, 18VAC110-20-276, 18VAC110-20-515)

A. **Prior to January 1, 2021**, a pharmacist not licensed in Virginia, but currently licensed in another state, may practice pharmacy in an affected area of the Commonwealth or may provide central/remote order processing or order verification services on behalf of an out-of-state pharmacy during a declared state of emergency when:

1. The pharmacist and out-of-state pharmacy, if applicable, have identification to verify current unrestricted licensure in another state;
2. The pharmacist is engaged in a legitimate relief effort during the emergency period; and,
3. The pharmacist and pharmacy immediately notify the board of this professional practice.

B. **Prior to January 1, 2021**, a pharmacy technician not registered in Virginia, but currently licensed or registered in another state or maintaining current national certification, may practice as a pharmacy technician in an affected area of the Commonwealth or may participate in central/remote order processing on behalf of an out-of-state pharmacy during a declared state of emergency when:

1. The pharmacy technician and out-of-state pharmacy, if applicable, have identification to verify current unrestricted licensure in another state or national certification;
2. The pharmacy technician is engaged in a legitimate relief effort during the emergency period; and,
3. The pharmacy technician and pharmacy immediately notify the board of this professional practice.

C. Nothing in this section shall prohibit the pharmacist or pharmacy technician as described in subsections A and B or a pharmacist licensed in Virginia or pharmacy technician registered in

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Virginia from accessing the employer pharmacy's database from a remote location for the purpose of performing certain prescription processing functions provided the pharmacy establishes controls to protect the privacy and security of confidential records.

D. The authority provided for in this section shall cease with the termination of the state of emergency.

E. As of January 1, 2021, pharmacists and pharmacy technicians may not practice in Virginia unless they are properly licensed or registered with the Virginia Board of Pharmacy.

AMENDED as of 9/25/2020: Pharmacy Technician Trainee Allowance (18VAC110-20-111(C))

Prior to January 1, 2021, the Board waives the requirements of 18VAC110-20-111(C) to authorize a pharmacy technician trainee who is currently enrolled in a board-approved pharmacy technician training program and whose 9-month allowance for performing duties restricted to a pharmacy technician is about to expire or has recently expired, to continue performing pharmacy technician duties for the duration of the declared emergency. At the conclusion of the emergency or prior to January 1, 2021, whichever occurs first, the trainee whose 9-month allowance has expired must obtain registration from the board as a pharmacy technician prior to resuming duties of a pharmacy technician.

Amended 5/4/2020: General Reminders for Pharmacy Personnel to Mitigate Risk of Exposure

1. Use calming and reassuring language when patients ask for information.
2. Encourage people to buy cold medicine and refill prescriptions now, if possible, so they do not have to go out if they develop COVID-19.
3. Establish a process for reducing or eliminating the amount of time older adults, pregnant women, and people with chronic health conditions wait in line to pick up medications.
4. Implement infection control procedures, especially for waiting areas:
 - a. Staff should maintain a distance of 6 feet from patients and other staff members.
 - b. Regularly clean counters, waiting areas, and other spaces where public interaction occurs with disinfectant. It is recommended to clean at least every hour or after every 10 patients, whichever is more frequent.
 - c. Place alcohol-based hand sanitizer with at least 60% isopropyl alcohol or ethyl alcohol next to the cash register or check out area so people can sanitize their hands after using common items like pens.
 - d. Wash hands with soap and water frequently and for at least 20 seconds. Avoid touching eyes, nose, and mouth.
 - e. Cover cough and sneeze with tissue and discard.
5. Monitor all staff for sickness regularly. Staff should stay home if they have symptoms of a respiratory infection.
6. Per CDC guidance:

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- a. Everyone entering the pharmacy should wear a face covering, regardless of symptoms. Cloth face coverings should not be placed on young children under age 2, anyone who has trouble breathing, or is unconscious, incapacitated or otherwise unable to remove the mask without assistance.
- b. Pharmacists and pharmacy technicians should always wear a facemask while they are in the pharmacy for source control.

