HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: PCS for HB 1063 Administration of Vaccines
SPONSOR(S): Professions & Public Health Subcommittee
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
Orig. Comm.: Professions & Public Health Subcommittee		Morris	McElroy

SUMMARY ANALYSIS

Current law authorizes pharmacists and registered interns who meet certain educational requirements to administer vaccines to adults within an established protocol with a supervising physician. A pharmacist may administer:

- Immunizations or vaccines listed on the U.S. Centers for Disease Control and Prevention (CDC) Adult Immunization Schedule as of February 1, 2015;
- Vaccines recommended by the CDC for international travel as of July 1, 2015;
- Immunizations or vaccines approved by the Board of Pharmacy in rule; and
- Immunizations or vaccines approved by the Board of Pharmacy in response to a state of emergency declared by the Governor.

PCS/HB 1063 authorizes qualified Florida-licensed pharmacists or registered pharmacy interns to administer any CDC-recommended vaccine or vaccine licensed for use in the United States by the U.S. Food and Drug Administration (FDA) to an adult. The PCS allows the Board of Pharmacy to authorize by rule additional immunizations or vaccines, as they are recommended by the CDC or licensed by the FDA, that a qualified pharmacist or registered pharmacy intern may administer. The PCS also authorizes pharmacists to provide influenza vaccines to individuals age 7 and older.

The PCS also repeals the specific statutory limitation to the 2015 CDC-recommended vaccines.

The PCS has an insignificant, negative fiscal impact on the Department of Health, which can be absorbed within existing resources. The PCS has no fiscal impact on local governments.

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Vaccinations

CDC Immunizations Recommendations

The Advisory Committee on Immunization Practices (ACIP) is comprised of medical and public health experts who develop recommendations on the use of vaccines in the United States.[1] 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.[2] The Centers for Disease Control and Prevention (CDC) reviews the ACIP's recommendations; and once approved, they are published as the CDC's official recommendations for immunizations of the U.S. population.[3] The current recommended immunization schedule for those ages 18 and under includes:[4]

- Hepatitis B
- Diphtheria, tetanus, & acellular pertussis
- Pneumococcal conjugate
- Influenza
- Varicella
- Meningococcal
- Meningococcal B
- Tetanus, diphtheria, and acellular pertussis
- Rotavirus
- Haemophilus influenza type b
- Inactivated poliovirus
- Measles, mumps, rubella (MMR)
- Hepatitis A
- Human papillomavirus
- Pneumococcal polysaccharide

The current recommended immunization schedule for adults includes:[5]

- Influenza (annually)
- Measles, mumps, rubella (if born in 1957 or later)
- Zoster
- Pneumococcal polysaccharide
- Haemophilus influenza type b
- Hepatitis B
- Meningococcal B
- Varicella (if born in 1980 or later)
- Tetanus, diphtheria, pertussis (booster every 10 years)
- Human papillomavirus
- Pneumococcal conjugate
- Hepatitis A
- Meningococcal A, C, W, Y

New vaccines are considered for addition to the schedule after licensure by the United States Food and Drug Administration.[6] Not all newly licensed vaccines are added to the schedule. Some licensed vaccines are only recommended for people who are traveling to areas where other vaccine preventable

[1] Centers for Disease Control and Prevention, Advisory Committee on Immunization Practices (ACIP), *General Committee-Related Information*, available at https://www.cdc.gov/vaccines/acip/committee/index.html (last visited March 8, 2021).
[2] 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 March 8, 2021).
[3] Id.
[4] Centers for Disease Control and Prevention, *Recommended Child and Adolescent Immunization Schedule for Ages 18 Years and Younger, United States, 2021*, available at https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html (last visited March 8, 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 these individuals at higher risk.
[5] Centers for Disease Control and Prevention, *Recommended Adult Immunization Schedule for Ages 19 Years or Older, United States, 2021*, available at https://www.cdc.gov/vaccines/schedules/hcp/imz/adult.html (last visited March 8, 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 these individuals at higher risk.
[6] 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 March 8, 2021).

diseases occur, such as yellow fever, cholera, dengue, Japanese encephalitis, plague, rabies, smallpox, and typhoid.[7]

