HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 1047 Health Quality Subcommittee; Department of Health

SPONSOR(S): Gonzalez

TIED BILLS: IDEN./SIM. BILLS: SB 1486

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	12 Y, 0 N, As CS	Siples	McElroy
2) Health Care Appropriations Subcommittee	11 Y, 0 N	Mielke	Pridgeon
3) Health & Human Services Committee			

SUMMARY ANALYSIS

HB 1047 makes several changes related to programs overseen by Medical Quality Assurance, within the Department of Health (DOH), which licenses and regulates health care practitioners in this state.

The bill:

- Authorizes DOH to request a date of birth on a licensure application;
- Authorizes DOH to adopt rules to implement the Conrad 30 Waiver program;
- Authorizes expedited licensure and fee waivers for the spouse of an active duty military member who holds an
 active license in another jurisdiction to practice dentistry;
- Repeals a requirement that a Florida-licensed dentist grade the dental licensure examination and that a Florida-licensed dentist or dental hygienist grade the dental hygienist examination;
- Requires dentists and dental hygienist to report adverse incidents to the Board of Dentistry;
- Repeals the licensure of dental laboratories;
- Repeals the voluntary registration of registered chiropractic assistants;
- Authorizes DOH to accept passing scores on the examination for optometry licensure if the examination is taken within 3 years of applying for licensure;
- Authorizes the Board of Optometry to issue a licensure by endorsement;
- Authorizes the Board of Nursing to adopt rules related to standards of care and to issue a licensure by endorsement:
- Establishes standards for permitting and regulating in-state sterile compounding pharmacies and outsourcing facilities:
- Authorizes DOH to issue a single license to a prosthetist-orthotist;
- Authorizes an individual to provide dietary or nutritional information for compensation if he or she does not hold themselves out as a licensed or registered dietitian or licensed nutritionist.
- Requires an athletic trainer to work within his or her scope of practice and revises licensure requirements;
- Limits massage therapy apprenticeships to those in colonic irrigations, and authorizes the Board of Massage Therapy to take action against a massage therapy establishment under certain circumstances;
- Requires a clinical laboratory director to meet federal licensure requirements;
- Updates the name of the accreditation body for psychology programs and revises psychology licensure requirements;
- Authorizes the Board of Clinical Social Work, Marriage and Family Therapists, and Mental Health Counseling to approve a one-time exception to the 60-month limit on an internship registration;
- Revises the licensure requirements for Marriage and Family Therapists;
- Deletes obsolete language and makes technical and conforming changes.

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

The bill provides an effective date of July 1, 2018.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

The Division of Medical Quality Assurance (MQA), within the Department of Health (DOH), has general regulatory authority over health care practitioners. The MQA works in conjunction with 22 boards and 4 councils to license and regulate 7 types of health care facilities and more than 40 health care professions.² Each profession is regulated by an individual practice act and by ch. 456, F.S., which provides general regulatory and licensure authority for the MQA.

General Licensure Requirements

There are general licensure provisions that apply to all licensure applications, regardless of profession. For example, all applicants for licensure must apply in writing on an application form approved by DOH or electronically on a web-based application form.³ Additionally, an applicant must provide his or her social security number for identification purposes. 4 However, an applicant is not required to provide his or her date of birth as DOH is not currently authorized to collect this information.

Conrad 30 Waiver Program

Federal law requires a foreign physician pursing graduate medical education or training in the United States to obtain a J-1 visa. A holder of a J-1 visa is ineligible to apply for an immigrant visa, permanent residence, or certain nonimmigrant statuses unless he or she has resided and been physically present in his or her country of nationality for at least two years after completion of the J-1 visa program.⁵ However, the Conrad 30 Waiver program allows such foreign physicians to apply for a waiver of the two-year residency requirement upon the completion of the J-1 visa program. To be eligible for a Conrad 30 Waiver, the foreign physician must:

- Obtain a contract for full-time employment at a health care facility in an area dedicated as a Health Professional Shortage Area, Medically Underserved Area, or Medically Underserved Population:
- Obtain a "no objection" letter from his or her home country if the home government funded his or her exchange program; and
- Agree to begin employment at the health care facility within 90 days of receipt of the waiver, no later than the date his or her J-1 visa expires.⁶

DATE: 2/6/2018

visited January 18, 2018).

¹ Pursuant to s. 456.001(4), F.S., health care practitioners are defined to include acupuncturists, physicians, physician assistants, chiropractors, podiatrists, naturopaths, dentists, dental hygienists, optometrists, nurses, nursing assistants, pharmacists, midwives, speech language pathologists, nursing home administrators, occupational therapists, respiratory therapists, dieticians, athletic trainers, orthotists, prosthetists, electrologists, massage therapists, clinical laboratory personnel, medical physicists, dispensers of optical devices or hearing aids, physical therapists, psychologists, social workers, counselors, and psychotherapists, among others. ² Florida Department of Health, Division of Medical Quality Assurance, Annual Report and Long-Range Plan, Fiscal Year 2016-2017, available at http://www.floridahealth.gov/licensing-and-regulation/reports-and-publications/ documents/annual-report-1617.pdf (last

³ Section 456.013, F.S. If an applicant does not have a social security number, DOH may issue a unique personal identification number to the applicant.

⁴ Id.

⁵ Department of Homeland Security, U.S. Citizenship and Immigration Services, Conrad 30 Waiver Program, (last rev. May 5, 2014), available at https://www.uscis.gov/working-united-states/students-and-exchange-visitors/conrad-30-waiver-program#Background (last visited January 18, 2018).

A state may only be issued 30 waivers per year and each state may develop its own applications rules and guidelines. DOH does not currently have statutory authority to develop rules and guidelines for its Conrad 30 program.

Currently, there are 90 physicians practicing in Florida under the Conrad 30 Waiver program. More than 70 percent, or nearly 450 physicians have remained in practice in Florida since the inception of the Conrad 30 Waiver Program. Currently, Florida approves these waivers on a first come basis.

Licensure of Military Spouses

Military Spouses

DOH offers expedited licensing and fee waivers to the spouse of a person serving on active duty with the United States Armed Forces who holds an active license to practice a health care profession in another state or jurisdiction. To qualify for expedited licensure and fee waivers, the military spouse must: 10

- Submit a complete application;¹¹
- Submit evidence of training or experience substantially equivalent to the requirements for licensure in this state for that health care profession and evidence that he or she has obtained a passing score on an appropriate licensing examination, if required for licensure in this state;
- Attest that he or she is not, at the time of submission, the subject of a disciplinary proceeding in a jurisdiction in which he or she holds a license or by the U.S. Department of Defense for a reason related to the practice of the profession for which he or she is applying;
- Have actively practiced the profession for which he or she is applying for the 3 years preceding the date of application; and
- Submits to a background screening, if required for the profession for which he or she is applying, and does not have any disqualifying offenses.

Under current law, military spouses who are dentists are not eligible for expedited licensing and fee waivers. No other health care profession is excluded.

The regulatory boards, or DOH if there is no board, are also authorized to issue temporary licenses to the spouse of a member of the U.S. Armed Forces to practice his or her health care profession in Florida, including dentistry. ¹² A temporary license is valid for one year and is not renewable. ¹³ To be eligible for a temporary license, a military spouse must: ¹⁴

- Submit a completed application and application fee;¹⁵
- Provide proof that he or she is married to a member of the U.S. Armed Forces serving on active duty in this state pursuant to official military orders;
- Provide proof of a valid license from another state or jurisdiction to practice the health
 profession for which he or she is applying and that such license is not subject to any disciplinary
 proceeding;

⁷ E-mail correspondence with the Department of Health, dated January 22, 2018 (on file with the Health Quality Subcommittee).

⁸ Department of Health, 2017 Physician Workforce Annual Report, (November 2017), available at http://www.floridahealth.gov/licensing-and-regulation/reports-and-publications/documents/annual-report-1617.pdf (last visited January 18, 2018).

⁹ Section 456.024(3), F.S. The application fee, licensure fee, and unlicensed activity fee is waived for such applicants.

¹⁰ Section 456.024(3)(b), F.S.

¹¹ DOH operates the Veterans Application for Licensure Online Response System (VALOR) to provide expedited licensing for active duty military members, honorably discharged veterans, and spouses of active duty military members with an active license in another state. See http://www.flhealthsource.gov/valor (last visited January 18, 2018).

¹² Section 456.024(4), F.S.

¹³ Section 456.024(4)(f), F.S.

¹⁴ Section 456.024(4)(a)-(d), F.S.

¹⁵ Pursuant to rule 64B-4.007, F.A.C., the application fee is \$65.

- Provide proof that he or she would otherwise be entitled to full licensure and is eligible to take the respective licensure examination as required in this state; and
- · Pass a criminal background screening.

A military spouse who holds a temporary license to practice dentistry must practice under the indirect supervision¹⁶ of a dentist who holds an active license to practice in this state.¹⁷ This requirement does not apply to any other profession.

