

## HOUSE OF REPRESENTATIVES STAFF ANALYSIS

**BILL #:** CS/CS/HB 693 Department of Health

**SPONSOR(S):** Health & Human Services Committee, Professions & Public Health Subcommittee, Drake

**TIED BILLS:** IDEN./SIM. BILLS: SB 768

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Professions & Public Health Subcommittee	18 Y, 0 N, As CS	Morris	McElroy
2) Health & Human Services Committee	20 Y, 0 N, As CS	Morris	Calamas

### SUMMARY ANALYSIS

CS/HB 693 makes numerous changes to programs under the Department of Health (DOH) and health care professions regulated by the Division of Medical Quality Assurance (MQA) within DOH.

DOH administers the Targeted Outreach for Pregnant Women Act (TOPWA) Program which supports high risk pregnant women to prevent health issues for themselves and their newborns. The bill updates the TOPWA to account for current medication options, information on HIV, and mental health issues that may lead to a pregnancy being high risk.

DOH is responsible for ensuring medical marijuana products are safe for human consumption and meet THC and CBD potency and labeling requirements. The bill requires medical marijuana treatment centers to recall all marijuana that fails to meet the safety and potency requirements, authorizes DOH to test samples of all forms of marijuana from MMTCs, and immunizes DOH staff from prosecution for possessing marijuana for this purpose.

The bill amends licensure laws for various professions regulated by DOH. The bill:

- Updates institutional accreditation references for chiropractic medicine, clinical laboratory personnel, and mental clinical social workers and marriage and family therapists;
- Authorizes DOH to deny a nursing application or discipline a nurse licensed under ch. 464, F.S. under certain circumstances;
- Removes obsolete references to DOH-issued licensure examinations for clinical social workers and marriage and family therapists;
- Revises education, training, and temporary certification requirement for midwives;
- Removes obsolete form and fee requirements for fingerprinting of orthotists and prosthetists;
- Revises educational requirements for psychologists applying for licensure by endorsement; and
- Allows DOH to continue to issue licenses to marriage and family therapy graduates until July 1, 2026, while such programs seek accreditation.
- Requires allopathic and osteopathic physicians to provide proof of payment of NICA assessments as a condition of licensure;

The bill also:

- Requires DOH to determine who is responsible for the medical supervision of each special needs shelter;
- Allows the administrative service organization for Healthy Start coalitions to meet by telecommunication;
- Removes requirement that medical examiners certify all deaths within specified categories;
- Requires the President of the Senate and the Speaker of the Florida House of Representative each to appoint two individuals who are caregivers of an individual with a rare disease to the Rare Disease Advisory Council; and
- Requires compounding pharmacy licensees which ship compounded drugs interstate to report certain information to the National Association of Boards of Pharmacy Information-Sharing Network pursuant to an agreement between DOH and the Food and Drug Administration.

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, 2022.

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

**STORAGE NAME:** h0693b.HHS

**DATE:** 2/18/2022

# FULL ANALYSIS

## I. SUBSTANTIVE ANALYSIS

### A. EFFECT OF PROPOSED CHANGES:

#### **Targeted Outreach for Pregnant Women**

##### Current Situation

The Targeted Outreach for Pregnant Women Act (TOPWA) supports targeted outreach programs that aim to prevent vertical HIV transmission and other health issues by linking high-risk pregnant women with services that can help them have healthier pregnancies and deliveries and can aid them in ensuring their newborn gets a healthy start.<sup>1</sup> TOPWA programs aim to provide outreach and linkage services to pregnant women who may not seek proper prenatal care, who suffer from substance-use disorders, or who are living with HIV or are at increased risk for HIV acquisition.

In 2021, there were eight funded TOPWA programs in Florida. TOPWA programs provided services to 7,292 women from January 2018 to December 2021. Black women represented 49 percent of enrollees, Hispanic women represented 40 percent, and white women represented 8 percent. Women living with HIV made up just over 9 percent of TOPW enrollments.<sup>2</sup>

If a pregnant woman tests positive for HIV, medical interventions like antiretroviral (ARV) medication and delivery by caesarian section can greatly reduce her risk of transmitting the virus to her baby during childbirth. Prevention methods, like avoiding breastfeeding, can reduce her risk of transmitting the virus to her child post childbirth. Providing ARV medication to the newborn also decreases the chances of seroconversion in the event of an HIV-exposed birth. DOH has developed a program, Baby Rpress, which provides a six-week course of ARV medication to HIV-exposed newborns at no cost to the mother. In 2021, this program filled 330 prescriptions to 232 HIV-exposed newborns.<sup>3</sup>

Many of the women targeted by TOPWA programs would not otherwise receive prenatal care or know their HIV status. In 2020, there were 439 HIV-exposed births in Florida and four reported cases of perinatal HIV transmission. TOPWA programs aim to engage women into care who very likely do not already have knowledge of or access to these interventions. Without these types of interventions, a mother's chances of transmitting HIV to her newborn can be up to 45 percent. With these interventions, the chances of transmission are less than 2 percent.<sup>4</sup>

##### Effect of Proposed Changes – Targeted Outreach for Pregnant Women

The bill adds pregnant women who are suffering from mental health problems to the list of outreach targets. It also includes mental health services as a linkage option.

The bill revises the duties of DOH's administration of the TOPWA and the information and services DOH provides to the women it serves. The bill requires DOH to encourage high-risk pregnant women to be tested for other sexually transmitted diseases, in addition to HIV, as specified by rule. The bill requires DOH to give pregnant women who have HIV information on the need for ARV medication for their newborn, their medication options, and how to access medication after hospital discharge. The bill removes a reference to a specific type of ARV medication DOH may provide information on and incorporates more general information on ARV medications, allowing for additional options. The bill requires DOH to educate pregnant women who have HIV on the importance of engaging in and continuing HIV care. Lastly, the bill requires DOH to conduct additional follow up for HIV-exposed newborns to ensure final HIV status is known and necessary linkages to care are made.

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<sup>1</sup> Department of Health, *Targeted Outreach for Pregnant Women Act*, <http://stlucie.floridahealth.gov/programs-and-services/infectious-disease-services/hiv-aids/topwa.html> (last visited Jan. 20, 2022).

<sup>2</sup> Email from Gangul Gabadage, Legislative Planning Coordinator, Department of Health, TOPWA Numbers (Jan. 24, 2022).

<sup>3</sup> Id.

<sup>4</sup> Id.

## Institutional Accreditation

### Current Situation

Accreditation is the recognition from an accrediting agency that an institution maintains a certain level of educational standards. Institutional accreditation normally applies to an entire institution and indicates that each entity of a school contributes to the achievement of the school's objectives. This does not necessarily mean that all parts of the school have the same quality level of education.<sup>5</sup> Accrediting agencies issue accreditations.<sup>6</sup> Institutions or programs that request an agency's evaluation and that meet an agency's criteria are then accredited by that agency.<sup>7</sup> Accrediting agencies are organizations made up of educational professionals that:<sup>8</sup>

- Establish the operating standards for educational or professional institutions and programs;
- Determine if a school meets those standards; and
- Publicly announce their findings through the issuance of accreditations.

