HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 1209 Administration of Vaccines
SPONSOR(S): Professions & Public Health Subcommittee, Tuck and others
TIED BILLS: **IDEN./SIM. BILLS:** SB 1892

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Professions & Public Health Subcommittee	17 Y, 1 N, As CS	Morris	McElroy
2) Health & Human Services Committee	18 Y, 1 N	Morris	Calamas

SUMMARY ANALYSIS

Pharmacists, pharmacy interns, and pharmacy technicians are regulated under ch. 465, F.S., and by the Board of Pharmacy (Board) within the Department of Health (DOH). 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 or a pharmacy intern may administer:

- Immunizations or vaccines listed on the U.S. Centers for Disease Control and Prevention (CDC) Adult Immunization Schedule as of April 20, 2021;
- Vaccines recommended by the CDC for international travel as of April 30, 2021;
- Immunizations or vaccines licensed for use in the United States by the U.S. Food and Drug Administration (FDA) as of April 30, 2021;
- Immunizations or vaccines authorized for emergency use by the FDA as of April 30, 2021;
- Immunizations or vaccines approved by the Board of Pharmacy (Board) in rule; and
- Immunizations or vaccines approved by the Board of Pharmacy in response to a state of emergency declared by the Governor.

Pharmacy technicians are not currently authorized by law to administer immunizations or vaccines.

CS/HB 1209 authorizes qualified Florida-registered pharmacy technicians to administer to adults the above-referenced immunizations or vaccines under the supervision of a certified pharmacist.

The bill requires pharmacy technicians to become certified to administer such immunizations and vaccines. To become certified, a registered pharmacy technician must complete a certification program approved by the Board, in consultation with the Board of Medicine and the Board of Osteopathic Medicine. The training curriculum must have at least 6 hours of training that, at a minimum, includes instruction on the safe and effective administration of vaccines and potential allergic reactions to such vaccines. Upon registration renewal, pharmacy technicians must have completed at least two hours of additional continuing education.

The bill updates the authorized immunizations or vaccines that may be administered from those listed in the CDC Recommended Immunization Schedule for adults, the CDC's Health Information for International Travel, and those licensed or authorized for emergency use by the FDA as of April 30, 2021 to those listed or approved as of March 31, 2022.

The bill has an insignificant fiscal impact on DOH which can be absorbed within existing resources. There is no fiscal impact on local governments.

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Vaccinations

CDC Immunization Recommendations

The Advisory Committee on Immunization Practices (ACIP) develops recommendations on the use of vaccines in the United States.[1] The ACIP is comprised of medical and public health experts, and 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; once approved by the CDC Director and the U.S. Department of Health and Human Services, they are published as the CDC's official recommendations for immunizations of the U.S. population.[3]

The current recommended immunization schedule for adults includes:[4]

- 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 (FDA).[5] 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 diseases occur, such as yellow fever, cholera, dengue, Japanese encephalitis, plague, rabies, smallpox, and typhoid.[6]

The 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

[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 Jan. 28, 2022). Established under Title 42 U.S.C. § 217a, ACIP members are appointed by the Secretary of the Department of Health and Human Services and consist of a mix of medical and public health experts from private industry and the public sector. There are 15 voting members (14 are industry experts and one consumer member), 6 non-voting, ex-officio members consisting of specific federal government employees, and 30 non-voting representatives from professional health care organizations.

[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 Jan. 28, 2022).

[3] Id.

[4] 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 Jan. 28, 2022). The schedule provides the recommended age, as well as the administration intervals for vaccines that require multiple doses. Some vaccines are r ecommended only for populations with special situations that put these individuals at higher risk.

[5] 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 Jan. 28, 2022).