Chiropractic Assistants

There are two types of chiropractic assistants: certified and registered.¹⁸ A certified chiropractic assistant is an allied health professional who, under supervision, performs tasks or a combination of tasks traditionally performed by a chiropractic physician.¹⁹ A registered chiropractic assistant is a professional, multi-skilled person dedicated to assisting in all aspects of chiropractic medical practice under the direct supervision of a chiropractic physician or certified chiropractic assistant.²⁰

A registered chiropractic assistant voluntarily registers with the board.²¹ There are no educational or eligibility standards set in rule or statute for such registration. However, a person who becomes a registered chiropractic assistant must adhere to ethical and legal standards of professional practice, recognize and respond to emergencies, and demonstrate professional characteristics.²² A registered chiropractic assistant may:²³

- Prepare patients for the chiropractic physician's care;
- Take vital signs;
- · Observe and report patients' signs and symptoms;
- Administer basic first aid;
- Assist with patient examinations or treatments other than manipulations or adjustments;
- Operate office equipment;
- Collect routine laboratory specimens as directed by the chiropractic physician or certified chiropractic assistant;
- Administer nutritional supplements as directed by the chiropractic physician or certified chiropractic assistant; and
- Perform office procedures under the direct supervision of by the chiropractic physician or certified chiropractic assistant.

As of June 30, 2017, there were 3,800 active registered chiropractic assistants.²⁴ DOH does not regulate the practice of registered chiropractic assistants.²⁵

Optometry

Optometry Licensure

The practice of optometry includes the diagnosis of conditions of the human eye and its appendages; the use of objective and subjective means or methods to determine the refractive powers of the human

¹⁶ Section 466.003(9), F.S., defines indirect supervision as supervision whereby a Florida-licensed dentist authorizes the procedure and a Florida-licensed dentist is on the premises while the procedures are performed.

¹⁷ Section 456.024(4)(j), F.S.

¹⁸ Sections 460.4165 and 460.4166, F.S.

¹⁹ Rule 64B2-18(5), F.A.C.

²⁰ Section 460.4166(1), F.S.

²¹ Section 460.4166(3), F.S.

²² Supra note 20.

²³ Section 460.4166, F.S.

²⁴ Department of Health, *2018 Agency Legislative Bill Analysis*, (Dec. 19, 2017), on file with the Health Quality Subcommittee.

eye or any visual, muscular neurological, or anatomic anomalies of the human eye or its appendages; and the prescribing and use of lenses, prisms, frames, mountings, contact lenses, orthoptic exercises, light frequencies, or other means to correct, remedy, or relieve any insufficiencies or abnormal conditions of the eyes and their appendages.²⁶

The Board of Optometry (Board) regulates the practice of optometry in this state.²⁷ Any person seeking to be licensed as an optometrist must apply to DOH to take the licensure and certification examinations.²⁸ To qualify for licensure, an applicant must:²⁹

- Be 18 years of age or older;
- Have graduated from an accredited school or college of optometry approved by rule of the Board;
- Be of good moral character;
- Have successfully completed at least 110 hours of transcript-quality coursework and clinical training in general and ocular pharmacology; and
- Have completed at least 1 year of supervised experience in differential diagnosis of eye disease
 or disorders as part of the optometric training or in a clinical setting as part of the optometric
 experience.

In addition, an applicant must pass the Florida licensure examination, which consists of:³⁰

- Part I the Applied Basic Science (ABS) portion of the examination developed by the National Boards of Examiners in Optometry (NBEO);
- Part II the Patient Assessment and Management (PAM) portion of the examination developed by NBEO, which includes an embedded Treatment of Ocular Disease (TMOD) examination;
- Part III the Clinical Skills portion of the examination developed by NBEO; and
- Part IV A written examination on applicable Florida laws and rules governing the practice of optometry.

An applicant for licensure must pass all 4 parts of the examination.³¹ An applicant who fails to pass any part of the licensure examination may retake the applicable part; however, the reexamination must occur within 18 months of the date of the original failure.³²

Administrative Challenge to Licensure Rule

Prior to 2017, an individual licensed as an optometrist in another state could apply for a Florida license without having to sit for a licensure examination if the applicant passed the NBEO examination within the 7 years preceding the application.³³ In 2016, two out-of-state optometrists applying for licensure in Florida petitioned the Board to waive the rule requirement to retake the NBEO examination since more than seven years had passed since they received passing scores.³⁴ One of the optometrists was

³⁴ Yontz and Johnson v. Department of Health, Board of Optometry, Case No. 16-6663RX (Fla. DOAH Apr. 14, 2017). After the DOAH order was issued, DOH repealed this provision from r. 64B13-4.001(2), F.A.C.

²⁶ Section 463.002(7), F.S.

²⁷ Section 463.005, F.S.

²⁸ Section 463.006, F.S.

Za Id.

³⁰ Rule 64B13-4.001, F.A.C., and Department of Health, Board of Pharmacy, *Certified Optometrist Licensing Requirements*, available at http://floridasoptometry.gov/licensing/certified-optometrist/ (last visited January 19, 2018).

³² Rule 64B13-4.002, F.A.C. The Board of Optometry may grant a 1 year extension to allow an additional retake based on medical disability.

Rule 68B13-4.001(2), F.A.C. At that time, the relevant part of the rule read: "Given constant advances in research, developing knowledge in the area of basic and clinical science as applied to the diagnosis, correction, remedy, and relief of insufficiencies or abnormal conditions of the human eyes and their appendages, variances the scope of optometric practice among the states, and the importance of fundamental clinical skills to patient health and safety, passing scores on Part I, Part II, Part III and Part IV of the licensure examination must be obtained within the seven (7) year period immediately preceding licensure application."

licensed in Nevada and had passed the NBEO in 2007; the other was licensed in Michigan and had passed the NBEO in 1998.³⁵ The Board denied both requests, and each applicant filed a petition with the Division of Administrative Hearings (DOAH) to invalidate the rule.³⁶

DOAH held that the look-back provision of the rule was an invalid exercise of delegated legislative authority because it enlarged the authority the Board was given under statute being implemented, s. 463.006(1), F.S. Specifically, the administrative law judge found that s. 463.006(1), F.S., requires applicants to submit the application for licensure before taking the NBEO examination, and that the plain language of the section would prohibit the Board from accepting any scores from an NBEO examination taken before an individual files an application for licensure.

Eleven out of 23 accredited schools of optometry in the United States require students to take some or all of the NBEO examination prior to graduation, including optometry schools in Florida.³⁸ As a result of the DOAH decision, graduating students applying for licensure are required to retake examinations they have previously passed while in school or college, and all out-of-state applicants must retake the examination.39

Board of Nursing

Rulemaking Authority

The Board of Nursing has authority to adopt rules to implement ch. 464, F.S., which regulates the practice of nursing in this state. 40 The Board of Nursing oversees the licensure and practice of certified nursing assistants, licensed practical nurses, registered nurses, and advanced registered nurse practitioners.

In 2011, the Board of Nursing proposed a rule that adopted standards related to moderate sedation in a rule that addressed unprofessional conduct. The Joint Administrative Procedures Committee (JAPC) opined that the proposed rule may enlarge the Board of Nursing's authority to adopt rules because the rule established separate and specific education and training to practice professional, creating an unauthorized level of licensure for nurses.41

The Florida Medical Association, the Florida Osteopathic Association, and the Florida Podiatric Medical Association filed a petition with the Division of Administrative Hearings (DOAH) alleging the Board of Nursing exceeded its delegated legislative authority. 42 The administrative law judge (ALJ) ultimately held that although the Board of Nursing is granted general rulemaking authority in ch. 464, F.S., the Legislature had not expressly granted the Board of Nursing authority to promulgate nursing standards of practice. 43 The ALJ noted that other practice acts, such as ch. 458, F.S., which regulates allopathic physicians, and ch. 459, F.S., which regulates osteopathic physicians specifically grant those Boards authority to define standards of practice. 44 The ALJ found the rule to be invalid. Subsequently, the First District Court of Appeals upheld the DOAH decision.⁴⁵

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³⁵ ld.

³⁶ Johnson v. Florida Board of Optometry, Case No. 15-5655 and Yontz v. Florida Board of Optometry and the Florida Optometric Ass'n, Case No. 16-6123. The cases were consolidated, see footnote 34.

Supra note 34 at pp. 32-33.

³⁸ Supra note 24.

³⁹ ld.

⁴⁰ Section 464.006, F.S.

⁴¹ Florida Medical Ass'n, Inc., Florida Osteopathic Medical Ass'n, and Florida Podiatric Ass'n v. Department of Health, Florida Ass'n of Nurse Anesthetists, and Florida Nurses Ass'n, Case No. 12-1545RP (Fla. DOAH Nov. 2, 2012). ⁴² ld.

⁴³ ld. at 80.

⁴⁴ Id.

