

**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 Health Policy

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BILL: CS/SB 1892

INTRODUCER: Health Policy Committee and Senator Burgess

SUBJECT: Administration of Vaccines

DATE: February 10, 2022

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

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Brown	Brown	HP	<b>Fav/CS</b>
2.			ED	
3.			RC	

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

COMMITTEE SUBSTITUTE - Substantial Changes

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**I. Summary:**

CS/SB 1892 expands the scope of practice of registered pharmacy technicians by authorizing a registered pharmacy technician, who meets specified requirements regarding education and training, to become certified to administer immunizations and vaccines to adults under the supervision of a licensed pharmacist who is also certified to administer immunizations and vaccines within the framework of an established protocol under a supervising physician.

The bill also updates the statutory list of immunizations and vaccines that pharmacists, registered pharmacy interns, and (under the bill) registered pharmacy technicians may become certified to administer.

The bill provides an effective date of July 1, 2022.

**II. Present Situation:**

**The Practice of Pharmacy**

The Board of Pharmacy (BOP), in conjunction with the Department of Health (DOH), regulates the practice of pharmacy pursuant to ch. 465, F.S.

### ***Pharmacist Licensure***

To be licensed as a pharmacist in Florida, a person must:<sup>1</sup>

- Complete an application and remit an examination fee;
- Be at least 18 years of age;
- Hold a degree from an accredited and approved school or college of pharmacy;<sup>2</sup>
- Have completed a BOP-approved internship; and
- Successfully complete the BOP-approved examination.

A pharmacist must complete at least 30 hours of BOP-approved continuing education during each biennial licensure renewal period.<sup>3</sup> Pharmacists who are certified to administer vaccines or epinephrine auto-injections must complete a three-hour continuing education course on the safe and effective administration of vaccines and epinephrine injections, as a part of their licensure renewal.<sup>4</sup>

### ***Scope of Pharmacy Practice***

In Florida, the practice of the profession of pharmacy includes:<sup>5</sup>

- Compounding, dispensing, and consulting concerning the contents, therapeutic values, and uses of a medicinal drug;
- Consultation concerning therapeutic values and interactions of patented or proprietary preparations;
- Monitoring a patient's drug therapy and assisting the patient in the management of his or her drug therapy;
- Reviewing, and making recommendations regarding the patient's drug therapy and health care status in communication with the patient's prescribing health care provider as authorized by the patient;
- Initiating, modifying, or discontinuing drug therapy for a chronic health condition under a collaborative pharmacy practice agreement;<sup>6</sup>
- Transmitting information from prescribers to their patients;
- Administering anti-psychotropic medications by injection;<sup>7</sup>
- Preparing prepackaged drug products in facilities holding Class III institutional facility permits;<sup>8</sup>
- Ordering and dispensing over-the-counter drugs approved by the U.S. Food and Drug Administration (FDA);<sup>9</sup>

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<sup>1</sup> Section 465.007, F.S. 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>2</sup> 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 BOP-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>3</sup> Section 465.009, F.S.

<sup>4</sup> Section 465.009(6), F.S.

<sup>5</sup> Section 465.003(13), F.S.

<sup>6</sup> Section 465.1865, F.S.

<sup>7</sup> Section 465.1893, F.S.

<sup>8</sup> A Class III institutional pharmacy are those pharmacies affiliated with a hospital. *See s. 465.019(2)(d), F.S.*

<sup>9</sup> Section 465.186, F.S.

- Ordering and dispensing within his or her professional judgment, subject to specified conditions:<sup>10</sup>
  - Certain oral analgesics for mild to moderate pain;
  - Anti-nausea preparations;
  - Certain antihistamines and decongestants;
  - Certain topical antifungal/antibacterial;
  - Topical anti-inflammatory preparations containing an amount of hydrocortisone not exceeding 2.5 percent;
  - Otic antifungal/antibacterial;
  - Salicylic acid;
  - Vitamins;
  - Ophthalmics;
  - Certain histamine H2 antagonists;
  - Acne products; and
  - Topical antivirals for herpes simplex infections of the lips.

#### ***Pharmacist Authorization to Administer Immunizations and Epinephrine Auto-Injections***

A pharmacist may be authorized to administer immunizations to adults, according to guidelines issued by the federal Centers for Disease Control and Prevention (CDC), and epinephrine auto-injections to address unforeseen allergic reactions, within the framework of an established protocol with a supervising physician. A pharmacist must first become certified to administer immunizations and vaccines, and, once certified, may administer immunizations and vaccines that are:<sup>11</sup>

- Listed in the CDC Adult Immunization Schedule as of April 30, 2021, or so listed after that date if authorized by BOP rule;
- Recommended by the CDC for international travel as of April 30, 2021, or so recommended after that date if authorized by BOP rule;
- Licensed for use in the United States, or authorized for emergency use, by the FDA as of April 30, 2021, or so licensed or authorized after that date if authorized by BOP rule; or
- Approved by the BOP in response to an emergency declared by the Governor.

