

## HOUSE OF REPRESENTATIVES STAFF ANALYSIS

**BILL #:** CS/CS/HB 543 Regulation of Nursing  
**SPONSOR(S):** Health & Human Services Committee; Health Innovation Subcommittee; Pigman  
**TIED BILLS:** **IDEN./SIM. BILLS:** SB 328

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Innovation Subcommittee	11 Y, 0 N, As CS	Siples	Poche
2) Health Care Appropriations Subcommittee	15 Y, 0 N	Mielke	Pridgeon
3) Health & Human Services Committee	17 Y, 0 N, As CS	Siples	Calamas

### SUMMARY ANALYSIS

CS/CS/HB 543 makes several changes to nursing education program regulation and many other programs within the Department of Health (DOH).

First, the bill makes changes to nursing education program regulation. The bill authorizes the Board of Nursing (BON) to grant a one-year extension to a nursing education program that is on probation for failure to meet the graduate passage rate, if the program shows progress. The BON retains authority to terminate a program after the two-year probation period. A program on probation must notify its students and applicants of that status and its implications in writing. The bill removes a requirement that a nursing student who does not take the licensure examination within six months of graduation successfully complete a licensure examination preparatory course. The bill prohibits a program that was terminated or closed from reapplying for approval for three years. It authorizes the BON to adopt rules related to nursing education programs, and to perform an on-site evaluation of a nursing education program applicant. Finally, it eliminates annual reports by the Office of Program Policy Analysis and Government Accountability on the status of nursing education programs, but requires the Florida Center for Nursing to issue the annual reports and include an assessment progress accreditation status for certain nursing programs

The bill makes various changes to many other programs at DOH. The bill:

- Authorizes DOH to request a date of birth on a licensure application and removes requirements for the size and forms of licenses
- Requires DOH to deny license renewal of an applicant who owes fines and costs imposed in a licensure disciplinary proceeding unless the applicant has received an extension of time to pay;
- Authorizes a regulatory board or DOH, if there is no board, to transfer funds from a profession's operating trust fund to cover a deficit related to prosecuting unlicensed activity and to waive licensure or renewal fees under certain circumstances;
- Authorizes DOH to administer the Conrad 30 Waiver program, which allows a limited number international physicians, employed by a facility in an underserved area, to waive certain federal requirements;
- Requires certain pain management clinics to register with DOH at no cost;
- Authorizes any entity approved by the BON to offer the required 3-hour continuing education class on the safe and efficient prescription of controlled substances;
- Requires an ARNP to maintain a copy of his or her protocol at the location the ARNP practices and if the ARNP works with multiple supervising physicians in a group practice, the ARNP has to enter into a protocol with at least one physician;
- 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;
- Establishes a path to licensure for certain students enrolled in physical therapist assistant programs;
- Updated national licensure examinations for marriage and family therapists; and
- Deletes obsolete language and makes technical changes.

The bill has an insignificant, indeterminate 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, 2017, except as otherwise expressly provided.

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

**STORAGE NAME:** h0543f.HHS

**DATE:** 4/3/2017

## FULL ANALYSIS

### I. SUBSTANTIVE ANALYSIS

#### A. EFFECT OF PROPOSED CHANGES:

##### Current Situation

The Division of Medical Quality Assurance (MQA), within the Department of Health (DOH), has general regulatory authority over health care practitioners.<sup>1</sup> 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.<sup>2</sup> 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

Under its general licensure authority, there are uniform provisions that apply to all licensure applications, regardless of profession. All applications must apply in writing, on an application form approved by DOH, which includes the individual's social security number.<sup>3</sup> DOH is required to issue a wallet-sized identification card to each licensee, as well as wall certificate measuring 6-1/2 inches by 5 inches. Both of these documents must be surrendered if a license is revoked or issued in error.

A board or DOH, if there is no board, may deny a license if the applicant:

- Is under prosecution or investigation in another jurisdiction for an action that would constitute a licensure violation under Florida law;
- Has been convicted of a felony related to the practice or ability to practice any health care profession; or
- Fails to appear before a board or DOH, if there is no board, when a personal appearance is required.<sup>4</sup>

##### Costs of Licensure Programs

It is the intent of the Legislature that the costs associated with regulating health care professions and health care practitioners be borne by the licensees and the licensure applicants.<sup>5</sup> The boards, in consultation with DOH, or DOH if there is no board, is required to set licensure renewal fees by rule which must:

- Be based on revenue projections;
- Be adequate to cover all expenses related to that board identified in the DOH's long-range plan;<sup>6</sup>

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<sup>1</sup> 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.

<sup>2</sup> Florida Department of Health, Division of Medical Quality Assurance, *Annual Report and Long-Range Plan, Fiscal Year 2015-2016*, available at <http://mqawebteam.com/annualreports/1516/#7/z> (last visited March 27, 2017).

<sup>3</sup> 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.

<sup>4</sup> Section 456.013(3), F.S.

<sup>5</sup> Section 456.025(1), F.S.

<sup>6</sup> Pursuant to s. 456.005, F.S., the long-range policy plan is used to facilitate efficient and cost-effective regulation by evaluating whether the DOH is operating efficiently and effectively and if there is a need for a board or council to assist in cost-effective regulation; how and why the various professions are regulated; whether there is a need to continue regulation and to what degree; whether or not consumer protection is adequate and how it can be approved; whether there is consistency between the various practice acts; and whether unlicensed activity is adequately enforced.

- Be reasonable, fair, and not serve as a barrier to licensure;
- Be based on potential earnings from working under the scope of the license;
- Be similar to fees imposed on similar licensure types; and
- Not be more than 10 percent greater than the actual cost to regulate that profession for the previous biennium.<sup>7</sup>

The chairpersons of the boards and councils must meet annually to review the long-range policy plan and the current and proposed fee schedules.<sup>8</sup> The chairpersons are required to make recommendations for any necessary statutory changes relating to fees and fee caps, which are to be included in DOH's annual report to the Legislature.

All funds collected by DOH from fees, fines, or costs awarded to the agency by a court are paid into the MQA Trust Fund.<sup>9</sup> DOH is prohibited from expending funds from one profession to pay expenses incurred on behalf of another profession, except that the Board of Nursing may pay for costs incurred in the regulation of Certified Nursing Assistants.<sup>10</sup>

### *Unlicensed Activity*

Florida law requires an individual wishing to provide health care or medical services to a patient in this state to meet standards for licensure, including minimum education, training, and experience requirements. Each profession has requirements for licensure by examination and licensure by endorsement if the practitioner is licensed in another jurisdiction. Unlicensed practice of a health care profession occurs when an individual delivers health care or medical services to a patient for which he or she does not have a valid, active license.<sup>11</sup>

If DOH has probable cause to believe an individual or entity is practicing a health care profession without a valid, active license, DOH may issue a cease and desist notice and impose an administrative penalty of up to \$5,000 per incident.<sup>12</sup> In addition to or in lieu of these administrative penalties, DOH may seek a civil penalty of \$500 to \$5,000 through a circuit court in this state. Unlicensed practice of a health care profession is also a crime.<sup>13</sup>

All health care professions share the cost of regulating unlicensed activity through a \$5 fee at the time of initial licensure.<sup>14</sup> The fee is credited to the MQA trust fund by profession in a separate category. If there is a positive balance in the unlicensed activity category at the end of a renewal cycle, the balance may be transferred to the profession's operating fund. However, there is no mechanism in statute to transfer funds from the operating fund of a profession to the unlicensed activity category if there is a negative balance in the latter.

