

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/CS/HB 1387 Department of Health

SPONSOR(S): Health & Human Services Committee, Healthcare Regulation Subcommittee, Porras

TIED BILLS: IDEN./SIM. **BILLS:** SB 1506

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Healthcare Regulation Subcommittee	17 Y, 0 N, As CS	Osborne	McElroy
2) Health & Human Services Committee	17 Y, 0 N, As CS	Osborne	Calamas

SUMMARY ANALYSIS

CS/CS/HB 1387 makes numerous changes to programs under the Department of Health (DOH) and health care professions regulated by the Division of Medical Quality Assurance within DOH.

Gain-of-function research involves experimentation that may produce an enhanced potential pandemic pathogen (PPP). An enhanced PPP is a potential pandemic pathogen which has been modified to increase transmissibility or virulence. The bill prohibits any such research from being conducted in the state. The bill also requires researchers applying for state or local funding must disclose in the application for funding whether the research involves enhanced PPPs.

DOH is responsible for ensuring medical marijuana products are safe for human consumption, not attractive to children and that medical marijuana treatment centers (MMTC) meet all background screening requirements, among others. The bill prohibits MMTCs from advertising or producing products that are attractive to children or that promote recreational use. The bill also revises background screening requirements for MMTCs and certified medical marijuana testing laboratories.

The Office of Vital Statistics, under the state registrar within DOH, facilitates uniform and efficient registration, compilation, storage, and preservation of all vital records in the state. The bill allows vital records to be filed electronically with DOH's electronic registration system, and specifies the timeframe by which the courts must electronically transmit certain records to DOH. The bill also raises the age at which birth certificates become public record from 100 to 125 years.

Brain death occurs when a person's respiratory and circulatory functions are maintained by artificial means of support, but there is irreversible cessation of the functioning of the entire brain including the brain stem. Under current law, two physicians must certify brain death. The bill authorizes autonomous advanced practice registered nurse practitioners to certify brain death if they are the patient's treating health care practitioner. In such cases, brain death must also be certified by two specialist physicians.

Emergency medical technicians (EMTs) and paramedics must complete training programs that meet requirements set in statute and by DOH, pass a certification exam, and apply to DOH under oath. The bill revises the application process for EMTs and paramedics, and deletes obsolete language regarding DOH administration of certification exams. The bill revises requirements for EMTs and paramedics performing health care tasks in a nonemergency environment.

Certified Nursing Assistants (CNAs) provide care and assistance with the activities of daily living. A CNA performs services under the general supervision of a registered nurse or licensed practical nurse. CNAs are certified by the Board of Nursing within DOH. In order to be certified as a CNA, an applicant must pass the CNA exam, which consists of a clinical skills test and a written test. CS/CS/HB 1387 exempts individuals who have successfully completed a board-approved CNA training program within six months of applying for licensure from the clinical skills portion of the exam.

In 2022, the US Food & Drug Administration finalized a rule establishing a new category for over-the-counter (OTC) hearing aids and specifying what constitutes an OTC hearing aid. The rule prohibits state and local governments from interfering with the servicing, marketing, sale, dispensing, use, customer support, or distribution of OTC hearing aids. The bill amends statute to align with the requirements of this rule.

The bill has an insignificant, negative fiscal impact on DOH, which current resources are adequate to absorb. The bill has no fiscal impact on local governments.

The bill provides an effective date of July 1, 2023, except for those sections which take effect upon becoming law.

FULL ANALYSIS

This document does not reflect the intent or official position of the bill sponsor or House of Representatives .

STORAGE NAME: h1387d.HHS

DATE: 4/11/2023

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Enhanced Potential Pandemic Pathogen Research

Current Situation

Gain-of-function (GOF) research involves experimentation that aims to increase a pathogen's transmissibility and/or ability to cause damage to a host (known as virulence).¹ Such research can improve our understanding of pathogens, their interactions in the human body and potential to cause pandemics, with the ultimate goal of informing public health and preparedness efforts and the development of medical countermeasures.²

GOF research may involve "potential pandemic pathogens" (PPPs), infectious agents with known or likely efficient transmission among humans, with significant virulence, and for which there is limited population immunity.³ An enhanced PPP is a PPP which has been modified to increase transmissibility or virulence. Naturally occurring PPPs are not considered enhanced, regardless of their pandemic potential.⁴ The primary concern over PPPs is that they could be accidentally or deliberately released and spread rapidly due their high transmissibility.⁵

GOF research first gained public notice in 2012 after a study was published regarding increased transmissibility of a specific strain of influenza.⁶ In 2014, the Federal Government paused funding for GOF research projects, specifically those involving influenza, SARS, and MERS viruses, while new GOF research policy addressing the risks involved was developed.⁷ In 2017, the White House Office of Science and Technology Policy published new guidance for federal agencies regarding federally funded research that is anticipated to create, transfer, or use enhanced PPPs.⁸ The US Department of Health and Human Services is the only federal agency that has reported GOF research funding involving enhanced PPPs.⁹ Federal agencies have been criticized for insufficient oversight of grant-funded projects, including those involving naturally occurring pathogens and enhanced PPPs.¹⁰

There are currently no known labs in Florida that are capable of conducting enhanced PPP research.¹¹

¹ Selgelid, M. (2016). Gain-of-Function Research: Ethical Analysis. *Science & Engineering Ethics*, 22(4), 923–964. <https://doi.org/10.1007/s11948-016-9810-1>.

² *Id.*

³ Lipsitch, M., & Galvani, A. P. (2014). *Ethical alternatives to experiments with novel potential pandemic pathogens*. *PLoS Medicine*, 11(5). <https://link.gale.com/apps/doc/A382807145/AONE?u=statelibraryfl&sid=bookmark-AONE&xid=41e75a11> (last visited March 29, 2023).

