HOUSE OF REPRESENTATIVES STAFF FINAL BILL ANALYSIS

BILL #: CS/CS/HB 1063 Administration of Vaccines
SPONSOR(S): Health & Human Services Committee and Professions & Public Health Subcommittee, Fernandez-Barquin and others
TIED BILLS: **IDEN./SIM. BILLS:** CS/CS/SB 768

FINAL HOUSE FLOOR ACTION: 112 **Y's** 4 **N's** **GOVERNOR'S ACTION:** Approved

SUMMARY ANALYSIS

CS/CS/HB 1063 passed the House on April 28, 2021, as CS/CS/SB 768.

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.

The bill authorizes qualified Florida-licensed pharmacists or registered pharmacy interns to administer to adults immunizations or vaccines, which, as of April 30, 2021, are recommended by the CDC, licensed in the United States by the U.S. Food and Drug Administration (FDA), or authorized for emergency use by the FDA. The bill authorizes the Board of Pharmacy to authorize additional immunizations or vaccines for administration as they are licensed or authorized for emergency use by the FDA. The bill also authorizes pharmacists to provide influenza vaccines to individuals age 7 and older.

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

The bill was approved by the Governor on June 21, 2021, ch. 2021-127, L.O.F., the effective date of this bill is July 1, 2021.

I. SUBSTANTIVE INFORMATION

A. EFFECT OF 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 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
- 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

[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 April 29, 2021). 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 April 29, 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 April 29, 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 April 29, 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.

- Meningococcal B

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

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]

FDA Licensure and Emergency Use Authorization

The United States Food and Drug Administration (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.[13]

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[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 April 29, 2021).
[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 April 29, 2021).
[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 April 29, 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 April 29, 2021).
[12] Id.
[13] U.S. Food and Drug Adminisration, *Vaccine Development – 101,* https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/vaccine-development-101 (last visited April 29, 2021).

All vaccines must be licensed (approved) by the FDA in order to be marketed in the United States.[14] However, during public health emergencies, the FDA may authorize vaccines for emergency use, which speeds up the process of brining a vaccine to market.[15]

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.[16] Under section 564 of the Federal Food, Drug, and Cosmetic Act,[17] when the Secretary of the United States Department of Health and Human Services (HHS) 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.[18]

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.[19] The FDA expects all manufacturers who receive an EUA to pursue licensure.[20]

Practice of Pharmacy

Licensure

Pharmacy is the third largest health profession behind nursing and medicine.[21] The Board of Pharmacy (Board), in conjunction with the Department of Health (DOH), regulates the practice of pharmacists pursuant to ch. 465, F.S.[22] To be licensed as a pharmacist, a person must:[23]

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

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[14] 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 April 29, 2021).
[15] 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 April 29, 2021). Medical countermeasures are FDA-regulated products (biologics, drugs, and devices) that may be used in the event of a public health emergency.
[16] Id.
[17] 21 U.S.C. § 360bbb-3.
[18] *Supra,* note 15. A determination that a public health emergency exists does not enable the FDA to issue EUAs.
[19] Id.
[20] 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 April 29, 2021).
[21] American Association of Colleges of Pharmacy, *About AACP*, available at https://www.aacp.org/about-aacp (last visited April 29, 2021).
[22] Sections 465.004 and 465.005, F.S.
[23] 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.
[24] 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
[25] Section 465.009, F.S.
[26] 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.[27]

Scope of Practice

In Florida, the practice of the profession of pharmacy includes:[28]

- 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;[29]
- Administering epinephrine injections;[30] and
- Administering antipsychotic medications by injection.[31]

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.[32] 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.[33]

A pharmacist is responsible for any delegated act performed by a registered pharmacy intern employed or supervised by the pharmacist.[34]

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.[35] The protocol between the pharmacist and the supervising physician dictates which types of patients to whom the pharmacist may administer allowable vaccines.[36] 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.[37]