<sup>7</sup> *Supra* note 5.

<sup>8</sup> Section 456.025(2), F.S.

<sup>9</sup> Section 456.025(8), F.S.

<sup>10</sup> *Id.*

<sup>11</sup> Section 456.065(1), F.S.

<sup>12</sup> Section 456.065(2), F.S.

<sup>13</sup> *Id.* An individual found to be practicing, attempting to practice, or offering to practice a health care profession without a valid, active Florida license in that profession commits a felony of the third degree. The minimum penalty is a fine of \$1,000 and a minimum mandatory period of incarceration of one year. It is a felony of the second degree to practice a health care profession without a valid, active Florida license to practice that profession when such practice results in serious bodily injury. The minimum penalty is a fine of \$1,000, and a minimum mandatory period of incarceration of one year. It is a misdemeanor in the first degree to practice, attempt to practice, or offer to practice a health care profession with an inactive or delinquent license for any period of time up to 12 months. However, practicing, attempting to practice, or offering to practice when that person's license has been inactive or delinquent for more than 12 months, is a felony of the third degree. The minimum penalty for a previously licensed practitioner practicing, attempting to practice, or offering to practice a profession is a \$500 fine and 30 days of incarceration.

<sup>14</sup> Section 456.065(3), F.S.

## Conrad 30 Waiver Program

Federal law requires a foreign physician pursuing 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.<sup>15</sup> 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.<sup>16</sup>

A state may only be issued 30 waivers per year and each state may develop its own applications rules and guidelines. Currently, there are 90 physicians practicing in Florida under the Conrad 30 Waiver program.<sup>17</sup> More than 70 percent, or nearly 450 physicians have remained in practice in Florida since the inception of the Conrad 30 Waiver Program.<sup>18</sup> Currently, Florida approves these waivers on a first come basis.

## Pain Management Clinics

Pain clinics are facilities or offices which advertise in any medium for any type of pain-management services or the majority of the patients are prescribed opioids, benzodiazepines, barbiturates, carisoprodol for the treatment of chronic nonmalignant pain.<sup>19</sup> Pain-management clinics are regulated by the practice acts for allopathic and osteopathic physicians in ss. 458.3265, and 459.0137, F.S. Pain clinics must register with DOH; however, the following entities are exempt from registration:

- Hospitals;
- Clinics primarily providing surgical services;
- Certain publicly held corporations;
- Clinics affiliated with medical schools;
- Clinics that do not prescribe controlled substances;
- Not-for-profit clinics;
- Clinics wholly owned and operated by one or more board-eligible or board-certified anesthesiologists, physiatrists, rheumatologists, or neurologists; or
- Clinics wholly owned and operated by one or more board-eligible or board-certified physicians who have completed certain fellowships in pain medicine.

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<sup>15</sup> 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 March 27, 2017).

<sup>16</sup> Id.

<sup>17</sup> E-mail correspondence with DOH staff dated April 3, 2017, (on file with the Health and Human Services Committee).

<sup>18</sup> Department of Health, *2016 Physician Workforce Annual Report*, (November 2016), available at <http://www.floridahealth.gov/provider-and-partner-resources/community-health-workers/physician-workforce-development-and-recruitment/2016%20DOH%20Physician%20Workforce%20Report.pdf> (last visited April 2, 2017).

<sup>19</sup> Chronic nonmalignant pain is defined as pain unrelated to cancer which persists beyond the usual course of disease or the injury that is the cause of the pain or more than 90 days after surgery. Section 458.3265(1)(a)1.b., F.S.

Pain-management clinics are subject to annual inspection and are subject to registration revocation and fines of up to \$5,000 per day for violations. The registration fee is \$150, and the annual inspection fee is \$1,500.<sup>20</sup>

Each clinic must designate a physician who is responsible for complying with the registration and other requirements in law.<sup>21</sup> This designated, fully licensed physician must practice at the clinic, and if the clinic does not have this designated physician, the clinic is at risk for summary suspension.<sup>22</sup> The designated physician is responsible for ensuring compliance with quality assurance<sup>23</sup> and reporting requirements.<sup>24</sup>

Every physician practicing in a pain-management clinic must ensure compliance with a list of requirements, which relate to clinic access, clinic infrastructure, patient privacy, clinic security,<sup>25</sup> infection control,<sup>26</sup> clinic safety, and clinic personnel.<sup>27</sup> However, these requirements do not supersede the standard of care, skill, and treatment required of physicians recognized in general law related to health care licensure.<sup>28</sup>

Since not all pain management clinics are required to be registered, DOH faces some difficulty in determining which clinics are exempt from registration and which are operating illegally.

### Advanced Registered Nurse Practitioners

Part I of ch. 464, F.S., governs the licensure and regulation of advanced registered nurse practitioners (ARNPs) in Florida. Nurses are licensed by the Department of Health (DOH) and are regulated by the Board of Nursing (BON).<sup>29</sup> There are 26,691 actively licensed ARNPs in Florida.<sup>30</sup>

In Florida, an ARNP is a licensed nurse who is certified in advanced or specialized nursing practice and may practice as a certified registered nurse anesthetist, a certified nurse midwife, or a nurse practitioner.<sup>31</sup> Advanced or specialized nursing practice includes the performance of advanced-level nursing acts approved by the BON, which by virtue of postbasic specialized education, training, and experience are appropriately performed by an ARNP.<sup>32</sup> In addition to advanced or specialized nursing practices, ARNPs are authorized to practice certain medical acts, as opposed to nursing acts, as authorized within the framework of an established supervisory physician's protocol.<sup>33</sup>

The BON establishes the eligibility criteria for an applicant to be certified as an ARNP and the applicable regulatory standards for ARNP nursing practices.<sup>34</sup> To be certified as an ARNP, the applicant must be licensed as a registered nurse, have a master's degree in a clinical nursing specialty area with preparation in specialized practitioner skills, and submit proof that the applicant holds a

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<sup>20</sup> Rule 64B-7.001, F.A.C.

<sup>21</sup> SS. 458.3265(1)(c) and 459.0137(1)(c), F.S.

<sup>22</sup> Id.

<sup>23</sup> SS. 458.3265(2)(i) and 459.0137(2)(i), F.S.

<sup>24</sup> SS. 458.3265(2)(j) and 459.0137(2)(j), F.S.

