~~Indicates Matter Stricken~~

Indicates New Matter

COMMITTEE REPORT

March 25, 2015

**H. 3348**

Introduced by Reps. Spires and Toole

S. Printed 3/25/15--H.

Read the first time January 20, 2015.

**THE COMMITTEE ON MEDICAL,**

**MILITARY, PUBLIC AND MUNICIPAL AFFAIRS**

To whom was referred a Bill (H. 3348) to amend Section 40‑43‑83, Code of Laws of South Carolina, 1976, relating to in‑state facilities dealing with prescription drugs in a certain capacity, etc., respectfully

**REPORT:**

That they have duly and carefully considered the same and recommend that the same do pass with amendment:

Amend the bill, as and if amended, Section 40‑43‑83(L), as contained in SECTION 1, by deleting the subsection in its entirety and inserting:

/ (L) All facilities permitted by this State shall notify the board within twenty‑one days of receipt of any final order or final decision by a regulatory agency imposing disciplinary action on the facility. If the permit or registration in the state where the facility is located is suspended or revoked, then the facility’s registration in this State immediately must be suspended or revoked for the same period of time. Failure to notify the board within twenty‑one days will result in suspension pending board action. /

Amend the bill further, Section 40‑43‑89(A)(1)(e), as contained in SECTION 2, by deleting the subitem in its entirety and inserting:

/ (e) evidence of:

(i) a minimum one hundred thousand dollars surety bond or certified letter of credit for a facility with more than ten million dollars annual gross receipts; or

(ii) a minimum twenty five thousand dollars surety bond or certified letter of credit for a facility with ten million dollars or less annual gross receipts; and/

Renumber sections to conform.

Amend title to conform.

LEON HOWARD for Committee.

**STATEMENT OF ESTIMATED FISCAL IMPACT**

**Fiscal Impact Summary**

House Bill 3348 is not expected to have an expenditure impact on the general fund, federal funds, or other funds. Revenue of the Department of Labor, Licensing and Regulation is expected to increase by $416,800 in FY 2015-16.

**Explanation of Fiscal Impact**

**State Expenditure**

House Bill 3348 amends the Pharmacy Practices Act by expanding the permitting requirement to all out-of-state prescription drug facilities that do business in this State. In addition, the bill requires permitted facilities to notify the Board of Pharmacy of any disciplinary action imposed by a regulatory agency. The bill authorizes inspections of out-of-state facilities and imposes fees. The fees are to be retained by the Department of Labor, Licensing and Regulation to offset the cost of the inspections. The bill also requires wholesale distributors to post a surety bond, undergo a criminal record check and meet certain other requirements in order to be certified as a “designated representative.”

**Department of Labor, Licensing and Regulation.**

The department indicates that this bill will have no expenditure impact on the agency since LLR is already conducting inspections of out-of-state facilities directly or by reciprocal agreement. Any additional costs associated with out-of-state inspections would be offset by fees (received as other funds) which are retained by the agency. There is no expenditure impact on the general fund or federal funds.

**Secretary of State.**

The Secretary of State reports that this bill will have no expenditure impact on the general fund, federal funds, or other funds.

**State Law Enforcement Division.**

The agency estimates that this bill will have a minimal impact on other funds, which the agency can absorb at their current level of funding. The agency charges $25 for criminal background checks; therefore, any additional background checks as noted in the bill would be funded by such fees. However, the bill does not indicate whether both a state and federal criminal record check conducted by SLED are required.

**Department of Health & Environmental Control.** The Department indicates that this bill will have no impact on the general fund, federal funds, or other funds.

**State Revenue**

This bill amends Section 40-43-83 by requiring all out of state pharmacies, wholesalers, distributors, manufacturers and medical gas device entities whose primary business is mail order pharmacy to be permitted by the Board of Pharmacy. This Section also outlines the increased application and renewal fees for the nonresident facilities noted above. Additionally, Section 40-43-89 has been amended to require all wholesale distributors to provide evidence of a $100,000 surety bond or certified Letter of Credit. The revenue generated pursuant to this bill must be used to offset costs incurred by the Board of Pharmacy for nonresident facility permitting and inspections.

