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SECRETARY OF STATE

JEFF MORGAN
INTERIM DEPUTY SECRETARY OF STATE

ARCHIVES DIVISION
STEPHANIE CLARK
DIRECTOR

800 SUMMER STREET NE
SALEM, OR 97310
503-373-0701

TEMPORARY ADMINISTRATIVE ORDER

INCLUDING STATEMENT OF NEED & JUSTIFICATION

BP 1-2020

CHAPTER 855
BOARD OF PHARMACY

FILED
03/23/2020 7:46 PM
ARCHIVES DIVISION
SECRETARY OF STATE
& LEGISLATIVE COUNSEL

FILING CAPTION: Emergency temporary rule (COVID-19) defines Pharmacist supervision

EFFECTIVE DATE: 03/23/2020 THROUGH 09/17/2020

AGENCY APPROVED DATE: 03/23/2020

CONTACT: Rachel Melvin
971-673-0001
pharmacy.rulemaking@oregon.gov

800 NE Oregon St., Suite 150
Portland,OR 97232

Filed By:
Rachel Melvin
Rules Coordinator

NEED FOR THE RULE(S):

On March 8, 2020 Governor Brown declared a public health emergency in Oregon related to the coronavirus pandemic (COVID-19); On March 23, 2020 Governor Brown issued Executive Order No. 20-12 ("Stay home, save lives") describing updated social distancing requirements.

JUSTIFICATION OF TEMPORARY FILING:

Whereas, during a declared emergency, the Board (or the Executive Director acting on behalf of the Board pursuant to OAR 855-007-0040) may adopt a temporary emergency rule as a way to address regulations impacting the health, safety and welfare of Oregonians. Whereas, ORS 689.225 directs the Board to adopt rules relating to the use of pharmacy technicians working under the supervision, direction and control of a pharmacist.
Whereas, in accordance with the nature of this COVID-19 pandemic, the focus remains on minimization of individuals in close contact with one another ("social distancing") to reduce transmission of the coronavirus. The Board expects pharmacies to continue to care for their patients in a manner that assures access and safety to citizens and pharmacy personnel. This temporary emergency rule permits a pharmacist, pharmacy intern or pharmacy technician to work remotely at a secured off-site, non-pharmacy location, during the declared public health emergency timeframe, for safe social distancing.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:

Executive Order No. 20-03 and Executive Order No. 20-12 located on the Governor's website https://coronavirus.oregon.gov/

AMEND: 855-006-0005

RULE SUMMARY: Definitions for words used in OAR Chapter 855

CHANGES TO RULE:

855-006-0005

Definitions ¶

As used in OAR chapter 855:¶
(1) "Board" means the Oregon Board of Pharmacy unless otherwise specified or required by the context.¶
(2) "Certified Oregon Pharmacy Technician" means a person licensed by the State Board of Pharmacy who assists the pharmacist in the practice of pharmacy pursuant to rules of the Board and has completed the specialized education program pursuant to OAR 855-025-0005. Persons used solely for clerical duties, such as recordkeeping, cashiering, bookkeeping and delivery of medications released by the pharmacist are not considered pharmacy technicians.¶
(3) "Clinical Pharmacy Agreement" means an agreement between a pharmacist or pharmacy and a health care organization or a physician that permits the pharmacist to engage in the practice of clinical pharmacy for the benefit of the patients of the health care organization or physician.¶
(4) "Collaborative Drug Therapy Management" means the participation by a pharmacist in the management of drug therapy pursuant to a written protocol that includes information specific to the dosage, frequency, duration and route of administration of the drug, authorized by a practitioner and initiated upon a prescription order for an individual patient and:¶
(a) Is agreed to by one pharmacist and one practitioner; or¶
(b) Is agreed to by one or more pharmacists at a single pharmacy registered by the board and one or more practitioners in a single organized medical group, such as a hospital medical staff, clinic or group practice, including but not limited to organized medical groups using a pharmacy and therapeutics committee.¶
(5) "Compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug or device:¶
(a) As the result of a practitioner's prescription drug order, or initiative based on the relationship between the practitioner, the pharmacist and the patient, in the course of professional practice; or¶
(b) For the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or dispensing; or¶
(c) The preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.¶
(6) "Confidential Information" means any patient information obtained by a pharmacist or pharmacy.¶
(7) "Consulting Pharmacist" means a pharmacist that provides a consulting service regarding a patient medication, therapy management, drug storage and management, security, education, or any other pharmaceutical service.¶
(8) The "Container" is the device that holds the drug and that is or may be in direct contact with the drug.¶
(9) "Dispensing or Dispense" means the preparation and delivery of a prescription drug pursuant to a lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration to or use by a patient or other individual entitled to receive the prescription drug.¶
(10) "Interpretation and evaluation of prescription orders" means the review of the order for therapeutic and legal correctness. Therapeutic review includes identification of the prescription drug ordered, its applicability and its relationship to the other known medications used by the patient and determination of whether or not the dose and time interval of administration are within accepted limits of safety. The legal review for correctness of the prescription order includes a determination that the order is valid and has not been altered, is not a forgery, is prescribed for a legitimate medical purpose, contains all information required by federal and state law, and is within the practitioner's scope of practice.¶
(11) "Labeling" means the process of preparing and affixing of a label to any drug container exclusive, however, of the labeling by a manufacturer, packer or distributor of a non-prescription drug or commercially packaged legend drug or device.¶
(12) "Monitoring of therapeutic response or adverse effect of drug therapy" means the follow up of the therapeutic or adverse effect of medication upon a patient, including direct consultation with the patient or his agent and review of patient records, as to result and side effect, and the analysis of possible interactions with other medications that may be in the medication regimen of the patient. This section shall not be construed to prohibit monitoring by practitioners or their agents.¶

