

BOARD OF PHARMACY

DIVISION 7

PUBLIC HEALTH EMERGENCY

855-007-0010

Declaration of Emergency

(1) With the exception of sub-section (2)(a) of OAR 855-007-0060, section (2) of OAR 855-007-0080, and sub-sections (7)(a) and (7)(b) of OAR 855-007-0080 that are always in effect, the rules in this Division are only effective when:

(a) A State of Emergency or a Public Health Emergency has been declared by the Governor of Oregon under ORS 401.055 or ORS 433.441 through 433.452; and

(b) The provisions of any relevant rules in Chapter 855 Oregon Administrative Rules have been suspended by the Governor under the authority of ORS 401.065(2); or

(c) A signatory to the Pacific Northwest Emergency Management Arrangement (the states of Alaska, Idaho, Oregon, Washington, the Province of British Columbia, and Yukon) has requested assistance during a civil emergency as authorized in Chapter 25 Oregon Laws 2008.

(d) A signatory to the Emergency Management Assistance Compact has requested assistance during a civil emergency as authorized in ORS 401.043.

(2) When a state of emergency or a public health emergency has been declared such that these rules are in effect, if there is any contradiction between these rules and rules in other divisions of Chapter 855, these rules shall govern, otherwise rules in those other divisions shall continue to apply.

Stat. Auth.: ORS 401.043, 401.065, 433.441, 689.205

Stats. Implemented: Chapter 25 Oregon Laws 2008, ORS 401.055, 689.155

855-007-0020

Applicability

(1) These rules apply to all persons licensed or registered with the Board under OAR Chapter 855 and to any persons acting under the authority of Oregon State Public Health Division or any other state agency, or any local or county health department or emergency manager, during a Declared Emergency or a Public Health Emergency, or to any such person acting in preparation for a Public Health Emergency.

(2) These rules may apply to the whole state of Oregon or only to a county or area included in the declared emergency. They also apply to the activities of any licensee or registrant who is working during a declared emergency in the state or territory of any of the signatories of Pacific Northwest Emergency Management Arrangement or the Emergency Management Assistance Compact.

(3) These rules apply to the dispensing and administration of drugs and vaccines to any person within an area subject to an emergency declaration or to any person who has been displaced from their place of residence even if the place to which they have been displaced has not been included in the emergency declaration.

(4) Insofar as neither the Governor of Oregon nor the Board has the authority to waive any provisions of Federal Law, nothing in these rules that conflicts with the Federal Controlled Substances Act (CSA) or the implementing regulations in 21 CFR, shall apply to controlled substances as listed in Division 80 of this chapter of rules, unless an agency of the US Government has waived the appropriate section of the CSA or the implementing regulations in 21 CFR.

Stat. Auth.: ORS 401.065, 433.441, 689.205

Stats. Implemented: Chapter 25 Oregon Laws 2008, ORS 689.155

855-007-0030

Definitions

(1) Emergency Management Assistance Compact (EMAC) means the compact for mutual assistance that was ratified by Congress and signed by all states, and is codified in ORS 401.043.

(2) “Emergency Prescription” means a record that is created in a pharmacy that records the dispensing of a refill of a medication, or a new or modified medication therapy to a patient in the absence of a valid prescription.

(3) “Emergency Prescription Drug Order” means an order issued by the State Public Health Officer during a Public Health Emergency for pharmacists to dispense designated prescription drugs to treat or provide prophylaxis to large numbers of patients designated by OSPHD protocols.

(4) “Medications”: In this division of rules, the term “medications” means drugs or vaccines or medical devices, or any combination of these terms.

(5) “Mobile Pharmacy” means a pharmacy that is self propelled or movable by another vehicle that is self propelled.

(6) “Oregon State Public Health Division” (OSPHD) means that division of the Oregon Department of Human Services (DHS) that is responsible for planning for and responding to a public health emergency.

(7) “Pacific Northwest Emergency Management Arrangement” (PNEMA) means the compact, ratified in Chapter 25 Oregon Laws 2008, between the states of Alaska, Idaho, Oregon and Washington, and the Province of British Columbia, and Yukon, to provide mutual assistance in an emergency or public health emergency.

(8) “Public Health Emergency” means an imminent threat or occurrence of an illness or health condition caused by terrorism, bioterrorism, epidemic or pandemic disease, novel and highly fatal infectious agent or biological toxin, or natural or man-made disaster, that poses a substantial risk of a significant number of human fatalities or incidents of permanent or long-term disability that is beyond the capacity of local government or non-governmental organizations to resolve.

(9) “State of Emergency” means a governmental declaration, usually issued because of a Public Health Emergency or a natural or human-caused disaster that may authorize the suspension of certain administrative rules, alert citizens to alter their normal behaviors, and direct government agencies to implement emergency preparedness plans.

