



May 27, 2022

Karen Winkel  
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Dear Karen,

QPharma, Inc (QPharma) is a compliance-based service provider to the pharmaceutical industry. On behalf of QPharma and our industry partners, I am respectfully submitting these comments on the preliminary rules for enforcement of SB 763. In doing so, our interest is to help ensure we are offering our clients comprehensive compliance services and recommendations that align to the intent of federal, state, and local laws, regulations, and rules.

The comments reflect concerns, interests and questions raised by our clients in reviewing the rules and the disclosure log distributed to sales representatives licensed in the state.

Please feel free to contact me with any questions.

Kind Regards,  
Judy Fox  
Director of Compliance Services  
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DEPARTMENT OF CONSUMER AND BUSINESS SERVICES  
FILED 04/26/2022  
INSURANCE REGULATION

FILING CAPTION: Pharmaceutical Representative Licensing Rules

836-200-0605 Definitions

(3) "Pharmaceutical representative" means a person that markets or promotes pharmaceutical products to health care providers

836-200-0610 License Required

(1) 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.

**Comments: Based on these two sections of the rules, it is recommended that tele-detailers and others who are not physically located in Oregon but may contact health care professionals who are licensed and practice in the state would NOT be required to obtain a license. Often, tele-detailers are contracted through a third party that may call on health care professionals throughout the county. It would be an economical and practical burden to require tele-detailers to obtain a license and maintain a disclosure log. It is recommended that the rule clarify that the definitions exclude tele-detailers and others who are not physically within the state.**

836-200-0620 Licensee Reporting Requirements

(3) The report described in subsection (2) of this rule must contain the following information in a form specified by the department:

(e) Whether 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; and

(f) Whether and how the licensee otherwise compensated the health care provider for contact with the licensee.

**Comments:**

(e) Sales representatives will often provide information about a product but will not provide samples of the product immediately and instead will obtain a request for the samples to be shipped by the manufacturer directly to the practitioner. It is recommended that the final rule clarify that the licensed sales representative is only responsible for recording sample disbursements that occurred at the time of the interaction and not report on samples shipped by the manufacturer at a later date. Having to include samples shipped would pose an unnecessary burden on the sales representative when completing the disclosure log as that is not something typically tracked by sales representatives

(e) continued – sales representatives will often provide health care professionals with marketing materials that help explain the features and benefits of their promoted products. Marketing materials such as detail aids are often left with health care providers, and while there is a cost to produce such materials, there typically is not a value assigned to such materials. In general, the industry no longer distributes “reminder items” such as pens, mugs, etc. It is recommended that the requirements include exception for recording marketing materials such as detail aids and patient informational materials from the reporting requirements.

(f) A licensee would never be accountable for or have knowledge of any compensation provided to a health care professional for a bona fide service under an agreement with a manufacturer such as serving as a Speaker on a promotional Speaker Program. In such situations, the sales representative is present and can log some items such as the cost of the meal provided during the program. The fee paid to the Speaker would not be within the sales representative’s scope of the interaction. As such, it is recommended that the final rule include exceptions to clarify that any payments made by a manufacturer to health care professionals for a bona fide service, regardless of whether the sales representative was present, is exempt from the sales representative’s disclosure log.

**Additional general comments on the final rule:**

It is recommended that the final rule allow a manufacturer to submit a disclosure log on behalf of a sales representative. Some of the information required is not readily available to sales representatives, such as the value of samples, and the manufacturer may be needed to convert the number of samples to the value of said samples. It is also recommended that the final rule require sales representatives to submit their disclosure log at the time of termination from a manufacturer.