

**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.)

---

Prepared By: The Professional Staff of the Committee on Health Policy

---

BILL: SB 524

INTRODUCER: Senator Brandes

SUBJECT: Influenza Virus and Streptococcal Infections

DATE: February 5, 2018

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

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Rossitto-Van Winkle	Stovall	HP	<b>Pre-meeting</b>
2.	_____	_____	AHS	_____
3.	_____	_____	AP	_____

---

**I. Summary:**

SB 524 amends the definition of the practice of pharmacy to include testing for and treating the influenza virus and streptococcal infections. The bill authorizes a pharmacist to test and treat for the influenza virus and streptococcal infections within the framework of an established written protocol with a supervising physician. The Board of Pharmacy (board) is authorized to expand by rule on the minimum requirements for the protocol that are provided in the bill. A pharmacist must be certified pursuant to an approved certification program that includes at least eight hours of continuing education (CE) on specified subject matter to be eligible for this expanded practice.

**II. Present Situation:**

**The Practice of Professional Pharmacy**

Pharmacy is the third largest health care profession in the United States behind nursing and medicine.<sup>1</sup> The board, in conjunction with the Department of Health (DOH), regulates the practice of pharmacists pursuant to ch. 465, F.S.<sup>2</sup>

The scope of “practice of the profession of pharmacy” includes:

- Compounding, dispensing, and consulting concerning the contents, therapeutic values, and uses of any medicinal drug;
- The administration of vaccines to adults;<sup>3</sup> and
- Other pharmaceutical services.<sup>4</sup>

---

<sup>1</sup> American Association of Colleges of Pharmacy, *About AACP*, <https://www.aacp.org/about-aacp> (last visited Jan. 31, 2018).

<sup>2</sup> Sections 465.004 and 465.005, F.S.

<sup>3</sup> See s. 465.189, F.S.

<sup>4</sup> Section 465.003(13), F.S.

The term “other pharmaceutical services” includes:

- Monitoring a patient’s drug therapy;
- Assisting a patient with drug therapy management;
- Reviewing a patient’s drug therapy;
- Communicating with a patient’s prescribing health care practitioner; and
- Any other act, service, operation, research, or transaction incidental to any branch of the pharmaceutical profession.<sup>5</sup>

Pharmacists are specifically prohibited from altering a prescriber’s directions, diagnoses or treatment plan, initiating any drug therapy, and practicing medicine, unless permitted by law.<sup>6</sup>

To be licensed as a pharmacist in Florida, a person must:

- Be at least 18 years of age;
- Hold a degree from an accredited and approved school or college of pharmacy;<sup>7</sup>
- Have completed a board-approved internship; and
- Obtain a passing score on the board-approved examination.<sup>8</sup>

A pharmacist must complete at least 30 hours of continuing education (CE) for each biennial license renewal period.<sup>9</sup> A pharmacist who is certified to administer vaccines or epinephrine autoinjections must complete three hours of CE on the safe and effective administration of vaccines and epinephrine injections as a part of his or her licensure renewal. This three hours of CE is included within the 30-hour requirement for licensure renewal.<sup>10</sup>

### ***Pharmacist Administration of Vaccines and Injections***

A pharmacist may become certified to administer the immunizations or vaccines listed in the Centers for Disease Prevention and Control (CDC) Adult Immunization Schedule as of February 1, 2015, as well as those recommended for international travel as of July 1, 2015.<sup>11</sup>

To be certified to administer vaccines, a pharmacist must:

- Enter into a written protocol with a supervising physician which is filed with the board. The protocol must include:<sup>12</sup>
  - The categories and conditions of patients to whom the pharmacist may administer vaccines;

---

<sup>5</sup> *Id.*

<sup>6</sup> Section 464.003(13), F.S.

<sup>7</sup> Section 465.007(1)(b)2., F.S. If the applicant has graduated from a four year undergraduate pharmacy program of a school or college of pharmacy located outside the United States, the applicant must demonstrate proficiency in English, pass the board-approved Foreign Pharmacy Graduate Equivalency Examination, and complete a minimum of 500 hours in a supervised work activity program within Florida under the supervision of a DOH-licensed pharmacist.

