

FIRST REGULAR SESSION

[CORRECTED]

SENATE BILL NO. 557

92ND GENERAL ASSEMBLY

INTRODUCED BY SENATOR SHIELDS.

Read 1st time February 20, 2003, and 1,000 copies ordered printed.

1742S.031

TERRY L. SPIELER, Secretary.

AN ACT

To repeal sections 338.013, 338.055, 338.065, 338.220, and 338.353, RSMo, and to enact in lieu thereof ten new sections relating to the licensure and regulation of pharmacists, pharmacies, drug distributors and related pharmaceutical services and personnel, with penalty provisions.

Be it enacted by the General Assembly of the State of Missouri, as follows:

Section A. Sections 338.013, 338.055, 338.065, 338.220, and 338.353, RSMo, are repealed and ten new sections enacted in lieu thereof, to be known as sections 338.013, 338.055, 338.065, 338.075, 338.145, 338.155, 338.220, 338.353, 338.380, and 338.390, to read as follows:

338.013. 1. Any person desiring to assist a pharmacist in the practice of pharmacy as defined in this chapter shall apply to the board of pharmacy for registration as a pharmacy technician. [Such applicant shall not have engaged in conduct or behavior determined to be grounds for discipline pursuant to this chapter.] Such applicant shall **be at least twenty-one years of age and** forward to the board the appropriate fee and written application on a form provided by the board. Such registration shall be the sole authorization permitted to allow persons to assist licensed pharmacists in the practice of pharmacy as defined in this chapter.

2. The board may refuse to issue a certificate of registration as a pharmacy technician to an applicant that has been adjudicated and found guilty, or has entered a plea of guilty or nolo contendere to a violation of any state, territory, or federal drug law, or to any felony or has violated any provision of subsection 2 of section 338.055. However, the board may issue such person a certificate of registration, but

EXPLANATION—Matter enclosed in bold-faced brackets [thus] in this bill is not enacted and is intended to be omitted in the law.

may authorize the person to work as a pharmacy technician provided that person adheres to certain terms and conditions imposed by the board. The board shall place on the employment disqualification list the name of an applicant who the board has refused to issue a certificate of registration as a pharmacy technician, or the name of a person who the board has issued a certificate of registration as a pharmacy technician but has authorized to work under certain terms and conditions. The board shall notify the applicant of the applicant's right to file a complaint with the administrative hearing commission as provided by chapter 621, RSMo.

[2.] 3. If an applicant has submitted the required fee and an application for registration to the board of pharmacy, the applicant for registration as a pharmacy technician may assist a licensed pharmacist in the practice of pharmacy as defined in this chapter for a period of up to ninety days prior to the issuance of a certificate of registration. The applicant shall keep a copy of the submitted application on the premises where the applicant is employed. **However, if the board refuses to issue a certificate of registration as a pharmacy technician to an applicant, the applicant must immediately cease assisting a licensed pharmacist in the practice of pharmacy.**

[3.] 4. A certificate of registration issued by the board shall be conspicuously displayed in the pharmacy or place of business where the registrant is employed.

[4.] 5. Every pharmacy technician who desires to continue to be registered as provided in this section shall, within thirty days before the registration expiration date, file an application for the renewal, accompanied by the fee prescribed by the board. No registration as provided in this section shall be valid if the registration has expired and has not been renewed as provided in this subsection.

[5.] 6. The board shall maintain an employment disqualification list [of the names of all pharmacy technicians who have been adjudicated and found guilty, or have entered a plea of guilty or nolo contendere to violation of any state, territory or federal drug law, been found guilty, pled guilty or nolo contendere to any felony or have violated any provision of subdivision (2), (3), (4), (6), (7), (11), (12) or (15) of subsection 2 of section 338.055]. **No person whose name appears on the employment disqualification list shall work as a pharmacy technician, except as otherwise authorized by the board. The board may authorize a person whose name appears on the employment disqualification list to work or continue to work as a pharmacy technician provided that person adheres to certain terms and conditions imposed by the board.**

7. The board may place on the employment disqualification list the name of a pharmacy technician who has been adjudicated and found guilty, or has entered a plea of guilty or nolo contendere to a violation of any state, territory, or federal drug law, or to any felony or has violated any provision of subsection 2 of section 338.055.

