

1. Purpose and Statutory Authority

The purpose of these temporary rules is to administer the licensure of Pharmaceutical Sales Representatives doing business in the state of Oregon pursuant to 2021 Or Laws ch 593.

2. Definitions

For the purposes of these temporary rules, the following definitions apply, unless the context requires otherwise:

(1) The “Department” means the Oregon Department of Consumer and Business Services.

(3) “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.

(4) “Pharmaceutical representative” means a person that markets or promotes pharmaceutical products to health care providers.

(5) “License” means a license issued to a pharmaceutical representative by the Department pursuant to these temporary rules.

(6) “Licensee” means a person that holds a valid and unexpired license issued under these temporary rules.

(7) “Calendar year” means each successive period of twelve (12) calendar months commencing on January 1 and ending on December 31.

(8) “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.

3. License Required

- (1) A pharmaceutical representative who does business with health care professionals while both are within the State of Oregon must acquire a license from the department prior to doing business in the State on fifteen 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 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.

4. 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 ten hours of professional education as described in these temporary rules.
- (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 the professional education course described in these temporary rules;
- (d) The application for licensure must be accompanied by a license fee of \$750.

(3) An incomplete application for initial licensure or an application for license renewal under these rules will be considered abandoned if not completed within thirty 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 (6) 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.

5. Education and Continuing Education Requirements

(1) Education requirements for initial licensure in 2022:

(a) Applicants for initial licensure must certify that they plan to complete at least 15 hours of education prior to applying for licensure renewal.

(2) Qualified education for the **purpose of prelicensure education or continuing education in 2022:**

(a) The department will accept as qualified education any credit hours earned in education programs approved for pharmaceutical representatives seeking licensure or license renewal by another United States jurisdiction, except as otherwise provided in this rule.

(b) Credit hours must be provided by entities registered as education providers with the National Insurance Producer Registry (NIPR).

(c) The department will not accept any credits for continuing education programs provided by a licensee's employer.

(3) A license issued under these temporary rules shall be considered a provisional license with renewal conditioned upon the completion of at least 15 hours of education, consisting of 10 hours of pre-licensure education and 5 hours of continuing education as described in subsection 4 of this rule.

(4) Education requirement for license renewal:

(a) In order to renew a pharmaceutical representative license, applicants must complete five hours of continuing professional education. By applying for renewal, an applicant is affirming that they have completed five hours of continuing education during the preceding twelve months. Continuing 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.

6. 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; or

(3) Attend an examination of a patient without the patient's consent.

(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.

7. Civil penalties and license revocation

(1) The department may revoke a license, suspend a license, or impose civil penalties on licensees for violations of 2021 Or Laws ch 593 and these temporary rules, including but not limited to the following violations:

(a) Engaging in any of the prohibited conduct described in these temporary rules.

(b) Failure to timely report any of the information **described in 2021 Or Laws ch 593 SECTION 1 (6)**

(c) Engaging in business as a pharmaceutical representative in the state of Oregon for fifteen or more days without first obtaining a license from the department.