

**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: SB 768

INTRODUCER: Senator Baxley

SUBJECT: Immunizations

DATE: February 16, 2021

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

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Rossitto Van Winkle	Brown	HP	<b>Favorable</b>
2.	_____	_____	CF	_____
3.	_____	_____	RC	_____

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**I. Summary:**

SB 768 expands the scope of authority for certified pharmacists and pharmacy interns to administer vaccines within the framework of an established protocol with a supervising physician.

Under the bill, pharmacists and pharmacy interns are authorized to administer vaccines to persons six years of age or older, as opposed to current law which limits such administration to adults. To administer vaccines to children, the bill requires the pharmacist or intern to obtain a medical consent form for minors, with a notice that the parent or guardian may opt-out from the child's information being reported to the statewide immunization registry. The bill requires pharmacists and pharmacy interns to either report the child's vaccination data to the registry or send a completed opt-out form.

The bill authorizes pharmacists and pharmacy interns to administer to persons six years of age or older, under the protocol, any immunization or vaccine that is:

- Listed in the federal Centers for Disease Control and Prevention's (CDC) Adult Immunization Schedule, for adult patients;
- Listed in the CDC's Child and Adolescent Schedule, for patients who are children;
- Recommended by the CDC for international travel; or
- Approved by the Board of Pharmacy (BOP) in response to a state of emergency declared by the Governor.

The bill provides an effective date of July 1, 2021.

## II. Present Situation:

### 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>1</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>2</sup>

#### *The Centers for Disease Control and Prevention's Immunization Recommendations*

The CDC, under the Secretary of HHS,<sup>3</sup> sets the adult and childhood immunization and vaccination schedules based on the recommendations from the Advisory Committee on Immunization Practices (ACIP).<sup>4</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>5</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>6</sup> The current recommended immunization schedule for persons 18 years of age and older includes:<sup>7</sup>

- 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);

<sup>1</sup> U.S. Department of Health & Human Services, *Vaccines & Immunizations*, available at <https://www.hhs.gov/vaccines/index.html> (last visited Feb. 4, 2021).

<sup>2</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. 4, 2021).

<sup>3</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. 4, 2021).

<sup>4</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 Feb. 4, 2021).

<sup>5</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. 4, 2021).

<sup>6</sup> *Id.*

<sup>7</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. 4, 2021). 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.

- 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 Food and Drug Administration (FDA).<sup>8</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>9</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>10</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>11</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.<sup>12</sup> Additionally, the Yellow Book recommends additional vaccinations based on a traveler's destination and other factors.

### **Florida's Immunization Policy**

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

The Department of Health (DOH) is responsible for the state's public health system.<sup>13</sup> 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>14</sup>

The DOH communicable disease program includes, but need not be limited to, programs for the prevention and control of:

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<sup>8</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. 4, 2021).

<sup>9</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. Apr. 24, 2020), available at <https://www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states> (last visited Feb. 4, 2021).

<sup>10</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. 1, 2021).

<sup>11</sup> *Id.*

<sup>12</sup> *Supra*, note 10.

<sup>13</sup> Section 381.001, F.S.

<sup>14</sup> Section 381.003(1), F.S.

- Tuberculosis;
- Human immunodeficiency virus (HIV) infection;
- Acquired Immune Deficiency Syndrome (AIDS);
- Sexually transmissible diseases;
- Communicable diseases of public health significance; and
- Vaccine-preventable diseases,<sup>15</sup> including programs to immunize school children<sup>16</sup> and the development of an automated, electronic, and centralized database or registry for immunization records.<sup>17</sup>

The DOH may adopt rules related to the prevention and control of communicable diseases and the administration of the immunization registry. Such rules may include procedures for:<sup>18</sup>

- Investigating disease;
- Timeframes for reporting disease;
- Definitions;
- Procedures for managing specific diseases;
- Requirements for follow-up reports on disease exposure; and
- Procedures for providing access to confidential information necessary for disease investigations.

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

The DOH recommends the following vaccines for adults:<sup>19</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

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<sup>15</sup> Measles, mumps, rubella, pertussis, diphtheria, tetanus, polio, varicella, pneumococcal disease, hepatitis A, hepatitis B, influenza, meningococcal and Haemophilus influenza type b (Hib) are all preventable by vaccine. See Department of Health, *Vaccine Preventable Diseases*, available at <http://www.floridahealth.gov/diseases-and-conditions/vaccine-preventable-disease/index.html> (last visited Feb. 1, 2021).