[6.] 8. After an investigation and a determination has been made to place a person's name on the employment disqualification list, the board shall notify such person in writing mailed to the person's last known address that:

(1) An allegation has been made against the person, the substance of the allegation and that an investigation has been conducted which tends to substantiate the allegation;

(2) Such person's name [will be included in] **has been added to** the employment disqualification list of the board;

(3) The consequences to the person of being listed and the length of time the person's name will be on the list; and

(4) The person's [rights and the procedure to challenge the inclusion of the person's name on the disqualification list] **right to file a complaint with the administrative hearing commission as provided in chapter 621, RSMo.**

[7. If no reply has been received by the board within thirty days after the board mailed the notice, the board may include the name of such person on such disqualification list.] 9. The length of time a person's name shall remain on the disqualification list shall be determined by the board. [The board may, also, provide for alternative sanctions, including, but not limited to, conditional employment based on a requirement that the person submit certain documentation within a certain period of time. Any person who receives notice that the board intends to place the person's name on the employment disqualification list may file an appeal with the administrative hearing commission as provided in chapter 621, RSMo.]

8.] 10. No hospital or licensed pharmacy shall knowingly employ any person whose name appears on the employee disqualification list[.], **except that a hospital or licensed pharmacy may employ a person whose name appears on the employment disqualification list that the board has authorized to work under certain terms and conditions. Any hospital or licensed pharmacy shall report to the board any final disciplinary action taken against a pharmacy technician or the voluntary resignation of a pharmacy technician against whom any complaints or reports have been made which might have led to final disciplinary action that can be a cause of action for discipline by the board as provided in subsection 2 of section 338.055.** Compliance with the foregoing sentence may be interposed as an affirmative defense by the employer.

338.055. 1. The board may refuse to issue **or renew** any certificate of registration or authority, permit or license required pursuant to this chapter for one or any combination of causes stated in subsection 2 of this section. The board shall notify the applicant in writing of the reasons for the refusal and shall advise the applicant of his right to file a complaint with the administrative hearing commission as provided by chapter 621, RSMo.

2. The board may cause a complaint to be filed with the administrative hearing commission as provided by chapter 621, RSMo, against any holder of any certificate of

registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered his certificate of registration or authority, permit or license for any one or any combination of the following causes:

(1) Use of any controlled substance, as defined in chapter 195, RSMo, or alcoholic beverage to an extent that such use impairs a person's ability to perform the work of any profession licensed or regulated by this chapter;

(2) The person has been finally adjudicated and found guilty, or entered a plea of guilty or nolo contendere, in a criminal prosecution under the laws of any state or of the United States, for any offense reasonably related to the qualifications, functions or duties of any profession licensed or regulated under this chapter, for any offense an essential element of which is fraud, dishonesty or an act of violence, or for any offense involving moral turpitude, whether or not sentence is imposed;

(3) Use of fraud, deception, misrepresentation or bribery in securing any certificate of registration or authority, permit or license issued pursuant to this chapter or in obtaining permission to take any examination given or required pursuant to this chapter;

(4) Obtaining or attempting to obtain any fee, charge, tuition or other compensation by fraud, deception or misrepresentation;

(5) **[Incompetency] Incompetence**, misconduct, gross negligence, fraud, misrepresentation or dishonesty in the performance of the functions or duties of any profession licensed or regulated by this chapter;

(6) Violation of, or assisting or enabling any person to violate, any provision of this chapter, or of any lawful rule or regulation adopted pursuant to this chapter;

(7) Impersonation of any person holding a certificate of registration or authority, permit or license or allowing any person to use his or her certificate of registration or authority, permit, license or diploma from any school;

(8) **Denial of licensure to an applicant or disciplinary action against an applicant or** the holder of a license or other right to practice any profession regulated by this chapter granted by another state, territory, federal agency, or country **whether or not voluntarily agreed to by the licensee or applicant, including but not limited to, surrender of the license** upon grounds for which [revocation or suspension] **denial or discipline** is authorized in this state;

(9) A person is finally adjudged incapacitated by a court of competent jurisdiction;

(10) Assisting or enabling any person to practice or offer to practice any profession licensed or regulated by this chapter who is not registered and currently eligible to practice under this chapter;