Based on information provided by the Board of Pharmacy, there are currently 631 permitted nonresident pharmacies, 933 permitted nonresident wholesalers, distributors and manufacturers, and 258 permitted nonresident medical gas and legend device entities. This bill increases both the initial application and renewal fees each by $250 for nonresident pharmacies, $250 for nonresident wholesalers, distributors, and manufacturers, and $100 for nonresident medical gas and legend device entities. Since the Board of Pharmacy reports there are currently 1,822 permitted nonresident facilities, we expect a minimal increase in revenue due to new applications. However, based on the numbers stated above, we expect the increased renewal fees to raise other funds of the Department of Labor, Licensing and Regulation by $416,800 in FY 2015-16.

Frank A. Rainwater, Executive Director

Revenue and Fiscal Affairs Office

**A** **BILL**

TO AMEND SECTION 40‑43‑83, CODE OF LAWS OF SOUTH CAROLINA, 1976, RELATING TO IN‑STATE FACILITIES DEALING WITH PRESCRIPTION DRUGS IN A CERTAIN CAPACITY, SO AS TO APPLY NOTICE PROVISIONS TO OUT‑OF‑STATE FACILITIES THAT SIMILARLY DEAL WITH PRESCRIPTION DRUGS, TO PROVIDE ALL SUCH FACILITIES PERMITTED IN THIS STATE MUST PROVIDE NOTICE OF DISCIPLINARY ACTION TO THE PHARMACY BOARD, TO REQUIRE INSPECTIONS OF OUT‑OF‑STATE FACILITIES BY THE BOARD, TO PROVIDE AN OUT‑OF‑STATE FACILITY SHALL PAY CERTAIN FEES RELATED TO INSPECTIONS, TO PROVIDE FOR THE USE OF OUT‑OF‑STATE FACILITY INSPECTION FEES COLLECTED BY THE BOARD, TO PROVIDE THE BOARD MAY ENTER INTO MEMORANDUM OF UNDERSTANDING AGREEMENTS WITH THE REGULATORY AUTHORITY OF THE STATE IN WHICH AN OUT‑OF‑STATE FACILITY IS LOCATED TO CONDUCT INSPECTIONS OF THESE FACILITIES, AND TO PROVIDE THE BOARD MAY CONTRACT WITH A THIRD‑PARTY TO INSPECT FACILITIES OF A LICENSEE; AND TO AMEND SECTION 40‑43‑89, RELATING TO WHOLESALE DISTRIBUTOR PERMITS, SO AS TO REQUIRE A MINIMUM SURETY BOND OR LETTER OF CREDIT, TO REQUIRE A CRIMINAL BACKGROUND CHECK OF THE APPLICANT, TO PROVIDE REQUIREMENTS FOR THE CERTIFICATION AND CONDUCT OF A DESIGNATED REPRESENTATIVE OF A WHOLESALE DISTRIBUTOR.

Be it enacted by the General Assembly of the State of South Carolina:

SECTION 1. Section 40‑43‑83 of the 1976 Code is amended to read:

“Section 40‑43‑83. (A) All facilities, whether located ~~within~~ in this State or outside of this State, engaging in the manufacture, production, sale, distribution, possession, or dispensing of prescription drugs or devices and all facilities located outside of this State whose primary business is mail order pharmacy service engaging in the sale, distribution, or dispensing of prescription drugs or devices in this State must be permitted by the Board of Pharmacy, and annually shall renew the permit by June first. Where operations are conducted at more than one location, each location must be permitted by the Board of Pharmacy.

This subsection does not apply to a college or university athletic department that dispenses prescription drugs or devices.

(B) Each permittee located outside of this State who ships, mails, distributes, or delivers prescription drugs or devices in this State and every pharmacy located outside of this State who ships, mails, distributes, or delivers prescription drugs or devices in this State shall designate a registered agent in this State for service of process. Any such permittee or pharmacy who does not so designate a registered agent is deemed to have designated the Secretary of State of this State to be its true and lawful attorney, upon whom may be served all legal process in any action or proceeding against such permittee growing out of or arising from such delivery. A copy of any such service of process shall be mailed to such permittee or pharmacy by the board by certified mail, return receipt requested, postage prepaid, at the address such permittee has designated on its application for licensure in this State. If any such person is not permitted in this State, service on the Secretary of State only is sufficient service.

(C) The board shall determine and promulgate the permit classifications of all permits by regulation under this chapter and establish minimum standards for such permits.

(D) Each pharmacy shall have a pharmacist‑in‑charge; however, a college or university athletic department pharmacy is not required to have a pharmacist‑in‑charge. Whenever an applicable rule requires or prohibits action by a pharmacy, responsibility is that of the permit holder and the pharmacist‑in‑charge of the pharmacy, whether the ownership is a sole proprietor, partnership, association, corporation, or otherwise.