While the United States Department of Education (DOE) does not issue accreditations, it does hold accrediting agencies accountable by ensuring that such agencies enforce their accreditation standards effectively. As part of DOE oversight, the Secretary of Education is required by law to publish a list of nationally recognized accrediting agencies that the Secretary determines to be reliable authorities as to the quality of education or training provided by the institutions of higher education and the higher education programs they accredit.<sup>9</sup>

The U.S. DOE issued finalized regulations in the Federal Register in October 2019 relating to institutional accrediting agencies.<sup>10</sup> DOE issued a letter of guidance on February 26, 2020, specifying that final regulations omit references to "regional" and "national" accreditation.<sup>11</sup> The letter specifies, "[b]ecause the Department holds all accrediting agencies to the same standards, distinctions between regional and national accrediting agencies are unfounded." Provisions implemented in 34 C.F.R. § 602.32(d), relating to the recognition of accrediting agencies, became effective January 1, 2021.

However, the education requirements in current Florida law distinguish regional from institutional accrediting agencies for chiropractic medicine, clinical laboratory directors, orthotists and prosthetists, clinical social workers, and marriage and family therapists. This does not align with the federal guidance. DOE's letter of guidance gave notice to states to come into compliance with federal regulations which took effect on July 1, 2020. Alignment with federal guidance is necessary to ensure compliance with federal accreditation standards and to avoid delays in implementation of DOE review of accrediting agency applications and DOE processes for responding to accrediting agency applications.<sup>12</sup>

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<sup>5</sup> U.S. Department of Homeland Security – Study in the States, *The Basics of School Accreditation*, <https://studyinthestates.dhs.gov/the-basics-of-school-accreditation> (last visited Jan. 20, 2022).

<sup>6</sup> *Id.* See also U.S. Department of Education, *Database of Accredited Postsecondary Institutions and Programs*, <https://ope.ed.gov/dapip/#/home> (last visited March 20, 2021).

<sup>7</sup> U.S. Department of Education, *Database of Accredited Postsecondary Institutions and Programs*, <https://ope.ed.gov/dapip/#/home> (last visited Jan. 20, 2022).

<sup>8</sup> *Supra*, note 5.

<sup>9</sup> *Supra*, note 7.

<sup>10</sup> 84 C.F.R. § 58834 (2020). The new regulations delayed implementation of changes to DOE staff's review of accrediting agency applications for initial or renewal of recognition under 34 C.F.R. § 602.32(d) until January 1, 2021. The new regulations also delayed implementation of changes to DOE staff's process for responding to accrediting agency applications and allowing agency responses within 180 days under 34 C.F.R. § 602.32(h) until July 1, 2021.

<sup>11</sup> U.S. Department of Education, Re: Final Accreditation and State Authorization Regulations (February 26, 2021) <https://sacscoc.org/app/uploads/2020/03/State-Authorization-Letter-w-Diane-Signature-2.26.19.pdf> (last visited Jan. 20, 2022).

<sup>12</sup> *Id.*

## Effect of Proposed Changes – Institutional Accreditation

The bill removes all references to “regional” accreditation in the practice acts for chiropractic medicine, clinical laboratory directors, orthotists and prosthetists, clinical social workers, and marriage and family therapists. The bill replaces the references with “institutional” accreditation throughout. This conforms Florida law to the terminology used in U.S. Department of Education regulations.

## **Nursing**

### Current Situation

The Board of Nursing (Board) within DOH, oversees the licensure and regulation of certified nursing assistants (CNA), licensed practical nurses (LPN), registered nurses (RN), and advanced practice registered nurses (APRN). The Board has the authority to adopt rules to implement ch. 464, F.S., which regulates the practice of nursing in this state.<sup>13</sup> Additionally, the Board is responsible for administratively disciplining a CNA, LPN, RN, and APRN who commits an act prohibited under s. 464.018 or s. 456.072, F.S.

Current law specifies that being found guilty of any offense prohibited by s. 435.04, F.S., or an act of domestic violence, regardless of adjudication, or entering a plea of nolo contendere or guilty to, is ground for denial of a nursing license application or disciplinary action against a nursing licensee.<sup>14</sup> However, entering a guilty plea, or pleading nolo contendere, to these crimes is only grounds for licensure denial if there is a conviction. Other practice acts authorize license denial and discipline for pleading guilty or nolo contendere regardless of adjudication.<sup>15</sup>

### Effect of Proposed Changes – Nursing

The bill moves “regardless of adjudication” after “or entered a plea of nolo contendere or guilty to” which allows DOH to deny a nursing licensure application or discipline a licensed CNA, LPN, RN, or APRN who is found guilty of, or pleads guilty or no contest to an offense prohibited in ch. 435, F.S., or domestic violence under s. 741.28, F.S.

## **Midwifery**

### Current Situation

Chapter 467, F.S., is the practice act for midwifery (Act). DOH licenses and regulates the practice of midwifery in this state. Midwifery is the practice of supervising a normal labor and childbirth, with the informed consent of the parent, advising the parents as to the progress of childbirth, and rendering prenatal and postpartal care.<sup>16</sup> The Council of Licensed Midwifery assists and advises DOH on midwifery, including the development of rules relating to regulatory requirements. These regulations include training requirements, the licensure examination, responsibilities of midwives, emergency care plans, and reports and records to be filed by licensed midwives.<sup>17</sup>

### *Licensure*

An individual must graduate from an approved midwifery program and pass a licensure examination to be eligible for licensure as a midwife.<sup>18</sup> A licensed midwife must submit a general emergency care plan to DOH, which addresses consultation with other health care providers, emergency transfer protocols, and access to neonatal intensive care units and obstetrical units or other patient care areas with his or

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<sup>13</sup> Section 464.006, F.S.

<sup>14</sup> Section 464.018(1)(e), F.S.

<sup>15</sup> Examples of other practice acts include allopathic physicians under in s. 458.331(1)(c), F.S., osteopathic physicians in s. 459.015(1)(c), F.S., pharmacists in s. 465.016(1)(f), F.S., and dentists and dental hygienists in s. 466.028(1)(c), F.S.

<sup>16</sup> Section 467.003(8), F.S.

<sup>17</sup> Section 467.004, F.S.

<sup>18</sup> Section 467.011, F.S. Section 467.0125, F.S. DOH no longer administers licensure examinations.

her application for licensure and licensure renewal.<sup>19</sup> A licensed midwife must also submit proof of professional liability coverage of at least \$100,000, with an annual aggregate of at least \$300,000.<sup>20</sup>

DOH may issue a license by endorsement for midwifery applicants who:<sup>21</sup>

- Holds a valid certificate or diploma from a foreign institution of medicine or from midwifery program in another state provided the requirements for licensure or certification in another country or another state are equivalent to or exceed that which is required for licensing in Florida; or
- Holds a valid certificate or license to practice midwifery in another state provided the requirements for licensure or certification in another state are equivalent to or exceed that which is required for licensing in Florida; and
- Has completed a 4-month prelicensure course conducted by an approved program; and
- Has successfully passed the licensed midwifery examination.

