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Disaster Guidance for Pharmacies Affected by Floods

This document provides regulatory guidance for pharmacies that were forced to close due to the flooding and are seeking to set up temporary a pharmacy location. For additional information, definitions, and requirements, please review the sources noted below.

Flooded Pharmacies

- Notify the Board within 48 hours if the pharmacy has closed unexpectedly. Do this through your Online Services Account using the “update” license feature.
- Notify the public promptly.
 - See Rule 8.3 of the Administrative Rules of the Board of Pharmacy for requirements for notifying the public.
- Notify the Board immediately if the flooding has affected the strength, purity or labeling of any drugs, medications, legend devices or other materials in the pharmacy. See 26 V.S.A. § 2063(b). Do this through your Online Services Account using the “update” license feature.
- Remove any adulterated drugs from inventory.
 - Drugs are adulterated if any part is filthy, putrid, or decomposed, or does not meet FDA standards. See Rule 9.9.
 - See Rule 9.10 for additional information on the requirements for removing adulterated drugs from inventory.
- Unadulterated drugs may be sold or transferred between pharmacies.
 - Pharmacies must follow the requirements for transferring or selling unadulterated drugs, including special requirements for transferring controlled substances. See Rule 9.20 for the requirements.
 - If transferring unadulterated drugs to an emergency pharmacy location, Board approval for the transfer of the drugs must be obtained. See Rule 7.11.
- A pharmacy may operate out of a trailer or other temporary structure without obtaining a new pharmacy license so long as
 - the structure is stationary and located at the same physical location as the pharmacy, such as the pharmacy’s parking lot;

- the licensee complies with Rule 7.10, Renovations, including the requirement to pre-submit a floor plan and other documentation. Do this through your Online Services account using the “update” license feature.
- Get an inspection. An inspection of the temporary structure is required before operation, as with any other significant renovation. Rule 7.10.
 - Your license update must be complete in order for the Office to schedule the inspection.
 - The office will contact you with a date and time of the inspection once your application is complete.
 - Once an inspection is complete the inspector will notify you directly at the email the office has on file. Please make sure the address in your application is current and accurate.
- Pass an OPR inspection. To pass an OPR inspection, the temporary structure must meet the following standards:
 - Security (Rule 9.7)
 - Hygiene (Rule 9.8)
 - Drug storage (Rule 9.13)
 - Equipment (Rule 9.14)
 - Reference materials (may be provided electronically) (Rule 9.15)

Opening an Emergency Pharmacy Location

For pharmacies seeking to open a temporary, emergency pharmacy at a new location, please take the following steps:

- Apply for an emergency license for the new pharmacy location. To do so, you must apply through OPR’s website using your Online Services Account and select the emergency license type.
- Schedule and pass an inspection as described above.
- Request Board approval before using any equipment, supplies, or drug inventory from the old location. See Rule. 7.11 and applicable USP standards. Submit requests through your Online Services account.
 - The Board may approve the use of unadulterated drug stock from flooded pharmacies if the bottles’ outer safety seals are intact and if floodwaters did not actually touch the bottles. *See USP <659> regarding the definition and conditions of a “dry space”.* Temperature fluctuation during the flood shall also be considered. *See Rule 9.13 and USP <1079>.*

- An emergency license is valid for 60 days.
 - Upon application, the Board may extend the emergency license for the new location for up to 2 years from *issuance of the original emergency license*.
 - You must apply for an extension before the expiration of the original emergency license by uploading an extension request to your Online Services account using the “update” feature.

Reopening a pharmacy after repairs/clean-up from disaster

- If flooding or remodeling affected a pharmacy’s security, the pharmacy must be reinspected by OPR before reopening.
- Before renewing operations out of the pharmacy, document remodeling and renovation as required under Rule 7.10 and schedule and pass an inspection as explained above.

Resources

- Title 26, Chapter 36 of the Vermont Statutes Annotated:
<https://legislature.vermont.gov/statutes/chapter/26/036>
- Administrative Rules of the Board of Pharmacy:
<https://sos.vermont.gov/media/3tjpp5kk/5-rx-rules-2015-final-adopted-august-24-2015.pdf>