<sup>8</sup> The DOH may also issue a license by endorsement to a pharmacist who is licensed in another state upon meeting the applicable requirements set forth in law and rule. *See s. 465.0075, F.S.*

<sup>9</sup> Section 465.009, F.S.

<sup>10</sup> Section 465.009(6), F.S.

<sup>11</sup> Section 465.189, F.S., A registered intern may also administer immunizations or vaccines under the supervision of a certified pharmacist.

<sup>12</sup> Section 465.189(1) and (7), F.S.

- Terms, scope and conditions that are appropriate to the pharmacist's training and certification; and
- The process and schedule for the review of the administration of vaccines by the supervising physician pursuant to the written protocol.
- Complete a board-approved vaccine administration certification program that consists of at least 20 hours of CE, and provide evidence of this to the supervising physician;<sup>13</sup>
- Demonstrate vaccine administration techniques;<sup>14</sup> and
- Maintain at least \$200,000 of professional liability insurance.<sup>15</sup>

A pharmacist may also administer epinephrine using an autoinjector delivery system, within a protocol with the supervising physician to treat any allergic reactions resulting from a vaccine.<sup>16</sup> A pharmacist administering vaccines must provide the DOH with a patient's vaccination records for inclusion in the state's immunization registry.<sup>17</sup>

### ***Pharmacist Administration of Antipsychotic Medication by Injection***

In 2017, the Legislature authorized a licensed pharmacist to administer an injection of a long-acting antipsychotic medication<sup>18</sup> approved by the United States Food and Drug Administration.<sup>19</sup> To be eligible to administer such injections, a pharmacist must:<sup>20</sup>

- Be authorized in a protocol with the prescribing physician;
- Practice at a facility that accommodates privacy for non-deltoid injections and provides for safe disposal of medications and medical waste;<sup>21</sup> and
- Complete eight hours of CE on the safe and effective administration of behavioral health and antipsychotic medications by injection, including potential allergic reactions.

A separate prescription from a physician is required for each injection administered.

### **Diagnostic Tests for Influenza and Streptococcus**

#### ***Influenza Tests***

Influenza is a viral, contagious respiratory illness.<sup>22</sup> Although the influenza virus may be detected at any time of the year, the influenza virus is most common during the fall and winter.<sup>23</sup>

<sup>13</sup> Section 465.189(6), F.S., and Rule 64B16-26.1031, F.A.C., provides more detail regarding subject matter that must be included in the certification course.

<sup>14</sup> Section 465.189(3), F.S.

<sup>15</sup> *Id.*

<sup>16</sup> Section 465.189(2), F.S.

<sup>17</sup> Section 465.189(5), F.S.

<sup>18</sup> A long-acting injectable antipsychotic medication may be prescribed to treat symptoms of psychosis associated with schizophrenia and schizoaffective disorder and provided once or twice a month. It may be prescribed for individuals who have difficulty remembering to take daily medications or who have a history of discontinuing medication. National Alliance on Mental Illness, *Mental Health Medications* (August 2017) available at <https://www.nami.org/Learn-More/Treatment/Mental-Health-Medications> (last visited Jan. 31, 2018).

<sup>19</sup> Section 465.1893, F.S.

<sup>20</sup> *Id.*

<sup>21</sup> Section 381.0098, F.S., and Rule 64E-16, F.A.C., regulate the disposal of biomedical waste.

<sup>22</sup> U.S. Department of Health and Human Services, Center for Disease Control and Prevention, *About Flu*, (Oct. 5, 2017), available at <https://www.cdc.gov/flu/about/index.html> (last visited Jan. 31, 2018).