(13) "Medication Therapy Management (MTM)" means a distinct service or group of services that is intended to optimize therapeutic outcomes for individual patients. Medication Therapy Management services are independent of, but can occur in conjunction with, the provision of a medication product.¶
(14) "Nationally Certified Exam" means an exam that is approved by the Board which demonstrates successful completion of a Specialized Education Program. The exam must be reliable, psychometrically sound, legally defensible and valid.¶
(15) "Non-legend drug" means a drug which does not require dispensing by prescription and which is not restricted to use by practitioners only.¶
(16) "Offering or performing of those acts, services, operations or transactions necessary in the conduct, operation, management and control of pharmacy" means, among other things:¶
(a) The creation and retention of accurate and complete patient records;¶
(b) Assuming authority and responsibility for product selection of drugs and devices;¶
(c) Developing and maintaining a safe practice setting for the pharmacist, for pharmacy staff and for the general public;¶
(d) Maintaining confidentiality of patient information.¶
(17) "Oral Counseling" means an oral communication process between a pharmacist and a patient or a patient's agent in which the pharmacist obtains information from the patient (or agent) and the patient's pharmacy records, assesses that information and provides the patient (or agent) with professional advice regarding the safe and effective use of the prescription drug for the purpose of assuring therapeutic appropriateness.¶
(18) Participation in Drug Selection and Drug Utilization Review:¶
(a) "Participation in drug selection" means the consultation with the practitioner in the selection of the best possible drug for a particular patient.¶
(b) "Drug utilization review" means evaluating prescription drug order in light of the information currently provided to the pharmacist by the patient or the patient's agent and in light of the information contained in the patient's record for the purpose of promoting therapeutic appropriateness by identifying potential problems and consulting with the prescriber, when appropriate. Problems subject to identification during drug utilization review include, but are not limited to:¶
(A) Over-utilization or under-utilization;¶
(B) Therapeutic duplication;¶
(C) Drug-disease contraindications;¶
(D) Drug-drug interactions;¶
(E) Incorrect drug dosage;¶
(F) Incorrect duration of treatment;¶
(G) Drug-allergy interactions; and¶
(H) Clinical drug abuse or misuse.¶
(19) "Pharmaceutical Care" means the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life. These outcomes include:¶
(a) Cure of a disease;¶
(b) Elimination or reduction of a patient's symptomatology;¶
(c) Arrest or slowing of a disease process; or¶
(d) Prevention of a disease or symptomatology.¶
(20) "Pharmacy Technician" means a person licensed by the State Board of Pharmacy who assists the pharmacist in the practice of pharmacy pursuant to rules of the Board but has not completed the specialized education program pursuant to OAR 855-025-0012.¶
(21) "Practice of clinical pharmacy" means:¶
(a) The health science discipline in which, in conjunction with the patient's other practitioners, a pharmacist provides patient care to optimize medication therapy and to promote disease prevention and the patient's health and wellness;¶
(b) The provision of patient care services, including but not limited to post-diagnostic disease state management