⁴ Congressional Research Service, *Oversight of Gain of Function Research with Pathogens: Issues for Congress* (2022). Available at <https://crsreports.congress.gov/product/pdf/R/R47114> (last visited March 29, 2023).

⁵ *Supra*, note 3.

⁶ See, Herfst, S., et al. (2012). *Airborne transmission of influenza A/H5N1 virus between ferrets*. *Science* (New York, N.Y.), 336(6088), 1534–1541. <https://doi.org/10.1126/science.1213362>

⁷ Office of Science and Technology Policy, *U.S. Government Gain-of-Function Deliberative Process and Research Funding Pause on Selected Gain-of-Research Involving Influenza, MERS, and SARS Viruses* (2014). Available at <https://www.phe.gov/s3/dualuse/documents/gain-of-function.pdf> (last visited March 29, 2023).

⁸ White House Office of Science and Technology Policy, *Recommended Policy Guidance for Departmental Development of Review Mechanisms for Potential Pandemic Pathogen Care and Oversight (P3CO)* (2017). Available at <https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/p3co-final-guidance-statement.pdf> (last visited March 29, 2023).

⁹ *Supra*, note 4.

¹⁰ Office of Inspector General, US Department of Health and Human Services, *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* (2023). Available at <https://oig.hhs.gov/oas/reports/region5/52100025.pdf> (last visited March 29, 2023).

¹¹ In order to conduct research on highly infectious agents, a laboratory must meet the safety equipment and procedure requirements of Biosafety Levels (BSL) 3 or 4 as established by the CDC. The BSL required for a project depend upon the specific research being conducted. There are no known BSL 3 or 4 labs in Florida. See, Global Biolabs. Available at <https://global-biolabs.github.io/> (last visited March 29, 2023). See also, Centers for Disease Control and Prevention, *Biosafety in Microbiological and Biomedical Laboratories*, 6th Edition (2020). Available at https://www.cdc.gov/labs/pdf/SF_19_308133-A_BMBL6_00-BOOK-WEB-final-3.pdf (last visited March 29, 2023).

Effect of Proposed Changes – Enhanced Potential Pandemic Pathogen Research

CS/CS/HB 1387 prohibits 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, known as enhanced potential pandemic pathogen research, from being conducted in the state. The bill also requires researchers applying for state or local funding must disclose in the application for funding whether the research it intends to conduct is enhanced potential pandemic pathogen research. The bill does not affect research funded or conducted prior to the bill taking effect.

The bill authorizes the Florida Department of Health (DOH) to utilize its enforcement authority under s. 381.0012, F.S., to enjoin violations of this section.

This provision is effective upon becoming law.

Medical Marijuana

Current Situation

Marijuana for Medical Use

Section 381.986, F.S., authorizes patients with any of the following debilitating medical conditions to obtain medical marijuana from Medical Marijuana Treatment Centers (MMTC):

- Cancer
- Epilepsy
- Glaucoma
- Positive status for human immunodeficiency virus
- Acquired immune deficiency syndrome
- Post-traumatic stress disorder
- Amyotrophic lateral sclerosis
- Crohn's disease
- Parkinson's disease
- Multiple sclerosis
- Medical conditions of the same kind or class as or comparable to those enumerated above

To obtain marijuana for medical use from a MMTC, and maintain the immunity from criminal prosecution, the patient must obtain a physician certification from a qualified physician¹² and an identification card from DOH.

Advertising

MMTCs are currently prohibited from engaging in advertising that is visible to members of the public from any street, sidewalk, park, or other public place, except they may:¹³

- Have a sign on the outside or hanging in the window of the premises which identifies the dispensary by the licensee's business name, a department-approved trade name, or a department-approved logo, as long as the trade name and logo does not contain wording or images commonly associated with marketing targeted toward children or which promote the recreational use of marijuana; and
- Engage in Internet advertising and marketing under the following conditions:
 - All advertisements are approved by the DOH;
 - An advertisement's content does not specifically target individuals under the age of 18;

¹² To certify patients for medical use of marijuana, a physician must hold an active, unrestricted license as an allopathic physician under chapter 458 or as an osteopathic physician under chapter 459 and comply with certain physician education requirements. See ss. 381.986(1)m, F.S. and 381.986(3)(a), F.S.

¹³ S. 381.986(8)(h), F.S.

- An advertisement is not an unsolicited pop-up advertisement; and
- Any opt-in marketing includes an easy and permanent opt-out feature.

Regulation of Edibles

Current law regulates the manner in which edibles may be produced. Edibles may 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.

Medical Marijuana Background Screening

Section 381.986, F.S., requires any person who registers as a qualified patient's caregiver, as well as the owners, operators, board members, managers, and employees of a MMTC, to 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 89613 or similar law of another jurisdiction.

Section 381.988, F.S., establishes requirements for persons or entities seeking to be certified as a Certified Marijuana Testing Laboratory (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.

Effect of the Bill – Medical Marijuana

The bill makes edible production regulations applicable to all marijuana products.

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.

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 offenses 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.