#### ***Certification Requirements***

To be certified to administer vaccines, a pharmacist must:

- Enter into a written protocol with a supervising allopathic or osteopathic physician, and the protocol must:<sup>12</sup>
  - Specify the categories of patients and patient conditions for which the pharmacist may administer vaccines;
  - Be appropriate to the pharmacist's training and certification for administering the vaccine;
  - Outline the process and schedule for the review of the administration of vaccines by the pharmacist under the written protocol; and
  - Be submitted to the BOP;

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<sup>10</sup> Fla. Admin. Code R. 64B16-27.220

<sup>11</sup> Section 465.189(1), F.S.

<sup>12</sup> Section 465.189(8), F.S.

- Complete a BOP-approved vaccine administration certification program that consists of at least 20 hours of continuing education;<sup>13</sup>
- Pass an examination and demonstrate vaccine administration technique;<sup>14</sup>
- Maintain and make available patient records using the same standards for confidentiality and retention of such records as required by s. 456.057, F.S., and maintain the records for at least five years;<sup>15</sup> and
- Maintain at least \$200,000 of professional liability insurance.<sup>16</sup>

A certified pharmacist may administer epinephrine using an auto-injector delivery system within the framework of the established protocol under a supervising physician in order to address any unforeseen allergic reactions.

As of January 11, 2022, there were 15,675 pharmacists certified under Florida Statutes to administer immunizations and vaccines.<sup>17</sup>

### ***Pharmacist Vaccination of Children***

In 2021, the Legislature authorized a certified pharmacist to also administer influenza vaccines to children seven years of age or older if such administration is included in the written protocol with a supervising physician.<sup>18</sup>

### ***Pharmacy Interns***

To register with the state as a pharmacy intern, a person must be certified by the BOP as being enrolled in an intern program at an accredited school or college of pharmacy or as a graduate of an accredited school or college of pharmacy and not yet licensed as a pharmacist in Florida.<sup>19</sup> The DOH is required to register as a pharmacy intern a person so certified by the BOP.

For brevity, this analysis henceforth refers to registered pharmacy interns as “pharmacy interns” or “interns.”

A pharmacist is responsible for any delegated act performed by a pharmacy intern employed or supervised by the pharmacist.<sup>20</sup>

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<sup>13</sup> Section 465.189(7), F.S., Fla. Admin. Code R. 64B16-26.1031, provides more detail regarding subject matter that must be included in the certification course.

<sup>14</sup> *Id.*

<sup>15</sup> Section 456.057, F.S., requires certain health care practitioners to develop and implement policies, standards, and procedures to protect the confidentiality and security of medical records, provides conditions under which a medical record may be disclosed without the express consent of the patient, provides procedures for disposing of records when a practice is closing or relocating, and provides for enforcement of its provisions.

<sup>16</sup> Section 465.189(4), F.S.

<sup>17</sup> Department of Health, *2022 Agency Legislative Bill Analysis: HB 1209*, Jan. 28, 2022 (on file with the Senate Health Policy Committee).

<sup>18</sup> Section 465.189(2), F.S., as created in CS/CS/SB 768 (2021).

<sup>19</sup> Section 465.013, F.S.

<sup>20</sup> Fla. Admin. Code R. 64B16-27.430

To administer vaccines, a pharmacy intern must complete the same BOP-approved vaccine administration certification program as the pharmacist and also be supervised by a certified pharmacist, at a ratio of one pharmacist to one intern.<sup>21</sup>

Pharmacy interns are not authorized under Florida Statutes to administer immunizations or vaccines to children.

As of January 11, 2022, there were 3,635 pharmacy interns certified under Florida Statutes to administer immunizations and vaccines.<sup>22</sup>

### ***Pharmacy Technicians***

Pharmacy technicians assist pharmacists in dispensing medications and are accountable to a supervising pharmacist who is legally responsible for the care and safety of the patients served.<sup>23</sup> A person must register with the DOH to practice as a pharmacy technician. To register, an individual must:<sup>24</sup>

- Be at least 17 years of age;
- Submit an application and pay an application fee; and
- Complete a BOP-approved pharmacy technician training program.<sup>25</sup>

As of January 11, 2022, there were 57,521 registered pharmacy technicians in Florida.<sup>26</sup>

For brevity, this analysis henceforth refers to registered pharmacy technicians as “pharmacy technicians” or “technicians.”

A pharmacist is responsible for any delegated act performed by a pharmacy technician who is supervised by the pharmacist.<sup>27</sup>

A pharmacy technician must renew his or her registration biennially. For each renewal cycle, a pharmacy technician must complete 20 continuing education hours.<sup>28</sup>

### ***Pharmacy Technician Training Programs***

The BOP has preapproved certain training programs that have been accredited by certain accreditation agencies or provided by a branch of the U.S. Armed Forces.<sup>29</sup> The BOP may review and approve other training programs that do not meet the criteria for pre-approval. Such programs must be licensed by the Commission for Independent Education or equivalent licensing

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<sup>21</sup> *Supra* note 11.

<sup>22</sup> *Supra* note 17.

<sup>23</sup> Section 465.014(1), F.S.

<sup>24</sup> Section 465.014(2), F.S.

<sup>25</sup> An individual is exempt from the training program if he or she was registered as a pharmacy technician before January 1, 2011, and either worked as a pharmacy technician at least 1,500 hours under a licensed pharmacist or received certification from an accredited pharmacy technician program.

<sup>26</sup> *Supra* note 17.