(11) Issuance of a certificate of registration or authority, permit or license based upon a material mistake of fact;

(12) Failure to display a valid certificate or license if so required by this chapter or any rule promulgated hereunder;

(13) Violation of any professional trust or confidence;

(14) Use of any advertisement or solicitation which is false, misleading or deceptive to the general public or persons to whom the advertisement or solicitation is primarily directed;

(15) Violation of the drug laws or rules and regulations of this state, any other state or the federal government;

(16) The intentional act of substituting or otherwise changing the content, formula or brand of any drug prescribed by written or oral prescription without prior written or oral approval from the prescriber for the respective change in each prescription; provided, however, that nothing contained herein shall prohibit a pharmacist from substituting or changing the brand of any drug as provided under section 338.056, and any such substituting or changing of the brand of any drug as provided for in section 338.056 shall not be deemed unprofessional or dishonorable conduct unless a violation of section 338.056 occurs;

(17) Personal use or consumption of any controlled substance unless it is prescribed, dispensed or administered by a health care provider who is authorized by law to do so.

3. After the filing of such complaint, the proceedings shall be conducted in accordance with the provisions of chapter 621, RSMo. Upon a finding by the administrative hearing commission that the grounds, provided in subsection 2, for disciplinary action are met, the board may, singly or in combination, censure or place the person named in the complaint on probation on such terms and conditions as the board deems appropriate for a period not to exceed five years, or may suspend, for a period not to exceed three years, or revoke the license, certificate, or permit. The board may impose additional discipline on a licensee, registrant or permittee found to have violated any disciplinary terms previously imposed under this section or by agreement. The additional discipline may include, singly or in combination, censure, placing the licensee, registrant or permittee named in the complaint on additional probation on such terms and conditions as the board deems appropriate, which additional probation shall not exceed five years, or suspension for a period not to exceed three years, or revocation of the license, certificate or permit.

4. If the board concludes that a **[pharmacist] licensee or registrant** has committed an act or is engaging in a course of conduct which would be grounds for disciplinary action which constitutes a **[clear and present] probability of serious** danger to the public health and safety, the board may file a complaint before the administrative hearing commission requesting an expedited hearing and specifying the activities which give rise to the danger and the nature of the proposed restriction or suspension of the **[pharmacist's] licensee's or registrant's** license. Within fifteen days after service of the complaint on the **[pharmacist] licensee or registrant**, the administrative hearing commission shall conduct a preliminary hearing to

determine whether the alleged activities of the **[pharmacist] licensee or registrant** appear to constitute a **[clear and present] probability of serious** danger to the public health and safety which justify that the **[pharmacist's] licensee's or registrant's license or registration** be immediately restricted or suspended. The burden of proving that **[a pharmacist is a clear and present] the actions of a licensee or registrant constitute a probability of serious** danger to the public health and safety shall be upon the state board of pharmacy. The administrative hearing commission shall issue its decision immediately after the hearing and shall either grant to the board the authority to suspend or restrict the license or dismiss the action.

5. If the administrative hearing commission grants temporary authority to the board to restrict or suspend the **[pharmacist's] licensee's or registrant's** license, such temporary authority of the board shall become final authority if there is no request by the **[pharmacist] licensee or registrant** for a full hearing within thirty days of the preliminary hearing. The administrative hearing commission shall, if requested by the **[pharmacist] licensee or registrant** named in the complaint, set a date to hold a full hearing under the provisions of chapter 621, RSMo, regarding the activities alleged in the initial complaint filed by the board.

6. If the administrative hearing commission dismisses the action filed by the board pursuant to subsection 4 of this section, such dismissal shall not bar the board from initiating a subsequent action on the same grounds.

