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CLIENT ALERT

FDA Final Guidance for PPE Shortages at Sterile Compounding Pharmacies not Registered as Outsourcing Facilities

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On April 10, The U.S. Food and Drug Administration (FDA) issued a Final Guidance for sterile compounding pharmacies not registered as outsourcing facilities. Due to the COVID-19 pandemic, supply chains for personal protective equipment (PPE), including masks, gowns, gloves, and masks, which are critical for operations in compounding pharmacies, have been disrupted.

In response to the short supply of PPE, FDA is recommending modifications to compounding facilities' practices. In an effort to reduce the need for PPE, the Agency recommends limiting compounding activities as well as the number of personnel conducting them. It further recommends that facilities obtain other PPE that confers equivalent or better protection if possible (see this Guidance for more information).

To support these recommendations, FDA "does not intend to take enforcement action regarding compliance with the insanitary conditions provision when drugs intended or expected to be sterile are compounded without standard PPE" if:

- The compounding facility is unable to obtain sufficient supply of PPE that it typically relies on;
- The drugs compounded meet conditions in section 503A of the Federal Food Drug and Cosmetic Act;
- The compounder either (i) employs appropriate mitigation strategies to reduce contamination risk when compounding is performed without PPE, *or* (ii) employs terminal sterilization where standard PPE is not used, but basic garbing expectations are followed; and
- The compounder (i) keeps a record when compounding is performed without standard PPE, (ii) keeps a record when there are changes in sterilization approach, *and* (iii) documents mitigation strategies in a new or updated standard operating procedure.

To further support pharmacy compounders, the Final Guidance details specific contamination mitigation strategies for different types of PPE. The recommended strategies are set forth below.

Contamination Mitigation Strategies for PPE Reuse/Inferior PPE

All PPE

- Unused PPE such as masks and gloves may be used beyond the manufacture designated shelf life if it has been stored under appropriate conditions and has no visible defects.

Masks

- If masks that are beyond their shelf life are unavailable, masks may be reused during the same shift but may not be removed from the compounding area or shared among personnel.

- If reuse during a single shift does not alleviate the shortage, masks may also be reused on subsequent days if the masks have no visible defects and are stored in clean, low particle-shedding fabric mesh bags or stainless steel lattice containers that allow for airflow and can promote drying, and that are kept in a controlled or classified area.
- Reused masks may be disinfected using an appropriate agent.
- If masks are unavailable and reuse does not alleviate the shortage, compounders may use clean fabric to cover the nose and mouth as long as the fabric is new for each compounding session and labeled as "low linting." This should be considered a last resort.

Gloves

- If sterile gloves that are beyond their designated shelf life are unavailable, nonsterile gloves may be used if they have been disinfected with an appropriate agent.

Foot Coverings

- Foot coverings should not be reused. If a facility is short on foot coverings, it should use dedicated cleanroom shoes that are regularly cleaned and disinfected.

Contamination Mitigation Strategies Without Standard PPE

- Increase the frequency of cleaning and disinfecting surfaces within compounding areas.
- Judiciously use sporicidal agents on surfaces within compounding areas.
- Disinfect gloves more frequently during compounding activities.
- Consider more frequent environmental monitoring (e.g., fingertip sampling after each shift, weekly surface sampling in ISO 5 areas, or more frequent passive air sampling) to assess the effectiveness of cleaning and disinfecting.

Strategies to Reduce Risk of Microbial Proliferation in Compounded Products

- Utilize the following beyond use dates: 24 hours for products stored at room temperature; 3 days for products stored refrigerated; and 45 days for frozen products.
- When available, use a sterilizing and pharmaceutical grade syringe filter during compounding to remove microbial contamination that may have been inadvertently introduced by operating under conditions where standard PPE is unavailable. This measure is only applicable when the compounded formulation is chemically and physically compatible with the syringe filter. Low-protein binding filters should be used for preparation and administration of biological products.

Even these recommended strategies, however, are not intended to be an exhaustive list and FDA says compounders may consider other alternatives. It simply cautions that compounders should "consider such alternate approaches carefully and on a case by-case basis to evaluate whether they provide protection to the drug product that is comparable to that provided by the risk mitigation strategies described" in the Final Guidance. When taking an alternate approach, we recommend documenting, in addition to the records FDA otherwise requires, the reason for the decision and the justification for why the approach provides comparable protection.

For more information, please contact the professional(s) listed below, or your regular Crowell & Moring contact.

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