NCPA Member Summary: Pharmacy Compounding During COVID-19

Below is NCPA's current interpretation of the various compounding guidances and resources put out by the Food and Drug Administration (FDA) and the United States Pharmacopeia (USP) as it applies to community and long-term care (LTC) pharmacies for the duration of the COVID-19 public health emergency (PHE).

NCPA advocacy at work for you

NCPA, along with the compounding pharmacy industry, successfully advocated that:

- FDA clarify certain hand sanitizer guidelines, which if not addressed by FDA in a timely manner, would limit pharmacy compounders' ability to aid in this crisis.
- FDA help pharmacists provide urgently needed compounded products as certain prescription drug products are at risk for shortage during the current COVID-19 crisis.

- **April 20, 2020**: FDA Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Pharmacy Compounders not Registered as Outsourcing Facilities

FDA released guidance consistent with NCPA's ask, stating it does not intend to take action against a 503A pharmacy for compounding a drug that is essentially a copy of a commercially available drug, or providing a drug to a hospital without obtaining a patient-specific prescription, if certain circumstances are met. Among some of the requirements: the compounded drug product appears on the guidance's list in Appendix A (sterile drugs), the hospital is treating patients with COVID-19 and unable to obtain the drug product, and the compounding pharmacy must seek approval from its state board of pharmacy. The guidance also provides information on beyond-use dates that must follow Appendix B of the guidance.

- **April 10, 2020:** FDA Temporary Policy Regarding Non-Standard PPE Practices for Sterile Compounding by Pharmacy Compounders not Registered as Outsourcing Facilities

FDA does not intend to take enforcement action regarding compliance with the unsanitary conditions provision when drugs are intended to or expected to be sterile are compounded without standard personal protective equipment (PPE) provided that 1) the compounder is unable to obtain sufficient PPE; 2) drugs compounded meet 503A and FD&C Act requirements; 3) the compounder employs mitigation strategies and terminal sterilization where standard PPE is not used; and 4) the compounder keeps a record of when compounding is performed without standard PPE, keeps a record of changes in sterilization approach, and documents mitigation strategies

The policy also includes strategies to: 1) reuse PPE or use inferior PPE; 2) reduce the risk of contamination when compounding without standard PPE; and 3) reduce the risk of microbial proliferation in a potentially contaminated product.

- **April 6, 2020:** In response to recent questions on drug compounding policy, FDA clarified the following:

Pharmacy compounders will not be held to the draft Memorandum of Understanding 5 percent limit on interstate distribution of compounded drug products until after it has finalized the MOU and given states an opportunity to sign;

Pharmacy compounders may compound a drug that is 1) on FDA's shortage list or 2) has been discontinued and is no longer marketed as "commercially available" without violating the "essentially a copy" provision;

Outsourcing facilities may compound a drug that is 1) identical or nearly identical to an FDA-approved drug that is on FDA's drug shortage list; and 2) is essentially a copy of an approved drug that has been discontinued and is no longer marketed without violating the "essentially a copy" provision; and

FDA will issue revisions to its draft guidance on compounding policy for hospital and health systems.

See human drug compounding and drug shortages for more information.

- **March 19, 2020, updated April 15, 2020**: Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products, FDA's response to industry for more guidance in addition to its **March 14, 2020, updated April 15, 2020**: Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products

FDA does not intend to take action against firms that prepare alcohol-based hand sanitizers for consumer and health care personnel use for the duration of the PHE, provided only the following ingredients are used : **(1)** alcohol (ethanol) that is not less than 94.9% ethanol **OR** USP grade Isopropyl Alcohol (IPA); **(2)** glycerin (glycerol) USP or Food Chemical Codex (FCC) (also known as "food grade"); **(3)** hydrogen peroxide; **and** (4) sterile water.

The guidance also includes considerations for these ingredients in preparation of the product:

1. The alcohol (ethanol) used is derived from distillation of fermentation process typically used for consumable goods. Alcohol derived from synthetic processes meets USP or FCC grade.
2. The alcohol (ethanol) is denatured either by the alcohol producer or at the point of production of the finished hand sanitizer product.[1]
3. The hand sanitizer is manufactured according to the following formula consistent with World Health Organization (WHO) recommendations stated in the guidance.[2]
4. A record should be used to document key steps to assure each batch matches the formula.
5. The hand sanitizer is prepared under sanitary conditions and equipment utilized is maintained.
6. The firm uses the most accurate method of analysis for verification of alcohol content in samples.

[1] *See* FDA guidance for industry "Temporary Policy for Manufacture of Alcohol for Incorporation Into Alcohol Based Hand Sanitizer Products During the Public Health Emergency (COVID-19)."

[2] WHO's recommendations, titled "Guide to Local Production: WHO-recommended Handrub Formulations," are available at https://www.who.int/gpsc/5may/Guide_to_Local_Production.pdf.

7. The hand sanitizer product is produced as an aqueous solution. The firm packages the product in packaging appropriate for liquid drug products that will seal sufficiently to prevent evaporation, such as manual pumps sprays.
8. The hand sanitizer is labeled consistent with Appendixes A through D of the guidance.
9. Firms register their facility and list these products in the FDA Drug Registration and Listing System.

In addition, the firm must not add other active or inactive ingredients due to the risk of accidental ingestion in children and impact on the quality and potency of the product. Firms must also have a way to accept and submit adverse event reports.

- **USP continues to provide resources in response to the COVID-19 pandemic:**

Compounding Alcohol-Based Hand Sanitizer During COVID-19 Pandemic
FAQs – Alcohol-Based Hand Sanitizer During COVID-19 Pandemic
Compounding Alcohol-Based Hand Sanitizer During COVID-19 Pandemic Infographic
Hand Sanitizer Toolkit During COVID-19
FAQs – COVID-19 Compounding Resources

USP Education is also providing all on-demand education at a 75 percent discount available **until May 31**. Click on the links below for compounding related courses and use the code **USPEDU75OFF** to receive the discount.

USP <795> Pharmaceutical Compounding – Nonsterile Preparations
USP <797> Pharmaceutical Compounding – Sterile Preparations for Compounding Professionals
USP <800> Hazardous Drugs – Handling in Healthcare Settings for Compounding Professionals

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