

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 275 Pharmacy

SPONSOR(S): Garcia and others

TIED BILLS: **IDEN./SIM. BILLS:** SB 334

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) <u>Committee on Health Quality</u>	_____	Owen	Lowell
2) <u>Healthcare Council</u>	_____	_____	_____
3) <u>Policy & Budget Council</u>	_____	_____	_____
4) _____	_____	_____	_____
5) _____	_____	_____	_____

SUMMARY ANALYSIS

The bill broadens licensure by endorsement for pharmacists by deleting the requirement that an applicant for licensure must have obtained a passing score on the licensure examination not more than 12 years prior to application.

Effective January 1, 2010, the bill increases the number of pharmacy technicians a pharmacist may supervise from three to four under guidelines approved by the Board of Pharmacy (board).

In addition, effective January 1, 2010, the bill requires pharmacy technicians to register with the board; applicants must be at least 16 years of age. A person whose license to practice pharmacy has been suspended, denied, or restricted is prohibited from registering as a pharmacy technician. The bill specifies registration renewal requirements for pharmacy technicians and grounds for discipline against a registered pharmacy technician and the denial of registration as a pharmacy technician. A pharmacy technician must complete biennially complete 20 hours of continuing education as a condition of registration renewal. The bill exempts from the registration requirements pharmacy technician students obtaining practical training required by a pharmacy technician-training program and persons licensed as pharmacy interns. The bill requires the board to maintain a directory of registered pharmacy technicians indicating their place of employment and publish the directory on the Internet.

According to the Department of Health, they will need eight full-time equivalent positions to implement the provisions of the bill. If the number of registrants does not produce sufficient revenue to support the program costs, there will be a negative fiscal impact on the Medical Quality Assurance Trust Fund (see fiscal impact).

The bill is effective upon becoming law, except as specified in the bill.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Provide limited government - The bill proposes the new regulation of a profession--pharmacy technicians--through registration with the Department of Health.

B. EFFECT OF PROPOSED CHANGES:

Present Situation

Pharmacists

Chapter 465, F.S., governs the practice of pharmacy, creating the Board of Pharmacy (board) within the Department of Health (department) to regulate the profession. According to the department, there are approximately 17,000 licensed pharmacists in Florida.

An individual seeking to be licensed as a pharmacist in Florida has two paths to licensure: licensure by examination and licensure by endorsement. Section 465.007, F.S. sets out the requirements for licensure by examination, allowing an applicant to sit for the examination¹ if the board certifies the applicant:

- Has completed the application form and submitted an examination fee no greater than \$100 plus the actual cost to the department for purchase of portions of the examination from the National Association of Boards of Pharmacy or a similar national organization.
- Is 18 years of age or older.
- Has received a degree from a school or college of pharmacy accredited by an accrediting agency recognized and approved by the United States Office of Education or has graduated from a four-year undergraduate pharmacy program of a school or college of pharmacy located outside the United States and has demonstrated proficiency in English by passing both the Test of English as a Foreign Language and the Test of Spoken English.
- Has completed an internship program approved by the board.

In addition, the board must certify that a graduate of a foreign school or college of pharmacy has also completed a minimum of 500 hours of supervised work in Florida under a licensed pharmacist and has passed the board-approved Foreign Pharmacy Graduate Equivalency Examination.

Licensure by endorsement is a licensing procedure that allows an out-of-state practitioner who holds an active license in a state that has licensing requirements substantially equivalent to, or more stringent than, those in the state in which the practitioner is seeking licensure to obtain a license without meeting all of the licensure requirements for a person who is obtaining licensure for the first time. Section 465.0075, F.S., sets out the requirements for licensure by endorsement for pharmacists, requiring the applicant to have:

- Successfully met the age and educational requirements listed above for licensure by examination.²
- Obtained a passing score on the licensure examination of the National Association of Boards of Pharmacy or a similar nationally recognized examination, if the board certifies the applicant has taken the examination not more than 12 years prior to application.
- Submitted evidence of the active licensed practice of pharmacy in another jurisdiction for two of the immediately preceding five years or evidence of successful completion of board-approved

¹ The examination is comprised of two parts: Part A is the North American Pharmacist Licensure Examination (NAPLEX); Part B is the Multistate Pharmacy Jurisprudence Examination (Florida Version).

² Section 465.0075(1)(b) and (c), F.S.

postgraduate training, a board-approved clinical competency examination within one year immediately preceding application for licensure, or completion of an internship within two years immediately preceding application.

- Obtained a passing score on the pharmacy jurisprudence portions of the licensure examination.