services; and¶
(c) The practice of pharmacy by a pharmacist pursuant to a clinical pharmacy agreement.¶
(22) "Practice of pharmacy" is as defined in ORS 689.005.¶
(23) "Prescription released by the pharmacist" means, a prescription which has been reviewed by the pharmacist that does not require further pharmacist intervention such as reconstitution or counseling.¶
(24) "Prohibited conduct" means conduct by a licensee that:¶
(a) Constitutes a criminal act against a patient or client; or¶
(b) Constitutes a criminal act that creates a risk of harm to a patient or client.¶
(25) "Proper and safe storage of drugs and devices and maintenance of proper records therefore" means housing drugs and devices under conditions and circumstances that:¶
(a) Assure retention of their purity and potency;¶
(b) Avoid confusion due to similarity of appearance, packaging, labeling or for any other reason;¶
(c) Assure security and minimize the risk of their loss through accident or theft;¶
(d) Accurately account for and record their receipt, retention, dispensing, distribution or destruction;¶
(e) Protect the health, safety and welfare of the pharmacist, pharmacy staff and the general public from harmful exposure to hazardous substances.¶
(26) "Quality Assurance Plan" is a written set of procedures to ensure that a pharmacy has a planned and systematic process for the monitoring and evaluation of the quality and appropriateness of pharmacy services and for identifying and resolving problems.¶
(27) "Responsibility for advising, when necessary or when regulated, of therapeutic values, content, hazards and use of drugs and devices" means advice directly to the patient, either verbally or in writing as required by these rules or federal regulation, of the possible therapeutic response to the medication, the names of the chemicals in the medication, the possible side effects of major importance, and the methods of use or administration of a medication.¶
(28) "Specialized Education Program" means;¶
(a) A program providing education for persons desiring licensure as pharmacy technicians that is approved by the board and offered by an accredited college or university that grants a two-year degree upon successful completion of the program; or¶
(b) A structured program approved by the board and designed to educate pharmacy technicians in one or more specific issues of patient health and safety that is offered by:¶
(A) An organization recognized by the board as representing pharmacists or pharmacy technicians;¶
(B) An employer recognized by the board as representing pharmacists or pharmacy technicians; or¶
(C) A trade association recognized by the board as representing pharmacies.¶
(29) "Supervision by a pharmacist" means being stationed within the same work area as the pharmacy technician or certified Oregon pharmacy technician being supervised, coupled with the ability to control and be responsible for the pharmacy technician or certified Oregon pharmacy technician's action. During the declared public health emergency timeframe related to the 2020 COVID-19 pandemic, "supervision by a pharmacist" means pharmacist monitoring of a pharmacy technician or intern being supervised, coupled with the ability to control and be responsible for the technician or interns actions and for the following remote processing functions only: prescription or order entry, other data entry, and insurance processing of prescriptions and medication orders. ¶
(30) "Therapeutic substitution" means the act of dispensing a drug product with a different chemical structure for the drug product prescribed under circumstances where the prescriber has not given clear and conscious direction for substitution of the particular drug for the one which may later be ordered.¶
(31) "Verification" means the confirmation by the pharmacist of the correctness, exactness, accuracy and completeness of the acts, tasks, or functions performed by an intern or a pharmacy technician or a certified Oregon pharmacy technician.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155

OFFICE OF THE SECRETARY OF STATE
BEV CLARNO
SECRETARY OF STATE

JEFF MORGAN
INTERIM DEPUTY SECRETARY OF STATE

ARCHIVES DIVISION
STEPHANIE CLARK
DIRECTOR

800 SUMMER STREET NE
SALEM, OR 97310
503-373-0701

TEMPORARY ADMINISTRATIVE ORDER

INCLUDING STATEMENT OF NEED & JUSTIFICATION

BP 2-2020

CHAPTER 855
BOARD OF PHARMACY

FILED
03/25/2020 10:51 AM
ARCHIVES DIVISION
SECRETARY OF STATE
& LEGISLATIVE COUNSEL

FILING CAPTION: Prohibits dispensing of certain drugs for COVID19 prevention; limits treatment to COVID19 hospitalized patients

