

Pharmacy - Guidance Personal Protective Equipment and Cleaning Supplies Management in Compounding

Revised May 5, 2020 (revisions highlighted in yellow)

Purpose: To provide guidance for CommonSpirit Health (CSH) pharmacy compounding activities when the supply of manufactured pharmacy personal protective equipment (PPE) and/or cleaning supplies may be insufficient or unavailable. Pharmacy management strategies should be implemented without delay. Some of the pharmacy management strategies may be in conflict in meeting the requirements set forth by United States Pharmacopeia (USP) and/or an individual state Board of Pharmacy (BoP).

Procedure:

1. The pharmacist-in-charge (PIC) or designated person will decide whether the current stock and supply chain of PPE and cleaning supplies is insufficient, or is at imminent risk of becoming insufficient, to maintain compliance with USP <795>, <797>, and state BOPs.
2. After the determination of insufficient supply is made:
 - a. A facility level document shall be developed or reviewed (if developed previously) to reflect standards of practice used during extenuating circumstances and details for the conditions under which PPE may be reused and/or cleaning activities may be modified.
 - b. Master formulas used for the preparation of compounded sterile preparations (CSP) should be evaluated to determine if changes are necessary to the criteria for establishing beyond-use dating (BUD).
 - c. Surface sampling schedule will be reviewed for the possible need to increase the frequency.
3. Appendix A will be used as guidance by the PIC or designated person for necessary procedural changes based upon the availability of PPE and/or cleaning supplies.
4. The reuse process for PPE worn in non-hazardous and hazardous sterile compounding is an interim procedure and may not be compliant with current 2008 USP <797> standards. Pharmacy management strategies outlined in this document supersede any facility standard within the sterile, non-sterile, and hazardous drug compounding policies that are in direct conflict of each other. Any conflicts between a policy and pharmacy management strategy must be documented. All staff must receive notification and documented training for any new process associated with pharmacy management strategies.
 - a. Upon implementation of PPE reuse, documentation is maintained indicating the duration of time the pharmacy is operating under these conditions and state BoP waiver information (as deemed appropriate).
5. For sterile compounding without the proper PPE, BUD and environmental monitoring for “high-risk” compounding under current 2008 USP <797> will be followed.

Pharmacy management strategies through staffing and operations

1. If obtainable, use PPE that confers equivalent or better protection for compounding sterile products
2. Minimize the number of personnel conducting compounding activities
3. Reduce unnecessary traffic into the compounding area by non-compounding personnel
4. Reduce the frequency of compounding staff exiting the compounding area that would require donning of new PPE
5. Eliminate EVS and/or outside agencies from completing the required daily and terminal cleans and have already garbed compounding personnel perform all required cleaning (may require additional training)

6. Evaluate additional operational opportunities to reduce PPE consumption such as implementation of a contingency plan for a sister facility to compound for multiple facilities, the use of a 503A compounding pharmacy, or the use of a 503B outsourcing facility.
7. Limit annual sterile compounding recertification to compounding personnel only where possible (check with state Board of Pharmacy)
8. Aseptic Isolator's (CAI and CACIs): under current 2008 USP <797> general chapter, under Personnel Cleansing and Garbing: "When CAIs and CACIs are the source of the ISO Class 5 environment, the garbing and gloving requirements for compounding personnel should be described as above (referring to normal personnel cleansing and garbing), *unless the isolator manufacturer can provide written documentation based on validated environmental testing that any component(s) of PPE or personnel cleansing are not required.*"
 - a. If allowed by the local state BoP, temporarily ceasing the use of a face mask to prioritize the use for direct patient care personnel may be implemented under two conditions:
 1. there is written documentation from the isolator manufacturer;
 2. there is a policy/SOP with documentation for training of compounding personnel to this policy prior to policy implementation.

