STATE OF VERMONT
SECRETARY OF STATE
OFFICE OF PROFESSIONAL REGULATION
BOARD OF PHARMACY

COVID-19 EMERGENCY GUIDANCE

This guidance document clarifies Vermont Office of Professional Regulation and Vermont Board of Pharmacy policies, interpretations, and recommendations to address the COVID-19 pandemic. This guidance will be modified and expanded in response to new developments.

New content in this version (v2020-5-21) addresses:
- **Pharmacy-based testing (p. 7)**

New content in the previous version (v2020-4-10) addressed:
- **Prescription Extension & Therapeutic Substitution (Act 91)**
- **Drug Utilization Review relative to inappropriate COVID-19 related prescribing**
- **Interruption of Operations: Wholesale Distributors, Third-Party Logistics Providers, Warehouses**
- **Interruption of Operations: Retail Pharmacies**
- **Modification of Facility Access, Counseling Practices, and Employee Work Sites**

The Office of Professional Regulation is closed to the public. The Vermont Board of Pharmacy will convene meetings by webinar for the duration of the declared state of emergency. Videoconference links will be included in all meeting agendas.

Adjustment of Fill Quantity; 30-to-90 Switches

In a declared State of Emergency, a pharmacist may disregard individual fill quantities, up to the total prescribed quantity or ninety days, whichever first occurs. For example, a prescription for six-month supply, to be dispensed in 30-day fills, may be dispensed in two, 90-day fills. Fill quantities may not be extended for controlled drugs.

Effect of Online Consultation on Legitimacy of Prescriptions

Rule 10.2 provides:

> *10.2 Legitimate Prescriptions. A prescription or drug order for a legend drug is not valid unless it is issued for a legitimate medical purpose arising from a prescriber-patient relationship which includes a documented patient evaluation adequate to establish diagnoses and identify underlying conditions and/or contraindications to the treatment. Treatment, including issuing a prescription or drug order, based solely on an online questionnaire or consultation outside of an ongoing clinical relationship does not constitute a legitimate medical purpose.*

The purpose of Rule 10.2 is to ensure that a prescription drug order is based upon a legitimate and competent medical assessment of a patient based upon a bona fide prescriber-patient relationship. Remote consultation *by an existing care provider* is adequate to render a prescription "legitimate" for purposes of the Rule.

In a declared state of emergency, remote consultation *by a provider who had no previous relationship with a patient* may be "legitimate" if a pharmacist is comfortable that:

(1) the provider is lawfully authorized to prescribe;
(2) the provider collected from the patient, whether in-person or otherwise, information adequate to assess the patient's fitness for the pharmacotherapy ordered;
(3) the provider appears to have exercised responsible professional discretion; and
(4) the prescription otherwise passes drug-utilization review.

Compounding Alcohol-Based Hand Sanitizer Products

To address shortages and prevent consumers attempting to produce homemade hand-sanitizer products, FDA has issued a *Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency*. Vermont compounders may produce products consistent with FDA policy.

Conservation of Personal Protective Equipment and Garb

In a declared State of Emergency, compounding garb and personal protective equipment (PPE) may not be available in quantities sufficient to support USP standards. In such a case, the Office of Professional Regulation recommends following the guidance found in USP Response to Shortages of Garb and Personal Protective Equipment (PPE) for Sterile Compounding During COVID-19 Pandemic whenever possible, but will exercise its enforcement discretion to permit adherence to best practices outside USP <797> when necessary to preserve the safe continuity of pharmacy operations. If reuse of disposable garb is unavoidable, the Board and Office endorse the following bulleted guidance on such practices, adapted from our counterparts in Iowa:

Recommendations:

❏ Inventory your pharmacy's current supplies of garb to determine how long the garb is likely to last under current policies. If your current supply is running low, attempt to order more (regular size order, not hoarding) if you can. If your supply (existing plus future order capability) will not be sufficient to last TWO months, consider immediate implementation of one or more of these strategies for conservation.