7. **If the board concludes that a licensee or registrant has committed an act or is engaging in a course of conduct which would be grounds for disciplinary action and which constitutes a probability of serious danger to the public health and safety, the board may restrict or suspend the license, registration, or permit of the licensee, registrant, or permittee pending action of the administrative hearing commission. Within ten business days of such restriction or suspension, the board shall file a complaint before the administrative hearing commission requesting an expedited hearing and decision pursuant to subsection 4 of this section.**

338.065. 1. **[After August 28, 1990,]** At such time as the final trial proceedings are concluded whereby a licensee **[or], permittee, registrant, or any person who has failed to renew or has surrendered his or her certificate of registration or authority, permit, or license** has been adjudicated and found guilty, or has entered a plea of guilty or nolo contendere, in a felony prosecution pursuant to the laws of the state of Missouri, the laws of any other state, territory or the laws of the United States of America for any offense reasonably related to the qualifications, functions or duties of a licensee, **permittee**, or registrant pursuant to this chapter or any felony offense, an essential element of which is fraud, dishonesty or an act of violence, or for any felony offense involving moral turpitude, whether or not sentence is imposed, the board of pharmacy may hold a disciplinary hearing to singly or in combination censure or place the licensee or registrant named in the complaint on probation on such terms

and conditions as the board deems appropriate for a period not to exceed five years, or may suspend, for a period not to exceed three years, or revoke the license, certificate, registration or permit.

2. Anyone who has been revoked or denied a license, permit or certificate to practice in another state may automatically be denied a license or permit to practice in this state. However, the board of pharmacy may establish other qualifications by which a person may ultimately be qualified and licensed to practice in Missouri.

3. The board may conduct a disciplinary hearing to determine discipline on any applicant for a license, permit, or registration or on any licensee, permittee, or registrant who has been disciplined by another state, territory, or federal agency for grounds that are the basis for disciplinary action in this state, and may impose discipline on the license, permit, or registration in the same manner as provided for in subsection 1 of this section. The board may conduct a disciplinary hearing pursuant to this subsection only after the board has determined that the licensee, permittee, or registrant was afforded sufficient due process rights by the original state, territory, or federal agency prior to the imposition of discipline or denial of licensure. The board shall set forth, by rule, the basis for determining whether an applicant or licensee, permittee, or registrant was afforded sufficient due process rights by the state territory or federal agency originally imposing discipline.

338.075. 1. When any person offers to engage in or engages in any act or practice for which a certificate of registration or authority, permit, or license is required and upon a showing that such act or practice was performed or offered to be performed without a license, the board may impose civil penalties in an amount not to exceed one thousand dollars for each violation and for each day that the violation occurs.

2. Any person who receives notice concerning the imposition of a civil penalty by the board may file an appeal with the administrative hearing commission as provided for in chapter 621, RSMo. Any action brought pursuant to this section shall be in addition and not in lieu of any penalty provided by law and may be brought concurrently with other actions to enforce the provisions of this chapter.

3. The board may enforce its imposition of a civil penalty by applying to the circuit court of Cole County, the county of the investigation, hearing, or proceeding, or any county where the person resides or may be found, for an order upon any person who shall fail to pay any civil penalty imposed. A show cause order and a copy of the application therefore shall be served upon the person in the same manner as a summons in a civil action. If the circuit court shall, after a hearing, determine that the civil penalty should be sustained and enforced, such court shall proceed to

enforce the civil penalty. Any person who fails to comply with a circuit court order that sustains the action of the board shall be considered in contempt and subject to penalties as provided by law.

338.145. 1. The president of the board may administer oaths, issue subpoenas duces tecum and require production of documents and records not otherwise available to the board pursuant to the inspection authority granted to the board pursuant to sections 338.100 to 338.150. Subpoenas duces tecum shall be served by a person authorized to serve subpoenas of courts of record. In lieu of requiring attendance of a person to produce original documents in response to a subpoena duces tecum, the board may require sworn copies of such documents to be filed or delivered to a designated representative.

2. The board may enforce its subpoenas duces tecum by applying to the circuit court of Cole County, the county of the investigation, hearing, or proceeding, or any county where the records reside or may be found, for any order upon any person who shall fail to obey a subpoena duces tecum to show cause why such subpoena duces tecum should not be enforced, which such order and a copy of the application therefore shall be served upon the person in the same manner as a summons in a civil action. If the circuit court shall, after a hearing, determine that the subpoena duces tecum should be sustained and enforced, such court shall proceed to enforce the subpoena duces tecum in the same manner as though the subpoena had been issued in a civil case in the circuit court.

3. Failure of a licensee to comply with the requirements of a validly enforced subpoena duces tecum shall constitute grounds for disciplinary action as defined in section 338.055.

