

TO: Numi Lee Griffith, DCBS

FROM: Chloe Becker (OCAP) and Rick Blackwell (PacificSource)

DATE: October 19th, 2021

Thank you for the opportunity to provide feedback on the proposed rules for SB 763 (2021) on behalf of the Oregon Coalition for Affordable Prescriptions (OCAP) and PacificSource. OCAP and PacificSource supported SB 763 in the 2021 session and look forward to the transparency and structure of this new licensing system. Our initial comments and suggested changes are below, and we look forward to the continued conversation around these rules.

836-200-XXX1: Definitions

Add further clarity to the definition of pharmaceutical representative:

(4) "Pharmaceutical representative" means a person that markets or promotes pharmaceutical products to health care providers on behalf of the manufacturer.

As discussed during the meeting, remove the text at the top of page two in (c) of the material change definition. "Any change in the company(s) that manufacture the pharmaceutical product(s) that the licensee markets or promotes" is too broad of language. The other components in (8)(a)-(c) make sense.

836-200-XXX3

License Application and Renewal Application

There was discussion around whether or not license fees should be prorated depending on when in the calendar year a pharmaceutical representative is applying for their license. We believe the department should keep (1)(d) as proposed as other licenses are not prorated.

We support changing (1)(a) and (2)(a) from "residence telephone number" to "personal telephone number".

The current language in (1)(b) and (2)(b) is broad and everyone applying for the license is in the same general business. Changing the language to "A description of the business activities in which the applicant will engage" would help to add specificity. Activities could include in person, electronic, sales, provision of samples, etc.

836-200-XXX4

Education and Continuing Education Requirements

Given the importance of this new licensing program, OCAP strongly supports the coursework component requirements for initial licensure as proposed in (1), especially (1)(a)(D) the comparative cost effectiveness of pharmaceutical products.

Coursework on “the comparative clinical effectiveness of pharmaceutical products” as listed in both (1)(a)(C) and (2)(a)(C) may be difficult due to the wide variety of pharmaceutical products that representatives are promoting. Courses on how comparative cost effectiveness research is conducted may make more sense.

(2)(a)(I) “Anatomical and physiological effect of pharmaceuticals” is a very broad subject area for continuing education coursework. We suggest that the department narrow this subject area or remove it from the list.

We encourage the department to add further clarity to the rules around the education and continuing education requirements by reiterating from statute that the education may not be provided by employers:

SB 763, Section 1, (5)(b) “The director may designate and publish a list of persons that provide professional education that meets the director’s specifications under this section. *An applicant or a licensee may not receive professional education from the applicant’s or licensee’s employer.*”

836-200-XX12

Licensee Reporting Requirements

Though the quarterly reporting dates outlined in (2) make sense to OCAP given the parallels that have been drawn to lobbying reporting, we would support moving the reporting to twice a year. Representatives reporting on a less frequent would make it extremely difficult for the agency to know if a licensee is complying with statute and these rules when it comes time for renewal. Reporting compliance or lack of reporting must be taken into account.

In (3)(c) we suggest adding in “The location or electronic contact and duration of the licensee’s contact with each health care provider” as interactions may not always be in person.

We suggest that the agency seek clarity from the Department of Justice around (3)(e) and the questions that were raised on reporting the monetary value of samples. It may make sense to instead ask for the volume of samples.