



South Carolina
Department of Labor, Licensing and Regulation



Board of Pharmacy

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Henry D. McMaster
Governor

Emily H. Farr
Director

PUBLIC HEALTH STATE OF EMERGENCY ORDER 2020-BOP-PH-06

**ORDER ESTABLISHING SAFE HARBOR FOR PREPARATION OF
PHARMACEUTICAL PRODUCTS
IN LIGHT OF NATIONAL GARB/PPE SHORTAGE**

WHEREAS, on March 13, 2020, Governor Henry McMaster issued Executive Order No. 2020-08 declaring a public health emergency due to the evolving nature and scope of the public health threat or other risks posed by COVID-19 and the actual and anticipated impacts associated with the same;

WHEREAS, Governor McMaster has issued subsequent Executive Orders in which he has taken additional action to protect the citizens of South Carolina, including Executive Order No. 2020-10, which “authorize[d] and direct[ed] any agency within the undersigned’s Cabinet or any other department within the Executive Branch, as defined by section 1-30-10 of the South Carolina Code of Laws, as amended, through its respective director or secretary, to waive or ‘suspend provisions of existing regulations prescribing procedures for conduct of state business if strict compliance with the provisions thereof would in any way prevent, hinder, or delay necessary action in coping with the emergency,’ [. . .];”

WHEREAS, S.C. Code Ann. § 40-43-10 provides that the purpose of the South Carolina Board of Pharmacy (“Board”) is to “promote, preserve, and protect the public health, safety, and welfare by and through the effective control and regulation of the practice of pharmacy; the licensure of pharmacists; the licensure, permitting, control, and regulation of all sites or persons, in or out of this State, that distribute, manufacture, possess, or sell drugs or devices within this State, as may be used in the diagnosis, treatment, and prevention of injury, illness, and disease of a patient or other individual;”

WHEREAS, the South Carolina Pharmacy Practice Act requires appropriate garb for personnel involved in the preparation of sterile products. *See* S.C. Code Ann. § 40-43-88(F)(1). Likewise, appropriate personal protective equipment (“PPE”) must be worn by personnel compounding hazardous agents. S.C. Code Ann. § 40-43-88(E)(2);

WHEREAS, the Board recognizes that a shortage of appropriate garb and PPE has arisen as a result of the COVID-19 pandemic;

WHEREAS, this nationwide shortage has resulted in uncertainty in the pharmacy community and has made strict compliance with applicable compounding standards difficult;

WHEREAS, the Board concludes that it is necessary to provide a safe harbor for its permittees affected by the shortage of garb and PPE so that they can continue to produce much-needed drugs;

NOW, THEREFORE, for the reasons set forth above, effective immediately, the Board hereby establishes the safe harbor provisions attached hereto as “Exhibit A” and incorporated by reference herein for permittees facing a shortage of garb and/or PPE. To the extent practice within these safe harbor provisions violate any provision of the South Carolina Pharmacy Practice Act, the Board hereby suspends enforcement of any such provision for the duration of this Order. This Order shall remain in effect for the duration of the declared public health state of emergency, unless otherwise modified, amended, or rescinded by subsequent order.

IT IS SO ORDERED.

March 23, 2020

STATE BOARD OF PHARMACY

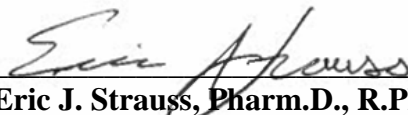

Eric J. Strauss, Pharm.D., R.Ph.
Board Chair

EXHIBIT A

Masks:

- Mask may be reused.
- Must be marked on the outside, prior to use, with initials of staff member.
- Doff the mask on the dirty side of the ante-room.
- Place each mask for reuse in its own appropriate enclosure. Be sure to use a new enclosure each time, discarding the previous enclosure.
- Place all masks in their enclosures in a container located where the masks are normally donned.
- Masks should be donned in normal garbing order.
- **DO NOT TOUCH YOUR MASK ONCE IT IS DONNED!**
- Mask should be discarded when:
 - It is visibly soiled or torn
 - It has touched a contaminated surface
 - It has been worn during cleaning activities
- Masks should not be reused when compounding HDs

Shoe Covers:

- Do not reuse shoe covers including turning them inside out for reuse.
- If normal supply of shoe covers is running low, we suggest implementing “facility-dedicated” shoes (shoes that do not leave the compounding area).
- Shoe covers still need to be worn for compounding HDs – consider the use of dedicated shoes in the HD compounding areas and reduce use to one set of shoe covers.

Gowns:

- 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.
- When gowns are reused, add disposable sleeve covers
- Gowns should be discarded when:
 - It is visibly soiled or torn
 - It has touched a contaminated surface
 - It has been worn during cleaning activities
- Doffing Gowns (for reuse):
 - Remove gowns slowly and carefully.
 - Try to remove gown standing near a return.
 - Hang gowns on clean side of the anteroom far away from the sink.
- Never reuse HD gowns or gowns that have been used in cleaning.

Disposable Sleeve Covers:

- Sleeve covers should be opened in the buffer room 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.

Alcohol-Based Hand Rub:

- Conserve for applying during the glove change only.
- Alcohol-based hand sanitizer not intended for clean room or surgical use may be utilized.

If you have implemented any of the above recommendations, implement additional environmental monitoring in the PEC used for sterile compounding.

- Weekly, dynamic microbial surface sampling inside the PEC on the Direct Compounding Area.
- If growth occurs, consider changes to cleaning/disinfecting procedures, changes to the procedure for material transfer into the PEC or increasing the frequency of DCA sanitation procedures.
- If a growth occurs that exceeds action levels, retrain staff, resample the site and potentially decrease the BUD until a compliant sample is obtained.
- While weekly dynamic microbial surface sampling inside the PEC is preferred, if this is not possible, BUDs must be limited to Category 1 compounding (12 hours at room temperature or 24 hours under refrigeration).

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

- 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 the number of HD personnel,
 - Encourage handling in PECs, some PPEs may not be required when using a PEC,
 - Consider using other respiratory protection