#### *Areas of Critical Need*

DOH may also issue a temporary certificate to a midwife who qualifies for licensure by endorsement to practice in areas of critical need.<sup>22</sup> Currently, a temporary certificate issued to practice in areas of critical need valid as long as an area for which it's issued remains an area of critical need, but not longer than two years, and the certificate is not renewable.<sup>23</sup> Currently, if the area in which a midwife is practicing ceases to be an area of critical need, DOH must immediately initiate disciplinary action to revoke his or her temporary certificate.<sup>24</sup>

#### *Midwifery Students*

The Act uses the terms “applicant” and “student midwife” interchangeably. It also sets standards for admission, education, and clinical training in the context of student requirements, which, according to DOH, may cause confusion.<sup>25</sup> As an example, current law requires a student midwife to have a high school diploma or the equivalent to enroll in an education program, but the act does not clearly state that a high school diploma is a requirement for licensure.<sup>26</sup>

According to DOH, the use of the undefined term “student midwife” has led to unlicensed persons attempting to work with clients and complete clinical requirements without enrolling in or being educated by an approved midwifery program, as well as midwives attempting to serve as preceptors who are not affiliated with an approved midwifery program.<sup>27</sup>

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<sup>19</sup> Section 467.017, F.S.

<sup>20</sup> Rule 64B24-7.013, F.A.C. An applicant does not have to submit proof of professional liability insurance if the applicant practices exclusively as an officer, employee, or agent of the federal government, practices only in conjunction with teaching duties at an approved midwifery school that provides such coverage on the applicant's behalf, or who does not practice midwifery in this state and provides proof of such.

<sup>21</sup> Section 467.0125(1), F.S.

<sup>22</sup> Section 467.0125(2), F.S.

<sup>23</sup> *Id.*

<sup>24</sup> Department of Health Agency Analysis of 2022 House Bill 693, (Jan. 7, 2022)

<sup>25</sup> *Id.*

<sup>26</sup> Section 467.009, F.S. See also *Supra*, note 24.

<sup>27</sup> *Supra*, note 2. In general, health care practitioners do not start seeing clients in a clinical setting until they have completed prerequisite portions of a course of study and are near the end of their educational program.

## *Midwifery Education Programs*

Any accredited or state-licensed institution of higher learning may provide midwifery education and training. Midwifery education programs may apply to DOH to obtain approved program status.<sup>28</sup> Approval may be obtained if a program meets requirements for accreditation, faculty, curriculum, and clinical training.<sup>29</sup> Current law requires nonpublic educational institutions be accredited by the Commission on Recognition of Postsecondary Accreditation (CRPA) in order to be approved as a midwifery program.<sup>30</sup> However, CRPA has been succeeded by the Council for Higher Education Accreditation, which is not recognized in current law.<sup>31</sup>

Currently, the Act does not address midwifery programs which are seeking accreditation and are provisionally approved while awaiting their first graduating class.

Current law allows DOH to place a midwifery educational program on probationary status if it no longer meets required standards; if the program fails to correct these conditions, DOH may rescind its approval.<sup>32</sup> However, statutes provide no guidance regarding notification to the program or length of time a school may remain in probationary status. Additionally, the circumstances under which DOH may rescind the approval of a midwifery education program under the Act is unclear as it does not provide a definitive timeline for a non-compliant program to come back into compliance before DOH may rescind its approval. Current law allows a non-compliant program to correct itself “within a specified period of time”<sup>33</sup>; however, no timeline is provided in statute or rule.

### Effect of Proposed Changes – Midwifery

The bill makes numerous changes to the midwifery practice act.

#### *Licensure*

The bill prohibits endorsement without a license or certification in another state, territory or jurisdiction and creates a pathway to licensure by examination for applicants who have completed education equivalent to or exceeds that which is required for licensing in Florida in a state, territory, or jurisdiction that does not license midwives. These revisions do not change what is actually required to qualify for a midwifery license, but instead help applicants better understand those requirements.<sup>34</sup>

The bill allows midwifery programs to be provisionally approved for five years. This change conforms to the five-year period that such programs can be provisionally licensed by the U.S. Department of Education’s Commission for Independent Education when seeking accreditation status. DOH will be able to give provisional approval to a new program which has met all requirements except for showing their students have an 80% passage rate on the national exam. Programs provisionally approved will have five years to demonstrate the required exam approval rate after they are preliminarily approved. This time period allows completion of the three-year education program for at least one cohort of students, and for those students to take the exam before the Department tries to determine the passing rate.<sup>35</sup>

The bill removes obsolete references to the DOH-issued exam for midwifery licensure as DOH no longer administers licensure examinations.

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<sup>28</sup> Section 467.205, F.S.

<sup>29</sup> Rule 64B24-4.002, F.A.C.

<sup>30</sup> Section 467.009(8), F.S.

<sup>31</sup> *Supra*, note 24.

<sup>32</sup> Section 467.205, F.S.

<sup>33</sup> *Id.*

<sup>34</sup> *Supra*, note 24.

<sup>35</sup> *Id.*

## *Areas of Critical Need*

When a practice area is no longer designated as an area of critical need, the bill requires a certified midwife who practices in an area of critical need to relinquish his or her certificate within 30 days, or move his or her practice to another area of critical need, rather than being immediately subject to disciplinary action. Only if the midwife holding the temporary certificate fails to act within those thirty days will DOH initiate disciplinary action to revoke the certificate.<sup>36</sup>

## *Midwifery Students*

The bill prohibits a preceptor from supervising a midwifery student unless the student has been enrolled in an approved midwifery program. This means that an individual cannot begin their clinical practice before enrolling in an approved midwifery program and will explicitly conform midwifery training with the requirements of other medical professions, with students having to complete the majority of their classroom training before working with patients in a clinical setting.

## *Midwifery Education Programs*

The bill updates the accreditation requirement for private educational institutions by replacing the defunct Commission on Recognition of Postsecondary Accreditation with the Council for Higher Education Accreditation or provisional licensing by the Commission for Independent Education. The bill also allows DOH to approve midwifery programs at private educational institutions which are accredited by an agency recognized and approved by the U.S. Department of Education.

The bill authorizes DOH to grant provisional approval of a new midwifery education program which is seeking accreditation for up to 5 years.

Lastly, the bill authorizes DOH to place a midwifery program on probationary status for up to 3 years if such program fails to maintain the requirements of an approved program or has lost accreditation. If a program in probationary status fails to come into compliance with the requirements of an approved program or does not regain its accreditation, DOH may rescind the program's approval.

## **Orthotists and Prosthetists**

### Current Situation

The Board of Orthotists and Prosthetists oversees licensure and regulation of orthotists<sup>37</sup> and prosthetists.<sup>38</sup> A person applying for licensure must first apply to DOH to take the appropriate licensure examination. The board may accept the exam results of a national orthotic or prosthetic, standards organization in lieu of administering the state exam.<sup>39</sup> The board must verify that an applicant for licensure examination meets the following requirements:<sup>40</sup>

- Has completed the application form and paid all applicable fees;
- Is of good moral character;
- Is 18 years of age or older;
- Has completed the appropriate educational preparation, including practical training requirements; and
- Has successfully completed an appropriate clinical internship in the professional area for which the license is sought.

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<sup>36</sup> *Supra*, note 24.

<sup>37</sup> An orthotist is a health care professional who evaluates, formulates treatment, measures, designs, fabricates, assembles, fits, adjusts, services, or provides necessary training to accomplish the fitting of an orthosis or a pedorthic device (s. 468.80(9)-(10), F.S.)

<sup>38</sup> A prosthetist is a health care professional who evaluates, formulates treatment, measures, designs, fabricates, assembles, fits, adjusts, services, or provides necessary training to accomplish the fitting of a prosthesis (s. 468.80(15)-(16), F.S.)