(6/28/2020) Refer to: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/pharmacies.html> and <https://www.osha.gov/SLTC/covid-19/controlprevention.html> and <http://www.vdh.virginia.gov/content/uploads/sites/182/2020/03/Pharmacists-Can-Help-Slow-The-Spread-COVID19-03242020.pdf>

Amended as of 4/10/2020: Dispensing of New Prescriptions or Refills (18VAC110-20-320, §54.1-3410, (18VAC110-20-290(C)(4)))

Schedule VI

1. Pharmacists may exercise professional judgement regarding the dispensing of early refills for Schedule VI drugs and must document the reason for the early refill.
2. Pharmacists may refill a Schedule VI drug without authorization from the prescriber if the pharmacist ascertains that patient's health would be in imminent danger without the benefits of the drug.

Schedule III-V

1. Pharmacists may dispense a one-time early refill of schedule III-V prescriptions and must document the reason for the early refill.

Schedule II

1. Pharmacists may dispense a one-time early dispensing of a Schedule II prescription for a chronic condition and must document the reason for the early dispensing.
2. **4/10/2020:** Emergency CII Prescriptions (18VAC110-20-290(C)(4))

Notwithstanding 18 VAC 110-20-290(C)(4), within fifteen days after authorizing an emergency oral prescription, the prescribing practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of § 54.1-3410 of the Drug Control Act, the prescription shall have written on its face "Authorization for Emergency Dispensing" and the date of the oral order. The written prescription may be delivered to the pharmacist in person or by mail postmarked within the fifteen-day period or transmitted as an electronic prescription in accordance with federal law and regulation to include annotation of the electronic prescription with the original authorization and date of the oral order. In lieu of delivering the written

prescription to the pharmacist, the practitioner may send the follow-up prescription to the pharmacy via facsimile, or take a photograph or scan of the follow-up prescription and send the photograph or scan to the pharmacy as long as the original written prescription is maintained in the patient's record. Upon receipt, the dispensing pharmacist shall attach the paper prescription, facsimile, photograph, or scan to the oral emergency prescription, which had earlier been reduced to writing. The pharmacist shall notify the nearest office of the Drug Enforcement Administration and the board if the prescribing practitioner fails to deliver a written prescription to the pharmacist. Failure of the pharmacist to do so shall void the authority conferred by this subdivision to dispense without a written prescription of a prescribing practitioner.

Inpatient Hospital Pharmacy Dispensing to Discharge Patient (§54.1-3410, §54.1-3463, and 18VAC110-20-330)

- An inpatient pharmacy may label a dispensed drug for a discharged patient that does not contain all the required elements of a label for an outpatient prescription if the patient is provided reasonably adequate information to ensure safe use of the drug that properly identifies the names of the patient, prescriber, and pharmacy; drug name and strength; date of dispensing; and, the prescribed directions for use.

Amended 5/4/2020: Compounding of Hand Sanitizer (§54.1-3410.2)

- Pharmacists may compound, in accordance with USP <795> standards, hand sanitizer containing at least 60% isopropyl or ethyl alcohol for sale to the general public at a reasonable price without obtaining a prescription to authorize the compounding. The pharmacist must ensure the product is labeled to identify the ingredients, appropriate BUD, and directions for safe use.
- Alcohol produced by firms that manufacture alcohol (i.e., ethanol or ethyl alcohol) for use as the Active Pharmaceutical Ingredient (API) may be used in alcohol-based hand sanitizers provided the alcohol is manufactured in accordance with FDA guidance "Temporary Policy for Manufacture of Alcohol for Incorporation Into Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19)" available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/temporary-policy-manufacture-alcohol-incorporation-alcohol-based-hand-sanitizer-products-during>
- USP information - https://go.usp.org/hand_sanitizer

Reference added 4/10/2020: Conserving Garb (§54.1-3410.2)

- In anticipation of possible shortages of masks, USP supports appropriate risk-based enforcement discretion during the COVID-19 pandemic, in the interest of conserving garbing and personal protective equipment. FDA has also issued a statement regarding conservation strategies. Therefore, pharmacists may implement a process for reusing masks in a manner that does not compromise the microbial state of control in cleanrooms.