CDC Health Information for International Travel

CDC's Health Information for International Travel, commonly called the Yellow Book (Book), is published biannually by the CDC as a reference for those who advise international travelers about health risks.[8] The Book includes the CDC's most current travel health guidelines, including pre-travel vaccine recommendations and destination-specific health advice. The Book is authored by subject-matter experts both within and outside the CDC and the guidelines in the Book are evidence-based and supported by best practices.[9]

Vaccinations are recommended by the CDC to protect international travelers from illness and prevent the importation of infectious diseases across international borders. The Book recommends that persons traveling internationally should be up to date on all CDC-recommended vaccines.[10] Additionally, the Book may recommend additional vaccinations based on traveler's destination and other factors. Examples of additional vaccines required for travelers based on the country of entry is yellow fever, meningococcal, and polio.[11] An example of a vaccine the CDC recommends travelers obtain to protect their health, even if they aren't required for entry into the country, is the typhoid vaccine.[12]

Practice of Pharmacy

Licensure

Pharmacy is the third largest health profession behind nursing and medicine.[13] The Board of Pharmacy (Board), in conjunction with the Department of Health (DOH), regulates the practice of pharmacists pursuant to ch. 465, F.S.[14] To be licensed as a pharmacist, a person must:[15]

- 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;[16]
- Have completed a Board-approved internship; and
- Successfully complete the Board-approved examination.

A pharmacist must complete at least 30 hours of Board-approved continuing education during each biennial renewal period.[17] Pharmacists who are certified to administer vaccines or epinephrine autoinjections must complete a 3-hour continuing education course on the safe and effective administration of vaccines and epinephrine injections as a part of the biennial licensure renewal.[18]

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[7] 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. 16, 2020), available at https://www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states (last visited February 4, 2020).
[8] 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 March 8, 2021).
[9] Id.
[10] Id.
[11] Centers for Disease Control and Prevention, *Travelers' Health Most Frequently Asked Questions,* available at https://wwwnc.cdc.gov/travel/page/faq (last visited March 8, 2021).
[12] Id.
[13] American Association of Colleges of Pharmacy, *About AACP*, available at https://www.aacp.org/about-aacp (last visited March 8, 2021).
[14] Sections 465.004 and 465.005, F.S.
[15] Section 465.007, F.S. 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.
[16] If the applicant has graduated from a 4-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
[17] Section 465.009, F.S.
[18] Section 465.009(6), F.S.

Pharmacists who administer long-acting antipsychotic medications must complete an approved 8-hour continuing education course as a part of the continuing education for biennial licensure renewal.[19]

Scope of Practice

In Florida, the practice of the profession of pharmacy includes:[20]

- Compounding, dispensing, and consulting concerning contents, therapeutic values, and uses of a medicinal drug;
- Consulting concerning therapeutic values and interactions of patent or proprietary preparations;
- Monitoring a patient's drug therapy and assisting the patient in the management of his or her drug therapy, including the review of the patient's drug therapy and communication with the patient's prescribing health care provider or other persons specifically authorized by the patient, regarding the drug therapy;
- Transmitting information from prescribers to their patients;
- Administering vaccines to adults;[21]
- Administering epinephrine injections;[22] and
- Administering antipsychotic medications by injection.[23]

Pharmacy Interns

To become a pharmacy intern, a person must be certified by the Board as 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.[24] The Board'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.[25]

A pharmacist is responsible for any delegated act performed by a registered pharmacy intern employed or supervised by the pharmacist.[26]

Pharmacist Vaccine Administration

A pharmacist, or registered pharmacy intern under the supervision of a certified pharmacist, may administer immunizations and vaccines to adults within an established protocol under a licensed supervising physician.[27] The protocol between the pharmacist and the supervising physician dictates which types of patients to whom the pharmacist may administer allowable vaccines.[28] The terms, scope, and conditions set forth in the protocol must be appropriate to the pharmacist's training and certification. A supervising physician must review the administration of vaccines by the pharmacist.[29]

To be certified to administer vaccines, a pharmacist or registered pharmacy intern must successfully complete a Board-approved vaccine administration certification program. The certification program requires a pharmacist or registered intern to complete 20 hours of Board-approved continuing education that addresses:[30]

- Mechanisms of action for vaccines, contraindications, drug interactions, and monitoring after vaccine administration;

[19] Section 465.1893, F.S.
[20] Section 465.003(13), F.S.
[21] *See* s. 465.189, F.S.
[22] Id.
[23] Section 465.1893, F.S.
[24] Section 465.013, F.S.
[25] Rule 64B16-26.2032, F.A.C. (U.S. pharmacy students/graduates); Rule 64B16-26.2033, F.A.C. (foreign pharmacy graduates).
[26] Rule 64B16-27.430, F.A.C.
[27] Section 468.189(1), F.S.
[28] Section 465.189(7), F.S.
[29] Id.
[30] Rule 64B16-26.1031, F.A.C.