❏ Utilize existing Standard Operating Procedures to limit exposure and limit use of garb.

❏ Limit personnel entering the clean room (exclude anyone exhibiting signs of any illness, reduce the number of personnel engaged in compounding activities, stage supplies outside the compounding area, minimize trips into the clean room, etc.).

❏ Limit contamination (ensure personnel hygiene, wear freshly laundered scrubs every day, meticulous disinfection, walk slowly and deliberately in the clean room, re-sanitize frequently, don't talk while compounding, don't touch your face mask after donning, etc.).

❏ If circumstances require re-use of PPE or garbing, a beyond use date should never be extended beyond USP <795> or <797> standards.

❏ Responses to a shoe cover shortage

- ❑ Consider use of cleanable, facility-dedicated shoes that are not worn outside the compounding area.
- ❑ Source alternative shoe covers, such as those used on construction sites.
- ❑ Use dedicated shoes in Hazardous Drug (HD) compounding areas and reduce use to one set of covers.
- ❑ Do not reuse shoe covers, including turning them inside out for reuse.
- ❑ Develop systems to deliver materials to compounding employees to reduce HD garb change required when entering the HD space. The use of pass-throughs and dedicated carts should be formalized and maximized.

❑ Responses to a mask shortage

- ❑ If available, substitute N-95 masks for clean room masks. When using an N-95 mask for non-HD sterile compounding procedures, fit testing is not required.
- ❑ Employ use of washable, polyester fabric masks as described in the USP guidance.
- ❑ Consider limited reuse of face masks used in non-HD compounding, if washable, polyester fabric masks is not possible.
- ❑ Store the carefully doffed mask for reuse in a new paper bag.
- ❑ Masks should never be shared between employees.
- ❑ Retained masks should be stored where they are donned, individually identified, donned prior to hand washing, and not touched on the inside or outside after proper placement.
- ❑ Retained masks should be replaced when the mask condition is questionable, the mask is visibly soiled, or after a workday.

❑ Responses to a gown shortage

- ❑ Decrease the number of employees in the sterile compounding area to reduce use.
- ❑ Consider using already garbed compounding staff for facility cleaning/disinfecting activities, rather than utilizing more garb for environmental services employees.
- ❑ Retain and reuse gowns for an entire shift/day.
- ❑ If gowns are reused for longer periods of reuse (no more than 1 week), store them on individual hooks. Do not store them inside out. Deliberate and careful removal is recommended.
- ❑ Gowns should be stored on the clean side of the ante room away from the sink.
- ❑ Gowns should be discarded when they are visibly soiled or after a period of time as determined in facility policy.
- ❑ Gowns used for cleaning or HD compounding should not be retained or reused.
- ❑ Disposable sleeve covers (sterile or non-sterile are permitted) may influence the reasonable re-use of gowns.

❑ Use of sleeve covers

- ❑ Sleeve covers should be opened in the buffer room/SCA area after handwashing procedures and the gown is donned.
- ❑ Sleeve covers should be placed over the donned gown sleeve and should close tightly at the wrist.
- ❑ Sterile gloves should be donned last and cover the wrist of the sleeve cover.

❑ Response to hand sanitizer shortage

- ❑ Consider limiting hand sanitizer use to glove change procedures only.
- ❑ Alcohol-based hand sanitizer not intended for clean room or surgical use may be utilized as a replacement.

❑ IF you have implemented any of the above recommended conservation strategies, implement additional environmental monitoring in the PEC used for sterile compounding.

- ❑ Weekly, dynamic microbial surface sampling inside the PEC on the Direct Compounding Area (DCA).
  - ❑ If growth occurs, consider changes to supply cleaning/disinfecting procedures, changes to the procedure for material transfer into the PEC, or increasing the frequency of DCA sanitation procedures. Further testing growth to genus level would only be expected when growth exceeds action levels.
  - ❑ If a growth occurs that exceeds action levels, retrain staff, resample the site, and potentially decrease the BUD until a compliant sample is obtained.