<sup>25</sup> SS. 458.3265(2)(f)(1.) and 459.0137(2)(f)(1.), F.S.

<sup>26</sup> SS. 458.3265(2)(g) and 459.0137(2)(g), F.S.

<sup>27</sup> SS. 458.3265(2)(h) and 459.0137(2)(h), F.S.

<sup>28</sup> SS. 458.3265(2)(f)(2.) and 459.0137(2)(f)(2.), F.S.

<sup>29</sup> Pursuant to s. 464.004, F.S., the Board of Nursing is comprised of 13 members appointed by the Governor and confirmed by the Senate who serve 4-year terms. The Board is comprised of three licensed practical nurses who have practiced for at least four years, seven members who are registered nurses who have practiced for at least 4 years; three Florida residents who have never been licensed as nurses, are not connected to the practice of nursing, and have no financial interest in any health care facility, agency, or insurer; and seven members who are registered nurses who have practiced at least four years. Among the seven members who are registered nurses, there must be at least one must be an ARNP, one nurse educator of an approved program, and one nurse executive.

<sup>30</sup> E-mail correspondence with the Department of Health on February 2, 2017 (on file with the staff of the Health Innovation Subcommittee). This number includes all active licenses, including out-of-state practitioners.

<sup>31</sup> S. 464.003(3), F.S.

<sup>32</sup> S. 464.003(2), F.S.

<sup>33</sup> Id.

<sup>34</sup> S. 464.012(2), F.S.

current national advanced practice certification from a board-approved nursing specialty board.<sup>35</sup> The nursing specialty board must:

- Attest to the competency of nurses in a clinical specialty area;
- Require nurses to take a written examination prior to certification;
- Require nurses to complete a formal program prior to eligibility for examination;
- Maintain program accreditation or a review mechanism that adheres to criteria which are substantially equivalent to requirements in Florida; and
- Identify standards or scope of practice statements appropriate for each nursing specialty.<sup>36</sup>

An ARNP must enter into a written supervisory protocol with a physician which is filed with the BON biennially with license renewal and within 30 days after entering into a supervisory relationship with a physician or changes to the protocol. Within the framework of the written protocol, an ARNP may:

- Prescribe, dispense, administer, or order any drug;<sup>37</sup>
- Initiate appropriate therapies for certain conditions;
- Perform additional functions as may be determined by board rule;
- Order diagnostic tests and physical and occupational therapy;
- Order any medication for administration to a patient in certain licensed health care facilities;
- Perform certain acts within his or her specialty; and
- Perform medical acts authorized within the framework of an established protocol.<sup>38</sup>

All nurses are required to complete at least 30 hours of continuing education biennially as a condition of license or certificate renewal.<sup>39</sup> As a part of these 30 hours, ARNPs must complete 3 hours of continuing education on the safe and effective prescription of controlled substances, offered by a statewide professional association of physicians in this state accredited to provide educational activities designated for the American Medical Association Physician's Recognition Award Category 1 credit, the American Nurses Credentialing Center, the American Association of Nurse Anesthetists, or the American Association of Nurse Practitioners.

### Nursing Education Programs

To be licensed as a registered nurse (RN) or a practical nurse (LPN) in this state, an individual must, among other things, graduate from an accredited or a BON-approved nursing program or its equivalent.<sup>40</sup> A registered nurse is authorized to practice professional nursing<sup>41</sup> and an LPN is authorized to practice practical nursing.<sup>42</sup>

Nursing programs in Florida are offered by public school districts, Florida colleges, state universities, private institutions licensed by the Commission for Independent Education, private institutions that are

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<sup>35</sup> S. 464.012(1), F.S., and Rule 64B9-4.002, F.A.C.

<sup>36</sup> Rule 64B9-4.002(3), F.A.C.

<sup>37</sup> Controlled substances may only be prescribed or dispensed if the ARNP has graduated from a program leading to a master's or doctoral degree in a clinical specialty area with training in specialized practitioner skills.

<sup>38</sup> SS. 464.012(3),(4), and 464.003(2), F.S.

<sup>39</sup> S. 464.013(3), F.S.

<sup>40</sup> S. 464.008(1)(c), F.S.

<sup>41</sup> The practice of professional nursing means the performance of those acts requiring substantial specialized knowledge, judgment, and nursing skills, including observation, assessment, nursing diagnosis, planning, intervention, and evaluation of care; teaching and counseling of the ill, injured, or infirm; promotion of wellness, maintenance of health, prevention of illness in others; and the administration of medication and treatment as authorized or prescribed. A RN is responsible and accountable for making decisions that are based upon the individual's educational preparation and experience in nursing. (Ss. 464.003(20) and (22), F.S.)

<sup>42</sup> The practice of practical nursing means the performance of selected acts in the care of the ill, injured, or infirm; the promotion of wellness, maintenance of health, and prevention of illness of others under the direction of a registered nurse, a licensed physician, or a licensed dentist. An LPN is responsible and accountable for making decisions that are based upon the individual's educational preparation and experience in nursing (Ss. 464.003(16) and (19), F.S.).

members of the Independent Colleges and Universities of Florida (ICUF), and Pensacola Christian College, which is statutorily authorized by s. 1005.06(1)(e), F.S.<sup>43</sup>

### *Board-Approved Nursing Education Programs*

To be an approved program, an educational institution must apply to DOH. An application to become an approved program must document compliance with program standards for faculty qualifications, clinical training requirements, written policies for faculty, signed agreements with clinical training sites in the curriculum plan, and curriculum and instruction requirements.<sup>44</sup>

An application deemed complete by the DOH is forwarded to the BON for approval. Within 90 days of receipt of the application by the DOH, the BON must approve the application or notify the applicant of the intent to deny the application. If noticed of the intent to deny, the applicant may request a hearing under chapter 120, F.S.<sup>45</sup>

An approved program's curriculum must consist of at least 50 percent clinical training for an associate's degree RN program or at least 40 percent clinical training for a bachelor's degree RN program.<sup>46</sup> No more than 50 percent of an approved program's clinical training may consist of clinical simulation.<sup>47</sup>

Approved programs must submit an annual report by November 1 of each year to the BON. The report must document application and enrollment, student retention rates, and accreditation status.<sup>48</sup> The BON must publish on its website for each program its:

- Accreditation status;
- Probationary status;
- Graduate passage rate on the National Council on State Boards of Nursing Licensing Examination (NCLEX) for the most recent two calendar years;
- Student retention rates;
- Annual report summary; and
- Application documentation.<sup>49</sup>

If the nursing education program fails to submit its annual report, the director of the nursing education program must appear before the BON, at its next regularly scheduled meeting, to explain the reason for the delay. If the annual report is not submitted within six months of its due date, the BON must terminate the program.<sup>50</sup>

### *Accountability Requirements*

An approved program may not have a graduate passage rate for first-time takers who sit for the licensure examination within six months of graduation that is 10 percentage points or more below the national average for two consecutive years.<sup>51</sup> If a program fails to meet the required graduate passage rate, the program is placed on probation by the BON and the program must present a plan for

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<sup>43</sup> This section of law exempts schools from the Commission for Independent Education's licensure requirements if the institution: had been so exempted prior to 2001; is incorporated in this state; the institution's credits or degrees are accepted for credit by at least three colleges that are fully accredited by an agency recognized by the U.S. Department of Education; the institution was exempt under that category prior to July 1, 1982; and the institution does not enroll any students who receive state or federal financial aid. Only two institutions in Florida, Pensacola Christian College and Landmark Baptist College, are subject to this exemption. Landmark Baptist College does not offer a nursing program.

