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.)

Prepared By: The Professional Staff of the Committee on Health Policy

BILL:	SB 1506
INTRODUCER:	Senator Rodriguez
SUBJECT:	Department of Health
DATE:	March 24, 2023
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Rossitto Vanwinkle	Brown	HP	**Pre-meeting**
2.			RC	

I. Summary:

SB 1506 revises statutes relating to the Department of Health (DOH). The bill:

- Creates s. 381.87, F.S., to prohibit research that is reasonably likely to create an enhanced potential pandemic pathogen (ePPP) or that has been determined by the U.S. Department of Health and Human Services (HHS), or other federal agency or state agency, to create such a pathogen. The bill defines terms, and requires researchers applying for funding to disclose in the application if the research meets the definition of ePPP research.
- Makes several revisions to statutes governing the DOH medical marijuana program, including:
  - Defining the term "attractive to children" and expanding a prohibition that edibles not be attractive to children.
  - Expanding the DOH rulemaking authority to require the DOH to adopt rules it deems necessary to protect the health and safety of qualified patients and minors.
  - Amending background screening provisions related to medical marijuana and certified marijuana testing laboratories (CMTL).
- Updates ch. 382, F.S., vital statistics, to make electronic filing mandatory, when possible;
- Amends s. 382.009, F.S., to no longer require that two physicians must make a determination of brain death for a comatose patient. Instead, the bill would require such a determination be made by two licensed health care practitioners who must be physicians, physician assistants (PAs) or autonomous advanced practice registered nurses (A-APRNs), with one being the patient's treating health care practitioner.
- Amends s. 382.025, F.S., to increase the age at which birth records will remain confidential and exempt, from 100 years of age to 125 years of age;
- Removes a requirement for emergency medical technicians (EMTs) and paramedics applying to the DOH for licensure to do so "under oath" and replaces the legal term with an attestation, and removes the obsolete National Standard Curriculum from the training materials.

- Amends s. 401.34, F.S., to delete obsolete same-day grading of EMT and paramedic examinations, walk-in eligibility for determinations and examinations, and the fees for EMT and paramedic examination reviews;
- Amends s. 401.272, F.S., to eliminate an EMT's or paramedic's ability to partner with local county health departments and:
  - Requires EMTs and paramedics to practice under the medical direction of a physician through two-way voice communication or established standing orders or protocols when providing Basic Life Support (BLS), Advanced Life Support (ALS), and health promotion and wellness activities in a nonemergency environment.
  - Deletes the required supervision of an EMT and paramedic by a medical director in a nonemergency environment.
  - Eliminates blood pressure screening from the activities an EMT or paramedic may perform only under medical direction in a nonemergency environment.
- Amends s. 401.435, F.S., to remove the obsolete term "first responder" and replaces it with "emergency medical responder."
- Amends s. 464.203, F.S., to exempt certified nursing assistant (CNA) applicants who have completed an approved training program from the licensure requirement of taking the skills-demonstration portion of the examination.
- Amends numerous sections of Part I, ch. 468 and Part II, ch. 484, F.S., to narrow the scope of practice for audiologists and hearing aid specialists to the dispensing of prescription hearing aids; and
  - Deletes regulation of the sale of over-the-counter (OTC) hearing aids to consumers with perceived mild to moderate hearing impairment through in-person transactions, by mail, or online;
  - Authorizes licensed hearing aid specialists to service, market, sell, dispense, provide customer support for, and distribute prescription and OTC hearing aids; and
  - Removes restrictions and criminal penalties for the sale or distribution of hearing aids through the mail.

The bill directs the Division of Law Revision to replace the phrase "the effective date of this act" with the date the act becomes law.

The bill provides an effective date of July 1, 2023, unless otherwise indicated.

II. Present Situation:

The Department of Health

The DOH is responsible for the protection and promotion of the health of Florida residents and visitors through organized state and community efforts, including, among other things, the responsibility to identify, diagnose, and conduct surveillance of diseases and health conditions in the state, accumulate the health statistics necessary to establish trends, and regulate health care practitioners for the preservation of the health, safety, and welfare of the public.[1]

[1] Section 20.43, F.S.

Enhanced Potential Pandemic Pathogen Research

Since 2012, with the emergence of gain of function (GOF) research,[2] a lack of oversight monitoring this sort of research has been noted. The risk of this type of research was addressed by a report from the HHS Inspector General after concerns that the early onset of the COVID-19 pandemic in 2019 stemmed from SARS-like coronavirus research in Wuhan, China. The HHS report found that while the National Institutes of Health (NIH) oversight of research being performed by EcoHealth Alliance (EcoHealth)[3] with NIH grant funding was adequate in certain areas, it was insufficient in monitoring EcoHealth's compliance with federal requirements in other areas. Specifically, the NIH did not ensure EcoHealth submitted a progress report in a timely manner that contained evidence of a virus with growth that should have been reported immediately; did not ensure EcoHealth publicly reported required sub-award data; misused grant funds; and did not follow proper procedures to terminate the award to EcoHealth.[4]

Laboratories that conduct GOF research are classified in biosafety levels (BSL) ranging from one through four, with Biosafety Level Four (BSL-4) posing the greatest risk. The BSLs are used to identify the protective measures needed in a laboratory setting to protect, workers, the environment, and the public.

BSL-1 laboratories are used to study infectious agents or toxins not known to consistently cause disease in healthy adults. BSL-2 laboratories are used to study moderate-risk infectious agents or toxins that pose a risk if accidentally inhaled, swallowed, or exposed to the skin. BSL-3 laboratories are used to study infectious agents or toxins that may be transmitted through the air and cause potentially lethal infection through inhalation exposure. BSL-4 laboratories are used to study infectious agents or toxins that pose a high risk of aerosol-transmitted laboratory infections and life-threatening disease for which no vaccine or therapy is available.[5]

According to the DOH, there are no known BSL-4 laboratories in the State of Florida.[6,7]

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[2] Congressional Research Service, IN FOCUS, *Global Pandemics: Gain-of-Function Research of Concern*, Nov. 21, 2022, available at https://crsreports.congress.gov/product/pdf/IF/IF12021 (last visited Mar. 23, 2023). Gain-of-Function (GOF) research is a broad area of scientific inquiry where an organism gains a new property or an existing property is altered. The terms gain of function and loss of function refer to any genetic mutation in an organism that either confers a new or enhanced ability or causes the loss of an ability. Such changes often occur naturally. Additionally, scientists can induce some changes to organisms through experimentation.

[3] EcoHealth Alliance, *Local Conservation. Global Health.*, available at https://www.ecohealthalliance.org/about (last visited Mar. 23, 2023. EcoHealth Alliance is an international nonprofit dedicated to a 'One Health' approach to protecting the health of people, animals and the environment from emerging infectious diseases. The organization formed with the merger of two highly respected organizations, Wildlife Trust and the Consortium for Conservation Medicine. The urgent concern for wildlife conservation and the overall health of our planet has led EcoHealth Alliance to become an environmental science and public health leader working to prevent pandemics in global hotspot regions across the globe and to promote conservation.

[4] U.S. Department of Health and Human Services, *Office of Inspector General: The National Institutes of Health and EcoHealth Alliance Did Not Effectively Monitor Awards and Subawards, Resulting in Missed Opportunities to Oversee Research and Other Deficiencies*, Jan., 2023, available at https://oig.hhs.gov/oas/reports/region5/52100025.pdf (last visited Mar. 23, 2023).

[5] *Id.*

[6] Department of Health, 2023 Agency Legislative Bill Analysis, *Senate Bill 1506* (on file with the Senate Committee on Health Policy).