<sup>27</sup> Section 465.014(1), F.S.

<sup>28</sup> Section 465.014(6), F.S.

<sup>29</sup> Fla. Admin. Code R. 64B16-26.351(1)-(2)

authority or be within the public school system of this state and offer a course of study that includes:

- Introduction to pharmacy and health care systems;
- Confidentiality;
- Patient rights and the federal Health Insurance Portability and Accountability Act;
- Relevant state and federal law;
- Pharmaceutical topics, including medical terminology, abbreviations, and symbols; medication safety and error prevention; and prescriptions and medication orders;
- Records management and inventory control, including pharmaceutical supplies, medication labeling, medication packaging and storage, controlled substances, and adjudication and billing;
- Interpersonal relations and ethics, including diversity of communications, empathetic communications, ethics governing pharmacy practice, patient and caregiver communications; and
- Pharmaceutical calculations.<sup>30</sup>

The training program must provide the BOP with educational and professional background of its faculty.<sup>31</sup> A licensed pharmacist or pharmacy technician with appropriate expertise must be involved with planning and instruction and must supervise learning experiences.<sup>32</sup>

The BOP may also review and approve employer-based pharmacy technician training programs. An employer-based program must be offered by a Florida-permitted pharmacy or affiliated group of pharmacies under common ownership.<sup>33</sup> The program must include 160 hours of training over a period of no more than six months and may be provided only to the employees of that pharmacy.<sup>34</sup> The employer-based training program must:

- Meet the same qualifications as required for non-employment based pharmacy technician training programs as indicated above;
- Provide an opportunity for students to evaluate learning experiences, instructional methods, facilitates, and resources;
- Ensure that self-directed learning experience, such as home study or web-based courses, evaluate the participant's knowledge at the completion of the learning experience; and
- Designate a person to assume responsibility for the pharmacy technician-training program.<sup>35</sup>

### ***Pharmacy Technician Scope of Practice***

A pharmacy technician may not engage in the practice of the profession of pharmacy; however, a licensed pharmacist may delegate those duties, tasks, and functions that do not fall within the definition of the practice of professional pharmacy.<sup>36</sup> The BOP specifies, by rule, certain acts that pharmacy technicians are prohibited from performing, which include:

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<sup>30</sup> Fla. Admin. Code R. 64B16-26.351(3)(b)

<sup>31</sup> Fla. Admin. Code R. 64B16-26.351(3)(e)

<sup>32</sup> *Id.*

<sup>33</sup> Fla. Admin. Code R. 64B16-26.351(4)

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

<sup>35</sup> *Id.*

<sup>36</sup> Section 465.014(1), F.S.

- Receiving new verbal prescriptions or any change in the medication, strength, or directions of an existing prescription;
- Interpreting a prescription or medication order for therapeutic acceptability and appropriateness;
- Conducting a final verification of dosage and directions;
- Engaging in prospective drug review;
- Monitoring prescription drug usage;
- Transferring a prescription;
- Overriding clinical alerts without first notifying the pharmacist;
- Preparing a copy of a prescription or reading a prescription to any person for the purpose of providing reference concerning treatment of the patient for whom the prescription was written;
- Engaging in patient counseling; or
- Engaging in any other act that requires the exercise of a pharmacist's professional judgment.<sup>37</sup>

A pharmacy technician must wear an identification badge with a designation of “registered pharmacy technician” and identify herself or himself as being registered with the state as a pharmacy technician in telephone conversations or other forms of communication that pertain to pharmacy care.<sup>38</sup>

Pharmacy technicians are not authorized under Florida Statutes to administer immunizations or vaccines to anyone.

### **Pharmacist Supervision of Pharmacy Technicians**

A licensed pharmacist must directly supervise the performance of a pharmacy technician<sup>39</sup> and is responsible for acts performed by technicians under his or her supervision.<sup>40</sup> A pharmacist may use technological means to communicate with or observe a pharmacy technician who is performing delegated tasks.<sup>41</sup>

Florida law prohibits a pharmacist from supervising more than one pharmacy technician at a time, unless otherwise permitted by guidelines adopted by the BOP.<sup>42</sup> The guidelines include the following restrictions:<sup>43</sup>

- A pharmacist engaging in sterile compounding may supervise up to three pharmacy technicians.

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<sup>37</sup> Fla. Admin. Code R. 64B16-27.420(2)

<sup>38</sup> Fla. Admin. Code R. 64B16-27.100(2)

<sup>39</sup> Direct supervision means supervision by a pharmacist who is on the premises at all times the delegated tasks are being performed; who is aware of delegated tasks being performed; and who is readily available to provide personal assistance, direction, and approval throughout the time the delegated tasks are being performed (Fla. Admin. Code R. 64B16-27.4001(2)(a))

<sup>40</sup> Fla. Admin. Code R. 64B16-27.1001(7)

<sup>41</sup> Fla. Admin. Code R. 64B16-27.4001(2)(b)

<sup>42</sup> Section 465.014(1), F.S.