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The user should visibly inspect the product prior to use and, if there are concerns (such as degraded materials or visible tears), discard the product.

- A policy and procedure should clearly indicate how an employee's reused mask will be identified, stored, and under what conditions it may no longer be used.
- Garb (gowns and masks) for non-hazardous drug compounding may be reused in accordance with facility standard operating procedures. Gowns must be stored in a manner that minimizes contamination (e.g., away from sinks to avoid splashing).
- Soiled, contaminated, torn, or punctured garb must be changed immediately and not re-used.
- Be aware that counterfeit masks and gowns may be on the market, especially during this time of reduced supply.
- Weekly surface sampling inside ISO 5 space must be performed when garbing in a manner that is not consistent with USP requirements.
- Refer to:
 - CDC's Interim Guidance on preventing COVID-19 from spreading, which includes *Strategies for Optimizing the Supply of N95 Respirators* <https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/>
 - *Healthcare Supply of Personal Protective Equipment* and <https://www.cdc.gov/coronavirus/2019-ncov/hcp/healthcare-supply-ppe-index.html>
 - FDA's *Surgical Mask and Gown Conservation Strategies - Letter to Healthcare Providers* at <https://www.fda.gov/medical-devices/letters-health-care-providers/surgical-mask-and-gown-conservation-strategies-letter-healthcare-providers>
 - 4/10/2020 - FDA's *Temporary Policy Regarding Non-Standard PPE Practices for Sterile Compounding by Pharmacy Compounders* <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/temporary-policy-regarding-non-standard-ppe-practices-sterile-compounding-pharmacy-compounders-not>

Emergency Closing of Pharmacy

- Notwithstanding the closing requirements for a pharmacy in 18VAC110-20-130, to assist statewide efforts in evaluating adequate access to pharmaceutical services, if a pharmacy must close for longer than 72 hours due to emergency circumstances, it is strongly recommended that the pharmacy notify the board of the closing, the anticipated duration of the closing, and actions taken to ensure patient continuity of care and to mitigate diversion of drug.

NEW as of 3/24/2020: Emergency Purchase of Drugs from another Pharmacy

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In anticipation of possible drug shortages, please recall that Regulation 18VAC110-20-395 authorizes a pharmacist to make an emergency purchase from another pharmacy.

18VAC110-20-395. Purchase of drugs.

Except for an emergency purchase from another pharmacy, a pharmacist may only purchase Schedule II through VI drugs from a wholesale distributor or warehouse licensed or registered by the board.

NEW as of 3/24/2020: Stat Box and Emergency Kit Replenishment (18VAC110-20-540, 18VAC110-20-550, 18VAC110-20-555)

At the direction of the pharmacist-in-charge and in the event of a confirmed COVID-19 test or presumptive positive test in a facility using a stat box, emergency kit, or automated dispensing device to store such drugs as authorized in Regulations 18VAC110-20-540, 18VAC110-20-550, and 18VAC110-20-555, the following waived provision is authorized:

- The provider pharmacy is not required to exchange the stat box or emergency kit after opening, but rather replacement drugs may be sent by the provider pharmacy to the facility for a nurse to replace in the box, kit, or device and appropriately re-seal and secure.

The provider pharmacy shall develop and maintain a policy and procedure to ensure proper oversight of the notification, delivery, and replacement process to mitigate risk of diversion and to protect public safety.