[7] *See also* Global Biolabs, available at https://www.globalbiolabs.org/map (last visited Mar. 23, 2023).

Medical Marijuana

Amendment 2

On November 4, 2016, Amendment 2 was approved by the statewide electorate and established Article X, section 29 of the Florida Constitution. This section of the constitution became effective on January 3, 2017, and created several exemptions from criminal and civil liability for:

- Qualifying patients who medically use marijuana in compliance with the amendment;
- Physicians, solely for issuing physician certifications with reasonable care and in compliance with the amendment; and
- MMTCs and their agents and employees for actions or conduct under the amendment and in compliance with rules promulgated by the DOH.

Subsequently, the Legislature passed SB 8-A in Special Session A of 2017.[8] The bill revised the Compassionate Medical Cannabis Act of 2014[9] in s. 381.986, F.S., to implement Article X, section 29 of the State Constitution.

Medical Marijuana Related Background Screening

Section 381.986, F.S., requires background screening for any person who registers as an qualified patient's caregiver[10] as well as the owners, operators, board members, managers, and employees of a MMTC. Individuals who are required to undergo background screening must pass a level 2 background screening. In addition to the disqualifying offenses included in s. 435.04, F.S., the section adds an arrest awaiting final disposition for, being found guilty of, regardless of adjudication, or entering a plea of nolo contendere or guilty to an offense under chapter 837,[11] chapter 895,[12] or chapter 896[13] or similar law of another jurisdiction.

Section 381.988, F.S., establishes requirements for persons or entities seeking to be certified as a CMTL. Among the requirements, s. 381.988(1)(d), F.S., requires all owners and managers, but not employees, of a CMTL to pass a level 2 background screening.

Both sections specify that:

- Individuals required to undergo a background screening must submit a full set of fingerprints to the DOH or to a vendor, entity, or agency authorized by s. 943.053(13), F.S. The DOH, vendor, entity, or agency must forward the fingerprints to the Department of Law Enforcement (FDLE) for state processing, and the FDLE must forward the fingerprints to the Federal Bureau of Investigation (FBI) for national processing.
- Fees for state and federal fingerprint processing and retention will be borne by the individual or, in the case of CMTLs, the owners or managers of the CMTL. The state cost for fingerprint processing must be as provided in s. 943.053(3)(e), F.S.,[14] for records provided to persons or entities other than those specified as exceptions therein.

[8] Chapter 2017-232, Laws of Fla.
[9] Chapter 2014-157, Laws of Fla.
[10] Under subsection (6) of s. 381.986, F.S.
[11] Perjury.
[12] Offenses concerning racketeering and illegal debts.
[13] Offenses related to financial transactions.
[14] The fee is $24 per name submitted.

- Fingerprints submitted to the FDLE must be retained by the FDLE as provided in s. 943.05(2)(g) and (h), F.S., and enrolled in the FBI's national retained print arrest notification program. Any arrest record identified must be reported to the DOH.

Level 2 Background Screening

Section 435.04, F.S., establishes the standards for level 2 background screenings. The section specifies that a background screening under its provisions must include fingerprinting for statewide criminal history records checks through the FDLE and a national criminal history records checks through the FBI, and may include local criminal records checks through local law enforcement agencies. Fingerprints submitted must be submitted electronically to the FDLE and agencies may contract with one or more vendors to perform all or part of the electronic fingerprinting.

In order to pass a level 2 background screening, the individual being screened may not have been arrested for and are awaiting final disposition of, have been found guilty of, regardless of adjudication, or entered a plea of nolo contendere or guilty to, or have been adjudicated delinquent and the record has not been sealed or expunged for any of the offenses listed in the section or similar provisions in other jurisdictions. The section provides additional disqualifying offenses applicable to participation in the Medicaid program.

Exemptions

Section 435.07, F.S., allows heads of agencies to grant an exemption from disqualification for an employee who would be disqualified under s. 435.04, F.S., or other background screening provisions. These exemptions may be granted for:

- Felonies for which at least three years have elapsed since the applicant for the exemption has completed or been lawfully released from confinement, supervision, or nonmonetary condition imposed by the court for the disqualifying felony;
- Misdemeanors prohibited under any of the statutes cited in this chapter or under similar statutes of other jurisdictions for which the applicant for the exemption has completed or been lawfully released from confinement, supervision, or nonmonetary condition imposed by the court;
- Offenses that were felonies when committed but that are now misdemeanors and for which the applicant for the exemption has completed or been lawfully released from confinement, supervision, or nonmonetary condition imposed by the court; or
- Findings of delinquency. For offenses that would be felonies if committed by an adult and the record has not been sealed or expunged, the exemption may not be granted until at least three years have elapsed since the applicant for the exemption has completed or been lawfully released from confinement, supervision, or nonmonetary condition imposed by the court for the disqualifying offense.

In order to be granted an exemption, the employee seeking the exemption must provide clear and convincing evidence that he or she should not be disqualified from employment. The employing, or potentially employing, agency may consider crimes committed or that he or she has been arrested for after the disqualifying offense, even if the crime is not itself a disqualifying offense. The decision regarding whether to grant an exemption is subject to the due process provisions in ch. 120, F.S. Additionally, the section specifies that disqualification cannot be removed if the

employee is seeking a child care position, if the employee is a sex offender, or if the disqualifying offense is one of a list of specified offenses.

Vital Statistics

The Office of Vital Statistics,[15] housed within the DOH, is responsible for compiling, storing, and preserving the vital records of the state. Vital records[16] are the official certificates or reports of birth, death, fetal death, marriage, dissolution of marriage, certain name changes, and data related to these records.

Florida officially began collecting birth and death records in 1917. Two years later, the state became a nationally recognized death registration jurisdiction. In 1924, the state became a nationally recognized birth registration jurisdiction. Since 1927, marriage and dissolution records have been filed with the Office of Vital Statistics.[17] In addition to the state office, which operates under the direction of the state registrar, district offices operate under the direction of local registrars.

Local Registrars

Each local registrar is charged with the enforcement of the provisions of ch. 382, F.S., and the rules adopted pursuant thereto, in his or her district, and must report to the DOH any violations. A local registrar must make blank forms available and examine each certificate of live birth, death, or fetal death when presented to determine if it has been fully completed as required by law. All birth, death, and fetal death certificates must be typewritten in permanent black ink. A certificate is not complete if it does not supply each item of information required or satisfactorily account for any omissions.

A local registrar, immediately upon appointment, must designate one or more deputy registrars to act on behalf of the local registrar, and if authorized by the DOH, to sign as registrar in attestation of the date of registration and may also make and preserve local records of birth, death, and fetal death certificates registered in the manner required by the DOH. The local registrar must monthly transmit to the DOH all original certificates registered. If no births, deaths, or fetal deaths occurred in a month, the local registrar or deputy must, on the seventh day of the following month, report that fact to the DOH on a DOH approved form.[18]

Death, Fetal Death, and Nonviable Birth Registration

A certificate for each death and fetal death in Florida must be filed electronically on the DOH electronic death registration system or filed, on a form prescribed by the DOH, with the DOH or the local registrar within five days after such death and prior to final disposition, and must be

[15] The vital statistics statutes consistently refer to the "Office" of Vital Statistics and not the "Bureau" of Vital Statistics. For example, s*ee* s. 382.003, F.S. While the statutes refer to an Office of Vital Statistics, the DOH has established this responsibility at the bureau level. *See* the DOH's organizational chart available at https://www.floridahealth.gov/about/_documents/orgchart.pdf (last visited Mar. 23, 2023).
[16] Section 382.002(17), F.S.
[17] Department of Health, *Florida Vital Statistics Annual Report 2021*, Dec. 2022, p. *vii*, available at http://www.flpublichealth.com/VSbook/PDF/2021/VSCOMP.pdf (last visited Mar. 23, 2023).
[18] Section 382.005, F.S.

registered by the DOH correctly completed and filed. The certificate must include the decedent's social security number, if available, and the following:

- The decedent's name of record and aliases or "also known as" (AKA) names, if requested by the informant;
- The place of death. If unknown, then the registration district in which the dead body or fetus is found within five days after the occurrence; and
- If the death occurs in a moving conveyance, then the death must be registered in the district in which the dead body was first removed from such conveyance.

