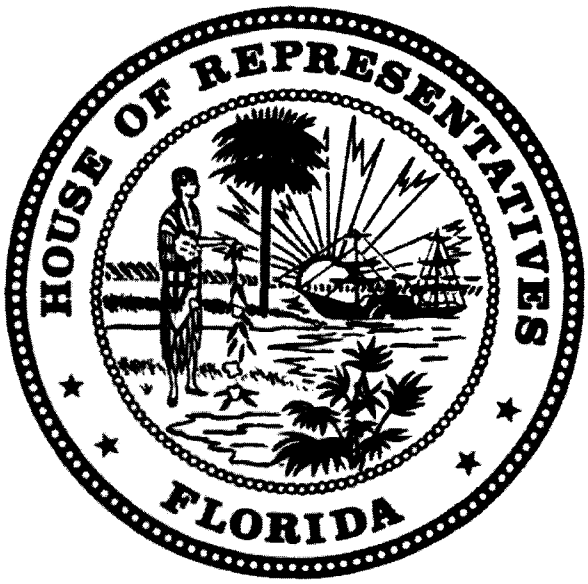

Health Quality Subcommittee

Monday, January 25, 2016
4:00 PM – 6:00 PM
306 HOB

Steve Crisafulli
Speaker

Cary Pigman
Chair

Committee Meeting Notice

HOUSE OF REPRESENTATIVES

Health Quality Subcommittee

Start Date and Time:	Monday, January 25, 2016 04:00 pm
End Date and Time:	Monday, January 25, 2016 06:00 pm
Location:	306 HOB
Duration:	2.00 hrs

Consideration of the following bill(s):

HB 977 Behavioral Health Workforce by Peters
HB 1151 Parentage by Richardson
HB 1211 Drugs, Devices, and Cosmetics by Plakon
HB 1277 Licensure of Foreign-Trained Physicians by Campbell
HB 1313 Low-THC Cannabis for Medical Use by Brodeur
HB 1411 Termination of Pregnancies by Burton

Pursuant to rule 7.12, the deadline for amendments to bills on the agenda by non-appointed members is 6:00 p.m., Friday, January 22, 2016.

By request of the chair, all committee members are asked to have amendments to bills on the agenda submitted to staff by 6:00 p.m., Friday, January 22, 2016.

NOTICE FINALIZED on 01/21/2016 4:15PM by Ellerkamp.Donna

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 977 Behavioral Health Workforce
SPONSOR(S): Peters
TIED BILLS: **IDEN./SIM. BILLS:** SB 1250

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee		Siples	O'Callaghan
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

The bill expands the authority of psychiatric nurses, by allowing such nurses to release a patient involuntary examined under the Baker Act from any receiving facility, not just receiving facilities owned or operated by a hospital or health system.

The bill makes the process of retaining a patient in a receiving facility, or placing a patient in a treatment facility, after an involuntary examination under the Baker Act more efficient by allowing the psychiatrist providing the first opinion and the psychiatrist or clinical psychologist providing a second opinion about the patient's placement to examine the patient electronically. Currently, only the psychiatrist or clinical psychologist providing a second opinion may perform an examination electronically.

The bill makes a clarification in the law that persons employed with the Department of Corrections in an inmate substance abuse program are exempt from a fingerprinting and background check requirement, unless they have direct contact with unmarried inmates under the age of 18 or with inmates who are developmentally disabled. The current law erroneously states the inverse.

The bill expands who is eligible to be a service provider under a substance abuse program by allowing those persons who have had a disqualifying offense that occurred 5 or more years ago and who have requested an exemption from disqualification to work with adults with substance use disorders under the supervision of a qualified psychologist, clinical social worker, marriage and family therapist, or mental health counselor, or a master's level certified addiction professional until the agency makes a final determination regarding the request for an exemption from disqualification.

The bill amends s. 409.909, F.S., related to the Statewide Medicaid Residency Program, to add psychiatry to the list of primary care specialty programs included in the program. This would allow for any psychiatry resident training beyond the initial residency period to be counted as one full-time equivalent (FTE), instead of the current 0.5 FTE, under the program for the purpose of calculating the amount of funds to be allocated to hospitals.

The bill amends s. 456.44, F.S., to require a physician assistant (PA) or an advanced registered nurse practitioner (ARNP), who prescribes any controlled substance for the treatment of chronic nonmalignant pain to register with DOH as a controlled substance prescribing practitioner. This new requirement also subjects PAs and ARNPs who are registered as a controlled substance prescribing practitioner to meet the statutory practice standards for such prescribing practitioners.

The bill exempts physicians who are board-eligible or board-certified medical specialists and who have completed a fellowship in pain medicine approved by the American Board of Interventional Pain Physicians or the American Association of Physician Specialists from the requirement to register as a controlled substance prescribing practitioner.

The bill may have an insignificant negative fiscal impact on DOH, and appears to have no fiscal impact on local governments.

The bill provides an effective date of July 1, 2016.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Behavioral Health Workforce Shortage

The Institute of Medicine (IOM) has chronicled efforts, beginning as early as the 1970s, which have attempted to deal with some of the workforce issues regarding mental and substance use disorders, but notes that most have not been sustained long enough or been comprehensive enough to remedy the problems.[1] Shortages of qualified workers, recruitment and retention of staff and an aging workforce have long been cited as problems.[2] Lack of workers in rural areas and the need for a workforce more reflective of the racial and ethnic composition of the U.S. population create additional barriers to accessing care for many.[3] Recruitment and retention efforts are hampered by inadequate compensation, which discourages many from entering or remaining in the field.[4] In addition, the misperceptions and prejudice surrounding mental and substance use disorders and those who experience them are imputed to those who work in the field.[5]

Of additional concern, a 2012 IOM report notes that the workforce is unprepared to meet the mental and substance use disorder treatment needs of the rapidly growing population of older adults.[6] The IOM report's data indicate that 5.6 to 8 million older adults, about one in five, have one or more mental health and substance use conditions which compound the care they need.[7] However, there is a dearth of mental health or substance abuse practitioners who are trained to deal with this population.[8]

It is projected that by 2020, there will be 12,624 child and adolescent psychologists needed, but a supply of only 8,312 is anticipated.[9] In 2010, the Substance Abuse and Mental Health Services Administration (SAMHSA) reported that more than two-thirds of primary care physicians who tried to

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[1] U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, *Report to Congress on the Nation's Substance Abuse and Mental Health Workforce Issues*, January 24, 2013, pg. 4, citing the following Institute of Medicine reports: Institute of Medicine, (2006), *Improving the quality of health care for mental and substance-use conditions.*, Washington, DC, National Academies Press; Institute of Medicine, (2003), Greiner, A., & Knebel, E. (Eds.), *Health professions education: A bridge to quality.*, Washington, DC, National Academies Press; Institute of Medicine, (2004), Smedley, B. D., Butler, A. S., Bristow, L. R. (Eds.), *In the nation's compelling interest: Ensuring diversity in the health-care workforce.*, Washington, DC, National Academies Press; and Institute of Medicine, & Eden, J., (2012), *The mental health and substance use workforce for older adults: In whose hands?*, Washington, DC, National Academies Press; *available at* https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0ahUKEwjK9-voubzKAhVCVyYKHYx5DHYQFggdMAA&url=https%3A%2F%2Fstore.samhsa.gov%2Fshin%2Fcontent%2FPEP13-RTC-BHWORK%2FPEP13-RTC-BHWORK.pdf&usg=AFQjCNGxewm3bHzmpsqu5zeWfUdqYhVpiw&sig2=WC81nKPjgNdMdm00jN20fw (last accessed on January 21, 2016).

[2] U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, *Report to Congress on the Nation's Substance Abuse and Mental Health Workforce Issues*, January 24, 2013, pg. 4, *available at* https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0ahUKEwjK9-voubzKAhVCVyYKHYx5DHYQFggdMAA&url=https%3A%2F%2Fstore.samhsa.gov%2Fshin%2Fcontent%2FPEP13-RTC-BHWORK%2FPEP13-RTC-BHWORK.pdf&usg=AFQjCNGxewm3bHzmpsqu5zeWfUdqYhVpiw&sig2=WC81nKPjgNdMdm00jN20fw (last accessed on January 21, 2016).

