

Title: COVID-19 Public Health Emergency:  
Compounding Hand Sanitizer for OTC Sale

Policy No. I.D.4

Issued: 03-16-2020  
Ratified: 05-27-2020  
Extended: 11-18-2020

Revised: 02-10-2021  
Terminated: 11-17-2021  
Expired: 12-31-2021

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1. §2535 – *General Standards* requires pharmacies engaged in compounding activities to comply with various standards, including the requirement for all such activity to occur pursuant to a patient-specific prescription. There are provisions for veterinarian-administered compounds as well as anticipatory compounding based on previous orders.
  2. The preparation of medications for over-the-counter (OTC) sale is not considered compounding by the Board and is considered manufacturing by the federal Food & Drug Administration (FDA).
  3. The FDA published a Final Guidance Document on March 14 titled *Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency*
  4. The Board President directed Board staff to exercise enforcement discretion relative to pharmacies compounding hand sanitizer for OTC sale as long as those activities were in compliance with the FDA policy guidance.
  5. During their November 18, 2020 meeting, the members voted to extend this interim policy until the conclusion of the public health emergency unless terminated sooner.
  6. The FDA issued a revision to their guidance document relative to the compounding of hand sanitizer products; it became effective on February 10, 2021. The [\*Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency Immediately in Effect Guidance for Industry\*](#) is available here.
  7. The FDA announced their intention to withdraw, effective December 31, 2021, their guidances originally issued in March 2020 outlining temporary policies for manufacturers that were not drug manufacturers at the time to produce certain alcohol-based hand sanitizer and alcohol for use in hand sanitizers during the public health emergency. Effective December 31, 2021, companies manufacturing alcohol-based hand sanitizers under the temporary policies must cease production of such products. After that date, manufacturers intending to continue producing hand sanitizer may do so provided they comply with the tentative final monograph for over-the-counter topical antiseptics and other applicable requirements, including the FDA's [\*Current Good Manufacturing Practice \(CGMP\)\*](#) requirements. Hand sanitizers manufactured before or on

December 31, 2021 and produced under the temporary guidances must no longer be sold after March 31, 2022.