

November 9, 2021

Andrew Stolfi, Director Oregon Department of Consumer and Business Services 350 Winter St NE 2nd floor Salem, OR 97301

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

Re: Comments on 10/25/21 draft of OAR 836-200-XXX0 to 836-200-XX14

Dear Director Stolfi:

On behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA), I am writing to offer comments and seek clarification on draft rules OAR 836-200-XXX0 to 836-200-XX14, implementing temporary rules for licensing of pharmaceutical representatives pursuant to 2021 Or Laws ch 593 (enacted as 2021 SB 763). PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives.

PhRMA appreciates the Department focusing the draft temporary rule on the most urgent requirements in order to get a system in place in a timely manner and looks forward to future discussions on the remaining requirements implemented in the final rule.

Definitions

PhRMA would like to reiterate our concern that the definition of "pharmaceutical representative" in OAR 836-200-XXX1 is overly broad and might inadvertently capture – and require licensure of – several other types of employees that were not intended by the legislation. We seek clarification from the Department that managers or supervisors would not be included in licensure if they are not in direct contact with health care professionals in Oregon. PhRMA would also like to reiterate our concerns that Medical Science Liaisons, who are technical experts who engage in scientific exchange with health care providers, often in a responsive role, should be clearly and explicitly excluded from licensure. To that end, PhRMA



offers the following language that is used in a similar Chicago, IL ordinance (Section 4-6-310 of the Municipal Code of Chicago)¹:

"Pharmaceutical representative" means a person who markets or promotes pharmaceuticals to health care professionals and excludes Medical Science Liaisons, Wholesale Distributors, and pharmaceutical representative managers or supervisors who do not interact directly with health care professionals while in [the State of Oregon].

Should the Department wish to provide a definition for "medical science liaison," PhRMA suggests the following definition which reflects the common understanding of the term in the industry:

"Medical science liaison" is a person who engages in scientific exchange with health professionals, researchers, and/or payers for non-promotional reasons and does not market, sell, or promote pharmaceuticals. Medical science liaisons may also be known by other titles, including but not limited to Medical Liaison, Medical Manager, Regional Scientific Manager, Clinical Liaison, and Scientific Affairs Manager.

Confidentiality of Licensee and Reported Information

PhRMA has concerns that a licensee's residential contact information could be subject to disclosure under the Oregon Public Records Law. With the addition of Social Security Number as a requirement for licensure in the current draft, we want to take this opportunity to reiterate the need to ensure confidentiality of licensees' personal information. We understand that the Department has a need for this information because it may need to contact these individuals, and that the names and basic business information of licensed pharmaceutical sales representatives will be posted on a public-facing website. However, public disclosure of personal information could create privacy and safety concerns for licensees, and we therefore ask the Department to clarify how personal information will be handled. The Public Records Law recognizes the privacy interests of license applicants like construction contractors or health professionals, and we ask that a similar approach be taken for pharmaceutical representatives' license information.

¹ City of Chicago Rules, Pharmaceutical Representative License, June 1,2017 https://www.chicago.gov/content/dam/city/depts/dol/rulesandregs/PharmaRepLicenseRules6.1.17Final.pdf



PhRMA and its member companies look forward to continued engagement throughout the regulation amendment process. Thank you for your consideration of these requests and our feedback related to the rules for the Oregon pharmaceutical sales representative licensure law.

Sincerely,

Dharia McGrew Director, State Policy Sandy Ahn Assistant General Counsel Washington, DC