State of Wisconsin
2021 - 2022 LEGISLATURE

LRB-4357/1
EKL:wlj

2021 SENATE BILL 548

September 2, 2021 – Introduced by Senators ERPENBACH, JOHNSON, AGARD, BEWLEY, CARPENTER, LARSON, PFAFF and RINGHAND, cosponsored by Representatives SUBECK, S. RODRIGUEZ, ANDERSON, BALDEH, CABRAL-GUEVARA, CABRERA, CONLEY, EMERSON, HEBL, HESSELBEIN, HONG, MILROY, L. MYERS, NEUBAUER, OHNSTAD, POPE, SHANKLAND, SHELTON, SINICKI, SNODGRASS, SPREITZER, STUBBS and VRUWINK. Referred to Committee on Insurance, Licensing and Forestry.

AN ACT ***to create*** 601.31 (1) (nv) and 632.863 of the statutes; **relating to:** licensure of pharmaceutical representatives.

Analysis by the Legislative Reference Bureau

This bill requires a pharmaceutical representative to be licensed by the Office of the Commissioner of Insurance and to display his or her license during each visit with a health care professional. The bill defines "pharmaceutical representative" to mean an individual who markets or promotes pharmaceuticals to health care professionals on behalf of a pharmaceutical manufacturer for compensation.

Under the bill, the license must be annually renewed. The application to obtain or renew a license must include the applicant's contact information, a description of the type of work in which he or she will engage, an attestation that the professional education requirements are met, the license fee, proof that any penalties and other fees are paid, and any other information required by OCI. Under the bill, the license fee is set by the commissioner. The bill requires the pharmaceutical representative to report, within four business days, any change to the information provided on the application or any material change to his or her business operations or other information required to be reported under the bill.

The bill requires that a pharmaceutical representative complete a professional education course prior to becoming licensed and to annually complete at least five hours of continuing professional education. The coursework must include, at a minimum, training in ethical standards, whistleblower protections, and the laws and rules applicable to pharmaceutical marketing. The bill directs the commissioner to regularly publish a list of courses that fulfill the education requirements. Under

the bill, a course provider must disclose any conflict of interest and the courses may not be provided by an employer of a pharmaceutical representative or be funded by the pharmaceutical industry or a third party funded by the industry.

The bill requires that, no later than June 1 of each year, a pharmaceutical representative report to OCI his or her total number of contacts with health care professionals in Wisconsin, the specialties of those health care professionals, the location and duration of each contact, the pharmaceuticals discussed, and the value of any item provided to a health care professional. The bill directs the commissioner to publish the information on OCI's website, without identifying individual health care professionals.

The bill requires that a pharmaceutical representative, during each contact with a health care professional, disclose the wholesale acquisition cost of any pharmaceuticals discussed and the names of at least three generic prescription drugs from the same therapeutic class.

The bill directs the commissioner to promulgate ethical standards for pharmaceutical representatives. Additionally, the bill prohibits a pharmaceutical representative from engaging in deceptive or misleading marketing of a pharmaceutical product; using a title or designation that could reasonably lead a licensed health care professional, or an employee or representative of such a professional, to believe that he or she is licensed to practice in a health occupation unless he or she holds a license to practice; or attending an examination without the patient's consent.

Under the bill, an individual violating any of these provisions is subject to a fine and his or her license may be suspended or revoked. An individual whose license is revoked must wait at least two years before applying for a new license.

For further information see the state fiscal estimate, which will be printed as an appendix to this bill.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

SECTION 1. 601.31 (1) (nv) of the statutes is created to read:

601.31 **(1)** (nv) For issuing or renewing a license to a pharmaceutical representative under s. 632.863, an amount to be set by the commissioner by rule.

SECTION 2. 632.863 of the statutes is created to read:

632.863 Pharmaceutical representatives. (1) DEFINITIONS. In this section:

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

(b) "Pharmaceutical" means a medication that may legally be dispensed only with a valid prescription from a health care professional.

(c) "Pharmaceutical representative" means an individual who markets or promotes pharmaceuticals to health care professionals on behalf of a pharmaceutical manufacturer for compensation.

(d) "Wholesale acquisition cost" means the most recently reported manufacturer list or catalog price for a brand–name drug or generic drug available to wholesalers or direct purchasers in the United States, before application of discounts, rebates, or reductions in price.

