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ARCHIVES DIVISION
STEPHANIE CLARK
DIRECTOR

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

NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 836
DEPARTMENT OF CONSUMER AND BUSINESS SERVICES
INSURANCE REGULATION

FILED
04/26/2022 4:32 PM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Pharmaceutical Representative Licensing Rules

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 05/27/2022 5:00 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.

CONTACT: Karen Winkel
503-947-7694
karen.j.winkel@dcbs.oregon.gov

350 Winter Street NE
Salem,OR 97301

Filed By:
Karen Winkel
Rules Coordinator

HEARING(S)

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

DATE: 05/23/2022
TIME: 11:00 AM
OFFICER: Numi Griffith
ADDRESS: Labor & Industries Building
350 Winter St NE
Salem, OR 97301
SPECIAL INSTRUCTIONS:
Microsoft TEAMS meeting
Call in (audio only):
+1 503-446-4951,,967652967# United States, Portland
Phone Conference ID: 967 652 967#

NEED FOR THE RULE(S)

These rules establish provisions for the permanent administration of the pharmaceutical representative licensing program created by 2021 Senate Bill 763. Temporary rules were put in place in December of 2021 to facilitate administration of the licensing program during calendar year 2022. These temporary rules will expire in June 2022.

The rules promulgate definitions to facilitate the administration of the program, define procedures for licensure application and renewal, specify prohibited conduct and penalties for licensees, define expectations for the continuing education necessary to maintain licensure, define expectations for licensees to report information to DCBS, define procedures for the registration of education providers, define procedures for the registration of education courses, and define procedures for recording credit for continuing education.

The rules are necessary to facilitate continued operation of the licensing program after the expiration of the temporary rules in June 2022.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

Draft rules are available from Karen Winkel, Rules Coordinator, Division of Financial Regulation located at 350 Winter St. NE, Salem, OR 97301 and are available on the division's website: https://dfr.oregon.gov/laws-rules/Pages/proposed-rules.aspx.

STATEMENT IDENTIFYING HOW ADOPTION OF RULE(S) WILL AFFECT RACIAL EQUITY IN THIS STATE

The proposed rules will directly impact pharmaceutical representatives, pharmaceutical manufacturers, providers of professional education, and secondary effects on certain health care providers. DCBS is not aware of any particular impacts of these rules on members of specific communities such as LGBTQ+, BIPOC, religious, veterans, age groups, or individuals with disabilities except to the extent that members of such communities may be employed as pharmaceutical representatives or users of prescription medication. Because of this, no changes in racial equity are anticipated due to adoption of these rules.

The rules require individuals who do business in Oregon as pharmaceutical representatives to pay a license fee and to fulfill specified professional education requirements. DCBS understands that most manufacturers who employ pharmaceutical representatives who do business in the state of Oregon will reimburse said employees for both the licensing fee and the cost of any required education. If any manufacturer does not do so, however, application of the rules may make it difficult for individuals with lower income to maintain employment as a pharmaceutical representative. As both the continuing education and fee requirements are written in statute, it is unlikely that the rules could be drafted in a way that ameliorates this issue and is also consistent with the law. Because of this, no changes in racial equity are anticipated due to adoption of these rules.

FISCAL AND ECONOMIC IMPACT:

Any cost of complying with these rules will fall on pharmaceutical manufacturers and representatives employed by pharmaceutical manufacturers who do business in the state of Oregon. DCBS does not have complete information on the business structure of pharmaceutical manufacturers, but has no information to suggest that any affected entity meets the definition of small business under ORS 183.310, as manufacturers generally have more than 50 employees and are not independently owned and operated.

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).

(1) Based on information currently available to DCBS, the proposed rule would not have a fiscal or economic impact on state agencies, local government units, nor the public.

(2)(a) Any cost of complying with these rules will fall on pharmaceutical manufacturers and representatives employed by pharmaceutical manufacturers who do business in the state of Oregon. DCBS does not have complete information on the business structure of pharmaceutical manufacturers, but has no information to suggest that any affected entity meets the definition of small business under ORS 183.310, as manufacturers generally have more than 50 employees and are not independently owned and operated.