Pharmacy Technicians

A pharmacy technician assists the pharmacist in performing a number of routine and administrative tasks, including:

- Counting tablets.
- Labeling bottles.
- Stocking shelves.
- Verifying prescriptions.³

A pharmacy technician may work in a variety of settings, such as hospitals and mail-order pharmacies, although most work within a retail pharmacy.⁴ While a majority of pharmacy technicians receive training on-the-job, numerous educational institutions throughout the country offer a pharmacy technician training program.⁵ In addition, the Pharmacy Technician Certification Board and the Institute for the Certification of Pharmacy Technicians offer certification exams that test the knowledge and skills of the technician across multiple practice settings.⁶ The minimum educational qualification to sit for either certification exam is a GED or high school diploma.

Nationwide, there are approximately 285,000 pharmacy technicians⁷; in Florida, the number may range from approximately 19,000⁸ to as high as 51,000 (registration applications estimated to be received by the department in the first four years after the bill is enacted). According to the Institute for the Certification of Pharmacy Technicians, 39 states require registration or licensure of pharmacy technicians. The requirements range from simple registration to full licensure with continuing education requirements.

Section 465.014, F.S., specifies the tasks and functions of pharmacy technicians. A person other than a pharmacist or pharmacy intern may not engage in the practice of pharmacy, except that a pharmacist may delegate to a pharmacy technician those duties, tasks, and functions that do not fall within the definition of the practice of the profession of pharmacy. The acts delegated to a pharmacy technician by a pharmacist must be performed under the direct supervision of a licensed pharmacist who is responsible for all such acts performed by persons under the pharmacist's supervision. Under the supervision of a pharmacist, a pharmacy technician may initiate or receive communications with a practitioner or his or her agent on behalf of a patient regarding prescription refill authorization requests.

A pharmacist may not supervise more than one pharmacy technician unless permitted by the board.⁹ The board has determined that the following tasks may be performed by a pharmacy technician under a supervisory ration of 2:1 or 3:1:

- Community pharmacies may have a pharmacy technician enter prescription information into a computer.
- Community pharmacies servicing nursing homes and community or special pharmacies providing parenteral and/or enteral services may allow a pharmacy technician to:
 - Enter prescription information into a computer.
 - Prepackage and label unit dose medication.

³ <http://www.bls.gov/oco/ocos252.htm> (viewed February 11, 2008).

⁴ *Id.*

⁵ http://www.ashp.org/s_ashp/technician_index.asp?CID=3494&DID=5428 (viewed February 13, 2008).

⁶ See https://www.ptcb.org/AM/Template.cfm?Section=Guidebook_to_Certification (viewed February 13, 2008) (providing a link to a certification exam guidebook that discusses the material tested in detail).

⁷ *Id.*

⁸ <http://flahec.org/hlthcareers/PHARMTEC.HTM> (viewed February 13, 2008).

⁹ Rule 64B16-27.420, F.A.C.

- Reconstitute bulk parenteral/enteral preparations to be sorted for dispensing at a later date.
- Refill unit dose mobile transport systems (carts).
- Distribute bulk medicinal drugs, appliances and other auxiliary health care products to other departments.
- Institutional pharmacies and nuclear pharmacies may allow a pharmacy technician to:
 - Enter prescription information into a computer.
 - Prepackage and label unit dose medication.
 - Reconstitute bulk parenteral/enteral preparations to be sorted for dispensing at a later date.
 - Refill unit dose mobile transport systems (carts).
 - Distribute bulk medicinal drugs, appliances and other auxiliary health care products to other departments.
- Nuclear pharmacy permits allow the pharmacy technician to receive diagnostic orders only. Therapy or blood product procedure orders must be received by a pharmacist.

The Sunrise Act

Section 11.62, F.S., the “Sunrise Act,” (the act) states that it is the intent of the Legislature that:

- No profession or occupation is subject to regulation by the state unless the regulation is necessary to protect the public health, safety, or welfare from significant and discernible harm or damage and that the police power of the state be exercised only to the extent necessary for that purpose; and
- No profession or occupation is regulated by the state in a manner that unnecessarily restricts entry into the practice of the profession or occupation or adversely affects the availability of the professional or occupational services to the public.

In determining whether to regulate a profession or occupation, the act requires the Legislature to consider the following:

- Whether the unregulated practice of the profession or occupation will substantially harm or endanger the public health, safety, or welfare, and whether the potential for harm is recognizable and not remote.
- Whether the practice of the profession or occupation requires specialized skill or training, and whether that skill or training is readily measurable or quantifiable so that examination or training requirements would reasonably assure initial and continuing professional or occupational ability.
- Whether the regulation will have an unreasonable effect on job creation or job retention in the state or will place unreasonable restrictions on the ability of individuals who seek to practice or who are practicing a given profession or occupation to find employment.
- Whether the public is or can be effectively protected by other means.
- Whether the overall cost-effectiveness and economic impact of the proposed regulation, including the indirect costs to consumers, will be favorable.

