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October 18, 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 OAR 836-200-XXX0 to 836-200-XXX7

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-XXX7, implementing requirements 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 being included in the RAC panel for this rule and looks forward to working with the Department to address our concerns with the current draft.

Definitions

PhRMA is concerned 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. PhRMA requests that the definition be further clarified, and 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

[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

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.

Address Overlap with Federal Reporting Requirements

PhRMA is concerned that the reporting regarding samples, materials, or gifts overlaps with existing federal law and respectfully asks the Department to clarify how it will address these overlapping reporting requirements. The CMS Physician Open Payments Program, enacted as part of the Affordable Care Act, requires prescription drug manufacturers to annually report payments and "transfers of value," including gifts that are provided to a health care provider. The federal government makes this data available to the public each year on a website.[2]

In implementing its own disclosure law, Vermont addressed this issue of overlapping federal and state reporting requirements by explicitly recognizing where federal requirements apply. Vermont does not require reporting of information that falls within the scope of these federal requirements:

> [S]ome of Vermont's disclosure requirements are preempted by the Physician Payments Sunshine Provision (§ 6002) of the Patient Protection and Affordable Care Act (Pub. L. No. 11-148)....Vermont may not require manufacturers to disclose those allowable expenditures and permitted gifts which are required to be reported to the federal government under the Physician Payments Sunshine Provision of the Patient Protection and Affordable Care Act.[3]

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[2] Centers for Medicare and Medicaid Services, What is Open Payments?, available at https://www.cms.gov/openpayments/.

[3] Vermont Office of the Attorney General, "Guide to Vermont's Prescribed Product Gift Ban and Disclosures of 2020 Data–Due April 1, 2021," Jan. 2021, https://ago.vermont.gov/wp-content/uploads/2021/03/RY-2020-Vermont-Prescribed-Products-Gift-Ban-Guide-.pdf (emphasis omitted).

We request that the Department take a similar approach in reconciling these overlapping requirements.

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. We understand that the Department has a need for this information because it may need to contact these individuals but ask that the Department acknowledge that this information is private and that public disclosure of it could create privacy and safety concerns for licensees. 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.

Finally, PhRMA believes that information provided to the Department pursuant to these requirements is trade secret and could competitively harm pharmaceutical manufacturers if disclosed to third parties. We strongly urge the Department to safeguard the confidentiality of this information. Specifically, we recommend including the following statement in OAR 836-200-XX12:

> Notwithstanding any provision of law to the contrary, information submitted to the department hereunder shall be considered confidential, proprietary and trade secret pursuant to ORS 192.45(2), and shall be exempt from disclosure under ORS 192.311 to 192.478.

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

Merlin Brittenham,
Senior Director, Law