(10) “Strategic National Stockpile” (SNS) means the US Government stockpile of antiviral medications and other medications and medical supplies that can be made available to a state in an emergency.

(11) “Temporary Pharmacy” means a facility established during a Public Health Emergency or State of Emergency to temporarily provide pharmacy services within or adjacent to an area covered by a State of Emergency.

Stat. Auth.: ORS 401.065, 433.441, 689.205

Stats. Implemented: Chapter 25 Oregon Laws 2008, ORS 689.155

855-007-0040

Delegation of Authority

In this division of rules, any authority vested in the Board may be exercised by the Executive Director, any person acting as Executive Director in his absence or incapacity, or any person he designates to make such decisions on his behalf.

Stat. Auth.: ORS 689.205,

Stats. Implemented: ORS 689.165

855-007-0050

Emergency Licensure

(1) Article V of ORS 401.043 (EMAC) and Article V of Annex B of PNEMA provide that whenever a person holds a license, certificate or other permit issued by a signatory to the compact evidencing the meeting of qualifications for professional, mechanical or other skills, and when such assistance is requested by the receiving signatory, the person is deemed to be licensed, certified or permitted by the signatory requesting assistance to render aid involving the skill to meet an emergency or disaster, to the extent allowed by law and subject to limitations and conditions as the requesting signatory prescribes by executive order or otherwise.

(2) When an emergency has been declared, a drug outlet may employ a pharmacist, intern or pharmacy technician who does not hold a license issued by the Board, provided that the individual provides evidence that they hold a comparable license issued by any other state or signatory to PNEMA or EMAC.

(3) In an emergency, the Board may grant an emergency temporary license to a licensee of the board of pharmacy of any state, province, foreign state or political sub-division that is not a signatory to PNEMA or EMAC as follows:

(a) A pharmacist, intern, pharmacy technician or certified pharmacy technician who holds an active license in another state, province, foreign state or political sub-division that is not suspended or restricted for any reason and who is sponsored by a pharmacy that has an active registration from the Board may be granted an emergency temporary license subject to approval by the Board of an application that contains:

(A) The name, permanent address and phone number of the applicant;

(B) The license number and state, province or political sub-division of permanent licensure;

(C) The name and license number of the sponsoring Oregon pharmacy; and

(D) Any other information requested by the Board.

(b) The emergency temporary license issued under these rules shall be valid for a period determined by the Board, but not exceeding six months. If the emergency still exists after six months, the Board may renew any emergency temporary license for an additional six months.

(c) The Board shall notify the sponsoring pharmacy of the approval of each emergency temporary license.

(d) A licensee granted an emergency temporary license under this rule may only practice in the sponsoring pharmacy or a pharmacy under common ownership with the sponsoring pharmacy, except that the licensee may transfer to another pharmacy that is not under common ownership with the sponsoring pharmacy, provided that they notify the Board within three days.

(4) Inactive License Reactivation: In an emergency, the Board may allow a pharmacist whose license has been inactive for no more than two years to reactivate their license without completing any required continuing education. The license will revert to an inactive status at the end of six months unless all required continuing education has been completed.

Stat. Auth.: ORS 401.065, 433.441, 689.205

Stats. Implemented: Chapter 25 Oregon Laws 2008, ORS 689.151, 689.155

855-007-0060

Emergency Medication Distribution and Storage

(1) General: When an emergency is declared that requires medications from the Strategic National Stockpile (SNS), these will be delivered to a state Receipt, Staging and Storage center (RSS) for further distribution to Points of Dispensing (PODs) selected by OSPHD.

(2) Storage of medications from SNS:

(a) The RSS is authorized to store any medications from the SNS prior to and during an emergency without any registration from the Board. This authority to possess medications shall extend beyond the declared emergency until procedures issued by OSPHD for the return or destruction of unused medications have been completed.

(b) PODs are authorized to store any medications from the SNS during an emergency without any registration from the Board. This authority to possess medications shall extend beyond the declared emergency until procedures issued by OSPHD for the return or destruction of unused medications have been completed.

(3) Repackaging: If it is necessary to repackage medications into unit-of-use regimen packages, this will be done at RSS under Centers for Disease Control (CDC) protocols as follows:

(a) Repackaging equipment will be provided by SNS;

(b) Staff from the CDC Technical Advisory Response Unit (TARU) will train the repackaging team members on the use of the equipment and will provide team leadership.

(c) OSPHD will establish procedures and provide team members.