The act requires the proponents of the proposed regulation to submit information documenting how the regulation meets specific criteria outlined in the act. These criteria include:

- Documentation of the nature and extent of the harm to the public caused by the unregulated practice of the profession or occupation, including a description of any complaints that have been lodged against persons who have practiced the profession or occupation in this state during the preceding 3 years.
- An explanation of the reasons why other types of less restrictive regulation would not effectively protect the public.
- A description of the voluntary efforts made by members of the profession or occupation to protect the public and a statement of the reasons why these efforts are not adequate to protect the public.

This bill proposes the new regulation of a profession. However, the information required to be submitted by the act has not been provided to the committee.

Effect of Proposed Changes

The bill broadens the licensure by endorsement provision by deleting the requirement that an applicant for licensure as a pharmacist must have obtained a passing score on the licensure examination not more than 12 years prior to application.

Effective January 1, 2010, the bill expands the number of pharmacy technicians a pharmacist may supervise from three to four under board-approved guidelines. When a pharmacist supervises four pharmacy technicians, at least one of the four technicians must be certified by the Pharmacy Technician Certification Board or any other nationally accredited certifying body approved by the board.

The bill requires a person seeking to work as a pharmacy technician in Florida to register with the board by filing an application form furnished by the board. The bill requires the board to register an applicant who has remitted a registration fee no greater than \$50 every two years as set by the board, completed the application form, and remitted a nonrefundable application fee no greater than \$50 as set by the board. Pharmacy technician applicants must be at least 16 years of age. A person whose license to practice pharmacy has been denied, suspended, or restricted for disciplinary purposes is not eligible to be registered as a pharmacy technician.

The bill exempts from the pharmacy technician registration requirements:

- A pharmacy technician student who may be placed in a pharmacy for the purpose of obtaining practical training required by the body accrediting the pharmacy technician training program. The bill requires the pharmacy technician student to wear identification that indicates his or her student status when performing pharmacy technician functions.
- A person licensed by Florida as a pharmacy intern.

The bill requires a pharmacy technician, as a condition of registration renewal, to complete 20 hours of continuing education courses approved by the board or the Accreditation Council for Pharmaceutical Education. Four hours of the continuing education must be via live presentation and two hours must be related to the prevention of medication errors and pharmacy law.

The bill requires the board to adopt rules that require a registration issued to a pharmacy technician by the board to be displayed so that it is available to the public and to facilitate inspection by the department. The board is authorized to adopt other rules to administer the pharmacy technician requirements.

The bill authorizes the board to deny registration, or take disciplinary action, as applicable, against an applicant for registration as a pharmacy technician or registered pharmacy technician who has committed an act that constitutes a substantial violation of the general regulatory provisions of Chapter 456, F.S., or the pharmacy practice act, which occurred before the applicant or registrant was registered as a pharmacy technician.

The board must adopt rules requiring and specifying the manner in which a pharmacy must notify the board when a registered technician is employed or ceases employment with the pharmacy. The board must maintain a current directory of registered pharmacy technicians indicating their place of employment and the directory must be published on the Internet.

Effective January 1, 2010, the bill imposes a first degree misdemeanor for a person who is not registered as a pharmacy technician, or who is not otherwise exempt from the requirement to register, to perform the functions of a registered pharmacy technician or to otherwise hold himself or herself out to others as a person who is registered to perform the functions of a registered pharmacy technician in Florida.

C. SECTION DIRECTORY:

Section 1: Amends s. 465.0075, F.S., revising provisions governing licensure by endorsement.

Section 2: Amends s. 465.014, F.S., providing for the registration of pharmacy technicians, effective January 1, 2010.

Section 3: Amends s. 465.015, F.S., prohibiting unauthorized activity as an unregistered pharmacy technician, providing penalties, effective January 1, 2010.

Section 4: Amends s. 465.019, F.S., conforming references relating to use of pharmacy technicians in institutional pharmacies, effective January 1, 2010.

Section 5: Provides an effective date of upon becoming law, except as otherwise expressly provided.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

Currently, there are 17,000 licensed pharmacists in the state. Based on the provisions in this bill, a pharmacist could supervise up to four pharmacy technicians. So, there are 68,000 registered pharmacy technician slots available. However, it is very unlikely that every pharmacist would supervise the maximum number of technicians.