EFFECTIVE DATE: 03/25/2020 THROUGH 09/20/2020

AGENCY APPROVED DATE: 03/25/2020

CONTACT: Rachel Melvin
971-673-0001
pharmacy.rulemaking@oregon.govv

800 NE Oregon St., Suite 150
Portland,OR 97232

Filed By:
Rachel Melvin
Rules Coordinator

NEED FOR THE RULE(S):

On March 8, 2020 Governor Brown declared a public health emergency in Oregon related to the coronavirus pandemic (COVID-19). Whereas, during a declared emergency, the Board (or the Executive Director acting on behalf of the Board pursuant to OAR 855-007-0040) may adopt a temporary emergency rule as a way to address regulations impacting the health, safety and welfare of Oregonians. Chloroquine is effective for malaria treatment and prophylaxis, and hydroxychloroquine is effective for treatment of rheumatoid arthritis, systemic lupus erythematosus and porphyria cutanea tarda. There are no data currently available to justify the use of chloroquine or hydroxychloroquine for prevention or treatment of sub-critical COVID-19 infection. There are no data currently available on the use, dosing, or duration of these medication for COVID-19 infection. Use of these agents for the presumptive treatment or prevention of COVID-19 infection threatens the supply for patients who depend on its availability.

JUSTIFICATION OF TEMPORARY FILING:

Use of these agents for the presumptive treatment or prevention of COVID-19 infection threatens the supply for patients who depend on its availability.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:

Executive Order No. 20-03 located on the Governor's website at https://govstatus.egov.com/or-covid-19

ADOPT: 855-007-0085

RULE TITLE: Prescriptions for Chloroquine and Hydroxychloroquine during COVID-19 Public Health Emergency

RULE SUMMARY: This temporary emergency rule prohibits the dispensing of chloroquine and hydroxychloroquine for presumptive treatment or prevention of COVID-19 infection to preserve supplies for treatment of malaria, inflammatory conditions, and documented COVID-19 infection in hospitalized patients.

RULE TEXT:

(1) Prescription drug orders for chloroquine or hydroxychloroquine may only be dispensed if:

(a) The prescription is a continuation of therapy begun prior to March 8, 2020; or

(b) The prescriber has provided a diagnosis code based on clinical findings for which the medication is medically indicated; or

(c) If written for a COVID-19 diagnosis, the patient is hospitalized with a positive test result for COVID-19 infection.

(2) Dispensing prescriptions for chloroquine or hydroxychloroquine other than as outlined in this rule is prohibited.

(3) This temporary rule is in effect for the duration of the COVID-19 public health emergency or until rescinded.

STATUTORY/OTHER AUTHORITY: ORS 689.205

STATUTES/OTHER IMPLEMENTED:

OFFICE OF THE SECRETARY OF STATE
BEV CLARNO
SECRETARY OF STATE

JEFF MORGAN
INTERIM DEPUTY SECRETARY OF STATE

ARCHIVES DIVISION
STEPHANIE CLARK
DIRECTOR

800 SUMMER STREET NE
SALEM, OR 97310
503-373-0701

TEMPORARY ADMINISTRATIVE ORDER

INCLUDING STATEMENT OF NEED & JUSTIFICATION

BP 3-2020

CHAPTER 855
BOARD OF PHARMACY

FILED
04/02/2020 5:06 PM
ARCHIVES DIVISION
SECRETARY OF STATE
& LEGISLATIVE COUNSEL

FILING CAPTION: Prohibits dispensing of certain drugs for COVID19 prevention; limits treatment to COVID19 hospitalized patients

EFFECTIVE DATE: 04/02/2020 THROUGH 09/20/2020

AGENCY APPROVED DATE: 04/02/2020

CONTACT: Rachel Melvin
971-673-0001
pharmacy.rulemaking@oregon.gov

800 NE Oregon St., Suite 150
Portland,OR 97232

Filed By:
Rachel Melvin
Rules Coordinator

NEED FOR THE RULE(S):

On March 8, 2020 Governor Brown declared a public health emergency in Oregon related to the coronavirus pandemic (COVID-19). Whereas, during a declared emergency, the Board (or the Executive Director acting on behalf of the Board pursuant to OAR 855-007-0040) may adopt a temporary emergency rule as a way to address regulations impacting the health, safety and welfare of Oregonians. Chloroquine (CQ) is effective for malaria treatment and prophylaxis, and hydroxychloroquine (HCQ) is effective for treatment of rheumatoid arthritis, systemic lupus erythematosus and porphyria cutanea tarda. There are no data currently available to justify the use of chloroquine or hydroxychloroquine for prevention or treatment of sub-critical COVID-19 infection. There are no data currently available on the use, dosing, or duration of these medication for COVID-19 infection. Use of these agents for the presumptive treatment or prevention of COVID-19 infection threatens the supply for patients who depend on its availability. Temporary emergency rule adopted 3/25/2020.