- Immunization schedules;
- Immunization screening questions, provision of risk/benefit information, informed consent, recordkeeping, and electronic reporting into the statewide immunization registry maintained by DOH;
- Vaccine storage and handling;
- Bio-hazardous waste disposal and sterile technique;
- Entering, negotiating, and performing pursuant to physician oversight protocols;
- Community immunization resources and programs;
- Identifying, managing and responding to adverse incidents including but not limited to potential allergic reactions associated with vaccine administration;
- Procedures and policies for reporting adverse incidents to the Vaccine Adverse Event Reporting System;
- Reimbursement procedures and vaccine coverage by federal, state, and local governmental jurisdictions and private third party payers;
- Administration techniques;
- Administration of epinephrine using an autoinjector delivery system;
- The February 1, 2015, CDC Recommended Adult Immunization Schedule;
- The immunizations or vaccines recommended for international travel as of July 1, 2015, found in the CDC Health Information for International Travel (2014 Edition);
- State of emergency administration of immunizations or vaccines;
- Review of the current law permitting a pharmacist to administer vaccinations and epinephrine; and
- CPR training.

A pharmacist must also pass an examination and demonstrate vaccine administration technique.[31] Pharmacists who are certified to administer vaccines must maintain at least $200,000 of professional liability insurance.[32] A pharmacist is permitted to administer epinephrine to treat any allergic reaction resulting from a vaccine.

Current law restricts the vaccines a pharmacist may administer to adults to those vaccines listed in the February 1, 2015, CDC Recommended Adult Immunization Schedule, which is the same as the 2021 list of recommended vaccines (see pg. 3), except that the CDC has added the Meningococcal B vaccine to the list.[33]

The Board may authorize, by rule, additional vaccines a pharmacist may administer.[34] The Board may authorize pharmacists to administer vaccines in response to a declared state of emergency.[35] There are 14,579 Florida-licensed pharmacists and 3,579 pharmacy interns who are certified to administer vaccines.[36]

Pharmacist Vaccination and Age Restrictions

In August of 2020, the U.S. Department of Health and Human Services amended the Declaration under the Public Readiness and Emergency Preparedness Act to authorize pharmacists and registered or licensed pharmacy interns acting under the supervision of a pharmacist to administer vaccines to individuals aged three to 18 years.[37]

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[31] Id.
[32] Section 465.189(3), F.S.
[33] Centers for Disease Control and Prevention, *Recommended Adult Immunization Schedule, United States - 2015*, available at https://www.cdc.gov/vaccines/schedules/downloads/past/2015-adult.pdf (last visited March 8, 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 these individuals at higher risk. *See also supra* note 5.
[34] Section 465.189, F.S..
[35] Section 465.189(1)(c), F.S.
[36] E-mail correspondence with DOH, dated March 8, 2021 on file with the Professions and Public Health Subcommittee.
[37] U.S. Department of Health and Human Services, *Third Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19,* https://www.hhs.gov/sites/default/files/third-amendment-declaration.pdf (last visited March 8, 2021).

Currently, all 50 states authorize pharmacists to administer vaccinations; however, that authority may vary by, among other things, the age of the patients that a pharmacist may vaccinate.[38] Four states, including Florida, limit pharmacist vaccinations to adult patients.[39] Twenty six states allow pharmacists to administer vaccines to individuals of any age.[40] The remaining states have minimum age restrictions that range from 12 years to 2 years.[41]

Authority to administer influenza vaccines to minors differ by state. For example, some states, such as Arizona, allow pharmacists to administer influenza vaccines to children age 3 and over, while other states, such as West Virginia, only allow pharmacists to administer influenza vaccines to those age 11 and older. Three states, including Florida, do not authorize pharmacists to administer influenza vaccines to minors, 19 states have age restrictions, and 28 others allow pharmacists to give influenza vaccines to children of any age. Sixteen states require a prescription for an influenza vaccine.[42]

Effect of Proposed Changes

PCS/HB 1063 revises the list of immunizations that qualified pharmacists and registered pharmacy interns can provide to adults. Currently, pharmacists may only administer those vaccines listed in 2015 CDC-recommended immunization for adults and the 2015 CDC-recommended immunizations for international travels. The PCS authorizes pharmacists to administer those vaccines or immunizations listed in the 2021 CDC Recommended Immunization Schedule for adults and the CDC's Health Information for International Travel. Therefore, pharmacists may administer the Meningococcal B vaccine, which is on the current recommended immunization schedule but was not on the 2015 recommended schedule.