(2)(b) Any cost of complying with these rules will fall on pharmaceutical manufacturers and representatives employed by pharmaceutical manufacturers who do business in the state of Oregon. DCBS does not have complete information on the business structure of pharmaceutical manufacturers, but has no information to suggest that any affected entity

meets the definition of small business under ORS 183.310, as manufacturers generally have more than 50 employees and are not independently owned and operated.

(2)(c) Any cost of complying with these rules will fall on pharmaceutical manufacturers and representatives employed by pharmaceutical manufacturers who do business in the state of Oregon. DCBS does not have complete information on the business structure of pharmaceutical manufacturers, but has no information to suggest that any affected entity meets the definition of small business under ORS 183.310, as manufacturers generally have more than 50 employees and are not independently owned and operated.

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

Representatives of small businesses, including health care providers operating in small or individual practice, were invited to provide comment on the rule.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? YES

RULES PROPOSED:
836-200-0600, 836-200-0605, 836-200-0610, 836-200-0615, 836-200-0620, 836-200-0625, 836-200-0630, 836-200-0635, 836-200-0640, 836-200-0645, 836-200-0650, 836-200-0655, 836-200-0660, 836-200-0670

ADOPT: 836-200-0600

RULE SUMMARY: States purpose of rules and statutory authority for adoption.

CHANGES TO RULE:

836-200-0600
Purpose and Statutory Authority
The purpose of OAR 836-200-0600 to 836-200-0670 is to administer the licensure of pharmaceutical representatives doing business in the state of Oregon pursuant to Oregon Laws 2021, chapter 593.
Statutory/Other Authority: ORS 731.244, Or Laws 2021, ch 593
Statutes/Other Implemented: Or Laws 2021, ch 593

ADOPT: 836-200-0605

RULE SUMMARY: Defines necessary terms for implementation of the pharmaceutical sales representative licensing program, including: department, pharmaceutical product, pharmaceutical representative, license, licensee, calendar year, material change in a licensee's business operations, monetary value, in writing, and gift.

CHANGES TO RULE:

836-200-0605
Definitions
For the purposes of OAR 836-200-0600 to 836-200-0670 the following definitions apply, unless the context requires otherwise:¶
(1) The "department" means the Oregon Department of Consumer and Business Services.¶
(2) "Pharmaceutical product" means a medication approved for human use by the federal Food and Drug Administration that may be legally dispensed only with a valid prescription from a health care provider.¶
(3) "Pharmaceutical representative" means a person that markets or promotes pharmaceutical products to health care providers.¶
(4) "License" means a license issued to a pharmaceutical representative by the department pursuant to OAR 836-200-0600 to 836-200-0670.¶
(5) "Licensee" means a person that holds a valid and unexpired license issued under this section.¶
(6) "Calendar year" means each successive period of 12 calendar months commencing on January 1 and ending on December 31.¶
(7) "Material change in a licensee's business operations" means any change in the following information:¶
(a) A change in the business activity in which the licensee engages;¶
(b) Termination for cause from any employer or company that the licensee represents;¶
(c) Any complaints made to the licensee, the licensee's employer, or a company that the licensee represents regarding the licensee's activities conducted under a license issued under these rules.¶
(8) "Monetary value," for the purposes of describing the value of drug samples for reports made pursuant to OAR 836-200-0620(3)(e), means the monetary value of an equivalent volume or quantity of the prescription drug estimated using the WAC price for the most comparable NDC.¶
(9) "In writing" means through NIPR as allowed or by electronic mail.¶
(10) "Gift" means anything of economic value given to, or for the personal benefit of, a health care provider without consideration of equivalent or market value.
Statutory/Other Authority: ORS 731.244, Or Laws 2021, ch 593
Statutes/Other Implemented: Or Laws 2021, ch 593

ADOPT: 836-200-0610

RULE SUMMARY: Defines conditions that require licensure as a pharmaceutical representative, term of license, non-transferability of license, and requires licensee to produce proof of licensure upon request by a health care provider.

