North Carolina Board of Pharmacy Recommendations Concerning Potential Compounding Garb Shortages

In light of the current escalation of the spread of COVID-19, there may be limitations in the supply chain for protective garbing supplies. This Board guidance offers recommendations and strategies to conserve protective garb while maintaining an appropriate level of containment and limiting exposure of compounded sterile products to contaminants.

Please note that engaging in some of these recommendations may result in your pharmacy being out of compliance with USP Chapters <795> and <797>. The Board will exercise enforcement discretion during this time of limited supplies ***IF*** your pharmacy can demonstrate it complied with best practices during a period of documented supply limitations. If your pharmacy decides to implement any of the following recommendations during a shortage period, and implementation results in noncompliance with USP Chapters <795> and <797>, you must develop and maintain a policy demonstrating compliance with best practices (e.g., if reusing face masks, you must develop a policy and procedure for identification, storage, and handling of face masks subject to reuse).

Recommendations:

1. **In considering and implementing recommendations for conserving protective garb, priority must be given to preserving garb for direct patient care personnel.**

2. Inventory your pharmacy's current protective garb supplies and assess 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.

3. Utilize existing Standard Operating Procedures to limit exposure and limit use of garb
    a. 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.)
    b. 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.)

4. In Response to a mask shortage
    a. United States Pharmacopeia (USP) issued guidance concerning garb shortages. The link can be found here: https://www.usp.org/sites/default/files/usp/document/about/public-policy/usp-covid19-garb-and-ppe.pdf

    b. Consider limited reuse of face masks used in non-HD compounding.
        i. Store the mask in a new, paper bag (or something clean and breathable) after each use.
        ii. Do not touch inside of mask.
        iii. Masks should never be shared between employees.

        iv. Retained masks should be stored where they are donned, individually identified, donned prior to hand washing, and not touched after proper placement.
        v. Retained masks should be replaced when the mask condition is questionable, the mask is visibly soiled, or after a period of time as determined in facility policy. This policy should be based on handling technique and condition of the mask.

5. In Response to a gown shortage
    a. Decrease the number of employees in the sterile compounding area to reduce use.
        i. Consider using already garbed compounding staff for facility cleaning/disinfecting activities, rather than utilizing more garb for environmental services employees.
    b. Retain and reuse gowns for an entire shift/day.
    c. 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 essential.
        i. Remove gowns slowly and carefully.
        ii. Gowns should be stored on the clean side of the ante room away from the sink.
        iii. Gowns should be discarded when they are visibly soiled or after a period of time as determined in facility policy.
        iv. Gowns used for cleaning or HD compounding should not be retained or reused.
    d. When gowns are reused, add disposable sleeve covers (sterile or non-sterile are permitted)

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

7. In Response to a shoe cover shortage
    a. Do not reuse shoe covers, including turning them inside out for reuse.
    b. Consider use of cleanable, facility-dedicated shoes that are not worn outside the compounding area.
    c. Source alternative shoe covers, such as construction grade shoes covers.
    d. Consider the use of dedicated shoes in Hazardous Drug (HD) compounding areas and reduce use to one set of shoe covers.
    e. 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.

