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NOTICE OF PROPOSED RULEMAKING

INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 855
BOARD OF PHARMACY

FILED
08/28/2018 10:30 AM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Implementation of 2017 HB 2397 - Pharmacist Authority to Prescribe via Formulary and Protocol Compendia

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 09/27/2018 4:30 PM

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:
Karen MacLean
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HEARING(S)

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

DATE: 09/27/2018
TIME: 9:30 AM
OFFICER: Staff
ADDRESS: Portland State Office Building
800 NE Oregon St., Conf. Rm 1E
Portland, OR 97232

NEED FOR THE RULE(S):

ORS 689.645 and 689.649 require rules to implement pharmacist prescriptive authority for items recommended by the multi-disciplinary Public Health and Pharmacy Formulary Advisory Committee to the Board to adopt for the Formulary and Protocol Compendia.

These rules establish a pharmacist's authority to prescribe a drug, device, and via protocols recommended by the Committee and adopted by Board rule. These rules create the Formulary and Protocol Compendia, per Committee recommendations. They contemplate this authority for an Oregon licensed pharmacist, practicing in Oregon, and performing a patient assessment via a face-to-face, in-person interaction. Participation in prescribing authorities is voluntary, and only a pharmacist is entitled to practice pharmacy, pursuant to ORS 689.005.

These rules describe the Board's compliance expectations for prescribing from the authorized Compendia. Standards defined include (1) education and competency, (2) patient assessment, and determination of inclusion, exclusion and referral criteria (3) collaboration with other healthcare providers, including mandated notification (4) treatment and follow-up care planning, (5) record-keeping, and (6) prohibited practices.

These rules codify the Committee's recommendations from January 2018, February 2018 and July 2018. Additions to the Formulary and Protocol Compendia are: (1) devices, (2) continuation of therapy, (3) cough and cold symptom management, and (4) emergency contraception.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:

2017 HB 2397, Joint Commission of Pharmacy Practitioners Pharmacist's Patient Care Process 5/29/14, Oregon Board of Pharmacy and Public Health and Pharmacy Formulary Advisory Committee Core Elements approved 2/16/18, Minutes of the Public Health and Pharmacy Formulary Advisory Committee 1/24/18, 2/16/18 and 7/13/18 meetings. Documents are available on the Board's website at:
https://www.oregon.gov/pharmacy/Pages/PharmacyFormularyAdvisoryCommittee.aspx

FISCAL AND ECONOMIC IMPACT:

These fiscal and economic impact is dependent upon whether or not a pharmacist chooses to participate in prescribing services and if a pharmacy outlet chooses to offer pharmacist prescriptive services. Participation is voluntary.

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).

State agencies and local government are not impacted by these rules. Pharmacy stakeholders and the public may be impacted by these rules if utilized. Provision of formulary prescribing services by a pharmacist/pharmacy is voluntary.
2. a. Of the approximately 1500 pharmacy outlets registered in Oregon, about 50 to 100 are residential and may be considered small businesses.
2.b and c. The professional time to offer these services and comply with recordkeeping requirements may increase costs to the outlet, which may possibly be passed on to the public for prescribing services. Outlets will be required to establish and enforce policies and procedures and pharmacists must comply with the rules if they offer the services.

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

This is voluntary and a pharmacist is not mandated to offer prescribing services.

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

The statutorily mandated Public Health and Pharmacy Formulary Advisory Committee informed the content of these rules.

RULES PROPOSED:
855-019-0200, 855-020-0110, 855-020-0120, 855-020-0200, 855-020-0300, 855-041-1040

AMEND: 855-019-0200

RULE SUMMARY: General responsibilities of a pharmacist now include statutory authority to prescribe certain drugs and devices.

