

**The Florida Senate**  
**BILL ANALYSIS AND FISCAL IMPACT STATEMENT**

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

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Prepared By: The Professional Staff of the Committee on Rules

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BILL: CS/CS/CS/SB 278

INTRODUCER: Rules Committee; Regulated Industries Committee; Health Policy Committee; and Senator Grimsley

SUBJECT: Pharmacy

DATE: April 3, 2014

REVISED: \_\_\_\_\_

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Peterson</u>	<u>Stovall</u>	<u>HP</u>	<u>Fav/CS</u>
2.	<u>Niles</u>	<u>Imhof</u>	<u>RI</u>	<u>Fav/CS</u>
3.	<u>Peterson</u>	<u>Phelps</u>	<u>RC</u>	<u>Fav/CS</u>

**Please see Section IX. for Additional Information:**

COMMITTEE SUBSTITUTE - Substantial Changes

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**I. Summary:**

CS/CS/CS/SB 278 removes the cap of three pharmacy technicians that the Board of Pharmacy (board) may authorize one pharmacist to supervise.

The bill also revises the composition of the board. The number of pharmacists representing both community and institutional class II pharmacies is increased from a minimum of one in each category, to a minimum of two each.

The bill amends s. 465.189, F.S., to authorize pharmacists to administer the meningococcal vaccine under physician protocol and removes the requirement for a pharmacist to have a prescription from a physician to administer the shingles vaccine.

The bill amends s. 456.42, F.S., and s. 863.04(2)(d) by permitting a date on a prescription for a controlled substance listed in ch. 893, F.S., to be in the numeric month/day/year format or the month written out in whole.

The bill removes the requirement that the date required under s. 456.42, F.S., and the written quantity and date required under s. 839.04(2), F.S. must be on the face of the prescription.

The bill amends s. 839.04(2), F.S., by adding the requirement that the notation of the date be legible.

The bill provides an effective date of July 1, 2014.

## II. Present Situation:

### Pharmacists

Pharmacists are regulated under ch. 465, F.S., the Florida Pharmacy Act (act), by the board within the Department of Health (department). A pharmacist is any person licensed under the act to practice the profession of pharmacy.<sup>1</sup>

The practice of professional pharmacy includes:<sup>2</sup>

- Compounding, dispensing, and consulting related to contents, therapeutic values, and uses of any medicinal drug;
- Consulting related to therapeutic values and interactions of patent or proprietary preparations; and
- Other pharmaceutical services, which include: monitoring, reviewing, or assisting a patient in the management of the patient's drug therapy and communicating with the patient's prescribing health care provider or others, as authorized by the patient, regarding the drug therapy.

A person practicing the profession of pharmacy is not authorized to alter a prescriber's instructions, diagnose or treat any disease, initiate any drug therapy, or practice medicine or osteopathic medicine, unless specifically permitted by law. A pharmacist is authorized to transmit information from persons authorized to prescribe medicinal drugs to their patients.<sup>3</sup>

To be licensed as a pharmacist, a person must:

- Submit an application form and the required fees.
- Submit satisfactory proof that the applicant is not less than 18 years of age and is a recipient of a degree from an accredited school or college of pharmacy; or is a graduate of a 4-year undergraduate pharmacy program of a school or college of pharmacy located outside the United States, has demonstrated proficiency in English, has passed the Foreign Pharmacy Graduate Equivalency Examination, and has completed a minimum of 500 hours in a supervised work activity program within Florida under the supervision of a pharmacist licensed by the department.
- Submit satisfactory proof that the applicant has completed an internship program, which must not exceed 2,080 hours.
- Successfully complete the licensure examination.<sup>4</sup>

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<sup>1</sup> Section 465.003(10), F.S.

<sup>2</sup> Section 465.003(13), F.S.

<sup>3</sup> Section 465.003(13), F.S.