[3] *Id.*

[4] *Id.*

[5] *Id.*

[6] *Id.*

[7] *Id.*

[8] *Id.*

[9] *Id.* at 10.

obtain outpatient mental health services for their patients reported they were unsuccessful because of shortages in mental health care providers, health plan barriers, and lack of coverage or inadequate coverage.[10]

As of January 2016, the Health Resources and Services Administration has designated 4,362 Mental Health Professional Shortage Areas, including one or more in each state, the District of Columbia, and each of the territories.[11]

Behavioral Health Practice

In the U.S., states generally require a person to achieve higher levels of education to become a mental health counselor compared to that of a substance abuse counselor. As of 2011, almost all states (98 percent) required a master's degree to qualify as a mental health counselor but 45 percent of states did not require any college degree to qualify as a substance abuse counselor. For behavioral health care disciplines, independent practice requires a master's degree in most states; however, for addiction counselors, data available a decade ago indicated that about 50-55 percent of those certified or practicing in the field had at least a master's degree, 75 percent hold a bachelor's degree, and the reminder had either some college, a high school diploma or equivalent.[12]

Because of major changes to the field of behavioral health, including the integration of behavioral health and primary care, a push to accelerate the adoption of evidence-based practices, and a model of care that is recovery-oriented, person-centered, integrated, and utilizes multi-disciplinary teams, behavioral health workers are in need of additional pre-service training and continuing education.[13] Behavioral health has moved to a chronic care, public health model to define needed services. This model recognizes the importance of prevention, the primacy of long-term recovery as its key construct, and is shaped by those with lived experience of recovery.[14] This new care model will require a diverse, skilled, and trained workforce that employs a range of workers, including people in recovery, recovery specialists, case workers and highly trained specialists.[15] In fact, the movement to include primary care providers into the field of behavioral health has meant that there is currently no consensus as to which health care provider types make up the workforce.[16] Generally, however, the workforce is made up of professionals practicing psychiatry, clinical psychology, clinical social work, advanced practice psychiatric nursing, marriage and family therapy, substance abuse counseling, and counseling.[17]

Involuntary Examination under the Baker Act

In 1971, the Legislature passed the Florida Mental Health Act (also known as the Baker Act[18]), codified in part I of ch. 394, F.S., to address mental health needs in the state.[19] The Baker Act provides the

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[10] *Id.*

[11] Health Resources and Services Administration, *Data Warehouse, Health Professional Shortage Areas (HPSA) and Medically Underserved Areas / Populations (MUA/P)*, *available at* http://datawarehouse.hrsa.gov/topics/shortageAreas.aspx#chart (last accessed on January 21, 2016).
shortageAreas.aspx#chart .

[12] *Supra* note

[13] *Id.* at 4-5.

[14] *Id.* at 6.

[15] *Id.*

[16] Congressional Research Service, *The Mental Health Workforce: A Primer*, April 16, 2015, *available at* http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=3&cad=rja&uact=8&ved=0ahUKEwjK9-voubzKAhVCVyYKHYx5DHYQFgguMAI&url=http%3A%2F%2Ffas.org%2Fsgp%2Fcrs%2Fmisc%2FR43255.pdf&usg=AFQjCNHkmHp_4SMtmCWS7gImwEWxhPGl1g&sig2=5JBwSXTV1PHBeGZJGig0Xw(last accessed on January 21, 2016).

[17] *Id.* at 2 (using the Substance Abuse and Mental Health Services Administration definition).

[18] "The Baker Act" is named for its sponsor, Representative Maxine E. Baker, one of the first two women from Dade County elected to office in the Florida Legislature. As chair of the House Committee on Mental Health, she championed the treatment of mental illness in a manner that would not sacrifice a patient's rights and dignity. Baker served five terms as a member of the Florida House of Representatives from 1963-1972 and was instrumental in the passage of the Florida Mental Health Act. *See* University of Florida Smathers Libraries, *A Guide to the Maxine E. Baker Papers*, *available at* http://www.library.ufl.edu/spec/pkyonge/baker.htm (last

authority and process for the voluntary and involuntary examination of persons with evidence of a mental illness and the subsequent inpatient or outpatient placement of such individuals for treatment.

The Department of Children and Families (DCF) administers the Baker Act through receiving facilities that examine persons with evidence of mental illness. Receiving facilities are designated by the DCF and may be public or private facilities that provide the examination and short-term treatment of persons who meet the criteria under the Baker Act.[20] Subsequent to examination at a receiving facility, a person who requires further treatment may be transported to a treatment facility. Treatment facilities designated by the DCF are state hospitals (e.g. Florida State Hospital) which provide extended treatment and hospitalization beyond what is provided in a receiving facility.[21]

Current law provides that an involuntary examination may be initiated if there is reason to believe a person has a mental illness and because of the illness:[22]

- The person has refused a voluntary examination after explanation of the purpose of the exam or is unable to determine for himself or herself that an examination is needed; and
- The person is likely to suffer from self-neglect or substantial harm to her or his well-being, or be a danger to himself or herself or others.

Courts, law enforcement officers, and certain health care practitioners are authorized to initiate such involuntary examinations.[23] A circuit court may enter an *ex parte* order stating a person meets the criteria for involuntary examination. A law enforcement officer[24] may take a person into custody who appears to meet the criteria for involuntary examination and transport them to a receiving facility for examination. Health care practitioners may initiate an involuntary examination by executing the *Certificate of a Professional Initiating an Involuntary Examination*, an official form adopted in rule by the DCF.[25] The health care practitioner must have examined the person within the preceding 48 hours and state that the person meets the criteria for involuntary examination.[26] The Baker Act currently authorizes the following health care practitioners to initiate an involuntary examination by certificate:[27]

- A physician licensed under ch. 458, F.S., or ch. 459, F.S., who has experience in the diagnosis and treatment of mental and nervous disorders.
- A clinical psychologist, as defined in s. 490.003(7), F.S., with three years of postdoctoral experience in the practice of clinical psychology, inclusive of the experience required for licensure.

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accessed January 21, 2016), and Department of Children and Families and University of South Florida, Department of Mental Health and Law, *Baker Act Handbook and User Reference Guide 2014 (2014), available at* http://myflfamilies.com/service-programs/mental-health/baker-act (select "2014 Baker Act Manual) (last accessed January 21, 2016).

[19] Chapter 71-131, s. 1, Laws of Fla.

[20] Section 394.455(26), F.S.

[21] Section 394.455(32), F.S.

[22] Section 394.463(1), F.S.

[23] Section 394.463(2)(a)1.-3., F.S.

[24] "Law enforcement officer" means any person who is elected, appointed, or employed full time by any municipality or the state or any political subdivision thereof; who is vested with authority to bear arms and make arrests; and whose primary responsibility is the prevention and detection of crime or the enforcement of the penal, criminal, traffic, or highway laws of the state. This definition includes all certified supervisory and command personnel whose duties include, in whole or in part, the supervision, training, guidance, and management responsibilities of full-time law enforcement officers, part-time law enforcement officers, or auxiliary law enforcement officers but does not include support personnel employed by the employing agency. s. 943.10(1), F.S.

[25] The Certificate of a Professional Initiating an Involuntary Examination is a form created by the DCF which must be executed by health care practitioners initiating an involuntary examination under the Baker Act. The form contains information related to the person's diagnosis and the health care practitioner's personal observations of statements and behaviors that support the involuntary examination of such person. See Florida Department of Children and Families, CF-MH 3052b, incorporated by reference in Rule 65E-5.280, F.A.C., and available at http://www.dcf.state.fl.us/programs/samh/MentalHealth/laws/3052b.pdf. (last visited January 21, 2016).

[26] Section 394.463(2)(a)3., F.S.

[27] *Id.*

- A physician or psychologist employed by a facility operated by the United States Department of Veterans Affairs that qualifies as a receiving or treatment facility.
- A psychiatric nurse licensed under part I of ch. 464, F.S., who has a master's degree or a doctorate in psychiatric nursing, holds a national advanced practice certification as a psychiatric mental health advance practice nurse, and has two years of post-master's clinical experience under the supervision of a physician.
- A mental health counselor licensed under ch. 491, F.S.
- A marriage and family therapist licensed under ch. 491, F.S.
- A clinical social worker licensed under ch. 491, F.S.

In 2014, there were 181,471 involuntary examinations initiated in the state. Law enforcement initiated half of the involuntary examinations (50.18 percent), followed closely by mental health professionals (47.86 percent), with the remaining initiated pursuant to *ex parte* orders by judges (1.96 percent).[28]

Background Screening of Substance Abuse Treatment Provider Staff

Substance abuse treatment programs are licensed by the DCF Substance Abuse Program Office under authority granted in s. 397.401, F.S., which states, "It is unlawful for any person to act as a substance abuse service provider unless it (sic) is licensed or exempt from licensure under this chapter." In order to obtain a license, a provider must apply to the department and submit "sufficient information to conduct background screening as provided in s. 397.451, F.S."[29] According to the administrative rule implementing this section, the required documentation is verification that fingerprinting and background checks have been completed as required by ch. 397, F.S., and ch. 435, F.S.[30]

Section 397.451, F.S., requires that "all owners, directors, and chief financial officers of service providers are subject to level 2 background screening as provided under chapter 435. . . . All service provider personnel who have direct contact with children receiving services or with adults who are developmentally disabled receiving services are subject to level 2 background screening as provided under chapter 435." Members of a foster family and persons who live in the foster home who are between 12 and 18 years of age are not required to be fingerprinted, but these youth must have background checks for delinquency records. All other members of a foster family and any other persons residing with a foster family who are over 18 years of age must have complete background checks. Church or nonprofit religious organizations that are exempt from licensure as substance abuse treatment programs must also comply with personnel screening requirements.