On April 2, 2020 the Board was notified of the challenges healthcare providers are facing related to COVID-19 testing capabilities and delayed turn-around times in Oregon This new language permits dispensing of chloroquine and hydroxychloroquine to patients with a clinical diagnosis of COVID-19 infection.

JUSTIFICATION OF TEMPORARY FILING:

Use of these agents for the presumptive treatment or prevention of COVID-19 infection threatens the supply for patients who depend on its availability. On 3/31/2020, the FDA added hydroxychloroquine to its shortage list; the Board was notified that distributors are allocating this drug.

Due to variations in COVID-19 testing availability and timeliness of results, pharmacists may dispense chloroquine and hydroxychloroquine to hospitalized patients with a positive test for or a clinical diagnosis of COVID-19 infection.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:

FDA National Drug Shortage List-
https://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Hydroxychloroquine%20Sulfate%2

ADOPT: 855-007-0085

SUSPEND: Temporary 855-007-0085 from BP 2-2020

RULE SUMMARY: This temporary emergency rule updates the prohibitions for the dispensing of chloroquine and hydroxychloroquine for presumptive treatment or prevention of COVID-19 infection to preserve supplies for treatment of malaria, inflammatory conditions, and documented COVID-19 infection in hospitalized patients.

CHANGES TO RULE:

855-007-0085
Prescriptions for Chloroquine and Hydroxychloroquine during COVID-19 Public Health Emergency
(1) Prescription drug orders for chloroquine or hydroxychloroquine may only be dispensed if:¶
(a) The prescription is a continuation of therapy begun prior to March 8, 2020; or¶
(b) The prescriber has provided a diagnosis code based on clinical findings for which the medication is medically indicated; or ¶
(c) If written for a COVID-19 diagnosis, the patient is hospitalized with a positive test result for or clinical diagnosis of COVID-19 infection.¶
(2) Dispensing prescriptions for chloroquine or hydroxychloroquine other than as outlined in this rule is prohibited.¶
(3) This temporary rule is in effect for the duration of the COVID-19 public health emergency or until rescinded.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented:

OFFICE OF THE SECRETARY OF STATE
BEV CLARNO
SECRETARY OF STATE

JEFF MORGAN
INTERIM DEPUTY SECRETARY OF STATE

ARCHIVES DIVISION
STEPHANIE CLARK
DIRECTOR

800 SUMMER STREET NE
SALEM, OR 97310
503-373-0701

TEMPORARY ADMINISTRATIVE ORDER

INCLUDING STATEMENT OF NEED & JUSTIFICATION

BP 5-2020

CHAPTER 855
BOARD OF PHARMACY

FILED
04/09/2020 11:24 AM
ARCHIVES DIVISION
SECRETARY OF STATE
& LEGISLATIVE COUNSEL

FILING CAPTION: Temporary extension of Pharmacy Technician licenses to 12/31/2020 (COVID-19)

EFFECTIVE DATE: 04/09/2020 THROUGH 10/05/2020

AGENCY APPROVED DATE: 04/09/2020

CONTACT: Rachel Melvin
971-673-0001
pharmacy.rulemaking@oregon.gov

800 NE Oregon St., Suite 150
Portland,OR 97232

Filed By:
Rachel Melvin
Rules Coordinator

NEED FOR THE RULE(S):

Due to COVID-19 public health emergency testing centers have closed or have limited testing capabilities and technicians are unable to take and pass the certification exam required to apply for a Certified Oregon Pharmacy Technician license.