<sup>44</sup> S. 464.019(1), F.S.

<sup>45</sup> S. 464.019(2), F.S.

<sup>46</sup> S. 464.019(1)(b), F.S.

<sup>47</sup> S. 464.019(1)(c), F.S.

<sup>48</sup> S. 464.019(3), F.S.

<sup>49</sup> S. 464.019(4), F.S.

<sup>50</sup> S. 464.019(5), F.S.

<sup>51</sup> Id.

remediation to the BON, which includes specific benchmarks for achieving the required graduate passage rate. If a program on probation does not achieve the required graduate passage rate for any one calendar year during the two calendar years it is on probation, the BON must terminate the program.<sup>52</sup> However, the BON is authorized to extend the probationary status for an additional year if the program demonstrates progress toward the graduate passage rate goal by meeting the majority of the benchmarks established in the remediation plan.<sup>53</sup>

### *Accredited Nursing Education Programs*

To qualify as an accredited program, a nursing education program must be accredited by a specialized nursing accrediting agency that is nationally recognized by the United States Secretary of Education to accredit nursing education programs.<sup>54</sup> Because accredited programs have to meet stringent criteria to maintain program accreditation, many of the statutory requirements for approved programs are not applicable to accredited programs.<sup>55</sup> However, an accredited program is subject to the accountability requirements.

If an accredited program ceases to be accredited, it must, within 10 business days, provide written notice to the BON, its students and applicants, and its clinical training sites.

In 2014, legislation was enacted that required all nursing education programs that prepare students to be RNs to become accredited by July 1, 2019, or within 5 years after the enrollment of the program's first students.<sup>56</sup>

Accredited programs' accreditation status and graduate NCLEX passage rates must be published on the BON website.<sup>57</sup>

### *Reform of Nursing Education Programs*

In 2009, the Legislature created a statutory framework for the approval of nursing education programs.<sup>58</sup> Prior to 2009, the BON had the authority to prescribe the process by rule. The new law:

- Established standards for faculty qualifications, clinical training and clinical simulation requirements, and curriculum and instruction requirements;
- Required all nursing education programs to submit an annual report to the BON, including information that the BON must publish on its website;
- Required the BON to place an approved nursing education program on probation if its graduate passage rate fell 10 percent or more below the national average passage rate on the NCLEX for two consecutive years;
- Required the BON to terminate a program if the approved nursing education program's graduates failed to achieve compliance within the next two consecutive years; and
- Required the Florida Center on Nursing and the Office of Program Policy Analysis and Government Accountability (OPPAGA) to monitor the implementation of the new approval process and to annually report to the Governor and the Legislature regarding the approval process, nursing program availability and quality, and the BON's compliance with the law.

In 2010, the Legislature made additional changes to the nursing education program approval process to address implementation issues.<sup>59</sup> These changes included:

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<sup>52</sup> Id.

<sup>53</sup> Id.

<sup>54</sup> S. 464.003(1), F.S.

<sup>55</sup> S. 464.019(9), F.S.

<sup>56</sup> Chapter 2014-92, Laws of Fla.

<sup>57</sup> Supra, note 49.

<sup>58</sup> Chapter 2009-168, Laws of Fla.

<sup>59</sup> Chapter 2010-37, Laws of Fla.



- Requiring the BON to approve or deny a nursing education program application within 90 days after receipt of a complete application;
- Specifying that a program may be removed from probation if its graduates attain the required passage rate after one calendar year during the probation period;
- Making the passage rate requirement adopted in 2009 prospective so that it would apply beginning with the 2010 calendar year; and
- Clarifying that the graduate passage rate must be 10 percentage points or more below the national average passage rate on the NCLEX for two consecutive years, rather than 10 percent below the national average passage rate.

In 2014, the Legislature made additional revisions to the requirements for nursing education programs.<sup>60</sup> These revisions included:

- Authorizing the BON to adopt rules for documenting nursing education program accreditation;
- Requiring all nursing education programs that prepare students as RNs to be accredited by a nationally recognized accreditation agency by July 2019, or within 5 years of the date of enrollment of the program's first students;
- Requiring the Florida Center for Nursing and OPPAGA to submit the annual report to the Governor and the Legislature until January 2020;
- Limiting the graduate passage rate requirement to only those students who take the licensure examination for the first time within six months of graduation;
- Requiring an approved program to require any graduate who does not take the licensure examination within six months of graduation to enroll in and successfully complete a licensure examination preparatory course;
- Requiring programs on probation to develop and submit a remediation plan for attaining the required graduate passage rate, including benchmarks; and
- Authorizing the BON to extend a nursing education program's probationary status for one additional year if the program shows adequate progress towards the achieving the graduate passage rate by meeting a majority of the benchmarks established in the remediation plan.

### *Current Status of Nursing Education Programs*

Since 2009, the BON has approved 303 new nursing programs. Currently, the total number of nursing education programs is 350,<sup>61</sup> which is down from the 369 open nursing programs in 2015. Overall, there has been a 105 percent increase in the number of nursing education programs since 2009. Of the nursing education programs in this state, 93 are accredited.<sup>62</sup>

In 2015, 128 nursing education programs (or 42 percent) had graduate passage rates that were 10 percent or below the national average rate.<sup>63</sup> The majority of these programs were associate degree programs; however, 27 percent were practical nursing programs and 10 percent were Bachelor of Science in nursing programs. Of the 128 programs that failed to meet the graduate passage rate:

- 14 were placed on probation;
- 11 were terminated by the BON;
- 11 were exempt from being placed on probation because they were accredited;

<sup>60</sup> Chapter 2014-92, Laws of Fla.

<sup>61</sup> OPPAGA, *Review of Florida's Nursing Education Programs, 2016*, Report No. 17-03 (January 2017), available at <http://www.oppaga.state.fl.us/MonitorDocs/Reports/pdf/1703rpt.pdf> (last visited February 15, 2017). The total number takes into account new approvals, terminations, and closures of nursing education programs that have occurred since 2009.

<sup>62</sup> Id. 40 bachelor's degree programs, 43 associate degree programs, and 10 practical nursing programs are accredited.

<sup>63</sup> OPPAGA, *Approximately 42% of Nursing Programs Had a Licensure Exam Passage Rate Below the Required Legislative Standard in 2015*, Report No. 16-05 (July 2016), available at <http://www.oppaga.state.fl.us/MonitorDocs/Reports/pdf/1605rpt.pdf> (last visited February 18, 2017).