Reuse of pharmacy sterile compounding PPE

1. **Face Mask:** conditions under which a face mask may be reused are outlined in Appendix A.
 - a. Pharmacy staff may reuse their own face mask worn for non-hazardous and hazardous sterile compounding for one shift if:
 1. the process is approved by the local state Board of Pharmacy
 2. the face mask is not reused for any activity other than compounding
 3. the face mask is not visibly soiled, damp, or potentially contaminated
 4. there is a policy/SOP with documentation for training of compounding personnel to this policy prior to policy implementation
 5. all required processes for reuse are followed as outlined below
 - b. Required process for the reuse of a face mask: Storage recommendations differ between the Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC). The previous required process in this document followed CDC and if already implemented should be transitioned to the process below as deemed practical.
 1. Without touching the inside of the mask, doff the mask on the dirty side of the line of demarcation in the anteroom or segregated compounding area (same place the mask is donned).
 2. Write the initials of the compounding personnel along with date of initial use on the outside of the mask (location defined by the facility).
 3. Store masks to be reused in clean, low-particle-shedding fabric mesh bags, or stainless steel lattice containers that allow for airflow and can promote drying.
 - i. Use a dedicated individual fabric mesh bag or a stainless steel lattice container for each user
 4. Keep stored masks in a classified area or segregated compounding area (SCA).
 5. Discard mask at the end of the shift.
 6. Clean and disinfect fabric mesh bag or stainless steel lattice between different users and daily at a minimum.
 - i. May employ autoclaving of stainless steel lattice containers between users and prior to disinfecting when reintroducing to the controlled environment or SCA

2. **Non-Hazardous Gown:** conditions under which non-hazardous gowns may be reused are outlined in Appendix A.
 - a. Pharmacy staff may reuse their own non-hazardous gown worn for non-hazardous and hazardous sterile compounding (worn under the HD gown) for one shift if:
 1. the process is approved by the local state Board of Pharmacy
 2. the non-hazardous gown is not reused for any activity other than compounding (i.e. gowns used for cleaning in the compounding areas should not be used for subsequently for compounding)
 3. the non-hazardous gown is not visibly soiled or potentially contaminated
 4. all required processes for reuse are followed as outlined below
 - b. Required process for the reuse of a non-hazardous gown:
 1. In the same PPE doffing order and being careful not to touch critical areas of the exterior of the non-HD gown (i.e. sleeves, cuffs, torso area), slowly doff the non-HD gown on the clean side of the line of demarcation in the anteroom or SCA
 2. Write the initials of the compounding person along with the date of initial use on the inside of the non-HD gown (location by the facility)
 3. Retain the non-HD gown on the clean side of the line of demarcation in the anteroom or SCA in a manner that prevents the gown from becoming soiled or potentially contaminated.
 4. Before the non-HD gown is re-donned by the same individual, the gown is inspected (each time it is reused) to ensure the gown provides adequate control (i.e. condition of the gown, whether it is visibility soiled).
 5. The non-HD gown is re-donned in a manner that avoids touching critical areas of the exterior of the non-HD gown (i.e. sleeves, cuffs, torso area).
 6. The non-HD gown is appropriately discarded at the end of the shift
 - c. HD gowns must not be reused.

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Appendix A: Pharmacy Compounding PPE and Cleaning Supply Management Response Plan

Product	Supply Status	PPE Utilization Process	Cleanroom Process	Additional Requirements
Face Masks <i>(non-HD and HD compounding)</i>	Normal continuous supply	<ul style="list-style-type: none"> No change from standard P&Ps 	<ul style="list-style-type: none"> Normal operating conditions Low & Medium risk compounding BUDs 	
	Limited Supply	<ul style="list-style-type: none"> Use alternative surgical masks or face shields Use unused face masks that are beyond the manufacturer designated shelf life, only if stored under appropriate conditions and there are no visible holes, discolorations, or other physical defects 	<ul style="list-style-type: none"> Normal operating conditions Low & Medium risk compounding BUDs 	Deploy all pharmacy management strategies under “Pharmacy management strategies through staffing and operations” <i>Note: In an effort to protect staff and our patients, reserve N95, N99, R95, R99, and CAPRs for clinical care areas. PAPRs must be reserved for hazardous drugs (HD) activities only.</i>
	Face masks not available	<ul style="list-style-type: none"> Reuse mask for compounding for a single shift 		
	No masks available	<ul style="list-style-type: none"> Use a clean fabric to cover the nose and mouth for non-HD compounding processes but only if a new covering is used for each compounding session and the fabric is labeled as low linting 	<ul style="list-style-type: none"> All CSPs classified as High Risk level compounding Maximum BUD: 24 hours at room temperature 3 days refrigerated 45 days frozen 	Increase surface sampling in all primary engineering controls (PECs) to weekly
Gowns <i>(non-HD compounding)</i>	Normal continuous supply	<ul style="list-style-type: none"> No change from standard P&Ps 	<ul style="list-style-type: none"> Normal operating conditions Low & Medium risk compounding BUDs 	
	Limited supply	<ul style="list-style-type: none"> Save and reuse non-HD gown throughout a single shift by one individual Save a limited supply of non-HD gowns for potential use in place of a limited supply of HD gowns 	<ul style="list-style-type: none"> Normal operating conditions Low & Medium risk compounding BUDs 	Deploy all pharmacy management strategies under “Pharmacy management strategies through staffing and operations”
	No regular non-HD gowns available	<ul style="list-style-type: none"> Use any available alternative gown such as laundered gowns, bunny suits, isolations gowns 		
	No gowns available	<ul style="list-style-type: none"> Gown not donned for non-HD compounding Clean scrubs recommended 	<ul style="list-style-type: none"> All CSPs classified as High Risk level compounding Maximum BUD: 24 hours at room temperature 3 days refrigerated 45 days frozen 	Increase surface sampling in all primary engineering controls (PECs) to weekly