<sup>39</sup> Section 468.803(4), F.S. The Board has approved the American Board for Certification in Orthotics, Prosthetics, and Pedorthics (ABC) exam for orthotist and prosthetist applicants (r. 64B14-4.001, F.A.C.)

<sup>40</sup> Section 468.803(2), F.S.

## *Background Screening*

Chapter 435, F.S., establishes standard procedures and requirements for criminal history background screening of prospective employees. There are two levels of background screening: level 1 and level 2. Level 1 screening includes, at a minimum, employment history checks and statewide criminal correspondence checks through the Florida Department of Law Enforcement (FDLE) and a check of the Dru Sjodin National Sex Offender Public Website,<sup>41</sup> and may include criminal records checks through local law enforcement agencies. A level 2 background screening includes, but, is not limited to, fingerprinting for statewide criminal history records checks through FDLE and national criminal history checks through the Federal Bureau of Investigation (FBI), and may include local criminal records checks through local law enforcement agencies.<sup>42</sup>

Every person required by law to be screened pursuant to ch. 435, F.S., must submit a complete set of information necessary to conduct a screening to his or her employer.<sup>43</sup> Such information for a level 2 screening includes fingerprints, which are taken by a vendor that submits them electronically to FDLE.<sup>44</sup>

### Effect of Proposed Changes – Orthotists and Prosthetists

The bill removes obsolete references to form and fee requirements for background screening of orthotists, prosthetists, and pedorthists which are no longer collected by DOH.

## **Psychologists**

### Current Situation

The Board of Psychology oversees the licensure and regulation of psychologists.<sup>45</sup> To receive a license to practice psychology, an individual must:<sup>46</sup>

- Meet one of the following educational requirements:
  - Received a doctoral-level psychological education from an institution that had institutional accreditation from an agency recognized by the United States Department of Education or was recognized as a member in good standing with the Association of Universities and Colleges of Canada, and had programmatic accreditation from the American Psychological Association (APA);<sup>47</sup> or
  - Received the equivalent of a doctoral-level education from a program at a school or university located outside of the United States, which is officially recognized by the government of the country in which it is located as a program or institution to train students to practice professional psychology.
- Complete 2 years or 4,000 hours of supervised experience;
- Pass the Examination for Professional Practice in Psychology;<sup>48</sup> and
- Pass an examination on Florida laws and rules.

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<sup>41</sup> The Dru Sjodin National Sex Offender Public Website is a U.S. government website that links public state, territorial, and tribal sex offender registries in one national search site. The website is available at <https://www.nsopw.gov/> (last visited Jan. 20, 2022).

<sup>42</sup> Section 435.04, F.S.

<sup>43</sup> Section 435.05(1)(a), F.S.

<sup>44</sup> Sections 435.03(1) and 435.04(1)(a), F.S.

<sup>45</sup> Section 490.004, F.S.

<sup>46</sup> Section 490.005(1), F.S.

<sup>47</sup> Section 490.003(3), F.S., defines doctoral-level education as a Psy.D, an Ed.D., or a Ph.D in psychology.

<sup>48</sup> Rule 64B19-11.001, F.A.C.

Applicants for licensure by endorsement must:<sup>49</sup>

- Be a diplomate in good standing with the American Board of Professional Psychology;
- Hold a doctoral degree in psychology with at least 10 years of experience as a licensed psychologist in any jurisdiction or territory of the U.S. within the 25 years preceding the date of application.

The APA is recognized by the U.S. Department of Education and the Council for Higher Education Accreditation as the national accrediting authority for professional education and training in psychology.<sup>50</sup> To be licensed as a psychologist in this state, an applicant with a Doctoral degree must have received that degree from a program accredited by the APA. Lack of APA accreditation is grounds for licensure denial under the licensure by endorsement method.<sup>51</sup>

### Effect of Proposed Changes – Psychologists

The bill allows a psychologist applying by endorsement to obtain a license regardless of whether the doctoral program was APA accredited. This will allow applicants who did not graduate from an APA accredited program to be licensed by endorsement while maintaining the needed accreditation and educational standards for licensure by examination.<sup>52</sup>

## **Clinical Social Work, Marriage and Family Therapy, and Mental Health Counseling**

### Current Situation

#### *Clinical Social Workers*

To be licensed as a clinical social worker, an applicant must meet educational requirements, complete at least two years of postgraduate or postmaster's clinical practice supervised by a licensed practitioner, and pass a theory and practice examination.<sup>53</sup> Current board rule requires licensure applicants to pass the board-approved examination from the Association of Social Work Boards.<sup>54</sup> This conflicts with current law, which requires applicants to pass an exam administered by DOH.<sup>55</sup> However, DOH no longer administers licensure examinations.

#### *Marriage and Family Therapists*

Marriage and family therapy incorporates marriage and family therapy, psychotherapy, hypnotherapy, sex therapy, counseling, behavior modification, consultation, client-centered advocacy, crisis intervention, and the provision of needed information and education to clients.<sup>56</sup> An applicant seeking licensure as a mental health counselor must:<sup>57</sup>

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<sup>49</sup> Section 490.006, F.S.

<sup>50</sup> American Psychological Association, *Understanding APA Accreditation*, <http://www.apa.org/ed/accreditation/about/index.aspx> (last visited Jan. 20, 2022).

<sup>51</sup> *Supra*, note 24

<sup>52</sup> *Id.*

<sup>53</sup> Section 491.005, F.S.

<sup>54</sup> Rule 64B4-3.003(2)(a), F.A.C.

<sup>55</sup> Section 491.005(1)(d)

<sup>56</sup> American Association for Marriage and Family Therapy, *About Marriage and Family Therapists*, [https://www.aamft.org/About/AAMFT/About\\_Marriage\\_and\\_Family\\_Therapists.aspx](https://www.aamft.org/About/AAMFT/About_Marriage_and_Family_Therapists.aspx) (last visited Jan. 20, 2022).

<sup>57</sup> Section 491.005(3), F.S. An individual may qualify for a dual license in marriage and family therapy if he or she passes an examination in marriage and family therapy and has held an active license for at least three years as a psychologist, clinical social worker, mental health counselor, or advanced registered nurse practitioner who is determined by the Board of Nursing to be a specialist in psychiatric mental health (s. 491.0057, F.S.)

- Possess a master's degree from:
  - An institution of higher learning accredited by a regional accrediting body recognized by the Commission on Recognition of Postsecondary Accreditation (CRPA); and
  - A program accredited by the Commission on Accreditation for Marriage and Family Therapy Education; or
  - A Florida university program accredited by the Council for Accreditation of Counseling and Related Educational Programs and board-approved graduate courses.<sup>58</sup>
- Complete two years of post-master's supervised experience under the supervision of a licensed marriage and family therapist with five years of experience or the equivalent who is a qualified supervisor as determined by the board;
- Pass a board-approved examination; and
- Demonstrate knowledge of laws and rules governing the practice.

Current law requires licensure applicants to hold a master's degree from an institution of higher learning accredited by a regional accrediting body recognized by the CRPA. The CRPA has been succeeded by the Council for Higher Education Accreditation, which is not recognized in current law. Additionally, current board rule requires licensure applicants to pass the board-approved examination developed by the Examination Advisory Committee of the Association of Marital and Family Therapy Regulatory Board.<sup>59</sup> This conflicts with current law, which requires applicants to pass an exam administered by DOH.<sup>60</sup> However, DOH no longer administers licensure examinations.

