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May 26, 2022

Department of Consumer and Business Services
Division of Financial Regulation
350 Winter St. NE
Salem, OR 97309-0405
Email: DFR.Rules@oregon.gov

Submitted via email

Re: Notice of Proposed Rulemaking on Pharmaceutical Representative Licensing Rules

Dear Ms. Winkel:

We submit these comments on behalf of the Ad Hoc Sunshine and State Law Compliance Group (the "Ad Hoc Group" or the "Group") regarding the proposed pharmaceutical representative licensing permanent rules published on April 26, 2022 by the Department of Consumer and Business Services (the "Department") to implement the Oregon Pharmaceutical Representative Licensing Law (SB 763).

Established in 2004, the Ad Hoc Group is a coalition of over 80 pharmaceutical, medical device, and biotechnology manufacturers that focuses on compliance with federal and state laws that regulate the life sciences industry. The Group is particularly focused on federal and state laws that directly regulate the industry's interactions with health care professionals, including transparency laws, code of conduct and gift ban laws, and sales/marketing representative licensing requirements. Ad Hoc Group member companies have substantial collective experience complying with these requirements. The Group has a strong sense of the types of implementation proposals that are likely to cause ambiguity and unintended consequences.

The Ad Hoc Group's comments generally reflect the perspectives of a diverse range of industry stakeholders. Manufacturers that participate in the Ad Hoc Group range in size, types of products manufactured and marketed, and corporate structure (ranging from multi-national corporations to small, privately held companies). Accordingly, we address in this letter only those comments that are universal to all the Group's diverse members. Other aspects of the proposed rules that are not addressed in these comments are outside the scope of this letter and are neither supported nor critiqued. Some individual manufacturers that participate in the Ad Hoc Group may independently also submit their own comments to the Department.

I. THE DEPARTMENT SHOULD WITHDRAW ITS PROPOSED CHANGES TO THE PROVISION THAT GIVES RISE TO THE LICENSING OBLIGATION

Ad Hoc Group members believe that the Department should withdraw the proposed changes to the provisions that give rise to an obligation for a pharmaceutical representative to be licensed, as the proposed change would exceed the licensing regime contemplated under the statute.

The Oregon Pharmaceutical Representative Licensing Law (SB 763) requires that "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."[1] Consistent with the statute, the Department's temporary rules require a pharmaceutical representative "who does business with health care professionals while both are within the state of Oregon [to] acquire a license from the department prior to doing business in the state on 15 or more days in a calendar year."[2]

The Department's proposed permanent rule sets forth a revised threshold for the license obligation, providing that "[a] pharmaceutical representative who does business with health care professionals located within the state of Oregon must acquire a license from the department prior to doing business in the state on 15 or more days in a calendar year."[3] The proposed permanent rule would impermissibly expand the scope of the license requirement to include pharmaceutical representatives who are *not* in Oregon, if they do business with health care professionals in Oregon. This proposed language directly conflicts with the statute's requirement that a pharmaceutical representative must engage in business "in this state" in order to require a license. The Department is impermissibly attempting to expand and exceed the statutory obligations with its proposed change. Accordingly, Ad Hoc Group members request that the Department withdraw the proposed change so that the regulatory obligations continue to align with the statute.

II. THE DEPARTMENT SHOULD WITHDRAW ITS PROPOSED DEFINITION OF "MONETARY VALUE"

Ad Hoc Group members believe that the Department should withdraw the proposed definition of "monetary value" for samples because it is inconsistent with the statutory requirements for licensee reporting under SB 763, would lead to inaccurate misperceptions that samples have monetary value to health care providers, and could consequently cause confusion and misunderstanding as to the value actually conferred upon Oregon health care providers.