⁴⁵ Department of Health Board of Nursing v. Florida Medical Ass'n, Inc., et al, 132 So.3d 225 (Fla. 1d DCA 2014); Florida Ass'n of Nurse Anesthetists v. Florida Medical Ass'n, Inc. et al, 132 So.3d 225 (Fla. 1d DCA 2014); and Florida Nurse Ass'n v. Florida Medical Ass'n. Inc. et al, 132 So.3d 225 (Fla. 1d DCA 2014).

Certified Nursing Assistants

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. An applicant for certification as a CNA must complete an approved training program, pass a competency examination, and pass a background screening. A CNA who is certified in another state, is listed on that state's CNA registry, and has not been found to have committed abuse, neglect, or exploitation in that state, is eligible for certification by endorsement in Florida. However, a CNA from a territory of the United States or the District of Columbia, is not eligible for certification by endorsement.

The Board of Nursing may discipline a CNA for:

- Obtaining or attempting to obtain certification or an exemption, or possessing or attempting to
 possess certification or letter of exemption, by bribery, misrepresentation, deceit, or through an
 error of the board; or
- Intentionally violating any provision of ch. 464, F.S., the practice act for nursing professions, ch. 456, F.S., the general licensing act, or the rules adopted by the Board of Nursing.

Pharmacy Regulation

Chapter 465, F.S., regulates pharmacies in Florida and contains the minimum requirements for safe practice. ⁴⁹ A person who wants to operate a pharmacy in Florida must one of the following DOH-issued permits:

- Community pharmacy A permit is required for each location where medicinal drugs are compounded, dispensed, stored, or sold or where prescriptions are filled or dispensed on an outpatient basis.⁵⁰
- Institutional pharmacy A permit is required for every location in a hospital, clinic, nursing home, dispensary, sanitarium, extended care facility, or other facility where medicinal drugs are compounded, dispensed, stored, or sold.⁵¹
- Nuclear pharmacy A permit is required for every location where radioactive drugs and chemicals within the classification of medicinal drugs are compounded, dispensed, stored, or sold. The term "nuclear pharmacy" does not include hospitals licensed under chapter 395 or the nuclear medicine facilities of such hospitals.⁵²
- Special pharmacy A permit is required for every location where medicinal drugs are compounded, dispensed, stored, or sold if the location does not otherwise meet an applicable pharmacy definition in s. 465.003, F.S.⁵³
- Internet pharmacy A permit is required for a location not otherwise licensed or issued a permit
 under this chapter, within or outside this state, which uses the Internet to communicate with or
 obtain information from consumers in this state to fill or refill prescriptions or to dispense,
 distribute, or otherwise practice pharmacy in this state.⁵⁴

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⁴⁶ Section 464.201(5), F.S.

⁴⁷ Section 464.203, F.S. See also Department of Health, Board of Nursing, Certified Nursing Assistant (CNA) by Examination, available at http://floridasnursing.gov/licensing/certified-nursing-assistant-examination/ (last visited January 19, 2018). An applicant who fails the competency examination 3 times, may not take the exam again until he or she completes an approved training program.

A CNA Registry is a listing of CNAs who received certification and maintain an active certification. (Rule 64B9-15.004, F.A.C.)

⁴⁹ Section 465.002, F.S.

⁵⁰ Sections 465.003(11)(a)1. and 465.018, F.S.

⁵¹ Sections 465.003(11)(a)2. and 465.019, F.S.

⁵² Sections 465.003(11)(a)3. and 465.0193, F.S.

⁵³ Sections 465.003(11)(a)4. and 465.0196, F.S.

⁵⁴ Sections 465.003(11)(a)5. and 465.0197, F.S.

All licensed pharmacies must pass an on-site inspection before DOH will issue an initial permit; an onsite inspection is also required any time a pharmacy changes its ownership or address. 55

Compounding

Compounding is the professional act by a pharmacist or other practitioner authorized by law, incorporating ingredients to create a finished product for dispensing to a patient or for administration by a practitioner or the practitioner's agent. 56

There are two types of compounding: sterile and non-sterile. Sterile compounding is the preparation of a custom medication or product in a sterile environment to prevent contamination and protect patient safety.⁵⁷ Nonsterile compounding includes capsules, ointments, creams, gels, and suppositories that do not require a sterile preparation environment. 5

Special Sterile Compounding Permit

Current law does not expressly provide for an in-state sterile compounding permit. However, s. 456.0196, F.S. grants DOH rule-making authority to create and issue special pharmacy permits. Under that authority, DOH has adopted rules for the issuance of a special sterile compounding permit to regulate in-state pharmacies and outsourcing facilities that perform sterile compounding. Rule 64B-28.802, F.A.C., requires that a pharmacy engaging in the preparation of compounded sterile products in this state must obtain a Special Sterile Compounding Permit (SSCP). The Board of Pharmacy has adopted standards of practice in rule for compounding sterile products, including the Current Good Manufacturing Practices and specific chapters of the United States Pharmacopoeia. 59 Stand-alone special parenteral/enteral pharmacies and special parenteral/enteral extended scope pharmacies are not required to obtain the SSCP.60

Applications for new establishments submitted after March 21, 2014, must be accompanied with a \$255 application fee. However, pharmacies holding a sterile compounding permit prior to that date do not have to pay such fee. The SSCP is issued in addition to the pharmacy permit (.i.e. community pharmacy or institutional pharmacy).⁶¹

Nonresident Sterile Compounding Permit

All out-of-state pharmacies or outsourcing facilities must obtain a nonresident sterile compounding permit prior to shipping, mailing, delivering, or dispensing a compound sterile product⁶² into this state. Any compounded product sent into this state must meet or exceed Florida's standards for sterile

⁵⁵ Rule 64B16-28(1)(d), F.A.C.

⁵⁶ Rule 64B16-27.700, F.A.C.

⁵⁷ U.S. Dept. of Health and Human Services, Office of Inspector General, *Memorandum Report: High-Risk Compounded Sterile* Preparations and Outsourcing by Hospitals That Use Them, OEI-01-13-00150, (April 10, 2013), available at https://oig.hhs.gov/oei/reports/oei-01-13-00150.pdf (last visited January 19, 2018).

National Conference of State Legislatures, *Legisbrief: Regulating Compounding Pharmacies*, (June 2015), available at

http://www.ncsl.org/research/health/regulating-compounding-pharmacies-lb-june-2015.aspx (last visited January 19, 2018).

Rule 64B16-28.797, F.A.C. The Current Good Manufacturing Practice regulation is the main regulatory standard used by the Food and Drug Administration to ensure pharmaceutical quality by assuring proper design, monitoring, and control of manufacturing processes and facilities. See U.S. Food and Drug Administration, Facts about the Current Good Manufacturing Practices (CGMPs), available at https://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/ucm169105.htm (last visited January 19, 2018). The U.S. Pharmacopeia sets standards for the identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements manufactured, distributed, and consumed worldwide. See U.S. Pharmacopeial Convention, About USP, available at http://www.usp.org/about-usp (last visited January 19, 2018).

Rule 64B16-28.100, F.A.C.

⁶¹ Rule 64B16-28.802, F.A.C.

⁶² Section 465.003(20), F.S., defines "compounded sterile product" as a drug that is intended for parenteral administration, an ophthalmic or oral inhalation drug in aqueous format, or a drug or product that is required to be sterile under federal or state law or rule, which is produced through compounding, but is not approved by the FDA.

compounding.⁶³ To obtain the permit, a registered nonresident pharmacy or outsourcing facility must submit an application and a \$255 fee to DOH. The application must include:

- Proof of registration with the U.S. Food and Drug Administration (FDA) as an outsourcing facility:64
- Proof of registration as a nonresident pharmacy under s. 465.0156, F.S., or, if the applicant is not a pharmacy, proof of an active and unencumbered license, registration, or permit issued by the state, territory, or district where the applicant is located, which is required to compound sterile products in that jurisdiction;
- An attestation by an owner or officer and the prescription department manager or the pharmacist in charge that:
 - They have read and understand Florida law and rules governing sterile compounding;
 - Any sterile compounded product shipped or otherwise introduced into this state will meet or exceed Florida law and rules governing sterile compounding; and
 - Any sterile compounded product shipped or otherwise introduced has not been, and will not be, compounded in violation of laws and rules governing sterile compounding where the applicant is located.
- Copies of existing policies and procedures governing sterile compounding that meet certain standards; and
- A current inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state, territory or district where the applicant is located. 65

The Board of Pharmacy has authority to administratively discipline a nonresident sterile compounding permittee for violation of laws or rules governing pharmacies and entities licensed under MQA.

In-state sterile compounding pharmacies and outsourcing facilities are not statutorily required to obtain a permit for compounding in a manner similar to out-of-state compounding pharmacies or outsourcing facilities.

