CHAMBER ACTION

Senate | House

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Representative Geller offered the following:

Amendment (with title amendment)

Between lines 2813 and 2814, insert:

Section 20. Licensed pharmaceutical representatives and medical affairs professionals.—

(1) Definitions.—As used in this section, the term:

(a) "ACMA" means the Accreditation Council for Medical Affairs.

(b) "Health care professional" means any physician or other health care practitioner who is licensed to provide health care services or to prescribe pharmaceutical or biologic

products. However, the term does not include persons who work exclusively with animals.

(c) "Medical affairs professionals" means medical and scientific professionals within medical affairs functions within pharmaceutical companies, including medical science liaisons.

(d) "Medical science liaison" means a person typically with a doctoral degree in science or medicine who engages in nonpromotional scientific exchange with health care professionals and does not market, sell, or promote pharmaceuticals to health care professionals. Medical science liaisons may also be known by other titles, including but not limited to, medical liaison, medical manager, regional scientific manager, clinical liaison, and scientific affairs manager.

(e) "Pharmaceutical representative" means a person who markets or promotes pharmaceuticals to health care professionals. The term dos not include medical science liaisons, wholesale distributors, and pharmaceutical representative managers or supervisors who do not interact directly with health care professionals while in this state.

(f) "Wholesale distributor" means a person engaged in wholesale distribution who is not a manufacturer, a manufacturer's co-licensed partner, a third-party logistics provider, or repackager.

(2) EDUCATION REQUIREMENTS.—There are professional education requirements which must be satisfied to obtain a license. An applicant must complete the standardized independent, online programs offered by the ACMA for the respective license described in subsections (3) and (4). Proof of completion of the online course must accompany the application for the pharmaceutical representative or medical affairs license.

(3) MEDICAL AFFAIRS PROFESSIONALS.—

(a) Medical affairs professionals must become board certified in medical affairs by completing the board certified medical affairs specialist program (BCMAS). Once board certified, they would be eligible to use the "BCMAS" designation in their professional title and obtain their license.

(b) The Board Certified Medical Affairs Specialist Program (BCMAS) covers the following:

1. The pharmaceutical industry.

2. The medical device industry.

3. The diagnostics industry.

4. Rules governing interactions with health care professionals.

5. Health economics outcomes research.

6. Evidence-based medicine.

7. Clinical trial designs.

8. Presentation and communication skills.

9. Regulatory affairs.

10. Compliance.

11. Abstract and medical writing.

12. Publication practices.

13. Drug development process.

14. Medical information.

15. Medical science liaisons and field based medical teams.

16. Grant and investigator initiated study funding and process.

17. Advisory boards.

18. Phase IV/post-marketing studies.

19. Risk evaluation and mitigation strategies.

20. Medication safety and pharmacovigilance.

(4) PHARMACEUTICAL REPRESENTATIVES.—

(a) Pharmaceutical representatives must complete the Pharmaceutical Representative Credentialing Program offered by the ACMA. In order to renew a pharmaceutical representative license, applicants must maintain their certification according to ACMA requirements.

(b) The pharmaceutical representative credentialing program covers the following:

1. Medical terminology and abbreviations.

2. Federal Food and Drug Administration laws and regulations related to pharmaceutical industry marketing.

3. Comparison of therapeutic drug classes, their mechanisms of action, and delivery systems.

4. Principles of pharmacoeconomics or health care economics.

5. Professional ethics related to opioid use for pharmaceutical industry professionals.

6. Analyzing peer-reviewed literature on pharmacological treatments.

7. Anatomical and physiological effects of drugs.

8. Basic Principles of pharmacology.

9. Preventing fraud and abuse of prescription drugs.

(5) CONTINUING EDUCATION.—The ACMA will audit a selection of renewal applications to confirm that licensees completed the continuing education requirements. Upon request, licensees must provide information on courses completed, including the title and date of the course, number of credit hours completed, name of the education provider, and signed certificate of completion. The state may confirm this information with the ACMA. If the continuing education requirements have not been met or were fraudulently affirmed, the individual in violation may face suspension or revocation of the license, inclusion in a public list whose licenses have been revoked, and a fine of no less than $1,000 and no more than $3,000 per day of violation.

(6) DISCLOSURE.—

(a) After a pharmaceutical representative or medical affairs professional receives the initial license, he shall provide the information required by the ordinance upon request by the Commissioner of Public Health. The pharmaceutical representative shall compile and submit the information to the Florida Department of Public Health in a format that will be described on the Florida Department of Public Health's website. Only pharmaceutical representatives and medical affairs professionals who educate, market or promote pharmaceuticals, pharmacologic classes, or categories of pharmaceuticals will be obliged to disclose the information required by the ordinance. This includes medical affairs professionals who engage in research activities with health care providers or institutions or are involved in educating on investigational drugs by providing disease state information.

(b) When the Commissioner of Public Health requests the information, the information will be due within 30 days of the request and shall cover a time period designated by the Commissioner of Public Health, provided that the time period covers no more than 1 year and ends no later than 30 days before the request was made and does not cover business that the pharmaceutical representative conducted prior to the day of initial licensure or eligibility.

(c) The disclosure obligations shall not apply to activities that take place at large conferences, symposia,

conventions, or like gatherings that are expected to be attended by a regional, national, or international audience and where representatives from at least three pharmaceutical companies, which shall not be subsidiaries or affiliations of the same company or parent company, are marketing or promoting products. This exemption shall not apply to activities that take place concurrently with such an event but that are not officially part of the event.

(7) ETHICAL STANDARDS.—Licensed pharmaceutical representatives and board certified medical affairs professionals shall adhere to the following ethical standards:

(a) They shall not engage in any illegal, fraudulent, or other deceptive marketing of a pharmaceutical product, including the knowing concealment, suppression, omission, misleading representation, or misstatement of any material fact.

(b) They shall not use a title or designation that could reasonably lead a health care professional, or an employee or representative of a health care professional, to believe that the pharmaceutical representative is licensed to practice medicine, nursing, dentistry, optometry, pharmacy, or any other similar health occupation, unless the pharmaceutical representative holds an active license to practice that health occupation.

(c) They shall not attend patient examinations without the express, written consent of the patient. The representatives

also shall not enter an area meant primarily for health care providers and patients, other than a designated waiting area, unless invited in by a health care provider working on site.

(d) They shall comply with the applicable policies and procedures of the health care facilities and health care professionals' offices he visits.

(e) They shall not harass, intimidate, or coerce a health care professional, or an employee or representative of a health care professional, through any form of communication.

(f) They shall cease making sales calls to a health care professional, or an employee or representative of a health care professional, if the health care professional requests it in writing or verbally to the pharmaceutical representative or the representative's employer.

(g) They shall not make any misleading statements to gain access to a health care professional.

(h) They shall provide health care professionals with information that is truthful, accurate, and nonmisleading, consistent with Food and Drug Administration laws and regulations.

T I T L E A M E N D M E N T

Remove line 122 and insert:

the act; providing definitions; specifying professional education requirements for licensed pharmaceutical representatives and medical affairs professionals; providing continuing education requirements; providing for licensure; requiring disclosures; specifying ethical standards; providing effective dates.