[6] Id. For a complete list of FDA-licensed vaccines, *see* U.S. Food & Drug Administration, *Vaccines Licensed for Use in the United States*, (as of Dec. 1, 2021), available at https://www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states (last visited Jan. 28, 2022).

health risks.[7] 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.[8]

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.[9] 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.[10] An example of a vaccine the CDC recommends travelers obtain to protect their health, even if they are not required for entry into the country, is the typhoid vaccine.[11]

FDA Licensure and Emergency Use Authorization

The FDA oversees the safety, effectiveness, and quality of vaccines used in the United States. Once a vaccine is developed, the pre-clinical phase begins, which consists of laboratory research and testing on animals. If the pre-clinical phase shows the vaccine is likely to be safe and work well in humans, it is tested on humans through clinical trials. While clinical trials are underway, the FDA assesses the manufacturing process to ensure that the vaccine can be produced reliably and consistently. Once a manufacturing process is developed and pre-clinical and clinical trials are successfully completed, developers submit a Biologics License Application to the FDA, which includes details on the manufacturing process and data from pre-clinical and clinical trials. The FDA evaluates the application and decides whether to license the vaccine for use in the United States. The FDA continues to monitor and regulate vaccines and manufacturers after licensing.[12]

All vaccines must be licensed (approved) by the FDA in order to be marketed in the United States.[13] However, during public health emergencies, the FDA may authorize vaccines for emergency use, which speeds up the process of bringing a vaccine to market.[14]

Emergency use authorization (EUA) allows the FDA to help strengthen the nation's public health protections against chemical, biological, radiological, and nuclear threats including infectious diseases, by facilitating the availability and use of medical countermeasures need during public health emergencies.[15] Under section 564 of the Federal Food, Drug, and Cosmetic Act,[16] when the Secretary of the United States Department of Health and Human Services declares that an emergency use authorization is appropriate, the FDA may authorize unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious life-threatening diseases or conditions caused by chemical, biological, radiological, and nuclear threats.[17]

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[7] Centers for Disease Control and Prevention. *CDC YellowBook 2020: Health Information for International Travel*, available at https://wwwnc.cdc.gov/travel/page/yellowbook-home (last visited Jan. 28, 2022).
[8] Id.
[9] Id.
[10] Centers for Disease Control and Prevention, *Travelers' Health Most Frequently Asked Questions,* available at https://wwwnc.cdc.gov/travel/page/faq (last visited Jan. 28, 2022).
[11] Id.
[12] U.S. Food and Drug Administration, *Vaccine Development – 101,* https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/vaccine-development-101 (last visited Jan. 28, 2022).
[13] U.S. Food and Drug Administration, *Ensuring the Safety of Vaccines in the United States,* https://www.fda.gov/files/vaccines,%20blood%20&%20biologics/published/Ensuring-the-Safety-of-Vaccines-in-the-United-States.pdf (last visited Jan. 28, 2022).
[14] Food and Drug Administration, *Emergency Use Authorization,* https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization (last visited Jan. 28, 2022). Medical countermeasures are FDA-regulated products (biologics, drugs, and devices) that may be used in the event of a public health emergency.
[15] Id.
[16] 21 U.S.C. § 360bbb-3.
[17] *Supra,* note 14. A determination that a public health emergency exists does not enable the FDA to issue EUAs.

Vaccine manufacturers seeking EUA must follow the same processes as a license applicant, but instead of submitting a license application, the manufacturer files for EUA.[18] The FDA expects all manufacturers who receive an EUA to pursue licensure.[19]

Practice of Pharmacy

Licensure

Pharmacy is the third largest health profession behind nursing and medicine.[20] The Board of Pharmacy (Board), in conjunction with the Department of Health (DOH), regulates the practice of pharmacists pursuant to ch. 465, F.S.[21] To be licensed as a pharmacist, a person must:[22]

- 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;[23]
- 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.[24] 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.[25] 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.[26]

Scope of Practice

In Florida, the practice of the profession of pharmacy includes:[27]

- 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;[28]
- Administering epinephrine injections;[29] and
- Administering antipsychotic medications by injection.[30]

[18] Id.
[19] U.S. Food and Drug Administration, *Emergency Use Authorization for Vaccines Explained,* https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained (last visited Jan. 28, 2022).
[20] American Association of Colleges of Pharmacy, *About AACP*, available at https://www.aacp.org/about-aacp (last visited Jan. 28, 2022).
[21] Sections 465.004 and 465.005, F.S.
[22] 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.
[23] 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
[24] Section 465.009, F.S.
[25] Section 465.009(6), F.S.
[26] Section 465.1893, F.S.
[27] Section 465.003(13), F.S.
[28] *See* s. 465.189, F.S.
[29] Id.
[30] Section 465.1893, F.S.