The funeral director who first assumes custody of a dead body or fetus must file the certificate of death or fetal death. In the absence of the funeral director, the physician, PA, A-APRN , or other person in attendance at or after the death or the district medical examiner of the county in which the death occurred or the body was found, must file the certificate of death or fetal death. The person who files the certificate must obtain personal data from a legally authorized person[19] or the best qualified person or source available. The medical certification of cause of death must be furnished to the funeral director, either in person or via certified mail or electronic transfer, by the physician, PA, A-APRN, or medical examiner responsible for furnishing such information. For fetal deaths, the physician, PA, A-APRN, midwife, or hospital administrator must provide any medical or health information to the funeral director within 72 hours after expulsion or extraction.

The state registrar may receive electronically a certificate of death, fetal death, or nonviable birth which is required to be filed with the registrar under ch. 382, F.S., through facsimile or other electronic transfer for the purpose of filing. The receipt of a certificate of death, fetal death, or nonviable birth by electronic transfer constitutes delivery to the state registrar as required by law.[20]

Brain Death Recognition

Where respiratory and circulatory functions are maintained by artificial means to preclude a determination that these functions have ceased, Florida law permits the occurrence of death to be determined where there is the irreversible cessation of the functioning of the entire brain, including the brain stem.

This determination of brain death must be made in accordance with currently accepted reasonable medical standards by two physicians who may be allopathic or osteopathic physicians. One physician must be the treating physician and the other must be a board-eligible or board-certified neurologist, neurosurgeon, internist, pediatrician, surgeon, or anesthesiologist.

[19] *See* s .497.005(43), F.S., which defines a "legally authorized person," in order of the priority as follows: 1)The decedent, when written inter vivos authorizations and directions are provided by the decedent; 2) the person designated by the decedent as authorized to direct disposition pursuant to Pub. L. No. 109-163, s. 564, as listed on the decedent's U.S. Department of Defense Record of Emergency Data, DD Form 93, or its successor form, if the decedent died while in military service as described in 10 U.S.C. s. 1481(a)(1)-(8) in any branch of the United States Armed Forces, United States Reserve Forces, or National Guard; 3) the surviving spouse, unless the spouse has been arrested for committing an act of domestic violence as defined in s. 741.28, F.S., against the deceased that resulted in or contributed to the decedent's death; 4) a son or daughter who is 18 years of age or older; 5) a parent; 6) a brother or sister who is 18 years of age or older; 7) a grandchild who is 18 years of age or older; 8) a grandparent; or 9) any person in the next degree of kinship.

[20] Section 382.008, F.S.

The patient's next of kin must be notified as soon as practicable of the procedures for the legal determination of brain death. The medical records must reflect the notice given, and, if notice was not given, the medical records must reflect the attempts to identify and notify the next of kin.

No recovery is permitted, nor may criminal proceedings be instituted, against a physician or licensed medical facility that makes a determination of brain death under Florida law or when acting in reliance on it, if such determination is made in accordance with the accepted standard of care[21] by such physician or facility. Except for a diagnosis of brain death, the standard set forth under this Florida law is not the exclusive standard for determining death or for the withdrawal of life support system.[22]

Birth Registration

A certificate for each live birth that occurs in this state must be filed within five days after the birth. The certificate may be filed with the local registrar of the district where the birth occurred or submitted electronically to the state registrar. Responsibility for filing the certificate is assigned to various persons depending upon where the birth occurs. If the birth occurs in a hospital, birth center, or other health care facility, or in route thereto, the person in charge of the facility is responsible for filing the certificate. The health care practitioner in attendance is responsible for providing the facility with the information required by the birth certificate. If the birth occurs outside a facility and a physician, certified nurse midwife, midwife, or a public health nurse employed by the DOH who was in attendance, must file the certificate.[23]

New Certificate of Live Birth

The clerk of court in which any proceeding for adoption, annulment of an adoption, affirmation of parental status, or determination of paternity is to be registered, must within 30 days after the final disposition, forward to the DOH a certified copy of the court order, or a report of the proceedings upon a form furnished by the DOH, together with sufficient information to identify the original birth certificate and to enable the preparation of a new birth certificate. The clerk of court must implement a monitoring and quality control plan to ensure that all judicial determinations of paternity are reported to the DOH. The DOH must track paternity determinations reported monthly by the county, monitor compliance within the 30 day timeframe, and report the data to the clerks of court quarterly.[24]

Marriage Licenses

On or before the fifth day of each month, the county court judge or clerk of the circuit court must transmit all original marriage licenses, with endorsements, received during the preceding calendar month, to the DOH. Any marriage licenses issued and not returned, or any marriage

[21] Section 766.102, F.S., does not set forth the "acceptable standard of care" as used in s. 382.009, F.S., to determine brain death; but defines the *prevailing professional standard of care* for a given health care provider as that level of care, skill, and treatment which, in light of all relevant surrounding circumstances, is recognized as acceptable and appropriate by reasonably prudent similar health care providers.
[22] Section 382.009, F.S.
[23] Section 382.013, F.S.
[24] Section 382.015, F.S.

licenses returned but not recorded, must be reported by the issuing county court judge or clerk of the circuit court to the DOH at the time of transmitting the recorded licenses on forms prescribed and provided by the DOH. If, during any month, no marriage licenses are issued or returned, the county court judge or clerk of the circuit court must report that fact to the DOH upon forms prescribed and furnished by the DOH.[25]

Dissolution of Marriage Records

Clerks of the circuit courts must collect for their services at the time of the filing of a final judgment of dissolution of marriage a fee of up to $10.50, of which 43 percent must be retained by the circuit court as a part of the cost in the cause in which the judgment is granted. The remaining 57 percent must be sent to the Department of Revenue (DOR) for deposit to the DOH account to defray part of the cost of maintaining the dissolution-of-marriage records. A record of each judgment of dissolution of marriage granted by the court during the preceding month, must be transmitted to the DOH, on or before the tenth day of each month, giving the names of parties and such other data as required by DOH prescribed forms, along with an accounting of the funds remitted to the DOR.[26]

Certified Copies of Vital Records and Confidentiality

Except for birth records over 100 years old, which are not under seal pursuant to court order, all birth records of this state are confidential and exempt from inspection and copying by any person desiring to do so, at any reasonable time, under reasonable conditions, and under supervision by the custodian of the public records.[27]

Certified copies of an original birth certificate or a new or amended certificate are confidential and exempt from inspection and copying by any person desiring to do so, at any reasonable time, under reasonable conditions, and under supervision by the custodian of the public records and, upon receipt of a request and payment of the fee, must be issued only as authorized by the DOH and in the form prescribed by the DOH, and only:

- To the registrant, if the registrant is of legal age, is a certified homeless youth, or is a minor who has had the disabilities of nonage removed;[28]
- To the registrant's parent or guardian or other legal representative;
- Upon receipt of the registrant's death certificate, to the registrant's spouse or to the registrant's child, grandchild, or sibling, if of legal age, or to the legal representative of any of such persons;
- To any person if the birth record is over 100 years old and not under seal pursuant to court order;
- To a law enforcement agency for official purposes;

[25] Section 382.021, F.S.
[26] Section 382.023, .F.S.
[27] Section 382.025, F.S. referencing s. 119.07, F.S., the public records law and exemptions.
[28] *See* ss. 743.01 and 743.015, F.S. The removal of the disability of age occurs when a petition is filed in the circuit court by a minor's natural or legal guardian or, if there is none, by a guardian ad litem, to remove the disabilities of nonage for a minor age 16 or older due to marriage, dissolution of marriage, or widowhood. Once removed, the minor may assume the management of his or her estate, contract and be contracted with, sue and be sued, and perform all acts that he or she could do as if he or she were an adult.