Florida Vital Statistics

Current Situation

Electronic Filing of Records

The Office of Vital Statistics (Office), under direction of the state registrar, is housed within DOH and facilitates the uniform and efficient registration, compilation, storage, and preservation of all vital records in the state.¹⁴ The state registrar appoints local registrars in each of Florida's 67 counties; local registrars are responsible for making and preserving a local record of each birth, death, or fetal death certificate registered in the county, and transmitting these records to DOH.¹⁵ The state registrar and local registrars are the only individuals authorized to issue an original certificate of live birth, death, or fetal death;¹⁶ however, DOH has a current Memorandum of Understanding with the Florida Tax Collectors Association and Highway Safety and Motor Vehicles to issue birth records in agreement with the local county health departments.¹⁷

Current law outlines processes for the filing of paper records by local registrars;¹⁸ however, since 2009, the Office has primarily relied upon an electronic registration system.¹⁹ Certificates for each live birth in the state are required to be filed by with the local registrar within five days of the birth.²⁰ Death and fetal death records must be filed with DOH or the local registrar by the funeral director who first assumes custody of the dead body or fetus, or a specified health care practitioner in attendance at or after the death.²¹

The court system is responsible for ensuring that all court records relevant to the maintenance of vital statistics in the state are transmitted to DOH. This includes all court proceedings which may require a new birth certificate to be issued, such as those regarding adoption, annulment of adoption, affirmation of parental status, or determination of paternity, which must be forwarded to DOH within 30 days after the final disposition.²² The courts must also provide DOH with all new, endorsed marriage licenses and dissolution-of-marriage records on a monthly basis.²³

Current law does not contemplate the electronic filing of vital records with DOH.

Brain Death

Brain death occurs when a person's respiratory and circulatory functions are maintained by artificial means of support, but there is irreversible cessation of the functioning of the entire brain including the brain stem.²⁴ Under current law, brain death must be determined by two physicians, one of which must be the patient's treating physician, the other must be a board-eligible or board-certified neurologist, neurosurgeon, internist, pediatrician, surgeon, or anesthesiologist.²⁵

Centenarian Birth Records

Under current law, birth records over 100 years of age are considered public record and may be produced upon a public records request.²⁶ The average life expectancy in the US has increased significantly over the last century, leading to a much larger number of individuals surviving past the age of 100 than in previous decades. The number of centenarians living in the US increased from

¹⁴ S. 382.003, F.S.

¹⁵ S. 382.005, F.S.

¹⁶ S. 382.025(4), F.S.

¹⁷ Florida Department of Health, *Agency Analysis for HB 1387 (2023)*, p. 5. On file with the Healthcare Regulation Subcommittee.

¹⁸ *Id.*

¹⁹ *Id.*

²⁰ S. 382.013, F.S.

²¹ S. 382.008, F.S.

²² S. 382.015, F.S.

²³ Ss. 382.021 and 382.023, F.S.

²⁴ S. 382.009, F.S.

²⁵ *Id.*

²⁶ S. 382.025, F.S.

approximately 29,000 in 1990²⁷ to 89,000 in 2021.²⁸ The 2010 Census data showed that Florida had 4,090 residents 100 years of age or older at the time;²⁹ under current law, the birth records of such individuals are subject to public records requests.

Effect of the Bill – Florida Vital Statistics

Electronic Filing of Records

CS/CS/HB 1387 requires local registrars to electronically file all live birth, death, and fetal death records occurring within their jurisdiction in DOH's electronic registration system. The bill requires local registrars to make blank paper forms available to be completed and filed with DOH should the electronic registration system be unavailable. The bill specifies processes for the managing of paper records by the local registrars.

The bill specifies that death and fetal death records and birth certificates are to be filed electronically and makes conforming changes throughout Ch. 382, F.S.

The bill requires court orders and proceedings that may result in the issuance of a new birth certificate to be forwarded electronically to DOH. The bill requires that the courts electronically transmit all original marriage licenses to DOH on a weekly basis, or submit the preceding month's records by the fifth day of each month. The courts may submit dissolution-of-marriage records electronically to DOH on a weekly basis, or submit the preceding month's records by the 10th day of each month.

The bill authorizes DOH to appoint persons to be authorized to issue certificates of live birth, death, or fetal death, in addition to the state and local registrars.

Brain Death

CS/CS/HB 1387 authorizes an autonomous advanced practice nurse practitioner registered under s. 464.0123, F.S., to certify brain death if they are the patient's treating practitioner. In such cases, the brain death must also be certified by two licensed physicians who are board-eligible or board-certified in one of the following specialties: neurology, neurosurgery, internal medicine, pediatrics, surgery, or anesthesiology.

Birth Records

CS/CS/HB 1387 extends the length of time that birth records are exempt from public record from 100 years to 125 years. This change will prevent the birth records of living centenarians from being released under a public records request.

Emergency Medical Services

Current Situation

Emergency Medical Responder Certification

Emergency medical responders, formerly referred to as first responders, include paramedics and emergency medical technicians (EMTs) certified by DOH. EMTs are certified to provide basic life

²⁷ Krach, C. & Velkoff, V. (1999). *Centenarians in the United States – Current Population Reports*. U.S. Census Bureau. Available at <https://www2.census.gov/library/publications/1999/demographics/p23-1999v.pdf> (last visited March 30, 2023).

²⁸ Boston University, *Centenarian Statistics* (2023). Available at <https://www.bumc.bu.edu/centenarian/statistics/#:~:text=USA%20number%20of%20centenarians,or%20a%20prevalence%20of%200.27%25>. (last visited March 30, 2023).

²⁹ Huriash, L. & Maines, J. (2017) *100 Years and Counting: South Florida Centenarians Honored for Lives Well Lived*. South Florida Sun Sentinel. Available at <https://www.sun-sentinel.com/local/broward/fl-tamarac-residents-centenarian-celebration-20170127-story.html> (last visited March 30, 2023).

support (BLS), while paramedics are certified to provide both basic and advanced life support (ALS) to patients.