CHANGES TO RULE:

836-200-0610
License Required
(1) A pharmaceutical representative who does business with health care professionals located within the state of Oregon must acquire a license from the department prior to doing business in the state on 15 or more days in a calendar year.¶
(2) A license issued pursuant to these rules is valid until the end of the calendar year in which the license was issued.¶
(3) A license issued pursuant to these rules is not transferable.¶
(4) A pharmaceutical representative must show their license or an exact copy of it when a health care provider asks to see it. An exact copy may include a legible reproduction, such as a photocopy or an image saved or produced on an electronic device.
Statutory/Other Authority: ORS 731.244, Or Laws 2021, ch 593
Statutes/Other Implemented: Or Laws 2021, ch 593

ADOPT: 836-200-0615

RULE SUMMARY: Describes necessary information to be included in an application for licensure or license renewal as a pharmaceutical representative, department authority to collect and use the social security number of an applicant for licensure.

CHANGES TO RULE:

836-200-0615
License Application and Renewal Application
(1) An applicant for a license to engage in business as a pharmaceutical representative must submit the following information in a form and manner specified by the department:¶
(a) The applicant's full name, Social Security number, email address, residence address, personal telephone number, business address, and business telephone number;¶
(b) A description of the business activities in which the applicant will engage;¶
(c) Documentation that shows the applicant has completed at least 10 hours of professional education as described in OAR 836-200-0635(1);¶
(d) The application for licensure must be accompanied by a license fee of $750.¶
(2) A pharmaceutical representative may apply for a license renewal if they held a valid and unrevoked license through the end of the preceding calendar year. An applicant for renewal must submit the following information on a form specified by the department:¶
(a) The applicant's full name, Social Security number, email address, residence address, personal telephone number, business address, and business telephone number;¶
(b) A description of the business activities in which the applicant will engage;¶
(c) Documentation that shows the applicant has completed at least five hours of continuing education as described in OAR 836-200-0635(2);¶
(d) For any application submitted on or after April 1, 2023, documentation that shows the applicant for renewal has submitted the information required by OAR 836-200-0620;¶
(e) The application for license renewal must be accompanied by a license fee of $750.¶
(3) An incomplete application for initial licensure or application for license renewal under these rules will be considered abandoned if not completed within 30 days of opening the application process.¶
(4) The $750 application fee is not refundable.¶
(5) The department may collect Social Security numbers submitted in applications under this rule and may use a Social Security number of an individual when authorized to do so for the purposes specified in this section. In addition to the governmental uses for which a Social Security number is required in an application under federal and state law, when authorized by the holder of a Social Security number, the director may use a Social Security number for any of the following purposes:¶
(a) As an identification number in maintaining records and reporting grades or examination scores;¶
(b) For licensing purposes; and¶
(c) For use by other government agencies to carry out their statutory duties.¶
(6) An applicant may voluntarily allow the department to use the Social Security number of the applicant, as the director may request in the application form, for the purposes specified in section (5) of this rule. Refusal to voluntarily allow such use of the Social Security number will not result in the denial of any individual right, benefit or privilege provided by law. The use authorized by an applicant is in addition to uses authorized by state and federal law for which collection of Social Security numbers is mandatory.
Statutory/Other Authority: ORS 731.244, Or Laws 2021, ch 593
Statutes/Other Implemented: Or Laws 2021, ch 593

ADOPT: 836-200-0620

RULE SUMMARY: Describes information that must be reported by licensee to the department, defines deadline for annual reports by pharmaceutical representative licensees.

CHANGES TO RULE:

836-200-0620
Licensee Reporting Requirements
(1) A licensee must report to the department in writing, in a form specified by the department, any changes to the information submitted in an initial license application submitted pursuant to OAR 836-200-0615(1) or a renewal application submitted pursuant to OAR 836-200-0615(2), including any material changes made in the licensee's business operations, as defined in OAR 836-200-0605(7).¶
(2) A licensee must report the information regarding contacts specified in subsection (3) of this rule no later than April 1, 2023, and each year thereafter.¶
(3) The report described in subsection (2) of this rule must contain the following information in a form specified by the department:¶
(a) A list of health care providers within this state that the licensee contacted during the preceding calendar year;¶
(b) The number of times the licensee contacted each health care provider during the preceding calendar year;¶
(c) The location and duration of the licensee's contact with each health care provider;¶
(d) Which pharmaceutical products the licensee promoted;¶
(e) Whether the licensee provided the health care provider with any product samples, materials or gifts, and, if so, the monetary value of the samples, materials or gifts; and¶
(f) Whether and how the licensee otherwise compensated the health care provider for contact with the licensee.
Statutory/Other Authority: Or Laws 2021, ch 593, ORS 731.244
Statutes/Other Implemented: Or Laws 2021, ch 593