338.155. 1. Any person who in good faith and without malice reports, provides information or cooperates in any manner with the board, or assists the board in any manner, including, but not limited to, any applicant or licensee, whether or not the applicant or licensee is the subject of an investigation, record custodians, consultants, attorneys, board members, agents, employees, staff, or expert witnesses, in the course of any investigation, hearing, or other proceeding conducted by or before the board pursuant to the provisions of this chapter shall not be subject to an action for civil damages as a result of providing such information and cooperating with the board.

2. No physician or other authorized prescriber who, in good faith, cooperates with the board by writing a prescription or drug order at the request of the board pursuant to a routine inspection or a lawful investigation, shall, by virtue of that cooperation, be in violation of this chapter or any drug laws of this state and shall be acting as an agent of the state, and as such, shall have sovereign immunity for

those actions.

3. No licensee, registrant, permit holder, or other individual or entity subject to the board's jurisdiction who, in good faith, fills a prescription presented by the board as part of an inspection or investigation, shall, by virtue of that act, be in violation of this chapter or the drug laws of this state, provided the prescription is otherwise prepared and dispensed in a lawful manner.

338.220. 1. It shall be unlawful for any person, copartnership, association, corporation or any other business entity to open, establish, operate or maintain any pharmacy, as defined by statute without first obtaining a permit or license to do so from the Missouri board of pharmacy. The following classes of pharmacy permits or licenses are hereby established:

- (1) Class A: Community/ambulatory;
- (2) Class B: Hospital outpatient pharmacy;
- (3) Class C: Long-term care;
- (4) Class D: ~~[Home health care]~~ **Nonsterile compounding**;
- (5) Class E: Radio pharmaceutical;
- (6) Class F: Renal dialysis;
- (7) Class G: Medical gas;
- (8) Class H: Sterile product compounding;
- (9) Class I: Consultant services;
- (10) Class J: Shared service;
- (11) Class K: Internet.**

2. Application for such permit or license shall be made upon a form furnished to the applicant; shall contain a statement that it is made under oath or affirmation and that its representations are true and correct to the best knowledge and belief of the person signing same, subject to the penalties of making a false affidavit or declaration; and shall be accompanied by a permit or license fee. The permit or license issued shall be renewable upon payment of a renewal fee. Separate applications shall be made and separate permits or licenses required for each pharmacy opened, established, operated or maintained by the same owner.

3. All permits, licenses or renewal fees collected pursuant to the provisions of sections 338.210 to 338.370 shall be deposited in the state treasury to the credit of the Missouri board of pharmacy fund, to be used by the Missouri board of pharmacy in the enforcement of the provisions of sections 338.210 to 338.370, when appropriated for that purpose by the general assembly.

338.353. 1. The board of pharmacy is hereby authorized and empowered, when complaints, examinations or inspection of a wholesale drug distributor or pharmacy distributor disclose to the board that a wholesale drug distributorship or pharmacy distributorship is not being operated or conducted according to such legal rules and regulations and the laws of

Missouri or any other state or the federal government with respect thereto, to cause a complaint to be filed before the administrative hearing commission pursuant to chapter 621, RSMo, charging the holder of a license to operate a drug distributorship or pharmacy wholesale operation constituting grounds for discipline in accordance with section 338.055.

2. If the board concludes that a wholesale drug distributor or pharmacy distributor has committed an act or is engaging in a course of conduct which constitutes a [clear and present] **probability of serious** danger to the public health and safety in Missouri, the board may file a complaint before the administrative hearing commission requesting an expedited hearing [and specifying the activities which give rise to the danger and the nature of the proposed restriction or suspension of the wholesale drug distributor's or pharmacy distributor's license. Within fifteen days after service of the complaint on a wholesale drug distributor or pharmacy distributor, the administrative hearing commission shall conduct a preliminary hearing to determine whether the alleged activities of the wholesale drug distributor or pharmacy distributor appear to constitute a clear and present danger to the public health and safety which justify that the wholesale drug distributor's or pharmacy distributor's license be immediately restricted or suspended. The burden of proving that a wholesale drug distributor or pharmacy distributor is a clear and present danger to the public health and safety shall be upon the state board of pharmacy. The administrative hearing commission shall issue its decision immediately after the hearing and shall either grant to the board the authority to suspend or restrict the license or dismiss the action.