SB 763 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."[4] The statute does not define "monetary value." The Department proposes to define "monetary value" as follows: "for the purposes of describing the value of drug samples for reports … [monetary value] means the monetary value of an equivalent volume or quantity of the prescription drug estimated using the WAC price for the

[1] Or. Laws 2021 Ch. 593, Sec. 1(2)(a) (emphasis added).
[2] Oregon Temporary Rule, OAR 836-200-0610(1) (emphasis added).
[3] Oregon Proposed Permanent Rule, OAR 836-200-0610(1) (emphasis added).
[4] Or. Laws 2021 Ch. 593, Sec. 1(6)(a)(F).

most comparable NDC."[5] This proposal would require companies to report a value that is not, by definition, the value of the sample provided to the health care provider. The statute does not require representatives to report a value of an item that is "most comparable" to the item provided, but instead requires reporting the value of the item that is actually provided. The Department is attempting to inappropriately expand and contort the reporting requirement by suggesting that licensees report a monetary value for samples that have no such value.

The Department's proposed definition would also frustrate and directly contradict extensive efforts that manufacturers take to ensure that samples have no monetary value. Manufacturers do not consider prescription drug samples to have any value, and indeed, 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. In addition, guidance from the U.S. Department of Health and Human Services Office of Inspector General advises that manufacturers should 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."[6] Manufacturers have also taken steps to distinguish samples from commercial products. For example, many companies utilize separate 11-digit national drug codes ("NDCs") for samples. (As a general matter, each distinct drug product is given its own NDC-11; sample products often have distinct NDC-11s from their commercial counterparts to help distinguish commercial stock that is sold from sample products that are made available for free and have no value.) In addition, samples are required under federal law to bear a label that clearly denotes their status as drug samples (e.g., "sample," "not for sale," or "professional courtesy package").[7] Furthermore, samples generally do not have a published wholesale acquisition cost ("WAC") because they are not sold to wholesalers or other purchasers, and are not able to be lawfully sold.

It is also unclear what policy goal Oregon seeks to advance by assigning a monetary value to samples that have no such value. Under the Oregon Administrative Procedure Act, an agency must provide "[a] statement of the need for the rule and a statement of how the rule is intended to meet the need."[8] Requiring that licensees invent a monetary value for samples using a value that is "most comparable" to the item actually provided clearly is not mandated by SB 763. The Department has inappropriately exceeded its statutory mandate and failed to articulate such a need as there is no readily apparent public benefit to requiring manufacturers to submit inaccurate information about the monetary value of samples.

Oregon's proposal for samples is also noticeably inconsistent with approaches taken by other federal and state/local jurisdictions that require reporting for samples (e.g., Vermont, U.S. FDA), as none of these jurisdictions require manufacturers to report any monetary value of samples, recognizing that requiring such reporting would provide an inappropriate perception that these samples have value when they do not.

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[5] Oregon Proposed Permanent Rule, OAR 836-200-0605(8) (emphasis added).
[6] Office of Inspector General, HHS, OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731, 23739 (May 5, 2003).
[7] 21 C.F.R. § 203.38(c).
[8] Or. Rev. Stat. § 183.335(2)(b)(C).

Ad Hoc Group members believe that the Department's proposed definition of "monetary value" for samples is inconsistent with the statute and would create material compliance misperceptions for manufacturers and health care providers in light of the extensive efforts undertaken to ensure that samples in fact have no monetary value to health care providers, as required by federal authorities. The Ad Hoc Group respectfully requests that the Department withdraw its proposed definition of "monetary value" to avoid potential challenges to its implementation efforts, as well as to help avoid confusion and misperceptions among industry stakeholders and Oregon health care providers.

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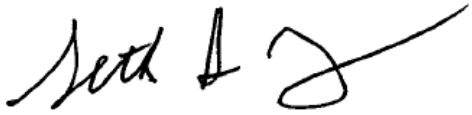
The Ad Hoc Group appreciates the opportunity to provide comments on the proposed rule, and thanks the Department for the opportunity to participate in this process. Please do not hesitate to contact us for additional information or discussion regarding our comments. We can be reached at 202.626.5413 or by email at bbohnenkamp@kslaw.com.

Respectfully,

Nikki Reeves
King & Spalding LLP



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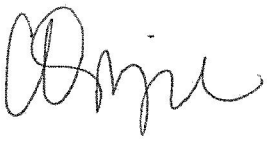

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On behalf of the Ad Hoc Sunshine and State Law Compliance Group

CC: Andrew Stolfi, Director/Insurance Commissioner, DCBS
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