CHANGES TO RULE:

855-019-0200
General Responsibilities of a Pharmacist ¶

ORS 689.025 states that "the practice of pharmacy in the State of Oregon is declared a health care professional practice affecting the public health, safety and welfare". Pharmacy practice is a dynamic patient-oriented health service that applies a scientific body of knowledge to improve and promote patient health by means of appropriate drug use, drug-related therapy, and communication for clinical and consultative purposes. A pharmacist licensed to practice pharmacy by the Board has the duty to use that degree of care, skill, diligence and professional judgment that is exercised by an ordinarily careful pharmacist in the same or similar circumstances.¶
(1) A pharmacist while on duty must ensure that the pharmacy complies with all state and federal laws and rules governing the practice of pharmacy.¶
(2) Only a pharmacist may practice pharmacy as defined in ORS 689.005, to include the provision of patient care services. Activities that require the professional judgment of a pharmacist include but are not limited to:¶
(a) Drug Utilization Review;¶
(b) Counseling;¶
(c) Drug Regimen Review;¶
(d) Medication Therapy Management;¶
(e) Collaborative Drug Therapy Management or other post-diagnostic disease state management, pursuant to a valid agreement;¶
(f) Practice pursuant to State Drug Therapy Management Protocols;¶
(g) Prescribing a drug or device, as authorized by statute; ¶
(h) Ordering, interpreting and monitoring of a laboratory test;¶
(~~h~~i) Oral receipt or transfer of a prescription; and¶
(~~i~~j) Final verification of the work performed by those under their supervision.¶
(3) A pharmacist may not delegate any task listed in OAR 855-019-0200(2), except that a pharmacist may permit an intern to perform the duties of a pharmacist under their direction and supervision, after the intern has successfully completed his or her first academic year, and only after successful completion of coursework corresponding to those duties.¶
(4) An intern cannot prescribe a drug or device and cannot perform final verification.¶
(5) A pharmacist who is supervising an intern is responsible for the actions of that intern; however, this does not absolve the intern from responsibility for their own actions.¶
(6) A pharmacist on duty is responsible for supervising all pharmacy personnel, and ensuring that pharmacy personnel only work within the scope of duties allowed by the Board.¶
(7) A pharmacist may not permit non-pharmacist personnel to perform any duty they are not licensed and trained to perform.¶
(8) A pharmacist while on duty is responsible for the security of the pharmacy area including:¶
(a) Providing adequate safeguards against theft or diversion of prescription drugs, and records for such drugs;¶
(b) Ensuring that all records and inventories are maintained in accordance with state and federal laws and rules;¶
(c) Ensuring that only a pharmacist has access to the pharmacy when the pharmacy is closed.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.025, 689.151, 689.155, 689.645, 689.682, 689.689

ADOPT: 855-020-0110

RULE SUMMARY: These rules describe the Board's compliance expectations for prescribing from the formulary. These rules establish a pharmacist's authority to prescribe drugs and devices, and via protocols recommended by the committee adopted by the Board's formulary. They contemplate this authority for an Oregon licensed pharmacist, practicing in Oregon and the patient assessment must be performed via a face-to-face, in-person interaction. Recognize that participation in prescribing authorities is voluntary, and only a pharmacist is entitled to practice pharmacy, pursuant to ORS 689.005.

CHANGES TO RULE:

855-020-0110
Prescribing Practices
(1) A pharmacist located and licensed in Oregon may prescribe and dispense FDA-approved drugs and devices included on either the Formulary or Protocol Compendia, set forth in this Division. A pharmacist shall only prescribe a drug or device consistent with the parameters of the Formulary and Protocol Compendia, and in accordance with federal and state regulations. ¶
(2) The pharmacist is responsible for recognizing limits of knowledge and experience and for resolving situations beyond his or her pharmacist expertise by consulting with or referring patients to another health care provider.¶
(3) At a minimum, for each drug or device the pharmacist prescribes, the pharmacist must document the following, which constitutes the Visit Summary:¶
(a) Create, approve, and maintain a drug therapy management protocol based on current and referenced clinical guidelines that must include:¶
(A) Patient inclusion and exclusion criteria; and¶
(B) Explicit medical referral criteria; and¶
(b) Collect subjective and objective information about the patient's health history and clinical status. The patient assessment shall be performed in a face-to-face, in-person interaction and not through electronic means; and¶
(c) Utilize information obtained in the assessment to evaluate and develop an individualized patient-centered care plan, pursuant to the pharmacist's established drug therapy management protocol; and¶
(d) Implement the care plan, to include appropriate treatment goals, monitoring parameters, and follow-up; and¶
(e) Provide notification, preferably via an interoperable information technology system, to the patient's identified primary care provider or other care providers when applicable, within five business days following the prescribing of a compendia drug or device. ¶
(4) The pharmacist shall maintain all records associated with prescribing for a minimum of 10 years, including but not limited to the drug therapy management protocol, the prescription record, consultation, and Visit Summary, and a copy must be made available to the patient, provider, and Board upon request.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.645, ORS 689.649

ADOPT: 855-020-0120

RULE SUMMARY: This rule describes the Board's compliance expectations for prescribing from the formulary.