Exemptions from personnel screening requirements include:

- Persons who volunteer at a program for less than 40 hours per month and who are under direct and constant supervision by persons who meet all screening requirements;
- Service providers that are exempt from licensing;
- Persons employed by the Department of Corrections in a substance abuse service
- component who have direct contact with unmarried inmates under the age of 18 or with inmates who are developmentally disabled.3[31]

The requirements for level 1 and level 2 screening are found in ch. 435, F.S. Level 1 screening includes, at a minimum, employment history checks and statewide criminal correspondence

[28] Annette Christy & Christina Guenther, Baker Act Reporting Center, College of Behavioral & Community Sciences, University of South Florida, *Annual Report of Baker Act Data: Summary of 2014 Data*, available at http://bakeract.fmhi.usf.edu/document/BA_Annual_2014.pdf (last visited January 21, 2016).
[29] Section 397.403, F.S.
[30] Rule 65D-30.003(6)(s), F.A.C.
[31] Section 397.451(2)(c), F.S.

checks through the Florida Department of Law Enforcement (FDLE) and may include criminal records checks through local law enforcement agencies. Level 2 screening is required for all employees in positions designated by law as positions of trust or responsibility, and it includes security background investigations which consist of at least fingerprinting, statewide criminal and juvenile records checks through FDLE, and federal criminal records checks through the Federal Bureau of Investigation (FBI) and may include local criminal records checks through local law enforcement agencies.[32]

Within five working days after starting to work, it is incumbent upon an employee who is in a position for which employment screening is required to submit to the employer a complete set of information necessary to conduct a screening. For level 1 screening, the employer then submits the information to FDLE within five working days after receiving it. The FDLE conducts a search of its records and responds to the employer who then informs the employee whether screening has revealed any disqualifying information. For level 2 screening, the employer or the licensing agency submits the screening information to FDLE within five working days after receiving it; FDLE conducts its search of criminal and juvenile records and requests that the FBI conduct a search. The employee must supply any missing criminal or other necessary information to the employer within 30 days after the employer requests the information or they are subject to automatic disqualification. After the background screening is complete, FDLE responds to the employer or licensing agency who informs the employee whether screening has revealed disqualifying information.5[33]

Under certain circumstances, DCF may grant an exemption from disqualification as provided in s. 435.07, F.S. These circumstances are:

- Felonies committed more than three years prior to the date of disqualification;
- Misdemeanors prohibited under any of the Florida Statutes cited in the chapter or under similar statutes of other jurisdictions;
- Offenses that were felonies when committed but are now misdemeanors;
- Findings of delinquency; or
- Commissions of acts of domestic violence as defined in s. 741.30, F.S. 6

Section 435.07, F.S., requires that "(i)n order for a licensing department to grant an exemption to any employee, the employee must demonstrate by clear and convincing evidence that the employee should not be disqualified from employment. Employees seeking an exemption have the burden of setting forth sufficient evidence of rehabilitation, including, but not limited to, the circumstances surrounding the criminal incident for which an exemption is sought, the time period that has elapsed since the incident, the nature of the harm caused to the victim, and the history of the employee since the incident, or any other evidence or circumstances indicating that the employee will not present a danger if continued employment is allowed. The decision of the licensing department regarding an exemption may be contested through the hearing procedures set forth in chapter 120." However, disqualification may not be removed from, and no exemption may be granted to, an individual who is found guilty of, regardless of adjudication, or who has entered a plea of nolo contendere or guilty to any felony covered by s. 435.03, F.S., solely by pardon, executive clemency, or restoration of civil rights.[34]

Since many substance abuse treatment programs employ persons who are themselves in recovery, DCF is authorized to grant additional exemptions from disqualification for employees of substance abuse treatment programs. Section 397.451 (4), F.S., provides, "Since rehabilitated substance abuse impaired persons are effective in the successful treatment and rehabilitation of substance abuse impaired adolescents, for service providers which treat adolescents 13 years of

[32] Section 435.04(1), F.S.
[33] Section 435.05, F.S.
[34] Section 435.07(4), F.S.

age and older, service provider personnel whose background checks indicate crimes under s. 817.563, s. 893.13, or s. 893.147[35] may be exempted from disqualification from employment pursuant to this paragraph."[36] This provision also authorizes DCF to grant exemptions from disqualification for personnel who work exclusively with adults in substance abuse treatment facilities. Employees must submit a request for an exemption from disqualification within 30 days after being notified of a pending disqualification. The statute provides that the "employment of service provider personnel shall not be adversely affected pending disposition of the request for an exemption. Disapproval of a request for an exemption shall result in the immediate dismissal of the service provider personnel from employment with the provider."[37]

Physician Assistants

Licensure and Regulation

A physician assistant (PA) is a person who has completed an approved medical training program and is licensed to perform medical services, as delegated by a supervising physician.[38] PAs licensure is governed by ss. 458.347(7) and 459.022(7), F.S. The Department of Health (DOH) licenses PAs, and the Florida Council on Physician Assistants (Council) regulates the practice of PAs in conjunction with either the Florida Board of Medicine (Board of Medicine) for PAs licensed under ch. 458, F.S., or the Board of Osteopathic Medicine (Osteopathic Board) for PAs licensed under ch. 459, F.S. Currently, 7,987 PAs hold active licenses in Florida.[39]

To be licensed as a PA , an applicant must demonstrate to the Council that he or she has met the following requirements:

- Satisfactory passage of the proficiency examination administered by the National Commission on Certification of Physician Assistants;
- Completion of an application and remittance of the applicable fees to the DOH; [40]
- Completion of an approved PA training program;
- Submission of a sworn statement of any prior felony convictions;
- Submission of a sworn statement of any revocation or denial of licensure or certification in any state;
- Submission of two letters of recommendation; and
- If the applicant is seeking prescribing authority, a submission of a copy of course transcripts and the course description from a PA training program describing the course content in pharmacotherapy.[41]

Licenses are renewed biennially.[42] At the time of renewal, a PA must demonstrate that he or she has met the continuing medical education requirements of 100 hours and must submit a sworn statement that he or she has not been convicted of any felony in the previous two years.[43] If a PA is licensed as a

[35] Section 817.563, F.S., relates to fraudulent sale of all controlled substances; s. 893.13, F.S., relates to sale, manufacture, or delivery, or possession with intent to sell, manufacture, or deliver, a controlled substance; s. 893.147, F.S., relates to use or possession of drug paraphernalia.
[36] Section 397.451(4)(b), F.S.
[37] Section 397.451(1)(f), F.S.
[38] Sections 458.347(2)(e) and 459.022(2)(e), F.S.
[39] Email correspondence with the Department of Health on November 9, 2015. The number of active-licensed PAs include both in-state and out-of-state licensees, as of November 9, 2015.
[40] The application fee is $100 and the initial license fee is $200. Applicants must also pay an unlicensed activity fee of $5. See Rules 64B8-30.019 and 64B15-6.013, F.A.C.
[41] Sections 458.347(7) and 459.022(7), F.S.
[42] For timely renewed licenses, the renewal fee is $275 and the prescribing registration fee is $150. Additionally, at the time of renewal, the PA must pay an unlicensed activity fee of $5. See Rules 64B8-30.019 and 64B15-6.013, F.A.C.
[43] Sections 458.347(7)(c)-(d) and 459.022(7)(c)-(d), F.S.

prescribing PA, an additional 10 hours of continuing medical education in the specialty areas of his or her supervising physician must be completed.[44]

Education of PAs

According to the American Academy of Physician Assistants, all accredited PA educational programs include pharmacology courses, and the average amount of formal classroom instruction in pharmacology is 75 hours.[45] Course topics, include pharmacokintetics, drug interactions, adverse effects, contraindications, indications, and dosage, generally by doctoral-level pharmacologists or clinical pharmacists.[46] Additionally, pharmacology education occurs on all clinical clerkships or rotations.[47]

Supervision of PAs

A PA may only practice under the delegated authority of a supervising physician. A supervising physician may only delegate tasks and procedures to the PA that are within the supervising physician's scope of practice.[48] Supervision is defined as responsible supervision and control that requires the easy availability or physical presence of the licensed physician for consultation and direction of the PA.[49] A physician may not supervise more than four PAs at any time.[50]

The Board of Medicine and the Osteopathic Board have prescribed by rule what constitutes adequate responsible supervision. Responsible supervision is the ability of a supervising physician to reasonably exercise control and provide direction over the services or tasks performed by the PA.[51] Whether the supervision of the PA is adequate is dependent on the:

