CommonSpirit

Alcohol-Based Hand Sanitizer Management Guidance
April 8, 2020

Purpose: To provide guidance for CommonSpirit Health (CSH) facilities for the management of alcohol-based hand sanitizer for when supply may be insufficient or unavailable.

Procedure: Due to the public health emergency posed by COVID-19 the FDA has published an interim policy allowing temporary compounding of certain alcohol-based hand sanitizer products during the public health emergency. All CommonSpirit Health facilities are expected to follow the guidance on compounding or procurement of compounded alcohol-based hand sanitizer products set forth by the FDA.

SECTION I: FDA policy for temporarily compounding alcohol-based hand sanitizer

The FDA does not intend to take action against compounders that prepare alcohol-based hand sanitizer for consumer use for the duration of the public health emergency declared by the Secretary of HHS on January 31, 2020, provided the following circumstances are present:

1. The [alcohol-based] hand sanitizer is compounded using **only** the following ingredients in the preparation of the product:
    a. (*Select one of two options)* (1) Alcohol (ethanol) that is not less than 94.9% ethanol by volume; **OR** (2) Isopropyl Alcohol
    b. Glycerin (glycerol) United States Pharmacopeia (USP) or Food Chemical Codex (also known as "food grade")
    c. Hydrogen peroxide
    d. Sterile water *(e.g., by boiling, distillation, or other process that results in water that meets the specifications for Purified Water USP).* Water should be used as quickly as possible after it is rendered sterile or purified.

2. The **alcohol (ethanol) is denatured** either by the alcohol producer or at the point of production of the finished hand sanitizer product. Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20 and 21 provide a number of formulas for denaturing alcohol. Formulas for use in hand sanitizers include:
    a. Formula 40A or 40B with or without the tert-butyl alcohol
    b. Formula 3C (isopropyl alcohol)

3. The hand sanitizer is compounded according to the following formula consistent with World Health Organization (WHO) recommendations:
    a. Alcohol (ethanol) (80%, volume/volume (v/v)) in an aqueous solution; **or** Isopropyl Alcohol (75%, v/v) in an aqueous solution
    b. Glycerin (glycerol) (1.45% v/v)
        i. *Although WHO's recommended formulation includes glycerol 1.45% (v/v), reports indicate that glycerol negatively impacts effectiveness of isopropyl alcohol and reports studying the effectiveness of WHO's formulation have suggested a reduction from 1.45% to 0.725%*
    c. Hydrogen peroxide (0.125% v/v)
    d. Sterile distilled water or boiled cold water

    The compounder does not add other active or inactive ingredients, such as ingredients to improve the smell or taste due to the risk of accidental ingestion in children. Different or additional ingredients may impact the quality and potency of the product.

4. The compounder pays particular attention to ensure the ethanol or isopropyl alcohol active ingredient is correct and the correct amount of the active ingredient is used.

5. The hand sanitizer is prepared under conditions routinely used by the compounder to compound similar nonsterile drug

6. The hand sanitizer is labeled consistent with the labeling in Appendix A, B, C or D in the FDA's guidance document for compounding alcohol based sanitizer *(see link in references below)*

SECTION II: Facility alternate procurement strategies for alcohol-based hand sanitizer

1. Local facilities, in coordination with SSRM (supply chain/sourcing), should reach out to vendors to secure allocation of alcohol-based hand sanitizer based on historical usage and explore alternative vendor and/or product selection.

2. Winery or distillery: many wineries and distilleries are shifting their operations to produce alcohol-based hand sanitizer
   a. Appropriate vetting of the facility must be completed prior to procuring product
      i. Ensure formulation and processes follow all of the FDAs requirements in the interim policy guidance (*see FDA requirements in section I above*)
      ii. Ensure safe environmental conditions for compounding
      iii. Ensure there are no restrictions made by the county or state
   b. Assigned beyond-use-date (BUD) does not exceed 30 days at room temperature
   c. If provided in a bulk container, repackaging must be in a container that will prevent accidental ingestion
      i. The use of an amber bottle with a traditional child proof cap is prohibited
      ii. The cap of the container must either be a flip-top or pump/spray nozzle
   d. Supply chain/materials management to coordinate the distribution of product