(2) LICENSURE. (a) No individual may act as a pharmaceutical representative in this state without obtaining a pharmaceutical representative license. In order to obtain a license, an individual shall apply to the commissioner, on a form prescribed by the commissioner. A license issued under this paragraph shall be renewed on an annual basis. The application to obtain or renew a license shall include all of the following information:

1. The applicant's full name, residence address and telephone number, and business address and telephone number.

2. A description of the type of work in which the applicant will engage.

3. The fee under s. 601.31 (1) (nv).

4. An attestation that the applicant meets the professional education requirements under sub. (3).

5. Proof that the applicant has paid any assessed penalties and fees.

6. Any other information required by the commissioner.

(b) The pharmaceutical representative shall report, in writing, to the commissioner any change to the information submitted on the application under par. (a) or any material change to the pharmaceutical representative's business operations or to any information provided under this section. The report shall be made no later than 4 business days after the change or material change occurs.

(c) A pharmaceutical representative shall display his or her license during each visit with a health care professional.

(3) PROFESSIONAL EDUCATION REQUIREMENTS. (a) In order to become initially licensed under sub. (2) (a), a pharmaceutical representative shall complete a professional education course as determined by the commissioner. A pharmaceutical representative shall, upon request, provide the commissioner with proof of the coursework's completion.

(b) In order to renew a license under sub. (2) (a), a pharmaceutical representative shall complete a minimum of 5 hours of continuing professional education courses. A pharmaceutical representative shall, upon request, provide the commissioner with proof of the coursework's completion.

(c) The professional education coursework required under pars. (a) and (b) shall include training in ethical standards, whistleblower protections, laws and rules applicable to pharmaceutical marketing, and other areas that the commissioner may identify by rule.

(d) The commissioner shall regularly designate courses that fulfill the requirements under this subsection and publish a list of the designated courses.

(e) The professional education coursework required under this subsection may not be provided by the employer of a pharmaceutical representative or be funded, in

any way, by the pharmaceutical industry or a 3rd party funded by the pharmaceutical industry. A provider of a course designated under par. (d) shall disclose any conflict of interest.

(4) DISCLOSURE TO COMMISSIONER. (a) No later than June 1 of each year, a pharmaceutical representative shall provide to the commissioner, in the manner prescribed by the commissioner, all of the following information from the previous calendar year:

1. The total number of times the pharmaceutical representative contacted health care professionals in this state and the specialties of the health care professionals contacted.

2. For each contact with a health care professional in this state, the location and duration of the contact, the pharmaceuticals for which the pharmaceutical representative provides information, and the value of any item, including a product sample, compensation, material, or gift, provided to the health care professional.

(b) The commissioner shall publish the information provided under par. (a) on the commissioner's Internet site in a manner in which individual health care professionals are not identifiable by name or other identifiers.

(5) DISCLOSURE TO HEALTH CARE PROFESSIONALS. During each contact with a health care professional, a pharmaceutical representative shall disclose the wholesale acquisition cost of any pharmaceutical for which the pharmaceutical representative provides information and the names of at least 3 generic prescription drugs from the same therapeutic class, or if 3 are not available, as many as are available for prescriptive use.

(6) ETHICAL STANDARDS. The commissioner shall promulgate a rule that contains ethical standards for pharmaceutical representatives and shall publish the

ethical standards on the commissioner's Internet site. In addition to the ethical standards contained in the rule, a pharmaceutical representative may not do any of the following:

(a) Engage in deceptive or misleading marketing of a pharmaceutical, including the knowing concealment, suppression, omission, misleading representation, or misstatement of a material fact.

(b) Use a title or designation that could reasonably lead a licensed health care professional, or an employee or representative of a licensed health care professional, to believe that the pharmaceutical representative is licensed to practice medicine, nursing, dentistry, optometry, pharmacy, or other similar health occupation in this state unless the pharmaceutical representative holds a license to practice.

(c) Attend a patient examination without the patient's consent.

(7) ENFORCEMENT. (a) Any individual violating this section shall be fined not less than $1,000 nor more than $3,000 for each offense. Each day the violation continues shall constitute a separate offense.

(b) The commissioner may suspend or revoke the license of a pharmaceutical representative who violates this section. A suspended or revoked license may not be reinstated until all violations related to the suspension or revocation have been remedied and all assessed penalties and fees have been paid. An individual whose pharmaceutical representative license is revoked for any cause may not be issued a license under sub. (2) (a) until at least 2 years after the date of revocation.

(c) A health care professional who meets with a pharmaceutical representative who does not display his or her license or share the information required under sub. (5) may report the pharmaceutical representative to the commissioner for further action.

(8) RULES. The commissioner may promulgate rules to implement this section.

(END)