- Complexity of the task;
- Risk to the patient;
- Background, training, and skill of the PA;
- Adequacy of the direction in terms of its form;
- Setting in which the tasks are performed;
- Availability of the supervising physician;
- Necessity for immediate attention; and
- Number of other persons that the supervising physician must supervise.[52]

Direct supervision refers to the physical presence of the supervising physician so that the physician is immediately available to the PA when needed.[53] Indirect supervision refers to the reasonable physical proximity of the supervising physician to the PA or availability by telecommunication.[54] The decision to permit a PA to perform a task or procedure under direct or indirect supervision is made by the supervising physician based on reasonable medical judgment regarding the probability of morbidity and mortality to the patient.[55]

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[44] Rules 64B8-30.005(6) and 64B15-6.0035(6), F.A.C.
[45] American Academy of Physician Assistants, *PAs as Prescribers of Controlled Medications, Professional Issues – Issue Brief* (Dec. 2013), (on file with the staff of the Health and Human Services committee).
[46] Id.
[47] Id.
[48] Rules 64B8-30.012(1) and 64B15-6.010(1), F.A.C. The term "scope of practice" refers to those tasks and procedures that the supervising physician is qualified by training or experience to support.
[49] Sections 458.347(2)(f) and 459.022(2)(f), F.S.
[50] Sections 458.347(3) and 459.022(3), F.S.
[51] Rules 64B8-30.001(3) and 64B15-6.001(3), F.A.C.
[52] Id.
[53] Rules 64B8-30.001(4) and 64B15-6.001(4), F.A.C.
[54] Rules 64B8-30.001(5) and 64B15-6.001(5), F.A.C.
[55] Rules 64B8-30.012(2) and 64B15-6.010(2), F.A.C.

Delegable Tasks

Rules of both the Board of Medicine and the Osteopathic Board place limitations on a supervising physician's ability to delegate certain tasks. Prescribing, dispensing, or compounding medicinal drugs and making a final diagnosis are not permitted to be delegated to a PA, except when specifically authorized by statute.[56]

A supervising physician may delegate authority to a PA the authority to:

- Prescribe or dispense any medicinal drug used in the supervising physician's practice;[57]
- Order medicinal drugs for a hospitalized patient of the supervising physician;[58] and
- Administer a medicinal drug under the direction and supervision of the physician.

Currently, PAs are prohibited from prescribing controlled substances, anesthetics, and radiographic contrast materials.[59] However, physicians may delegate the authority to order controlled substances in facilities licensed under ch. 395, F.S.[60]

Advanced Registered Nurse Practitioners

Licensure and Regulation

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 DOH and are regulated by the Board of Nursing.[61] There are 22,003 actively licensed ARNPs in Florida.[62]

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.[63] Section 464.003(2), F.S., defines "advanced or specialized nursing practice" to include the performance of advanced-level nursing acts approved by the Board of Nursing, which by virtue of postbasic specialized education, training, and experience are appropriately performed by an ARNP.[64]

Florida recognizes three types of ARNPs: nurse anesthetist, certified nurse midwife, and nurse practitioner. The Board of Nursing, created by s. 464.004, F.S., establishes the eligibility criteria for an applicant to be certified as an ARNP and the applicable regulatory standards for ARNP nursing practices.[65] To be certified as an ARNP, the applicant must:

- Have a registered nurse license;

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[56] *Supra* note 12.
[57] Sections 458.347(4)(f)1., F.S., and 459.022(4)(e), F.S., directs the Council to establish a formulary listing the medical drugs that a PA may not prescribe. The formulary in Rules 64B8-30.008 and 64B15-6.0038, F.A.C., prohibits PAs from prescribing controlled substances, as defined in Chapter 893, F.S., general, spinal, or epidural anesthetics, and radiographic contrast materials.
[58] Sections 458.347(4)(g), and 459.022(4)(f), F.S., provides that an order is not a prescription.
[59] Rules 64B8-30.008, F.A.C., and 64B15-6.0038, F.A.C.
[60] Sections 458.347(4)(g), F.S., and 459.022(4)(f), F.S.; the facilities licensed in ch. 395, F.S., include hospitals, ambulatory surgical centers, and mobile surgical facilities.
[61] 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 numbers 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.
[62] E-mail correspondence with the Department of Health (Nov. 9, 2015) (on file with the staff of the Health and Human Services Committee). This number includes all active licenses, including out of state practitioners.
[63] Section 464.003(3), F.S.
[64] Section 464.003(2), F.S.
[65] Section 464.012(2), F.S.

- Have earned, at least, a master's degree; and
- Submit proof to the Board of Nursing of holding a current national advanced practice certification obtained from a board-approved nursing specialty board.[66]

All ARNPs must carry malpractice insurance or demonstrate proof of financial responsibility.[67] An applicant for certification is required to submit proof of coverage or financial responsibility within sixty days of certification and with each biennial renewal.[68] An ARNP must have professional liability coverage of at least $100,000 per claim with a minimum annual aggregate of at least $300,000, or an unexpired irrevocable letter of credit, which is payable to the ARNP as beneficiary, in the amount of at least $100,000 per claim with a minimum aggregate availability of at least $300,000.[69]

Supervision of ARNPs

Pursuant to s. 464.012(3), F.S., ARNPs may only perform nursing practices delineated in an established protocol filed with the Board of Nursing that is filed within 30 days of entering into a supervisory relationship with a physician and upon biennial license renewal.[70] Florida law allows a primary care physician to supervise ARNPs in up to four offices, in addition to the physician's primary practice location.[71] If the physician provides specialty health care services, then only two medical offices, in addition to the physician's primary practice location, may be supervised.

The supervision limitations do not apply in the following facilities:

- Hospitals;
- Colleges of medicine or nursing;
- Nonprofit family-planning clinics;
- Rural and federally qualified health centers;
- Nursing homes;
- Assisted living facilities;
- Student health care centers or school health clinics; and
- Other government facilities.[72]

To ensure appropriate medical care, the number of ARNPs a supervising physician may supervise is limited based on consideration of the following factors:

- Risk to the patient;
- Educational preparation, specialty, and experience in relation to the supervising physician's protocol;
- Complexity and risk of the procedures;
- Practice setting; and
- Availability of the supervising physician or dentist.[73]

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[66] Section 464.012(1), F.S., and Rule 64B9-4.002, F.A.C. A 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 of examination, maintain program accreditation, and identify standards or scope of practice statements appropriate for each nursing specialty.
[67] Section 456.048, F.S.
[68] Rule 64B9-4.002(5), F.A.C.
[69] *Id.*
[70] Physicians are also required to provide notice of the written protocol and the supervisory relationship to the Board of Medicine or Board of Osteopathic Medicine, respectively. See ss. 458.348 and 459.025, F.S.
[71] Sections 458.348(4) and 459.025(3), F.S.
[72] Sections 458.348(4)(e), and 459.025(3)(e), F.S.
[73] Rule 64B9-4.010, F.A.C.

Delegable Tasks

Within the framework of a written physician protocol, an ARNP may:

- Monitor and alter drug therapies;
- Initiate appropriate therapies for certain conditions;
- Order diagnostic tests and physical and occupational therapy;
- Perform certain acts within his or her specialty;
- Perform medical acts authorized by a joint committee; and
- Perform additional functions determined by rule.[74]

Florida law does not authorize ARNPs to prescribe, independently administer, or dispense controlled substances.[75]

Controlled Substances

Controlled substances are drugs with the potential for abuse. Chapter 893, F.S., sets forth the Florida Comprehensive Drug Abuse Prevention and Control Act (Act) and classifies controlled substances into five categories, known as schedules.[76] The distinguishing factors between the different drug schedules are the "potential for abuse" of the substance and whether there is a currently accepted medical use for the substance. Schedules are used to regulate the manufacture, distribution, preparation and dispensing of the substances. The Act provides requirements for the prescribing and administering of controlled substances by health care practitioners and proper dispensing by pharmacists and health care practitioners.[77]

Controlled Substance Prescribing for Chronic Nonmalignant Pain in Florida

As of January 1, 2012, every physician, podiatrist, or dentist, who prescribes controlled substances in the state for the treatment of chronic nonmalignant pain,[78] must register as a controlled substance prescribing practitioner and comply with certain practice standards specified in statute and rule.[79] Before prescribing controlled substances for the treatment of chronic nonmalignant pain, a practitioner must:

- Document certain characteristics about the nature of the patient's pain, success of past treatments, and a history of alcohol and substance abuse;
- Develop a written plan for assessing the patient's risk for aberrant drug-related behavior and monitor such behavior throughout the course of controlled substance treatment;
- Develop an written individualized treatment plan for each patient stating the objectives that will be used to determine treatment success; and
- Enter into a controlled substance agreement with each patient that must be signed by the patient or their legal representative and by the prescribing practitioner. Such agreements must include:
    - The number and frequency of prescriptions and refills;
    - A statement outlining expectations for patience compliance and reasons for which the drug therapy may be discontinued, such as violation of the agreement; and

[74] Section 464.012(3), F.S. Pursuant to s. 464.012(4), F.S., certified registered nurse anesthetists, certified nurse midwives, and certified nurse practitioners are authorized to perform additional acts that are within their specialty and authorized under an established supervisory protocol.
[75] Sections 893.02(21) and 893.05(1), F.S. The definition of practitioner does not include ARNPs.
[76] *See* s. 893.03, F.S.
[77] Sections 893.04 and 893.05, F.S.
[78] "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 456.44(1)(e), F.S.
[79] Chapter 2011-141, s. 3, Laws of Fla. (creating ss. 456.44, F.S., effective July 1, 2011).