<sup>23</sup> *Id.*

Each year, on average 5 to 20 percent of the United States population gets the influenza, tens of thousands are hospitalized, and thousands die from influenza related illnesses.<sup>24</sup> It is estimated that the influenza results in \$10.4 billion in direct medical expenses and an additional \$16.3 billion in lost earnings annually.<sup>25</sup>

A person who has contracted the influenza virus is typically contagious for the first three to four days after the illness begins.<sup>26</sup> However, some individuals may be able to infect others beginning one day before symptoms develop and up to five to seven days after becoming sick.<sup>27</sup> According to the CDC, most people infected with influenza will have a mild illness and do not need medical care or antiviral medication.<sup>28</sup> However, the CDC advises individuals who develop influenza symptoms and are at higher risk of complications to contact a health care practitioner as early as possible to begin antiviral treatment.<sup>29</sup> The CDC recommends an annual vaccination as the best way to prevent influenza.<sup>30</sup>

Individuals with weakened immune systems, the elderly, young children, or those with certain health conditions, may be at high risk of serious flu complications.<sup>31</sup> Complications of influenza may include bacterial pneumonia, ear infections, sinus infections, and worsening of chronic medical conditions, such as congestive heart failure, asthma, or diabetes.<sup>32</sup> Serious influenza infections can result in hospitalizations or death.

In recent years, the Food and Drug Administration has approved more than 10 rapid influenza diagnostic tests (RIDTs) to screen for influenza virus infection.<sup>33</sup> These tests can provide results within approximately 15 minutes and may be used to help with diagnosis and treatment decisions for patients.<sup>34</sup> However, a variety of factors can influence the accuracy of an RIDT, including the type of specimen tested, whether the specimen is collected within 72 hours of the onset of the illness, and the prevalence of flu activity in the area.<sup>35</sup> False positive results are more likely at the beginning or end of the influenza season or during periods when the flu virus is not circulating, such as the summer. False negative results are more likely at the peak of the influenza season.<sup>36</sup>

---

<sup>24</sup> U.S. Department of Health and Human Services, Center for Disease Control and Prevention, Foundation, *Flu Prevention*, available at <https://www.cdcfoundation.org/businesspulse/flu-prevention-infographic> (last visited Jan. 31, 2018).

<sup>25</sup> *Id.*

<sup>26</sup> U.S. Department of Health and Human Services, Center for Disease Control and Prevention, *Key Facts about Influenza (Flu)*, (Oct. 5, 2017), available at <https://www.cdc.gov/flu/keyfacts.htm> (last visited Jan. 31, 2018).

<sup>27</sup> *Id.*

<sup>28</sup> U.S. Department of Health and Human Services, Center for Disease Control and Prevention, *The Flu: What to Do if You Get Sick*, (Feb. 14, 2017), available at <https://www.cdc.gov/flu/takingcare.htm> (last visited Jan. 31, 2018).

<sup>29</sup> *Id.*

<sup>30</sup> *Id.*

<sup>31</sup> *Supra* note 22.

<sup>32</sup> *Supra* note 29.

<sup>33</sup> U.S. Department of Health and Human Services, Center for Disease Control and Prevention, *Rapid Diagnostic Testing for Influenza: Information for Clinical Laboratory Directors*, (Oct. 26, 2016), available at <https://www.cdc.gov/flu/professionals/diagnosis/rapidlab.htm> (last visited Jan. 31, 2018).

<sup>34</sup> *Id.*

<sup>35</sup> U.S. Department of Health and Human Services, Center for Disease Control and Prevention, *Guidance for Clinicians on the Use of Rapid Influenza Diagnostic Tests*, [https://www.cdc.gov/flu/pdf/professionals/diagnosis/clinician\\_guidance\\_ridt.pdf](https://www.cdc.gov/flu/pdf/professionals/diagnosis/clinician_guidance_ridt.pdf) (last visited Jan. 31, 2018).

<sup>36</sup> *Id.*

A health care practitioner may diagnose an individual with influenza based on symptoms and his or her clinical judgment, irrespective of the test results.<sup>37</sup>

Some pharmacies may currently provide influenza testing, as well as other health screenings.<sup>38</sup> However, these pharmacies vary by the types of patients seen, the array of services offered, the type of health care practitioner available, and the type of medications prescribed.