- 55 were not on probation, but were at risk of being placed on probation if their graduate passage rate continues to be 10 percent or more below the national average in 2016; and
- 37 closed.<sup>64</sup>

According to OPPAGA, the majority of the nursing programs that failed to meet the graduate passage rate requirement were relatively new and unaccredited.<sup>65</sup>

In 2016, there were 42 programs on probation for failing to meet the graduate exam passage rate and 50 nursing education programs closed.<sup>66</sup> Of those 50 closed programs, 37 programs closed voluntarily and 13 programs were terminated by the BON; 22 of these programs were on probation immediately prior to their termination or closure.

### Pharmacy Regulation

Chapter 465, F.S., regulates pharmacies in Florida and contains the minimum requirements for safe practice.<sup>67</sup> 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.<sup>68</sup>
- 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.<sup>69</sup>
- 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.<sup>70</sup>
- 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.<sup>71</sup>
- 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.<sup>72</sup>

### *Compounding*

Compounding is the professional act by a pharmacist or other practitioner authorized by law, employing the science or art of any branch of the profession of pharmacy, incorporating ingredients to create a finished product for dispensing to a patient or for administration by a practitioner or the practitioner’s agent.<sup>73</sup>

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

<sup>64</sup> Id.

<sup>65</sup> Id.

<sup>66</sup> Supra, FN 37.

<sup>67</sup> S. 465.002, F.S.

<sup>68</sup> SS. 465.003(11)(a)1. and 465.018, F.S.

<sup>69</sup> SS. 465.003(11)(a)2. and 465.019, F.S.

<sup>70</sup> SS. 465.003(11)(a)3. and 465.0193, F.S.

<sup>71</sup> SS. 465.003(11)(a)4. and 465.0196, F.S.

<sup>72</sup> SS. 465.003(11)(a)5. and 465.0197, F.S.

<sup>73</sup> Rule 64B16-27.700, F.A.C.

safety.<sup>74</sup> Nonsterile compounding includes capsules, ointments, creams, gels, and suppositories that do not require a sterile preparation environment.<sup>75</sup>

### *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.<sup>76</sup> Stand-alone special parenteral/enteral pharmacies and special parenteral/enteral extended scope pharmacies are not required to obtain the SSCP.<sup>77</sup>

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).<sup>78</sup>

### *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 product<sup>79</sup> into this state. Any compounded product sent into this state must meet or exceed Florida's standards for sterile compounding.<sup>80</sup> 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;<sup>81</sup>
- 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:

<sup>74</sup> 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 March 28, 2017).

<sup>75</sup> 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 March 28, 2017).

<sup>76</sup> 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 March 28, 2017). 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 March 28, 2017).

<sup>77</sup> Rule 64B16-28.100, F.A.C.

<sup>78</sup> Rule 64B16-28.802, F.A.C.

<sup>79</sup> 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.

<sup>80</sup> S. 465.0158, F.S.

<sup>81</sup> 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.

- 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.<sup>82</sup>

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.

### *End Stage Renal Dialysis Special Pharmacy Permit*

The Board of Pharmacy recognizes six types of pharmacy permits, including Special Pharmacy - End Stage Renal Dialysis (ESRD).<sup>83</sup> The Special Pharmacy – ESRD is a special pharmacy which is limited to the provision of dialysis<sup>84</sup> products and supplies to persons with chronic kidney failure<sup>85</sup> for self-administration at the person's home or specified address.<sup>86</sup> To obtain a permit to operate a special pharmacy, the applicant must:

- Complete an application and pay a \$255 application fee;
- A legible set of fingerprint cards for each person having an ownership interest of at least 5 percent and any person who, directly or indirectly, manages, oversees, or controls the operation of the pharmacy, including officers and members of the board of directors, if the applicant is a corporation;
- Pass an on-site inspection;
- Provide written policies and procedures for preventing and controlled substance dispensing based on fraudulent representations or invalid practitioner-patient relationships; and
- Designate a prescription department manager or consultant pharmacist of record.<sup>87</sup>

Hemodialysis may be performed at a dialysis center or in the patient's home, and peritoneal dialysis is performed in the patient's home. Generally, a training nurse will teach the patient and his or her caregiver how to properly care for the dialysis equipment, run the dialysis procedure, store and order supplies, and recognize and report problems, among other topics.<sup>88</sup>

<sup>82</sup> S. 465.0158 (3), F.S.

<sup>83</sup> Rule 64B16-28.100(5)(d), F.A.C.

<sup>84</sup> Dialysis is a treatment employed to perform the work of kidneys that are no longer functioning properly. There are two types of dialysis – hemodialysis and peritoneal dialysis, both of which may be performed at home. National Kidney Foundation, *Dialysis*, available at <https://www.kidney.org/atoz/content/dialysisinfo> (last visited March 28, 2017).

<sup>85</sup> Chronic kidney disease is a condition in which a person gradually loses kidney function over time. The National Kidney Foundation divides kidney disease into five different stages representing progressively higher loss of kidney function. Two of the primary causes of chronic kidney disease are diabetes and high blood pressure, which account for nearly two-thirds of cases. National Kidney Foundation, *About Chronic Kidney Disease*, available at <https://www.kidney.org/kidneydisease/aboutckd> (last visited March 28, 2017).

<sup>86</sup> Rule 64B16-28.100(5)(d)4., F.A.C.

<sup>87</sup> Rule 64B16-28.100(1) and (5), F.A.C.

<sup>88</sup> Home Dialysis Central, *Daily Home Dialysis*, available at <http://homedialysis.org/home-dialysis-basics/daily-home-hemodialysis>, and *Peritoneal Dialysis*, available at <http://homedialysis.org/home-dialysis-basics/peritoneal-dialysis> (last visited March 28, 2017).

A manufacturer that engages solely in the manufacture or distribution of dialysate, drugs, or devices necessary to perform home renal dialysis on a patient with chronic failure is exempt from pharmacy permitting requirements.<sup>89</sup> To qualify for the exemption, the dialysate, drugs, or devices must be:

- Approved or cleared by the FDA; and
- Delivered in the original, sealed packaging after receipt of a physician's order to:
  - A patient with chronic kidney failure, or the patient's designee, for the patient's self-administration of dialysis therapy; or
  - A health care practitioner or an institution for administration or delivery of dialysis therapy to a patient with chronic kidney failure.

Although a manufacturer of such products is not required to obtain a Special Pharmacy – ESRD permit, a third party logistics provider that provides warehousing and distribution services to a manufacturer is subject to permitting requirements.

### Orthotists and Prosthetists

The Board of Orthotists and Prosthetists<sup>90</sup> oversees the licensure and regulation of orthotists<sup>91</sup> and prosthetists.<sup>92</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>93,94</sup> 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.<sup>95</sup>

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 appropriate internship of one year of qualified experience or a residency program recognized by the board;
- Completion of the mandatory classes;<sup>96</sup> and

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<sup>89</sup> S. 465.027, F.S.