- An agreement that the patient's chronic nonmalignant pain only be treated by a single treating practitioner unless otherwise authorized and documented in the medical record.[80]

Patients being treated with controlled substances for chronic nonmalignant pain must be seen by their prescribing practitioners at least once every three months to monitor progress and compliance, and detailed medical records relating to such treatment must be maintained.[81] Patients at special risk for drug abuse or diversion may require consultation with or a referral to an addiction medicine physician or a psychiatrist.[82] Anyone with signs or symptoms of substance abuse must be immediately referred to a pain-management physician, an addiction medicine specialist, or an addiction medicine facility.[83]

Drug Enforcement Administration

The Drug Enforcement Administration (DEA), housed within the U.S. Department of Justice, enforces the controlled substances laws and regulations of the United States, including preventing and investigating the diversion of controlled pharmaceuticals.[84]

Any health care professional wishing to prescribe controlled substances must apply for a registration number from the DEA. Registration numbers are linked to state licenses and may be suspended or revoked upon any disciplinary action taken against a licensee.[85] The DEA will grant registration numbers to a wide range of health care professionals, including physicians, nurse practitioners, physician assistants, optometrists, dentists, and veterinarians, but such professionals may only prescribe controlled substances as authorized under state law.[86] The DEA provides that a controlled substance prescription may only be issued by a registered practitioner who is:

- Authorized to prescribe controlled substances by the jurisdiction in which the practitioner is licensed to practice; and
- Registered with the DEA, or exempt from registration (e.g., Public Health Service, Federal Bureau of Prisons, or military practitioners); or
- An qualified agent or employee of a hospital or other institution acting in the normal course of business or employment under the DEA registration number of the hospital or other institution which is registered in lieu of the individual practitioner being registered.[87]

The DEA's Practitioner Manual includes requirements for valid prescriptions. The DEA defines "prescription" as an order for medication which is dispensed to or for an ultimate user, but is not an order for a medication dispensed for immediate administration to the user, such as an order to dispense a drug to a patient in a hospital setting.[88]

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[80] Section 465.44(3), F.S.
[81] Section 465.44(3)(d), F.S.
[82] Section 465.44(3)(e), F.S.
[83] Section 456.44(3)(g), F.S.
[84] Drug Enforcement Administration, *About Us*, available at http://www.deadiversion.usdoj.gov/Inside.html (last accessed January 15, 2016).
[85] Registration numbers must be renewed every three years. *Drug Enforcement Administration, Practitioners Manual, 7(2006)*, available at http://www.deadiversion.usdoj.gov/pubs/manuals/pract/pract_manual012508.pdf (last accessed January 15, 2016).
[86] *Id.* at 7.
[87] DEA, Practitioner Manual, 18.
[88] *Id.*

Controlled Substance Prescriptive Authority for ARNPs and PAs in Other States

ARNPs

An ARNP's ability to prescribe, dispense, or administer controlled substances is dependent on his or her specific state's law. Forty-nine states authorize ARNPs to prescribe controlled substances.[89] Twenty-one states and the District of Columbia allow an ARNP to practice independently, including evaluating, diagnosing, ordering, and interpreting diagnostic tests, and managing treatment, including prescribing medications, of a patient without physician supervision.[90] Twenty-two states specifically prohibit certified registered nurse anesthetists from prescribing controlled substances.[91]

Some states have specific limitations regarding ARNPs prescribing authority for Schedule II controlled substances.[92] For example, 7 states authorize ARNPs to prescribe all levels of scheduled drugs, except for Schedule II. Some states have specific education requirements for those ARNPs who wish to prescribe Schedule II substances or require additional registration for ARNPs to be authorized to prescribe.[93]

PAs

A PA's ability to prescribe, dispense, or administer controlled substances is dependent on their specific state's law. Forty-eight states authorize PAs to prescribe controlled substances within an agreement with a supervisory physician, with varying limitations on administration, dispensing, and independent prescribing.[94]

Of the 48 states, some have specific restrictions on PAs' prescribing authority for schedule II controlled substances; for example, Texas and Hawaii only authorize PAs to order schedule II controlled substances in an inpatient hospital setting. Some states have medication quantity restrictions on prescriptions for schedule II drugs and some states give PAs' prescriptive authority for all levels of scheduled drugs except for schedule II.[95] Some states also have a formulary determined by the relevant PA licensing board which identifies the controlled substances that PAs are authorized to prescribe.

Statewide Medicaid Residency Program

Chapter 2013-48, Laws of Florida, created the Statewide Medicaid Residency Program (SMRP) in the Agency for Health Care Administration (AHCA). Through the SMRP, Medicaid Graduate Medical Education dollars are removed from regular hospital reimbursement payments and are subject to a formula-based redistribution. Each hospital participating in the SMRP receives an annual allocation determined by a calculation of its percentage of total residents statewide and its percentage of total Medicaid inpatient reimbursement among participating hospitals.

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[89] Drug Enforcement Agency, *Mid-Level Practitioners Authorization by State* (January 15, 2016), *available at* http://www.deadiversion.usdoj.gov/drugreg/practioners/mlp_by_state.pdf (last visited January 15, 2016). The Commonwealth of Puerto Rico also prohibits ARNPs from prescribing controlled substances.

[90] Alaska, Arizona, Colorado, Connecticut, District of Columbia, Hawaii, Idaho, Iowa, Maine, Maryland, Minnesota, Montana, Nebraska, Nevada, New Hampshire, New Mexico, North Dakota, Oregon, Rhode Island, Vermont, Washington, and Wyoming allow for independent practice. See American Association of Nurse Practitioners, *State Practice Environment*, *available at* https://www.aanp.org/legislation-regulation/state-legislation/state-practice-environment/66-legislation-regulation/state-practice-environment/1380-state-practice-by-type (last visited January 15, 2016).

[91] American Association of Nurse Anesthetists, AANA Journal, June 2011; 79(3):235, on file with committee staff.

[92] *Supra* note 51.

[93] *Id.*

[94] *Id.* Every state, except Florida and Kentucky, has some form of controlled substance prescriptive authority for PAs.

[95] *Id.*

In 2014, a bill was passed to require AHCA – beginning in the 2015-2016 fiscal year – to reconcile each participating hospital's number of residents calculated under the SMRP's statutory formula with the most recent Medicare cost report submitted by the hospital.[96] In any year in which retroactive adjustments are needed due to the reconciliation, those adjustments will be applied to the hospital's allocation for that year.

In 2015, the Legislature created the Graduate Medical Education Startup Bonus Program within the SMRP.[97] In any fiscal year in which funds are appropriated for the startup bonus program, hospitals eligible to participate in the SMRP may apply for up to $100,000 per newly created residency slot that is dedicated to a physician specialty in statewide supply/demand deficit. Such physician specialties and subspecialties are those identified in the General Appropriations Act.

Effect of Proposed Changes

The bill seeks to address a behavioral health workforce shortage through several different mechanisms, as expressed in a legislative intent provision in the bill, which states that the Legislature finds:

- A need for additional psychiatrists and recommends the establishment of an additional psychiatry program to be offered by one of Florida's schools of medicine, which shall seek to integrate primary care and psychiatry, and other evolving models of care for persons with mental health and substance use disorders.
- The use of telemedicine for patient evaluation, case management, and ongoing care will improve management of patient care and reduce costs of transportation.

The bill also expands the authority of psychiatric nurses, by allowing such nurses to release a patient involuntary examined under the Baker Act from any receiving facility, not just receiving facilities owned or operated by a hospital or health system.

The bill makes the process of retaining a patient in a receiving facility, or placing a patient in a treatment facility, after an involuntary examination under the Baker Act more efficient by allowing the psychiatrist providing the first opinion and the psychiatrist or clinical psychologist providing a second opinion about the patient's placement to examine the patient electronically. Currently, only the psychiatrist or clinical psychologist providing a second opinion may perform an examination electronically.