- To any agency of the state or the United States for official purposes upon approval of the DOH; or
- Upon order of any court of competent jurisdiction.[29]

Emergency Medical Technicians, Paramedics and Community Health Services

EMTs and Paramedics Education

Any person desiring to be certified or recertified as an EMT or paramedic must apply to the DOH under oath on forms provided by the DOH which must contain information reasonably required by the DOH, which may include affirmative evidence of the ability to comply with applicable laws and rules. The DOH must determine whether the applicant meets the statutory and DOH rule requirements and must issue a certificate to any person who meets such requirements.[30]

An applicant for certification or recertification as an EMT or paramedic must:[31]

- Have completed an appropriate training program as follows:
  - For an EMT, a program approved by the DOH as equivalent to the most recent EMT-Basic National Standard Curriculum or the National Emergency Medical Services (EMS) Education Standards of the U.S. Department of Transportation (DOT);
  - For a paramedic, a paramedic training program approved by the DOH as equivalent to the most recent EMT-Paramedic National Standard Curriculum or the National EMS Education Standards of the U.S. DOT.
- Certify under oath[32] that the applicant is not addicted to alcohol or any controlled substance;
- Certify under oath that the applicant is free from any physical or mental defect or disease that might impair the applicant's ability to perform his or her duties;
- Within two years after program completion have passed an examination developed or required by the DOH;
- Hold the following certifications:
  - For an EMT, hold a current American Heart Association (AHA) cardiopulmonary resuscitation course card or an American Red Cross cardiopulmonary resuscitation course card or its equivalent as defined by DOH rule;
  - For a paramedic hold a certificate in advanced cardiac life support from the AHA or its equivalent as defined by DOH rule.
- Submit the certification fee and the nonrefundable examination fee, required for each examination administered to an applicant; and
- Submit a completed application to the DOH which must be submitted at least 30 calendar days before the next regularly scheduled examination for which the applicant desires to be scheduled.

The DOH certification examination must be offered monthly. The DOH must issue an examination admission notice to the applicant advising him or her of the time and place of the

[29] Section 382.025, F.S.
[30] Section 401.27, F.S.
[31] *Id.*
[32] Section 1.01(5), F.S., defines an oath to include affirmations.

examination for which he or she is scheduled. Individuals achieving a passing score on the certification examination may be issued a temporary certificate with their examination grade report. The DOH must issue an original certification within 45 days after the examination.[33]

Currently the DOH offers EMT and Paramedic examinations daily at testing centers throughout the state using the National Registry for Emergency Medical Technicians (NREMT) examinations. The DOH transitioned to using the NREMT in 2016 due to s. 456.017(1)(c)(2), F.S., mandating that neither the board nor the DOH may administer a state-developed written examination if a national examination has been certified by the DOH.[34]

Emergency Medical Services Training Programs

Any private or public institution in Florida desiring to conduct an approved program for the education of EMTs and paramedics must:

- Submit a completed application on a form provided by the DOH, which must include:
  - Evidence that the institution is in compliance with all applicable requirements of the Department of Education (DOE).
  - Evidence of an affiliation agreement with a hospital that has an emergency department staffed by at least one physician and one registered nurse.
  - Evidence of an affiliation agreement with a current emergency medical services provider that is licensed in this state. Such agreement must include a commitment by the provider to conduct the field experience portion of the education program.
  - Documentation verifying faculty, including:
    - A medical director who is a licensed physician meeting the applicable requirements for EMS medical directors. The medical director must have the duty and responsibility of certifying that graduates have successfully completed all phases of the education program and are proficient in basic or advanced life support techniques, as applicable.
    - A program director responsible for the operation, organization, periodic review, administration, development, and approval of the program.
  - Documentation verifying that the curriculum:
    - Meets the most recent EMT-Basic National Standard Curriculum or the National EMS Education Standards approved by the department for emergency medical technician programs and EMT-Paramedic National Standard Curriculum or the National EMS Education Standards approved by the department for paramedic programs.
    - Includes two hours of instruction on the trauma scorecard methodologies for assessment of adult trauma patients and pediatric trauma patients as specified by the DOH by rule.
  - Evidence of sufficient medical and educational equipment to meet EMS training program needs.
- Receive a scheduled site visit from the DOH to the applicant's institution. The site visit must be conducted within 30 days after notification to the institution that the application was

[33] *Id.*
[34] Department of Health, 2023 Agency Legislative Bill Analysis, *Senate Bill 1506* (on file with the Senate Committee on Health Policy).

accepted. During the site visit, the DOH must determine the applicant's compliance with specific criteria.[35]

Emergency Medical Services in Community Health Care

Florida encourages the more effective utilization of the skills of EMTs and paramedics by enabling them to perform, in partnership with local county health departments, specific additional health care tasks that are consistent with the public health and welfare.[36]

Paramedics or EMTs may perform health promotion and wellness activities and blood pressure screenings in a nonemergency environment, within the scope of their training, and under the direction of a medical director. The term "health promotion and wellness" means the provision of public health programs pertaining to the prevention of illness and injury.[37]

Paramedics may administer immunizations in a nonemergency environment, within the scope of their training, and under the direction of a medical director. There must be a written agreement between the paramedic's medical director and the county health department located in each county in which the paramedic administers immunizations. This agreement must establish the protocols, policies, and procedures under which the paramedic must operate.[38]

Paramedics may provide BLS services[39] and advanced life support (ALS) services[40] to patients receiving acute and post-acute hospital care at home as specified in the paramedic's supervisory relationship with a physician or standing orders[41] A physician who supervises or provides medical direction to a paramedic who provides BLS services or ALS services to patients receiving acute and post-acute hospital care at home pursuant to a formal supervisory relationship or standing orders is liable for any act or omission of the paramedic acting under the physician's supervision or medical direction when providing such services.[42]

Each medical director under whose direction a paramedic administers immunizations must verify and document that the paramedic has received sufficient training and experience to administer immunizations. The verification must be documented on DOH-developed forms, and the

[35] Section 401. 2701, F.S.
[36] Section 401.272, F.S.
[37] *Id.*
[38] *Id.*
[39] Section 401.23(8) and (9), F.S., defines Basic Life Support (BLS) as any emergency medical service which uses only basic life support techniques. BLS services includes assessment or treatment by a qualified person using techniques described in the EMT-Basic National Standard Curriculum or the National EMS Education Standards of the U.S. DOT and approved by the DOH. The term includes the administration of oxygen and other techniques that have been approved and are performed under conditions specified by DOH rules.
[40] Section 401.23(3) and (4), F.S., defines advanced life support (ALS) services as any emergency medical transport or nontransport service which uses ALS techniques. ALS means the assessment or treatment by a qualified person qualified to use medical techniques such as endotracheal intubation, the administration of drugs or intravenous fluids, telemetry, cardiac monitoring, cardiac defibrillation, and other techniques described in the EMT-Paramedic National Standard Curriculum or the National EMS Education Standards, pursuant to DOH rules.
[41] Section 401.272, F.S. refers to "standing orders" described in ss. 401.265, 458.348, or 459.025. F.S., requires the physician who enters into a standing order relationship with an EMT or paramedic, and the standing orders contemplate the performance of medical acts, the physician must notify the Board of Medicine or Board of Osteopathic Medicine, as applicable.
[42] *Id.*

completed forms must be maintained at the service location of the licensee and made available to the DOH upon request.[43]