❑ When a garb shortage affects Personal Protective Equipment (PPE) used for HD compounding:

- ❑ The current recommendation is that garb used in HD compounding should not be reused.
- ❑ Implement process changes that reduce the use of PPE, such as:
  - ❑ Grouping HD compounding together,
  - ❑ Designating a time when HD compounding is performed,
  - ❑ Adjusting personnel schedules to limit to the extent possible the number of HD compounding personnel,
  - ❑ Encouraging HD handling in PECs (per Assessments of Risk (AoRs), PPE including respiratory protection may be required when handling occurs outside a PEC, but some may not be required when using a PEC), and/or
  - ❑ Considering the use of other respiratory protection such as a PAPR (Powered Air Purifying Respirator), if available, when an N95 mask is otherwise required.

Prescription Extension and Therapeutic Substitution

Act 91, Sec. 10 (eff. March 30, 2020), authorizes pharmacists to extend prescriptions as follows:

> ***Sec. 10. Extension of Prescription for Maintenance Medication***
> *(a) During a declared state of emergency in Vermont as a result of COVID-19, a pharmacist may extend a previous prescription for a maintenance medication for which the patient has no refills remaining or for which the authorization for refills has recently expired if it is not feasible to obtain a new prescription or refill authorization from the prescriber.*
> *(b) A pharmacist who extends a prescription for a maintenance medication pursuant to this section shall take all reasonable measures to notify the prescriber of the prescription extension in a timely manner.*
> *(c) As used in this section, "maintenance medication" means a prescription drug taken on a regular basis over an extended period of time to treat a chronic or long-term condition. The term does not include a regulated drug, as defined in 18 V.S.A. § 4201.*

Act 91, Sec 11 (eff. March 30, 2020), authorizes pharmacists to make therapeutic substitutions as follows:

> ***Sec. 11. Therapeutic Substitution Due to Lack of Availability***
> *(a) During a declared state of emergency in Vermont as a result of COVID-19, a pharmacist may, with the informed consent of the patient, substitute an available drug or insulin product for an unavailable prescribed drug or insulin product in the same therapeutic class if the available drug or insulin product would, in the clinical judgment of the pharmacist, have substantially equivalent therapeutic effect even though it is not a therapeutic equivalent.*
> *(b) As soon as reasonably possible after substituting a drug or insulin product pursuant to subsection (a) of this section, the pharmacist shall notify the prescribing clinician of the drug or insulin product, dose, and quantity actually dispensed to the patient.*

Recommended Procedure for Act 91 Prescription Extension or Therapeutic Substitution

1. Process the substitution in the same fashion as you would a telephone order with the prescriber - reduce it to writing to serve as a new prescription for processing, noting on the prescription, for example:
   For prescription extension: "Refill extension per Act 91"
   For therapeutic substitution "Proair being replaced with Xopenex – per Act 91—product unavailable"
   a. Whenever possible, use the original prescription order, to serve as documentation of the original prescription – either by printing it or via electronic means
   b. If the original prescription order cannot be printed/electronically assigned, write a new prescription using the information provided on the original order.
   c. Document the original prescription number for reference as necessary.
2. All other items on the prescription should remain the same: the prescriber, as well as remaining # refills from the original prescription.
3. This will generate a new prescription number in the dispensing system, and the original prescription should be deactivated. The original prescription may be reactivated, should the originally prescribed product become available with valid refills remaining.
4. The date on the new prescription should be the date the substitution is made

Understanding "Informed Consent" in the Context of Act 91 Therapeutic Substitution

Informed consent is a process of communication between patient and health care provider that often leads to agreement or permission for care, treatment, or services.