<sup>90</sup> The Board of Orthotists and Prosthetists is composed of seven members appointed by the Governor and confirmed by the Senate. It is composed of two licensed prosthetists, one orthotist, two public members who are prosthetic or orthotic users who have no financial interest in prosthetics or orthotics, one physician, and one member who is licensed as an orthotist, orthotic fitter, or pedorthist.

<sup>91</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 pedorthics. (S. 486.80(9)-(10), F.S.)

<sup>92</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 a prosthesis. (S. 486.80(15)-(16), F.S.)

<sup>93</sup> S. 486.803(4), F.S.

<sup>94</sup> The board has approved the American Board for Certification in Orthotics, Prosthetics, and Pedorthics (ABC) exam for orthotist and prosthetist applicants. (Rule 64B14-4.001, F.A.C.)

<sup>95</sup> S. 486.803(2), F.S.

<sup>96</sup> 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.

- 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.<sup>97</sup>

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

### *Continuing Education Requirements*

At the time of licensure and for each biennial licensure period, an orthotist or prosthetist must complete several mandatory classes that serve to safeguard the welfare of the public.<sup>98</sup> The mandatory classes 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.<sup>99</sup> Orthotists and prosthetists find it difficult to find medical error courses that address the specific needs of their respective professions.

### Physical Therapist Assistants

A physical therapist assistant (PTA) is an individual who performs patient-related activities, including the use of physical agents, under the direction of a physical therapist.<sup>100</sup> To be licensed as a PTA, an applicant must graduate from a school that provides at least a two-year course of study for the preparation of physical therapy assistants.<sup>101</sup> The course must be recognized by the appropriate accrediting agency recognized by the Commission on Recognition of Postsecondary Accreditation or the United States Department of Education at the time of graduation. An applicant must also pass a board-approved examination to determine his or her fitness to practice.

In 2016, the Legislature repealed a provision that allowed PTA programs to be regionally accredited in an effort to standardize the programs in the state and ensure that graduates of such programs would meet the standards established by Medicare to provide services to its enrollees.<sup>102</sup> However, students enrolled in regionally accredited programs at the time of the repeal, or graduated shortly thereafter, are currently ineligible for licensure.

### Licensed Mental Health Counselor

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>103</sup> Mental health counselors are regulated by the Board of Clinical Social Work, Marriage and Family Therapy, and Mental Health Counseling, within DOH, under ch. 491, F.S. To qualify for licensure as a mental health counselor, an individual must:

- 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 practicum, internship, or fieldwork of at least 60 semester hours or 80 quarter hours that meet certain requirements;

<sup>97</sup> S. 486.803(5), F.S. Licenses must be renewed biennially.

<sup>98</sup> S. 468.806(3), F.S.

<sup>99</sup> Rule 64B14-5.005, F.A.C.

<sup>100</sup> S. 486.021, F.S. Patient-related activities performed by a PTA for a board-certified orthopedic physician, psychiatrist, or chiropractor are done so under the general supervision of a physical therapist and does not require onsite supervision. However, such activities performed for podiatrist or dentists must be done under the onsite supervision of the physical therapist.

<sup>101</sup> S. 486.102, F.S.

<sup>102</sup> Chapter 2016-230, Laws of Fla.

<sup>103</sup> SS. 491.003(6) and (9), F.S.

- 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>104</sup>

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. The bill removes the requirement that DOH issue a wallet-sized license and the wall certificate of a specified size. DOH will be able to determine the most efficient method of providing licenses to licensees.

The bill authorizes a board or DOH, if there is no board, to deny an applicant if the applicant has not timely paid fines or costs imposed by a final order in a disciplinary proceeding, has a delinquent or void license, or has relinquished a license in any way, until such unpaid fees or costs are paid. Additionally, all delinquency fines and other fees associated with failure to timely renew a license must be paid in full. However, a board or DOH, if there is no board, may reinstate a license or issue a license with conditions that allow for the repayment of outstanding fines and costs imposed by a final order.

DOH may deny a licensure renewal if a licensee has not timely paid fines and costs imposed in a final order in a disciplinary proceeding unless a board or DOH, if there is no board, has granted a licensee an extension in the time to pay the fines and costs.

Under the bill, DOH must deny the renewal of a massage therapy licensee who has been convicted or found guilty of, or enters a plea of guilty or nolo contendere to, regardless of adjudication, of certain felonies and certain offenses related to prostitution. Current law provides that board has the authority to deny a license renewal in such circumstances.

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.

### **Costs of Regulation Programs**

The bill authorizes a board, or DOH if there is no board, to adopt rules waiving the application, licensure, unlicensed activity, or renewal fees for up to 2 years if based on projected revenue, the profession's trust fund balance will exceed the cost to regulate the profession. The bill authorizes DOH, with the concurrence of the affected regulatory board, to transfer funds from a profession's operating fund to cover a deficit in unlicensed activity category within the profession's cash balance.

### **Conrad 30 Waiver Program**

The bill authorizes DOH to adopt rules to implement the Conrad 30 Waiver program in this state. Under the federal law, each state may develop its own application rules and guidelines.

<sup>104</sup> S. 491.005(4), F.S., and r. 64B4-3.0035, F.A.C.  
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## Pain Management Clinics

The bill expands the pain management clinic registration requirement to include those that are exempt from registration under current law. However, these entities will be exempt from registration and inspection fees and other regulatory requirements. Registration of all pain management clinics will assist DOH with its regulation of pain clinics that are not registered and operating in violation of state law.

## Advanced Registered Nurse Practitioners

The bill deletes an obsolete provision of law that permitted a nurse to be certified as an ARNP if he or she completed a formal postbasic educational program of at least one academic year, the primary purpose of which is to prepare a nurse for advanced or specialized practice. Currently, to obtain certification as an ARNP in this state, an applicant must have a master's degree in a nursing clinical specialty area and hold a current national advanced practice certification from a board-approved nursing specialty board.<sup>105</sup> Due to the current graduate education and certification standards, the option to obtain certification as an ARNP by completing an additional postbasic educational program of at least one academic year is no longer in use.<sup>106</sup>

Under the bill, an ARNP would no longer be required to submit a copy of his or her supervisory protocol to the BON; but rather, keep a copy of the written protocol at the location he or she practices. The bill authorizes an ARNP who works with multiple physicians within the same group practice, to have a single supervisory protocol with a physician within the group practice.

The bill eliminates the requirement that specific entities offer the continuing education course on safe and effective prescription of controlled substances and requires such courses to be approved by the BON. As a result, ARNPs will likely have more opportunities to satisfy this continuing education requirement as more BON-approved entities provide the course.

## Nursing Education Programs

For a nursing education program applicant, the bill authorizes the Board of Nursing (BON) to perform an onsite inspection of the nursing education program to document the applicant's compliance with program requirements.