The bill makes a clarification in the law that persons employed with the Department of Corrections in an inmate substance abuse program are exempt from a fingerprinting and background check requirement, unless they have direct contact with unmarried inmates under the age of 18 or with inmates who are developmentally disabled. The current law erroneously states the inverse.

The bill expands who is eligible to be a service provider under a substance abuse program by allowing those persons who have had a disqualifying offense that occurred 5 or more years ago and who have requested an exemption from disqualification to work with adults with substance use disorders under the supervision of a qualified psychologist, clinical social worker, marriage and family therapist, or mental health counselor, or a master's level certified addiction professional until the agency makes a final determination regarding the request for an exemption from disqualification.

The bill amends s. 409.909, F.S., related to the Statewide Medicaid Residency Program, to add psychiatry to the list of primary care specialty programs included in the program. This would allow for any psychiatry resident training beyond the initial residency period to be counted as one full-time

[96] Chapter 2014-57, Laws of Fla.
[97] Chapter 2015-225, Laws of Fla.

equivalent (FTE), instead of the current 0.5 FTE, under the program for the purpose of calculating the amount of funds to be allocated to hospitals.

The bill amends s. 456.44, F.S., to require a physician assistant (PA) licensed under ch. 458 or 459 F.S., or an advanced registered nurse practitioner (ARNP) certified under part I of ch. 464, F.S., who prescribes any controlled substance for the treatment of chronic nonmalignant pain to register with DOH as a controlled substance prescribing practitioner. The bill changes the words "clinician" and "physician" to "registrant" throughout the section to conform to this change. This new requirement also subjects PAs and ARNPs who are registered as a controlled substance prescribing practitioner to meet the statutory practice standards for such prescribing practitioners.

The bill exempts physicians who are board-eligible or board-certified medical specialists and who have completed a fellowship in pain medicine approved by the American Board of Interventional Pain Physicians or the American Association of Physician Specialists from the requirement to register as a controlled substance prescribing practitioner who prescribes controlled substances for the treatment of chronic nonmalignant pain.

The bill provides an effective date of July 1, 2016.

B. SECTION DIRECTORY:

Section 1. Amends s. 394.453, F.S., relating to legislative intent.
Section 2. Amends s. 394.463, F.S., relating to involuntary examination.
Section 3. Amends s. 394.467, F.S., relating to involuntary inpatient placement.
Section 4. Amends s. 397.451, F.S., relating to background checks of service provider personnel.
Section 5. Amends s. 409.909, F.S., relating to the Statewide Medicaid Residency Program.
Section 6. Amends s. 456.44, F.S., relating to controlled substance prescribing.
Section 7. Provides an effective date of July 1, 2016.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

2. Expenditures:

The bill may have an insignificant negative fiscal impact on the DOH associated with the creation of practitioner profiles for PAs, and workload impacts related to potential additional practitioner complaints and investigations.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

If the intent of the bill is to authorize PAs and ARNPs to prescribe controlled substances, such authority would need to be provided in each practitioner's practice act (chapters 458, 459, and 464, F.S.) and authority to prescribe controlled substances and receive a DEA registry number would need to be included in ch. 893, F.S., under the Florida Comprehensive Drug Abuse Prevention and Control Act.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to behavioral health workforce; amending s. 394.453, F.S.; revising legislative intent; amending s. 394.463, F.S.; expanding the authority of a psychiatric nurse to approve the release of a patient from a receiving facility; amending s. 394.467, F.S.; authorizing procedures for recommending admission of a patient to a treatment facility; amending s. 397.451, F.S.; revising provisions relating to exemptions from disqualification for certain service provider personnel; amending s. 409.909, F.S.; adding psychiatry to a list of primary care specialties under the Statewide Medicaid Residency Program; amending s. 456.44, F.S.; deleting an obsolete date; requiring advanced registered nurse practitioners and physician assistants who prescribe controlled substances for pain management to make a certain designation, comply with registration requirements, and follow specified standards of practice; providing applicability; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 394.453, Florida Statutes, is amended to read:

394.453 Legislative intent.—It is the intent of the Legislature to authorize and direct the Department of Children and Families to evaluate, research, plan, and recommend to the Governor and the Legislature programs designed to reduce the occurrence, severity, duration, and disabling aspects of mental, emotional, and behavioral disorders. It is the intent of the Legislature that treatment programs for such disorders shall include, but not be limited to, comprehensive health, social, educational, and rehabilitative services to persons requiring intensive short-term and continued treatment in order to encourage them to assume responsibility for their treatment and recovery. It is intended that such persons be provided with emergency service and temporary detention for evaluation when required; that they be admitted to treatment facilities on a voluntary basis when extended or continuing care is needed and unavailable in the community; that involuntary placement be provided only when expert evaluation determines that it is necessary; that any involuntary treatment or examination be accomplished in a setting which is clinically appropriate and most likely to facilitate the person's return to the community as soon as possible; and that individual dignity and human rights be guaranteed to all persons who are admitted to mental health facilities or who are being held under s. 394.463. It is the further intent of the Legislature that the least restrictive means of intervention be employed based on the individual needs of each person, within the scope of available services. It is

the policy of this state that the use of restraint and seclusion on clients is justified only as an emergency safety measure to be used in response to imminent danger to the client or others. It is, therefore, the intent of the Legislature to achieve an ongoing reduction in the use of restraint and seclusion in programs and facilities serving persons with mental illness. The Legislature further finds the need for additional psychiatrists to be of critical state concern and recommends the establishment of an additional psychiatry program to be offered by one of Florida's schools of medicine currently not offering psychiatry. The program shall seek to integrate primary care and psychiatry and other evolving models of care for persons with mental health and substance use disorders. Additionally, the Legislature finds that the use of telemedicine for patient evaluation, case management, and ongoing care will improve management of patient care and reduce costs of transportation.

Section 2. Paragraph (f) of subsection (2) of section 394.463, Florida Statutes, is amended to read:

394.463 Involuntary examination.—

(2) INVOLUNTARY EXAMINATION.—

(f) A patient shall be examined by a physician, a clinical psychologist, or a psychiatric nurse performing within the framework of an established protocol with a psychiatrist at a receiving facility without unnecessary delay and may, upon the order of a physician, be given emergency treatment if it is determined that such treatment is necessary for the safety of

the patient or others. The patient may not be released by the receiving facility or its contractor without the documented approval of a psychiatrist, ~~or~~ a clinical psychologist, or~~, if the receiving facility is owned or operated by a hospital or health system, the release may also be approved by~~ a psychiatric nurse performing within the framework of an established protocol with a psychiatrist or an attending emergency department physician with experience in the diagnosis and treatment of mental and nervous disorders and after completion of an involuntary examination pursuant to this subsection. A psychiatric nurse may not approve the release of a patient if the involuntary examination was initiated by a psychiatrist unless the release is approved by the initiating psychiatrist. However, a patient may not be held in a receiving facility for involuntary examination longer than 72 hours.

Section 3. Subsection (2) of section 394.467, Florida Statutes, is amended to read:

394.467 Involuntary inpatient placement.—

(2) ADMISSION TO A TREATMENT FACILITY.—A patient may be retained by a receiving facility or involuntarily placed in a treatment facility upon the recommendation of the administrator of the receiving facility where the patient has been examined and after adherence to the notice and hearing procedures provided in s. 394.4599. The recommendation must be supported by the opinion of a psychiatrist and the second opinion of a clinical psychologist or another psychiatrist, both of whom have

personally examined the patient within the preceding 72 hours, that the criteria for involuntary inpatient placement are met. However, in a county that has a population of fewer than 50,000, if the administrator certifies that a psychiatrist or clinical psychologist is not available to provide the second opinion, the second opinion may be provided by a licensed physician who has postgraduate training and experience in diagnosis and treatment of mental and nervous disorders or by a psychiatric nurse. Any ~~second~~ opinion authorized in this subsection may be conducted through a face-to-face examination, in person or by electronic means. Such recommendation shall be entered on an involuntary inpatient placement certificate that authorizes the receiving facility to retain the patient pending transfer to a treatment facility or completion of a hearing.

Section 4. Paragraphs (e) and (f) of subsection (1) and paragraph (b) of subsection (4) of section 397.451, Florida Statutes, are amended to read:

397.451 Background checks of service provider personnel.—

(1) PERSONNEL BACKGROUND CHECKS; REQUIREMENTS AND EXCEPTIONS.—

(e) Personnel employed directly or under contract with the Department of Corrections in an inmate substance abuse program ~~who have direct contact with unmarried inmates under the age of 18 or with inmates who are developmentally disabled~~ are exempt from the fingerprinting and background check requirements of this section unless they have direct contact with unmarried

inmates under the age of 18 or with inmates who are developmentally disabled.

