From:	GRIFFITH Numi L * DCBS
To:	WINKEL Karen J * DCBS
Subject:	FW: Comments on Oregon Rep Licensing SB7630
Date:	Tuesday, October 12, 2021 2:52:43 PM
Attachments:	Oregon Rep Licensing 20211005-SB7630-rule-draft.QPharma Comments.docx

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From: Judy Fox <Judy.Fox@qpharmacorp.com>
Sent: Tuesday, October 12, 2021 11:43 AM
To: DFR.rules@oregon.gov.; GRIFFITH Numi L * DCBS <Numi.L.GRIFFITH@oregon.gov>
Cc: Keith Westrich <Keith.Westrich@qpharmacorp.com>; Judy Fox <Judy.Fox@qpharmacorp.com>
Subject: Comments on Oregon Rep Licensing SB7630

Good Afternoon Numi,

I hope this email finds you well. I am including you directly on this email because the DFR.rules@oregon.gov email address for comments is coming back as invalid.

QPharma is a consulting and warehousing vendor for the pharmaceutical industry. Attached to this email, please find our Comments on the draft rule of SB7630 that I am submitting as a result of meeting with several of our clients.

For some background on QPharma and our experience in this area, our services include assisting clients in managing sales representative licensing in Chicago and Washington DC and registrations in Nevada. This includes assisting in any transparency reporting required by federal and state regulations. As a CE provider in the industry, QPharma's course library has qualified us an approved provider of CE for both Chicago and Washington DC sales representative licensing. I also worked with Kate McCabe, former Vermont Assistant Attorney General and provided insight into the Vermont rule for sample and spend reporting during its rule change

I am including Keith Westrich on this email. Keith is the Managing Director of our CE Programs here at QPharma and he would be happy to work with the state for the initial sales representative CE requirements as QPharma goes through the application process to be an approved CE provider for licensing renewal.

Please feel free to contact me or Keith if you have any questions about how we comply with the other states or would like some insight into our CE programs.

Kind Regards,

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Your Commercial and Compliance Partner

836-200-XXX0
Purpose and Statutory Authority

The purpose of OAR 836-200-XXX0 to 836-200-XXX7 is to administer the licensure of Pharmaceutical Sales Representatives doing business in the state of Oregon pursuant to 2021 Or Laws ch 593

836-200-XXX1
Definitions

For the purposes of 836-200-XXX0 to 836-200-XXX7 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 OAR 836-200-XXX0 to 836-200-XXX7.

(6) “Licensee” means a person that holds a valid and unexpired license issued under this section.

(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.

pharmaceutical product(s) that the licensee markets or promotes, and any change in the company(s) that manufacture the pharmaceutical product(s) that the licensee markets or promotes.

Comment: the term "Insurance Provider" is used in section 836-200-XXX6 (3). If that is not a typographical error, we recommend including "Insurance Provider" in the definitions.

836-200-XXX2
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.

836-200-XXX3
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, email address, residence address, residence telephone number, business address, and business telephone number;

(b) A description of the business in which the applicant will engage;

(c) Documentation that shows the applicant has completed at least ten hours of professional education as described in OAR 836-200-XXX4(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 at

least 30 days before their license expires:

(a) The applicant's full name, email address, residence address, residence telephone number, business address, and business telephone number;

(b) A description of the business in which the applicant will engage;

(c) Documentation that shows the applicant has completed the professional education course described in OAR 836-200-XXX4(2);

(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.

Comment: We recommend including the following for a license application and/or renewal:

1. *The name of the business or manufacturer being represented*
2. *The license holder must notify the state if:*
    a. *The employer or business address changes*
    b. *The residence changes*

We also recommend adding an additional requirement that the licensee must immediately notify the state if their employer has changed or if they terminate employment.