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Gowns <i>(HD compounding)</i>	Normal continuous supply	<ul style="list-style-type: none"> No change from standard P&Ps 	<ul style="list-style-type: none"> Normal operating conditions Low & Medium risk compounding BUDs 	
	Limited supply	<ul style="list-style-type: none"> No change from standard P&Ps 	<ul style="list-style-type: none"> Normal operating conditions Low & Medium risk compounding BUDs 	Deploy all pharmacy management strategies under “Pharmacy management strategies through staffing and operations”
	HD gowns not available	<ul style="list-style-type: none"> Wear two non-HD gowns Outer gown closure in the back 		
	No gowns available	Stop compounding HDs and notify Division Pharmacy Leader		
Sterile Gloves <i>(non-HD compounding)</i>	Normal continuous supply	<ul style="list-style-type: none"> No change from standard P&Ps 	<ul style="list-style-type: none"> Normal operating conditions Low & Medium risk compounding BUDs 	
	Limited supply	<ul style="list-style-type: none"> No change from standard P&Ps Use unused sterile gloves that are beyond the manufacturer designated shelf life, only if stored under appropriate conditions and there are no visible holes, discolorations, or other physical defects 	<ul style="list-style-type: none"> Normal operating conditions Low & Medium risk compounding BUDs 	Deploy all pharmacy management strategies under “Pharmacy management strategies through staffing and operations”
	Sterile gloves not available	<ul style="list-style-type: none"> Use non-sterile gloves and continue hand hygiene and gloving procedures Increase frequency of sanitizing gloves and glove changes 	<ul style="list-style-type: none"> All CSPs classified as High Risk level compounding Maximum BUD: 24 hours at room temperature 3 days refrigerated 45 days frozen 	Increase surface sampling in all primary engineering controls (PECs) to weekly
	No gloves available	Stop compounding non-HDs and notify Division Pharmacy Leader		
Sterile gloves <i>(HD compounding)</i>	Normal continuous supply	<ul style="list-style-type: none"> No change from standard P&Ps 	<ul style="list-style-type: none"> Normal operating conditions Low & Medium risk compounding BUDs 	
	Limited supply	<ul style="list-style-type: none"> No change from standard P&Ps 	<ul style="list-style-type: none"> Normal operating conditions Low & Medium risk compounding BUDs 	Deploy all pharmacy management strategies under “Pharmacy management strategies through staffing and operations”
	Sterile HD gloves not available	<ul style="list-style-type: none"> Use non-sterile HD gloves and continue normal hand hygiene and gloving procedures 	<ul style="list-style-type: none"> All CSPs classified as High Risk level compounding Maximum BUD: 24 hours at room temperature 3 days refrigerated 45 days frozen 	Increase surface sampling in all primary engineering controls (PECs) to weekly
	No gloves available	Stop compounding HDs and notify Division Pharmacy Leader		

