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NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 855
BOARD OF PHARMACY

FILED
07/17/2020 1:44 PM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Permits pharmacist monitoring of technicians/interns for certain remote processing functions in COVID19 PHE

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 09/09/2020 9:30 AM

The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing negative economic impact of the rule on business.

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Filed By:
Rachel Melvin
Rules Coordinator

HEARING(S)

Auxiliary aids for persons with disabilities are available upon advance request. Notify the contact listed above.

DATE: 09/09/2020

TIME: 8:30 AM

OFFICER: Rachel Melvin

ADDRESS: Oregon Board of Pharmacy
800 NE Oregon St.
Suite #150
Portland, OR 97232

SPECIAL INSTRUCTIONS:

This hearing meeting will be held via telephonic conference call. To participate, call 1-877-873-8017, participant code 139360#. LAST DAY AND TIME TO OFFER WRITTEN COMMENT TO AGENCY: 09/08/2020 12:00 PM, EMAIL WRITTEN COMMENT TO PHARMACY.RULEMAKING@OREGON.GOV. ORAL COMMENT CAN BE OFFERED AT THE HEARING AT DATE AND TIME DESCRIBED BELOW. WRITTEN COMMENTS MUST BE SUBMITTED BY 09/08/2020 BY 12:00 PM AND WILL NOT BE ACCEPTED AT THE RULEMAKING HEARING.

IF YOU WISH TO SUBMIT WRITTEN COMMENT AND PARTICIPATE IN THE RULEMAKING HEARING, YOU MUST SUBMIT YOUR WRITTEN COMMENTS IN ADVANCE OF THE RULEMAKING HEARING, BY 09/08/2020 AT 12 PM.

NEED FOR THE RULE(S):

COVID-19 PHE continues to require social/physical distancing policies; Board rules are needed to continue to permit pharmacist monitoring of technicians/interns for certain remote processing functions (prescription or order entry, other data entry, and insurance processing of prescriptions and medication orders only) due to ongoing coronavirus pandemic Public Health Emergency (PHE)

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:

Oregon Governor's Executive Orders related to the coronavirus public health emergency, documents can be found at govstatus.egov.com/or-covid-19

FISCAL AND ECONOMIC IMPACT:

None

COST OF COMPLIANCE:

(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).

Costs to pharmacies are unknown. This is an option for a pharmacy drug outlet to create and maintain necessary temporary social distancing policies and procedures, in response to their individual needs of employees. This is an option; this is not a mandate.

DESCRIBE HOW SMALL BUSINESSES WERE INVOLVED IN THE DEVELOPMENT OF THESE RULE(S):

This is not a requirement, utilization of this temporary alternative is voluntary.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? NO IF NOT, WHY NOT?

Per Oregon Governor's Executive Orders related to the coronavirus ongoing PHE.

AMEND: 855-006-0005

RULE SUMMARY: Need to continue to permit pharmacist monitoring of technicians/interns for certain remote processing functions (prescription or order entry, other data entry, and insurance processing of prescriptions and medication orders only) due to ongoing coronavirus pandemic Public Health Emergency (PHE)

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