The PCS also authorizes a pharmacist to administer any vaccine that has been licensed for use in the United States by the U.S. Food and Drug Administration (FDA) and allows the Board to authorize by rule additional vaccines that may be administered as they are recommended by the CDC or licensed by the FDA. This allows a pharmacist to administer vaccines for yellow fever, cholera, dengue, Japanese encephalitis, plague, rabies, smallpox, and typhoid, which are not in the CDC-recommended schedule but have been approved by the FDA. The PCS expands the authority of qualified pharmacists and pharmacy interns to administer the influenza vaccines to allow them to administer the vaccine to individuals age 7 and older.

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

B. SECTION DIRECTORY:

Section 1 Amends s. 465.189, F.S., relating to administration of vaccines and epinephrine autoinjection.

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[38] Yvette C. Terrie, BSPharm, RPH, *Vaccinations: The Expanding Role of Pharmacists*, PHARMACY TIMES, Jan. 15, 2010, available at https://www.pharmacytimes.com/publications/issue/2010/january2010/featurefocusvaccinations-0110 (last visited March 8, 2021).
[39] National Alliance of State Pharmacy Associations, Pharmacist Administered Vaccines (Sept. 18, 2020), https://naspa.us/wp-content/uploads/2020/08/IZ-Authority-9_2020.pdf (last visited March 8, 2021). The states that limit pharmacist vaccinations to adults are Connecticut, Delaware, Florida, and Vermont.
[40] Id. The twenty six states that allow pharmacists to vaccinate individuals of any age are: Alabama, Alaska, California, Colorado, Georgia, Idaho, Indiana, Iowa, Louisiana, Michigan, Mississippi, Missouri, Nebraska, New Hampshire, Nevada, New Mexico, Oklahoma, Oregon, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, Washington, and Wisconsin.
[41] Id. Minimum age limits: Hawaii and West Virginia is 11 years; Illinois is 10 years; Massachusetts, Maryland, Pennsylvania, and Rhode Island is 9 years; Arkansas, Maine, Montana, New Jersey, Ohio, and Wyoming is 7 years; Kansas, Minnesota, and North Carolina is 6 years; North Dakota is 5 years; Arizona is 3 years; and New York is 2 years.
[42] Id at p. 11. The three states that do not allow pharmacists to administer influenza vaccines to minors are Connecticut, Florida, and Vermont. The states with age limits re: Hawaii and West Virginia is 11 years; Illinois is 10 years; Massachusetts, Maryland, Pennsylvania, and Rhode Island is 9 years; Arkansas, Maine, Montana, New Jersey, Ohio, and Wyoming is 7 years; Kansas, Minnesota, and North Carolina is 6 years; North Dakota is 5 years; Arizona is 3 years; and New York is 2 years. The twenty eight states that allow pharmacists to give influenza vaccines to children of any age are: Alabama, Alaska, California, Colorado, Delaware (with an adult dose), Georgia, Idaho, Indiana, Iowa, Kentucky, Louisiana, Michigan, Mississippi, Missouri, Nebraska, New Hampshire, New Mexico, Nevada, Oklahoma, Oregon, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, Washington, and Wisconsin. The sixteen states that require a prescription for an influenza vaccine are: California, Georgia, Hawaii, Idaho, Indiana, Iowa, Kentucky, Louisiana, Missouri, Oregon, South Carolina, Texas, Virginia, West Virginia, and Wisconsin.

Section 2 Provides an effective date of July 1, 2021.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   The PCS may have an insignificant, negative fiscal impact on DOH, as the Board of Pharmacy will need to amend its rules.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Those between the ages of 7 and 18 may obtain influenza vaccinations from a qualified pharmacist, which may reduce costs associated with travel and physician office visits.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   Not applicable. The PCS does not appear to affect county or municipal governments.

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

Rule-making authority is not needed to implement the provisions of the PCS.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES