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February 1, 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 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 on and seek clarification of draft permanent rules OAR 836-200-0600 to 836-200-0670, which implement the Pharmaceutical Representatives 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 Rules Advisory Committee panel for this rule and the Department of Consumer and Business Services's ("the Department") willingness to engage with PhRMA.

Proposed Definition of "Monetary Value"

PhRMA is concerned that the proposed definition of "monetary value" for drug samples is inconsistent with the statutory requirements for licensee reporting under Oregon's statute. The proposed definition also raises significant concerns in light of extensive efforts undertaken by manufacturers to ensure that samples have no monetary value. PhRMA respectfully requests that the Department withdraw the proposed definition of "monetary value" for samples.

The statute requires licensees to report to the Department, among other things, "[w]hether the licensee provided the health care provider with any product samples, materials or gifts and, if so, the monetary value of the samples, materials or gifts."[1] In the draft regulations, the Department proposes at OAR 836-200-0605(9) a definition of "monetary value" that defines the term "for the purposes of describing the value of drug samples for reports" to be "the monetary value of an equivalent volume or quantity of the prescription drug estimated using the WAC price for the most

[1] Or. Laws ch 593, Sec. 1(6)(a)(F).

comparable NDC."[2] However, 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 proposed definition is not supported by the statute.

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 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] Furthermore, samples generally do not have a published wholesale acquisition cost (WAC) because they are not sold to wholesalers or other purchasers, and drug samples are not able to be lawfully sold, 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.[6]

Additional Concerns

PhRMA would also like to reiterate and incorporate concerns raised in its October 18, 2021 comment letter that the Department has not addressed in this draft permanent rule, including our concern 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.

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[2] *See* 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] Other federal and state statutes that require drug sample reporting do not require the reporting of the samples' value despite requiring the reporting of other information. *See* Affordable Care Act § 6004, 42 U.S.C. § 1320a-7i; 18 Vt. Stat. Ann. § 4632(a)(2)(A)(i) and Guidance from the Vermont Office of the Attorney General, which explicitly states, "[t]he manufacturer need not assign a monetary value to a sample or other product when reporting, Vermont Office of Attorney General, Guide to Vermont's Prescribed Products Gift Ban and Disclosure Law for Disclosures of 2020 Data – Due April 1, 2021, at 27, *available at* https://ago.vermont.gov/wp-content/uploads/2021/03/RY-2020-Vermont-Prescribed-Products-Gift-Ban-Guide-.pdf (emphasis added); Nev. Rev. Stat. § 439B.660(4) and Nevada Department of Health and Human Services, Pharmaceutical Sales Representative Compensation & Samples Reporting Instructions (Dec. 15, 2021), *available at* https://dhhs.nv.gov/uploadedFiles/dhhsnvgov/content/HCPWD/Transparency_Reporting/Compensation_Samples_Reporting_Instructions_v12.15.2021.pdf.
[7] Centers for Medicare and Medicaid Services, What is Open Payments?, available at https://www.cms.gov/openpayments/.

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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 the Oregon 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,

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