The bill amends the accountability requirements for nursing schools by:

- Including all first-time test takers in the calculation of the graduate passage rate, rather than limiting it to only those that are within six months of graduation;
- Eliminating a requirement that an approved program require a graduate who does not take the licensure examination within six months of graduate to complete a licensure examination preparatory course;
- Clarifying that the BON has the authority to extend a nursing education program's probationary status for another calendar year if, during the two calendar years following its placement on probationary status, it fails to achieve the required passage rate but has demonstrated progress toward meeting the graduate passage rate goal;
- Clarifying that the BON retains the authority to terminate a nursing education program if it declines to grant an extension of probationary status or if the program fails to achieve the required graduation passage rate at the end of any such extension.

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<sup>105</sup> The bills provides that the proposed provision is effective after the Nurse Licensure Compact takes effect on December 31, 2018, or upon enactment of the Nurse Licensure Compact into law by 28 states, whichever occurs first.

<sup>106</sup> DOH, *Agency Legislative Bill Analysis for HB 543*, dated January 15, 2017, (on file with the Health Innovation Subcommittee).



- Authorizing the BON to terminate a program if the program director fails to appear before the BON to explain the reason for the delay in submitting the required annual report, or if the program fails to submit an annual report within six months after it is due; and
- Requiring a nursing education program, whether accredited or non-accredited, that is on probationary status to disclose the program's status, in a written format, to students and applicants. The written notification must include an explanation of the implication of the program's probationary status on employment and educational opportunities, as well as the prospects for a student wishing to matriculate to university.

The bill exempts accredited schools from the requirement to appear before the BON if they fail to timely submit the annual report.

The bill prohibits a nursing education program that is terminated or closed from seeking program approval under its original name or a new name for at least 3 years after the program is closed or terminated.

If a nursing education program fails to meet the accreditation requirements, the program must be terminated and may not apply for reapproval under its original name or a new program name for at least 3 years after the program is termination.

The BON is authorized to adopt rules related to the nursing curriculum and nursing program implementation plans, which may include a description of the various types and uses of simulation technology and limitations on its use. The bill also authorizes the BON to adopt rules related to program termination or closure under this section and the procedure for the subsequent approval of a program that was terminated or closed.

The bill eliminates the annual reports due to the Governor and the Legislature by OPPAGA related to nursing education programs; however, the Florida Center for Nursing must continue to provide such reports until January 2020. Additionally, the Florida Center for Nursing must include in its annual report an assessment of the compliance of nursing programs that are required to be accredited. The bill repeals a requirement that OPPAGA performs the annual report duties assigned to the Florida Center for Nursing in any state fiscal year in which the Florida Center for Nursing does not receive a legislative appropriation.

## Regulation of Pharmacies

### *In-State Sterile Compounding Permit*

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. 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. The bill expressly gives DOH authority to issue an in-state sterile compounding permit.

Under the bill, a pharmacy or outsourcing facility located in this state that dispenses, creates, delivers, ships, or mails a compound sterile product must obtain a sterile compounding permit. If, upon receipt of an application, DOH verifies that the application complies with the laws and rules governing pharmacies, DOH must issue the permit. 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.

### *Third-Party Logistics Providers*

The bill extends the current exemption from pharmacy permitting requirements that certain manufacturers of dialysis drugs or devices currently have to third party logistics providers holding an active permit under ch. 499, F.S. A third party logistics provider is an entity that contracts with a prescription drug manufacturer or wholesale distributor to provide warehousing, distribution or other logistic services on behalf of the manufacturer, distributor, dispenser but does not take title to the prescription drug or have responsibility to direct the sale or disposition of the drug.

### Orthotists and Prosthetists

The bill authorizes the Board of Orthotists and Prosthetists to issue a single license for a 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 recognized by the Commission on Accreditation of Allied Health Education Programs or a bachelor's degree from an accredited college or university and a certificate in orthotics and prosthetics from a program recognized by the Commission on Accreditation of Allied Health Programs;
- Complete an approved orthotics-prosthetics internship of at least 1 year of qualified experience, or a board-approved orthotics-prosthetics residency program;
- Complete the mandatory courses; and
- Successfully complete one of the following:
  - The state prosthetics-orthotics examination;
  - The board-approved prosthetics examination and the board-approved orthotics examination; or
  - If available, the board-approved prosthetics-orthotics examination.

The fee for the single license may not exceed \$1,000.

A prosthetist or orthotist must register with the Board of Orthotists and Prosthetists as a resident to practice prosthetics or orthotics, respectively. For a 12 month residency, the board may not approve a second registration until at least one year after the issuance of the first registration. However, for an 18-month residency, registration as a prosthetist and registration as an orthotist may be held concurrently, resulting in less time to complete a residency as a prosthetist-orthotist.

The bill reduces the required prevention of medical errors course from two hours to one hour.<sup>107</sup> The course must be approved by the Board of Orthotists and Prosthetists, be specifically developed for the field of orthotics and prosthetics, and include a study of root-cause analysis, error reduction and prevention, patient safety, and medical records.

### Physical Therapist Assistants

Due to a change in the accreditation requirements for physical therapist assistant programs in 2016, an individual who was enrolled in a program that was regionally accredited at the time of enrollment is

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<sup>107</sup> S. 456.013(7), F.S., requires health care practitioners licensed by MQA must complete a two-hour course on the prevention of medical errors as a part of the biennial licensure renewal process.

currently ineligible to be licensed as a physical therapist assistant. The bill creates a pathway to licensure for certain individuals affected by the change in law. The bill authorizes DOH to license applicants who were enrolled in any accredited physical therapist assistant program in this state, including regionally accredited programs, between July 1, 2014, and July 1, 2016. The applicants must graduate by July 1, 2018, and pass, to the satisfaction of the Board of Physical Therapy, an examination to determine his or her fitness to practice.

### Mental Health Counselors

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.

### Technical Amendments

The bill also makes various technical corrections to the statutes.

In 2016, the Legislature eliminated a joint committee of the Board of Nursing, Board of Medicine and Board of Osteopathic Medicine that determined the minimum standards for protocols for ARNPs.<sup>108</sup> The bill deletes an obsolete reference to this committee in s. 458.348(2), F.S.

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.

Section 395.3025(4), F.S., authorizes the Agency for Health Care Administration (AHCA) to subpoena hospital records if conducting an investigation under s. 456.071, F.S., which is part of the general licensure laws for health care practitioners under DOH. The reference to AHCA is obsolete, from a time when these functions were combined under AHCA. The bill changes "agency" to "department" to eliminate confusion as to whether DOH has the authority to subpoena such records.