<sup>16</sup> See s. 1003.22(3)-(11), F.S.

<sup>17</sup> Section 381.003(1), F.S.

<sup>18</sup> Section 381.003(2), F.S.

<sup>19</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. 1, 2021).

Certificate of Immunization (FCI) before entering or enrolling in school.<sup>20</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>21</sup> an FCI documenting that they have had the following immunizations:<sup>22</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
- 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>23</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>24</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>25</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>26</sup>

### ***The DOH Immunization Registry (Florida SHOTS) for Children***

The DOH must ensure that all children are immunized against vaccine-preventable diseases and be included in the immunization registry, for the purpose of enhancing the DOH's immunization

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<sup>20</sup> Section 1003.22(4), F.S.

<sup>21</sup> *Id.*

<sup>22</sup> See also Department of Health, *School Immunization Requirements* (last modified Aug. 19, 2016), available at <http://www.floridahealth.gov/programs-and-services/immunization/children-and-adolescents/school-immunization-requirements/index.html#childcare> (last visited Feb. 4, 2021).

<sup>23</sup> Department of Health, Form DH-680, *Florida Certification of Immunizations* (Jul. 2010) (on file with Senate Health Policy Committee).

<sup>24</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. 8, 2021).

<sup>25</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>26</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. 5, 2021).

activities and improve immunization for all children. Florida's State Health Online Tracking System (SHOTS) is the free, statewide, centralized online immunization registry that assists healthcare providers, schools, and parents keep track of immunization records.<sup>27</sup> The program seeks to ensure a cause-and-effect response by monitoring immunization levels in vulnerable populations throughout the state, thereby contributing to strategies to attain and sustain high immunization levels.

The DOH immunization registry allows for immunization records to be electronically available to entities that are required by law to have such records, including schools and licensed child care facilities.<sup>28</sup>

Currently only allopathic and osteopathic physicians and nurses who administer vaccinations to children from birth to 18 years of age, or to college or university students who are 18 to 23 years of age at student health center or clinic, are required to report certain vaccination data to the immunization registry, unless the parents, guardian, or the college or university student opts-out.<sup>29</sup>

To be excluded from the registry, the parent or guardian of the child birth through age 17, must sign a DOH form, obtained from the DOH or the child's health care provider. The parent or guardian must provide the opt-out form to the health care practitioner at the time of the immunization. The health care practitioner must then submit the form to the DOH; or the parent or guardian may submit the opt-out form directly. Any records or identifying information pertaining to the child must be removed from the registry if the parent or guardian opts-out. In addition, each consent form for the immunizations of the child must contain a notice stating that the parent or guardian may refuse to have the child included in the immunization registry.<sup>30</sup>

A college or university student who is 18 to 23 years old, who obtains an immunization at a student health center or clinic, may also opt-out of the immunization registry by signing a form obtained from the DOH, health center, or clinic which indicates that he or she does not want to be included. The student must provide the opt-out form to the health center or clinic at the time of the immunization. The health center or clinic must submit the form to the DOH; or the student may submit the form directly. Any records or identifying information pertaining to the college or university student must be redacted from the registry if the student has opted-out of the immunization registry.<sup>31</sup>

Vaccination data for students in other age ranges may also be submitted to the immunization registry but only if the student consents to the data being included. The uploading of data from existing automated systems is an acceptable method for updating immunization information into

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<sup>27</sup> Department of Health, Providing Records to Patients, *Deliver Accurate, Timely Records*, available at <http://www.floridahealth.gov/programs-and-services/immunization/information-for-healthcare-providers/providing-records-to-patients/> (last visited Feb. 4, 2021).

<sup>28</sup> Section 381.003(1)(e)4., F.S.

<sup>29</sup> Section 381.003(1)(e)5., F.S.

<sup>30</sup> Section 381.003 (1)(e)2., F.S.

<sup>31</sup> Section 381.003(1)(e)3., F.S.

the immunization registry. The information submitted to the immunization registry must include:<sup>32</sup>

- The child's name;
- Date of birth;
- Address;
- Any unique identifier necessary to identify the child;
- The immunization record, including:
  - The date of the immunization;
  - Type of vaccine administered;
  - Vaccine lot number;
  - The presence or absence of any adverse reaction; and
  - Any contraindications noted to the immunization.

