

Broadened Authority to Produce Hand Sanitizer During COVID-19 Pandemic

By: Julia Singer Bansal, Senior Legislative Attorney
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Issue

Summarize the governor's executive orders (EO) concerning the manufacture of hand sanitizer.

Summary

Following his emergency declarations, Governor Lamont issued two EOs allowing pharmacies and other non-traditional manufacturers to make hand sanitizer and sell it to the public ([EO 7B](#), § 2, March 14, 2020; [EO 70](#), § 3, March 27, 2020).

The EOs suspend state laws requiring one to register as a drug, device, or cosmetics manufacturer before compounding and selling hand sanitizer ([CGS § 21a-70\(b\)](#)). Generally, before engaging in such manufacturing, one must obtain a certificate of registration from the Department of Consumer Protection (DCP), valid for one year (the fee ranges from \$285-\$940, depending on the number of pharmacists or chemists employed). Registration is contingent on showing (1) a licensed pharmacist or qualified chemist will directly supervise the product's manufacture or compounding, (2) appropriate apparatus and facilities, and (3) compliance with the state's Uniform Food, Drug and Cosmetic Act and applicable regulations.

Initially, only licensed pharmacies were granted the authority to make hand sanitizer without the required DCP registration, and only upon the DCP commissioner's issuance of an implementing order ([EO 7B](#)). However, the registration requirement was later suspended for anyone making alcohol-based hand sanitizer, as long as it is produced in compliance with federal guidance ([EO 70](#)). (The DCP commissioner was authorized to issue any orders or guidance necessary.)

Implementing Order Applicable to Pharmacies

As required by [EO 7B](#), on March 15, 2020, DCP issued an [implementing order](#) requiring pharmacies making hand sanitizer to:

1. be licensed in Connecticut;
2. compound the product using processes that comply with United States Pharmacopeia (USP) chapter 795 on nonsterile compounding, creating a product that is greater than 60% alcohol as recommended by the Centers for Disease Control and Prevention (CDC);
3. use a formula from a reputable source;
4. follow all federal and state labeling requirements;
5. maintain records of what they have compounded;
6. before selling the hand sanitizer, obtain the purchaser's contact information sufficient to permit a recall if necessary and record the information on a log sheet with the product's lot number; and
7. make any of the above records available for DCP's inspection upon request and maintain the records for at least three years.

(The implementation order's requirements are also outlined in this [compounding guidance](#) for pharmacies.)

Guidance for Other Hand Sanitizer Makers

While the manufacturer registration requirements were waived for non-traditional alcohol-based hand sanitizer manufacturers (e.g., distilleries), [EO 70](#) requires these manufacturers to follow Food and Drug Administration (FDA) [guidelines](#).

These guidelines require alcohol-based hand sanitizer to be greater than 60% ethanol or 70% isopropanol alcohol. Under the FDA guidelines, among other requirements, ethanol must be derived from distillation or fermentation processes typically used for consumable goods (e.g., liquor), with some exceptions. Alcohol derived from synthetic processes may be used only if it meets USP or Food Chemical Codex (FCC) specifications.

The FDA's guidelines also provide information for manufacturers on permissible additives, manufacturing processes (including formulations), and packaging (including labels).

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