DOH must verify that an applicant's education matches the specified courses and hours as outlined in statute. However, there are organizations that accredit marriage and family therapy education programs, including the Commission on Accreditation for Marriage and Family Therapy Education (COAMFTE) and the Council for the Accreditation of Counseling and Related Educational Programs (CACREP) that establish the minimum standards to meet the requirements to practice the profession.<sup>61</sup>

In 2020, the Legislature passed HB 713, which, among other things, revised licensure requirements for marriage and family therapists. Beginning on July 1, 2020, applicants for licensure must possess a master's degree from an a program accredited by COAMFTE or from a Florida university program accredited by CACREP and board-approved graduate courses.<sup>62</sup> However, a window of time was not granted for education programs which were unaccredited at the time to apply for and obtain such accreditation, meaning students who graduate on or after July 1, 2020, from such programs do not meet the accreditation qualifications for licensure in Florida.<sup>63</sup> Currently, six universities in Florida have a marriage and family therapy program that is not accredited by either COAMFTE or CACREP.<sup>64</sup>

### *Mental Health Counselors*

A mental health counselor is an individual who uses scientific and applied behavioral science theories, methods, and techniques to describe, prevent, and treat undesired behavior and enhance mental health and human development and is based on research and theory in personality, family, group, and organizational dynamics and development, career planning, cultural diversity, human growth and development, human sexuality, normal and abnormal behavior, psychopathology, psychotherapy, and rehabilitation.<sup>65</sup> To qualify for licensure as a mental health counselor, an individual must:<sup>66</sup>

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<sup>58</sup> Ch. 2020-133, Laws of Fla, required applicants for licensure as a marriage and family therapist to graduate from an accreditd program or an accredited Florida university program.

<sup>59</sup> Rule 64B4-3.003(2)(c), F.A.C.

<sup>60</sup> Section 491.005(3)(d), F.S.

<sup>61</sup> See Commission on Accreditation for Marriage and Family Therapy Education, *What Are the Benefits of COAMFTE Accreditation*, [https://www.coamfte.org/COAMFTE/Accreditation/About\\_Accreditation.aspx](https://www.coamfte.org/COAMFTE/Accreditation/About_Accreditation.aspx) (last visited Jan. 20, 2022), and Council for the Accreditation of Counseling and Related Educational Programs, *About CACREP*, <https://www.cacrep.org/about-cacrep/> (last visited Jan. 20, 2022).

<sup>62</sup> Section 491.005, F.S. (2020).

<sup>63</sup> *Supra*, note 24.

<sup>64</sup> *Id.*

<sup>65</sup> Sections 491.003(6) and (9), F.S.

<sup>66</sup> Section 491.005(4), F.S.

- Have a master's degree from a mental health counseling program accredited by CACREP, or a program related to the practice of mental health counseling that includes coursework and a 700-hour practicum, internship, or fieldwork of which at least 280 hours must be in direct client services;
- Have at least two years of post-master's supervised clinical experience in mental health counseling;
- Pass an examination from the Professional Examination Service for the National Academy of Certified Clinical Mental Health Counselors; and
- Pass an eight-hour course on Florida laws and rules approved by the Board of Clinical Social Work, Marriage and Family Therapy, and Mental Health Counseling.<sup>67</sup>

Current board rule requires licensure applicants to pass the board-approved examination from the National Clinical Mental Health Counseling Examination.<sup>68</sup> This conflicts with current law, which requires applicants to pass an exam administered by DOH.<sup>69</sup> However, DOH no longer administers licensure examinations.

Ch. 2020-133, L.O.F, also revised licensure requirements for mental health counselors. Beginning July 1, 2025, applicants for licensure as a mental health counselor must hold a master's degree from a program accredited by CACREP.<sup>70</sup> The CACREP accreditation standards require 60 credits of specified educational content and a 700-hour practicum requiring face-to-face psychotherapy.<sup>71</sup> There are currently sixteen universities in this state accredited by CACREP.<sup>72</sup> The University of West Florida's (UWF) mental health counselor program is the only program accredited by the Masters in Psychology and Counseling Accreditation Council in this state.<sup>73</sup> Thus, beginning in 2025, UWF's current accreditation for its mental health counselor program will not be sufficient for graduates to meet licensure requirements in this state.

#### Effect of the Bill – Marriage and Family Therapy and Mental Health Counseling

##### *Clinical Social Workers*

The bill removes references to obsolete DOH-issued licensure exams for clinical social workers, aligning statute with Board rule.

##### *Marriage and Family Therapists*

The bill allows DOH to continue to issue licenses to graduates of otherwise qualified Florida marriage and family therapy programs until July 1, 2027, while such programs seek accreditation.

The bill also updates the accreditation requirement for institutions of higher education by replacing the defunct Commission on Recognition of Postsecondary Accreditation with the Council for Higher Education Accreditation.

Additionally, the bill removes obsolete references to DOH-issued licensure examinations.

<sup>67</sup> Section 491.005(4), F.S., and r. 64B4-3.0035, F.A.C.

<sup>68</sup> Rule 64B4-3.003(2)(b), F.A.C.

<sup>69</sup> Section 491.005(4)(d), F.S.

<sup>70</sup> Section 491.005(4)(b), F.S.

<sup>71</sup> *Supra*, note 24.

<sup>72</sup> Council for Accreditation for Counseling and Related Educational Programs, *Find a Program*, <https://www.cacrep.org/directory/> (last visited Jan. 20, 2022).

<sup>73</sup> Masters in Psychology and Counseling Accreditation Council, *Accredited Programs*, <http://mpcacaccreditation.org/accredited-programs/> (last visited Jan. 20, 2022).

The bill adds the Masters in Psychology and Counseling Accreditation Council, or an equivalent body, as an authorized accrediting body for mental health counselor education programs beginning on July 1, 2025. This will allow UWF to continue to graduate students who are eligible for licensure in this state.

## **Florida Birth-Related Neurological Injury Compensation Association**

### Current Situation

#### *Florida Birth-Related Neurological Injury Compensation Plan*

The Florida Birth-Related Neurological Injury Compensation Plan (Plan) was created by the Legislature to manage both rising medical malpractice costs and diminishing availability of liability insurance by creating a hybrid no-fault and tort medical liability system.<sup>74</sup> The Plan was created to pay for the care of infants born with certain neurological injuries and is available to eligible families without the need for litigation. By eliminating costly legal proceedings, the Plan aims to ensure that birth-injured infants receive the care they need while reducing the financial burden on both medical providers and families.

#### *Florida Birth-Related Neurological Injury Compensation Association*

In 1988, the Legislature created the Florida Birth-Related Neurological Injury Compensation Association (NICA) to manage the Plan.<sup>75</sup> NICA is an independent association. Although it is not a state agency, NICA is subject to regulation and oversight by the Office of Insurance Regulation (OIR) and the Joint Legislative Auditing Committee. Directors on NICA's board are appointed by the Chief Financial Officer.