Pharmacy Interns

A pharmacy intern is a person enrolled in a college of pharmacy and actively pursuing a pharmacy degree. 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.[31] 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.[32]

A pharmacist is responsible for any delegated act performed by a registered pharmacy intern employed or supervised by the pharmacist.[33]

Pharmacy Technicians

Pharmacy technicians assist, and work under the supervision of, licensed pharmacists. Section 465.014, F.S., authorizes a licensed pharmacist to delegate to registered pharmacy technicians those duties, tasks, and functions that do not fall within the definition of the practice of the profession of pharmacy. Registered pharmacy technicians' responsibilities include delegable tasks assigned by a pharmacist which do not require the technician to exercise independent professional judgment relating to the practice of pharmacy.[34] Examples include: retrieval of prescription files; data entry; counting, weighing, measuring, pouring, and mixing prescription medication; and acceptance of authorization for prescription renewals.

A pharmacist is responsible for acts performed by persons under his or her supervision.[35]

Pharmacy technicians must be over the age of 17, registered with the Board, and complete a Board-approved training program to practice in this state.[36] The training program includes classroom study and clinical instruction on:[37]

- Introduction to pharmacy and health care system;
- Pharmacy law;
- Pharmaceutical-medical terminology, abbreviations, and symbols;
- Records management and inventory control;
- Interpersonal relations, communications, and ethics; and
- Pharmaceutical calculations.

Registered pharmacy technicians must complete 20 hours of biennial continuing education upon registration renewal.[38] Such continuing education must include subject matter on:[39]

- Pharmacy technician practice areas and special health care problems;
- Biological, physical, behavioral and social sciences;
- The legal aspects of health care;
- Management and administration of health care personnel and patient care; and
- Teaching and learning processes of health care personnel and patient care.

The Board specifies by rule certain acts that pharmacy technicians are prohibited from performing, which includes:[40]

[31] Section 465.013, F.S.
[32] Rule 64B16-26.2032, F.A.C. (U.S. pharmacy students/graduates); Rule 64B16-26.2033, F.A.C. (foreign pharmacy graduates).
[33] Rule 64B16-27.4001, F.A.C.
[34] Rule, 64B16-27.420, F.A.C.
[35] Rule 64B16-27.1001(7), F.A.C.
[36] Section 465.014(2), F.S., and Rule 64B16-26.350, F.A.C.
[37] Rule 64B16-26.351, F.A.C.
[38] Section 465.014(6), F.S.
[39] Rule 65B16-26.355, F.A.C.

- Receiving new verbal prescriptions or any change in the medication, strength, or directions;
- Interpreting a prescription or medication order for therapeutic acceptability and appropriateness;
- Conducting a final verification of dosage and directions;
- Engaging in prospective drug review;
- Providing patient counseling;
- Transfer a prescription;
- Preparing copies of prescriptions or reading a prescription to any patient for the purpose of providing reference to the treatment of the patient;
- Receiving therapy or blood product procedures permitted in a nuclear pharmacy;
- Monitoring prescription drug usage;
- Overriding clinical alerts without first notifying the pharmacist; and
- Engaging in any other act which requires a pharmacist's professional judgment.

Pharmacy technicians are not currently authorized by law to administer immunizations or vaccines.

Pharmacist Vaccine Administration

Current law authorizes a pharmacist, or a registered pharmacy intern under the supervision of a certified pharmacist at a ratio of 1:1, to administer immunizations and vaccines to adults within an established protocol under a licensed supervising physician.[41] The protocol between the pharmacist and the supervising physician dictates which types of patients to whom the pharmacist may administer allowable vaccines.[42] 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.[43]

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:[44]

- Mechanisms of action for vaccines, contraindications, drug interactions, and monitoring after vaccine administration;
- Immunization schedules;
- Immunization screening questions, provision of risk/benefit information, informed consent, recordkeeping, and electronic reporting into the state immunization registry;
- 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 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 April 30, 2021 CDC Recommended Adult Immunization Schedule;
- The immunizations or vaccines recommended for international travel as of April 30, 2021 found in the CDC Health Information for International Travel (2020 Edition);

[40] *Supra,* note 34.
[41] Section 468.189(1), F.S.
[42] Section 465.189(7), F.S.
[43] Id.
[44] Rule 64B16-26.1031, F.A.C.