8. In Response to hand sanitizer shortage
    a. Consider limiting hand sanitizer use to glove change procedures only.
    b. Alcohol-based hand sanitizer not intended for clean room or surgical use may be utilized as a replacement.
    c. Do not apply IPA directly to hands.
    d. FDA has issued guidance concerning the compounding of Hand Sanitizer. : http://www.ncbop.org/PDF/Guidance_hand_sanitizers_031420.pdf
    e. USP has also issued guidance concerning the compounding of hand sanitizer: https://www.usp.org/sites/default/files/usp/document/about/public-policy/usp-covid19-handrub.pdf
        i. USP has recommended 3 formulas for compounding hand sanitizer
        ii. If implementing the provisions in this document, the expectation is that compounders follow USP General Chapter Pharmaceutical Compounding – Nonsterile Preparations, including the following:3 `
            1. Personnel trained in the compounding procedures
            2. USP, NF or Food Chemicals Codex (FCC) grade ingredients should be used as the recommended source of ingredients
                a. When components meeting compendial quality standards are not obtainable, components of equivalent quality – such as those that are chemically pure, analytical reagent grade or American Chemical Society-certified – may be used.
            3. All equipment to be clean, properly maintained, and used appropriately
            4. A Master Formulation Record and Compounding Record to be prepared
            5. A Beyond-Use Date to be assigned ` The preparation to be appropriately labeled
                a. Label to note the final concentration of ethanol or isopropyl alcohol
        iii. Understanding that there may be shortages of ingredients used to compound these formulations of alcohol-based sanitizers, the USP CMP EC provides the following notes on substitution.
            1. Both General Chapter and this document note that USP, NF or FCC grade ingredients should be used as the recommended source of ingredients. When components meeting compendial quality standards are not obtainable, components of equivalent quality – such as those that are chemically pure, analytical reagent grade, or American Chemical Society-certified – may be used.

2. Use denatured alcohol over nondenatured alcohol because there have been reports of adverse events, including deaths, from unintentional ingestion of hand sanitizer, particularly in young children.
3. Glycerin and glycerol are synonymous and may be interchanged. ` Glycerin or glycerol are added as a humectant, and not to enhance viscosity.
4. No ingredients should be added to enhance viscosity as they may decrease the effectiveness of the final preparation.

f. FDA has issued guidance concerning the manufacturing of Ethanol for the use in making Hand Sanitizer: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/temporary-policy-manufacture-alcohol-incorporation-alcohol-based-hand-sanitizer-products-during

9. In Response to Sterile Isopropyl Alcohol
   a. Always use sIPA
      i. When sanitizing sterile gloves
      ii. To wipe down Direct Compounding Area (DCA)
      iii. To wipe critical sites
   b. Consider using presaturated sterile wipes
   c. Consider using a registered low residue EPA registered disinfectant to wipe down all surfaces in PEC, staging areas, and equipment.
      i. Wipe only DCA with sIPA
   d. Wipe items with a low residue EPA registered disinfectant instead of using sIPA

10. If you have implemented any of the above recommended conservation strategies, implement additional environmental monitoring in the PEC used for sterile compounding.
    a. Weekly, dynamic microbial surface sampling inside the PEC on the Direct Compounding Area (DCA).
       i. 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.
       ii. If a growth occurs that exceeds action levels, retrain staff, resample the site, and potentially decrease the BUD until a compliant sample is obtained.
    b. While weekly, dynamic microbial surface sampling inside the PEC is preferred, if this is not possible, BUDs must be limited to 12 hours at room temperature or 24 hours under refrigeration.

11. When a garb shortage affects Personal Protective Equipment (PPE) used for HD compounding.
    a. The current recommendation is that garb used in HD compounding should not be reused.
    b. Implement process changes that reduce the use of PPE, such as:
       i. Grouping HD compounding together,
       ii. Designating a time when HD compounding is performed,
       iii. Adjusting personnel schedules to limit to the extent possible the number of HD compounding personnel,
       iv. 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
       v. Considering the use of other respiratory protection such as a PAPR (Powered Air

Purifying Respirator), if available, when an N95 mask is otherwise required.

For additional references, information, and resources on COVID-19:

CDC COVID-19

https://www.cdc.gov/coronavirus/2019-ncov/index.html

Strategies for Optimizing Supply of N-95 Mask

https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/index.html

Critical Point Peer Network- information, including a recorded webinar entitled "COVID-19: Downstream Implications for Sterile Compounding", is available via the FREE "Silver Subscription"

https://peernetwork.criticalpoint.info

United States Pharmacopeia Response to Shortage of Garb Personnel Protective Equipment for Sterile Compounding during COVID-19 Pandemic

https://www.usp.org/sites/default/files/usp/document/about/public-policy/usp-covid19-garb-and-ppe.pdf

North Carolina Department of Health and Human Services COVID-19 Response

https://www.ncdhhs.gov/divisions/public-health/coronavirus-disease-2019-covid-19-response-north-carolina