NEW as of 3/24/2020: Compounding for another Hospital (§54.1-3410.2)

The prohibition in §54.1-3410.2 (C) for a pharmacy to distribute compounded drug products to another pharmacy or other entity under common ownership or control is waived during the duration of the declared emergency if a hospital pharmacy is unable to compound sterile drugs to meet the demand of its own patients and 503B (outsourcing facilities) are unable to provide the compounded sterile products (CSP) in a reasonable period of time to meet patient need. The CSPs may be dispensed patient-specifically or may be provided as non-patient specific anticipatory CSPs. The compounding pharmacy shall immediately notify the board if this allowance will be utilized.

Nurses performing duties of pharmacy technician in opioid treatment center pharmacies (§54.1-3321)

Nurses practicing at an opioid treatment program (OTP) pharmacy may assist pharmacists by performing the duties of a pharmacy technician without holding such registration by preparing take-home doses which will be verified for accuracy by a pharmacist prior to dispensing.

NEW as of 4/7/2020: Physicians mailing or delivering dispensed drugs (§54.1-3401)

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Notwithstanding the definition of “dispense” in Va. Code § 54.1-3401, practitioners of medicine or osteopathy licensed by the Board of Pharmacy to sell controlled substances may dispense drugs to patients by mailing them to the patient’s residence or by delivering them to the patient’s residence under the following conditions: 1. Written notice shall be placed in each shipment alerting the consumer that under certain circumstances chemical degradation of drugs may occur; and 2. Written notice shall be placed in each shipment providing a toll-free or local consumer access telephone number or email address which is designed to respond to consumer questions pertaining to chemical degradation of drugs.

Amended 5/4/2020: Mailing Dispensed Drugs and Proof of Identity Requirements (§ 54.1-3420.1)

As a reminder and to decrease spread of virus through handling identification cards, § 54.1-3420.1 allows for simply recording the full name and address of the unknown person taking delivery of a Schedule II drug prescribed for someone else. This is an alternative option, in lieu of making a photocopy of the person’s identification. Additionally, please recall that a dispensed drug, including a Schedule II drug, may be delivered or mailed to a patient’s residence. It must be mailed such that the package does not indicate that it contains drugs and the pharmacy shall comply with delivery and proof of identity requirements found in 54.1-3420.1 and 54.1-3420.2.

Excerpt of § 54.1-3420.2. Delivery of prescription drug order.

A. Whenever any pharmacy permitted to operate in this Commonwealth or nonresident pharmacy registered to conduct business in the Commonwealth delivers a prescription drug order by mail, common carrier, or delivery service, when the drug order is not personally hand delivered directly, to the patient or his agent at the person's residence or other designated location, the following conditions shall be required:

1. Written notice shall be placed in each shipment alerting the consumer that under certain circumstances chemical degradation of drugs may occur; and
2. Written notice shall be placed in each shipment providing a toll-free or local consumer access telephone number which is designed to respond to consumer questions pertaining to chemical degradation of drugs.

B. If a prescription drug order for a Schedule VI controlled substance is not personally hand delivered directly to the patient or the patient's agent, or if the prescription drug order is not delivered to the residence of the patient, the delivery location shall hold a current permit, license, or registration with the Board that authorizes the possession of controlled substances at that location. The Board shall promulgate regulations related to the security, access, required records, accountability, storage, and accuracy of delivery of such drug delivery systems. Schedule II through Schedule V controlled substances shall be delivered to an alternate delivery location only if such delivery is authorized by federal law and regulations of the Board.

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§ 54.1-3420.1. Identification required for filling prescriptions.

A. Before dispensing any drug listed on Schedules III through V, a pharmacist may require proof of identity from any patient presenting a prescription or requesting a refill of a prescription.

B. A pharmacist, or his agent, shall require proof of identity at the time of delivery from any person seeking to take delivery of any drug listed on Schedule II pursuant to a valid prescription, unless such person is known to the pharmacist or to his agent. If the person seeking to take delivery of a drug listed on Schedule II pursuant to a valid prescription is not the patient for whom the drug is prescribed, and the person is not known to the pharmacist or his agent, the pharmacist or his agent shall either make a photocopy or electronic copy of such person's identification or record the full name and address of such person. The pharmacist shall keep records of the names and addresses or copies of proof of identity of persons taking delivery of drugs as required by this subsection for a period of at least one month. For the purposes of this subsection, "proof of identity" means a driver's license, government-issued identification card, or other photo identification along with documentation of the person's current address.