3. If the administrative hearing commission grants temporary authority to the board to restrict or suspend the wholesale drug distributor's or pharmacy distributor's license, such temporary authority of the board shall become final authority if there is no request by the wholesale drug distributor or pharmacy distributor for a full hearing within thirty days of the preliminary hearing. The administrative hearing commission shall, if requested by the wholesale drug distributor or pharmacy distributor named in the complaint, set a date to hold a full hearing under the provisions of chapter 621, RSMo, regarding the activities alleged in the initial complaint filed by the board.

4. If the administrative hearing commission dismisses the action filed by the board pursuant to subsection 2 of this section, such dismissal shall not bar the board from initiating a subsequent action on the same grounds] **as provided for in subsection 4 of section 338.055, or the board may restrict or suspend the license as provided for in subsection 7 of section 338.055.**

338.380. 1. Whenever a duly authorized representative of the board of pharmacy finds, or has probable cause to believe, that any drug or device is adulterated or misbranded within the meaning of the federal Food and Drug Act or received through means of theft or deceit or drugs which may be in the possession of a suspended, revoked, or nonrenewed licensee, after consultation with the board

president or executive director, he may affix to such drug or device a tag or other appropriate marking giving notice that such article is or is suspected of being adulterated, misbranded, or received through means of theft or deceit, has been detained or embargoed, and warning all persons not to remove or dispose of such article by sale or otherwise until approval for removal or disposal is given by the board, its agent, or the court. No person shall remove or dispose of such embargoed drug or device by sale or otherwise without the permission of the board or its agent or, after summary proceedings have been instituted, without permission from the court.

2. When a drug or device detained or embargoed pursuant to subsection 1 of this section has been declared by the board's duly authorized representative to be adulterated, misbranded, or received by theft or deceit, the board shall, within thirty days of the placing of the embargo, petition the circuit court in which jurisdiction the article is detained or embargoed for an order for condemnation of such article. If the court determines that the drug or device so detained or embargoed is not adulterated, misbranded, or received by theft or deceit, the board shall direct the immediate removal of the tag or other marking. If the board or the court lifts the embargo, the board shall not be held liable for damages because of such embargo if the court finds that there was probable cause for the embargo.

3. If the court finds the detained or embargoed drug or device is adulterated, misbranded, or received by theft or deceit, such drug or device, after entry of the decree, shall be destroyed at the expense of the owner of the detained or embargoed drug or device under the supervision of a board representative and all court costs and fees, storage, and other proper expenses shall be borne by the owner of such drug or device. When the adulteration or misbranding can be corrected by proper labeling or processing of the drug or device, the court, after entry of the decree and after such costs, fees, and expenses have been paid and a good and sufficient bond has been posted, may direct that such drug or device be delivered to the owner thereof for such labeling or processing under the supervision of a board representative. The owner shall pay the expense of such supervision. Any bond required by this section shall be returned to the owner of the drug or device on representation to the court by the board that the drug or device is no longer in violation of the embargo and any expenses for supervision have been paid.

338.390. 1. In any disciplinary case that results in a complaint filed by the board of pharmacy with the administrative hearing commission as provided by chapter 621, RSMo, and which results in discipline being imposed on a license, permit, or holder of any certificate of registration or authority the board may direct an order

for payment of a sum not to exceed the actual and reasonable costs of the investigation and prosecution of the case.

2. In the case of a pharmacy or drug distributor, the order may be made as to the corporate owner, if any, and as to any pharmacist, officer, owner, or partner of the pharmacy or drug distributor who is found to have had knowledge of or have knowingly participated in one or more of the violations set forth in this section.

3. Where an order for recovery of costs is made and timely payment is not made as directed in the board's decision, the board may enforce the order for payment in the circuit court of Cole County. This right of enforcement shall be in addition to any other rights the board may have as to any licensee directed to pay costs.

4. In any action for recovery of costs, proof of the board's decision shall be conclusive proof of the validity of the order of payment and the terms of payment.

5. Failure to provide timely payment shall constitute grounds for additional discipline as provided in section 338.055.

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