<sup>4</sup> Section 465.007, F.S. Florida law also allows a pharmacist to obtain a license by endorsement as an alternative to licensure by examination. *See s. 465.0075, F.S.*

## Pharmacy Technicians

Florida law authorizes a licensed pharmacist to delegate certain duties, exclusive of acts that constitute the practice of professional pharmacy as defined in s. 465.003(13), F.S., to a pharmacy technician who is registered with the board. All delegated acts must be performed under the direct supervision<sup>5</sup> of the pharmacist and the pharmacist retains the professional and personal responsibility for the acts.<sup>6</sup> The acts a registered pharmacy technician may perform include:<sup>7</sup>

- Retrieval of prescription files;
- Data entry;
- Label preparation;
- Counting, weighing, measuring, pouring, and mixing prescription medication or stock legend drugs and controlled substances;
- Initiating communication with a prescribing practitioner or medical staff regarding requests for prescription refill authorization, clarification of missing information on prescriptions, and confirmation of information such as names, medication, and strength; and
- Accepting authorization for prescription renewals.

Pharmacy technicians are prohibited from performing the following acts:<sup>8</sup>

- Receiving new verbal prescriptions or any change in the medication, strength, or directions;
- Interpreting a prescription or medication order for therapeutic acceptability and appropriateness;
- Conducting a final verification of dosage and directions;
- Engaging in prospective drug review;
- Providing patient counseling;
- Monitoring prescription drug usage; and
- Overriding clinical alerts without first notifying the pharmacist.

Any person desiring to become a registered pharmacy technician must register by filing an application with the board. The board must register each applicant who:

- Completes the application form and submits the required fees.
- Is at least 17 years of age.
- Has completed a pharmacy technician training program approved by the board. Approved programs include programs accredited or licensed by specified national organizations, and employer-based programs. Employer-based programs must provide 160 hours of training over a period not to exceed 6 months, limited to employees of the pharmacy, and subject to approval by the board.<sup>9</sup>
- A pharmacy technician who registered prior to January 1, 2011, and who has worked as a pharmacy technician for a minimum of 1,500 hours under the supervision of a licensed pharmacist or received certification as a pharmacy technician by a certification program

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<sup>5</sup> Chapter 465, F.S., does not contain a definition of “direct supervision.” The Rules Committee of the board discussed this issue at its February meeting, but did not take final action. The issue is expected to be on the committee’s agenda again during its April meeting.

<sup>6</sup> Section 465.014(1), F.S.; Rule 64B16-27.1001(7), F.A.C.

<sup>7</sup> Rule 64B16-27.420, F.A.C.

<sup>8</sup> *Id.*

<sup>9</sup> Rule 64B16-26.351 F.A.C.

accredited by the National Commission for Certifying Agencies is exempt from the requirement to complete an initial training program in order to register.<sup>10</sup>

A person who is licensed by the state as a pharmacy intern may be employed as a registered pharmacy technician without registering as a pharmacy technician.<sup>11</sup>

Pharmacy technicians must complete 20 hours of continuing education in one or more of the following areas during the 24 months prior to renewal:<sup>12</sup>

- Pharmacy technician practice areas and special health.
- Biological, physical, behavioral, and social sciences.
- Legal aspects of health care.
- Management/administration of health care personnel and patient care.
- Teaching/learning process of health care personnel and patients.

The board also recognizes advanced coursework at an accredited educational institution as continuing education.

### **Pharmacist Supervision**

A licensed pharmacist may not supervise more than one registered pharmacy technician, unless otherwise permitted by the guidelines adopted by the board. The board may authorize supervision of a maximum of three pharmacy technicians.<sup>13</sup>

The guidelines require a pharmacist to submit a written request and receive approval by the board before supervising more than one registered pharmacy technician. The board considers the following in determining the pharmacist-to-pharmacy technician ratio:<sup>14</sup>

- A brief description of the pharmacy's workflow justifying the request;
- The hours the pharmacy is open; and,
- The number of pharmacists, pharmacy interns, and pharmacy technicians employed.

