



Chelsea Ott, JD
Director, Global Regulatory
MedPro Systems LLC
100 Stierli Court | Mt. Arlington, NJ 07856
(973) 398-7800
Chelsea.Ott@MedProSystems.com
<https://www.medproid.com/>

May 27, 2022

Submitted via Email

Numi Griffith, Senior Policy Advisor
Karen Winkel, Rules Coordinator
Oregon Department of Consumer and Business Services
350 Winter St NE 2nd floor
Salem, OR 97301

RE: Comments on Notice of Proposed Rulemaking for Pharmaceutical Representative Licensing Rules

Dear Ms. Griffith and Ms. Winkel:

Thank you for this opportunity to provide comments on the Notice of Proposed Rulemaking associated with the Pharmaceutical Representative Licensing Rules.¹

MedPro Systems LLC (“MedPro”) has been a leading service provider to pharmaceutical companies for over 20 years and has particularly specialized in compliance and aggregate spend reporting. MedPro’s clients range from pre-commercial manufacturers to household names, and as such, our comments reflect a broad range of industry stakeholder perspectives. MedPro and its clients have substantial experience in complying with pharmaceutical representative licensure and reporting requirements and therefore have experience with the challenges involved in with pharmaceutical representative data capture and report generation.

MedPro is committed to supporting our clients in successfully meeting the requirements specified in SB763 as codified at ORS 689.503. As such, MedPro has closely followed the evolution of Oregon’s requirements, including attending the Department of Consumer and Business Services’ (“DCBS”) Rulemaking Advisory Committee (“RAC”) Meetings and subscribing to the relevant listserv for updates. There are items that MedPro believes require further clarification by DCBS in the Permanent Rule, Disclosure Log², and/or FAQs³.

We appreciate your staff’s ongoing efforts to provide clear guidance to the industry and hope that our comments are helpful in supporting this endeavor.

¹ Notice of Proposed Rulemaking, Pharmaceutical Representative Licensing Rules, published April 26, 2022, <https://secure.sos.state.or.us/oard/viewRedlinePDF.action?filingRsn=50887>.

² DFR Pharmaceutical Representative Licensing, Disclosure Log, <https://dfr.oregon.gov/business/licensing/pharmaceutical-rep/Documents/DCBS-Disclosure-Log.xlsx> (last accessed May 27, 2022).

³ DFR Pharmaceutical Representative Licensing, Pharmaceutical Representative License FAQs, <https://dfr.oregon.gov/business/licensing/pharmaceutical-rep/Pages/pharma-rep-faqs.aspx> (last visited May 27, 2022).

Requested Clarification

MedPro is requesting clarification of several of the items below, including:

- Pharmaceutical Representative Licensure Requirement Applicability
- Disclose Log Clarifications
 - HCP License Type
 - HCP Primary Business Address
 - Samples
- Disclosure Log Upload and Submission Process

Pharmaceutical Representative Licensure Requirement Applicability

SB763 as codified at ORS 689.503(2)(a) states, “A person may not engage in business as a pharmaceutical representative without first obtaining a license, unless the person engages in business as a pharmaceutical representative in this state for fewer than 15 days during each calendar year.” ORS 689.503(1)(d) states that “‘Pharmaceutical representative’ means a person that markets or promotes pharmaceutical products to health care providers.” Based on the relevant language, it is not clear whether this language requires a physical presence in Oregon to be triggered.

It is MedPro’s understanding based on comments at the January 18, 2022 RAC Meeting that teledetailers (i.e., individuals that work on behalf of pharmaceutical manufacturers to promote products by calling Health Care Providers in Nevada from another state, but do not have a physical presence in Nevada) are not required to be licensed as Pharmaceutical Representatives. MedPro is requesting formal clarification in the Permanent Rule. Similarly, MedPro is requesting formal clarification regarding the requirement for Pharmaceutical Representative licensure for Medical Science Liaisons, Market Access representatives, and Regional and District Managers.

Disclosure Log Clarification

On April 13, 2022, Kevin Kemper emailed an updated version of the Disclosure Log to Licensees explaining that it is the final revision for 2022. MedPro appreciates all of the feedback that was considered and the updates that were made. In order to ensure accurate data collection by Licensees and subsequent Disclosure Log population, MedPro is seeking clarification on a few items described in more detail below.

HCP License Type

At the March 1, 2022 RAC Meeting, the HCP License Type options available on the Disclosure Log were discussed. Licensed Clinical Social Worker and Psychologist were removed as options in the final version of the Log, as it was explained at the meeting that these License Types do not meet the definition of “Health Care Provider” (a person that is licensed, certified or otherwise authorized under the laws of this state to prescribe, provide or dispense pharmaceutical products to patients for the purposes of diagnosis, treatment or care of disease, injury or congenital conditions) in ORS 689.503(1)(a) and therefore would not be required to be included on the Log.