836-200-XXX4
Education and Continuing Education Requirements

(1) Education requirements for initial licensure:

(a) In order to satisfy the education requirement for an initial pharmaceutical representative license, applicants must complete a course of education of at least ten hours. The education program must be approved by the Department under OAR 836-200-XXX5 to OAR 836-200-XX11.The coursework must contain at least the following components:

(A) An introduction to the pharmaceutical representative license;

(B) An overview of the ethical standards and disclosure requirements required of licensees under Oregon law;

(C) The comparative clinical effectiveness of pharmaceutical products;

(D) The comparative cost effectiveness of pharmaceutical products; and

(E) Professional ethics.

(2) 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. The continuing education must be approved by the Department under OAR 836-200-XXX5 to OAR 836-200-XX11. 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.

836-200-XXX5
Continuing Education

(1) 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:

(a) For a registered course taken for academic credit, to the extent possible, the institution offering the course shall submit electronically a transcript, certificate of completion or grade or course completion report, whichever is issued by the institution offering the course, or a copy thereof. If it is not possible for the institution offering the course to submit a transcript, certificate of completion or grade or course completion report, the insurance producer shall submit the transcript, certificate of completion or grade or course completion report in accordance with directions provided on the Insurance Division website of the Department of Consumer and Business Services at www.insurance.oregon.gov. For purposes of this subsection, a course is taken for academic credit if it is offered by a community college or four-year college or university, and the pharmaceutical representative is given academic credit for the course by such an institution;

(c) For a registered course that is not offered for academic credit, the provider shall submit to the department course completion information containing at least the following: a statement of the hours of credit, the name of the pharmaceutical representative, the date of the course, and the course registration number;

(d) For a course that is not offered for academic credit and is not registered when taken by an pharmaceutical representative, a pharmaceutical representative must comply with the requirements of OAR 836-200-XX11.

(2) The Director may accept evidence of completion of a course from continuing education providers through electronic means as specified by the Director.

836-200-XXX6
Continuing Education; Standards for Granting Credit Hours

(1) Subject to the subject matter requirements of OAR 836-200-XXX4, a pharmaceutical representative may receive credit for continuing education for a course taken for academic credit, for a course registered under 836-200-XXX8 or a course certified under 836-200-XX11:

(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 continuing 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;

(d) For not more than eight credit hours in any given day;

(e) Only if the hour for which credit is taken was completed during the license period immediately preceding the renewal date;

(f) For a course taken through independent study, but only as provided in section (4) of this rule.

(2) A pharmaceutical representative may take credit for a course only if the pharmaceutical representative has successfully completed the course before the pharmaceutical representative applies for renewal or reinstatement. For the purpose of taking credit for a course other than one taken through independent study, a pharmaceutical representative successfully completes the course if the pharmaceutical representative is present for the full approved time and has signed in and out on the attendance register for the course.

(3) An insurance producer may not take continuing 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;

(f) Any course repeated within a two year period; or

(g) Any course during which the pharmaceutical representative is absent more than 5 minutes for each hour of credit granted, or is absent more than 20 minutes from the course as a whole.

(4) For purposes of subsection (1)(f) of this rule, a course is taken through independent study if the course is designed to allow each student to take the course at the student's own pace on an individual basis. A pharmaceutical representative may claim credit for an independent study course if the provider and the course are both registered with the Director when the course is taken, if the pharmaceutical representative passes an examination by a score of 70 percent or higher and if the proctor of the examination affirms and the provider certifies completion and passage as provided in this section. If the independent study course is a textbook, the examination must be conducted as a closed book examination. The examination for an independent study course need not be proctored if the course is computerized and includes safeguards ensuring that the pharmaceutical representative cannot review the study material while taking the examination and if the examination has safeguards ensuring that the pharmaceutical representative cannot change answers after completing the examination. Proctor

affirmation and provider certification shall be made as follows:

(a) The proctor must submit materials electronically that affirm by affidavit that the insurance producer took the examination for the course without assistance from the textbook or from any person. The proctor must disclose in the affidavit the proctor's name, address, telephone number and the proctor's position or connection with the pharmaceutical representative, such as a continuing education school or a librarian, and the proctor's registration number, if the proctor is required to be registered under section (7) of this rule. The provider must retain the affidavit with the examination.