<sup>43</sup> Fla. Admin. Code R. 64B16-27.410

- A pharmacist who is not engaged in sterile compounding may supervise up to six pharmacy technicians.
- In a pharmacy that does not dispense medicinal drugs, a pharmacist may supervise up to eight pharmacy technicians, as long as the pharmacist or pharmacy is not involved in sterile compounding.
- In a pharmacy that dispenses medicinal drugs in a physically separate area<sup>44</sup> of the pharmacy from which medicinal drugs are not dispensed, a pharmacist may supervise up to eight pharmacy technicians.

### **Immunizations – U. S. Department of Health and Human Services**

The Office of Infectious Disease and HIV/AIDS Policy (Office), in the U.S. Department of Health and Human Services (HHS), oversees the National Vaccine Program, which provides strategic leadership for vaccine and immunization activities among federal agencies and to the states and other stakeholders, to help reduce the burden of preventable infectious diseases. The Office's services include the National Vaccine Strategic Plans (NVSP) and National Vaccine Advisory Committee (NVAC).<sup>45</sup> The NVSP for 2021-2025, released January 19, 2021, is the newest roadmap to coordinate vaccine development and use and is based on the NVAC's recommendations that revise the Standards for Adult Immunization Practices.<sup>46</sup>

#### ***The CDC's Immunization Recommendations***

The CDC, under the Secretary of HHS,<sup>47</sup> sets the adult and childhood immunization and vaccination schedules based on the recommendations from the Advisory Committee on Immunization Practices (ACIP).<sup>48</sup> The ACIP works with professional organizations, such as the American Academy of Pediatrics, the American Academy of Family Physicians, the American College of Obstetricians and Gynecologists, and the American College of Physicians, to develop annual childhood and adult immunization schedules.<sup>49</sup> The CDC reviews the ACIP's recommendations and, if approved, they are published as the CDC's official recommendations for immunizations for the population.<sup>50</sup> The current recommended immunization schedule for persons 18 years of age and older includes:<sup>51</sup>

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<sup>44</sup> A "physically separate area" is a part of the pharmacy that is separated by a permanent wall or other barrier, which restricts access between the two areas.

<sup>45</sup> U.S. Department of Health & Human Services, *Vaccines & Immunizations*, available at <https://www.hhs.gov/vaccines/index.html> (last visited Feb. 3, 2022).

<sup>46</sup> U.S. Department of Health & Human Services, *Vaccines National Strategic Plan*, available at <https://www.hhs.gov/vaccines/vaccines-national-strategic-plan/index.html> (last visited Feb. 3, 2022).

<sup>47</sup> U.S. Department of Health & Human Service, HHS Leadership, *Office of the Secretary Leaders*, available at <https://www.hhs.gov/about/leadership/index.html#opdiv> (last visited Feb. 3, 2022).

<sup>48</sup> Center for Disease Control and Prevention, Advisory Committee on Immunization Practices (ACIP), *Role of the Advisory Committee on Immunization Practices in CDC's Vaccine Recommendations*, available at <https://www.cdc.gov/vaccines/acip/committee/role-vaccine-recommendations.html> (last visited Mar. Feb. 3, 2022).

<sup>49</sup> Centers for Disease Control and Prevention, Advisory Committee on Immunization Practices (ACIP), *ACIP Recommendations*, available at <https://www.cdc.gov/vaccines/acip/recommendations.html> (last visited Feb. 3, 2022).

<sup>50</sup> *Id.*

<sup>51</sup> Centers for Disease Control and Prevention, *Recommended Adult Immunization Schedule for Ages 19 Years or Older, United States, 2020*, available at <https://www.cdc.gov/vaccines/schedules/hcp/imz/adult.html> (last visited Feb. 3, 2022). The schedule provides the recommended age, as well as the administration intervals for vaccines that require multiple doses. Some vaccines are recommended only for populations with special situations that put those populations at higher risk.



- Influenza (annually) (IIV, RIV or LAIV);
- Measles, mumps, rubella (MMR) (if patient is born in 1957 or later);
- Zoster (ZVL) or (RZV);
- Pneumococcal polysaccharide (PPSV23);
- Haemophilus influenza Type B (Hib);
- Hepatitis B (HepB);
- Varicella (VAR) (if patient is born 1980 or later);
- Tetanus, diphtheria, pertussis (Tdap or Td) (booster every 10 years);
- Human papillomavirus (HPV);
- Pneumococcal conjugate (PCV13);
- Hepatitis A (HepA);
- Meningococcal A, C, W, Y (MenACWY); and
- Meningococcal B (MenB).

New vaccines are considered for addition to the schedule after being licensed by the FDA.<sup>52</sup> Not all newly licensed vaccines are added to the schedule. Some licensed vaccines are only recommended for people who are traveling to areas where certain vaccine-preventable diseases occur, such as yellow fever, cholera, dengue, Japanese encephalitis, plague, rabies, smallpox, and typhoid.<sup>53</sup>

### ***CDC Health Information for International Travel***

*The CDC's Health Information for International Travel*, commonly called the Yellow Book, is published biennially by the CDC as a reference to advise international travelers about health risks.<sup>54</sup> The Yellow Book includes the CDC's most current travel health guidelines, including pre-travel vaccine recommendations and destination-specific health advice. The Yellow Book is authored by subject-matter experts both within and outside the CDC and its guidelines are evidence-based and supported by best practices.<sup>55</sup>

Certain vaccinations are recommended by the CDC to protect international travelers from illness and prevent the importation of infectious diseases across international borders. The Yellow Book recommends that persons traveling internationally should be up to date on all CDC-recommended vaccines. Additionally, the Yellow Book recommends additional vaccinations based on a traveler's destination and other factors.