Information received by the DOH for the immunization registry is confidential medical information, and the DOH must maintain the confidentiality of that information. Health care practitioners who obtain information from the DOH immunization registry must also keep that information confidential.<sup>33</sup>

### **The Practice of Pharmacy**

The BOP, in conjunction with the DOH, regulates the practice of pharmacists and registered pharmacist interns pursuant to ch. 465, F.S.<sup>34</sup>

#### ***Licensure***

To be licensed as a pharmacist in Florida, a person must:<sup>35</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>36</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>37</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>38</sup>

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

<sup>33</sup> Sections 381.003(1)(e)5 and 456.057(9)(a), F.S.

<sup>34</sup> Sections 465.004 and 465.005, F.S.

<sup>35</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>36</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>37</sup> Section 465.009, F.S.

<sup>38</sup> Section 465.009(6), F.S.

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

In Florida, the practice of the profession of pharmacy includes:<sup>39</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>40</sup>
- Transmitting information from prescribers to their patients;
- Administering antipsychotropic medications by injection;<sup>41</sup>
- Preparing prepackaged drug products in facilities holding Class III institutional facility permits;<sup>42</sup>
- Ordering and dispensing over-the-counter drugs approved by the FDA;<sup>43</sup>
- Ordering and dispensing within his or her professional judgment, subject to specified conditions:<sup>44</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 CDC guidelines, and epinephrine auto-injections to address unforeseen allergic reactions, within the framework of an established protocol with a supervising physician. A pharmacist must become certified to administer immunizations and vaccines that are:

<sup>39</sup> Section 465.003(13), F.S.

<sup>40</sup> Section 465.1865, F.S.

<sup>41</sup> Section 465.1893, F.S.

<sup>42</sup> A Class III institutional pharmacy are those pharmacies affiliated with a hospital. *See* s. 465.019(2)(d), F.S.

<sup>43</sup> Section 465.186, F.S.

<sup>44</sup> Fla. Admin. Code R. 64B16-27.220 (2020).



- Listed in the CDC Adult Immunization Schedule as of February 1, 2015;
- Listed in the Adult Immunization Schedule after February 1, 2015, and authorized by BOP rule;
- Recommended by the CDC for international travel as of July 1, 2015;
- Recommended by the CDC for international travel after July 1, 2015, and authorized by BOP rule;<sup>45</sup> or
- Approved by the BOP in response to an emergency declared by the Governor.<sup>46</sup>

To be certified to administer vaccines, a pharmacist must:

- Enter into a written protocol with a supervising medical or osteopathic physician, and the protocol must:<sup>47</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;
- Successfully complete a BOP-approved vaccine administration certification program that consists of at least 20 hours of continuing education;<sup>48</sup>
- Pass an examination and demonstrate vaccine administration technique;<sup>49</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>50</sup> and
- Maintain at least \$200,000 of professional liability insurance.<sup>51</sup>

A pharmacist may also 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.<sup>52</sup>

A certified pharmacist is not authorized under Florida Statutes to administer immunizations to children.

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<sup>45</sup> Section 465.189(1)(b), F.S.

<sup>46</sup> Section 465.189, (1)(c), F.S.

<sup>47</sup> Section 465.189(7), F.S.

<sup>48</sup> Section 465.189(6), F.S., Fla. Admin. Code R. 64B16-26.1031 (2020), provides more detail regarding subject matter that must be included in the certification course.

<sup>49</sup> *Id.*

<sup>50</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>51</sup> Section 465.189(3), F.S.

<sup>52</sup> Section 465.189(2), F.S. A certified registered pharmacy intern is not permitted to administer epinephrine auto-injections.

