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Numi Lee Griffith
Senior Policy Advisor
Division of Financial Regulation
Numi.L.Griffith@dcbs.oregon.gov

Karen Winkel
Rules Coordinator
Division of Financial Regulation
Karen.J.Winkel@dcbs.oregon.gov

Numi and Karen,

In a follow-up to the last RAC meeting regarding the lasted version of the Proposed Final Rule, I have received the following questions from numerous pharmaceutical clients.

Background:

The Disclosure Log Instructions defining an interaction contains 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.”

Questions:

If an Oregon licensee provides information to an office staff member, e.g., medical assistant, regardless of the health care provider’s title or role that is not classified as “marketing” or “promoting”, does that interaction need to be captured and reported?

The disclosure log definition of an interaction (above) appears that these would not need to be recorded for telecommunication or written communications. Does that also apply if the non-marketing or promotion communication occurred in the office?



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Examples of non-marketing, promotional interactions include logistical communications, such as confirming an appointment with an office manager, receptionist, or nurse; providing product safety information without promotion or marketing information or materials; or providing educational materials/training on the safe handling and administration of a product to a nurse or patient educator.

These interactions are not considered promotional as they are not intended to encourage the use of the product. In addition, these types of interactions are not recorded as they are not considered a "promotional call".

Can you confirm if these types of interactions are consistent with the "marketing and promoting" intent of the interaction and if they are to be included in the report?

If the non-promotional interaction is to be recorded, what is to be entered into the "pharmaceutical product marketed or reported field"?

I appreciate both of you for your leadership and willingness to listen to industry representatives as we all want to ensure compliance with the intent of the regulation.

Regards,
Brian

Brian Van Hoy
VP Compliance
G&M Health, LLC
bvanhoy@gmhlc.com
cell: 317-374-8496