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<sup>52</sup> College of Physicians of Philadelphia, *The History of Vaccines: The Development of the Immunization Schedule*, available at <http://www.historyofvaccines.org/content/articles/development-immunization-schedule> (last visited Feb. 3, 2022).

<sup>53</sup> *Id.* For a complete list of FDA-licensed vaccines, see U.S. Food & Drug Administration, *Vaccines Licensed for Use in the United States*, (last rev. Jan. 1, 2022), available at <https://www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states> (last visited Feb. 3, 2022).

<sup>54</sup> Centers for Disease Control and Prevention. *CDC Yellow Book 2020: Health Information for International Travel*, available at <https://wwwnc.cdc.gov/travel/page/yellowbook-home> (last visited Feb. 3, 2022).

<sup>55</sup> *Id.*

## **Florida's Immunization Policy**

### ***Communicable Disease Prevention and Control***

The DOH is responsible for the state's public health system. As part of fulfilling its public health mission, the DOH is responsible for conducting a communicable disease prevention and control program. A communicable disease is any disease caused by the transmission of a specific infectious agent, or its toxic products, from an infected person, animal, or the environment to a susceptible host, either directly or indirectly.<sup>56</sup>

### ***Immunizations for Adults Recommended by the DOH***

The DOH recommends the following vaccines for adults:<sup>57</sup>

- Human Papillomavirus (HPV);
- Tetanus-diphtheria-pertussis (Tdap);
- Tetanus-diphtheria (Td) booster every ten years;
- Hepatitis A;
- Meningococcal;
- Measles-mumps-rubella (MMR);
- Varicella (chickenpox);
- Seasonal influenza;
- Zoster (shingles); and
- Pneumococcal.

### ***Required Immunizations for Children***

Each school district board and non-public school governing body is required to ensure that every child entering school in kindergarten through grade 12 must present or have on file a Florida Certificate of Immunization (FCI) before entering or enrolling in school.<sup>58</sup> Children entering, attending, or transferring to Florida public or non-public schools, kindergarten through grade 12, must have on file as part of their permanent school record<sup>59</sup> an FCI documenting that they have had the following immunizations:<sup>60</sup>

- Four or five doses of DTaP (Diphtheria-tetanus-acellular pertussis);
- Four or five doses of IPV (Inactivated polio vaccine);
- Two doses of MMR (Measles-mumps-rubella);
- Three doses of Hep B (Hepatitis B);
- One Tdap (Tetanus-diphtheria-acellular pertussis);
- Two doses of Varicella (unless there is a history of varicella disease documented by a health care provider); and

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<sup>56</sup> Section 381.003(1), F.S.

<sup>57</sup> The Florida Department of Health, *Don't Miss Opportunities to Vaccinate!*, available at <http://www.floridahealth.gov/programs-and-services/immunization/publications/documents/opportunities-to-vaccinate-adult.pdf> (last visited Feb. 3, 2022).

<sup>58</sup> Section 1003.22(4), F.S.

<sup>59</sup> *Id.*

<sup>60</sup> See also Department of Health, *School Immunization Requirements* (last modified Mar. 8, 2021), available at <http://www.floridahealth.gov/programs-and-services/immunization/children-and-adolescents/school-immunization-requirements/index.html#childcare> (last visited Feb. 3, 2022).

- If entering a public or non-public school in seventh grade or later, an additional dose of Tdap (Tetanus-diphtheria-acellular pertussis).

Private health care providers may grant a temporary medical exemption (TME), documented on the FCI form,<sup>61</sup> for those who are in the process of completing any necessary immunizations. The TME incorporates an expiration date after which the exemption is no longer valid, and the immunizations must be completed before or at that time. A permanent medical exemption may be granted if a child cannot be fully immunized due to medical reasons. In such case, the child's physician must state in writing the reasons for the exemption on the FCI form, based on valid clinical reasoning or evidence.<sup>62</sup>

A request for a religious exemption from immunizations requires the parent or guardian to provide the school or facility with a religious exemption immunization form.<sup>63</sup> The form is issued only by county health departments and only for children who are not immunized because of the family's religious tenets or practices. Exemptions for personal or philosophical reasons are not permitted under Florida law.<sup>64</sup>

### **Access to Vaccines via Pharmacies During the COVID-19 Pandemic**

#### ***State Emergency Action to Authorize Pharmacists and Interns to Vaccinate Children***

On March 9, 2020, Governor Ron DeSantis issued Executive Order 20-52 declaring a state of emergency for the entire state of Florida as a result of COVID-19, allowing for the suspension of certain statutes and rules that prevent, hinder, or delay any necessary action in dealing with the state of emergency caused by COVID-19.<sup>65</sup>

On October 1, 2020, the State Surgeon General issued an emergency order,<sup>66</sup> pursuant to authority granted by Executive Order No. 20-52, suspending the provision of s. 465.189(1), F.S., to the extent necessary to authorize a certified pharmacist, or a certified pharmacy intern, to administer vaccines approved or licensed by the FDA to individuals under 18 years of age if the vaccine were approved for use in individuals under 18 years of age and upon receipt of a medical

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<sup>61</sup> Department of Health, Form DH-680, *Florida Certification of Immunizations* (Jul. 2010) (on file with Senate Health Policy Committee).