### ***Pharmacy Interns***

To become a pharmacy intern, a person must be certified by the BOP and 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>53</sup> The BOP's rules outline the registration process for pharmacy interns and the internship program requirements for U.S. pharmacy students or graduates and foreign pharmacy graduates.<sup>54</sup>

A pharmacist is responsible for any delegated act performed by a registered pharmacy intern employed or supervised by the pharmacist.<sup>55</sup>

To administer vaccines, a registered 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 certified registered intern. Like pharmacists, pharmacy interns are not authorized under Florida Statutes to administer immunizations to children.<sup>56</sup>

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

On March 9, 2020, Governor 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>57</sup>

### ***Federal Action to Authorize Pharmacists to Vaccinate Children***

On August 19, 2020, the HHS issued an amendment to the declaration published on March 17, 2020,<sup>58</sup> relating to the Public Readiness and Emergency Preparedness Act (PREP Act).<sup>59</sup> The amendment authorizes, effective August 24, 2020, state-licensed pharmacists (and pharmacy interns acting under their supervision) to order and administer vaccines to individuals ages three through 18 years, nationwide, subject to several requirements:<sup>60</sup>

- The vaccine must be authorized or approved by the FDA.

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<sup>53</sup> Section 465.013, F.S.

<sup>54</sup> Fla. Admin. Code R. 64B16-26.2032 (U.S. pharmacy students/graduates); Fla. Admin. Code R. 64B16-26.2033 (foreign pharmacy graduates).

<sup>55</sup> Fla. Admin. Code R. 64B16-27.430 (2020).

<sup>56</sup> Section 465.189(6), F.S.

<sup>57</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. 10, 2021).

<sup>58</sup> 85 Fed. Reg. 15198 (2020).

<sup>59</sup> The PREP Act authorizes the Secretary of Health and Human Services the Secretary 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 Covered Countermeasures, except for claims involving “willful misconduct” as defined in the PREP Act. Under the PREP Act, a Declaration maybe amended as circumstances warrant. The PREP Act was enacted on December 30, 2005, as Public Law 109–148, Division C, section 2.

<sup>60</sup> 85 Fed. Reg. 136, 52136 - 52141 (2020). Also see <https://www.hhs.gov/about/news/2020/08/19/hhs-expands-access-childhood-vaccines-during-covid-19-pandemic.html> (last visited Feb. 12, 2021).

- The vaccination must be ordered and administered according to the ACIP's standard immunization schedule.<sup>61</sup>
- The licensed pharmacist must complete a practical training program of at least 20 hours that is approved by the Accreditation Council for Pharmacy Education (ACPE).
- The licensed or registered pharmacy intern must complete a practical training program that is approved by the ACPE.
- The licensed pharmacist and licensed or registered pharmacy intern must have current certificates in basic cardiopulmonary resuscitation.

According to the announcement of the amendment, this federal action was for the purpose of increasing access to lifesaving childhood vaccines and decreasing the risk of vaccine-preventable disease outbreaks so children across the United States could return to daycare, preschool, and school.<sup>62</sup>

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

On October 1, 2020, the State Surgeon General issued an emergency order,<sup>63</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, registered pharmacy intern, to administer vaccines approved or licensed by the FDA to individuals under 18 years of age if the vaccine is approved for use in individuals under 18 years of age and upon receipt of a medical 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 remains in effect until Executive Order No. 20-52, including any extensions, expires or is otherwise modified by order of the State Surgeon General.

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

SB 494 expands the scope of persons to whom certified pharmacists and pharmacy interns, under a protocol with a supervising physician, may administer CDC-listed and recommended

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<sup>61</sup> Centers for Disease Control and Prevention, Immunization Schedules: *For Health Care Providers*, available at <https://www.cdc.gov/vaccines/schedules/hcp/index.html> (last visited Feb.10, 2021). The immunization schedule recommends that certain vaccines be administered only to children of a certain age. For example, the second dose of both the measles, mumps, and rubella vaccine, as well as the varicella vaccine, should not be administered until a child is between four and six years old. See *Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger*, United States, 2020, CDC (Jan. 29, 2020), available at <https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf> (last visited Feb. 10, 2021).

<sup>62</sup> U.S. Department of Health and Human Services, *HHS Expands Access to Childhood Vaccines during COVID-19 Pandemic*, available at <https://www.hhs.gov/about/news/2020/08/19/hhs-expands-access-childhood-vaccines-during-covid-19-pandemic.html> (last visited Feb. 12, 2021).

<sup>63</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. 10, 2021).

immunizations and vaccines. Under the bill, pharmacists and pharmacy interns may vaccinate a person six years of age or older, instead of being limited to adults as under current law.