BLS refers to any emergency medical service that uses only basic life support techniques.³⁰ BLS includes basic non-invasive interventions to reduce morbidity and mortality associated with out-of-hospital medical and traumatic emergencies.³¹ The services provided may include stabilization and maintenance of airway and breathing, some pharmacological interventions, trauma care, and transportation to an appropriate medical facility.³²

ALS refers to any emergency medical or non-transport service that uses advanced life support techniques.³³ ALS includes the assessment or treatment of a person by a qualified individual, such as a paramedic, who is trained in the use of techniques such as the administration of drugs or intravenous fluid, endotracheal intubation, telemetry, cardiac monitoring, and cardiac defibrillation.³⁴

To be certified as an EMT, a person must complete an approved Florida EMT training course, submit an application to DOH, and pass the National Registry for Emergency Medical Technicians (NREMT) EMT certification examination.³⁵ To be certified as a paramedic, a person must complete an approved Florida paramedic training course, submit an application to DOH, and pass the NREMT paramedic certification examination.³⁶ Under current law, EMTs and paramedics are required to apply for certification under oath,³⁷ and paramedics must certify under oath that they are not addicted to any substances and free of any physical or mental defect that could impede their duties as a paramedic.³⁸ DOH has reported that this is an obstacle to the electronic application process.³⁹

Current law requires DOH to offer monthly certification examinations,⁴⁰ and outlines provisions for walk-in eligibility and same-day grading of exams;⁴¹ however, DOH transitioned from state-developed exams to the NREMT certification examinations in 2016.⁴² NREMT examinations are held daily at testing centers throughout the state.

Emergency Medical Service (EMS) Training Programs

Certification as an EMT or paramedic requires the completion of a DOH-approved EMS training program. In order for a program to be approved they must apply to DOH with documentation of the following:⁴³

- Compliance with any applicable Florida Department of Education requirements;
- An affiliation agreement with a hospital;
- An affiliation agreement with a current EMS provider licensed in Florida who is responsible for the field experience portion of the program;

³⁰ S. 401.23(8), F.S.

³¹ S. 401.23(7), F.S., and U.S. Department of Transportation, National Highway Safety Administration, *National EMS Scope of Practice Model 23-24*. Available at www.nhtsa.gov/people/injury/ems/pub/emtbnsnc.pdf (last visited March 29, 2023).

³² *Id.*

³³ S. 401.23(2), F.S.

³⁴ S. 401.23(1), F.S.

³⁵ Florida Department of Health, *Licensing*. Available at <https://www.floridahealth.gov/licensing-and-regulation/emt-paramedics/licensing/index.html> (last visited March 29, 2023).

³⁶ *Id.*

³⁷ S. 401.27(3), F.S.

³⁸ S. 401.27(4), F.S.

³⁹ *Supra*, note 17.

⁴⁰ S. 401.027(5), F.S.

⁴¹ S. 401.34, F.S.

⁴² *Supra*, note 39. See also, s. 465.017(1), F.S., DOH was required by statute to use national certification exams whenever such an exam was available and prohibited from developing their own exam when an acceptable national certification exam was available.

⁴³ S. 401.2701, F.S.

- Faculty including a medical director⁴⁴ and program director; and
- Curriculum meeting the standards set in statute and by the National EMS Education Standards.

The requirement that an EMS training program maintain an affiliation agreement with a licensed EMS provider has been interpreted as preventing EMS providers from also being approved EMS training providers and providing training internally.⁴⁵

Current law requires that DOH use the United States Department of Transportation and Medical Services: First Responder Training Course as the minimum standard for emergency medical service training;⁴⁶ however, The National Emergency Medical Service Education Standards (EMS Standards) replaced the First Responder Training Course as the national standard in 2009.⁴⁷ DOH has since transitioned to using the EMS Standards as the basis for EMT and paramedic training programs.⁴⁸

Emergency Medical Services Community Health Care

Under current law, EMTs and paramedics are authorized to perform health care tasks outside of an emergency medical setting and in partnership with a county health department.⁴⁹ This is intended to encourage more effective utilization of the skills of EMTs and paramedics.⁵⁰

Paramedics and EMTs are authorized to perform health promotion and wellness activities and blood pressure screening in a nonemergency environment.⁵¹ Paramedics with sufficient training and experience may administer immunizations under the direction of a medical director and in collaboration with a county health department.⁵² The medical director must have a written agreement with a county health department establishing the protocols, policies, and procedures under which the paramedic must operate.⁵³

In 2022, the Legislature authorized paramedics to provide BLS and ALS to patients receiving acute and post-acute hospital care at home as specified in a paramedic's supervisory relationship with a physician or in accordance with standing orders.⁵⁴ A physician who supervises or provides medical direction to a paramedic for acute hospital care at home is liable for any act or omission of the paramedic when performing ALS and BLS services in such setting.⁵⁵

Effect of Proposed Bill – Emergency Medical Services

Emergency Medical Responder Certification

CS/CS/HB 1387 removes the requirement that EMTs and paramedics apply under oath. The bill also removes the requirement that paramedics attest under oath that they are not addicted to any substances and free of any physical or mental defect that could impede their duties as a paramedic. Paramedics must still attest to meeting these requirements, but may now do so electronically.

The bill also deletes provisions relating to the frequency, grading, and required fees for the certification exam as administered by DOH. These provisions are obsolete as DOH no longer develops or administers the exam.

⁴⁴ See also, s. 401.265, F.S., and rule 64J-1.004, a medical director must be a licensed physician and is responsible for the medical performance of the EMTs and paramedics under their supervision.

⁴⁵ *Supra*, note 39.

⁴⁶ S. 401.435, F.S.