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

[27] Section 465.1893, F.S.
[28] Section 465.003(13), F.S.
[29] *See* s. 465.189, F.S.
[30] Id.
[31] Section 465.1893, F.S.
[32] Section 465.013, F.S.
[33] Rule 64B16-26.2032, F.A.C. (U.S. pharmacy students/graduates); Rule 64B16-26.2033, F.A.C. (foreign pharmacy graduates).
[34] Rule 64B16-27.430, F.A.C.
[35] Section 468.189(1), F.S.
[36] Section 465.189(7), F.S.
[37] Id.

requires a pharmacist or registered intern to complete 20 hours of Board-approved continuing education that addresses:[38]

- 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 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;
- 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.[39] Pharmacists who are certified to administer vaccines must maintain at least $200,000 of professional liability insurance.[40] 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. This is the same as the 2021 list of recommended vaccines (see pg. 3), except that the 2015 list does not include the Meningococcal B vaccine, which the CDC added in 2016.[41]

However, current law authorizes the Board to add additional vaccines a pharmacist may administer by rule.[42] The Board added the Meningococcal B vaccine in 2016 and the Zoster vaccine in 2018.[43] The Board may authorize pharmacists to administer vaccines in response to a declared state of emergency.[44]

Currently, 14,579 pharmacists and 3,579 pharmacy interns are certified to administer vaccines.[45]

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[38] Rule 64B16-26.1031, F.A.C.
[39] Id.
[40] Section 465.189(3), F.S.
[41] 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 April 29, 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 and Centers for Disease Control and Prevention, *Recommended Adult Immunization Schedule, United States – 2016,* available at https://www.cdc.gov/vaccines/schedules/downloads/past/2016-adult.pdf (last visited April 29, 2021).
[42] Section 465.189, F.S..
[43] Rule 64B16-27.630, F.A.C.
[44] Section 465.189(1)(c), F.S.
[45] E-mail correspondence with DOH, dated March 8, 2021 on file with the Professions and Public Health Subcommittee.

Pharmacist Vaccination and Age Restrictions

In 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.[46]

Currently, all 50 states authorize pharmacists to administer vaccinations; however, that authority may vary by.[47] For example, four states, including Florida, limit pharmacist vaccinations to adult patients.[48] Twenty-six states allow pharmacists to administer vaccines to individuals of any age.[49] The remaining states have minimum age restrictions that range from 2 years to 12 years.[50]

Authority to administer influenza vaccines to minors differ by state. 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.[51]

Effect of Proposed Changes

CS/CS/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 travel. The bill 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 as of April 30, 2021. This allows pharmacists to administer the Meningococcal B vaccine, which is on the 2021 recommended immunization schedule but was not on the 2015 schedule.

The bill also authorizes a pharmacist, or a registered intern under the supervision of a pharmacist, to administer any vaccine licensed or authorized for emergency use by the FDA as of April 30, 2021, and allows the Board to authorize by rule additional vaccines as they are licensed or authorized for emergency use by the FDA. This allows a pharmacist to administer vaccines for yellow fever, cholera,

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[46] 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 April 29, 2021).
[47] 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 April 29, 2021).
[48] 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 April 29, 2021). The states that limit pharmacist vaccinations to adults are Connecticut, Delaware, Florida, and Vermont.
[49] 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.
[50] 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.
[51] 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.

dengue, Japanese encephalitis, plague, rabies, smallpox, and typhoid, which are not in the CDC-recommended schedule but have been approved by the FDA. This also allows pharmacists to administer the COVID-19 vaccine, which is FDA-authorized for emergency use.

The bill expands the authority of qualified pharmacists to administer the influenza vaccines to allow them to administer the vaccine to individuals age 7 and older.

The bill 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 bill may have an insignificant, negative fiscal impact on DOH, for rulemaking activity, which 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:

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

D. FISCAL COMMENTS:

None.