The bill requires that a certified pharmacist or pharmacy intern who administers an immunization or vaccine to a child under 18 years of age, must:

- Obtain a medical consent form:
  - That contains an opt-out notice stating that a parent or guardian may opt-out of the DOH immunization registry; and
  - That is signed by a person who has the power to consent to medical care or treatment for the minor; which is defined as a natural or adoptive parent, legal custodian, or legal guardian; and, either
- Report vaccination data to the immunization registry; or
- Submit to DOH an opt-out immunization registry form that may be provided by the parent or guardian to the pharmacist or registered intern at the time the vaccine is administered.

The bill modifies the source list for immunizations and vaccines that certified pharmacists and pharmacy interns may administer. Currently, pharmacists and pharmacy interns, under a protocol with a supervising physician, are limited to administering vaccines to adults that are:

- Listed in the CDC's Adult Immunization Schedule as of February 1, 2015;
- Recommended by the CDC for international travel as of July 1, 2015;
- Authorized by BOP rule if listed or recommended, respectively, by the CDC after those dates; or
- Approved by the BOP in response to a state of emergency declared by the Governor.

The bill authorizes certified pharmacists and certified registered pharmacy interns, still under a protocol with a supervising physician, to administer vaccines and immunizations to persons six years of age or older that are:

- Listed in the CDC's Adult Immunization Schedule, without reference to the date they were listed, if the vaccine recipient is an adult;
- Listed in the CDC's Child and Adolescent Schedule, if the vaccine recipient is a child;
- Recommended by the CDC for international travel, without reference to the date they were recommended; or
- Approved by the BOP in response to a state of emergency declared by the Governor.

Under the bill, immunizations and vaccines added to the Adult Immunization Schedule after February 1, 2015, or recommended by the CDC for international travel after July 1, 2015, would no longer need authorization by BOP rule to be available for administration to adults by pharmacists and pharmacy interns. *See* Section IV.E. of this analysis for information concerning the removal of these dates from statute.

The bill provides an effective date of July 1, 2021.

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

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

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

Article II, Section 3, of the Florida Constitution has been interpreted by Florida courts to prohibit the Legislature from delegating its legislative power to others.<sup>64</sup> Under this non-delegation principle, Florida courts have held that the Legislature may enact laws that adopt federal statutes or other federal regulations in existence and in effect at the time the Legislature acts; however, if the Legislature incorporates into a Florida statute a *future* federal act or regulation, courts have held that such incorporation constitutes an unconstitutional delegation of legislative power.<sup>65</sup>

The bill incorporates CDC vaccination schedules and recommendations into Florida Statutes by reference and deletes the current statute's references to CDC schedules and recommendations that were in effect on certain dates in the past. The removal of those dates from statute could be viewed as opening-up authorization of vaccines that pharmacists and pharmacy interns may administer to include those currently listed or recommended by the CDC and those that may be listed or recommended by the CDC in the future.

However, when a statute incorporates a federal law or regulation by reference, in order to avoid holding the subject statute unconstitutional, Florida courts generally interpret the statute as incorporating only the federal law or regulation in effect on the date of the Legislature's action to enact the Florida law, reasoning that the Legislature is presumed to have intended to enact a valid and constitutional law.<sup>66</sup>

Under that premise, SB 768 may be interpreted by courts as authorizing pharmacists and pharmacy interns to administer vaccines that appear on the named CDC schedules or recommended by the CDC for international travel as of the date of the bill's passage or enactment, not vaccines that may be added to the CDC schedules or recommended by the CDC afterwards.

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<sup>64</sup>*Abbott Laboratories v. Mylan Pharmaceuticals, Inc.*, 15 So.3d 642 (Fla. 1d DCA 2009), citing *Gallagher v. Motors Ins. Corp.*, 605 So.2d 62, 71 (Fla. 1992).

<sup>65</sup>*State v. Rodriguez*, 365 So.2d 157, 160 (Fla. 1978).

<sup>66</sup> *Id.*

**V. Fiscal Impact Statement:****A. Tax/Fee Issues:**

None.

**B. Private Sector Impact:**

None.

**C. Government Sector Impact:**

By making childhood vaccinations available to Medicaid recipients through additional providers, the bill may result in additional childhood vaccinations being administered in the Medicaid program, which may increase the program's vaccination costs. The fiscal impact is indeterminate at this time.

**VI. Technical Deficiencies:**

None.

**VII. Related Issues:**

None.

**VIII. Statutes Affected:**

This bill substantially amends the following sections of the Florida Statutes: 381.003, 465.189, and 465.003.

**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.