An effective informed consent will communicate to the patient, in terms the patient can understand, the relevant risks, benefits, and choices confronting the patient; it will convey at least the following:

- ✓ that the drug to be dispensed will differ from the drug initially prescribed;
- ✓ the reasons for substitution;
- ✓ the relevant risks of substitution versus interruption or delay in pharmacotherapy;
- ✓ any known information about the likelihood the drug initially prescribed can be obtained elsewhere or later;
- ✓ that the patient may refuse substitution and seek the drug elsewhere or later;
- ✓ what the patient should do if an adverse reaction or outcome presents itself;

- ✓ what the patient should know about differences in appropriate storage, dosing, or administration.

It is wise to document informed consent to therapeutic substitution in writing. Pharmacies may use, but are not required to use, the template offered at the Board's Statutes Rules & Resources page. To minimize close contact and sharing of writing implements, manual patient signature is not required.

Drug Utilization Review: Clinically Inappropriate COVID-19 Related Prescribing

Pharmacists should be aware of, and are professionally responsible to adhere to, the April 10 Emergency Regulatory Order instructing pharmacists to employ enhanced drug utilization review to curb inappropriate prescribing.

For purposes of the Order, a prescription is not a "*newly established* outpatient prescription drug order" if it continues a pharmacotherapy initiated for an inpatient prior to discharge.

Interruption of Operations: Wholesale Distributors, Third-Party Logistics Providers, Warehouses

State-licensed wholesale distributors, third-party logistics providers, and warehouses may encounter operational disruptions if employee illness or facility sanitation requirements take a licensed supply-chain partner offline. For the duration of the declared state of emergency in Vermont, such licensed entities are authorized to source drugs from unlicensed sites, so long as source sites are licensed in good standing in any U.S. jurisdiction. As promptly as reasonably possible, the Vermont-licensed entity is to email the unlicensed site's (1) name, (2) address, and (3) anticipated stop and start dates to corey.young@vermont.gov and carrie.phillips@vermont.gov.

Interruption of Operations: Retail Pharmacies

A retail pharmacy compelled to close temporarily for COVID-19 related reasons is excused from the requirements of Board of Pharmacy Administrative Rule 8.3 if it promptly emails a concise statement of reasons and expected duration to corey.young@vermont.gov and carrie.phillips@vermont.gov.

Modification of Facility Access, Counseling Practices, and Employee Work Sites

A retail pharmacy may modify access to its premises—for example, by limiting dispensing to curbside or drive-up service—as necessary and appropriate to minimize in-person contact and adhere to CDC guidance.

Patient counseling obligations remain in force; however, intercom or telephonic consultation may be substituted for face-to-face consultation.

Employees who can work from home performing processing activities, such as order entry or remote utilization review, may and should. Routine quality assurance procedures should be employed to ensure

data privacy and security; reliable access to the patient records in the pharmacy system; and satisfactory function of video/telecommunication equipment.

COVID-19 Testing

The U.S. Department of Health & Human Services (HHS) has issued guidance under the Public Readiness and Emergency Preparedness Act ("the PREP Act") authorizing pharmacists to order and administer COVID-19 tests. See the HHS Guidance for Licensed Pharmacists, COVID-19 Testing, and Immunity under the PREP Act and FDA's Emergency Use Authorizations.

Pursuant to Executive Order 01-20, ¶¶ 15-16, the Commissioner of Health and the Secretary of State authorize Vermont pharmacists to order and administer COVID-19 tests approved by FDA and the Vermont Department of Health for pharmacy-based sample collection or administration.

Sites

Pharmacy-based COVID-19 testing sites are appropriate only for asymptomatic persons. Symptomatic persons should stay home and call their health care provider or 2-1-1 for guidance. All public notices or advertisements concerning pharmacy-based testing shall carry this instruction.

COVID-19 sample collection and testing are to occur in separately designated patient testing areas outside of pharmacies, such as drive-up windows or parking lots.