ADOPT: 836-200-0625

RULE SUMMARY: Defines prohibited conduct for pharmaceutical representative licensees.

CHANGES TO RULE:

836-200-0625
Prohibited Conduct for Licensees
A licensee may not:¶
(1) Engage in any deceptive or misleading marketing of a pharmaceutical product, including knowingly concealing, suppressing, omitting, misrepresenting, or misstating material facts concerning or related to a pharmaceutical product;¶
(2) Use a title or designation that could reasonably lead a health care provider or an employee of a health care provider to believe that the licensee is a health care provider if the licensee is not licensed as a health care provider or otherwise authorized to provide health care services; ¶
(3) Attend an examination of a patient without the patient's consent; or¶
(4) Make or file, or cause to be made or filed, to or with the director of the Department of Consumer and Business Services, any statement, report or document which is known to be false in any material respect or matter.
Statutory/Other Authority: ORS 731.244, Or Laws 2021, ch 593
Statutes/Other Implemented: Or Laws 2021, ch 593

ADOPT: 836-200-0630

RULE SUMMARY: Describes circumstances under which the department may discipline a pharmaceutical representative licensee, and allowable civil penalties or license revocation.

CHANGES TO RULE:

836-200-0630
Civil Penalties and License Revocation
The department may impose civil penalties on licensees, or to unlicensed pharmaceutical representatives under subsection (1)(c) of this rule, for violations of Oregon Laws 2021, chapter 593 and OAR 836-200-0600 to 836-200-0670, including but not limited to the following:¶
(1) Engaging in any of the prohibited conduct described in OAR 836-200-0625.¶
(2) Failure to timely report any of the information described OAR 836-200-0620.¶
(3) Engaging in business as a pharmaceutical representative in the state of Oregon for 15 or more days without first obtaining a license from the department.
Statutory/Other Authority: ORS 731.244, Or Laws 2021, ch 593
Statutes/Other Implemented: Or Laws 2021, ch 593

ADOPT: 836-200-0635

RULE SUMMARY: Describes education required for initial licensure or license renewal as a pharmaceutical representative.

CHANGES TO RULE:

836-200-0635
Education Requirements
(1) Education requirements for initial licensure. In order to satisfy the education requirement for an initial pharmaceutical representative license, applicants must complete a course of education of at least 10 hours. The education program must be approved by the department under OAR 836-200-0635 to 836-200-0670.The coursework must cover at least the following topics, and may also include any of the topics described in subsection (2)(a) of this rule:¶
(a) The comparative clinical effectiveness of pharmaceutical products, evidence based medicine, or basic pharmacology;¶
(b) The comparative cost effectiveness of pharmaceutical products, or pharmoeconomics; and¶
(c) Legal and ethical issues related to promoting pharmaceutical products to healthcare professionals, or professional ethics generally.¶
(2) Education requirement for license renewal. In order to renew a pharmaceutical representative license, applicants must complete at least five hours of education. By applying for renewal, an applicant is affirming that they have completed five hours of education during the preceding 12 months. The education must be approved by the department under OAR 836-200-0635 to 836-200-0670. Education coursework under this section must be in one or more of the following subject areas:¶
(a) General medical and pharmaceutical terminology and abbreviations;¶
(b) Food and Drug Administration laws and regulations pertaining to drug marketing, labeling, and clinical trials;¶
(c) The comparative cost effectiveness of pharmaceutical products;¶
(d) Therapeutic drug classes and categories;¶
(e) Professional ethics;¶
(f) Properties and actions of drugs and drug delivery mechanisms;¶
(g) Etiologies, characteristics, and therapeutics of disease states;¶
(h) Pharmacology;¶
(i) The anatomical and physiological effect of pharmaceuticals;¶
(j) The comparative effectiveness of pharmaceutical products;¶
(k) How to read and analyze peer-reviewed literature on pharmaceutical products; or¶
(l) Safe prescribing practices to prevent abuse.
Statutory/Other Authority: ORS 731.244, Or Laws 2021, ch 593
Statutes/Other Implemented: Or Laws 2021, ch 593