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Product	Supply Status	PPE Utilization Process	Cleanroom Process	Additional Requirements
Head Cover	Normal continuous supply	<ul style="list-style-type: none"> No change from standard P&Ps 	<ul style="list-style-type: none"> Normal operating conditions Low & Medium risk compounding BUDs 	
	Limited supply	<ul style="list-style-type: none"> No change from standard P&Ps May use alternative head cover such as a disposable surgical or shower cap 	<ul style="list-style-type: none"> Normal operating conditions Low & Medium risk compounding BUDs 	Deploy all pharmacy management strategies under “Pharmacy management strategies through staffing and operations”
	Head covers not available	<ul style="list-style-type: none"> No head cover donned for compounding 	<ul style="list-style-type: none"> All CSPs classified as High Risk level compounding Maximum BUD: 24 hours at room temperature 3 days refrigerated 45 days frozen 	Increase surface sampling in all primary engineering controls (PECs) to weekly
Beard Cover	Normal continuous supply	<ul style="list-style-type: none"> No change from standard P&Ps 	<ul style="list-style-type: none"> Normal operating conditions Low & Medium risk compounding BUDs 	
	Limited supply	<ul style="list-style-type: none"> No change from standard P&Ps 	<ul style="list-style-type: none"> Normal operating conditions Low & Medium risk compounding BUDs 	Deploy all pharmacy management strategies under “Pharmacy management strategies through staffing and operations”
	Beard covers not available	<ul style="list-style-type: none"> Use alternative (i.e. head cover) If no alternative available, initiate <u>no</u> compounding personnel with visible facial hair not covered by mask (i.e. shave) 	<ul style="list-style-type: none"> Normal operating conditions Low & Medium risk compounding BUDs 	
Shoe Covers <i>(non-HD compounding)</i>	Normal continuous supply	<ul style="list-style-type: none"> No change from standard P&Ps 	<ul style="list-style-type: none"> Normal operating conditions Low & Medium risk compounding BUDs 	
	Limited supply	<ul style="list-style-type: none"> No change from standard P&Ps 	<ul style="list-style-type: none"> Normal operating conditions Low & Medium risk compounding BUDs 	Deploy all pharmacy management strategies under “Pharmacy management strategies through staffing and operations”
	Shoe covers not available	<ul style="list-style-type: none"> Use cleanroom dedicated shoes (clean/disinfect prior to initial use and then regularly (i.e. on days worn) thereafter) 	<ul style="list-style-type: none"> Normal operating conditions Low & Medium risk compounding BUDs 	

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Shoe Covers <i>(HD compounding)</i>	Normal continuous supply	<ul style="list-style-type: none"> No change from standard P&Ps 	<ul style="list-style-type: none"> Normal operating conditions Low & Medium risk compounding BUDs 	
	Limited supply	<ul style="list-style-type: none"> No change from standard P&Ps 	<ul style="list-style-type: none"> Normal operating conditions Low & Medium risk compounding BUDs 	Deploy all pharmacy management strategies under “Pharmacy management strategies through staffing and operations”
	HD shoe covers not available	<ul style="list-style-type: none"> Wear two pair of non-HD shoe covers 	<ul style="list-style-type: none"> Normal operating conditions Low & Medium risk compounding BUDs 	
	No shoe covers available	<ul style="list-style-type: none"> Use cleanroom dedicated shoes Decontaminate bottom of shoes prior to exiting the HD buffer room or C-SCA 	<ul style="list-style-type: none"> Normal operating conditions Low & Medium risk compounding BUDs 	
Sterile 70% Isopropyl Alcohol	Normal continuous supply	<ul style="list-style-type: none"> No change from standard P&Ps 	<ul style="list-style-type: none"> Normal operating conditions Low & Medium risk compounding BUDs 	
	Limited supply	<ul style="list-style-type: none"> Preserve sterile alcohol for critical sites and direct compounding areas (DCA) only 	<ul style="list-style-type: none"> All other areas normal disinfected with sterile alcohol, change to an EPA 1 step cleaning and disinfecting agent and increase frequency of cleaning 	Deploy all pharmacy management strategies under “Pharmacy management strategies through staffing and operations”
	Sterile alcohol not available	Notify Division Pharmacy Leader		
Hand Scrub <i>(waterless alcohol based with persistent activity)</i>	Normal continuous supply	<ul style="list-style-type: none"> No change from standard P&Ps 	<ul style="list-style-type: none"> Normal operating conditions Low & Medium risk compounding BUDs 	
	Limited supply	<ul style="list-style-type: none"> No change from standard P&Ps 	<ul style="list-style-type: none"> Normal operating conditions Low & Medium risk compounding BUDs 	Deploy all pharmacy management strategies under “Pharmacy management strategies through staffing and operations”
	Hand scrub not available	<ul style="list-style-type: none"> Require hand washing before each glove change after initial garbing and hand hygiene procedures 	<ul style="list-style-type: none"> All CSPs classified as High Risk level compounding Maximum BUD: 24 hours at room temperature 3 days refrigerated 45 days frozen 	Increase surface sampling in all primary engineering controls (PECs) to weekly

