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Final Public Comments Proposed Rulemaking for Licensing of pharmaceutical representatives (SB 763)

1. Please provide a response or comment regarding clarification on non-promotional interactions as described in my letter dated March 11, 2022. See summary below.

The disclosure log instructions and definitions for interaction contain the following sentence:

“However, you do not need to report a telecommunication or written communication if it was done simply to set up a meeting or other communication with an HCP and no marketing or promotion took place.”

We assume these types of interactions also pertain to in-person interactions. Occasionally, in-person interactions are non-marketing/non-promotional only, e.g., scheduling appointments, providing safety information, providing education in-services/training on safe handling, preparation, and administration of a product to a nurse, nurse assistant, or patient educator.

***Can you confirm whether these types of interactions with no marketing or promotion associated with the interaction are excluded from tracking in the disclosure log?***

2. For Definitions Section of the Final Rule:

"Monetary value," for the purposes of describing the value of drug samples for reports made pursuant to OAR 836-200-0620(3)(e), means the monetary value of an equivalent volume or quantity of the prescription drug estimated using the WAC price for the most comparable NDC.

We request the rules to establish a specific date for the WAC price. For reporting consistency, we recommend that the price utilized is the WAC price that was in effect on December 31<sup>st</sup> of each reporting year when calculating the WAC price for samples distributed throughout the calendar year.

**Please include in the Monetary value definition the directions to calculate “value” utilizing the WAC price on December 31<sup>st</sup>.**



### 3. Disclosure Log

In addition, the disclosure log has the following definition:

**“Monetary Value of Samples.** SB 763 requires that we collect the monetary value of the samples, materials or gifts. Please provide the market value of the items provided. If you feel that this is information that you cannot provide, please seek legal counsel to determine your obligations under SB 763 and any federal law that may be relevant. **If there is a drug listed in the preceding box, then the field asking for a monetary value is a required field and cannot be left blank.”**

The text in red should be revised to allow for interactions that do not include leaving a sample. Some marketed or promoted products are not sampled. In addition, not every interaction with an HCP about a drug product will also include the sampling of that product. For example, the office may already have ample samples in their storage area and do not request additional quantities. **The disclosure log spreadsheet should be modified to indicate no sample provided or available or similar wording to accommodate these situations.**

Regards,

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