ADOPT: 836-200-0640

RULE SUMMARY: Establishes standards for proof of credit hours to satisfy education requirements for licensure as a pharmaceutical representative.

CHANGES TO RULE:

836-200-0640
Education
To demonstrate completion of a professional education course for the purpose of initial licensure as a pharmaceutical representative under these rules or renewal of licensure, documentation shall be submitted as follows:¶
(1) To the extent possible, the education provider offering the course shall submit electronically a transcript, certificate of completion or grade or course completion report, whichever is issued by the education provider offering the course, or a copy thereof. If it is not possible for the education provider offering the course to submit a transcript, certificate of completion or grade or course completion report, the pharmaceutical representative shall submit the transcript, certificate of completion or grade or course completion report in accordance with directions provided on the Department of Consumer and Business Services website. ¶
(2) The department may accept evidence of completion of a course from education providers through electronic means as specified by the department.
Statutory/Other Authority: Or Laws 2021, ch 593, ORS 731.244
Statutes/Other Implemented: Or Laws 2021, ch 593

ADOPT: 836-200-0645

RULE SUMMARY: Establishes standards for granting credit hours to satisfy education requirements for licensure as a pharmaceutical representative.

CHANGES TO RULE:

836-200-0645
Education; Standards for Granting Credit Hours
(1) Subject to the subject matter requirements of OAR 836-200-0635, a pharmaceutical representative may receive credit for a course registered under OAR 836-200-0655:¶
(a) For not more than the credit hours authorized by the director;¶
(b) Only if an hour includes at least 50 minutes of instruction or study;¶
(c) For class hours in which a pharmaceutical representative is an instructor of a course if the course meets the education requirements of an pharmaceutical representative attending it. Credit may be taken by pharmaceutical representative with respect to a course only once in each renewal period in which the pharmaceutical representative instructs the course.¶
(2) A pharmaceutical representative successfully completes the course if the pharmaceutical representative is present for the full approved time.¶
(3) A pharmaceutical representative may not take education credit for:¶
(a) Hours devoted to preparation for a course; when the pharmaceutical representative is acting as an instructor for the course;¶
(b) Travel time;¶
(c) Time exceeding the actual class time;¶
(d) Unplanned or incidental learning experiences;¶
(e) Any course not completed; or¶
(f) Any course repeated within a two year period.
Statutory/Other Authority: Or Laws 2021, ch 593, ORS 731.244
Statutes/Other Implemented: Or Laws 2021, ch 593

ADOPT: 836-200-0650

RULE SUMMARY: Requires registration of education providers of courses related to education requirements for licensure as a pharmaceutical representative.

CHANGES TO RULE:

836-200-0650
Education; Education Provider Registration
A provider of education courses must register with the department in order to register courses under OAR 836-200-0655. An education provider must register electronically in the method required by the director. The registration of an education provider shall include the education provider's business name, business address, and the business telephone number. In addition, a direct contact name and telephone number employed by the provider.¶
(1) A provider shall notify the department of any change in the address, telephone number, email address or contact person of the education provider within 30 days after any such change takes effect.¶
(2) Subject to revocation of registration under OAR 836-200-0665, an education provider registration expires on the second January 1 following the date of registration.
Statutory/Other Authority: Or Laws 2021, ch 593, ORS 731.244
Statutes/Other Implemented: Or Laws 2021, ch 593

ADOPT: 836-200-0655

RULE SUMMARY: Requires registration of courses by education provider, defines information that must be provided to department by education provider.