The DOH may adopt all rules necessary to enforce the provisions relating to a paramedic's administration of immunizations and the performance of health promotion and wellness activities and blood pressure screenings by a paramedic or an EMT in a nonemergency environment.[44]

EMT and Paramedic Certification Fees

Section 401.34, F.S., outlines the fees that the DOH may charge for various applications, permits, duplicate fees, and testing relating to EMT and paramedic services. EMTs pay $75 for the certification application and examination. Paramedics pay $85. The DOH may offer same day grading for EMTs and paramedic; and may offer walk-in eligibility determination and examination to applicants for EMTs and paramedic certifications who pay a nonrefundable fee not to exceed $65, in addition to the certification fee and examination fee. The DOH must establish locations and times for eligibility determinations and examinations. The cost of the EMT or paramedic certification examination review may not exceed $50.

First Responder Agencies and Training

Section 401.435, F.S., authorizes the DOH to adopt by rule the U.S. DOT EMS: First Responder Training Course as the minimum standard for first responder training. In addition, the DOH must adopt rules establishing minimum first responder instructor qualifications. A first responder includes any individual who receives training to render initial care to an ill or injured person, other than a law enforcement officer trained and certified under s. 943.1395(1), F.S., but who does not have the primary responsibility of treating and transporting ill or injured persons. Each first responder agency must take all reasonable efforts to enter into a memorandum of understanding with the EMS licensee within whose territory the agency operates in order to coordinate emergency services at an emergency scene.

The DOH must provide a model memorandum of understanding for this purpose which should include dispatch protocols, the roles and responsibilities of first responder personnel at an emergency scene, and the documentation required for patient care rendered. The term "first responder agency" includes a law enforcement agency, a fire service agency not licensed ch. 401, F.S., a lifeguard agency, and a volunteer organization that renders, as part of its routine functions, on-scene patient care before EMTs or paramedics arrive.

Certified Nursing Assistants

Florida's regulations of CNAs is found in Part II of ch. 464, F.S. Section 464.201(5), F.S., defines the practice of a CNA as providing care and assisting persons with tasks relating to the activities of daily living. Activities of daily living include tasks associated with: personal care, maintaining mobility, nutrition and hydration, toileting and elimination, assistive devices, safety and cleanliness, data gathering, reporting abnormal signs and symptoms, postmortem care,

[43] *Id.*

[44] Section 401.272, F.S. When a physician enters into a formal supervisory relationship or standing orders with an EMT or paramedic which orders contemplate the performance of medical acts, the physician must notify the Board of Medicine or Board of Osteopathic Medicine, as applicable.

patient socialization and reality orientation, end-of-life care, cardiopulmonary resuscitation (CPR) and emergency care, patients' rights, documentation of nursing-assistant services, and other tasks that a CNA may perform after training.[45]

A CNA can work in a nursing home, an assisted living facility, other community-based settings, a hospital, or a private home under general supervision.[46] The Board of Nursing (BON), within the DOH, certifies CNAs, who must, among other qualifications, also meet one of the following requirements:

- Completion a 120-hour, BON-approved training program and achieved a minimum score, established by BON rule, on the nursing assistant competency examination, which consists of a BON-approved written portion and skills-demonstration portion and in administered at a site and by personnel approved by the DOH;
- Achievement of a minimum score, or higher, established by BON rule, on the nursing assistant competency examination, which consists of a BON-approved written portion and skills-demonstration portion, site and by personnel approved by the DOH and:
  - Has a high school diploma, or its equivalent; or
  - Is at least 18 years of age.
- Current certification in another state or territory of the United States or the District of Columbia; is listed on that jurisdiction's certified nursing assistant registry; and has not been found to have committed abuse, neglect, or exploitation in that jurisdiction; or
- Completion of the curriculum developed under Enterprise Florida's Jobs and Education Partnership Grant and achieved or exceeded a minimum score, established by BON rule, on the nursing assistant competency examination, which consists of a BON-approved written portion and skills-demonstration portion, and administered at a site and by personnel approved by the DOH.[47]

A CNA must biennially complete 24 hours of in-service training to maintain certification.[48]

Hearing Aids

Federal Regulations

The Food and Drug Administration (FDA) Reauthorization Act of 2017 (FDARA), s. 709,[49] directed the FDA to establish a category of OTC hearing aids through rulemaking and set forth various requirements for OTC hearing aids, including defining general controls for reasonable assurance of safety and effectiveness, as well as Federal preemption provisions.

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[45] Section 464.201, F.S.

[46] Paraprofessional Healthcare Institute, *Who Are Direct-Care Workers?*, (Feb. 2011), available at https://phinational.org/wp-content/uploads/legacy/clearinghouse/NCDCW%20Fact%20Sheet-1.pdf (last visited Mar. 23, 2023).

[47] Section 464.203, F.S., and Fla. Admin. Code R. 64B9-15.006. Eighty hours must be classroom instruction and 40 hours must be clinical instruction, 20 of which must be in long term care clinical instruction in a licensed nursing home. 42 C.F.R. § 483.95 requires 75 hours of training; Florida training requirements exceed the federal minimum training requirements.

[48] Section 464.203(7), F.S.

[49] 21 U.S.C. 301, Food and Drug Administration Reauthorization Act of 1917, s. 709, *Regulation of Over-The-Counter Hearing Aids*, available at https://www.congress.gov/115/plaws/publ52/PLAW-115publ52.pdf (last visited Mar. 23, 2023).

On August 17, 2022, the FDA finalized a rule revising 21 C.F.R. 800,[50] 801,[51] and 874.[52] The FDA's new rule establishes a new category for OTC hearing aids. An OTC hearing aid is an air-conduction hearing aid that does not require implantation or other surgical intervention and is intended for use by a person age 18 or older to compensate for perceived mild to moderate hearing impairment. The device, through tools, tests, or software, allows the user to control the hearing aid and customize it to the user's hearing needs. The device may use wireless technology or may include tests for self-assessment of hearing loss.

The device is available OTC, without the supervision, prescription, or other order, involvement, or intervention of a licensed person, to consumers through in-person transactions, by mail, or online, provided that the device satisfies the requirements for consumers with "perceived mild to moderate hearing impairment who wish to buy lower cost hearing aids not bundled with professional services and not requiring professional advice, fitting, adjustment, or maintenance. The rule became effective on October 16, 2022.[53]

The FDA rule includes provisions for simplified labeling, output limits, maximum insertion depth, and conditions for sale and distribution for both OTC and prescription hearing aids. The rule prohibits states from requiring the order, involvement, or intervention of a licensed person for consumers to access over the counter hearing aids, a licensed person may service, market, sell, dispense, provide customer support for, or distribute OTC hearing aids.[54]

Florida Regulations

In Florida, there are currently 1,177 licensed hearing aid specialists, and 1,487 licensed audiologists.[55] Under Florida law, all hearing aids are dispensed by hearing aid specialists and audiologists who are subject to DOH regulation under the Board of Hearing Aid Specialist (BHAS) and Board of Speech-Language Pathology and Audiology (BSLPA).[56] Florida law does not currently distinguish between OTC and prescription hearing aids and imposes criminal penalties for dispensing hearing aids by mail to consumers.[57] Florida law does not currently contemplate the sale of hearing aids online.