All registered pharmacy technicians must wear a name badge that identifies them as a pharmacy technician, and verbally identify themselves as such during any communication.<sup>15</sup>

At the end of the first quarter of fiscal year 2013-2014, there were 44,492 registered pharmacy technicians, 31,445 pharmacists and 9,179 licensed pharmacies. Of the licensed pharmacies, 4,436 had a ratio of three pharmacy technicians to one pharmacist, and 580 pharmacies had a ratio of two pharmacy technicians to one pharmacist.<sup>16</sup> According to the December 2013 Aggregate Demand Index compiled by the Pharmacy Manpower Project, Inc. (project),<sup>17</sup> Florida

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<sup>10</sup> Section 465.014(2), F.S.

<sup>11</sup> Section 465.014(5), F.S.

<sup>12</sup> Rule 64B16-26.103(4), F.A.C.

<sup>13</sup> Section 465.014(1), F.S.

<sup>14</sup> Rule 64B16-27.410, F.A.C.

<sup>15</sup> Rule 64B16-27.420(4), F.A.C.

<sup>16</sup> Florida Dept. of Health, *2014 Agency Legislative Bill Analysis: SB 278* (Nov. 6, 2013).

<sup>17</sup> Members of the Pharmacy Manpower Project, which collects, analyzes, and disseminates data on the supply of licensed pharmacists in the United States, include: the Academy of Managed Care Pharmacy, the American Association of Colleges

has a ranking of 2.33, meaning Florida does not have a shortage of pharmacists. Specifically, the Florida ranking falls between “demand is less than the pharmacist supply available” and “demand is in balance with supply” on the scale used by the project.<sup>18</sup>

As of 2009, Florida was among 18 states allowing a maximum 1 to 3 pharmacist-to-pharmacist technician ratio.<sup>19</sup> Seventeen states and the District of Columbia had no ratio limits; eight states allowed a maximum 1 to 2 pharmacist-to-pharmacist technician ratio; seven states allowed a 1 to 4 ratio; and one state allowed a 1 to 1 ratio. More recently, Indiana and Idaho have allowed a 1 to 6 ratio.<sup>20</sup> Some states require that higher ratios are contingent on certification or licensure of technicians, or other quality assurance measures.<sup>21</sup>

According to Florida Retail Federation (FRF), pharmacy technicians are trained individuals who assist pharmacists in dispensing medications by doing routine pharmacy tasks such as taking customer phone calls, creating labels, and taking payment for prescriptions. Their role allows pharmacists to delegate specific tasks.<sup>22</sup> Valid training programs are listed under rule 64B16-26.351, F.A.C., which also provides for curriculum and provides that alternative programs must be a minimum of 160 hours in length (about one month full time) to six months maximum.

Concerns have been raised in past attempts to remove or alter the three technician cap. According to the Florida Pharmacy Association, pharmacists may have little say in their staffing needs or budget, and increased growth of health care needs can increase potential oversight by the supervising pharmacists who may not be able to accurately and appropriately review multiple technicians who hold no liability themselves.<sup>23</sup>

Section 465.004, F.S., establishes the Board of Pharmacy. The board consists of nine members appointed by the Governor and confirmed by the Senate. Seven members of the board must be licensed pharmacists who are residents of this state and engaged in the practice of pharmacy for at least 4 years. Of the pharmacist members, one must be currently engaged in the practice of pharmacy in a community pharmacy, one must be currently engaged in the practice of pharmacy

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of Pharmacy, the American College of Apothecaries, the American College of Clinical Pharmacy, the American Pharmaceutical Association, the American Society of Consultant Pharmacists, the American Society of Health-System Pharmacists, the Bureau of Health Professions, the Healthcare Distribution Management Association, the National Association of Chain Drug Stores, the National Community Pharmacists Association, the National Council of State Pharmacy Association Executives, the National Pharmaceutical Association, the Pharmaceutical Research and Manufacturers Association, and the Pharmacy Technicians Certification Board.