It was also pointed out that “Other” may cause confusion as to how it should be used (if at all). MedPro recommends that “Other” be removed as an option so the data collection requirements are clear for Pharmaceutical Representatives and to also ensure that each option available in this column is being used correctly and uniformly.

MedPro is aware that pursuant to 685.030(3)(a), Doctors of Naturopathy have prescriptive authority. Nonetheless, there is not an HCP License Type available for these Health Care Providers. Similarly, the Oregon Board of Naturopathic Medicine and website, <https://obnm.us.thentiacloud.net/webs/obnm/register/#>, is not listed on the Instructions tab of the Disclosure Log as a source to be consulted for license information. MedPro is requesting that if Doctors of Naturopathy are considered HCP License Types that must be disclosed, that a new option is added to the Disclosure Log for the sake of clarity and to ensure that Pharmaceutical Representatives are collecting this information. Because of the lack of clarity on this point, if collection is required by licensees, MedPro is requesting that it is made optional to report Doctors of Naturopathy for data collected in 2022.

Primary Business Address

HCP Primary Business Address is a required field on the Log. MedPro is seeking approval to use the information provided the relevant licensure board for each HCP License Type. We are requesting this approval for three reasons. First, there is the potential that the address where the interaction took place is not the relevant Health Care Provider’s Primary Business Address. Second, MedPro has identified instances where address information is not provided by the relevant licensing board, in which case this section may be blank. Lastly, there are also instances where a Health Care Provider has a British Columbia address, as opposed to the United States, so MedPro plans to use the Canadian Province Abbreviation instead of the two-digit U.S. state abbreviation.

Samples

MedPro echoes the sentiments expressed by other participants on RAC meeting calls and what PhRMA formally commented in its March 17, 2022 letter regarding the requirement to report the monetary value of samples and the proposed use of WAC price for the most comparable NDC.

Another potential complication is that the Licensee bears ultimate responsibility for the disclosure and faces potential penalties for violating the disclosure requirement, yet may not be privy to WAC price calculation. The Oregon Legislature passed the Prescription Drug Price Transparency Act (House Bill 4005) to increase prescription drug transparency, and as such requires certain disclosure of WAC prices. If this information is already being provided by the manufacturer, why is it also required to be provided by Licensees? Can the DCBS leverage the information it is already receiving instead of providing an additional burden on licensees?

Nonetheless, if this definition is not changed and this requirement stands MedPro is requesting clarification around this requirement. First, MedPro is seeking clarification on the definition of sample. MedPro is operating using the definition of “Drug Sample” provided in 21 CFR 203.3, which is, “A unit of a prescription drug that is not intended to be sold and is intended to promote

May 27, 2022

Page 4 of 4

the sale of the drug.” This is in juxtaposition to the state of Vermont as expressed in 18 V.S.A. § 4631a, which has a broader definition of “Sample” including, “starter packs and coupons or other vouchers that enable an individual to receive a prescribed product free of charge or at a discounted price.”

Second, what date should the WAC be calculated for purposes of populating the Disclosure Log? The date of submission may not align with when the sample was provided. Similarly, having to populate different WACs depending on the date the sample was provided would become very burdensome.

Lastly, is Column R “Pharmaceutical Marketed or Promoted” on the Disclosure Log required only if a Sample was provided? The comment bubble attached to Column S “Monetary Value of Samples Given for Drug 1,” which states “If there is a drug listed in the preceding column, then this field is required and cannot be left blank” implies that this is the case.

Disclosure Log Upload and Submission Process

MedPro is seeking guidance on the disclosure submission process. The FAQs state that Pharmaceutical Representatives may have someone else upload their contact spreadsheet, but the licensee is solely responsible for the content and timely filing of the report.

MedPro is seeking clarification on the process for an alternate upload process. Will this non-Licensee be permitted to upload one disclosure on behalf of all of its Licensees at one time to ease the administrative burden, since each line will specify the Licensee and Health Care Provider involved in the interaction? This would also minimize potential security risks of sharing passwords and log-in information with others besides the Licensee.

If a Licensee has no interactions to report in a given year, must the licensee submit a Disclosure Log?

Thank you in advance for your consideration of the above recommendations and requests. We would be pleased to discuss any aspect of this letter in greater detail at your convenience and provide additional information or examples that may be of interest. Please do not hesitate to contact me at (973) 398-7800 or Chelsea.Ott@MedProSystems.com with any questions.

Sincerely,

/s/ Chelsea Ott

Director, Global Regulatory, MedPro Compliance Advisory Services
MedPro Systems LLC