[50] 21 CFR 800.30, (Mar. 16, 2023) available at https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-800#800.30 (last visited Mar. 23, 2023).
[51] 21 CFR 801.60 - 63, (Jan. 17, 2023) available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=801 (last visited Mar. 23, 2023).
[52] 21 CFR 874.5300 available at https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-874/subpart-F/section-874.5300 (last visited Mar. 20, 2023).
[53] 21 CFR 800.30, (Mar. 16, 2023) available at https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-800#800.30 (last visited Mar. 23, 2023).
[54] 21 CFR 801, (2022).
[55] Florida Department of Health, Division of Medical Quality Assurance, *Annual Report and Long Range Plan, 2021 - 2022*, available at https://www.floridahealth.gov/licensing-and-regulation/reports-and-publications/_documents/annual-report-2122.pdf (last visited Mar. 23, 2023).
[56] *See* Part II, ch. 484 and Part I, ch. 468, respectively.
[57] Section 468.1265, F.S.

Scope of Practice

Florida law defines the scope of practice for hearing aid specialists and audiologists and specifies the procedures which each health care practitioner is authorized to perform. Presently, these are the only two health care practitioners who are authorized by law to sell or dispense a hearing aid.

Hearing Aid Specialists

Under s. 484.041, F.S., hearing aid specialists may dispense hearing aids. Dispensing includes conducting and interpreting hearing tests for purposes of selecting suitable hearing aids; making earmolds or ear impressions for the fitting of hearing aids; and providing appropriate counseling regarding a suitable hearing aid device. This also includes all acts pertaining to the selling, renting, leasing, pricing, delivery, and warranty of hearing aids. [58]

Hearing aid specialists are licensed and regulated by the BHAS.[59] Licensure for a hearing aid specialist is in accordance with s. 484.045, F.S. and includes the following requirements:

- Graduation of an accredited high school or its equivalent;
- Meeting one of the qualifying methods:
  - Completing a Florida sponsored training program; or
  - Having a valid, current license as a hearing aid specialist or its equivalent from another state and has been actively practicing[60] in such capacity for at least 12 months; or
  - Is currently certified by the National Board for Certification in Hearing Instrument Sciences (NBC-HIS) and has been actively practicing for at least 12 months.
- Has successfully completed:
  - International Licensing Examination (ILE); or
  - Active certification from the National Board for Certification in Hearing Instrument Sciences (NBC-HIS).
- Completion of a two hour course relating to Florida laws and rules taught by an instructor approved by the BHAS.

Audiologists

The practice of audiology includes the application of principles, methods, and procedures for the prevention, identification, evaluation, consultation, habilitation, rehabilitation, instruction, treatment, and research, relative to hearing and the disorders of hearing, and to related language and speech disorders.[61] Licensed audiologists may offer, render, plan, direct, conduct, consult, or supervise services to individuals or groups of individuals who have or are suspected of having disorders of hearing, including prevention, identification, evaluation, treatment, consultation, habilitation, rehabilitation, instruction, and research.[62] This includes the fitting and dispensing of hearing aids. They may also provide the following:

- Participate in hearing conservation, evaluation of noise environment, and noise control;

[58] Section 484.041(3)(a), F.S.
[59] Section 484.042, F.S.
[60] *See* Fla. Admin. Code R. 64B6-2.002 (2022), which defines "actively practicing" as dispensing hearing aids directly to clients for at least 12 months, as shown by at least two sales receipts per month for at least 12 months, each receipt bearing the applicant's signature and address of place(s) of business.
[61] Section 468.1125(6)(a), F.S.
[62] Section 468.1125(6)(b), F.S.

- Conduct and interpret tests of vestibular function and nystagmus, electrophysiologic auditory-evoked potentials, central auditory function, and calibration of measurement equipment used for such purposes;
- Habilitate and rehabilitate, including, but not limited to, hearing aid evaluation, prescription, preparation, fitting and dispensing, assistive listening device selection and orientation, auditory training, aural habilitation, aural rehabilitation, speech conservation, and speechreading;
- Fabricate earmolds;
- Evaluate tinnitus; and
- Conduct speech and language screening, limited to a pass-fail determination for identifying individuals with disorders of communication.[63]

Audiologists are licensed and regulated by the BSLPA.[64] Licensure for audiologists includes, among other requirements, the following:

- Submission of an application and all required fees;
- A doctoral degree with a major emphasis in audiology and:
  - Applicants who have earned a doctoral degree from an approved program before January 1, 2008, must complete 60 semester hours, 24 of which must be in audiology.[65]
  - Applicants who earned a doctoral degree from an approved program after January 1, 2008, must complete 75 semester hours.
  - 300 clock hours of supervised experience (clinical practicum) with at least 200 hours in the area of audiology.
- Eleven months of supervised clinical experience. This requirement may be met if the applicant holds a doctoral degree, meets the requirements of s. 468.1155, F.S., and can demonstrate one year of clinical work experience within the doctoral program.
- Applicants for licensure as an audiologist with a master's degree conferred before January 1, 2008, must document that prior to licensure the applicant completed one-year clinical work experience.
- Passed the licensure examination no more than three years prior to the date of the application.[66]

III. Effect of Proposed Changes:

Section 1 - Enhanced Potential Pandemic Pathogen Research

SB 1506 creates s. 381.87, F.S. which prohibits any research in Florida that is reasonably likely to create an enhanced potential pandemic pathogen (ePPP) or that has been determined by HHS, or other federal agency or state agency to create such a pathogen. The bill defines the terms:

- "Enhanced potential pandemic pathogen" (ePPP) is a potential pandemic pathogen that results from enhancing the transmissibility or virulence of a pathogen. The term does not

[63] *Id.*
[64] Section 468.1135, F.S.
[65] Section 468.1155, F.S.
[66] Section 468.1185, F.S. and Fla. Admin. Code R. 64B20-2.005 (2022) The BSDPA has designated the Educational Testing Services Praxis Series Examination in Speech-Language Pathology or Audiology as the licensure examination.

include naturally occurring pathogens circulating in or recovered from nature, regardless of their pandemic potential.

- "Enhanced potential pandemic pathogen (ePPP) research"[67] is research that may be reasonably anticipated to create, transfer, or use potential pandemic pathogens that result from enhancing a pathogen's transmissibility or virulence in humans.
- "Potential pandemic pathogen" is a bacterium, virus, or other microorganism that is likely to be both:
  - Highly transmissible and capable of wide, uncontrollable spread in human populations; and
  - Highly virulent, making it likely to cause significant morbidity or mortality in humans.

The bill requires any researcher applying for state or local funding to conduct research in Florida to disclose in the application if the research meets the definition of ePPP research. The bill authorizes the DOH to exercise its public health enforcement authority under s. 381.0012. F.S., to enjoin any violations of this section.

The bill does not affect research funded prior to its effective date.

Sections 2 and 3 - Office of Medical Marijuana Use

SB 1506 amends s. 381.986, F.S., to defines the term "attractive to children" to mean "the use of any image or words designed or likely to appeal to persons younger than 18 years of age, including, but not limited to, cartoons, toys, animals, food, or depictions of persons younger than 18 years of age; any other likeness to images, characters, or phrases that are popularly used to advertise to persons younger than 18 years of age; or any reasonable likeness to commercially available candy."