<sup>18</sup> Aggregate Demand Index, Supported by Pharmacy Manpower Project Inc., *available at* <http://www.pharmacymanpower.com/about.jsp> (last visited Feb. 20, 2014).

<sup>19</sup> National Association of Chain Drug Stores, *Standardized Pharmacy Technician Education and Training* (May 2009), *available at*: [http://www.nabp.net/events/assets/AnnualMtgTechTrainStd\(Nicholson\).pdf](http://www.nabp.net/events/assets/AnnualMtgTechTrainStd(Nicholson).pdf) (last visited Feb. 20, 2014).

<sup>20</sup> Indiana changed its ratio July 2, 2012. *See* Indiana Code, 25-26-13-18. *See also* Idaho Board of Pharmacy Rule 251. Pharmacy Technicians.

<sup>21</sup> *See* National Association of Boards of Pharmacy: Kansas News: Pharmacy Technician Ratio (2006), <http://www.nabp.net/news/kansas-news-pharmacy-technician-ratio> (Last visited Feb. 20, 2014).

<sup>22</sup> Florida Retail Technician, *Pharmacy Technician Ratio Expansion*, (2014) *available at* <http://www.frf.org/index.php/government-affairs/2014-issues/pharmacy/pharmacy-technician-ratio-expansion>.

<sup>23</sup> Conversation with Michael Jackson, Executive Vice President and CEO, Florida Pharmacy Association (March 14, 2014).

in a Class II institutional pharmacy<sup>24</sup> or a Modified Class II institutional pharmacy,<sup>25</sup> and five must be licensed pharmacists regardless of the type of practice.

Two members must be residents of this state who are not connected to the practice of pharmacy. One member of the board must be at least 60 years old. The members serve four years. Currently, there is one vacancy on the board.<sup>26</sup>

### **Written Prescriptions**

Section 456.42, F.S., provides that a written prescription for a controlled substance listed under ch. 893, F.S., must have the quantity of the drugs in both textual and written formats and must be dated with the abbreviated month written out on the face of the prescription. It also must be either written on a standardized counterfeit-proof prescription pad or electronically as defined in s. 408.0611, F.S.

Section 893.04, F.S., provides that each written prescription for a controlled substance listed in Schedule II, Schedule III, or Schedule IV must include both a written and a numerical notation of the quantity of the prescription on the face of the prescription and a notation of the date with the abbreviated month written out on the face of the prescription.

### **Vaccine Administration**

Section 465.189, F.S., authorizes a pharmacist to administer the influenza, pneumococcal, and shingles vaccines under the protocol of a licensed physician. The pharmacist must also have a prescription from a physician to administer the shingles vaccine. A pharmacist who administers vaccines must maintain at least \$200,000 in liability insurance and complete a 20-hour certification course in the administration of vaccines and a 3-hour continuing education course biennially, thereafter.

## **III. Effect of Proposed Changes:**

CS/CS/CS/SB 278 removes the cap on the number of pharmacy technicians the board may authorize a pharmacist to supervise. A licensed pharmacist may not supervise more than one technician, but may be able to supervise any number of technicians if permitted by the guidelines of the board.

The bill also revises the composition of the board to increase the number of pharmacists representing community and institutional class II pharmacies from one each to two each. The Governor is directed to make appointments in accordance with the revised composition as members' terms expire or vacancies occur.

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<sup>24</sup> A Class II institutional pharmacy is an institutional pharmacy which employs the services of a registered pharmacist or pharmacists who, in practicing institutional pharmacy, shall provide dispensing and consulting services on the premises to patients of that institution for use on the premises of that institution. Section 465.019(2)(b), F.S.

<sup>25</sup> A Modified Class II institutional pharmacy is a pharmacy in short-term, primary care treatment centers that meet all the requirements for a Class II permit, except space and equipment requirements. Section 465.019(2)(c), F.S.