Dentistry

Examination for Licensure

Any person wishing to practice dentistry in this state must apply to DOH and meet specified requirements. Section 466.006, F.S., requires dentistry licensure applicants to sit for and pass the following licensure examinations:

- The National Board of Dental Examiners dental examiner (NBDE);
- A written examination on Florida laws and rules regulating the practice of dentistry; and
- A practical examination, which is the American Dental Licensing Examination developed by the American Board of Dental Examiners, Inc., and graded by a Florida-licensed dentist employed by DOH for such purpose.⁶⁶

To qualify to take the Florida dental licensure examination, an applicant must be 18 years of age or older, be a graduate of a dental school accredited by the American Dental Association or be a student in the final year of a program at an accredited institution, and have successfully completed the NBDE dental examination.

Section 465.0158, F.S.

⁶⁴ To register with the FDA as an outsourcing facility, the facility must comply with Current Good Manufacturing Practices, be inspected by the FDA according to a risk-based schedule, and meet certain other conditions such as adverse event reporting and providing the FDA with certain information about the products they compound. ⁶⁵ Section 465.0158 (3), F.S.

⁶⁶ A passing score is valid for 365 days after the date the official examination results are published. A passing score on an examination obtained in another jurisdiction must be completed on or after October 1, 2011. STORAGE NAME: h1047c.HCA

Any person wishing to be licensed as a dental hygienist must apply to DOH and meet the following qualifications:

- Be 18 years of age or older;
- Be a graduate of an accredited dental hygiene college or school;⁶⁷ and
- Obtain a passing score on the:
 - o Dental Hygiene National Board Examination;
 - Dental Hygiene Licensing Examination developed by the American Board of Dental Examiners, Inc., which is graded by a Florida-licensed dentist or dental hygienist employed by DOH for such purpose; and
 - A written examination on Florida laws and rules regulating the practice of dental hygiene.

Adverse Incident Reporting

Dentists and dental hygienist certified by DOH to administer anesthesia must report, in writing, any adverse incident that occurs to the Board of Dentistry within 48 hours by registered mail. An adverse incident in an office setting is defined as any mortality that occurs during or as the result of a dental procedure, or an incident that results in a temporary or permanent physical or mental injury the requires hospitalization or emergency room treatment of a patient as a direct result of the use of general anesthesia, deep sedation, moderate sedation, pediatric moderate sedation, mitrous oxide, and local anesthesia. The dentist must file a complete written report with the Board of Dentistry within 30 days. Since 2014, 23 adverse incident reports have been filed with DOH. Of those, 17 were closed without discipline, 1 was issued a letter of guidance, 4 are currently being prosecuted, and 1 is still under investigation.

Dental Laboratories

A dental laboratory is a facility that supplies or manufactures artificial substitutes for natural teeth, or that furnishes, supplies, constructs, reproduces, or repairs a prosthetic denture, bridge, or appliance to be worn in the human mouth or that otherwise holds itself out as a dental laboratory. Dental laboratories must biennially register with DOH, and the owner or at least one employee must complete

⁶⁷ If the school is not accredited, the applicant must have completed a minimum of 4 years of postsecondary dental education and received a dental school diploma which

is comparable to a D.D.S. or D.M.

⁶⁸ Rule 64B5-14.006, F.A.C.

⁶⁹ General anesthesia is a controlled state of unconsciousness, produced by a pharmacologic agent, accompanied by a partial or complete loss of protective reflexes, including inability to independently maintain an airway and respond purposefully to physical stimulation or verbal command. (Rule 64B5-14.001(2), F.A.C.)

⁷⁰ Deep sedation is a controlled state of depressed consciousness accompanied by partial loss of protective reflexes, including either or both the inability to continually maintain an airway independently or to respond appropriately to physical stimulation or verbal command, produced by pharmacologic or non-pharmacologic method or combination thereof. (Rule 64B5-14.001(3), F.A.C.)

Moderate sedation is a depressed level of consciousness produced by the administration of pharmacologic substances, that retains the patient's ability to independently and continuously maintain an airway and respond appropriately to physical stimulation and verbal command. (Rule 64B5-14.001(4), F.A.C.)

⁷² Pediatric moderate sedation is a depressed level of consciousness produced by the administration of pharmacologic substances, that retains a child patient's ability to independently and continuously maintain an airway and respond appropriately to physical stimulation or verbal command. (Rule 64B5-14.001(5), F.A.C.)

⁷³ Minimal sedation involves the perioperative use of medication to relieve anxiety before or during a dental procedure and does not produce a depressed level of consciousness and maintains the patient's ability to maintain an airway independently and to respond appropriately to physical and verbal stimulation. (Rule 64B5-14.001(10), F.A.C.)

⁷⁴ The use of nitrous oxide produces an altered level of consciousness that retains the patient's ability to independently and continuously maintain an airway and respond appropriately to physical stimulation or verbal command. (Rule 64B5-14.001(6), F.A.C.)
⁷⁵ Local anesthesia involves the loss of sensation of pain in a specific area of the body. (Rule 64B5-14.001(7), F.A.C.)

⁷⁶ Supra note 68.

⁷⁷ Supra note 24

⁷⁸ Id.

⁷⁹ Section 466.031, F.S. **STORAGE NAME**: h1047c.HCA

18 hours on continuing education each biennium.⁸⁰ A dental laboratory is subject to inspection by DOH and must.⁸¹

- Maintain and make available to DOH a copy of the laboratory's registration;
- Be clean and in good repair;
- Properly dispose of all waste materials at the end of each day in accordance with local restrictions;
- Maintain the original or a copy of a prescription from a dentist for each appliance or artificial restorative oral device authorizing its construction or repair for 4 years;
- Maintain a written policy and procedure manual on sanitation; and
- Have a designated receiving area.

A dental laboratory may not have dental chairs, x-ray machines, or anesthetics, sedatives, or medicinal drugs.⁸² A dental laboratory may not solicit or advertise to the general public.⁸³

There are currently 12 states, including Florida that regulate dental laboratories in some way,⁸⁴ of which 7 require dental laboratories to be registered.⁸⁵ Since 2012, 6 administrative complaints were filed against dental laboratories in Florida, 4 of those resulted in disciplinary cases.⁸⁶

Dietetics and Nutrition

The Dietetics and Nutrition Practice Act governs the licensure and practice of dietitians and nutritionist.⁸⁷ The Council of Dietetics and Nutrition, under the delegated authority of the Board of Medicine, regulates the practice of dietitians and nutritionists.⁸⁸

The practice of dietetics and nutrition includes:

- Assessing nutritional needs and status using appropriate data:
- Recommending appropriate dietary regimens, nutrition support, and nutrient intake;
- Ordering therapeutic diets;
- Improving health status through nutrition, research, counseling, and education; and
- Developing, implementing, and managing nutrition care systems, including evaluating, monitoring, and maintaining appropriate standards of high quality food and nutrition services.

Nutrition counseling includes advising and assessing individuals or groups on appropriate nutritional intake by integrating information from a nutrition assessment. 90 A nutrition assessment is an evaluation of nutritional needs using appropriate data to determine nutrient needs or status and making appropriate nutrition recommendations. 91

⁸⁰ Section 466.032, F.S.

⁸¹ Rule 64B27-1.001, F.A.C.

⁸² Id. Personal prescriptions are permissible.

⁸³ Section 466.035, F.S.

⁸⁴ National Association of Dental Laboratories, *State Regulation*, available at http://dentallabs.org/state-regulation/ (last visited January 20, 2018). The other 11 states are Illinois, Kentucky, Minnesota, Missouri, North Carolina, Ohio, Oklahoma, Pennsylvania, South Carolina, Texas, and Virginia.

⁸⁵ Id. These include Florida, Kentucky, Minnesota, Oklahoma, Pennsylvania, South Carolina, and Texas.

⁸⁶ Supra note 24.

⁸⁷ Sections 468.501 – 468.518, F.S.

⁸⁸ Section 468.506, F.S.

⁸⁹ Section 468.503(5), F.S.

⁹⁰ Section 468.503(10), F.S.

⁹¹ Section 468.503(9), F.S.