(b) If the provider determines that the pharmaceutical representative completed and passed the examination, the provider may issue the certificate of completion. The provider shall date the certificate according to the date on which the provider received the examination for grading, state on the certificate that to the best of the provider's knowledge the pharmaceutical representative passed the examination and submit the certificate electronically to the Insurance Division in accordance with directions provided on the Insurance Division website of the Department of Consumer and Business Services at www.insurance.oregon.gov.

(5) The provider of a course shall submit electronically completion information for the course for each qualifying insurance producer not later than the 15th day after the date on which an insurance producer completes a course or not later than the 15th day after the date on which the Director approved the course, whichever date is later. The period for issuance of a certificate does not apply to a provider who discloses to the pharmaceutical representative in writing, when the pharmaceutical representative pays for or registers for the class, the date by which or the time period within which the certificate will be issued.

(6) A provider shall notify the Director immediately of any change in authorized signers for certificates.

(7) A person may act as a proctor for one or more independent study courses under section (4) of this rule only if the person is registered as a proctor with the Insurance Division. A person applying for registration must submit the name, address and telephone number of the person; the location or locations at which examinations will be proctored; the fee or fees that will be charged, if any, for the proctoring service; and whether the person will proctor examinations for the general insurance producer population. There is no registration fee. If the person will proctor independent study course examinations for other than the general insurance producer population, the person must specify for whom the proctoring will be done. The registration requirement under this section does not apply to city, county and state public libraries, state colleges and universities, private colleges and universities other than those that are owned by or operated primarily for the insurance industry, law offices or currently licensed certified public accountants.

836-200-XXX7
Continuing Education; Provider Registration

(1) A provider of continuing education courses must register with the Director in order to register courses under OAR 836-000-XXX8. A provider must register electronically in the method required by the Director. The registration of a provider shall include the provider's business name, main business address, the business telephone number, email address and the name of a contact person. If a provider is a firm or corporation or a trade association, registration shall also include the names of all principal officers.

(2) A provider shall notify the Director of any change in the address, telephone number,email address or contact person of the provider within 30 days after any such change takes effect.

(3) Subject to revocation of registration under OAR 836-200-XXX9, a provider registration expires on the second January 1 following the date of registration.

(4) A provider is subject to rejection of registration by the Director if the provider fails to meet any requirement of OAR 836-200-XXX5 to 836-200-XX11 applicable to the provider or to courses offered by the provider, or if any of its employees or contractors who supervise or conduct and certify completion of a course:

(a) Has a history of noncompliance with insurance statutes or rules; or

(b) Has had an insurance producer license, pharmaceutical representative license or other license issued by the department revoked, suspended or refused because of violations of or noncompliance with insurance statutes or rules.

836-200-XXX8
Continuing Education; Course Registration

1) A provider registered under OAR 836-200-XXX7 shall apply to the Director for registration of each course to be offered by the provider for continuing education credit. Application for registration shall be made electronically in the method required by the Director and shall include the name of the provider, the provider's registration number assigned by the Department, the course title and credit hours suggested by the provider for the course, and if known, the date, time and location of meetings of each course for which application is made. The provider shall include the course outline with the registration application and shall submit any other information requested by the Director. The course outline must show instruction in 50-minute periods.

(2) 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 provider must apply for registration of the course not later than the 60th day preceding the first date.

(3) 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. The provider must apply for renewal of a course not later than the 21st day prior to the date on which registration expires. If the Director determines that the course materials submitted with the renewal application are sufficiently changed or otherwise so different that the course as a whole should be treated as a new course rather than renewed, the course and its materials shall be reviewed according to the review period established in section (2) of this rule.