- State of emergency administration of immunizations or vaccines;
- 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.[45] Pharmacists who are certified to administer vaccines must maintain at least $200,000 of professional liability insurance.[46] 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 April 30, 2021, CDC Recommended Adult Immunization Schedule. No additional vaccines have been added to such list since April 30, 2021.

However, current law authorizes the Board to add additional vaccines a pharmacist may administer by rule.[47] The Board added the Meningococcal B vaccine in 2016 and the Zoster vaccine in 2018.[48] The Board may authorize pharmacists to administer vaccines in response to a declared state of emergency.[49]

Currently, 15,091 pharmacists and 3,802 pharmacy interns are certified to administer vaccines.[50]

Effect of Proposed Changes

CS/HB 1209 authorizes certified registered pharmacy technicians to administer vaccines to adults. To become certified, a registered pharmacy technician must complete a certification program approved by the Board, in consultation with the Board of Medicine and the Board of Osteopathic Medicine. The training curriculum must have at least 6 hours of training that, at a minimum, includes instruction on the safe and effective administration of vaccines and potential allergic reactions to such vaccines. Upon registration renewal, registered pharmacy technicians must have at least two hours of additional continuing education approved by the Board.

The bill requires registered pharmacy interns and registered pharmacy technicians who administer vaccines to adults to do so under the supervision of a certified pharmacist who has an established protocol with a supervising physician.

The bill updates the authorized immunizations or vaccines that may be administered from those listed in the CDC Recommended Immunization Schedule for adults, the CDC's Health Information for International Travel, and those licensed or authorized for emergency use by the FDA as of April 30, 2021 to those listed or approved as of March 31, 2022. Such CDC-recommended vaccines, and vaccines licensed or authorized for emergency use by the FDA have not changed since April 30, 2021. However, vaccines may be added to the CDC-recommend lists for adults or authorized for emergency use by the FDA on or before March 31, 2022.

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

B. SECTION DIRECTORY:

Section 1: Amends s. 465.014, F.S., relating to pharmacy technician.
Section 2: Amends s. 465.189, F.S., relating to administration of vaccines and epinephrine autoinfection.
Section 3: Provides an effective date of July 1, 2022.

[45] Id.
[46] Section 465.189(3), F.S.
[47] Section 465.189, F.S.
[48] Rule 64B16-27.630, F.A.C.
[49] Section 465.189(1)(c), F.S.
[50] E-mail from Gangul Gabadage, Legislative Planning Coordinator, Department of Health, Pharmacist Administered Vaccines dated Jan. 28, 2022.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   DOH estimates 3 full-time equivalent (FTE) positions will be needed for processing certifications of pharmacy technicians who wish to administer vaccines, rulemaking, receiving and processing complaints, updating technology and data systems, and conducting investigations and prosecution, at a total cost of $170,674, which includes:[51]

   - $132,942 in recurring funding for 3 FTE salaries;
   - $22,869 recurring funding and $13,947 non-recurring funding for expenses; and
   - $916 recurring funding for Human Resources.

   A review of the DOH's vacant positions shows there are sufficient existing vacancies from which resources can be redirected to fund these new positions to implement the provisions of this legislation. These positions have been vacant for over 180 days, and the department has the ability to internally reorganize personnel as needed. Additionally, the nonrecurring system updates can be absorbed within existing resources.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

   None.

D. FISCAL COMMENTS:

   None.

[51] Department of Health Agency Analysis of 2022 House Bill 1209 (Jan. 28, 2022).

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

Current law provides sufficient rulemaking authority to implement the bill's provisions.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

On February 2, 2022, the Professions and Public Health Subcommittee adopted an amendment and reported the bill favorably as a committee substitute. The amendment:

- Required pharmacy technicians to complete a certification program approved by the Board of Pharmacy in consultation with the Board of Medicine and the Board of Osteopathic Medicine in order to administer vaccines;
- Made a technical change to clarify that only pharmacists are required to have a protocol with a physician to administer vaccines; and
- Removed the vaccine specific pharmacist to pharmacist technician ratio.

This analysis is drafted to the committee substitute as passed by the Professions and Public Health Subcommittee.