(E) The board may enter into agreements with other states or with third parties for the purpose of exchanging information concerning the permitting and inspection of entities located in this jurisdiction and those located outside this State.

(F) Permits issued under this section must be displayed in a conspicuous place in the permitted facility for which it was issued in such a manner that will enable an interested person to determine the name of the permittee, permit number, and permit expiration date. The permits are not transferable.

(G) This section must not be construed as precluding any person from owning or being a permit holder if all of the dispensing, compounding, and retailing of prescription drugs in it are under the supervision and direction of a licensed pharmacist.

(H) The Board of Pharmacy may deny or refuse to renew a permit if it determines that the granting or renewing of such permit would not be in the public interest. If an application is refused, the board shall notify the applicant in writing of its decision and the reasons for its decision.

(I) A permit is required for the sale, distribution, possession, or dispensing of drugs bearing the legend ‘Caution: Federal law prohibits dispensing without a prescription’ including, but not limited to, pharmacies (institutional or community, public or private), nursing homes, hospitals, convalescent homes, extended care facilities, family planning clinics, public or private health clinics, infirmaries, wholesalers, correctional institutions, industrial health clinics, mail order vendors, and manufacturers within or outside this State.

(J) The board shall assess a civil penalty in the amount of fifty dollars for failure to display a permit as required by this section.

(K) The Department of Health and Environmental Control is exempt from the provisions of this section that require facilities distributing or dispensing prescription drugs to be permitted by the Board of Pharmacy and from the provisions of this section that require each pharmacy to have a pharmacist‑in‑charge; however, each health district in this State must have a permit to distribute or dispense prescription drugs.

(L) All facilities permitted by this State shall notify the board within ten days of receipt of any order or decision by a regulatory agency imposing disciplinary action on the facility. If the permit or registration in the state where the facility is located is suspended or revoked, then the facility’s registration in South Carolina must be immediately suspended or revoked for the same period of time. Failure to notify the board within ten days will result in suspension pending board action.

(M) The board shall require initial inspections and periodic inspections biennially thereafter for permitting or permit renewal.

(N)(1) A facility located outside of the State but permitted in this State shall pay the following fees for new and renewed permits, licenses, registrations, and certifications:

(a) nonresident pharmacy initial permit ‑ five hundred and fifty dollars, permit renewal ‑ four hundred and fifty dollars;

(b) nonresident wholesale distributor initial permit ‑ seven hundred and fifty dollars, permit renewal ‑ seven hundred and fifty dollars;

(c) nonresident medical gases or legend devices drug outlet initial permit ‑ four hundred dollars, permit renewal ‑ three hundred dollars.

(2) Fees collected pursuant to this subsection from nonresident permit holders must be used exclusively to offset costs incurred by the board for nonresident facility permitting and inspection activities.

(3) Nothing in this section may preclude the board from relying on an inspection of the facility conducted by the regulatory authority of the state within which the facility is located if the board has entered into a Memorandum of Understanding (MOU) with that state.

(O) The board may contract with a third party to undertake the inspection of the facilities of a person who seeks an initial permit or permit renewal if the third party maintains a program that has standards that are acceptable to the board that the facility must meet for accreditation or certification by the third party. The board may rely on this accreditation or certification in determining eligibility for an initial permit or permit renewal.”

SECTION 2. Section 40‑43‑89(A) of the 1976 Code is amended to read:

“(A)(1) The following information must be provided to the board with an application for a wholesale distributor permit, and for any subsequent permit renewals:

(a) name, full business address, and telephone number of the applicant;

(b) all trade or business names used by the applicant;

(c) addresses, telephone numbers, and the names of contact persons for the facility used by the applicant for storage, handling, and distribution of drugs;

(d) the type of ownership or operation, i.e., partnership, corporation, or sole proprietorship; ~~and~~

(e) evidence of a minimum one hundred thousand dollars surety bond or certified letter of credit; and

(~~e~~f) name of the owner ~~and/or~~, operator, and designated representative of the applicant, including:

(i) if a person, the name, address, and social security number or date of birth, or both, of the person;

(ii) if a partnership, the name, address, and social security number or date of birth, or both, of each partner, and the name of the partnership;

(iii) if a corporation, the name, address, social security number or date of birth, or both, and title of each corporate officer and director, the corporate names, the name of the state of incorporation, and the name of the parent company, if any; the name, address, and social security number of each shareholder owning ten percent or more of the voting stock of the corporation, including over‑the‑counter stock, unless the stock is traded on a major stock exchange and not over‑the‑counter;

(iv) if a sole proprietorship, the full name, address, and social security number or date of birth, or both, of the sole proprietor and the name of the business entity.

(2) To be certified as a designated representative a person must:

(a) submit an application on a form furnished by the board and provide information that includes, but is not limited to:

(i) information required to complete the criminal background checks;

(ii) date and place of birth;

(iii) occupations, positions of employment, and offices held during the past seven years;

(iv) principal business and address of any business corporation, or other organization in which the applicant held an occupation, position of employment, or office during the past seven years;

(v) whether the applicant, during the past seven years, has been enjoined, either temporarily or permanently, by a court of competent jurisdiction from violating any federal or state law regulating the possession, control, or wholesale distribution of prescription drugs or devices, together with details of the event;

(vi) description of any involvement by the applicant during the past seven years with any business, including any investments, other than the ownership of stock in a publicly traded company or mutual fund that manufactured, administered, prescribed, wholesale distributed, or stored prescription drugs and devices in which the business was named as a party in a lawsuit;

(vii) description of any criminal offense, excluding minor traffic violations, of which the applicant as an adult was found guilty, regardless of whether adjudication of guilt was withheld or whether he pled guilty or nolo contendere. If the applicant indicates that a criminal conviction is under appeal and submits a copy of the notice of appeal of the criminal offense, he must submit to the board a copy of the final written order of disposition within fifteen days after the disposition of the appeal;

(viii) photograph of the applicant taken within the previous thirty days under procedures as specified by the board; and

(ix) any other information the board considers relevant.

(b) The designated representative certification must be renewed every five years.

(3) A designated representative must have a minimum of two years of verifiable full‑time managerial or supervisory experience in a pharmacy or wholesale distributor permitted or registered in this State or another state, where his responsibilities included but were not limited to record keeping, storage, and shipment of prescription drugs or devices.

(4) A person may serve as the designated representative for only one wholesale distributor at a time, except where more than one permitted or registered wholesale distributor is colocated in the same facility and the wholesale distributors are members of an affiliated group, as defined in Section 1504 of the Internal Revenue Code.

(5) A designated representative must be actively involved in and aware of the actual daily operations of the wholesale distributor and must meet the following requirements:

(a) be employed full‑time in a managerial position by the wholesale distributor;

(b) be physically present at the wholesale distributor during normal business hours, except for time periods when absent due to illness, family illness or death, scheduled vacation, or other authorized absence; and

(c) be aware of, and knowledgeable about, all policies and procedures pertaining to the operations of a wholesale distributor.

(6) A designated representative must complete:

(a) continuing education programs specified by the board regarding federal and state laws in regard to the wholesale distribution, handling, and storage of prescription drugs or devices; or

(b) if no formal continuing education is specified by the board, then board‑approved training programs that address applicable federal and state laws and are provided by qualified in‑house specialists, outside counsel, or consulting specialists with capabilities to help ensure compliance.

(7) The information collected pursuant to this section shall be made available only to the board or its designee and to state and federal law enforcement officials, if requested as part of an investigation. The board or its designee shall ensure confidentiality of the information collected under this section.

(8) A permitted or registered wholesale distributor located outside of this State that conducts business in this State shall designate a registered agent in this State for service of process or must be considered to have designated the Secretary of State to be its true and lawful attorney, upon whom may be served all legal processes in any action or proceeding against such permitted or registered wholesale distributor growing out of or arising from such wholesale distribution. The board must send by certified mail, return receipt requested, postage prepaid, a copy of a service of process received by the board to the wholesale distributor at the address the permitted or registered wholesale distributor has designated on its application for a permit under this chapter.

(~~2~~9) Changes in any information in this subsection must be submitted to the Board of Pharmacy within thirty days of the change.

(~~3~~10) Pursuant to Section 40‑43‑83(E) and Section 40‑43‑90, the information required for initial permitting or renewal of a permit of a wholesale distributor must be submitted on forms prepared by the Board of Pharmacy or by the National Association of Boards of Pharmacy which shall act as a clearinghouse of applications for the board and must be submitted to the board or NABP accompanied by the applicable fee.

(~~4~~11) The board may suspend, revoke, deny, or refuse to renew the permit of wholesale drug distributors other than pharmacies dispensing or distributing drugs or devices directly to patients.”

SECTION 3. This act takes effect upon approval by the Governor.

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