⁴⁷ National Highway Traffic Safety Administration, 2021 National Emergency Medical Services Education Standards. Available at https://www.ems.gov/assets/EMS_Education-Standards_2021_FNL.pdf (last visited March 30, 2023).

⁴⁸ Rule 64J-1.008, F.A.C.

⁴⁹ S. 401.272(1), F.S.

⁵⁰ *Id.*

⁵¹ S. 401.272(2), F.S.

⁵² *Id.*

⁵³ *Id.*

⁵⁴ S. 401.272(2)(c), F.S., see also, ss. 401.265, 458.348, and 459.025, F.S., regarding standing orders.

⁵⁵ S. 401.272(2), F.S.

Emergency Medical Service Training Programs

The bill authorizes licensed EMS providers with permitted transport vehicles to be approved by DOH as an EMS training program without an affiliation agreement with an outside EMS provider. The bill also updates statute to reflect the current national education standards for paramedics and EMTs, the US Department of Transportation's National Emergency Medical Services Education Standards for the Emergency Medical Responder, and deletes references to the First Responder Training Course. The bill also changes "first responders" to "emergency medical responders" in statute to align with current nomenclature.

Emergency Medical Services Community Health Care

The bill removes language requiring that EMTs and paramedics "partner" with county health departments when performing health care tasks outside of an emergency environment. The bill removes references to "blood pressure screenings" in the descriptions of health care tasks that an EMT or paramedic pay perform. Such screenings may be presumed to be included in the "health promotion and wellness activities," that are permitted in statute.

The bill authorizes paramedics to administer immunizations under the medical direction of a physician, rather than a medical director affiliated with an EMS provider. The physician supervising a paramedic in the administration of immunizations must have a written agreement with a county health department or DOH establishing the protocols, policies, and procedures under which the paramedic must operate.

The bill stipulates that EMTs and paramedics must operate under the medical direction of a physician through two-way voice communication or pursuant to standing orders or protocols and within the scope of their training when performing health care tasks in a nonemergency environment or when transporting a patient to a facility other than an emergency department or hospital as defined in s. 395.002, F.S.

Certified Nursing Assistants

Present Situation

Certified Nursing Assistants (CNAs) provide care and assist individuals with tasks relating to the activities of daily living, such as those associated with personal care, nutrition and hydration, maintaining mobility, toileting, safety and cleaning, end-of-life care, cardiopulmonary resuscitation and emergency care.⁵⁶ A CNA performs services under the general supervision⁵⁷ of a registered nurse or licensed practical nurse.⁵⁸ CNAs are certified by the Board of Nursing (Board) within DOH.⁵⁹

To be certified as a CNA, an applicant must pass the Certified Nursing Assistant Examination (exam) which consists of a clinical skills test and a written test.⁶⁰ Under current law, completion of a board-approved training program is not required to take the exam and be certified as a CNA, so long as the applicant is over 18 years of age and has a high school diploma or its equivalent.⁶¹ Applicants who have completed a 120-hour, board-approved training program, or curriculum developed under the Enterprise Florida Jobs and Education Partnership Grant are required to pass the same exam in order to be certified as a CNA.⁶²

⁵⁶ S. 464.201(6), F.S.

⁵⁷ Under general supervision, the registered nurse or licensed practical nurse does not need to be present but must be available for consultation and advice, either in person or by a communication device. Rule 64B9-15.001(5), F.A.C

⁵⁸ Rule 64B9-15.002, F.A.C.

⁵⁹ S. 464.203, F.S.

⁶⁰ S. 464.203(1), F.S.

⁶¹ *Id.* See also, Florida Board of Nursing, *Certified Nursing Assistant (CNA) by Examination*. Available at <http://floridasnursing.gov/licensing/certified-nursing-assistant-examination/> (last visited March 29, 2023).

⁶² S. 464.203(1), F.S.

DOH has contracted with Prometric for the development and administration of the exam.⁶³ The written and clinical skills portions of the exam are administered separately and are effectively two different tests for the applicant. The written portion of the exam requires the candidate pay a \$35 fee, and is administered using a computerized testing system at designated testing sites.⁶⁴ The clinical skills portion of the exam requires a separate \$120 fee, and is an in-person test of five clinical skills relevant to the role of a CNA.⁶⁵ The skills portion is administered by Nurse Aid Evaluators who observe candidates perform each skill and compare performance to the checkpoints for the specified skill. DOH reports that on average, two Nurse Aid Evaluators are required to proctor each clinical skills test; and that due to illness and workforce shortages, there have been cancellations of the required clinical skills test, which have resulted in a delay of licensure.⁶⁶

Applicants who have failed any part of the exam three times must complete a board-approved training program before they are eligible to attempt the exam again.⁶⁷ In order to maintain certification, a CNA must biennially complete 24 hours of in-service training.⁶⁸

In response to the COVID-19 Public Health Emergency, the State Surgeon General issued Emergency Order 20-008 which waived the skills demonstration portion of the exam for applicants who successfully completed a board approved CNA training program within the prior 6 months.⁶⁹ DOH reports that during the effective period of the executive order, there were no adverse incidents, disciplinary cases, or complaints that resulted from this waiver.⁷⁰ The executive order expired on June 26, 2021.⁷¹

Effect of Proposed Changes – Certified Nursing Assistants

The bill codifies the provisions of Emergency Order 20-008 regarding CNA certification. Specifically, the bill exempts individuals who have successfully completed a board-approved CNA training program within six months of applying for certification from the clinical skills portion of the exam.