<sup>62</sup> Department of Health, *Exemptions from Required Immunizations*, (last updated Sept. 18, 2019), available at <http://www.floridahealth.gov/programs-and-services/immunization/children-and-adolescents/immunization-exemptions/index.html> (last visited Feb. 3, 2022).

<sup>63</sup> Department of Health, Form DH 681, *Religious Exemption From Immunization*, (Jul. 2008) puts a parent or guardian on notice that any child not immunized against a communicable disease that has been declared a communicable disease emergency will be temporarily excluded from school until such time as the county health department says the child can return. (on file with the Senate Health Policy Committee).

<sup>64</sup> Department of Health, Immunization Section, Bureau of Communicable Diseases, *Immunization Guidelines, Florida Schools, Childcare Facilities and Family Daycare Homes* (Mar. 2013), available at <http://www.floridahealth.gov/%5C/programs-and-services/immunization/schoolguide.pdf> (last visited Feb. 3, 2022).

<sup>65</sup> State of Florida, Office of the Governor, *Executive Order*, Number 20-52, available at [https://www.flgov.com/wp-content/uploads/orders/2020/EO\\_20-52.pdf](https://www.flgov.com/wp-content/uploads/orders/2020/EO_20-52.pdf) (last visited Feb. 3, 2022).

<sup>66</sup> State of Florida, Department of Health, State Surgeon General, *Emergency Order*, (Oct. 1, 2020) DOH No. 20-014, available at <https://floridahealthcovid19.gov/wp-content/uploads/2020/10/DOH-Emergency-Order-No-20-014.pdf> (last visited Feb. 3, 2022).

consent for the minor signed by a person who has the power to consent to the minor's medical care or treatment.

The Surgeon General's emergency order also authorized such practitioners to order and administer vaccines according to the CDC's ACIP immunization schedules and any vaccine approved by the FDA to immunize individuals against COVID-19.

This emergency order remained in effect until the expiration of all extensions of Executive Order No. 20-52 on June 26, 2021.

### ***Federal Authorization for Pharmacy Technicians to Vaccinate Children and Adults***

On January 31, 2020, HHS Secretary Alex M. Azar II issued an official determination that, due to confirmed cases of COVID-19, a public health emergency existed and had existed since January 27, 2020, nationwide.<sup>67</sup> That declaration has been renewed eight times, most recently on January 14, 2022, by current HHS Secretary Xavier Becerra, and is still in effect as of this writing.<sup>68</sup> The current renewal became effective January 16, 2022, and will expire after 90 days unless renewed again.

On October 20, 2020, HHS issued guidance<sup>69</sup> under the public health emergency regarding the administration of vaccines to children and adults by pharmacy interns and technicians during the COVID-19 pandemic.

Under the October 20, 2020, guidance, HHS authorized pharmacy interns and technicians, acting under the supervision of a qualified pharmacist and subject to satisfaction of specified requirements, to administer FDA-authorized or FDA-licensed COVID-19 vaccines to persons three years old or older and to administer FDA-authorized or FDA-licensed vaccines that are ACIP-recommended to persons three years old through 18 years old, according to ACIP's standard immunization schedule. The guidance also provides that such interns and technicians are "covered persons" under the federal Public Readiness and Emergency Preparedness Act (PREP Act).<sup>70</sup>

The guidance requires pharmacy interns and technicians who are not authorized to administer vaccines to children and adults by their licensing state, to satisfy a set of requirements before administering vaccines under the guidance, including:

- The vaccination must be ordered by the supervising pharmacist.

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<sup>67</sup> U.S. Dept. of Health and Human Services, *Determination that a Public Health Emergency Exists*, Jan. 31, 2020, available at: <https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx> (last visited Feb. 2, 2022).

<sup>68</sup> U.S. Dept. of Health and Human Services, *Renewal of Determination that a Public Health Emergency Exists*, Jan. 14, 2022, available at: <https://aspr.hhs.gov/legal/PHE/Pages/COVID19-14Jan2022.aspx> (last visited Feb. 2, 2022).

<sup>69</sup> U.S. Dept. of Health and Human Services, *Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID-19 Vaccines, and COVID-19 Testing*, Oct. 20, 2020, available at: <https://www.hhs.gov/sites/default/files/prep-act-guidance.pdf> (last visited Feb. 2, 2022).

<sup>70</sup> The PREP Act of 2005 authorizes the Secretary of HHS to issue a declaration to provide liability immunity to certain individuals and entities against any claim of loss caused by, arising out of, relating to, or resulting from the manufacture, distribution, administration, or use of medical countermeasures, except for claims involving "willful misconduct" as defined in the PREP Act. Under the PREP Act, a declaration may be amended as circumstances warrant.