Appendix B: Pharmacy Compounding Cleaning Agents and Alternatives

Cleaning Agent Type	Product	Active Ingredient(s)	Additional Information	Use
EPA Registered One Step Bactericidal Disinfectant Cleaning Agent	PREempt™ RTU	<i>Hydrogen peroxide 0.5%</i>	1 minute dwell time	<ul style="list-style-type: none"> Daily cleaning and disinfection of surfaces in the ISO Class rooms (i.e. cleanrooms) and Segregated Compounding Areas (SCAs) Cleaning and disinfection in primary engineering control (PEC), sterile 70% IPA must be subsequently used
	PeridoxRTU®	<i>Peroxyacetic acid 0.23% and hydrogen peroxide 4.4%</i>	2 minute dwell time	
	Oxivir® 1	<i>Hydrogen peroxide 0.5%</i>	1 minute dwell time	
	Oxivir® TB			
	Super Sani-Cloth® Germicidal Wipe (Purple top)	<i>Quaternary ammonium and isopropyl alcohol</i>	2 minute dwell time <i>*Not a sporicidal agent*</i>	
	CaviWipes 1™ (black top)	<i>Didecyldimethylammonium chloride 0.76% Ethanol 7.5%</i>	1 minute dwell time	
CaviCide 1™	<i>Isopropanol 15%</i>			
Sterile Disinfectant	Pharma-Hol™	<i>Sterile 70% isopropyl alcohol (IPA)</i>		<ul style="list-style-type: none"> Used as the final step for cleaning and disinfection regimen inside PECs Used to disinfect gloves regularly
	Pharma-Sat Plus™			
	Sterile 70% IPA (various)			
Sporicidal Agent	Clorox Healthcare® Bleach Germicidal Wipes (Orange top)	<i>Sodium hypochlorite 0.55%</i>	3 minute dwell time	<ul style="list-style-type: none"> Spore coverage for surfaces in cleanrooms and SCAs Spore coverage for PEC, sterile 70% IPA must be subsequently used
	PeridoxRTU®	<i>Peroxyacetic acid 0.23% and hydrogen peroxide 4.4%</i>	3 minute dwell time	
	TexCide™ TX690	<i>Peroxyacetic acid and hydrogen peroxide</i>	2 minute dwell time. Must be diluted to 1844 ppm for spore coverage	
	TexTab™ TX6460	<i>Sodium dichloro-s-triazinetrione 48.21%</i>	4 minute dwell time Requires 4 tabs per 1 gallon of water for spore coverage	
Sporicidal Agent (continued)	Sani-Cloth® Bleach Germicidal Wipe	<i>Sodium hypochlorite 0.63%</i>	4 minute dwell time	
	CaviWipes™ Bleach (Light blue top)	<i>Sodium hypochlorite 0.91%</i>	3 minute dwell time	

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Cleaning Agent Type	Product	Active Ingredient(s)	Additional Information	Use
Hazardous Drug Decontamination Agent	PeridoxRTU®	<i>Peroxyacetic acid 0.23% and hydrogen peroxide 4.4%</i>	Must apply to surface twice to achieve decontamination	<ul style="list-style-type: none"> Hazardous drug decontamination agent for Containment-Primary Engineering Control (C-PECs) and other surfaces
	Surface Safe™ Two-Step Applicator Kit	<i>Packet #1 - 2% sodium hypochlorite Packet #2 - 1% sodium thiosulfate (neutralizing agent)</i>	Two-step applicator kit	
	EPA-registered oxidizing agent	<i>2% sodium hypochlorite</i>	Should be prepared daily	
Waterless Alcohol-Based Hand Sanitizer with Persistent Activity	Avagard™ D	<i>Ethyl alcohol 61%</i>		<ul style="list-style-type: none"> Hand sanitizer applied to hands prior to donning sterile gloves After application, allow sanitizer to completely dry before donning sterile gloves
	Avagard™	<i>Ethyl alcohol 61% (with CHG)</i>		
	Purell® Surgical Scrub	<i>Ethyl alcohol 70%</i>		
	Surgicept®	<i>Ethyl alcohol 70% (with CHG)</i>		