Hearing Aids

Present Situation

Hearing Loss

A person who is not able to hear as well as someone with normal hearing – hearing thresholds of 20 decibels or better in both ears – is said to have hearing loss.⁷² There are four types of hearing loss:⁷³

- **Conductive Hearing Loss** – Occurs when something prevents sounds from getting through the outer or middle ear.
- **Sensorineural Hearing Loss** - Occurs when there is a problem in the way the inner ear or hearing nerve works.
- **Mixed Hearing Loss** - Hearing loss that includes both a conductive and a sensorineural hearing loss.

⁶³ Prometric, *Candidate Information Bulletin, State of Florida, Certified Nursing Assistant Examination*. Available at https://www.prometric.com/sites/default/files/2023-03/FL_CNA_CIB.2.27.23.pdf (last visited March 29, 2023).

⁶⁴ *Id.*

⁶⁵ *Id.*

⁶⁶ *Supra*, note 17, at p. 6.

⁶⁷ *Supra*, note 61.

⁶⁸ S. 464.203(7), F.S.

⁶⁹ Florida Department of Health, *Emergency Order DOH No. 20-008* (May 28, 2020). Available at <https://floridahealthcovid19.gov/wp-content/uploads/2020/05/DOH-EO-20-008.pdf> (last visited March 29, 2023).

⁷⁰ *Supra*, note 17.

⁷¹ *Id.*

⁷² World Health Organization, *Deafness and Hearing Loss*, Mar. 2, 2021, available at <https://www.who.int/news-room/fact-sheets/detail/deafness-and-hearing-loss> (last visited March 30, 2023). “Disabling hearing loss” refers to hearing loss greater than 35 decibels in the better hearing ear.

⁷³ Centers for Disease Control and Prevention, *Types of Hearing Loss*, available at <https://www.cdc.gov/ncbddd/hearingloss/types.html> (last visited on March 30, 2023).

- **Auditory Neuropathy Spectrum Disorder** - Hearing loss that occurs when sound enters the ear normally, but because of damage to the inner ear or the hearing nerve, sound is not organized in a way that the brain can understand.

In the United States, approximately 15% of adults (37.5 million) report some difficulty hearing and 29 million adults could benefit from hearing aids.⁷⁴ In 2019, there were 372,111 people with a hearing disability in Florida.⁷⁵ Hearing loss in adults is generally a result of aging or noise exposure, but the causes of hearing loss in children are much more varied and may be associated with other medical conditions that require medical evaluation.⁷⁶

A hearing aid is a small electronic device that goes in or behind an individual's ear to make sounds louder so the person can listen, communicate, and participate more fully in daily activities.⁷⁷ Most hearing aids work through air-conduction wherein they bring amplified sound into the ear canal. Certain types of hearing loss necessitate a bone-conduction hearing aid which sends sound through the skull to reach the inner ear.⁷⁸

Despite the high prevalence of hearing loss in the US, only one-fifth of the people who could benefit from a hearing aid use one.⁷⁹ Barriers to hearing aid use include high cost, access to health care and hearing specialists, social stigma, perceived value of the devices, and certain state and federal regulations.⁸⁰ High initial purchasing cost and continued maintenance costs are primary barriers to access; the average cost of a single hearing aid is over \$2,000, or \$4,000 for a pair.⁸¹

Under current law, consumers purchasing hearing aids are guaranteed certain rights relating to the purchase. For example, the prospective purchaser must be provided an itemized list of hearing aid prices,⁸² they must receive a written notice of a 30-day trial period with a money-back guarantee,⁸³ and they reserve the right to return the hearing aid within 60 days of purchase if they consult with a physician who determines that the use of the hearing aid is not beneficial.⁸⁴

Audiologists

The Board of Speech-Language Pathology & Audiology within DOH is responsible for licensing, monitoring, disciplining and educating audiologists.⁸⁵ 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. There are currently 1,193 licensed audiologists in Florida.⁸⁶

⁷⁴ United States Department of Health and Human Services, National Institute of Deafness and Other Communication Disorders, *Quick Statistics About Hearing*, available at <https://www.nidcd.nih.gov/health/statistics/quick-statistics-hearing> (last visited on March 30, 2023).

⁷⁵ Florida Department of Health – FLHealthCHARTS Community Health Assessment Resource Tool Set, *Census Population Under 18 with Hearing Disability, Census Population 18-64 with Hearing Disability, Hearing Disability 65-74, and Hearing Disability 75+*, available at <http://www.flhealthcharts.com/charts/SearchResult.aspx> (last visited Mar. 29, 2021).

⁷⁶ US Food & Drug Administration. *Hearing Aids and Personal Sound Amplification Products: What to Know*. (2023). Available at <https://www.fda.gov/consumers/consumer-updates/hearing-aids-and-personal-sound-amplification-products-what-know> (last visited March 30, 2023).

⁷⁷ *Id.*

⁷⁸ *Id.*

⁷⁹ US Food & Drug Administration, *FDA Issues Landmark Proposal to Improve Access to Hearing Aid Technology for Millions of Americans* (2021). Available at <https://www.fda.gov/news-events/press-announcements/fda-issues-landmark-proposal-improve-access-hearing-aid-technology-millions-americans#:~:text=However%2C%20despite%20the%20high%20prevalence%20and%20public%20health,the%20device%20or%20certain%20state%20and%20federal%20regulations>. (last visited March 31, 2023).

⁸⁰ *Id.*

⁸¹ Anderson, C. & Predith, A., (2016). *FDA Takes Action to Deliver Lower-Cost, Innovative Hearing Aids to Millions More Americans*. *Obama White House Archives*. Available at <https://obamawhitehouse.archives.gov/blog/2016/12/07/fda-takes-action-deliver-lower-cost-innovative-hearing-aids-millions-more-americans> (last visited March 31, 2023).

⁸² S. 468.1245, F.S.