Annually, NICA must furnish audited financial reports to any Plan participant upon request, OIR and the Joint Legislative Auditing Committee.<sup>76</sup> The reports must be prepared in accordance with accepted accounting procedures. OIR or the Joint Legislative Auditing Committee may conduct an audit of the Plan at any time.<sup>77</sup>

#### *Assessments*

The Plan is funded by a combination of physician fees and hospital assessments. All licensed Florida physicians pay a mandatory fee of \$250, regardless of specialty, upon initial licensure.<sup>78</sup> A participating physician<sup>79</sup> is required to pay a \$5,000 fee each year for coverage which runs January 1 through December 31.<sup>80</sup> Hospitals pay \$50 for each live birth during the previous calendar year. Certain exemptions apply to all of these categories, including resident physicians, retired physicians, government physicians, and physicians employed full time by state-owned mental health or developmental services facilities.<sup>81</sup>

Initial assessments are collected by DOH though current law states initial assessments are to be collected by the Department of Business and Professional Regulation (DBPR), though the Legislature

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<sup>74</sup> Id.

<sup>75</sup> Section 766.315, F.S. and ch. 88-1, s. 74, Laws of Fla.

<sup>76</sup> Id.

<sup>77</sup> Id.

<sup>78</sup> Section 766.314, F.S.

<sup>79</sup> A "participating physician" is a physician licensed in this state who practices obstetrics or performs obstetrical services, either full time or part time, and has paid the assessment required for participation in the plan for the year in which an injury occurred. This term also includes physicians licensed in this state who were exempted from the required payment to participate in the plan at the time of an injury. Any physician who practices medicine as an officer, employee, or agent of the Federal Government is not considered a participating physician. See s. 766.302(7), F.S.

<sup>80</sup> *Supra*, note 78

<sup>81</sup> Id.

moved the regulatory authority of health care practitioners to DOH in the early 2000's, where it remains.<sup>82</sup>

Between July 2018 and June 2020, NICA's audited financial statements showed a total of \$54,755,762 in assessments was collected.<sup>83</sup> However, a 2021 Auditor General report showed an increase in delinquent assessments between 2016 and 2021, totaling \$14.4 million.

**Active Non-Participating Physician Assessments Paid and Delinquent, 2016 – 2021**<sup>84</sup>

Assessment Year	Assessments Paid <sup>a</sup>		Delinquent Assessments		Total Assessment Amount	Delinquent Assessments as Percentage of Total Assessment Amount
	Amount	Number of Physicians	Amount	Number of Physicians		
2021	\$13,791,926	56,362	\$ 4,836,553	19,242	\$ 18,628,479	26%
2020	16,035,537	64,372	3,118,420	12,043	19,153,957	16%
2019	16,209,715	65,209	2,291,303	8,336	18,501,018	12%
2018	16,132,917	64,487	1,765,173	6,123	17,898,090	10%
2017	16,159,869	64,043	1,356,025	4,506	17,515,894	8%
2016	14,486,458	58,316	999,719	3,215	15,486,177	6%
<b>Totals</b>	<b><u>\$92,816,422</u></b>	<b><u>372,789</u></b>	<b><u>\$14,367,193</u></b>	<b><u>53,465</u></b>	<b><u>\$107,183,615</u></b>	<b><u>13%</u></b>

<sup>a</sup> Includes late payments and pre-payment amounts applicable to the assessment year.

NICA is authorized to enforce collection of unpaid assessments by filing suit in county court and may recover attorney fees, costs and interest related if it obtains a final judgment.<sup>85</sup> DOH is prohibited from renewing a physician's license if NICA notifies DOH that the physician has unpaid assessments and that there is an unsatisfied final judgment against the physician.<sup>86</sup>

Effect of the Bill – NICA

The bill addresses unpaid assessments by requiring allopathic and osteopathic physicians to provide proof of payment of NICA assessments as a condition of licensure. This may potentially increase timely payment of the assessment and reduce the need for NICA to seek judicial remedy for unpaid assessments. The bill also requires NICA to notify DOH and applicable boards of any unpaid final judgment within seven days of the final judgement.

The bill also updates references from DBPR to DOH throughout.

**Medical Marijuana Testing**

Current Situation

Presently, processed marijuana products must be tested for contaminants that are harmful for human consumption and to ensure that products meet the THC and CBD potency requirements.<sup>87</sup> The DOH must adopt rules determining what contaminants must be tested for and at what levels such

<sup>82</sup> Section 766.314, F.S. The Department of Business and Professional Regulation previously licensed health care practitioners in Florida when NICA was created. The Legislature later moved this responsibility to the Division of Medical Quality Assurance within DOH in 2000.

<sup>83</sup> *Florida Birth-Related Neurological Injury Compensation Association*, State of Florida Auditor General – Operational Audit, August 2021.

<sup>84</sup> Id.

<sup>85</sup> Section 766.314(6)(b), F.S.

<sup>86</sup> Id.

<sup>87</sup> Section 381.986(8)(e)11.d., F.S.

contaminants are unsafe for human consumption, as well as rules for the treatment of marijuana products that fail the safety and potency requirements.<sup>88</sup>

Current law authorizes the DOH to select random samples of edible products available for purchase for testing to determine whether the THC and CBD potency level on the label is accurate and whether the edible is safe for human consumption. DOH does not have express authority to sample all other types of medical marijuana or medical marijuana delivery devices. Additionally, current law does not provide an exception to criminal law to allow DOH, and its employees acting within the scope of their employment, to acquire, possess, test, transport, and lawfully dispose of marijuana.

A medical marijuana treatment center (MMTC) must recall all edibles that fail to meet safety and potency requirements.<sup>89</sup> DOH does not have express authority to require MMTCs to recall other types of medical marijuana or medical marijuana delivery devices that fail to meet safety and potency requirements.

Each MMTC is required to contract with a certified marijuana testing laboratory (CMTL) to test processed marijuana before it is dispensed.<sup>90</sup> Testing results must indicate that the low-THC cannabis meets the statutory definition; THC potency meets statutory requirements; THC and CBD are labeled accurately; and the marijuana is safe for human consumption and free from contaminants that are unsafe for human consumption.<sup>91</sup>

### Effect of the Bill – Medical Marijuana Testing

The bill requires MMTCs to test all forms of its marijuana, not only processed marijuana, to ensure that it meets safety and potency requirements before it is dispensed. The bill requires MMTCs to recall all forms of marijuana that fail to meet the safety and potency requirements, rather than only edibles.

The bill authorizes the DOH to select available samples of all forms of marijuana available in a medical marijuana treatment center for testing to determine that the marijuana is safe for human consumption and that the THC and CBD potency level on the label is accurate or to verify medical marijuana testing laboratory results. The bill also authorizes the DOH to sample marijuana delivery devices from a marijuana treatment center to determine that the marijuana delivery device is safe for use by qualified patients. The bill permits the DOH, including employees acting within the scope of their employment, to acquire, possess, test, transport, and lawfully dispose of marijuana. The bill requires MMTCs to recall all forms of medical marijuana and marijuana delivery devices that fail to meet safety and potency requirements.

## **Special Needs Shelters**

### Current Situation

Special needs shelters ensure persons with special needs have a safe and secure location during an emergency or disaster. In 2000, the Legislature established a system to recruit health care practitioners to staff special needs shelters in times of emergencies or disasters, and required DOH to be the lead agency for these responsibilities.<sup>92</sup>

Current law establishes DOH's Division of Children's Medical Services (CMS) as the lead for the coordination of local medical and health care providers to develop a plan for the staffing and medical management of pediatric special needs shelters and to participate in local decision-making regarding the medical supervision of special needs shelters.<sup>93</sup> The CMS workforce consists of local health care practitioners with specialized training and experience in the provision of services for children with

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<sup>88</sup> Id.