(4) Each course registration application is subject to review by the Director for the purpose of evaluating and assigning credit hours and determining compliance with requirements of course content under OAR 836-200-XXX5. The Director may reject a course for registration or terminate a course's registration if the Director determines that the course does not so comply.

(5) A registered provider shall resubmit a registered course for review and approval whenever the provider substantially changes the content of the course as registered.

(6) A provider shall notify the Director immediately of a cancellation or a change of date, time or location of a scheduled class.

(7) A course registration application that is submitted after the 60th day before the date of the first meeting of the course is subject to approval or disapproval after the date of the first meeting. If the Director approves an application for registration of a course that is submitted after the 60th day before the date of the first meeting of the course and before the tenth day prior to the date of that meeting, and if the provider gives notice of the course meeting as required by OAR 836-200-XX10, the provider may grant credit for the course retroactively.

(8) A provider domiciled in another state that is a member of the Midwest Zone Continuing Education Reciprocity Agreement may offer in this state a course that is registered in its domiciliary state if the provider registers the course as provided in this rule. Such a course qualifies for registration if the Director determines that the subject matter of the course is not disqualified for credit under OAR 836-200-XXX5. A course to which this section applies is subject to renewal of its registration and the provider and the course are subject to the other provisions of this rule.

(9) All materials required under this rule shall be submitted electronically in accordance with directions of the director set forth on the Insurance Division website of the Department of Consumer and Business Services at www.insurance.oregon.gov.

836-200-XXX9
Continuing Education; Provider Trade Practices

(1) A registered provider shall not engage in false, misleading or deceptive advertising.

(2) A registered provider must disclose in writing the charges for a course to each

insurance producer applying to take the course, prior to enrollment of the insurance producer.

(3) If a registered provider cancels a course for any reason, the provider must refund all charges in full unless the refund policy is clearly described in the enrollment application for the course.

(4) A registered 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 provider shall include a statement in all material published by the provider to advertise or promote insurance license continuing education that the provider and courses are registered with the Insurance Division and that registration does not imply endorsement by the Insurance Division.

(6) A registered provider may not advertise continuing education hours until the course has been approved by the Division. If approval has been applied for, however, a registered provider may so advertise.

836-200-XX10
Continuing Education; Requirements for Granting Credit, Attendance Records

(1) A registered provider shall provide the Director with the meeting times and places of a registered course not later than the tenth day before the date that the course is given.

(2) A registered provider shall not give credit for a course unless the Director has approved the registration application for the course and the registered provider has given the Director notice of the meeting of the course as provided in section (1) of this rule.

(3) A registered provider of lecture 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.

(4) A provider of an independent study course shall maintain examination results and proctor affidavits for not less than three years after the date of course completion.

(5) A provider of an independent study course shall notify all vendors of the provider's course materials when credit hours for the course have changed or when the course is discontinued.

(6) A course that is registered in this state pursuant to OAR 836-200-XXX8(8) shall be allocated the times and credits determined pursuant to the Midwest Zone Continuing Education Reciprocity Agreement.

836-200-XX11

Continuing Education; Credit for Unregistered Courses

(1) A pharmaceutical representative may apply for credit as provided in this rule for a course that is not offered for academic credit and is not registered. In order to apply for credit, the pharmaceutical representative must submit to the Director an application on a form provided by the Director 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-XXX5, the pharmaceutical representative must substantiate to the Director's satisfaction that the course meets the requirements of OAR 836-200-XX10 and that the insurance producer attended and completed the course. To make the substantiation, the insurance producer must submit documentation of the course and proof of attendance provided by the provider concerning the course. The documentation may include, by way of example only, an outline of the course or course materials, workbooks or other materials issued by the provider that show the course work. The Director may request any other information as well, such as times allotted to the parts of the course.