CHANGES TO RULE:

836-200-0655
Education; Course Registration
(1) An education provider registered under OAR 836-200-0650 shall apply to the department for registration of each course to be offered by the provider for education credit. Application for registration shall be made electronically in the method required by the department and shall include the name of the provider, the education provider's registration number assigned by the department, the course title and credit hours suggested by the education provider for the course. The education provider shall include the course outline with the registration application and shall submit any other information requested by the department. The course outline must show instruction in 50-minute periods. In order to ensure that a course is eligible to be registered prior to the date of the first meeting of the course, a registered education provider must apply for registration of the course not later than the 60th day preceding the first date.¶
(2) The registration of a course expires on the last day of the 24th month after the date the course is registered unless the course is renewed prior to the date on which registration expires. ¶
(3) Each course registration application is subject to review by the department for the purpose of evaluating and assigning credit hours and determining compliance with requirements of course content under OAR 836-200-0635. The department may reject a course for registration or terminate a course's registration if the department determines that the course submitted fails to provide accurate, sufficient, or germane information, or fails to show good faith with meeting educational goals.¶
(4) A registered education provider shall resubmit a registered course for review and approval whenever the provider substantially changes the content of the course as registered.¶
(5) All materials required under this rule shall be submitted electronically in accordance with directions of the department set forth on the division's website.
Statutory/Other Authority: Or Laws 2021, ch 593, ORS 731.244
Statutes/Other Implemented: Or Laws 2021, ch 593

ADOPT: 836-200-0660

RULE SUMMARY: Describes trade practice standards for education providers.

CHANGES TO RULE:

836-200-0660
Education; Provider Trade Practices
(1) A registered education provider shall not engage in false, misleading or deceptive advertising.¶
(2) A registered education provider must disclose in writing the charges for a course to each pharmaceutical representative applying to take the course, prior to enrollment of the course.¶
(3) If a registered education provider cancels a course for any reason, the education provider must refund all charges in full unless the refund policy is clearly described in the enrollment application for the course.¶
(4) A registered education provider shall ensure that each registered course and each course for which registration is sought provides students with current and accurate information.¶
(5) A registered education provider shall include a statement in all material published by the education provider to advertise or promote pharmaceutical representative education that the education provider and courses are registered with the department and that registration does not imply endorsement by the department.¶
(6) A registered education provider may not advertise education hours until the course has been approved by the department. If approval has been applied for, however, a registered education provider may so advertise.¶
(7) A registered education provider shall not give credit for a course unless the department has approved the registration application for the course and the registered provider.¶
(8) A registered education provider of courses shall maintain an accurate record of each course offered, instructors and student attendance records for not less than three years after the date of completion of the course.
Statutory/Other Authority: Or Laws 2021, ch 593, ORS 731.244
Statutes/Other Implemented: Or Laws 2021, ch 593

ADOPT: 836-200-0670

RULE SUMMARY: Provides alternative method for a pharmaceutical representative licensee to apply for credit for a course not registered with the department.

CHANGES TO RULE:

836-200-0670
Education; Credit for Unregistered Courses
(1) A pharmaceutical representative may apply for credit as provided in this rule for a course that is not registered. In order to apply for credit, the pharmaceutical representative must submit to the department an application on a form provided by the department and substantiation of the course as provided in this rule. The application and substantiation must be submitted not later than the 180th day after the date of completion of the course.¶
(2) If an unregistered course is on a subject permitted under OAR 836-200-0635, the pharmaceutical representative must substantiate to the department's satisfaction that the course meets the requirements of OAR 836-200-0645 and that the pharmaceutical representative attended and completed the course. To make the substantiation, the pharmaceutical representative must submit documentation of the proof of attendance and course completion provided by the education provider concerning the course. ¶
(3) The application and substantiation required under this rule are subject to review by the department for the purpose of determining whether to certify the course for credit and evaluating and assigning credit hours. The department may certify the course, or may reject it if the department determines that the course does not meet applicable requirements.
Statutory/Other Authority: Or Laws 2021, ch 593, ORS 731.244
Statutes/Other Implemented: Or Laws 2021, ch 593