

**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 questions, new legislation, and executive orders. Action on emergency extension of maintenance prescriptions, for example, is expected soon.

To minimize person-to-person contact, 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. Please do not come in person to the Office of Professional Regulation.

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 will exercise its enforcement discretion to permit adherence to best practices outside USP <797> when necessary to preserve the safe continuity of pharmacy operations. The Board and Office endorse the following bulleted guidance, 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.
 - Consider limited reuse of face masks used in non-HD compounding.
 - 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.