(d) Unit-of-use regimens shall be labeled in accordance with SNS protocols as follows:

(A) Official health agency name, city and state;

(B) Prescriber's name – when using State protocols prescriber's name will be "State Protocol";

(C) Date repackaged;

- (D) Quantity of medications in the regimen;
- (E) Prescription number and lot number of the drug;
- (F) Number for 24-hour telephone line;
- (G) Patients name left blank – to be filled in by dispenser.

(4) Distribution: SNS medications shall be distributed from PODs in accordance with the dispensing procedures issued by OSPHD in the Standardized Point of Distribution Field Operation Guide.

(5) Administration: The POD supervisor or approved health care provider shall follow protocols approved by OSPHD or Centers for Disease Control (CDC) for distribution or administration of medications from SNS.

(6) An Intake Form that shall serve as a valid prescription is to be filled out for each person receiving medication at a POD. The intake form is to be retained as specified in OAR 855-007-0110(1).

(7) Returns: At the conclusion of the emergency, all such medications are to be returned to the RSS or other designated location under protocols issued by OSPHD.

Stat. Auth.: ORS 401.065, 433.441, 689.205

Stats. Implemented: ORS 689.155

855-007-0080

Emergency Immunization and Anti-viral Distribution

When these rules are in effect because of a Public Health Emergency that requires the distribution and administration of vaccines or antiviral medications, the following principles and procedures shall apply:

(1) The distribution of antiviral medications is to be in accordance with the Antiviral Distribution Plan promulgated by OSPHD as part of the Public Health Pandemic Influenza Plan.

(2) Local and county health departments (LHD) are authorized to store medications received from RSS, and to distribute these to designated Treatment Centers (TC) that may include but are not limited to:

- (a) LHD;
- (b) Clinicians;

- (c) Community health clinics;
- (d) Independent and chain pharmacies;
- (e) Hospitals and other health care facilities;
- (f) Temporary pharmacies;
- (g) Mobile pharmacies;
- (h) Tribal health care facilities;

(4) A facility designated as a Treatment Center may possess, dispense and administer vaccines and antiviral medications during the declared emergency. All such medications shall be stored in accordance with manufacturers' guidelines.

(5) The designated health-care provider at a Treatment Center shall be responsible for administration, distribution and tracking of vaccines and antiviral medications in accordance with procedures established by OSPHD. Only a health-care provider who has been appropriately trained may administer a medication. Duties, other than administering medications, may be performed by a pharmacy technician when under the supervision of a pharmacist or other appropriately trained health-care provider.

(6) An Individual Data Collection Form (IDCF) shall be filled out for each person receiving an immunization or antiviral medication at a Treatment Center, and this IDCF shall be treated as a valid prescription and retained as follows:

(a) An IDCF initiated at a pharmacy or other licensed or registered health-care facility shall be filed and retained for three years;

(b) An IDCF initiated at a facility that is not a licensed or registered health-care facility or at a temporary or mobile pharmacy shall be sent to OSPHD at the end of the state of emergency except that where the temporary or mobile facility has been established under the authority of OAR 855-007-0100(5) all records shall be filed in accordance with OAR 855-007-0110(4).

(7) Community Partner: In this rule, a Community Partner means any entity that is authorized by OSPHD or OBOP to:

(a) Purchase and store antiviral medications prior to a pandemic event;

(b) Store antiviral medications in a Board registered facility or at a tribal site in accordance with manufacture's guidelines;

(c) Take possession of the antiviral stock and distribute to critical infrastructure and key resources when so directed by OSPHD in accordance with OSPHD protocols and procedures, subject to:

(A) All medications must be distributed within 72 hours of removal from the storage site;

(B) Medications must be stored in accordance with manufacture's guidelines;

(C) All distributions must be recorded on a Distribution Log that shall include:

(i) The name and age of the person receiving the medication;

(ii) The name, strength and quantity of the medication;

(iii) The date and the time of the distribution.

(D) The Distribution Log shall be treated as a valid prescription and returned to OSPHD after the emergency is ended;

(3) This authority for LHDs, TCs and Community Partners to possess medications shall extend beyond the declared emergency until procedures issued by OSPHD for the return or destruction of unused medications have been completed.

Stat. Auth.: ORS 401.065, 433.441, 689.205

Stats. Implemented: ORS 689.155

855-007-0090

Emergency Pharmacy Rules

Refills:

(1) A pharmacist in the area covered by a declared emergency or in an area engaged in disaster assistance may dispense a refill of a prescription medication without a valid prescription provided that:

(a) In the pharmacist's professional judgment, the medication is essential to the maintenance of the patient's health or the continuation of therapy; and

(b) The pharmacist provides no more than a 30-day supply; and

(c) The pharmacist records all relevant information and indicates that it is an Emergency Prescription; and

(d) The pharmacist informs the patient or the patient's agent that the medication is being provided without a prescriber's authorization and that a prescriber authorization is required for any additional refill.