### ***Streptococcus Testing***

Streptococcus (Strep) is a bacteria that causes a variety of infections. There are two types of Strep. Group A Strep infections include Strep throat, scarlet fever, impetigo, toxic shock syndrome and cellulitis and necrotizing fasciitis.<sup>39</sup> Group B Strep may cause blood infections, pneumonia, and meningitis in newborns, as well as urinary tract infections, blood infections, skin infections, and pneumonia in adults.<sup>40</sup> Strep throat, along with minor skin infections, are the most common infection.<sup>41</sup>

Strep throat is a highly contagious Group A strep infection. It is most common in children between ages 5 and 15; however, anyone may contract it.<sup>42</sup> Strep throat is passed through person to person contact. A person who has been treated with antibiotics for 24 hours or longer however, can generally no longer transmit the bacteria.<sup>43</sup> If Strep throat is not diagnosed and treated, it may lead to complications such as rheumatic fever, which can damage the heart, or glomerulonephritis, which affects the kidney.<sup>44</sup>

Rapid antigen diagnostic tests (RADTs) may be used to determine the presence of Group A Strep in a patient's throat or other infected areas.<sup>45</sup> Results are generally available within ten to 20 minutes; however, some tests may be able to detect the presence of Group A Strep bacteria

---

<sup>37</sup> U.S. Department of Health and Human Services, Center for Disease Control and Prevention, *Diagnosing Flu: Questions and Answers*, (Oct. 3, 2017), available at <https://www.cdc.gov/flu/about/qa/testing.htm> (last visited Jan. 31, 2018).

<sup>38</sup> Examples are: CVS Pharmacy offers services through its MinuteClinic®, which is staffed by nurse practitioners or physician assistants (*see* CVS, *Want to Learn More about MinuteClinic®*, available at <https://www.cvs.com/minuteclinic/services/minor-illnesses/flu-like-symptoms/N-d8ZbtmkZd5> (last visited Jan. 31, 2018); Walgreens offers services through its Healthcare Clinic, which is staffed by professional healthcare professionals (*see* Walgreens, *Healthcare Clinic*, available at <https://www.walgreens.com/topic/pharmacy/healthcare-clinic.jsp> (last visited Jan. 31, 2018); Walmart offers services through *Walmart Care Clinics* which are staffed by ARNPs available at: <https://www.walmart.com/cp/care-clinics/1224932> (last visited Jan. 31, 2018).

<sup>39</sup> U.S. National Library of Medicine, Medline Plus, *Streptococcal Infections*, (Oct. 3, 2017), available at <https://medlineplus.gov/streptococcalinfections.html> (last visited Jan. 31, 2018).

<sup>40</sup> *Id.*

<sup>41</sup> National Institute of Allergy and Infectious Diseases, *Group A Streptococcal Infections*, (last rev. Sept. 29, 2015), available at <https://www.niaid.nih.gov/diseases-conditions/group-streptococcal-infections> (last visited Jan. 31, 2018).

<sup>42</sup> *Supra* note 39.

<sup>43</sup> U.S. Department of Health and Human Services, Center for Disease Control and Prevention, *Pharyngitis (Strep Throat)*, (Sept. 16, 2016), available at <https://www.cdc.gov/groupastrep/diseases-hcp/strep-throat.html#resources> (last visited Jan. 31, 2018).

<sup>44</sup> U.S. Department of Health and Human Services, Center for Disease Control and Prevention, *Strep Throat*, available at <https://www.cdc.gov/groupastrep/diseases-public/strep-throat.html#complications> (last visited Feb. 2, 2018).