<sup>89</sup> Id.

<sup>90</sup> Id.

<sup>91</sup> Id.

<sup>92</sup> Ch. 2000-140, L.O.F. See also *supra*, note 24.

<sup>93</sup> Section 381.0303, F.S.

special needs.<sup>94</sup> However, through a series of program and organizational changes toward more effective operation and costs, the CMS workforce has been reduced by more than 70% since 2018.<sup>95</sup> Due to this change in workforce, CMS can no longer support the charges of the statute.<sup>96</sup>

### Effect of the Bill – Special Needs Shelters

The bill designates DOH, rather than CMS specifically, as the lead for the coordination of local medical and health care providers in developing a plan for the staffing and medical management of pediatric special needs shelters. Additionally, the bill requires DOH to determine who is responsible for the medical supervision of each special needs shelter.

### **Medical Examiners – Death Certificates**

#### Current Situation

Florida medical examiners are local district officers appointed by the Governor<sup>97</sup> to one of 25 medical examiner districts<sup>98</sup> under ch. 406, F.S. Medical examiners are governed by the Medical Examiners Commission (Commission), which is administratively housed within the Florida Department of Law Enforcement.<sup>99</sup> The Commission has authority to investigate and suspend medical examiners for violations of ch. 406, F.S.<sup>100</sup>

Current law requires district medical examiners to determine the cause of death in certain circumstances, and to make any investigations, examinations, and autopsies necessary to make that determination, for the following deaths and circumstances:<sup>101</sup>

- Of criminal violence;
- By accident;
- By suicide;
- Suddenly, when in apparent good health;
- Unattended by a practicing physician or other recognized practitioner;
- In any prison or penal institution;
- In police custody;
- In any suspicious or unusual circumstance;
- By criminal abortion;
- By poison;
- By disease, injury, or toxic agent resulting from employment;
- When a dead body is brought into the state without proper medical certification; or
- When a body is to be cremated, dissected, or buried at sea.

In 2021, the Legislature provided that the obligation to determine the cause of death under certain circumstances includes certifying the death, as well, representing an overall workload increase.<sup>102</sup> This requires review of all records related to the case instead of reviewing only the death certificate signed by the attending physician.

### Effect of the Bill – Medical Examiners – Death Certificates

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<sup>94</sup> *Supra*, note 24.

<sup>95</sup> *Id.*

<sup>96</sup> *Id.*

<sup>97</sup> Section 406.02, F.S.

<sup>98</sup> The Commission establishes the districts by rule. See, ch. 11G-5.002, F.A.C. Medical examiner district boundaries usually align with the 20 court circuits, with some variations. Fla. Dept. Law Enforcement, Medical Examiners Commission, Coverage Map: Medical Examiner Districts, available at <https://www.fdle.state.fl.us/MEC/Maps/Documents/Coverage-Map.aspx> (last viewed March 20, 2021).

<sup>99</sup> Section 406.02, F.S. Commission members include two active medical examiners, a funeral director, a state attorney, a public defender, a sheriff, a county commissioner, the Attorney General (or designee) and the State Surgeon General (or designee).

<sup>100</sup> Sections 406.06 and 406.075, F.S.

<sup>101</sup> Section 406.11, F.S.

<sup>102</sup> Ch. 2021-8, L.O.F.

The bill removes the requirement that medical examiners certify all deaths within the specified categories.

## **Healthy Start MomCare Network**

### Current Situation

Healthy Start is a free home visiting program that provides education and care coordination to pregnant women and families of children under the age of three. The goal of the program is to lower risk factors associated with preterm birth, low birth weight, infant mortality and poor developmental outcomes.<sup>103</sup>

Responsibility for coordination of Healthy Start resides with the local Healthy Start Coalitions (coalitions). There are currently 33 coalitions, organized as non-profit agencies which serve all 67 counties.<sup>104</sup> The coalitions are overseen by DOH.

In 2001, the Agency for Health Care Administration (AHCA), in collaboration with DOH and the Healthy Start Coalition Association, developed a 1915(b) waiver to provide additional funds for Healthy Start services in order to increase the state's capacity to improve maternal and child health outcomes. The waiver, known as MomCare, was approved, and beginning July 1, 2001, Healthy Start services became eligible for Medicaid reimbursement for pregnant women and children up to age three who are enrolled in Medicaid.<sup>105</sup>

AHCA is required to contract with an administrative services organization representing all Healthy Start Coalitions in order to continue the MomCare waiver services of care coordination, and other services. The Healthy Start MomCare Network, Inc. (MomCare) is the administrative service organization representing all Healthy Start Coalitions. MomCare is tasked with implementing services provided to Medicaid recipients during pregnancy and after delivery, and contracts with AHCA and the coalitions to establish specific programs and procedures to improve pregnancy outcomes and infant health among Medicaid recipients. In addition, MomCare coordinates with managed care plans in providing care for Healthy Start participants.<sup>106</sup>

Current law does not authorize MomCare to meet via telecommunication to conduct authorized business.

### Effect of the Bill – Healthy Start MomCare Network

The bill authorizes MomCare to meet by telecommunication, provided proper public notice is given with reasonable access to meetings.

## **Compounding Pharmacy Reporting Requirements**

### Current Situation

Chapter 465, F.S., regulates the practice of pharmacy in Florida and contains the minimum requirements for safe practice.<sup>107</sup> In general, compounding is a practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a

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<sup>103</sup> Department of Health, *Healthy Start*, <http://www.floridahealth.gov/programs-and-services/childrens-health/healthy-start/index.html> (last visited Feb. 17, 2022).

<sup>104</sup> Florida Association of Healthy Start Coalitions, *Healthy Start Health Plan Contact List*, <https://www.healthystartflorida.com/wp-content/uploads/2021/01/HS-CONNECT-REFFERAL-AND-COORDINATION-CONTACT-INFORMATION-Update-12-2-20.pdf> (last visited Feb. 17, 2022).

<sup>105</sup> DOH, *Healthy Start Standards and Guidelines*, <http://www.floridahealth.gov/programs-and-services/childrens-health/healthy-start/documents/chapter-1-the-healthy-start-system-2008.pdf> (last visited Feb. 17, 2022).

<sup>106</sup> Florida Healthy Start, *Healthy Start MomCare Network*, available at <https://www.healthystartflorida.com/about-us/healthy-start-momcare-network/> (last visited Mar. 21, 2021).

<sup>107</sup> Section 465.002, F.S.

licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient.<sup>108</sup>

In 2020, the Food and Drug Administration (FDA) finalized a memorandum of understanding (MOU) which established an agreement between the FDA and state boards of pharmacy regarding the distribution of inordinate amounts of compounded human drugs interstate and the appropriate investigation by the state of complaints relating to human drug products compounded and distributed outside such state. Under the MOU, states must report the following to the FDA, via the National Association of Boards of Pharmacy Information-Sharing Network:<sup>109</sup>

- Pharmacies that are compounding human drug products and distributing inordinate amounts interstate, as well as their compounding data;
- Complaints of serious adverse experiences or quality issues relating to human drug products compounded by pharmacies and distributed interstate;
- Complaints of adverse experiences or quality issues relating to human drug products compounded by a physician and distributed interstate; and
- Information relating to the distribution interstate of any amount of human drug products compounded by physicians.