- The supervising pharmacist must be readily and immediately available to an immunizing pharmacy technician.
- In the case of a COVID-19 vaccine, the vaccination must be ordered and administered according to ACIP's COVID-19 vaccine recommendation(s).
- A pharmacy technician or intern must complete a practical training program that is approved by the Accreditation Council for Pharmacy Education (ACPE).<sup>71</sup> This training program must include hands-on injection technique and the recognition and treatment of emergency reactions to vaccines.
- A pharmacy technician or intern must have a current certificate in basic cardiopulmonary resuscitation.
- A pharmacy technician must complete a minimum of two hours of ACPE-approved, immunization-related continuing pharmacy education during his or her state licensing renewal period.
- The pharmacy technician or intern must, if the patient is 18 years of age or younger, inform the patient and the adult caregiver accompanying the patient of the importance of a well-child visit with a pediatrician or other licensed primary-care provider and refer patients as appropriate.

### ***Preemption of State or Local Law***

The HHS guidance further provides that its authorization described above preempts any state or local law that prohibits or effectively prohibits those who satisfy the guidance's requirements from administering COVID-19 or routine childhood vaccines according to the parameters found in the guidance.

Therefore, even though Florida law does not authorize pharmacy technicians to administer vaccines to anyone, and does not authorize pharmacy interns to administer vaccines to children, the HHS guidance prevails, and such interns and technicians meeting the requirements found in the guidance are federally authorized to vaccinate children and adults under the guidance despite Florida law to the contrary, until the HHS authority is terminated.

### ***Participation by Pharmacies and Pharmacy Technicians***

Only ten states currently allow pharmacy technicians to administer immunizations or vaccines under state regulatory authority, with varying requirements for training and supervision.<sup>72</sup> Florida is not among those states. However, with the HHS guidance, pharmacies nationwide have indicated a willingness to participate and utilize the federal authority for pharmacy technicians found in the guidance, with several national retail pharmacies encouraging the issuance of the guidance, according to Forbes Magazine, and one indicating its national

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<sup>71</sup> The ACPE sets standards for the education of pharmacists to prepare them for the delivery of pharmacist-provided patient care. The ACPE is recognized by the U.S. Dept. of Education as the national agency for the accreditation of professional degree programs in pharmacy. The ACPE also serves as the national agency for the accreditation of providers of continuing education. In collaboration with the American Society of Health-System Pharmacists, the ACPE accredits pharmacy technician education and training programs.

<sup>72</sup> *Supra* note 17.

workforce of 60,000 pharmacy technicians would be available, plus an additional 10,000 newly-hired technicians.<sup>73</sup>

### ***Pharmacy Technician Supervisory Ratio***

The HHS guidance authorizes pharmacy technicians to administer vaccines under the supervision of a qualified pharmacist but does not speak to how many pharmacy technicians may be supervised by a single pharmacist at one time during such vaccinations.

Under BOP rules, on most occasions, a Florida-licensed pharmacist is authorized to supervise up to six pharmacy technicians simultaneously. Under that authority, coupled with authority granted in the HHS guidance, a single pharmacist in Florida might currently be supervising up to six pharmacy technicians simultaneously while the pharmacy technicians are administering vaccines to children and adults, even though that six-to-one ratio was adopted by the BOP with the understanding that pharmacy technicians are not authorized to administer vaccines under any circumstances.<sup>74</sup>

### **Florida’s Board of Medicine and Board of Osteopathic Medicine**

The DOH is supported by numerous boards that oversee the regulation of various types of health care practitioners licensed by the state. Section 456.001(1), F.S., defines “board” as any board or commission, or other statutorily created entity to the extent such entity is authorized to exercise regulatory or rulemaking functions within the DOH. The Board of Medicine is created in s. 458.307, F.S., for the primary purpose of regulating and disciplining medical doctors and other practitioners licensed under ch. 458, F.S. The Board of Osteopathic Medicine is created in s. 459.004, F.S., for the primary purpose of regulating and disciplining osteopathic physicians and other practitioners licensed under ch. 459, F.S.

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

CS/SB 1892 expands the scope of practice of pharmacy technicians by authorizing a pharmacy technician, who meets specified requirements regarding education and training, to become certified to administer immunizations and vaccines to adults under the supervision of a licensed pharmacist who is also certified to administer immunizations and vaccines within the framework of an established protocol under a supervising physician.

**Section 1** of the bill creates s. 465.014(7), F.S., to require that a pharmacy technician seeking to administer immunizations and vaccines under s. 465.189, F.S., must be certified to do so pursuant to a certification program approved by the BOP, in consultation with the Board of Medicine and the Board of Osteopathic Medicine. The certification program must have at least 10 hours of immunization-related training approved by the BOP which must, at a minimum, have a curriculum of instruction concerning the safe and effective administration of immunizations

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<sup>73</sup> Bruce Jaspén, Forbes.com, *In Boost To CVS And Walgreens, U.S. Expands Covid-19 Vaccination Powers To Pharmacy Techs*, Nov. 2, 2020, available at: <https://www.forbes.com/sites/brucejapsen/2020/11/02/in-boost-to-cvs-and-walgreens-us-expands-covid-19-vaccination-powers-to-pharmacy-techs/> (last visited Feb. 2, 2022).

<sup>74</sup> The current version of Fla. Admin. Code R. 64B16-27.410, which allows for the six-to-one ratio, became effective January 16, 2019.

and vaccines that pharmacy technicians may become certified to administer under the bill, including, but not limited to, potential allergic reactions, first-aid training, and CPR training.