<sup>45</sup> John Mersch, MD, FAAP *Rapid Strep Test*, MedicineNet.Com (Aug. 23, 2016), [https://www.medicinenet.com/rapid\\_strep\\_test/article.htm](https://www.medicinenet.com/rapid_strep_test/article.htm) (last visited Jan. 31, 2018).

within eight minutes.<sup>46</sup> RADTs, in general, have high diagnostic accuracy, with tests using newer techniques providing the greatest accuracy.<sup>47</sup>

### III. Effect of Proposed Changes:

The bill amends the definition of the practice of the profession of pharmacy to expand the scope of practice for pharmacists to include testing for and treating influenza virus and streptococcal infections.

The bill creates s. 465.1895, F.S., to authorize a pharmacist to test and treat for the influenza virus and streptococcal infections within an established written protocol with a supervising physician licensed under chs. 458 or 459, F.S. Additionally, to be eligible to provide these services a pharmacist must:

- Complete an eight hour certification course approved by the board, in consultation with the Board of Medicine and the Board of Osteopathic Medicine, with curriculum concerning point-of-care testing for the influenza virus and streptococcal infections and the safe and effective treatment of the influenza virus and streptococcal infections;
- Maintain at least \$200,000 of professional liability insurance;
- Maintain, and make available, patient records for five years; and
- Obtain written approval of the pharmacy owner, if the pharmacist is acting as an employee of the pharmacy.

The bill provides that a supervising physician's decision to enter into a written protocol under this section is a professional decision and a person may not interfere with the physician's decision.

The bill authorizes the board to adopt rules establishing the requirements of the written protocol. The protocol must include:

- Any terms and conditions imposed by the supervising physician relating to testing for and treating the influenza virus and streptococcal infections;
- Appropriate terms and conditions relative to the pharmacist's training;
- Specific categories of patients that the supervising physician authorizes the pharmacist to test and treat;
- The supervising physician's instructions for the treatment of the influenza virus and streptococcal infections based on a patient's age, symptoms, and test results, including negative results;
- A process and schedule for the supervising physician to review the pharmacist's patient interactions and treatment;
- A process and schedule for the pharmacist to notify the supervising physician of a patient's condition, tests administered, test results, and course of treatment; and
- A process and schedule for the supervising physician to review the pharmacist's administration of vaccines.

---

<sup>46</sup> *Supra* note 44.

<sup>47</sup> W. L. Lean et al., *Rapid Diagnostic Tests for Group A Streptococcal Pharyngitis: A Meta-analysis*, PEDIATRICS Volume 134, Number 4, October 2014 available at

<http://pediatrics.aappublications.org/content/pediatrics/early/2014/09/02/peds.2014-1094.full.pdf> (last visited Jan. 31, 2018).

The bill requires the supervising physician to review the pharmacist's action.

Pharmacists who have been delegated the authority to test for and treat the influenza virus and streptococcal infections by a supervising physician must provide that physician with evidence of a current certification from the board.

The bill takes effect July 1, 2018.

#### **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:

Authorizing pharmacists to test and treat for the influenza virus and streptococcal infections might reduce the time from the occurrence of symptoms to treatment; and may reduce the cost to patients for obtaining these services without a doctor's office or emergency room visit.

Pharmacies may also experience increased revenue from this additional service.

C. Government Sector Impact:

The DOH may incur costs associated with requiring the board to approve certification programs, in consultation with the BOM and BOOM; and in adopting rules to establish the requirements for the written protocol between the pharmacist and supervising physician.

The DOH may experience a recurring increase in workload associated with the submission of written protocols between the pharmacists and supervising physician.

**VI. Technical Deficiencies:**

None.

**VII. Related Issues:**

The bill is silent regarding whether the eight hours of CE for the certification program may be part of the 30 hours of CE required for biennial license renewal. No ongoing CE is required. The authority to administer vaccines and epinephrine includes 20 hours of CE for certification and three hours for CE for each license renewal period.

**VIII. Statutes Affected:**

This bill substantially amends section 465.003, of the Florida Statutes.

This bill creates section 465.1895 of the Florida Statutes.

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

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

None.

**B. Amendments:**

None.