(f) Service provider personnel who request an exemption from disqualification must submit the request within 30 days after being notified of the disqualification. If 5 years or more have elapsed since the most recent disqualifying offense, service provider personnel may work with adults with substance use disorders under the supervision of a qualified professional licensed under chapter 490 or chapter 491 or a master's level certified addiction professional until the agency makes a final determination regarding the request for an exemption from disqualification ~~Upon notification of the disqualification, the service provider shall comply with requirements regarding exclusion from employment in s. 435.06~~.

(4) EXEMPTIONS FROM DISQUALIFICATION.—

(b) Since rehabilitated substance abuse impaired persons are effective in the successful treatment and rehabilitation of individuals with substance use disorders ~~substance abuse impaired adolescents~~, for service providers which treat adolescents 13 years of age and older, service provider personnel whose background checks indicate crimes under s. 817.563, s. 893.13, or s. 893.147 may be exempted from disqualification from employment pursuant to this paragraph.

Section 5. Paragraph (a) of subsection (2) of section 409.909, Florida Statutes, is amended to read:

409.909 Statewide Medicaid Residency Program.—

(2) On or before September 15 of each year, the agency shall calculate an allocation fraction to be used for distributing funds to participating hospitals. On or before the final business day of each quarter of a state fiscal year, the agency shall distribute to each participating hospital one-fourth of that hospital's annual allocation calculated under subsection (4). The allocation fraction for each participating hospital is based on the hospital's number of full-time equivalent residents and the amount of its Medicaid payments. As used in this section, the term:

(a) "Full-time equivalent," or "FTE," means a resident who is in his or her residency period, with the initial residency period defined as the minimum number of years of training required before the resident may become eligible for board certification by the American Osteopathic Association Bureau of Osteopathic Specialists or the American Board of Medical Specialties in the specialty in which he or she first began training, not to exceed 5 years. The residency specialty is defined as reported using the current residency type codes in the Intern and Resident Information System (IRIS), required by Medicare. A resident training beyond the initial residency period is counted as 0.5 FTE, unless his or her chosen specialty is in primary care, in which case the resident is counted as 1.0 FTE. For the purposes of this section, primary care specialties include:

1. Family medicine;

2. General internal medicine;

3. General pediatrics;

4. Preventive medicine;

5. Geriatric medicine;

6. Osteopathic general practice;

7. Obstetrics and gynecology;

8. Emergency medicine; and

9. General surgery.

10. Psychiatry.

Section 6. Subsections (2) and (3) of section 456.44, Florida Statutes, are amended to read:

456.44 Controlled substance prescribing.—

(2) REGISTRATION.—~~Effective January 1, 2012,~~ A physician licensed under chapter 458, chapter 459, chapter 461, or chapter 466, a physician assistant licensed under chapter 458 or chapter 459, or an advanced registered nurse practitioner certified under part I of chapter 464 who prescribes any controlled substance, listed in Schedule II, Schedule III, or Schedule IV as defined in s. 893.03, for the treatment of chronic nonmalignant pain, must:

(a) Designate himself or herself as a controlled substance prescribing practitioner on his or her ~~the physician's~~ practitioner profile.

(b) Comply with the requirements of this section and applicable board rules.

(3) STANDARDS OF PRACTICE.—The standards of practice in

this section do not supersede the level of care, skill, and treatment recognized in general law related to health care licensure.

(a) A complete medical history and a physical examination must be conducted before beginning any treatment and must be documented in the medical record. The exact components of the physical examination shall be left to the judgment of the registrant ~~clinician~~ who is expected to perform a physical examination proportionate to the diagnosis that justifies a treatment. The medical record must, at a minimum, document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, a review of previous medical records, previous diagnostic studies, and history of alcohol and substance abuse. The medical record shall also document the presence of one or more recognized medical indications for the use of a controlled substance. Each registrant must develop a written plan for assessing each patient's risk of aberrant drug-related behavior, which may include patient drug testing. Registrants must assess each patient's risk for aberrant drug-related behavior and monitor that risk on an ongoing basis in accordance with the plan.

(b) Each registrant must develop a written individualized treatment plan for each patient. The treatment plan shall state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial

function, and shall indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the registrant ~~physician~~ shall adjust drug therapy to the individual medical needs of each patient. Other treatment modalities, including a rehabilitation program, shall be considered depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment. The interdisciplinary nature of the treatment plan shall be documented.

(c) The registrant ~~physician~~ shall discuss the risks and benefits of the use of controlled substances, including the risks of abuse and addiction, as well as physical dependence and its consequences, with the patient, persons designated by the patient, or the patient's surrogate or guardian if the patient is incompetent. The registrant ~~physician~~ shall use a written controlled substance agreement between the registrant ~~physician~~ and the patient outlining the patient's responsibilities, including, but not limited to:

1. Number and frequency of controlled substance prescriptions and refills.

2. Patient compliance and reasons for which drug therapy may be discontinued, such as a violation of the agreement.

3. An agreement that controlled substances for the treatment of chronic nonmalignant pain shall be prescribed by a single treating registrant ~~physician~~ unless otherwise authorized by the treating registrant ~~physician~~ and documented in the

medical record.

(d) The patient shall be seen by the registrant ~~physician~~ at regular intervals, not to exceed 3 months, to assess the efficacy of treatment, ensure that controlled substance therapy remains indicated, evaluate the patient's progress toward treatment objectives, consider adverse drug effects, and review the etiology of the pain. Continuation or modification of therapy shall depend on the registrant's ~~physician's~~ evaluation of the patient's progress. If treatment goals are not being achieved, despite medication adjustments, the registrant ~~physician~~ shall reevaluate the appropriateness of continued treatment. The registrant ~~physician~~ shall monitor patient compliance in medication usage, related treatment plans, controlled substance agreements, and indications of substance abuse or diversion at a minimum of 3-month intervals.

(e) The registrant ~~physician~~ shall refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention shall be given to those patients who are at risk for misusing their medications and those whose living arrangements pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder requires extra care, monitoring, and documentation and requires consultation with or referral to an addiction medicine specialist or psychiatrist.

(f) A registrant ~~physician~~ registered under this section

must maintain accurate, current, and complete records that are accessible and readily available for review and comply with the requirements of this section, the applicable practice act, and applicable board rules. The medical records must include, but are not limited to:

1. The complete medical history and a physical examination, including history of drug abuse or dependence.

2. Diagnostic, therapeutic, and laboratory results.

3. Evaluations and consultations.

4. Treatment objectives.

5. Discussion of risks and benefits.

6. Treatments.

7. Medications, including date, type, dosage, and quantity prescribed.

8. Instructions and agreements.

9. Periodic reviews.

10. Results of any drug testing.

11. A photocopy of the patient's government-issued photo identification.

12. If a written prescription for a controlled substance is given to the patient, a duplicate of the prescription.

13. The registrant's ~~physician's~~ full name presented in a legible manner.

(g) Patients with signs or symptoms of substance abuse shall be immediately referred to a board-certified pain management physician, an addiction medicine specialist, or a

mental health addiction facility as it pertains to drug abuse or addiction unless the registrant is a physician who is board-certified or board-eligible in pain management. Throughout the period of time before receiving the consultant's report, a prescribing registrant ~~physician~~ shall clearly and completely document medical justification for continued treatment with controlled substances and those steps taken to ensure medically appropriate use of controlled substances by the patient. Upon receipt of the consultant's written report, the prescribing registrant ~~physician~~ shall incorporate the consultant's recommendations for continuing, modifying, or discontinuing controlled substance therapy. The resulting changes in treatment shall be specifically documented in the patient's medical record. Evidence or behavioral indications of diversion shall be followed by discontinuation of controlled substance therapy, and the patient shall be discharged, and all results of testing and actions taken by the registrant ~~physician~~ shall be documented in the patient's medical record.

This subsection does not apply to a board-eligible or board-certified anesthesiologist, physiatrist, rheumatologist, or neurologist, or to a board-certified physician who has surgical privileges at a hospital or ambulatory surgery center and primarily provides surgical services. This subsection does not apply to a board-eligible or board-certified medical specialist who has also completed a fellowship in pain medicine approved by

the Accreditation Council for Graduate Medical Education or the American Osteopathic Association, or who is board eligible or board certified in pain medicine by the American Board of Pain Medicine, the American Board of Interventional Pain Physicians, the American Association of Physician Specialists, or a board approved by the American Board of Medical Specialties or the American Osteopathic Association and performs interventional pain procedures of the type routinely billed using surgical codes. This subsection does not apply to a registrant, advanced registered nurse practitioner, or physician assistant who prescribes medically necessary controlled substances for a patient during an inpatient stay in a hospital licensed under chapter 395.

Section 7. This act shall take effect July 1, 2016.

Amendment No.