The bill also requires that, as a condition of registration renewal, a pharmacy technician seeking to administer immunizations and vaccines under s. 465.189, F.S., must complete at least two hours of continuing education approved by the BOP relating to the technician certification program training, in addition to the biennial continuing education otherwise required for renewal.

**Section 2** of the bill amends s. 465.189, F.S., to add pharmacy technicians to the list of pharmacy practitioners who may become certified to administer immunizations and vaccines. Under current law, only pharmacists and pharmacy interns are so authorized.

The bill also changes the dates of certain federal immunization schedules, recommendations, licenses, and authorizations pertaining to the immunizations and vaccines that Florida pharmacy practitioners may become certified to administer, specifically those that are:

- Listed in the CDC Adult Immunization Schedule as of March 11, 2022, (instead of April 30, 2021, as in current law)<sup>75</sup> or so listed after that date if authorized by BOP rule;
- Recommended by the CDC for international travel as of March 11, 2022, (instead of April 30, 2021, as in current law) or so recommended after that date if authorized by BOP rule; and
- Licensed for use in the United States, or authorized for emergency use, by the FDA as of March 11, 2022, (instead of April 30, 2021, as in current law) or so licensed or authorized after that date if authorized by BOP rule.

The bill provides that a certified pharmacy intern or technician who administers an immunization or vaccine must be supervised by a certified pharmacist at a ratio of one pharmacist to one intern or technician.

The bill revises the requirements for a pharmacy practitioner to become certified to administer immunizations and vaccines by requiring pharmacy technicians, in order to become certified, to complete immunization-related training and continuing education as specified in s. 465.014(7), F.S., which is created in section 1 of the bill.

### **Other Provisions**

The bill makes technical revisions and clarifications to existing statutory language found in ss. 465.014 and 465.189, F.S.

The bill provides an effective date of July 1, 2022.

## **IV. Constitutional Issues:**

### **A. Municipality/County Mandates Restrictions:**

None.

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<sup>75</sup> April 30, 2021, was day 60 of the 2021 Regular Session of the Legislature. March 11, 2022, is day 60 of the 2022 Regular Session of the Legislature.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

**V. Fiscal Impact Statement:**

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

The bill might have the effect of making immunizations and vaccines more accessible and convenient for adults in Florida after the expiration of the HHS guidance that currently authorizes pharmacy technicians to administer vaccines to both children and adults.

The bill could allow Florida pharmacies to maintain a portion of the revenue stream they might currently be experiencing under the HHS guidance that authorizes pharmacy technicians to administer vaccines, despite state law to the contrary, assuming the COVID-19 pandemic eventually wanes and the federal authorization expires. Without expanding the scope of pharmacy technicians in state law to include the administration of vaccines, such a revenue stream, if any, will disappear altogether after the COVID-19 national public health emergency is terminated, along with the HHS guidance.

C. Government Sector Impact:

The DOH advises that, because the bill requires a pharmacy technician to apply to the BOP to become certified to administer immunizations and vaccines, and based on the population of pharmacy technicians in Florida (57,521), the likely increase in requests for certification will result in a significant impact to existing DOH staffing allocations, requiring additional staff to implement the bill's provisions and timely manage ongoing certification requests.<sup>76</sup>

The DOH further advises that:

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<sup>76</sup> *Supra* note 17.



- The DOH will be required to update applications and related electronic licensing systems to accommodate the new certification requirement.
- The BOP will be required to complete rulemaking to revise the existing application forms and to adopt language specific to the certification process.
- A communications plan will need to be developed by the DOH to ensure all information on its website reflects the bill's provisions, that affected parties are notified of the change in law, and to ensure personnel are trained to provide accurate information.
- The DOH will be required to update the pharmacy technician registration renewal application and associated electronic application systems and complete rulemaking to adopt the new forms.

The DOH estimates the bill creates a recurring negative fiscal impact of \$156,727 and a nonrecurring negative fiscal impact of \$13,947, which includes three full-time-equivalent positions the department believes it will need to implement the bill.<sup>77</sup> In providing this estimate, the DOH did not indicate whether general revenue will be required or whether applicable trust fund revenues are sufficient to cover these costs.

#### **VI. Technical Deficiencies:**

None.

#### **VII. Related Issues:**

None.

#### **VIII. Statutes Affected:**

This bill substantially amends the following sections of the Florida Statutes: 465.014, 465.189.

#### **IX. Additional Information:**

- A. **Committee Substitute – Statement of Substantial Changes:**  
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

##### **CS by Health Policy on February 10, 2022:**

The CS modifies the education and training requirements that pharmacy technicians must meet before being certified by the BOP to administer vaccines and immunizations. The CS requires 10 hours of training, as opposed to 20 hours in the underlying bill. The CS also specifies that the training must include, but not be limited to, potential allergic reactions, first-aid, and CPR training, and be approved by the BOP, while the underlying bill required training to be approved by the BOP or the ACPE and specified the training must include, but not be limited to, potential allergic reactions. Likewise, the CS requires the related continuing education for pharmacy technicians must be approved by the BOP while the underlying bill allowed the continuing education to be approved by the BOP or the ACPE.

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<sup>77</sup> *Id.*

B. Amendments:

None.

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This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.

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