⁸³ S. 468.1246, F.S.

⁸⁴ S. 468.1255, F.S.

⁸⁵ S. 468.1185, F.S.

⁸⁶ *Supra*, note 17 at p. 7.

In addition to conducting and interpreting hearing tests and dispensing hearing aids a licensed audiologist may also:⁸⁷

- Offer, render, plan, direct, conduct, consult, or supervise certain services to individuals who have or are suspected of having hearing disorders;
- Participate in hearing conservation, evaluation of noise environments, and noise control;
- Habilitate and rehabilitate, including, but not limited to, hearing aid evaluation, prescription, preparation, fitting, assistive listening device selection and orientation, auditory training, aural habilitation and rehabilitation, speech conservation, and speechreading;
- Fabricate ear molds;
- Evaluate tinnitus; and
- Provide speech and language screening, limited to a pass/fail determination for identifying individuals with disorders of communication.

Audiologists are required to follow certain minimum procedures and conduct certain tests when fitting a patient for a hearing aid, including:⁸⁸

- Pure tone audiometric testing by air and bone to determine the type and degree of hearing deficiency when indicated;
- Effective masking when indicated; and
- Appropriate testing to determine speech reception thresholds, speech discrimination scores, the most comfortable listening levels, uncomfortable loudness levels, and the selection of the best fitting arrangement for maximum hearing aid benefit when indicated.

All audiometric tests must be conducted in a testing room that has been certified by DOH not to exceed certain sound pressure levels and specified frequencies.⁸⁹ An audiologist is required to perform a final fitting for a patient to ensure the physical and operational comfort of the hearing aid when indicated.⁹⁰

Hearing Aid Specialists

The Board of Hearing Aid Specialists within DOH is responsible for licensing, monitoring, disciplining and educating hearing aid specialists. There are currently 1,035 licensed hearing aid specialists in Florida.⁹¹ A licensed hearing aid specialist may practice the dispensing of hearing aids, which includes:⁹²

- Conducting and interpreting hearing tests for purposes of selecting suitable hearing aids;
- Making ear molds or ear impressions;
- Providing appropriate counseling; and
- All acts pertaining to the selling, renting, leasing, pricing, delivery, and warranty of hearing aids.

Hearing aid specialists are required to follow certain minimum procedures and conduct certain tests when fitting a patient for a hearing aid, including:⁹³

- Pure tone audiometric testing by air and bone to determine the type and degree of hearing deficiency;
- Effective masking when indicated; and

⁸⁷ S. 468.1125(6)(b), F.S.

⁸⁸ S. 468.1225(1), F.S.

⁸⁹ S. 468.1225(6), F.S.

⁹⁰ S. 468.1225(3), F.S.

⁹¹ *Supra*, note 17 at p. 7.

⁹² S. 484.045, F.S.

⁹³ S. 484.0501(1), F.S.

- Appropriate testing to determine speech reception thresholds, speech discrimination scores, the most comfortable listening levels, uncomfortable loudness levels, and the selection of the best fitting arrangement for maximum hearing aid benefit.

All audiometric tests must be conducted in a testing room that has been certified by DOH not to exceed certain sound pressure levels and specified frequencies.⁹⁴ A hearing aid specialist is required to perform a final fitting for a patient to ensure the physical and operational comfort of the hearing aid.⁹⁵

Over-the-Counter Hearing Aids

The US Food & Drug Administration (FDA) regulates hearing aids to ensure they provide reasonable assurance of safety and effectiveness.⁹⁶ In the FDA Reauthorization Act of 2017 (FDARA), Congress directed the FDA to establish a category of over-the-counter (OTC) hearing aids which could be purchased through in-person transactions, by mail, or online without a medical exam, prescription, or fitting adjustment by a practitioner.⁹⁷ FDARA also incorporated federal preemption provisions prohibiting state and local governments from interfering with the servicing, marketing, sale, dispensing, use, customer support, or distribution of OTC hearing aids.⁹⁸

On August 17, 2022, the FDA finalized a rule revising 21 CFR Parts 800, 801, and 874, as directed by FDARA, with the goal of improving access to and reducing the cost of hearing aids for Americans.⁹⁹ The FDA's new rule establishes a new category for OTC hearing aids for adult 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."¹⁰⁰ Consumers are now able to purchase specified hearing aids directly from retailers, without the need for a prescription from their physician or other medical professional. The rule became effective on October 17, 2022.¹⁰¹

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.¹⁰² The FDA rule defines OTC hearing aids as a 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. The rule prohibits states from requiring the order, involvement, or intervention of a licensed person for consumers to access over the counter hearing aid. A licensed person may still service, market, sell, dispense, provide customer support for, or distribute OTC hearing aids.¹⁰³

Florida law does not currently distinguish between OTC and prescription hearing aids,¹⁰⁴ nor does it contemplate the sale of hearing aids online. Under current law, the dispensing of hearing aids to consumers by mail is prohibited and subject to criminal penalties.¹⁰⁵

Effect of Proposed Changes – Hearing Aids

The bill defines "over-the-counter hearing aid" to mean 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. The bill specifies that a "prescription hearing aid" is any hearing aid that is not considered an OTC hearing aid.

⁹⁴ S. 484.0501(6), F.S.

⁹⁵ S. 484.0501(3), F.S.

⁹⁶ *Supra*, note 76.

⁹⁷ FDA Reauthorization Act of 2017 s. 709. Regulation of Over-the-Counter Hearing Aids.

⁹⁸ *Id.*

⁹⁹ *Supra*, note 79.

¹⁰⁰ See, Federal Register, *Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids*. Available at <https://www.govinfo.gov/content/pkg/FR-2022-08-17/pdf/2022-17230.pdf> (last visited March 31, 2023).