An individual must be licensed to practice dietetics and nutrition or provide nutrition counseling for remuneration or to hold oneself out as a practitioner of dietetics and nutrition practice or nutrition counseling.⁹² To qualify for licensure, an applicant must:

- Possess a baccalaureate or post baccalaureate degree in human nutrition, food and nutrition, dietetics, or food management, or an equivalent course of study, from an accredited school or program;
- Complete preprofessional experience of at least 900 hours or has education or experience determined to be equivalent by the Board of Medicine; and
- Pass a licensure examination.⁹³

However, there are a number of exceptions to this licensure requirement:94

- A person who is licensed in this state as an acupuncturist, allopathic or osteopathic physician, physician assistant, chiropractic physician, podiatric physician, naturopath, optometrist, registered nurse, licensed practical nurse, advanced registered practice nurse, pharmacist, dentist, dental hygienist, massage therapist, psychologist, licensed clinical social worker, marriage and family therapist, or mental health counselor, as long as such person is engaging in the practice of the profession for which he or she is licensed.
- A dietitian employed by the federal government, if such person engages in dietetics solely under the direction or control of the organization by which the person is employed.
- A person employed as a cooperative extension home economist.
- A person pursuing a course of study leading to a degree in dietetics and nutrition from an
 accredited school, if the activities and services are a part of a supervised course of study and
 the person's title clearly indicates that he or she is a student or trainee.
- A person is fulfilling the required preprofessional experience required for licensure.
- A registered dietitian or licensed dietitian or nutritionist from another state practicing dietetics or nutrition incidental to a course of study when taking or giving a postgraduate course or other course of study in this state, if the person holds an appointment on the faculty of an accredited school.
- A person who markets or distributes food, food materials, or dietary supplements, or any person
 who engages in the explanation of the use and benefits of those products or the preparation of
 those products, if the person does not engage for a fee in dietetics and nutrition practice or
 nutrition counseling.
- A person who markets or distributes food, food materials, or dietary supplements, or any person who engages in the explanation of the use or preparation of such products, as an employee of a permitted pharmacy.
- An educator who is employed by a nonprofit organization approved by the council, a governmental entity, an elementary or secondary school, an accredited institution of higher education, if his or her activities are part of such employment.
- A person who provides weight control services or related weight control products, provided that
 the program has been reviewed by, consultation is available from, and no program change can
 be made without approval by a licensed dietitian/nutritionist.
- A person employed by a licensed hospital, nursing home, continuing care facility, or assisted living facility, if the person is employed in compliance with governing facility licensure laws and rules regarding the operation of its dietetic department.
- A person employed by a nursing facility exempt from licensure or a person exempt from licensure under ch. 464, F.S.
- A person employed as a dietetic technician.

⁹⁴ Section 468.505, F.S. **STORAGE NAME**: h1047c.HCA

² Section 468.504, F.S.

⁹³ Section 468.509, F.S. An individual may be licensed without examination if the individual demonstrates that he or she is a registered dietician or nutritionist with the Commission on Dietetic Registration or is a certified as nutrition specialist by the Certification Board of Nutrition Specialist or is a diplomate of the American Clinical Board of Nutrition.

• A person who disseminates information, conducts a class or seminar, or gives a speech related to nutrition, if such information, class, seminar or speech is provided without a fee.

Individuals who provide dietary or nutrition information for compensation as a part of a profession that is not regulated, such as a fitness trainer or a life coach are subject to prosecution for unlicensed practice of a regulated health profession.⁹⁵

Currently, 7 states that do not register or license dietitians: Arizona, California, Colorado, Michigan, New Jersey, Texas, and Virginia. However, California, Texas, and Virginia provide title protection for dietitians. Texas, and Virginia provide title protection for dietitians.

Athletic Trainers

Athletic trainers provide service and care to individuals related to the prevention, recognition, evaluation, management, disposition, treatment, or rehabilitation of a physically active person who sustained an injury, illness, or other condition involving exercise, sport, recreation, or related physical activity.⁹⁸ To be licensed as an athletic trainer, an applicant must:⁹⁹

- Hold a bachelor's degree or higher from an accredited athletic training degree program and pass the national examination to be certified by the Board of Certification;¹⁰⁰
- If graduated before 2004, hold a current certification from the Board of Certification;
- Hold a current certification in both cardiopulmonary resuscitation and the use of an automated external defibrillator at the professional rescue level; and
- Pass a background screening.

An athletic trainer must practice under the direction of an allopathic, osteopathic, or chiropractic physician, ¹⁰¹ and may provide care such as: ¹⁰²

- Injury prevention, recognition, and evaluation;
- First aid and emergency care;
- Injury management and treatment;
- Rehabilitation through the use of safe and appropriate physical rehabilitation practices;
- Conditioning:
- Performance of tests and measurements to prevent, evaluate, and monitor acute and chronic injuries;
- Therapeutic exercises;
- Massage;
- Cryotherapy and thermotherapy;
- Therapy using other agents such as water, electricity, light, or sound; and
- The application of topical prescription medications at the direction of a physician.

⁹⁵ An individual prosecuted for the unlicensed practice of a regulated health care profession may be subject to both administrative and criminal sanctions if found guilty.

Gommission on Dietetic Registration, Academy of Nutrition and Dietetics, *Laws the Regulate Dietitians/Nutritionists*, available at https://www.cdrnet.org/vault/2459/web/files/Licensurelawsregulations.pdf (last visited January 24, 2018).

97 Id.

⁹⁸ Section 468.701(2), F.S.

⁹⁹ Section 468.707, F.S.

¹⁰⁰ The Board of Certification is a not-for-profit credentialing agency to provide a certification program for the entry level athletic training profession. See Board of Certification for the Athletic Trainer, *What is the BOC?*, available at http://www.bocatc.org/about-us#what-is-the-boc (last visited January 20, 2018).

¹⁰¹ Section 468.713, F.S. ¹⁰² Rule 64B33-4.001, F.A.C.

Orthotists and Prosthetists

The Board of Orthotists and Prosthetists oversees the licensure and regulation of orthotists and prosthetists.¹⁰⁴ 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. ¹⁰⁵ The board must verify that an applicant for licensure examination meets the following requirements:

- 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. 106

In addition to the requirements listed above, an applicant must meet the following requirements for each license he or she is seeking:

- A Bachelor of Science degree in Orthotics and Prosthetics from a regionally accredited college or university from an accredited college or university recognized by the Commission on Accreditation of Allied Health Education Programs, or a bachelor's degree with a certificate in orthotics or prosthetics from a program recognized by the Commission on Accreditation of Allied Health Education Programs, or its equivalent;
- An internship of one year of qualified experience or a residency program recognized by the
- Completion of the mandatory classes: 107 and
- Passage of the state orthotic examination or board-approved orthotic examination if applying for an orthotist license, or the state prosthetic examination or board-approved examination if applying for a prosthetist license. 108

Currently, a person who qualifies to be licensed as both an orthotist and a prosthetist must obtain two separate licenses.

Massage Therapy

The "Massage Practice Act" (Act), governs the practice of massage in Florida. 109 A significant portion of the Act is dedicated to regulating massage establishments, which are sites or premises, or portion thereof, wherein a massage therapist practices massage. 110 Massage establishments must be licensed by DOH in accordance with rules adopted by Board of Massage Therapy. 111 A massage establishment must:112

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¹⁰³ 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 pedorthics (s. 468.80(9)-(10), F.S.) 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 a prosthesis (s. 468.80(15)-(16), F.S.)

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.)

Section 468.803(2), F.S.

Pursuant to r. 64B14-5.005, F.A.C., mandatory courses include two hours on Florida laws and rules, two hours on the prevention of medical errors, one hour on infection disease control, and a CPR certification course.

¹⁰⁸ Section 468.803(5), F.S. Licenses must be renewed biennially.

¹⁰⁹ Chapter 480, F.S.

¹¹⁰ Section 480.033(7), F.S.

¹¹¹ Section 480.043, F.S. Registration requirements do not apply to an allopathic, osteopathic, or chiropractic physician who employs a licensed massage therapist to perform massage on the physician's patients at the physician's practice location. ¹¹² Id. and r. 64B7-26.003, F.A.C.

- Have all individuals with an ownership interest, or for a corporation with more than \$250,000 in assets, the owner, officer, or management pass a background screening;
- Provide proof of property damage and bodily injury liability insurance coverage;
- Comply with local building code requirements;
- Provide a bathroom with at least one toilet and one sink with running water for its clients to use;
- Maintain toilet facilities in the common area of the establishment:
- Have a massage therapist on the premises if a client is in a treatment room for the purpose of receiving massage therapy;
- Maintain certain safety and sanitary requirements; and
- Pass initial and periodic inspections by DOH.

DOH must deny an application for a license or renewal of a license if a person with an ownership interest has been convicted or found guilty of, or entered a plea of nolo contedere to a crime related to prostitution or a felony offense related to certain other crimes, such as human trafficking or kidnapping. 113

Massage Therapists

To be licensed as a massage therapist, an applicant must: 114

- Be at least 18 years of age or have received a high school diploma or graduate equivalency diploma;
- Complete a course of study at a board-approved massage school or apprentice program;
- Pass an examination; and
- Pass a background screening.

DOH must deny an application if the applicant has been convicted or found guilty of, or entered a plea of nolo contedere to a crime related to prostitution or a felony offense related to certain other crimes. 115 In the 2016-2017 fiscal year, 2,076 individuals applied for licensure by examination, 12 of which qualified for licensure by completing an approved Florida apprenticeship program. 116

Colonic Irrigation Apprenticeship Programs

A massage therapist, a massage apprentice, or a student in a board-approved massage therapy school may study colonic irrigation 117 under the direct supervision of a sponsor. 118 The sponsor must be licensed to practice massage, authorized to practice colonic irrigation, and have practiced colonic irrigation for at least 3 years. 119 The apprenticeship must be completed within 12 months of commencement¹²⁰ and must consist of a minimum of 100 hours of training, including 45 hours of clinical practicum with a minimum of 20 treatments given. 121

Clinical Laboratory Directors

A clinical laboratory performs services to provide information for use in the diagnosis, prevention, or treatment of a disease or identification or assessment of a medical or physical condition. 122 The Agency

¹¹³ Section 480.043(8), F.S.