The bill expands production requirements that currently are specific to edibles to all types of marijuana products. These include that the products not be:

- Attractive to children;
- Manufactured in the shape of humans, cartoons, or animals;
- Manufactured in a form that bears any reasonable resemblance to products available for consumption as commercially available candy; or contain any color additives.

The bill prohibits an MMTC's logo, trade name, and advertisements from containing wording, images, or content that is attractive to children or promotes recreational use of marijuana.

[67]U.S. Department of Health and Human Services, *Office of Inspector General: The National Institutes of Health and EcoHealth Alliance Did Not Effectively Monitor Awards and Subawards, Resulting in Missed Opportunities to Oversee Research and Other Deficiencies*, Jan., 2023, available at https://oig.hhs.gov/oas/reports/region5/52100025.pdf (last visited Mar. 23, 2023). The report notes at p. 4, that the terms "gain of function (GOF)" and "enhanced potential pandemic pathogen (ePPP)" are both used in Federal Government guidance at different points during the audit period. While these terms may have some distinctions from a scientific perspective, for purposes of this audit, which does not assess the underlying science of the EcoHealth grants, we use the terms interchangeably. Both terms refer generally to research involving the enhancement of a pathogen's transmissibility or virulence. The NIH is now using the ePPP research classification on place of the GOF research classification.

The bill expands the DOH's rulemaking authority to authorize any "rules it deems necessary to protect the health and safety of qualified patients and minors, including, but not limited to, standards to ensure that medical marijuana treatment centers operate in a manner consistent with the provision of medical products and rules to discourage the diversion and illicit use of marijuana."

The bill amends ss. 381.986 and 381.988, F.S., to prohibit exemptions from disqualification due to a failed background screening from applying to these sections and to require that a caregiver, an MMTC, or a CMTL bear the costs of the background screening, as applicable. The bill also adds the requirement that all employees of a CMTL pass a level 2 background screening and makes the disqualifying offenses for CMTLs consistent with those for MMTCs. Specifically, the bill adds that disqualifying offense in s. 435.04, F.S., apply and adds that a person is disqualified if they have an arrest awaiting final disposition for an offense under chs. 837, 895, or 896, F.S.[68]

Sections 4 through 11 - Vital Statistics

SB 1506 updates ch. 382, F.S., to make electronic filing mandatory, when possible, and amends:

- Section 382.005, F.S., to require each local registrar to electronically file all live birth, death, and fetal death records within their respective jurisdictions in the DOH's electronic registration system; but if the system is unavailable, the local registrar must file a paper record, and make blank paper forms available.
- Section 382.008, F.S., to require the funeral director to file certificates of death and fetal death electronically.
- Section 382.009, F.S., to no longer require two physicians to make a determination of brain death for a comatose patient. The bill instead requires such determinations be made by two licensed health care practitioners who must be physicians, PAs or A-APRNs, with one being the patient's treating health care practitioner.
- Section 382.013, F.S., clarifying that certificates of live birth occurring in this state must be filed within five days after the birth in the DOH's electronic registration system with the local registrar; and that a birth in a hospital, birth center, or other health care facility, or en route, must also be filed in the DOH's electronic registration system with the local registrar by the person in charge of the facility.
- Section 382.015, F.S., requiring court clerks in adoptions, annulment of an adoptions, affirmations of parental status, or determinations of paternity to forward electronically to the DOH a certified copy of the court order, or a report of the proceedings, upon a DOH form with sufficient information to identify the original birth certificate and to enable the preparation of a new birth certificate.
- Section 382.021, F.S., requiring the county judge or court clerk to electronically transfer to the DOH marriage licenses weekly, instead of monthly.
- Section 382.023, F.S., requiring the county judge or court clerk to electronically transfer to the DOH judgments of dissolution of marriage granted by the court weekly, instead of monthly.
- Section 382.025, F.S., to increase the age at which birth records will remain confidential and exempt, except to a specific list of persons, from 100 years of age to 125 years of age; and

[68] Perjury, offenses concerning racketeering and illegal debts, offenses related to financial transactions, respectively.

authorized persons appointed by the DOH, to the state registrar and local registrars, as individuals who my issue certified copy of a certificate of live birth, death, or fetal death.

Sections 12 through 16 - EMTs and Paramedics

SB 1506 amends s. 401. 27, F.S., to remove the certification application requirement for EMTs and paramedics applying to the DOH that they do so "under oath;" and replaces the legal term with an attestation. The bill deletes obsolete language referring application filing deadlines before examination dates, certification examinations being offered monthly and the parameters for the DOH's grading process and administrative review.

The bill amends s. 401. 2701, F.S., to exempt Florida institutions desiring to conduct an approved program for the education of EMTs and paramedics, from the requirement that they have an affiliation agreement with a current licensed EMS provider which includes a commitment from the EMS provider to conduct the field experience portion of the education program, if the applicant is licensed as an ALS service under s. 401.25, F.S., with permitted transport vehicles under s. 401.26, F.S.

SB 1506 amends s. 401.272, F.S., to eliminate an EMT's or paramedic's ability to partner with local county health departments and requires that EMTs and paramedics operate under the medical direction of a physician through two-way voice communication or pursuant to established standing orders or protocols and within the scope of their training when providing BLS, ALS, and health promotion and wellness activities in a nonemergency environment.

The bill deletes the required supervision of the EMT and paramedic by a medical director in the nonemergency environment. Medical directors are employed by, or have contracted with, a BLS transportation service or ALS transport service to provides medical supervision, including appropriate quality assurance including administrative and managerial functions, for daily operations and training of an EMS transport provider.[69]

The bill eliminates blood pressure screening from the activities an EMT or paramedic may perform only under medical direction in a nonemergency environment.

The bill requires that EMTs and paramedics operate under the medical direction of a physician through two-way communication or pursuant to established standing orders or protocols and within the scope of their training when a patient is not transported to an emergency department or is transported to a facility other than a hospital.

Under current law, paramedics are authorized to administer immunizations in a nonemergency environment, within the scope of their training. The bill transfers their required supervision from the EMS medical director to a physician who will provide medical direction through two-way communication or pursuant to established standing orders or protocols and requires a written agreement between the physician providing the medical direction and the DOH or the county health department located in each county in which the paramedic administers immunizations. This agreement must establish the protocols, policies, and procedures under which the paramedic

[69] See ss. 401.23(16) and 401.265, F.S.

must operate. The physician providing direction to the paramedic administering immunizations must also verify and document that the paramedic has received sufficient training and experience to administer immunizations.

SB 1506 amends s. 401.34, F.S., to delete same-day grading of EMT and paramedic examinations, walk-in eligibility determinations and examinations, and the fees for EMT and paramedic examination review. The DOH no longer offers any of these.[70]

SB 1506 amends s. 401.435, F.S., to change the term "first responder" to "emergency medical responder." The change in terminology was done by the National Highway Traffic Safety Administration (NHTSA) in 2009. The term was also adopted by the National Registry of Emergency Medical Technicians (NREMT). The term "first responder" was commonly confused with other public safety professionals and not referenced as a medical certification level.[71]

Section 17 - CNAs

The bill amends s. 464.203, F.S., to exempt CNA applicants who have completed an approved training program from the licensure requirement of take the skills-demonstration portion of the licensure examination.

