USP Response to Shortages of Garb and Personal Protective Equipment (PPE) for Sterile Compounding During COVID-19 Pandemic

March 18, 2020

This document is for informational purposes only and is intended to address the garb and personal protective equipment (PPE) shortages caused by the COVID-19 pandemic. This does not reflect the Compounding Expert Committee's opinions on future revisions to official text of the *USP-NF*. USP is actively monitoring the evolving situation and will update this document accordingly.

Background and Introduction

USP General Chapter <797> *Pharmaceutical Compounding – Sterile Preparations* provides official standards for compounding quality sterile preparations. In addition to addressing personnel, facility, and monitoring requirements, the chapter sets forth garb requirements to minimize the microbial contamination risk for compounded sterile preparations (CSPs).[1] For compounding sterile hazardous drugs (HDs), General Chapter <797> requires PPE to minimize the exposure of healthcare workers to HDs. Additionally, USP General Chapter <800> *Hazardous Drugs – Handling in Healthcare Settings* is an official and informational chapter on handling HDs and includes PPE recommendations for compounding and other activities.[2]

In light of the rapidly evolving COVID-19 pandemic, the demand for garb and PPE is expected to continue to outpace available supply. During this pandemic, USP supports State Boards and other regulators using **risk-based enforcement discretion** related to the implementation of USP compounding standards.

The USP Compounding Expert Committee (CMP EC) provides the following garb and PPE conservation strategies for consideration and potential use during shortages for healthcare organizations and personnel during the COVID-19 pandemic. In light of the public health emergency posed by COVID-19, this document was developed without a public comment period. This document is not a USP compendial standard; rather, it reflects potential options developed by the USP CMP EC, based on their scientific and professional expertise, and with input from regulatory agencies at the federal and state level.

Implementing the strategies described below may not be aligned with provisions in General Chapter <797>. Reuse of garb and lack of garb may increase the risk of microbial contamination of the CSP and the environment. Facilities should carefully consider the impact on the CSP and the environment and implement risk-mitigating strategies to help ensure quality CSPs. Engineering controls are essential and must remain in effect to minimize the risk of contamination to the CSP and the environment. USP recommends that compounders also check with State Boards or regulatory bodies to determine the existence of waivers or interim requirements.

Conserve Garb and PPE.

Facilities should prioritize conservation of garb.

- Garb for direct patient care personnel should take priority.

[1] Free digital access to <797>: https://www.usp.org/compounding/general-chapter-797

[2] Free digital access to <800>: https://www.usp.org/compounding/general-chapter-hazardous-drugs-handling-healthcare

- Prioritize availability of sterile gloves above other garb for sterile compounding activities because direct contact contamination is the highest risk to the CSP.
- Inventory supply of garb to prepare and implement a temporary garb and PPE action plan. Ensure staff are properly trained to implement changes in garbing procedures. Check with suppliers on expected availability.
- Limit staff performing sterile compounding.
  - Schedule staff to maximize compounding time and limit number of compounders per day or shift.
  - Modify staging activities to minimize passage into and out of the compounding areas.
- If necessary, establish and document deviations from existing Standard Operating Procedures (SOPs).

For Shortages of Garb Used for Sterile Non-HD Compounding

- Face mask
  - Reuse of face masks is not recommended because of the risk of introducing microbial bioburden from used masks. Storage in bags (e.g., plastic or paper) is not recommended because they may contain bioburden and may generate particles and microbial contamination.
  - Use clean fabric (e.g., polyester) to cover nose and mouth (e.g., bandana, washable face mask). Don a clean face cover each time before entering the compounding area.
- Gown
  - Use clean, washable, dedicated non-disposable garments (e.g., gowns, lab coats). Long-sleeved garments are preferred, and if not available, wear sleeve covers. Preferably, wash garments after each shift or sooner when visibly soiled.
  - Retain and reuse disposable gowns as long as they are intact and not visibly soiled. Preferably, discard used disposable gowns each day.
  - Store garments in a manner that minimizes contamination.
    - Maintain garments inside of classified area or within the perimeter of the segregated compounding area (SCA).
- Head and hair cover
  - Use clean fabric to cover head and hair. Preferably, wash after each shift or sooner when visibly soiled.
- Shoe cover shortages
  - Implement dedicated shoes for the compounding area. Preferably, dedicated shoes should be cleaned regularly.

For Shortages of PPE Used for Sterile HD Compounding

- Prioritize gowns and chemotherapy gloves for preparing antineoplastic agents in Table 1 of the NIOSH list.[3]
- PPE is designed to minimize exposure of healthcare personnel to HDs. PPE should not be reused when compounding antineoplastic drugs in Table 1 of the NIOSH list.

If Facilities are Not Able to Obtain Garb or PPE

- Adopt a risk-based approach and limit anticipatory compounding.

[3] NIOSH List of Antineoplastic and other Hazardous Drugs in Healthcare Settings, 2016 at https://www.cdc.gov/niosh/docs/2016-161/pdfs/2016-161.pdf

- Storage times should be assigned conservatively based on patient need and the type of garb mitigation strategy that is used. Use the shortest feasible beyond-use dates (BUDs) while giving consideration to avoiding drug shortages and maintaining patient access to essential medications.
- Where feasible, increase cleaning and disinfecting frequency.
- Consider increasing frequency of surface sampling in the primary engineering control to determine effectiveness of cleaning procedures and work practices.
    - If any changes are needed, promptly remediate and consider assigning shorter BUDs.