¹¹⁴ Section 480.041, F.S.

Supra note 24.

¹¹⁷ Colonic irrigation is a method of hydrotherapy used to cleanse the colon with the aid of a mechanical device and water (s. 480.033(6), F.S.)

¹¹⁸ Rule 64B7-29.001, F.A.C.

¹¹⁹ ld.

¹²⁰ Rule 64B7-29.007, F.A.C.

¹²¹ Rule 64B7-25.001, F.A.C.

¹²² Section 483.041, F.S.

for Health Care Administration regulates clinical laboratories and DOH regulates clinical laboratory personnel, including clinical laboratory directors, supervisors, technologists, and technicians. 123

A clinical laboratory director is responsible for the overall operation and administration of a clinical laboratory. 124 A director may not direct more than 5 clinical laboratories and may delegate the performance of certain duties to licensed clinical supervisors, except that the director may not delegate the approval, signing, and dating of an initial procedure review or a substantive change in existing procedure. 125 However, the clinical laboratory director remains responsible that all duties of the laboratory are performed properly. 126 An applicant for licensure as a clinical laboratory director must meet the qualifications for a High Complexity Laboratory Director, which requires the applicant be either:127

- A licensed allopathic or osteopathic physician; and
- Be certified in anatomic or clinical pathology, or both:

- A licensed allopathic, osteopathic, or podiatric physician; and
- Have at least 1 year of laboratory training during medical residency or have at least 2 years' experience directing or supervising high complexity testing;

- Hold a doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution; and
- Be certified by a board approved by the federal Department Health and Human Services or meet specified training and experience requirements.

A clinical laboratory director must have at least 2 years' experience in the specialty to be directed or hold a national board certification in such specialty. 128

Psychologists

The Board of Psychology oversees the licensure and regulation of psychologists. 129 To receive a license to practice psychology, an individual must: 130

- Have received a doctoral-level psychological education from an accredited school in the United States or Canada;¹³¹
- Complete 2 years or 4,000 hours of supervised experience;
- Pass the Examination for Professional Practice in Psychology; ¹³² and
- Pass an examination on Florida laws and rules.

An applicant who holds an active, valid license in another state may also qualify for licensure in this state if at the time the license was issued, the requirements were substantially equivalent to or more stringent than those in Florida at that time. 133

¹²³ See generally, ch. 483, F.S.

¹²⁴ Rule 64B3-13.001(1), F.A.C.

¹²⁵ Rule 64B3-13.001(4)-(5), F.A.C.

¹²⁶ Rule 64B3-13.001(5), F.A.C.

¹²⁷ 42 C.F.R. s. 489.1443.

¹²⁸ See s. 483.824, F.S., and r. 64B3-5.007, F.A.C.

¹²⁹ Section 490.004, F.S.

¹³⁰ Section 490.005, F.S.

¹³¹ Section 490.003(3), F.S., defines doctoral-level education as a Psy.D, an Ed.D., or a Ph.D in psychology from an accredited educational institution.

132 Rule 64B19-11.001, F.A.C.

¹³³ Section 490.006, F.S.

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

Intern Registration

To be licensed as a clinical social worker, marriage and family therapist, or mental health counselor, an applicant must meet educational requirements, complete at least 2 years of postgraduate or postmaster's clinical practice supervised by a licensed practitioner, and pass a theory and practice examination. During the time in which an applicant is completing the required supervised clinical experience or internship, he or she must register with the DOH as an intern. The supervised clinical experience may be met by providing at least 1,500 hours of face-to-face psychotherapy with clients, which may not be accrued in less than 100 weeks.

An applicant seeking registration as an intern must: 137

- Submit a completed application form and the nonrefundable fee to the DOH;
- · Complete education requirements;
- Submit an acceptable supervision plan for meeting the practicum, internship, or field work required for licensure that was not satisfied by graduate studies; and
- Identify a qualified supervisor.

An intern registration expires 60 months after the date of issue and may only be renewed if the candidate has passed the theory and practice examination required for full licensure. 138

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. An applicant seeking licensure as a mental health counselor must: 140

- Possess a master's degree from an accredited program;
- Complete 36 semester hours of graduate coursework that includes a minimum of 3 semester hours of graduate-level coursework in:
 - The dynamics of marriage and family systems;
 - Marriage therapy and counseling theory;
 - o Family therapy and counseling theory and techniques;
 - o Individual human development theories throughout the life cycle;
 - Personality or general counseling theory and techniques;
 - Psychosocial theory; and
 - Substance abuse theory and counseling techniques.
- Complete at least one graduate level course of 3 semester hours in legal, ethical, and professional standards;
- Complete as least one graduate level course of 3 semester hours in diagnosis, appraisal, assessment, and testing for individual or interpersonal disorder or dysfunction;
- Complete at least one graduate level course of 3 semester hours in behavioral research;
- Complete at least one supervised clinical practicum, internship, or field experience in a marriage and family counseling setting, during which the student provided 180 direct client contact hours of marriage and family therapy services;

 $^{^{\}rm 134}$ Section 491.005, F.S. A procedure for licensure by endorsement is provided in s. 491.006, F.S.

¹³⁵ Section 491.0045, F.S.

¹³⁶ Rule 64B4-2.001, F.A.C.

¹³⁷ Section 491.0045(2), F.S.

¹³⁸ Section 491.0045(6), F.S.

¹³⁹ ld.

¹⁴⁰ Section 491.005(3), F.S. **STORAGE NAME**: h1047c.HCA

- 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 qualified as a supervisor by board;
- Pass a board approved examination; and
- Demonstrate knowledge of laws and rules governing the practice.

An individual may apply for a marriage and family therapy dual license if he or she passes an examination in marriage and family therapy and holds 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.¹⁴¹

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 develop 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. Mental health counselors are regulated by the Board of Clinical Social Work, Marriage and Family Therapy, and Mental Health Counseling, within DOH. To qualify for licensure as a mental health counselor, an individual must: 143

- Have a master's degree from a mental health counseling program accredited by the Council of the Accreditation of Counseling and Related Educational Programs, or a program related to the practice of mental health counseling that includes coursework and a 1,000-hoour practicum, internship, or fieldwork of at least 60 semester hours that meet certain requirements;
- 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.

Currently, an applicant for a mental health counselor license must, by rule, pass the National Clinical Mental Health Counseling Examination. Current law refers to an outdated mental health counseling examination.

Effect of Proposed Changes

General Licensure Requirements

The bill requires the application for licensure to include the applicant's date of birth, in addition to the currently required social security number. This will provide DOH an additional method of verify the identity of an individual applicant.

Conrad 30 Program

The bill authorizes DOH to adopt rules to implement the Conrad 30 Waiver program in this state. This allows DOH to set guidelines in addition to those required by federal law.

¹⁴¹ Section 491.0057, F.S.

¹⁴² Sections 491.003(6) and (9), F.S.

¹⁴³ Section 491.005(4), F.S.

¹⁴⁴ Section 491.005(4), F.S., and r. 64B4-3.0035, F.A.C.

Dentistry

Military Spouses

The bill expands the expedited licensure application process to include the spouse of an active duty military member who holds an active license to practice dentistry in another state or jurisdiction and waives the application, licensure, unlicensed activity fees. The bill also repeals a provision that requires the spouse of a member of the U.S. Armed Forces serving on active duty in this state who holds a temporary license to practice dentistry to practice under the supervision of a Florida-licensed dentist.

These provisions allow dentistry to be treated in the same manner as all other health professions for which a military spouse may pursue licensure in this state.

Dental Licensure Exams

The bill repeals a requirement that a Florida-licensed dentist grade the American Dental Licensing Examination, and that either a Florida-licensed dentist or dental hygienist grade Dental Hygienist Examination produced by the American Board of Dental Examiners, Inc., for applicants for licensure in this state.

Dental Adverse Incidents

Dentists and dental hygienist are currently required to submit adverse incidents related to the administration of anesthesia under rules adopted by the Board of Dentistry. The bill statutorily requires a dentist to report an adverse incident that occurs in his or her office to DOH in writing by certified mail and postmarked within 48 hours after the incident occurs. An adverse incident is any death that occurs during or as a result of a dental procedure, or a temporary or permanent physical or mental injury that requires hospitalization or emergency room treatment as a result of the use of general anesthesia. deep sedation, conscious sedation, pediatric conscious sedation, oral sedation, minimal sedation, nitrous oxide, or local anesthesia.

A dentist must also report any death or other adverse incident that occurs in the dentist's outpatient facility to the Board of Dentistry in writing by certified mail within 48 hours of such occurrence. Within 30 days, the dentist must file a complete report with the Board of Pharmacy.

