PhRMA
RESEARCH • PROGRESS • HOPE

1115 WEST BAY DRIVE NW, SUITE 205 • OLYMPIA, WA 98502 • 360-705-1276 • PhRMA.org

March 17, 2022

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 Draft Rule March 1, 2022 (OAR 836-200-0600 to 836-200-0670)

Dear Director Stolfi and Ms. Griffith:

On behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA), we are writing to offer comments and feedback on the March 1, 2022 draft permanent rules, OAR 836-200-0600 to 836-200-0670, which implement the Pharmaceutical Sales Representative Licensing Law, enacted in 2021 as Senate Bill 763 and codified at ORS 689.503 ("the statute"). 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 opportunity to be included in the Rulemaking Advisory Committee (RAC) panel for this rule and the Department of Consumer and Business Services's ("the Department") willingness to engage with PhRMA.

PhRMA would like to reiterate its ongoing concerns that were raised in previous comment letters dated October 18, 2021, and February 1, 2022, as well as provide feedback on the Department's request for suggestions on defining "gift."

Proposed Definition of "Monetary Value"

As voiced in the February 1, 2022 letter, PhRMA continues to be concerned that the proposed definition of "monetary value" for drug samples is not supported by the statute. The statute requires a licensed pharmaceutical sales representative to report "whether the licensee provided the health care provider any product samples, materials or gifts, and if so, the monetary value of the samples, materials or gifts."[1] However, the Department is proposing to define "monetary value" of drug samples as "an equivalent volume or quantity of the prescription drug estimated using the WAC

[1] Oregon Draft Permanent Rule, 836-200-0620(3).

price for the most comparable NDC."[2] The statute does not require representatives to report the value of an item that is "most comparable" to the sample provided, but instead requires reporting the value of the sample itself. Therefore, the Department's proposed definition is inconsistent with the statutory language.

PhRMA is also concerned that the Department's proposed definition is inconsistent with extensive efforts that manufacturers take to make sure that samples have no monetary value. There are stringent federal laws – including the U.S. Prescription Drug Marketing Act ("PDMA") and U.S. Anti-Kickback Statute – that prohibit manufacturers from using samples to confer value on health care professionals.[3] Guidance from the U.S. Department of Health and Human Services Office of Inspector General advises that manufacturers train their sales force to inform sample recipients in a meaningful manner that samples may not be sold or billed, "thus vitiating any monetary value of the sample."[4]

In addition, federal law requires samples to bear a label that clearly denotes their status as drug samples (e.g., "sample," "not for sale," or "professional courtesy package").[5] In addition, since samples are not sold to wholesalers or other purchasers, and drug samples are not able to be lawfully sold, samples generally do not have a published wholesale acquisition cost (WAC), so the proposed definition would require companies to report a value that is not "the monetary value of the sample" provided to the health care provider.

For the reasons cited above, PhRMA respectfully requests that the Department withdraw its proposed definition of "monetary value" for samples.

PhRMA also notes that the Department has posted a document of an email exchange titled, "FDA response to assigning a value to drug samples," on the RAC website.[6] This document appears to be an informal communication by a private third-party entity with a staff member at the U.S. Food and Drug Administration (FDA) who sought to connect the entity with the "appropriate people" at FDA about this question. If the Department is seeking guidance from FDA about assigning a monetary value to drug samples, PhRMA requests that the Department do so formally through FDA's established process with the Intergovernmental Affairs Staff in FDA's Office of Policy, Legislation, and International Affairs.

Additional Concerns

PhRMA would also like to reiterate and incorporate concerns raised in its October 18, 2021 and

[2] Oregon Draft Permanent Rule, 836-200-0605(9) *(emphasis added).*
[3] 21 U.S.C. §§ 331; 42 U.S.C. § 1320a-7b.
[4] Office of Inspector General, HHS, OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731, 23739 (May 5, 2003).
[5] 21 C.F.R. § 203.38(c).
[6] Oregon Division of Financial Regulation, Department of Consumer and Business Services, https://dfr.oregon.gov/help/committees-workgroups/Pages/rac-licensing-pharmaceutical-reps.aspx (last accessed March 17, 2022).

February 1, 2022 comment letters that the reporting requirement regarding samples, materials, or gifts overlaps with the CMS Physician Open Payments Program enacted as part of the Affordable Care Act.[7] We urge the Department to clarify how it plans to reconcile overlapping requirements.

Feedback on Defining "Gift"

In response to the Department's request on suggestions for defining the term "gift" under the licensee reporting requirement, PhRMA recommends the following definition, which is based on language in relevant state and federal requirements and industry codes of conduct:[8]

> A gift is anything of economic value given to, or for the personal benefit of, a health care professional without consideration of equivalent or market value.

PhRMA and its member companies look forward to continued engagement throughout the regulation process. Thank you for your consideration of these concerns and requests related to the rules for Oregon's Pharmaceutical Sales Representative Licensure Law. If you have any questions, please do not hesitate to contact Dharia McGrew at dmcgrew@phrma.org to discuss these concerns further.

Sincerely,

Dharia McGrew
Director, State Policy

Sandy H. Ahn
Assistant General Counsel, Law
Washington, D.C.

[7] Centers for Medicare and Medicaid Services, What is Open Payments?, available at https://www.cms.gov/openpayments/.
[8] *See* Oregon Draft Permanent Rule, 836-200-0620(3).