(3) If an unregistered course is not on a subject permitted under OAR 836-071-XXX5, the insurance producer must substantiate to the Director's satisfaction that the course meets the requirements of 836-071-XX10, that the course contributes to the pharmaceutical representative's professional competence and will benefit the public and that the pharmaceutical representative attended and completed the course. To make the substantiation, the pharmaceutical representative must submit documentation provided by the provider concerning the course. The documentation may include, by way of example only, an outline of the course or course materials, workbooks or other materials issued by the provider that show the course work, or proof of passing the final examination for the course or a letter, certificate or other documentation of completion from the provider. The Director may request any other information as well, such as times allotted to the parts of the course.

(4) The application and substantiation required under this rule are subject to review by the Director for the purpose of determining whether to certify the course for credit and evaluating and assigning credit hours. The Director may certify the course, or may reject it if the Director determines that the course does not meet applicable requirements.

836-200-XX12
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-XXX3(1) or a renewal application submitted pursuant to OAR 836-200-XXX3(2), including any material changes made in the licensee's business operations, as defined in OAR 836-200-XXX1(8).

(2) A licensee must report the information regarding contacts specified in subsection (3) of this rule, on the following dates for each quarter:

(a) April 15, for the quarter beginning January 1, and ending on March 31;

(b) July 15, for the quarter beginning April 1, and ending on June 30;

(c) October 15, for the quarter beginning July 1, and ending on September 30; and

(d) January 15, for the quarter beginning October 1, and ending on December 31.

Comment: While we don't object to quarterly reporting, the timing of the reports would be a challenge for most manufacturers. Sales Representatives do not typically have this data at hand, so the manufacturer would have to generate reports based on various sources such as expense reporting, AP, and CRM systems. Closing out a quarter and having that information available within fifteen (15) days of the end of a quarter is nearly impossible.

The report described in subsection (2) of this rule must contain the followinginformation in a form specified by the department:

(e) A list of health care providers within this state that the licensee contacted during the quarter;

(f) The number of times the licensee contacted each health care provider during the quarter;

(g) The location and duration of the licensee's contact with each health care provider;

(h) Which pharmaceutical products the licensee promoted;

(i) 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

(j) Whether and how the licensee otherwise compensated the health care provider for contact with the licensee.

Comment: The amount of time a sales representative spends in a provider's office is often a very short time and is not tracked. For section (g) we recommend an option similar to the Chicago reporting template where time is estimated in specific increments: </= 15 minutes, 15 to 30 minutes, 30 minutes to 2 hours, 2-8 hours, 8-24 hours. Typical interactions should fall into those categories based on the type of activity such as a detail

only call (<15 minutes), a lunch and learn (15-30 minutes) or a Speaker program (30 minutes to 2 hours).

Comment: Section (i) asks for the monetary value of any drug samples. Under federal law, drug samples are provided free of charge and cannot be sold. Rather that requiring the "monetary value of the samples", we recommend re-wording the section to say, "the cost to produce samples" or the "cost of the equivalent value in trade product" or eliminating the requirement all together if at all possible.

Comment: Section (j) asks for any other compensation the health care provider received for contact with the licensee. If a health care provider is conducting a Speaker Program on behalf of the manufacturer, the licensee would know the health care provider was compensated, but would not know the amount. Also, any payments made to the health care provider may include not only compensation for the health care provider's services as a contracted speaker, but reimbursement for travel and lodging. That would not be information that the licensee would have. To be able to include any of this type of payment within fifteen (15) days of closing the quarter to meet the requirements in 836-200-XX12 (2) would be very difficult, if not impossible for the manufacturer to comply, as stated in our comment above. If it is not the intent to include such compensation, we recommend that the state clarify that requirement.

836-200-XX13
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.

836-200-XX14
Civil penalties and license revocation

(1) The department may impose civil penalties on licensees for violations of 2021 Or Laws ch 593 and OAR 836-200-XXX0 to 836-200-XX13, including but not limited to the

following:

(a) Engaging in any of the prohibited conduct described in OAR 836-200-XX13.

(b) Failure to timely report any of the information described OAR 836-200-XX12

(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.