A certified dental hygienist who holds a certificate to administer local anesthesia must notify the Board of Dentistry in writing by registered mail within 48 hours of an adverse incident that was related to or the result of the administration of local anesthesia. The dental hygienist must file a complete report with the Board of Dentistry within 30 days.

DOH must review each adverse incident report to determine whether the incident involved conduct by a health care practitioner that warrants disciplinary action by the applicable regulatory board. A dentist or dental hygienist who fails to timely and completely report adverse incidents as required will be subject to disciplinary action by the Board of Dentistry.

Dental Laboratories

The bill repeals the regulation of dental laboratories.

Chiropractic Physician Assistants

The bill repeals the voluntary registration of registered chiropractic assistants.

Optometry

The bill requires optometry applicants to apply to DOH for licensure, rather than applying to take the licensure examination. This will allow applicants to take all or a portion of the licensure examination prior to applying to DOH. The bill requires an applicant to have obtained a passing score on licensure examination of the National Board of Examiners in Optometry or similar exam approved by the Board of Optometry. The bill repeals language related to the topics that must be tested on the licensure exam and authorizes DOH to use a national examination.

Currently, an out-of-state optometrist must take the licensure examination to be licensed in Florida. The bill creates licensure by endorsement for optometrists who are licensed in another jurisdiction. DOH may charge a nonrefundable application fee of no more than \$250 and a licensure fee of no more the \$325. For licensure by endorsement, an applicant must have:

- Graduated from an accredited school or college of optometry;
- Passed the licensure examination of National Board of Examiners in Optometry or other national examination approved by the Board of Optometry;
- An active license to practice optometry in another jurisdiction for at least 5 of the immediately preceding 7 years; or successful completion of a board-approved clinical competency examination within the year preceding the filing of an application for licensure;
- Successfully completed the clinical skills portion of the examination developed by the National Board of Examiners in Optometry, and achieved a score of at least 75 percent on each of the biomicroscopy, binocular indirect ophthalmoscopy, and dilated biomicroscopy and noncontact fundus lens evaluation skills individually;
- Successfully completed a written examination on the applicable general laws and rules governing the practice of optometry:
- Obtained a passing score on either the Treatment and Management of Ocular Disease examination in the Patient Assessment and Management portion of the examination developed by the National Board of Examiners in Optometry or the stand alone Treatment and Management of Ocular Disease examination; and
- Completed at least 30 hours of board-approved continuing education for the 2 calendar years immediately preceding application.

DOH may not issue a license by endorsement if the applicant is under investigation in any jurisdiction for an act or offense that would constitute a licensure violation in Florida until the investigation is complete. If the applicant has such violation license or does not otherwise meet the requirements of licensure, the Board of Optometry may:

- Refuse to certify the application for licensure or certification to DOH;
- Certify the application for licensure or certification to DOH with restrictions on the scope of practice; or
- Certify the application for licensure or certification to DOH with a probationary period subject to conditions specified by the Board of Optometry.

Nursing

The bill authorizes the Board of Nursing to adopt rules related to the standards of care for licensed practical nurses, registered nurses, advanced registered nurse practitioners, and CNAs. The bill authorizes CNA applicants who are licensed in other territories or the District of Columbia to qualify for licensure by endorsement. The bill authorizes the Board of Nursing to discipline CNAs for any violation of a law or rule regulating CNA practice. The bill removes the requirement that a violation must be intentional to be subject to disciplinary action.

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Pharmacy

In-state Sterile Compounding

Current law does not expressly provide for an in-state sterile compounding permit as it does for out-of-state pharmacies and outsourcing facilities that perform sterile compounding. However, s. 465.0196, F.S. grants the Board of Pharmacy rule-making authority to create and issue special pharmacy permits. Under that authority, the Board of Pharmacy has adopted rules for the issuance of a special sterile compounding permit to regulate in-state pharmacies and outsourcing facilities that perform sterile compounding. The bill expressly gives DOH authority to issue an in-state sterile compounding permit.

The bill requires a pharmacy or outsourcing facility located in this state that dispenses, creates, delivers, ships, or mails a compound sterile product to obtain a sterile compounding permit. If, upon receipt of an application, the Board of Pharmacy verifies that the application complies with the laws and rules governing pharmacies, DOH must issue the permit. Within 90 days before issuing the permit, DOH must conduct an onsite inspection. General requirements and disciplinary guidelines for pharmacies will apply to in-state sterile compounding permittees.

A licensed pharmacist must supervise the compounding and dispensing of all drugs. A permittee must notify DOH within 10 days of a change in the supervising physician. A permittee must have a written policy and procedural manual specifying the duties, tasks, and functions a registered pharmacy technician is allowed to perform, if it uses registered pharmacy technicians.

The bill authorizes the Board of Pharmacy to adopt rules for the standards of practice for sterile compounding. In adopting such rules, the Board of Pharmacy must consider the U.S. Pharmacopeia; and for outsourcing facilities, the Board of Pharmacy must consider the Current Good Manufacturing Practice regulations by the FDA. Other authoritative professional standards may also be considered.

On-site inspections

Currently, DOH performs onsite inspections prior to issuing any new pharmacy permit or a permit for a change of location pursuant to rules adopted by the Board of Pharmacy. The bill expressly requires DOH to perform such inspections within 90 days before the issuance of a permit.

Dietetics and Nutrition

The bill authorizes an individual to provide compensated dietary and nutritional information as long as the individual does not represent or imply that he or she is a dietician, licensed dietitian, registered dietitian, licensed nutritionist, licensed nutrition counselor, or use any other term or symbol that implies the he or she is a dietitian, nutritionist, or nutrition counselor. This allows individuals, such as fitness trainers, health coaches, and chefs, to provide nutritional advice for compensation.

Athletic Trainers

The bill requires athletic trainers to work within her or his scope of practice as defined by Board of Athletic Training in rule. The bill adds another route to licensure by authorizing individuals who hold a bachelor's degree, completed a Board of Certification internship, and holds a certification from the Board of Certification to be eligible for licensure.

The bill establishes that a licensed athletic trainer must maintain his or her certification from the Board of Certification in good standing to be eligible for licensure renewal. The bill requires the Board of Athletic Training to establish rules for the supervision of an athletic training student.

Orthotics and Prosthetics

The bill authorizes the Board of Orthotists and Prosthetists to issue a single license for prosthetics and orthotics practice. Currently, an individual must hold two separate licenses: one as a prosthetist and one as an orthotist. To qualify for the single license, an individual must hold a Bachelor of Science degree or higher in orthotics and prosthetics from an accredited college or university. The bill also authorizes the completion of a dual residency program to qualify for licensure.

Massage Therapy

The bill limits apprenticeships to only those in colonic irrigations. A licensed massage therapist must supervise a colonic irrigation apprentice.

The bill authorizes the Board of Massage Therapy to designate a national examination for licensure and repeals provisions requiring DOH to develop a licensure examination.

The bill eliminates a massage therapy apprenticeship as a path to licensure. However, if an individual has been issued a license as a massage therapy apprentice before July 1, 2018, he or she may continue to perform massage therapy until the license expires. A massage therapist apprentice may apply for full licensure upon completion of the apprenticeship and before July 1, 2021.

The bill authorizes the Board of Massage Therapy to revoke, suspend, or deny the licensure of a massage establishment that is owned by an individual who previously had a prior establishment license revoked if:

- The license was obtained by fraud or misrepresentation;
- The licensee is proven to be guilty of fraud, deceit, gross negligence, incompetence, or misconduct in the operation of the licensed establishment; or
- The owner of the massage therapy establishment or any person providing massage therapy services at the establishment has had 3 convictions of, or pleas of guilty or nolo contendere to, or dismissals of a criminal action after a successful completion of a pretrial intervention, diversion, or substance abuse program for any misdemeanor or felony, regardless of adjudication, or a crime related to prostitution and related acts that occur at or within the establishment.

DOH may not issue a license to an establishment disciplined under this provision unless there is change of ownership.

Clinical Laboratory Directors

The bill requires a clinical laboratory director to be licensed as clinical laboratory director under federal law to qualify for licensure in this state. A clinical laboratory director may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel or may delegate such duties as authorized under federal law.

Psychologists

The bill repeals obsolete provisions related to applicants for licensure prior to July 1, 1999. The bill requires psychology programs within educational institutions to be accredited by the American Psychological Association (APA), which is recognized as the national accrediting authority for professional education and training in psychology by the U.S. Department of Education and the Council for Higher Education Accreditation.¹⁴⁵ The bill replaces references to the Commission on Recognition of

¹⁴⁵ American Psychological Association, *Understanding APA Accreditation*, available at http://www.apa.org/ed/accreditation/about/index.aspx (last visited January 20, 2018). **STORAGE NAME**: h1047c.HCA

Postsecondary Accreditation to its successor organization, the Council for Higher Education Accreditation. ¹⁴⁶ For applicants for licensure who obtained their education in Canada, the bill authorizes those applicants to demonstrate that they have completed a program comparable to APA-accredited programs.