The department has projected that within the next four years a total of 51,000 persons will seek registration as a pharmacy technician. The initial and renewal fee is \$50 per application and will result in revenue of \$4.6 million in the first four years. Registration is renewable biannually so the revenue collected to support regulation will fluctuate.

Depending upon the number of persons seeking registration as a Pharmacy Technician, the revenue may not cover the cost of the regulatory requirements, per s. 216.0236, F.S. To meet the projected expenditures in the first year, the minimum number of persons to seek registration is 15,000 persons.

<u>Estimated Revenue</u>	<u>1st Year</u>	<u>2nd Year</u>	<u>2nd Year</u>	<u>4th Year</u>
Number of persons seeking registration	30,000	10,000	10,000	1,000
	persons x \$50	persons x \$50	persons x \$50	persons X \$50
Initial Registration Fee	\$1,500,000	\$ 500,000	\$ 500,000	\$ 50,000
Renewal Fee			1,500,000	500,000
Total	\$1,500,000	\$500,000	\$2,000,000	\$550,000

2. Expenditures:

The department estimates that they will need eight full-time equivalent positions to implement the provisions of the bill. Three of the positions will be located in the Board of Pharmacy Office to support the registration application process. One position will be located in Consumer Services Unit to receive and process complaints. Two positions will be located in the Investigative Services Unit to investigate all legally sufficient complaints received. Two positions will be for the Prosecution Services Unit to respond to all legally sufficient complaints to determine probable cause. Currently, the department contracts with a vendor to process initial and renewal applications and related fees at a rate of \$7.89 per application.

The total projected expenditures are \$2.1 million in the first four years.

<u>Estimated Expenditures</u>	<u>1st Year</u>	<u>2nd Year</u>	<u>3rd Year</u>	<u>4th Year</u>
Salaries				
<i>1- Regulatory Supervisor, PG 420 (Pharmacy)</i>	46,397	46,397	46,397	46,397
<i>1 – Regulatory Spec II, PG 17 (Pharmacy)</i>	39,627	39,627	39,627	39,627
<i>1 – Regulatory Spec I, PG 15 (Pharmacy)</i>	36,155	36,155	36,155	36,155
<i>1 - Government Analyst, PG 22 (CSU)</i>	51,748	51,748	51,748	51,748
<i>2 - Investigator Spec II, PG 20 (ISU)</i>	92,794	92,794	92,794	92,794
<i>1 - Senior Attorney, PG 230 (PSU)</i>	73,259	73,259	73,259	73,259
<i>1- Reg Spec II, PG 17 (PSU)</i>	39,627	39,627	39,627	39,627
Expense				
<i>Non-Recurring Exp Pkg 7 professional staff</i>	23,716			
<i>Non-Recurring Exp Pkg 1 support staff</i>	2,947			
<i>Rec exp, Max Travel - 2 FTE</i>	40,424	40,424	40,424	40,424
<i>Rec exp, Lmt Travel - 3 FTE</i>	36,804	36,804	36,804	36,804
<i>Rec exp, No Travel - 2 FTE</i>	13,400	13,400	13,400	13,400
<i>Rec exp, spt staff - 1 FTE</i>	5,426	5,426	5,426	5,426
Operating Capital Outlay				
<i>8 FTE OCO Pkg</i>	8,000			
Contracted Services				
<i>Initial & Renewal processing</i>	236,700	\$ 78,900	\$ 315,600	86,790
Human Resources Services				
<i>8 FTE HR</i>	3,184	3,184	3,184	3,184
Total	\$ 750,207	\$ 557,744	\$ 794,444	\$ 565,634

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:
None.

2. Expenditures:
None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Pharmacy technicians currently working in the state will incur costs associated with the registration and continuing education requirements.

Pharmacies that employ pharmacy technicians may indirectly incur higher costs to ensure compliance with the regulatory requirements of the bill.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable because the bill does not appear to require counties or cities to spend funds or take action requiring the expenditure of funds; reduce the authority that cities or counties have to raise revenues in the aggregate; or reduce the percentage of a state tax shared with cities or counties.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

No additional rulemaking authority is required as a result of this bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

On line 87, "board" should be replaced with "department". Professional licensure applicants apply to the department and the applicable board adopts the licensure application form by rule.

On line 158, "pharmacy technician" should be replaced with "registered pharmacy technician" to reflect the required registration of pharmacy technicians.

Section 465.0197(1), F.S., should be similarly amended the replace "pharmacy technician" with "registered pharmacy technician."

D. STATEMENT OF THE SPONSOR

No statement submitted.

IV. AMENDMENTS/COUNCIL SUBSTITUTE CHANGES