JUSTIFICATION OF TEMPORARY FILING:

Due to potential pharmacy staffing shortages this policy helps minimize distruptions to pharmacy work force.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:

Executive Order No. 20-03 located at https://www.oregon.gov/gov/admin/Pages/eo_20-03.aspx

AMEND: 855-025-0010

RULE TITLE: Licensure as a Pharmacy Technician

RULE SUMMARY: Pharmacy Technician license expiration date.

RULE TEXT:
(1) The license of a Pharmacy Technician expires the second June 30 from the date of issue and is not to exceed two years, except that due to the COVID-19 declared public health emergency, Pharmacy Technician (PT) licenses set to expire June 30, 2020, will instead expire on 12/31/2020.
(2) The Pharmacy Technician license is not renewable.
(3) A time limited extension of a Pharmacy Technician license may be granted once by petition to the Board. The written completed petition must be received by the Board prior to the expiration of the PT license.
(4) An individual may reapply for a Pharmacy Technician license if the previous PT license is lapsed for a period greater than five years.

STATUTORY/OTHER AUTHORITY: ORS 689.205

STATUTES/OTHER IMPLEMENTED: ORS 689.225, ORS 689.486

OFFICE OF THE SECRETARY OF STATE
BEV CLARNO
SECRETARY OF STATE

JEFF MORGAN
INTERIM DEPUTY SECRETARY OF STATE

ARCHIVES DIVISION
STEPHANIE CLARK
DIRECTOR

800 SUMMER STREET NE
SALEM, OR 97310
503-373-0701

TEMPORARY ADMINISTRATIVE ORDER

INCLUDING STATEMENT OF NEED & JUSTIFICATION

BP 4-2020

CHAPTER 855
BOARD OF PHARMACY

FILED
04/07/2020 4:25 PM
ARCHIVES DIVISION
SECRETARY OF STATE
& LEGISLATIVE COUNSEL

FILING CAPTION: Emergency temporary rule (COVID19) for preceptor monitoring of interns at certain school-based rotations

EFFECTIVE DATE: 04/07/2020 THROUGH 10/03/2020

AGENCY APPROVED DATE: 04/07/2020

CONTACT: Rachel Melvin
971-673-0001
pharmacy.rulemaking@oregon.gov

800 NE Oregon St., Suite 150
Portland,OR 97232

Filed By:
Rachel Melvin
Rules Coordinator

NEED FOR THE RULE(S):

Preceptor to intern ratio is temporarily suspended to permit students to complete non-direct patient care School-based Rotational Internships (SRIs) required for graduation purposes, via remote learning

JUSTIFICATION OF TEMPORARY FILING:

Due to the COVID-19 public health emergency , certain SRI sites have limited personnel to host pharmacy interns. If ratio is not temporarily suspended, students will not be able to complete required number of hours necessary to graduate.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:

N/A

AMEND: 855-031-0026

RULE SUMMARY: Intern ratio for School-Based Rotation

CHANGES TO RULE:

855-031-0026
Ratio & Supervision ¶

(1) A pharmacist may not supervise more than one intern at a time at a TPI site who performs the duties of an intern as listed in OAR 855-019-0200(3)(g). A pharmacist may supervise more than one intern if only one intern performs the duties of an intern as listed in OAR 855-019-0200(3)(g) and if other interns supervised by the pharmacist perform the duties listed in OAR 855-025-0040.¶
(2) A preceptor may not supervise more than two interns simultaneously during a shift at an SRI site where patient specific recommendations for care or medications are provided without prior written authorization of the Board. During the declared public health emergency related to the 2020 COVID-19 pandemic, a preceptor may monitor

as many interns as they believe in their professional judgment is appropriate to achieve desired experiential outcomes for non-direct patient care learning opportunities only, while also preserving and assuring patient safety. The preceptor must retain documentation of all interns monitored during this timeframe.¶
(3) With the written approval of a school of pharmacy, and when in their professional judgment it is appropriate, a preceptor may supervise up to 10 interns at public-health outreach programs such as informational health fairs that provide general information but not direct patient care.¶
(4) For immunization clinics, an immunizing pharmacist may supervise up to two immunizing interns.¶
(5) A licensed preceptor may delegate the preceptor responsibilities to another licensed pharmacist or preceptor.¶
(6) The majority of an intern's overall experience must be with a licensed pharmacist preceptor.
Statutory/Other Authority: ORS 689.151, 689.205
Statutes/Other Implemented: ORS 689.255, 2009 OL Ch. 536