In 2020, several compounding pharmacies challenged the FDA's implementation of the MOU in federal court. In September, 2020, the United States District Court for the District of Columbia issued a partial summary judgment ruling and remanded back to the FDA which must certify that the MOU will not have a significant economic effect on small businesses or prepare a regulatory flexibility analysis.<sup>110</sup>

As of December, 2021, the Colorado Board of Pharmacy and the New Hampshire Office of Professional Licensure and Certification have signed a MOU with the FDA.<sup>111</sup> Florida has not signed an MOU with the FDA.<sup>112</sup>

As of December, 2021, Florida has 10,897 permitted pharmacies which include 444 pharmacies permitted as special sterile compounding pharmacies. It is unknown how many pharmacies ship inordinate amounts interstate.<sup>113</sup>

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<sup>108</sup> U.S. Dept. of Health and Human Services, U.S. Food and Drug Administration, Compounding and the FDA: Questions and Answers, <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339764.htm> (last viewed on Feb. 17, 2022).

<sup>109</sup> U.S. Food and Drug Administration, Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products Between the State Board of Pharmacy or Other Appropriate State Agency and the U.S. Food and Drug Administration, <https://www.fda.gov/media/143283/download> (last visited Feb. 17, 2022). Under the MOU, a pharmacy has distributed an inordinate amount of compounded human drug products interstate if the number of prescription orders for compounded human drug products that the pharmacy distributed interstate during any calendar year is greater than 50 percent of the sum of: (i) the number of prescription orders for compounded human drug products that the pharmacy sent out of (or caused to be sent out of) the facility in which the drug products were compounded during that same calendar year; plus (ii) the number of prescription orders for compounded human drug products that were dispensed (e.g., picked up by a patient) at the facility in which they were compounded during that same calendar year.

<sup>110</sup> *Wellness Pharmacy, Inc., et al., v. Xavier Becerra, Secretary of Health and Human Services*, U.S. Dist., D.C., 2021 WL 4284567.

<sup>111</sup> *Id.*

<sup>112</sup> Email from Gangul Gabadage, Legislative Coordinator, Department of Health, HB 1109 Analysis (Jan. 24, 2022).

<sup>113</sup> *Id.*

## Effect of the Bill – Compounding Pharmacy Reporting Requirements

The bill requires pharmacy licensees which ship compounded drugs interstate to report the information required by the FDA MOU on an annual basis to the National Association of Boards of Pharmacy Information-Sharing Network, pursuant to an agreement between DOH and the FDA. The bill also requires licensees to submit such information to DOH upon request.

### **Rare Diseases Advisory Council**

#### Current Situation

In 2021, the Legislature created the Rare Diseases Advisory Council (Council) adjunct to DOH.<sup>114</sup> The purpose of the Council is to provide recommendations on ways to improve health outcomes for individuals with rare diseases affecting fewer than 200,000 people in the United States. The Council must:

- Consult with experts on rare diseases and solicit public comment to assist in developing recommendations on improving the treatment of rare diseases in this state.
- Develop recommended strategies for academic research institutions in this state to facilitate continued research on rare diseases.
- Develop recommended strategies for health care providers to be informed on how to more efficiently recognize and diagnose rare diseases in order to effectively treat patients. The advisory council shall provide such strategies to the DOH for publication on the department's website.
- Provide written input and feedback to the DOH, the Medicaid program, and other state agencies on specified matters.

There are 22 members of the Council which are appointed by the Governor, the President of the Senate (President), and the Speaker of the Florida House of Representatives (Speaker). Currently, the President and the Speaker each appoint one member to the Council who is a caregiver of an individual with a rare disease.

#### Effect of the Bill – Rare Diseases Advisory Council

The bill requires the President and the Speaker each to appoint two individuals who are caregivers of an individual with a rare disease to the Council, bringing the council membership to 24.

Finally, the bill makes various conforming changes.

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

#### **B. SECTION DIRECTORY:**

- Section 1:** Amends s. 381.0045, F.S., relating to targeted outreach for pregnant women.  
**Section 2:** Amends s. 381.0303, F.S., relating to special needs shelters.  
**Section 3:** Amends s. 381.986, F.S., relating to medical use of marijuana.  
**Section 4:** Amends s. 381.99, F.S., relating to Rare Diseases Advisory Council.  
**Section 5:** Amends s. 383.216, F.S., relating to community-based prenatal and infant health care.  
**Section 6:** Amends s. 406.11, F.S., relating to examinations, investigations, and autopsies.  
**Section 7:** Amends s. 456.039, F.S., relating to designated health care professionals; information required for licensure.  
**Section 8:** Amends s. 460.406, F.S., relating to licensure by examination.  
**Section 9:** Amends s. 464.008, F.S., relating to licensure by examination.  
**Section 10:** Amends s. 464.018, F.S., relating to disciplinary actions.  
**Section 11:** Creates s. 465.41, F.S., relating to distribution of compounded human drug products.  
**Section 12:** Amends s. 467.003, F.S., relating to definitions.

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<sup>114</sup> Ch. 2021-122, L.O.F.  
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- Section 13:** Amends s. 467.009, F.S., relating to midwifery programs; education and training requirements.
- Section 14:** Amends s. 467.011, F.S., relating to licensure by examination.
- Section 15:** Amends s. 467.0125, F.S., relating to licensure by endorsement.
- Section 16:** Amends s. 467.205, F.S., relating to approval of midwifery programs.
- Section 17:** Amends s. 468.803, F.S., relating to license, registration, and examination requirements.
- Section 18:** Amends s. 483.824, F.S., relating to qualifications of clinical laboratory director.
- Section 19:** Amends s. 490.003, F.S., relating to definitions.
- Section 20:** Amends s. 490.005, F.S., relating to licensure by examination.
- Section 21:** Amends s. 490.0051, F.S., relating to provisional licensure; requirements.
- Section 22:** Amends s. 491.005, F.S., relating to licensure by examination.
- Section 23:** Amends s. 766.314, F.S., relating to assessments; plan of operation.
- Section 24:** Provides an effective date of July 1, 2022.

## II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

### A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

DOH may experience an increase in workload to conduct rulemaking and updating online application websites to implement the provisions of the bill, the impact of which can be absorbed within current resources.<sup>115</sup>

DOH may also experience an increase in expenditures relating to medical marijuana sampling and testing, the impact of which can be absorbed within current resources.<sup>116</sup>

### B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

### C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

### D. FISCAL COMMENTS:

None.

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<sup>115</sup> Id.

<sup>116</sup> Id.

### III. COMMENTS

#### A. CONSTITUTIONAL ISSUES:

##### 1. Applicability of Municipality/County Mandates Provision:

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

##### 2. Other:

None.

#### B. RULE-MAKING AUTHORITY:

Current law and the bill provide sufficient rule-making authority to implement the provisions of the bill.

#### C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

### IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

On February 17, 2022, the Health and Human Services Committee adopted three amendments and reported the bill favorably. The amendments:

- Allows the administrative service organization for healthy start coalitions to meet by telecommunication;
- Removes requirement that medical examiners certify all deaths within specified categories;
- Requires pharmacy licensees which ship compounded drugs interstate to report certain information to the National Association of Boards of Pharmacy Information-Sharing Network pursuant to an agreement between DOH and the Food and Drug Administration; and
- Adds two members who are caregivers for individuals with rare diseases to the Rare Disease Advisory Council; one appointed by the President of the Senate and one appointed by the Speaker of the House of Representatives.

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