From: GRIFFITH Numi L * DCBS
To: WINKEL Karen J * DCBS
Subject: FW: Draft Proposed Rules Comments: SB 763 Licensure of Pharmaceutical Representatives RAC
Date: Tuesday, October 19, 2021 5:24:06 PM
Attachments: image001.png

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From: Murray, Anne <anne.murray@bms.com>
Sent: Tuesday, October 19, 2021 4:03 PM
To: GRIFFITH Numi L * DCBS <Numi.L.GRIFFITH@oregon.gov>
Cc: Matt Markee <matt@markee.org>
Subject: Draft Proposed Rules Comments: SB 763 Licensure of Pharmaceutical Representatives RAC

Hi, Numi –

Please see below for additional issues for DCBS consideration on the proposed draft rules implementing SB 763. I'd be happy to further discuss any of these points if helpful. Please note – I join in the comments submitted by PhRMA, but did not duplicate them below.

836-200-XXX1 Definition of "material change in licensee's business operations"

- Proposed definition would require licensee reporting of information that may not be known to the licensee.
- Consider limiting definition to reflect actual language of underlying bill: "*any material changes the licensee made in the licensee's business operations.*"

836-200-XXX4 (1)(D) - Education and Continuing Education Requirements - "Comparative cost effectiveness of pharmaceutical products"

- Consider deletion of *"comparative cost effectiveness of pharmaceutical products"* as educational requirement for initial licensure (not included in underlying bill)
- Under FDA guidance, sales reps generally are not authorized to have conversations regarding cost effectiveness. These specialized conversations regarding "health care economic information" (also called FDAMA 114 communications) are reserved for communications between manufacturer staff with appropriate expertise and provider and payer staff involved in formulary decision making.

836-200-XX12 (2) - Licensee Reporting Requirements – Two-week reporting timeframe and Reporting Frequency

- Consider giving more time after close of reporting time period. Two weeks is insufficient to turn around reports.
- It takes time for records to be entered into systems and expenses to be approved and reconciled (up to 30 days) before complied for reporting (sent to reporting systems). Additional time is required to compile the reports, quality check them, etc.
- While the bill authorizes the director to specify reporting frequency, please consider requiring reporting less than quarterly
- Six-month or annual reporting would limit the sheer volume of reports submitted, but

also would allow more efficient capture of reportable activity (speaker programs and other like payments could span time beyond the quarter)

836-200-XX12(3) - Licensee Reporting Requirements – Report content

- Requirements are specified in underlying bill, but further clarification as to required level of detail would be most helpful.
- Where will licensees access the department's defined list of covered recipients (providers) within the state?
- Do these provisions require one record for each HCP for the period or, alternatively, a record for each contact with each HCP for the period? Or both?
- "Location and duration" in subsection (c) suggests detail for each individual contact; other sections suggestion something more aggregate in nature.
- For the *"number of times the licensee contacted each HCP"***,** what specific interactions are covered? Those initiated by the licensee? Promotional contacts (and not incidental contact at congresses/conferences)? Speaker bureaus?
- As discussed at the first RAC meeting, reporting systems do not capture "duration" of interactions – the majority of which take place in minutes.
- Will the department establish a reporting template to capture required information (e.g., the Nevada reporting template)?

Thanks for your consideration. I look forward to our further discussions.

Anne

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