The bill eliminates a provision that allowed an applicant for licensure by endorsement to hold a license from another state that has licensure standards that are equivalent or more stringent than Florida to qualify for licensure. However, an individual may apply for licensure by endorsement if he or she has a doctoral degree in psychology and has practiced for at least 10 years of the last 25 years, rather than 20 years as required in current law.

Licensed Clinical Social Work, Marriage and Family Therapy, and Mental Health Counseling

Intern Registration

The bill authorizes the Board of Clinical Social Work, Marriage and Family Therapy, and Mental Health Counseling to make a one-time exception to the 60-month limit on an internship registration. Such exceptions may only be granted in an emergency or hardship case, as defined by rule. The bill deletes obsolete language related to biennial renewals of intern registrations.

Marriage and Family Therapists

The bill requires that an applicant for licensure hold a master's degree with an emphasis in marriage and family therapy from a program accredited by the Commission of Accreditation for Marriage and Family Therapy Education or a Florida university program accredited by the Council for Accreditation of Counseling and Related Educational Programs. An applicant may also qualify for licensure if he or she holds a master's degree in a closely related field and has completed graduated courses approved by the Board of Clinical Social Work, Marriage and Family Therapy, and Mental Health Counseling. The bill eliminates specified the coursework and clinical experience required for licensure that is currently enumerated in statute.

The bill updates the name of the licensure examination for mental health counseling licensure applicants to the National Clinical Mental Health Counseling Examination administered by the National Board for Certified Counselors or its successors. This will conform the law to current practice. The bill reduces the number of hours required for the clinical practicum or internship from 1,000 hours to 700 hours.

To be licensed as a marriage and family therapist s. 491.005(3), F.S., requires an applicant to complete two years of clinical experience. However, later in the same paragraph, it states the clinical experience required is three years. The bill corrects the scrivener's error in the paragraph.

The bill clarifies that DOH is deny or impose penalties on the license of a marriage and family therapist who violates the practice act or ch. 456, F.S., the general regulatory statute. This will alleviate confusion regarding the authority of DOH to impose such discipline or deny a license.

Licensure by endorsement

The bill deletes educational requirements for applicants for licensure by endorsement. Such applicant qualifies for licensure if he or she holds a valid, active license to practice in another state for 3 of the 5 years preceding the date of application, pass an equivalent licensure examination, and is not under investigation for and has not been found to have committed any act that would constitute a licensure violation in Florida.

⁴⁷ Supra note 24.

¹⁴⁶ U.S. Department of Education, *Accreditation in the U.S.*, available at https://www2.ed.gov/admins/finaid/accred/accredus.html (last yuly 20, 2018).

The bill makes other conforming changes.

The bill provides an effective date of July 1, 2018.

B. SECTION DIRECTORY:

- **Section 1:** Amends s. 381.4018, F.S., relating to physician workforce assessment and development.
- **Section 2:** Amends s. 456.013, F.S., relating to department; general licensing provisions.
- **Section 3:** Amends s. 456.024, F.S., relating to members of Armed Forces in good standing with administrative boards or the department; spouses; licensure.
- **Section 4:** Repeals s. 460.4166, F.S., relating to certified chiropractic physician's assistants.
- **Section 5:** Amends s. 463.006, F.S., relating to licensure and certification by examination.
- **Section 6:** Creates s. 463.0061, F.S., relating to licensure by endorsement; requirements; fees.
- **Section 7:** Amends s. 464.006, F.S., relating to rulemaking authority.
- **Section 8:** Amends s. 464.202, F.S., relating to duties and powers of the board.
- **Section 9:** Amends s. 464.203, F.S., relating to certified nursing assistants; certification requirement.
- **Section 10:** Amends s. 464.204, F.S., relating to denial, suspension, or revocation of certification; disciplinary actions.
- **Section 11:** Amends s. 465.019, F.S., relating to institutional pharmacies; permits.
- **Section 12:** Amends s. 465.0193, F.S., relating to nuclear pharmacy permits.
- **Section 13:** Creates s. 465.0195, F.S., relating to pharmacy or outsourcing facility; sterile compounding permit.
- **Section 14:** Amends s. 465.0196, F.S., relating to special pharmacy permits.
- **Section 15:** Amends s. 465.0197, F.S., relating to internet pharmacy permits.
- **Section 16:** Amends s. 466.006, F.S., relating to examination of dentists.
- **Section 17:** Amends s. 466.007, F.S., relating to examination of dental hygienists.
- **Section 18:** Amends s. 466.017, F.S., relating to prescription of drugs; anesthesia.
- **Section 19:** Amends s. 468.505, F.S., relating to exemptions; exceptions.
- **Section 20:** Repeals ss. 466.032, 466.033, 466.034, 466.035, 466.036, 466.037, 466.038, and 466.039, F.S., relating to registration; registration certificates; change of ownership or address; advertising; information; periodic inspections; equipment and supplies; suspension and revocation; administrative fine; rules; and violations.
- Section 21: Amends s. 468.701, F.S., relating to definitions.
- **Section 22:** Amends s. 468.707, F.S., relating to licensure requirements.
- Section 23: Amends s. 468.711, F.S., relating to renewal of license; continuing education.
- **Section 24:** Amends s. 468.723, F.S., relating to exemptions.
- **Section 25:** Amends s. 468.803, F.S., relating to license, registration, and examination requirements.
- **Section 26:** Amends s. 480.033, F.S., relating to definitions.
- **Section 27:** Amends s. 480.041, F.S., relating to massage therapists; qualifications; licensure; endorsement.
- **Section 28:** Repeals s. 480.042, F.S., relating to examinations.
- **Section 29:** Amends s. 480.046, F.S., relating to grounds for disciplinary action by the board.
- **Section 30:** Amends s. 483.824, F.S., relating to qualifications of clinical laboratory director.
- **Section 31:** Amends s. 490.003, F.S., relating to definitions.
- **Section 32:** Amends s. 490.005, F.S., relating to licensure by examination.
- **Section 33:** Amends s. 490.006, F.S., relating to licensure by endorsement.
- **Section 34:** Amends s. 491.0045, F.S., relating to intern registration; requirements.
- **Section 35:** Amends s. 491.005, F.S., relating to licensure by examination.
- **Section 36:** Amends s. 491.006, F.S., relating to licensure or certification by endorsement.
- **Section 37:** Amends s. 491.007, F.S., relating to renewal of license, registration, or certificate.
- **Section 38:** Amends s. 491.009, F.S., relating to discipline.
- **Section 39:** Amends s. 463.0057, F.S., relating to optometric faculty certificate.
- **Section 40:** Amends s. 491.0046, F.S., relating to provisional license; requirements.
- **Section 41:** Amends s. 945.42, F.S., relating to definitions; ss. 945.40-945.49.
- Section 42: Provides an effective date of July 1, 2018.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

DOH will no longer receive biennial registration and licensure revenue due to the repeal of the registration of chiropractic assistants and licensure of dental laboratories. However, the loss of revenue will be offset by eliminating the cost of regulating chiropractic assistants and dental laboratories. 148

DOH may experience a loss of revenue related to the exemption of dentists who are military spouses from the payment of application and licensure fees and from the elimination of the temporary dentistry license. It is unknown how many military spouses may seek these exemptions.

2. Expenditures:

The bill will have an insignificant, negative fiscal impact on DOH. The bill requires DOH, or the appropriate regulatory board, to adopt rules related to the Conrad 40 waiver program, standards of care for nurses, and the supervision of athletic training students. DOH will need to repeal adopted rules related to the deregulation of registered chiropractic assistants and licensed dental laboratories. Current resources can absorb these costs. 149

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1.	Revenues:
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None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Dentists who are spouses of active duty military members and currently hold temporary licenses will no longer have to pay fees associated with the temporary license and indirect supervision by a Floridalicensed dentist. Individuals who voluntary registered as chiropractic assistants or were required to be licensed as dental laboratory will no longer have to pay fees associated with such registration or licensure.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

¹⁴⁹ E-mail correspondence with DOH, dated January 22, 2018 (on file with the Health Quality Subcommittee).

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¹⁴⁸ E-mail correspondence with DOH, dated January 29, 2018 (on file with the Health Care Appropriations Subcommittee).

B. RULE-MAKING AUTHORITY:

The bill provides sufficient rulemaking authority for DOH or the applicable regulatory boards to adopt rules related to the Conrad 40 waiver program, standards of care for nurses, and the supervision of athletic training students.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On January 24, 2018, the Health Quality Subcommittee adopted two amendments that:

- Eliminates requirement that office surgery centers register with the Department of Health; and
- Authorizes individuals to provide paid dietary or nutrition advice, if they do not hold themselves out as being licensed as a dietician or nutritionist.

The bill was reported favorably as a committee substitute. The analysis is drafted to the committee substitute as passed by the Health Quality Subcommittee.

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