

USP PUBLISHES GUIDANCE ON CONSERVING PPE IN STERILE COMPOUNDING AND COMPOUNDING HAND-SANITIZER DURING COVID-19 PANDEMIC

On Wednesday, March 18, 2020, the United States Pharmacopeial Convention ("USP") Compounding Expert Committee published resources in response to **reported shortages** of gowns and personal protective equipment ("PPE") as well as shortages of alcohol-based hand sanitizers during the COVID-19 pandemic. While the expectation is that compounders continue to follow applicable USP standards, we anticipate agencies will begin to follow USP's recent guidance to enable a balance between compliance and access.

USP is an independent organization that establishes standards for health care products and product handling that have been deemed official by many federal and state governments. Under its recent guidance in response to the pandemic, USP offers recommendations for **conserving garb and PPE in sterile compounding** and for **compounding alcohol-based hand sanitizers**. For example, USP recommends that garb for direct patient care take priority and that sterile gloves take priority over other garb for sterile compounding activities because direct contact contamination is the highest contamination risk for compounded sterile products. Also, USP recommends different formulations for alcohol antiseptic topical solutions along with appropriate packaging and storage, labeling and beyond-use dating of products.

These recommendations are practical as the demand for garb, PPE and alcohol-based hand sanitizer outpaces available supply, but they are not intended to waive or replace federal or state requirements. For example, the FDA also recently published a **Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency**, which facilities should also follow.

USP affirmatively recommends that State Boards and other regulators use risk-based enforcement discretion regarding the application of USP compounding standards to the compounding of alcohol-based hand sanitizers for consumer use. If this occurs, then facilities should be prepared to demonstrate that they conducted risk assessments before implementing any protocol under USP's guidance, as well as comply with any other state-based or federal guidance. This approach should be developed and documented in consultation with legal departments.

Finally, not only is there an expectation that demand for garb, PPE and hand sanitizer will outpace supply, but there is also an expectation that drug shortages will result from the COVID-19 pandemic. USP's guidance offers insight into the role compounders might play due to potential drug shortages in the future. These recommendations will likely be supported for compounding in the future in the event of any drug shortages.

PRACTICAL TAKEAWAYS

- This guidance was published in response to the increased demand for garbing and PPE and alcohol-based hand sanitizer, which is expected to outpace available supply in response to the COVID-19 pandemic.
- These resources offer practical strategies to conserve garb and PPE and to compound alcohol-based hand sanitizers during the COVID-19 pandemic, but they are not meant to replace or waive federal or state regulatory requirements. Compounders should still refer to federal and state requirements when conducting compounding activities.
- Before implementing any recommendation under this guidance, compounders should conduct a risk-based assessment in consultation with legal departments or legal counsel.
- This guidance will also be relevant in the event of any drug shortages in the future.

If you have questions about these issues or would like to be updated on any further developments, please don't hesitate to contact:

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