3. Compounding of alcohol-based sanitizer by CSH pharmacies
   a. Ensure formulation and processes follow all of the FDAs requirements in the interim policy guidance (*see FDA requirements in section I above*)
   b. Assigned beyond-use-date (BUD) does not exceed 30 days at room temperature
   c. Container closure: must be in a container that will prevent accidental ingestion
      i. The use of an amber bottle with a traditional child proof cap is prohibited
      ii. The cap of the container must either be a flip-top or pump/spray nozzle
   d. Ensure conditions for compounding meet USP <795> Pharmaceutical Compounding - Nonsterile Preparations requirements following facility policies and procedures
   e. See attachment "A", and "B" for sample formulas
   f. Supply chain/materials management to coordinate the distribution of product
      i. See attachment "C" for sample Workflow for Refilling/Compounding of Hand Sanitizer Algorithm

References:

1. Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency Immediately in Effect Guidance for Industry, Food and Drug Administration, March 2020
2. World Health Organization Recommended Handrub Formulations, April 2010

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Attachment "A"
Sample formulas for 80% ethyl alcohol hand sanitizer

Product: 80% Ethyl Alcohol Hand Sanitizer Topical Solution **Batch Size:** 100 mL

Formula #1			Formula #2	
Ingredient	**Quantity**		**Ingredient**	**Quantity**
ethyl alcohol **95%**	84.3 mL		ethyl alcohol **96%**	83.3 mL
glycerin USP 98%	1.45 mL		glycerin USP 98%	1.45 mL
hydrogen peroxide 3%	4.17 mL		hydrogen peroxide 3%	4.17 mL
sterile water	QS to 100 mL		sterile water	QS to 100 mL

Compounding Procedures

In a designated non-sterile compounding area, perform the following compounding procedure:

1. Measure the appropriate amount of ethyl alcohol and transfer into a suitable calibrated container
2. Measure the appropriate amount of hydrogen peroxide and transfer into the calibrated container
3. Measure the appropriate amount of glycerin and transfer into the calibrated container
4. Use a small amount of sterile water to rinse any remaining glycerin from the device used to measure the glycerin, and add to the calibrated container
5. Add a sufficient volume of sterile water to the calibrated container to bring the solution to the final total volume and mix well
6. *If appropriate, divided the bulk solution into smaller final containers
7. Label product

Physical Description of Final Product:
Clear, slightly viscous liquid

Beyond-Use-Date and Storage Requirements:
No more than 30 days at controlled room temperature in a tightly closed container

Auxiliary Labeling:
External use only

References:

1. *Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency Immediately in Effect Guidance for Industry, Food and Drug Administration, March 2020*
2. *World Health Organization Recommended Handrub Formulations, April 2010*
3. *USP <795> Pharmaceutical Compounding – Nonsterile Preparations*

Attachment "B"
Sample formula for 75% isopropyl alcohol hand sanitizer

Product: 75% Isopropyl Alcohol Hand Sanitizer Topical Solution **Batch Size:** 100 mL

Formula #1			Formula #2	
Ingredient	**Quantity**		**Ingredient**	**Quantity**
isopropyl alcohol **99%**	75.8 mL		isopropyl alcohol **91%**	83.3 mL
glycerin USP 98%	1.45 mL		glycerin USP 98%	1.45 mL
hydrogen peroxide 3%	4.17 mL		hydrogen peroxide 3%	4.17 mL
sterile water	QS to 100 mL		sterile water	QS to 100 mL

Compounding Procedures

In a designated non-sterile compounding area, perform the following compounding procedure:

1. Measure the appropriate amount of isopropyl alcohol and transfer into a suitable calibrated container
2. Measure the appropriate amount of hydrogen peroxide and transfer into the calibrated container
3. Measure the appropriate amount of glycerin and transfer into the calibrated container
4. Use a small amount of sterile water to rinse any remaining glycerin from the device used to measure the glycerin, and add to the calibrated container
5. Add a sufficient volume of sterile water to the calibrated container to bring the solution to the final total volume and mix well
6. *If appropriate, divided the bulk solution into smaller final containers
7. Label product

Physical Description of Final Product:
Clear, slightly viscous liquid

Beyond-Use-Date and Storage Requirements:
No more than 30 days at controlled room temperature in a tightly closed container

Auxiliary Labeling:
External use only

References:

1. *Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency Immediately in Effect Guidance for Industry, Food and Drug Administration, March 2020*
2. *World Health Organization Recommended Handrub Formulations, April 2010*
3. *USP <795> Pharmaceutical Compounding – Nonsterile Preparations*

Attachment "C"

Sample: Workflow for Refilling/Compounding of Hand Sanitizer Algorithm

Distribution process should be managed by central supply/materials management.