G&M Health, LLC

"Compliance Management for the Healthcare Industry"

October 19, 2021

Numi Griffith
Senior Policy Advisor
Division of Financial Regulation

RE: Licensing of pharmaceutical representatives (SB763) rules advisory committee (RAC)

Thank you for inviting G&M Health to participate in the initial meeting held on October 19, 2021.

See below recommendations following the first meeting.

1. There is no systematic method for tracking/recording duration for each call. We either recommended deleting this requirement or allow the company to provide a single overall estimated time with the report.

2. To facilitate timely CE requirements, Oregon should allow reciprocation of existing approved CE providers and their courses for similar licensure requirements in other jurisdictions.

3. Regards to section (2) A pharmaceutical representative may apply for a license renewal if they held a valid and unrevoked license through the end of the preceding calendar year. An applicant for renewal must submit the following information on a form specified by the department at least 30 days before their license expires:

   We suggest modifying the renewal timeframe to allow representatives to renew their license up to 30-days following the expiration of their license as:

   a. Representatives may not know if their territory in the new year will remain to be within Oregon and requiring a renewal.
   b. It may be difficult for renewal completions due to holidays and PTO at the end of the year.
   c. Representatives are not required to obtain a license until their 15th working day in the new year.

4. It is recommended to remove the ten-hour training requirement provided by an approved provider. Rather, we would suggest that similar to Chicago, Oregon develop and provide applicants access to an initial training course which contains components A, B in the proposed rule. Sections C, D and E are provided to sales representatives during onboarding and refresh trainings. For reference, Chicago's only initial educational licensure requirement is fulfilled by completion of a free course which takes approximately 20 minutes to complete. The course was developed by Chicago and also requires successful completion of quiz/exam. By comparison, Oregon's proposed 10 hours seems excessive.

5. We recommend adding definition to the term "Materials and Gifts".

6. Regards to frequency of reports. SB 763 Section 1. (6)(a) At the director's request or at intervals the director specifies by rule, ..." We recommend that the rules require annual reporting from the pharmaceutical company for reporting since the director also has the ability to make requests at their discretion regardless of the frequency. The Chicago Representative License regulation requires representatives who market or promote specific pharmaceuticals listed on their website (currently Schedule II Medications) to maintain records but only submit this information upon a direct request from the appropriate department.

   In addition, to fulfill the intent of disclosure to the Oregon residents/patients to be able to see the relationships between pharmaceutical companies and their treating Health Care Providers (HCPs), they can currently access this information via CMS.gov.

7. Value of Samples. Samples, by definition established in 21CFR Parts 203 Prescription Drug Marketing Act (PDMA) is "free". Subpart A, 203.3 Definitions (i) Drug Sample means a unit of prescription drug that is not intended to be sold and is intended to promote the sale of the drug. In addition, The Final Rule of Section 6002 of the Affordable Care Act § 403.904 Reports of payments or other transfers of value to covered recipient (i.) exceptions from reporting (3) Product samples, including coupons

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and vouchers that can be used by a patient to obtain samples, which are not intended to be sold and are intended for patient use.

Section 6004 of the Affordable Care Act requires pharmaceutical companies to report annually the identity and quantity of the number of samples requested and distributed aggregated by licensed practitioner. This information is provided to the FDA on an annual basis. There is no cost or value attributed to the samples and the data is not available to the public as concerns were expressed by HCPs regarding security as the location and quantities of controlled and non-controlled drugs would be available to everyone, including those addicted to narcotics/pain medications. We recommend to either exclude this requirement or to take appropriate measures to secure the information from public access.

I appreciate your consideration of these recommendations to the final rule and look forward to the next RAC meeting on October 26th.

Regards,

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