Reporting

A pharmacy that offers COVID-19 testing must report test results to the Vermont Department of Health (VDH) Health Information Exchange, as required by the Reportable and Communicable Diseases Rule, CVR 13-140-007.

A pharmacy that collects specimen samples for transmission to a reference laboratory must ensure that the laboratory has a reliable process for reporting results to the VDH Health Information Exchange.

Electronic reporting capabilities for COVID-19 results must be established and validated before testing begins. Testing facilities performing rapid tests will have two options for electronic reporting: HL7 Results Interface or .CSV File. Pharmacies are encouraged to choose the option that can be most quickly and most reliably be implemented at the facility.

OPTION 1: HL7 Results Interface *preferred method*

- HL7 electronic lab reporting is designated as a requirement of Meaningful Use under the Affordable Care Act.
- If able, the clinical lab should use their Electronic Lab System and establish an interface with these instruments.
- Facilities should inform AHS.VDHELRSupport@vermont.gov about the HL7 capabilities.
- Facilities should send HL7 messages to VDH through existing testing feeds.
    - HL7 onboarding for these COVID-19 results will be expediated.

OPTION 2: .CSV File Upload to Globalscape (.sftp site)

- Data must be populated and submitted DAILY with the required variables, value set, and schema (see attached template: CSV_Required_Fields_COVID.xlsx).
- The Health Department will work with every facility to ensure a secure file drop mechanism through existing Globalscape accounts. Contact AHS.VDHELRSupport@vermont.gov.
- The Health Department will convert the data so it can be consumed by NBS.
- This will not replace the need for continued HL7 onboarding for Meaningful Use.

Notification to Patients

A pharmacy must convey test results to patients and their primary care providers of record within 24 hours of result, in a manner that maintains patient privacy in accordance with state and federal laws and regulations. A pharmacy that collects specimen samples for transmission to an outside laboratory must ensure that the laboratory has a reliable process for conveying test results to patients and their primary care providers within 24 hours of result. VDH will supply to participating pharmacies standard-form instructions to convey with test results.

Clinical Laboratory Improvement Act (CLIA) Certificates of Waiver

A CLIA Certificate of Waiver is not required for a pharmacy to collect specimen samples for transmission *to an outside laboratory*.

A CLIA Certificate of Waiver is required for a pharmacy to collect specimen samples for CLIA-waived testing *at the pharmacy*. See the CMS document How to Apply for a CLIA Certificate of Waiver.

A pharmacy may begin testing when its CLIA number is received by electronic mail.

Identifying CLIA-waived Point-of-Care COVID-19 Tests

FDA recently clarified that, when it grants an Emergency Use Authorization (EUA) for a point-of-care test, that test is deemed to be CLIA-waived.

To identify CLIA-waived point-of-care tests:

(a.) Access the FDA's EUA website.
(b.) Scroll down to find the "In Vitro Diagnostics EUAs."
(c.) Under the heading "Authorized Setting(s)," look for tests marked "W."

Personnel & Training

Licensed pharmacists, as well as pharmacy interns and registered pharmacy technicians under the direct supervision of a pharmacist, may collect specimen samples and perform point-of-care COVID-19 testing. A pharmacy shall implement policies and procedures suited to ensure that all personnel participating in sample collection or testing are trained to perform required tasks safely, effectively, and consistently. This includes adherence to the testing device manufacturer's instructions. Completion of training must be documented. For additional information, refer to the following CDC's website sections "Guidelines for Clinical Specimens" and the Office of the Assistant Secretary for Health (OASH) COVID-19 Fact Sheet for Nasal Specimen Collection.

Personal Protective Equipment & Supplies

Guidance on infection control measures and PPE appropriate for collection and handling of patient-collected specimens is available from CDC's website. Pharmacies generally must secure their own test kits, supplies, and PPE.

Checklist

Pharmacies interested in testing may find helpful the COVID-19 Molecular Testing Pharmacy Checklist.