The bill provides an effective date of July 1, 2017, except as otherwise expressly provided in the bill. The bill's provision updating the requirements for ARNP licensure will supersede the Nurse Licensure Compact when it becomes effective on December 31, 2018, or upon enactment of the Nurse Licensure Compact in 28 states.<sup>109</sup>

## **B. SECTION DIRECTORY:**

**Section 1:** Amends s. 381.4018, F.S., relating to physician workforce assessment and development.

**Section 2:** Amends s. 395.3025, F.S., relating to patient and personnel records; copies; examination.

**Section 3:** Amends s. 456.013, F.S., relating to department; general licensing provisions.

**Section 4:** Amends s. 456.025, F.S., relating to fees; receipts; disposition.

**Section 5:** Amends s. 456.065, F.S., relating to unlicensed practice of a health care profession; intent; cease and desist notice; penalties; enforcement; citations; fees; allocation and disposition of moneys collected.

**Section 6:** Amends s. 458.3265, F.S., relating to pain-management clinics.

**Section 7:** Amends s. 458.348, F.S., relating to formal supervisory relationships, standing orders, and established protocols; notice; standards.

**Section 8:** Amends s. 459.0137, F.S., relating to pain-management clinics.

**Section 9:** Amends s. 464.012, F.S.; relating to certification of advanced registered nurse practitioners; fees; controlled substance prescribing.

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<sup>108</sup> Chapter 2016-224, Laws of Fla.

<sup>109</sup> In 2016, the Legislature enacted the Nurse Licensure Compact which authorized Florida to join a multistate compact for nurses to practice in this state and other member state with a multistate license. See ch. 2016-139, Laws of Fla.

**Section 10:** Amends s. 464.012, F.S., relating to certification of advanced registered nurse practitioners; fees; controlled substance prescribing.

**Section 11:** Amends s. 464.013, F.S., relating to renewal of license or certificate.

**Section 12:** Amends s. 464.019, F.S., relating to approval of nursing education programs.

**Section 13:** Creates s. 465.0195, F.S., relating to in-state sterile compounding permit.

**Section 14:** Amends s. 465.027, F.S., relating to exceptions.

**Section 15:** Amends s. 468.80, F.S., relating to definitions.

**Section 16:** Amends s. 468.803, F.S., relating to license, registration, and examination requirements.

**Section 17:** Amends s. 480.041, F.S., relating to massage therapists; qualifications; licensure; endorsement.

**Section 18:** Amends s. 486.102, F.S., relating to physical therapist assistant; licensing requirements.

**Section 19:** Amends s. 491.005, F.S., relating to licensure by examination.

**Section 20:** Amends s. 491.009, F.S., relating to discipline.

**Section 21:** Provides an effective date of July, 1, 2017, except as otherwise expressly provided in the bill.

## **II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT**

### **A. FISCAL IMPACT ON STATE GOVERNMENT:**

#### **1. Revenues:**

DOH will experience a loss of revenue if a fee waiver is approved for a specific profession. However, the fee waiver should not be approved unless the profession's long range projections indicate it has sufficient funds available to absorb the loss of revenue.

#### **2. Expenditures:**

To the extent that the unlicensed activity fund runs a deficit, the particular profession affected may experience a negative fiscal impact to cover the deficit.

DOH may experience a recurring increase in workload associated with the registration of pain clinics that were previously exempt from registration; however, current resources are adequate to absorb these costs.<sup>110</sup>

DOH may experience a recurring increase in workload associated with conducting optional on-site evaluations of nursing education program applicants. The Board of Nursing anticipates on-site evaluations of applicants to be infrequent and current resources can absorb costs associated with these evaluations.<sup>111</sup>

### **B. FISCAL IMPACT ON LOCAL GOVERNMENTS:**

#### **1. Revenues:**

None.

#### **2. Expenditures:**

None.

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

If a profession determines that it meets the criteria for fee waivers, its licensees will save on licensure fees for the period the waiver is in effect.

<sup>110</sup> Department of Health, *Agency Bill Analysis*, on file with the Health and Human Services Subcommittee.

<sup>111</sup> Email from Joe Baker, Board of Nursing Executive Director, on file with Health Care Appropriations Subcommittee staff (3/7/17).

A pain clinic that is currently exempt from registration may incur additional administrative costs associated with registering with DOH. However, the pain clinic does not have pay a registration or inspection fee.

Nursing students that do not take the licensure exam within six months of graduation may realize cost savings by no longer being subject to a mandatory licensure examination preparatory course.

A nursing education program that is terminated or closed may incur costs or experience economic losses due to the 3-year waiting period imposed by the bill before it may reapply for approval.

For a prosthetist-orthotist, the cost of licensure will remain the same as the combined cost is equal to the total cost of obtaining individual licenses. However, a prosthetist-orthotist who completes an expedited residency, may realize a positive financial impact related to the shortened time to complete a residency and ability to be licensed sooner. The reduction from a two hour to a one hour continuing education course on medical errors for individuals licensed under the Board of Orthotics and Prosthetics may result in a cost savings for affected individuals.

**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.

**B. RULE-MAKING AUTHORITY:**

The rule-making authority created by the bill for the implementation of the Conrad Waiver 30 program is sufficient to implement those provisions of the bill.

The rule-making authority created by the bill for the BON to regulate nursing education programs is sufficient to implement those provisions of the bill.

The rule-making authority created by the bill for the Board of Pharmacy to regulate in-state sterile pharmacies is sufficient to implement those provisions of the bill.

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

None.

**IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES**

On February 22, 2017, the Health Innovation Subcommittee adopted an amendment that restored the authority of the BON to exclude the test score of certain students who transfer from a terminated nursing education program to an approved or accredited nursing education program from the calculation of the graduate passage rate of the program receiving the transferring students.

On March 23, 2017, the Health and Human Services Committee adopted an amendment that did the following:

- Authorized DOH to implement the Conrad 30 Waiver program;
- Authorized DOH to request the date of birth on licensure applications;
- Deleted requirements for the format of licenses issued by DOH;
- Required DOH to deny license renewal of an individual with unpaid fees and costs associated with a disciplinary proceeding, unless the board has extended the time to pay;
- Authorized DOH or a board to adopt a rule waiving licensure or renewal fees for up to 2 years if there are sufficient funds in the profession's trust fund;
- Authorized a transfer of operating funds from profession to cover the cost of prosecuting unlicensed activity;
- Required pain clinics that are currently exempt from registration to register with DOH at no cost;
- Required an ARNP to maintain a copy of his or her protocol at the location at which the ARNP practices, rather than filing it with the board;
- Authorized an ARNP who works at a physician group practice with multiple supervising physicians to enter into supervisory protocol with one physician in the group practice;
- Established standards for permitting and regulating in-state pharmacies and outsourcing facilities that perform sterile compounding;
- Exempted third party logistics providers who store or fill orders from manufacturers of certain dialysis drugs and supplies from pharmacy licensure;
- Authorized DOH to issue a single license for a prosthetist-orthotist;
- Authorized students of certain physical therapy assistant programs to apply for licensure;
- Updated the national licensure examination for marriage and family therapists; and
- Made other technical changes and updates cross-references.

The bill was reported favorably as a committee substitute. The analysis is drafted to the committee substitute as passed by the Health and Human Services Committee.