The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Board of Registration in Pharmacy
Bureau of Health Professions Licensure
239 Causeway Street, Suite 500, Boston, MA 02114

CHARLES D. BAKER
Governor

KARYN E. POLITO
Lieutenant Governor

MARYLOU SUDDERS
Secretary

MONICA BHAREL, MD, MPH
Commissioner

Tel: 617-973-0860
Fax: 617-973-0980
TTY : 617-973-0988
www.mass.gov/dph/boards/pharmacy

COMPOUNDING OVER THE COUNTER HAND SANITIZER

On March 10, 2020, Governor Charles D. Baker declared a State of Emergency in the Commonwealth to respond to the spread of COVID-19. On March 15, 2020, the Commissioner of Public Health issued an Order authorizing all Massachusetts pharmacies and pharmacists to compound hand sanitizer for use within their facilities as well as sell it over the counter ("OTC").

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

- The hand sanitizer formula is issued by an entity with validated, reviewed formulas including:
  - Food and Drug Administration Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency March 2020 https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-temporary-compounding-certain-alcohol-based-hand-sanitizer-products-during-public-health;
  - USP March 18, 2020 Compounding Alcohol-Based Hand Sanitizer During COVID-19 Pandemic https://www.usp.org/sites/default/files/usp/document/about/public-policy/usp-covid19-handrub.pdf; or
  - other professional compounding pharmacy organizations.

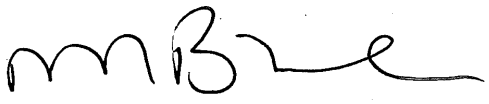
- The pharmacy and pharmacist comply with USP <795>, including beyond-use-dates and compounding records.
- The pharmacy labels each container of hand sanitizer in accordance with USP <795>, including ingredients, beyond use date, lot number, directions for use, etc. Specific patient information is not 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.

IT IS SO ORDERED.



Monica Bharel, MD, MPH
Commissioner, Massachusetts Department of Public Health

April 3, 2020