C. Whenever any pharmacist permitted to operate in the Commonwealth or nonresident pharmacist registered to conduct business in the Commonwealth delivers a prescription drug order for any drug listed on Schedule II by mail, common carrier, or delivery service to a Virginia address, the method of delivery employed shall require the signature of the recipient as confirmation of receipt.

New as of 4/28/2020: 5% Distribution Rule (§ 54.1-3435.02(A))

Notwithstanding Virginia Code § 54.1-3435.02(A), a permitted pharmacy that fully complies with all other requirements of 21 CFR 1307.11 may distribute controlled substances beyond five percent of the gross annual sales of prescription drugs by the relevant permitted pharmacy or beyond five percent of the total dosage units of the Schedule II through V controlled substances dispensed annually by the relevant permitted pharmacy without being licensed as a wholesale distributor. This exception is in effect until the public health emergency declared by the Governor in EO51 expires or is terminated, unless the Board of Pharmacy specifies an earlier date or otherwise first modifies or withdraws this exception. All distributions made by a permitted pharmacy from January 1, 2020, until the date this exception ends will be excluded from consideration in applying the five percent wholesale distribution restrictions in § 54.1-3435.02(A).

Amended 5/4/2020: Additional Resources:

(New as of 5/4/2020) DEA Actions to Address COVID-19 - <https://www.deadiversion.usdoj.gov/coronavirus.html>

(New as of 5/4/2020) FDA Actions to Address COVID-19 - <https://www.fda.gov/emergency-preparedness-and-response/counterterrorism-and-emerging-threats/coronavirus-disease-2019-covid-19>

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(New as of 4/10/2020) VDH Weekly Activity Report -
<http://www.vdh.virginia.gov/coronavirus/weekly-report/>

VDH Coronavirus Disease 2019 (COVID-19), including Information for Healthcare Professionals, and Print Resources/Infographics: <http://www.vdh.virginia.gov/surveillance-and-investigation/novel-coronavirus/>

Pharmacists Can Help Slow the Spread of COVID-19:
<http://www.vdh.virginia.gov/content/uploads/sites/182/2020/03/Pharmacists-Can-Help-Slow-The-Spread-COVID19-03242020.pdf>

Clinician Letters from the Health Commissioner:
<http://www.vdh.virginia.gov/clinicians/clinician-letters/>

CDC Interim Guidance for Businesses and Employers: https://www.cdc.gov/coronavirus/2019-ncov/community/guidance-business-response.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fspecific-groups%2Fguidance-business-response.html

CDC Information for Healthcare Professionals: <https://www.cdc.gov/coronavirus/2019-nCoV/hcp/index.html>

Virginia Board of Pharmacy: <https://www.dhp.virginia.gov/pharmacy/>

From *The Pharmacy Act and Drug Control Act with Related Statutes*, July 1, 2019:

§ 54.1-3307.3. Waiver of requirements; declared disaster or state of emergency.

When the Governor has declared a disaster or a state of emergency pursuant to Chapter 3.2 (§ 44-146.13 et seq.) of Title 44 and it is necessary to permit the provision of needed drugs, devices, and pharmacy services to the citizens of the Commonwealth, the Board may waive the requirements of this chapter, the Drug Control Act (§ 54.1-3400 et seq.), and the Board's regulations governing the practice of pharmacy (18 VAC 110-20-10 et seq.). However, the Board shall not authorize the administering or dispensing of controlled substances by persons whose scope of practice does not include such authority.

Executive Order Amended Number Fifty-One (2020):
<https://www.governor.virginia.gov/executive-actions/>