Sections 18 through 36 - Hearing Aids, Audiologists, Hearing Aid Specialists

SB 1506 amends numerous sections of Part I, ch. 468 and Part II, ch. 484, F.S., in response to recent federal rules permitting the sale of OTC hearing aids, without the supervision, prescription, or other order, involvement, or intervention of a licensed person, to consumers through in-person transactions, by mail, or online, provided that the device satisfies the rule requirements for consumers with "perceived mild to moderate hearing impairment" who wish to buy lower cost hearing aids not bundled with professional services and not requiring professional advice, fitting, adjustment, or maintenance.

Audiologists

SB 1560 amends s. 468.1225, F.S., to narrow the scope of the regulatory requirements for audiologists to the dispensing of prescription hearing aids but does not define the terms air conduction hearing aid, hearing aid, OTC hearing aid, or prescription hearing aid for the practice of audiology.

The bill also amends ss. 468.1245, 468.1246, 468.1255, 468.1265, and 468.1275, F.S., adding the term "prescription" in front of the term "hearing aid" to make clear that Florida's regulation of hearing aids only applies to "prescription hearing aids" and does not conflict with federal law. The bill also makes other technical changes to those statutory sections.

[70] Department of Health, *2023 Agency Legislative Bill Analysis, Senate Bill 1506* (on file with the Senate Committee on Health Policy).
[71] Department of Health, *2023 Agency Legislative Bill Analysis, Senate Bill 1506* (on file with the Senate Committee on Health Policy).

This bill amends s. 468.1246, F.S., to remove an obsolete reference to rulemaking that was required to be completed during the year the original bill was passed.

Hearing Aid Specialists

SB 1506 narrows the scope of the regulatory requirements for hearing aid specialists to the dispensing of prescription hearing aids.

The bill amends s. 484.041, F.S., to redefines hearing aid and hearing aid establishment for hearing aid specialists as follows:

- "Hearing aid" is any wearable device designed for, offered for the purpose of, or represented as aiding persons with, or compensating for, impaired hearing. This matches the federal definition.
- "Hearing aid establishment" is an establishment that offers, advertises, and performs hearing aid services for the general public, and the bill add the requirement that it must employ a licensed hearing aid specialist.

The bill further amends s. 484.041, F.S., to define OTC hearing aids and prescription hearing aids for hearing aid specialists:

- "OTC hearing aid" means an air-conduction hearing aid that does not require implantation or other surgical intervention and is intended for use by a person 18 years of age or older to compensate for perceived mild to moderate hearing impairment.
- "Prescription hearing aid" means a hearing aid that is not an over-the-counter hearing aid and that does not otherwise meet the criteria for a prescription hearing aid under this part.

The bill amends s. 484.059, F.S., to exempt from hearing aid specialist licensure requirements persons who services, markets, sells, dispenses, provides customer support for, or distributes exclusively OTC hearing aids, whether through in-person transactions, by mail, or online.

The bill defines, for the purpose of the exemption, OTC hearing aids as those that are available without the supervision, prescription, or other order, involvement, or intervention of a licensed person to consumers through in-person transactions, by mail, or online. It describes OTC hear aid devices as allowing the user to control the device and customize it to the user's hearing needs through the use of tools, tests, or software, including, among other things, wireless technology and tests for self-assessment of hearing loss.

The bill amends s. 484.0501, F.S., to authorize a licensed hearing aid specialist to service, market, sell, dispense, provide customer support for, and distribute prescription and OTC hearing aids.

The bill amends s. 484.054, F.S., to removes restrictions and criminal penalties for the sale or distribution of hearing aids through the mail.

The bill amends ss. 484.0401, 484.041, 484.042, 484.044, 484.0445, 484.045, 484.0501, 484.051, 484.0512, 484.0513, 484.053, 484.054, and 484.059, F.S., adding the term "prescription" in front of the term "hearing aid" to make clear that Florida's regulation of

hearing aids only applies to "prescription hearing aids" and does not conflict with federal law. The bill also makes other technical changes.

This bill also amends s. 484.512, F.S., to remove an obsolete reference to rulemaking that was required to be completed during the year the original bill was passed'

Section 37

The bill directs the Division of Law Revision to replace the phrase "the effective date of this act" with the date the act becomes law.

Section 38

The bill provides an effective date of July 1, 2023, unless otherwise indicated.

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, s. 3, of the Florida Constitution states "the powers of the state government shall be divided into legislative, executive and judicial branches. No person belonging to one branch shall exercise any powers appertaining to either of the other branches unless expressly provided herein."

The Legislature is permitted to transfer subordinate functions "to permit administration of legislative policy by an agency with the expertise and flexibility to deal with complex and fluid conditions." However, the Legislature "may not delegate the power to enact a law or the right to exercise unrestricted discretion in applying the law."[72] The Florida Supreme Court has found that "statutes granting power to the executive branch 'must clearly announce adequate standards to guide ... in the execution of the powers delegated. The

[72] *Bush v. Schiavo,* 885 So. 2d 321 (Fla. 2004)

statute must so clearly define the power delegated that the [executive] is precluded from acting through whim, showing favoritism, or exercising unbridled discretion.'"[73]

Section 2 of SB 1506 provides rulemaking language in s. 381.986(8)(k), F.S., which grants the DOH the authority to "adopt rules *it deems necessary* to protect the health and safety of qualified patients and minors." This grant of rulemaking authority places no boundaries on what rules the DOH may adopt to "protect the health and safety of qualified patients and minors" and grants the DOH unfettered authority to adopt such rules "it deems necessary." As such, it is possible that this rulemaking authority does not preclude the DOH from "acting through whim, showing favoritism, or exercising unbridled discretion" and may be found to be an unlawful delegation of authority violating Art. II, s. 3, of the Florida Constitution.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Persons with mild to moderate hearing impairment will now be able to purchase OTC hearing aids without the supervision, prescription, involvement, or intervention of a licensed person through in-person transactions, by mail, or online which will presumably reduce their cost.

C. Government Sector Impact:

Multiple sections of the bill will require rule making by various DOH boards, but it is unclear whether DOH can absorb those costs, or if additional funding is required.

VI. Technical Deficiencies:

The bill's definition of "prescription hearing aid" in Section 25, amending s. 484.041, F.S., is a non sequitur and an amendment should be considered to correct it.

The bill defines OTC hearing aids in two different ways for hearing aid specialists, one in Section 25 of the bill, amending s. 484.041, F.S., and one in Section 36, amending s. 484.059, F.S. An amendment should be considered to have consistent definitions or only one definition for OTC hearing aids in Section 25 that can be referenced in Section 36.

VII. Related Issues:

The rulemaking authority granted to the DOH on lines 511 through 517 of the bill may be an unlawful delegation of authority that violates Art. II, s. 3, of the Florida Constitution. See Section IV of this analysis.

[73] *Id.*

The bill does not appear to provide definitions for the practice of audiology for air conduction hearing aids, hearing aids, and prescription hearing aids and an amendment should be considered to add these terms for Part I, ch. 468, F.S.

The bill does not appear to provide definitions for hearing aid specialists for air conduction hearing aids, and an amendment should be considered to add that definition to Part II, ch. 484, F.S.

VIII. Statutes Affected:

This bill creates section 381.875 of the Florida Statutes.

This bill substantially amends the following sections of the Florida Statutes: 381.986, 381.988, 382.005, 382.008, 382.009, 382.013, 382.015, 382.021, 382.023, 382.025, 401.27, 401.2701, 401.272, 401.34, 401.435, 464.203, 468.1225, 468.1245, 468.1246, 468.1255, 468.1265, 468.1275, 484.0401, 484.041, 484.042, 484.044, 484.0445, 484.045, 484.0501, 484.051, 484.0512, 484.0513, 484.053, 484.054, and 484.059.

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.