¹⁰¹ *Id.*

¹⁰² *Id.*

¹⁰³ *Id.*

¹⁰⁴ See, s. 484.041, F.S.

¹⁰⁵ S. 468.1265, F.S.

The bill amends statute regulating the distribution of hearing aids by hearing aid specialists and audiologists to specify that the regulations apply exclusively to the dispensing of prescription hearing aids. The bill exempts individuals dispensing exclusively OTC hearing aids from regulation. This aligns statute with the federal rule which specifies that states may not establish regulatory measures or require licensure for individuals who dispense OTC hearing aids.¹⁰⁶ The bill makes conforming changes throughout Chs. 468 and 484, F.S., to specify that regulations apply only to prescription hearing aids.

The bill specifies that the consumer protections under current law only apply to the purchase of prescription hearing aids, and do not pertain to the purchase of OTC hearing aids. The bill also specifies that the restriction on the distribution of hearing aids by mail applies only to prescription hearing aids.

The bill deletes obsolete references to rulemaking deadlines which have already been met.

Effective Date

The bill provides an effective date of July 1, 2023, except for those sections which take effect upon becoming law. The bill provisions related to enhanced potential pandemic pathogen research take effect upon becoming law.

B. SECTION DIRECTORY:

- Section 1:** Creates s. 381.875, F.S., relating to enhanced potential pandemic pathogen research prohibited.
- Section 2:** Amends s. 381.986, F.S., relating to medical use of marijuana.
- Section 3:** Amends s. 381.988, F.S., relating to medical marijuana testing laboratories; marijuana tests conducted by a certified laboratory.
- Section 4:** Amends s. 382.005, F.S., relating to duties of local registrars.
- Section 5:** Amends s. 382.008, F.S., relating to death, fetal death, and nonviable birth registration.
- Section 6:** Amends s. 382.009, F.S., relating to recognition of brain death under certain circumstances.
- Section 7:** Amends s. 382.013, F.S., relating to birth registration.
- Section 8:** Amends s. 382.015, F.S., relating to new certificates of live birth; duty of clerks of court and department.
- Section 9:** Amends s. 382.021, F.S., relating to department to receive marriage licenses.
- Section 10:** Amends s. 382.023, F.S., relating to department to receive dissolution-of-marriage records; fees.
- Section 11:** Amends s. 382.025, F.S., relating to certified copies of vital records; confidentiality; research.
- Section 12:** Amends s. 401.27, F.S., relating to personnel; standards and certification.
- Section 13:** Amends s. 401.2701, F.S., relating to emergency medical services training programs.
- Section 14:** Amends s. 401.272, F.S., relating to emergency medical services community health care.
- Section 15:** Amends s. 401.34, F.S., relating to fees.
- Section 16:** Amends s. 401.435, F.S., relating to first responder agencies and training.
- Section 17:** Amends s. 464.203, F.S., relating to certified nursing assistants; certification requirement.
- Section 18:** Amends s. 468.1225, F.S., relating to procedures, equipment, and protocols.
- Section 19:** Amends s. 468.1245, F.S., relating to itemized listing of prices; delivery of hearing aid; receipt; guarantee; packaging; disclaimer.
- Section 20:** Amends s. 468.1246, F.S., relating to thirty-day trial period; purchaser's right to cancel; notice; refund; cancellation fee.

¹⁰⁶ *Supra*, note 100.

- Section 21:** Amends s. 468.1255, F.S., relating to cancellation by medical authorization; purchaser's right to return.
- Section 22:** Amends s. 468.1265, F.S., relating to sale or distribution of hearing aids through mail; penalty.
- Section 23:** Amends s. 468.1275, F.S., relating to place of business; display of license.
- Section 24:** Amends s. 484.0401, F.S., relating to purpose.
- Section 25:** Amends s. 484.041, F.S., relating to definitions.
- Section 26:** Amends s. 484.042, F.S., relating to Board of Hearing Aid Specialists; membership; appointment, terms.
- Section 27:** Amends s. 484.044, F.S., relating to authority to make rules.
- Section 28:** Amends s. 484.0445, F.S., relating to training program.
- Section 29:** Amends s. 484.045, F.S., relating to licensure by examination.
- Section 30:** Amends s. 484.0501, F.S., relating to minimal procedures and equipment.
- Section 31:** Amends s. 484.051, F.S., relating to itemization of prices; delivery of hearing aid; receipt, packaging, disclaimer, guarantee.
- Section 32:** Amends s. 484.0512, F.S., relating to thirty-day trial period; purchaser's right to cancel; notice; refund; cancellation fee; criminal penalty.
- Section 33:** Amends s. 484.0513, F.S., relating to cancellation by medical authorization; purchaser's right to return.
- Section 34:** Amends s. 484.053, F.S., relating to prohibitions; penalties.
- Section 35:** Amends s. 484.054, F.S., relating to sale or distribution of hearing aids through mail; penalty.
- Section 36:** Amends s. 484.059, F.S., relating to exemptions.
- Section 37:** Relating to the effective date of this act.
- Section 38:** Provides an effective date of July 1, 2023, except for where otherwise specified.

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 relating to rulemaking necessitated by the bill which can be absorbed within current resources.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill provides sufficient rule-making authority to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

On April 10, 2023, the Health and Human Services Committee adopted two amendments and reported the bill favorably as a committee substitute. The amendments:

- Remove the requirement that DOH adopt certain rules related to the medical marijuana program.
- Revise the definition of “prescription hearing aid.”

The analysis is drafted to the committee substitute passed by the Health and Human Services Committee.