CHANGES TO RULE:

855-020-0120
Prescribing Prohibited Practices
The responsibility and authority to prescribe pursuant to the Formulary and Protocol Compendia is upon the pharmacist. A pharmacist shall not prescribe a drug or device to self or immediate family members.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.645, ORS 689.649

ADOPT: 855-020-0200

RULE SUMMARY: These rules establish a pharmacist's authority to prescribe drugs and devices recommended by the Formulary Advisory Committee. These rules create the formulary compendia, per recommendations of the Committee.

CHANGES TO RULE:

855-020-0200
Formulary Compendium
A pharmacist may prescribe, according to regulations outlined in this Division, an FDA-approved drug and device listed in the following compendium, pursuant to a diagnosis by a health care practitioner who has prescriptive authority and who is qualified to make the diagnosis. The diagnosis must be documented on the Visit Summary.¶
(1) Devices and supplies¶
(a) Diabetic blood sugar testing supplies;¶
(b) Pen needles;¶
(c) Syringes;¶
(d) Nebulizers and associated supplies;¶
(e) Inhalation spacers;¶
(f) Peak flow meters;¶
(g) International Normalized Ratio (INR) testing supplies;¶
(h) Enteral nutrition supplies; and ¶
(i) Ostomy products and supplies.¶
(2) Medications (placeholder)
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.645, ORS 689.649

ADOPT: 855-020-0300

RULE SUMMARY: These rules establish a pharmacist's authority to prescribe drugs and devices via protocols recommended by the Formulary Advisory Committee. These rules create the protocol compendia, per recommendations of the Committee.

CHANGES TO RULE:

855-020-0300
Protocol Compendium
A pharmacist may prescribe, via drug therapy management protocol and according to regulations outlined in this Division, an FDA-approved drug and device listed in the following compendium:¶
(1) Continuation of therapy¶
(a) A pharmacist may prescribe any non-controlled medication to extend a patient's prescription therapy to avoid interruption of treatment; and¶
(b) In such cases, a pharmacist shall only prescribe a drug quantity sufficient for the circumstances, not to exceed a 60 day supply, and no more than two extensions in a 12 month period per medication.¶
(2) Conditions¶
(a) Cough and cold symptom management¶
(A) Pseudoephedrine products for patients 18 years of age and older, verified by positive identification, not to exceed 3.6 grams or a 60 count quantity per prescription, whichever is less, or a total of three prescriptions in a 12 month period. Pharmacist must review PDMP prior to issuing prescription and retain documentation of PDMP review;¶
(B) Benzonatate, for the treatment of cough, not to exceed a 7 day supply;¶
(C) Short-acting beta agonists, not to exceed 1 inhaler or 1 box of nebulizer ampules, per year; ¶
(D) Intranasal corticosteroids.¶
(b) Emergency Contraception, not including abortifacients.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.645, ORS 689.649

AMEND: 855-041-1040

RULE SUMMARY: This amendment adds the policy and procedure documentation requirements for a pharmacy drug outlet offering prescribing services.

CHANGES TO RULE:

855-041-1040
Drug Outlet Procedures ¶

Each drug outlet is accountable for establishing, maintaining, and enforcing their written procedures for:¶
(1) Securing their legend drugs and the area in which they are prepared, compounded, stored or repackaged;¶
(2) Performing mandatory prospective drug utilization reviews; on all prescriptions both new and refilled;¶
(3) Verifying the accuracy of all completed prescriptions and medical orders before they leave the pharmacy's secured legend area;¶
(4) Documenting the identification of the pharmacist responsible for the verification of each dispensed medication;¶
(5) Ensuring the delivery of each completed prescription to the correct party;¶
(6) Providing appropriate confidential professional advice concerning medications to patients or their agents;¶
(7) Prescribing services and maintenance of records for prescribing pharmacist;¶
(8) Ensuring that all who work in the pharmacy are appropriately licensed and adequately trained to perform their duties and;¶
(~~8~~9) Establishing and maintaining a Continuous Quality Assurance Program.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, 689.155, 689.508