<sup>26</sup> See The Board of Pharmacy, available at <http://floridaspharmacy.gov/the-board/> (Last visited March 18, 2014).

The bill amends s. 465.189, F.S., to authorize pharmacists to administer the meningococcal vaccine under physician protocol and removes the requirement for a pharmacist to have a prescription from a physician to administer the shingles vaccine.

The bill amends s. 456.42, F.S., and s. 863.04(2)(d) F.S., by requiring that a written prescription for a controlled substance listed in ch. 893, F.S., must be dated in the numeric month/day/year format, or with the abbreviated month written out, or the month written out in whole.

The bill removes the requirement that the date required under s. 456.42, F.S., must be on the face of the prescription, and the bill removes the requirement that the written quantity and date under s. 839.04(2), F.S., must be on the face of the prescription.

The bill also amends s. 839.04(2), F.S., by adding the requirement that the notation of the date be legible.

The bill provides an effective date of July 1, 2014.

#### **IV. Constitutional Issues:**

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

#### **V. Fiscal Impact Statement:**

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Privately-owned pharmacies may experience greater efficiency in operations, resulting in cost savings, by utilizing more pharmacy technicians in their operations. Individuals may be able to obtain meningococcal vaccine more easily and at a lower cost in a pharmacy. Likewise, the shingles vaccine may be more readily available from a pharmacy because the bill removes the requirement for a pharmacist to have a prescription in order to administer the vaccine.

**C. Government Sector Impact:**

The department will incur non-recurring costs for rulemaking, which current budget authority is adequate to absorb.<sup>27</sup> There will also be costs associated with requests made to the board to authorize a ratio greater than 1 to 1, although this cost is indeterminate because it is not possible to project how many pharmacies will make that request.

Like their private sector counterparts, publicly-owned pharmacies may experience greater efficiency in operations, resulting in cost savings, by utilizing more pharmacy technicians in their operations.

**VI. Technical Deficiencies:**

None.

**VII. Related Issues:**

None.

**VIII. Statutes Affected:**

This bill substantially amends the following sections of the Florida Statutes: 456.42, 465.004, 465.014, 465.189, and 893.04.

**IX. Additional Information:****A. Committee Substitute – Statement of Substantial Changes:**

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

**CS/CS/CS by Rules on April 2, 2014:**

The CS further revises the composition of the board to increase the number of representatives of community and institutional pharmacies by one each and provides for the transition in appointments to achieve the new composition.

The CS amends s. 465.189, F.S., to authorize pharmacists to administer the meningococcal vaccine under physician protocol and removes the requirement for a pharmacist to have a prescription from a physician to administer the shingles vaccine.

**CS/CS by Regulated Industries on March 20, 2014:**

The CS provides under s. 456.42, F.S., and s. 863.04(2)(d), F.S., that a written prescription for a controlled substance listed in ch. 893, F.S., must be dated in the numeric month/day/year format, or with the abbreviated month written out, or the month written out in whole.

The CS removes the requirement that the date required under s. 456.42, F.S., must be on the face of the prescription.

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<sup>27</sup> Florida Dept. of Health, *2014 Agency Legislative Bill Analysis: SB 278* (Nov. 6, 2013).

The CS removes the requirement that the written quantity and date under s. 839.04(2), F.S., must be on the face of the prescription.

The CS amends s. 839.04(2), F.S., by adding the requirement that the notation of the date be legible.

**CS by Health Policy on March 11, 2014:**

The CS restores current law regarding the number of pharmacy technicians a pharmacist can supervise without board approval by removing the cap of six proposed by the bill as filed.

The CS restores current law regarding the board's authority to adopt guidelines for determining when a pharmacist may supervise more than one pharmacist.

The CS revises the composition of the board to increase the number of pharmacists representing community and institutional class II pharmacies from one each to three each.

**B. Amendments:**

None.