

Janet T. Mills
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COMPOUNDING OVER THE COUNTER HAND SANITIZER

On March 15, 2020, Governor Janet Mills declared a State of Emergency to respond to the spread of COVID-19. On March 18, 2020, the Maine Department of Health and Human Services issued an Order authorizing Maine pharmacies and pharmacists to compound and sell hand sanitizer over the counter (“OTC”).

In accordance with the DHHS’s Order, pharmacies and pharmacists may compound and sell hand sanitizer OTC, provided the following requirements are satisfied:

- The hand sanitizer conforms to the March 2020 federal Food and Drug Administration Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-temporary-compounding-certain-alcohol-based-hand-sanitizer-products-during-public-health>)
- The pharmacy and pharmacist comply with USP <795>, including beyond-use-dates and compounding records.
- The pharmacy labels each container of hand sanitizer in accordance with USP <795>, including ingredients, beyond use date, lot number, directions for use, etc. Specific patient information is not required on the label for compounded OTC hand sanitizer.
- The compounded OTC hand sanitizer is labeled with the statement, “for external use only.”
- The pharmacy may not sell compounded OTC hand sanitizer to other retail establishments; the compounded OTC hand sanitizer may only be sold to end users.

The general public may visit a participating pharmacy on a walk-in basis and purchase compounded OTC hand sanitizer. The compounded OTC hand sanitizer may be sold in the front store.

The Board expects pharmacies and pharmacists to price products fairly, to use judgment to avoid bulk sales that may result in hoarding or resale, and to uphold the integrity of the profession during this emergency.

The Order and this guidance are effective immediately and shall remain in effect until the State of Emergency is terminated by the Governor, or the Order is rescinded by the Commissioner, whichever shall happen first.