(e) If the refill is for a controlled substance, permission has been granted by the DEA for this type of refill, either by waiver of appropriate controlled substance regulations or by notification to the Board.

New and modified medication therapy:

(2) A pharmacist in the area covered by a declared emergency or in an area engaged in disaster assistance may, after consultation with any authorized prescriber, initiate or modify any medication therapy, and dispense an amount of the medication to meet the patient's health needs until that patient can be seen by a health-care practitioner, provided that:

(a) The pharmacist acts in accordance with currently accepted standards of care; and

(b) In the pharmacist's professional judgment, the medication is essential to the maintenance of the patient's health or to the continuation of therapy; and

(c) The pharmacist records all relevant information to a form and indicates that a medication therapy has been initiated or modified and that this is an Emergency Prescription; and

(d) The pharmacist informs the patient or the patient's agent at the time of dispensing that the medication is being provided in the absence of a valid patient – prescriber relationship but that a prescriber was consulted regarding the appropriateness of the medication therapy; and

(e) The pharmacist informs the patient or the patient's agent that a prescriber authorization is required for any refill.

Stat. Auth.: ORS 401.065, 433.441, 689.205

Stats. Implemented: ORS 689.155

855-007-0100

Temporary Pharmacies

(1) When these rules are in effect, the Board may issue a Temporary Pharmacy Registration to any facility or mobile facility.

(2) A facility, including a mobile pharmacy, holding a Temporary Pharmacy Registration may store and dispense drugs in accordance with the requirements of OAR 855-041 and these rules. The supervising pharmacist of a mobile pharmacy shall notify the Board of the pharmacy location within three working days of commencing business, and within three working days of any change in location.

(3) A Temporary Pharmacy Registration automatically expires when the state of emergency ends unless specifically extended by the Board.

(4) Within 30 days of the end of the declared emergency, the holder of a Temporary Pharmacy Registration shall notify the Board as to the disposition of its drug inventory and records.

(5) A temporary or mobile pharmacy that is established for the sole purpose of expediting distribution of emergency immunizations, antibiotics or antiviral medications under OAR 855-007-0080, is located adjacent to an existing pharmacy registered with the Board and is under the supervision of the PIC of the existing pharmacy, does not need to be registered as a temporary pharmacy.

Stat. Auth.: ORS 401.065, 433.441, 689.205

Stats. Implemented: ORS 689.155

855-007-0110

Emergency Recordkeeping

All records initiated during a state of emergency shall be disposed of as follows:

- (1) Individual Data Collection Forms shall be transferred to OSPHD at the end of the emergency and stored for three years;
- (2) Community Partner's Logs shall be transferred to OSPHD at the end of the emergency and stored for three years;
- (3) Emergency Prescriptions and Individual Data Collection Forms for medications dispensed from a pharmacy that is not a Temporary or Mobile Pharmacy shall be stored at the pharmacy for three years.
- (4) Emergency Prescriptions and Individual Data Collection Forms for medications dispensed from a Temporary or Mobile Pharmacy shall be stored at whichever of the following locations is most appropriate:
 - (a) At the parent pharmacy that provided the majority of the drugs to the Temporary or Mobile Pharmacy; or
 - (b) At the pharmacy that employs the supervising pharmacist of the Temporary or Mobile Pharmacy; or
 - (c) At the pharmacy that receives the unused drugs from the Temporary or Mobile Pharmacy at the end of the emergency.

Stat. Auth.: ORS 401.065, 433.441, 689.205

Stats. Implemented: ORS 689.155

855-007-0120

Damage to a Pharmacy and Medication Integrity

(1) If a pharmacy prescription department sustains damage, whether by flood or otherwise, the entire medication inventory, including any prescriptions that are awaiting pickup, is unfit for dispensing, shall be classified as adulterated and must be destroyed unless, in the pharmacist's professional judgment, any items are deemed safe for dispensing. Any incident of this nature must be reported to the Board within three working days.

(2) If a pharmacy loses power that affects temperature or humidity controls such that USP standards for proper storage of medications have been violated, such medications shall be classified as adulterated and may not be dispensed. Note: for those medications labeled for storage at "controlled room temperature," the acceptable range of temperature is 68° to 77°F with allowances for brief deviations between 59° to 86°F.

(3) Controlled substances damaged, lost or stolen shall be documented and reported to the DEA and the Board on DEA Form 41 or DEA Form 106 as appropriate.

(4) A pharmacy that is required to temporarily close or relocate due to an emergency must report this event to the Board within three working days.

Stat. Auth.: ORS 689.205,

Stats. Implemented: ORS 689.155