COMMITTEE/SUBCOMMITTEE ACTION

ADOPTED	____	(Y/N)
ADOPTED AS AMENDED	____	(Y/N)
ADOPTED W/O OBJECTION	____	(Y/N)
FAILED TO ADOPT	____	(Y/N)
WITHDRAWN	____	(Y/N)
OTHER		

Committee/Subcommittee hearing bill: Health Quality Subcommittee

Representative Peters offered the following:

Amendment (with title amendment)

Remove everything after the enacting clause and insert:

Section 1. Subsection (7) of section 110.12315, Florida Statutes, is amended to read:

110.12315 Prescription drug program.—The state employees' prescription drug program is established. This program shall be administered by the Department of Management Services, according to the terms and conditions of the plan as established by the relevant provisions of the annual General Appropriations Act and implementing legislation, subject to the following conditions:

(7) The department shall establish the reimbursement schedule for prescription pharmaceuticals dispensed under the program. Reimbursement rates for a prescription pharmaceutical

must be based on the cost of the generic equivalent drug if a generic equivalent exists, unless the physician, advanced registered nurse practitioner, or physician assistant prescribing the pharmaceutical clearly states on the prescription that the brand name drug is medically necessary or that the drug product is included on the formulary of drug products that may not be interchanged as provided in chapter 465, in which case reimbursement must be based on the cost of the brand name drug as specified in the reimbursement schedule adopted by the department.

Section 2. Paragraph (c) of subsection (1) of section 310.071, Florida Statutes, is amended, and subsection (3) of that section is republished, to read:

310.071 Deputy pilot certification.—

(1) In addition to meeting other requirements specified in this chapter, each applicant for certification as a deputy pilot must:

(c) Be in good physical and mental health, as evidenced by documentary proof of having satisfactorily passed a complete physical examination administered by a licensed physician within the preceding 6 months. The board shall adopt rules to establish requirements for passing the physical examination, which rules shall establish minimum standards for the physical or mental capabilities necessary to carry out the professional duties of a certificated deputy pilot. Such standards shall include zero tolerance for any controlled substance regulated under chapter

893 unless that individual is under the care of a physician, advanced registered nurse practitioner, or physician assistant and that controlled substance was prescribed by that physician, advanced registered nurse practitioner, or physician assistant. To maintain eligibility as a certificated deputy pilot, each certificated deputy pilot must annually provide documentary proof of having satisfactorily passed a complete physical examination administered by a licensed physician. The physician must know the minimum standards and certify that the certificateholder satisfactorily meets the standards. The standards for certificateholders shall include a drug test.

(3) The initial certificate issued to a deputy pilot shall be valid for a period of 12 months, and at the end of this period, the certificate shall automatically expire and shall not be renewed. During this period, the board shall thoroughly evaluate the deputy pilot's performance for suitability to continue training and shall make appropriate recommendations to the department. Upon receipt of a favorable recommendation by the board, the department shall issue a certificate to the deputy pilot, which shall be valid for a period of 2 years. The certificate may be renewed only two times, except in the case of a fully licensed pilot who is cross-licensed as a deputy pilot in another port, and provided the deputy pilot meets the requirements specified for pilots in paragraph (1)(c).

Section 3. Subsection (3) of section 310.073, Florida Statutes, is amended to read:

310.073 State pilot licensing.—In addition to meeting other requirements specified in this chapter, each applicant for license as a state pilot must:

(3) Be in good physical and mental health, as evidenced by documentary proof of having satisfactorily passed a complete physical examination administered by a licensed physician within the preceding 6 months. The board shall adopt rules to establish requirements for passing the physical examination, which rules shall establish minimum standards for the physical or mental capabilities necessary to carry out the professional duties of a licensed state pilot. Such standards shall include zero tolerance for any controlled substance regulated under chapter 893 unless that individual is under the care of a physician, advanced registered nurse practitioner, or physician assistant and that controlled substance was prescribed by that physician, advanced registered nurse practitioner, or physician assistant. To maintain eligibility as a licensed state pilot, each licensed state pilot must annually provide documentary proof of having satisfactorily passed a complete physical examination administered by a licensed physician. The physician must know the minimum standards and certify that the licensee satisfactorily meets the standards. The standards for licensees shall include a drug test.

Section 4. Paragraph (b) of subsection (3) of section 310.081, Florida Statutes, is amended to read:

310.081 Department to examine and license state pilots and certificate deputy pilots; vacancies.—

(3) Pilots shall hold their licenses or certificates pursuant to the requirements of this chapter so long as they:

(b) Are in good physical and mental health as evidenced by documentary proof of having satisfactorily passed a physical examination administered by a licensed physician or physician assistant within each calendar year. The board shall adopt rules to establish requirements for passing the physical examination, which rules shall establish minimum standards for the physical or mental capabilities necessary to carry out the professional duties of a licensed state pilot or a certificated deputy pilot. Such standards shall include zero tolerance for any controlled substance regulated under chapter 893 unless that individual is under the care of a physician, advanced registered nurse practitioner, or physician assistant and that controlled substance was prescribed by that physician, advanced registered nurse practitioner, or physician assistant. To maintain eligibility as a certificated deputy pilot or licensed state pilot, each certificated deputy pilot or licensed state pilot must annually provide documentary proof of having satisfactorily passed a complete physical examination administered by a licensed physician. The physician must know the minimum standards and certify that the certificateholder or licensee satisfactorily meets the standards. The standards for certificateholders and for licensees shall include a drug test.

Upon resignation or in the case of disability permanently affecting a pilot's ability to serve, the state license or certificate issued under this chapter shall be revoked by the department.

Section 5. Section 394.453, Florida Statutes, is amended to read:

394.453 Legislative intent.—It is the intent of the Legislature to authorize and direct the Department of Children and Families to evaluate, research, plan, and recommend to the Governor and the Legislature programs designed to reduce the occurrence, severity, duration, and disabling aspects of mental, emotional, and behavioral disorders. It is the intent of the Legislature that treatment programs for such disorders shall include, but not be limited to, comprehensive health, social, educational, and rehabilitative services to persons requiring intensive short-term and continued treatment in order to encourage them to assume responsibility for their treatment and recovery. It is intended that such persons be provided with emergency service and temporary detention for evaluation when required; that they be admitted to treatment facilities on a voluntary basis when extended or continuing care is needed and unavailable in the community; that involuntary placement be provided only when expert evaluation determines that it is necessary; that any involuntary treatment or examination be accomplished in a setting which is clinically appropriate and

most likely to facilitate the person's return to the community as soon as possible; and that individual dignity and human rights be guaranteed to all persons who are admitted to mental health facilities or who are being held under s. 394.463. It is the further intent of the Legislature that the least restrictive means of intervention be employed based on the individual needs of each person, within the scope of available services. It is the policy of this state that the use of restraint and seclusion on clients is justified only as an emergency safety measure to be used in response to imminent danger to the client or others. It is, therefore, the intent of the Legislature to achieve an ongoing reduction in the use of restraint and seclusion in programs and facilities serving persons with mental illness. The Legislature further finds the need for additional psychiatrists to be of critical state concern and recommends the establishment of an additional psychiatry program to be offered by one of Florida's schools of medicine currently not offering psychiatry. The program shall seek to integrate primary care and psychiatry and other evolving models of care for persons with mental health and substance use disorders. Additionally, the Legislature finds that the use of telemedicine for patient evaluation, case management, and ongoing care will improve management of patient care and reduce costs of transportation.

Section 6. Subsection (2) of section 394.467, Florida Statutes, is amended to read:

394.467 Involuntary inpatient placement.—

(2) ADMISSION TO A TREATMENT FACILITY.—A patient may be retained by a receiving facility or involuntarily placed in a treatment facility upon the recommendation of the administrator of the receiving facility where the patient has been examined and after adherence to the notice and hearing procedures provided in s. 394.4599. The recommendation must be supported by the opinion of a psychiatrist and the second opinion of a clinical psychologist or another psychiatrist, both of whom have personally examined the patient within the preceding 72 hours, that the criteria for involuntary inpatient placement are met. However, in a county that has a population of fewer than 50,000, if the administrator certifies that a psychiatrist or clinical psychologist is not available to provide the second opinion, the second opinion may be provided by a licensed physician who has postgraduate training and experience in diagnosis and treatment of mental and nervous disorders or by a psychiatric nurse. Any ~~second~~ opinion authorized in this subsection may be conducted through a face-to-face examination, in person or by electronic means. Such recommendation shall be entered on an involuntary inpatient placement certificate that authorizes the receiving facility to retain the patient pending transfer to a treatment facility or completion of a hearing.

Section 7. Paragraphs (e) and (f) of subsection (1) and paragraph (b) of subsection (4) of section 397.451, Florida Statutes, are amended to read:

397.451 Background checks of service provider personnel.—

(1) PERSONNEL BACKGROUND CHECKS; REQUIREMENTS AND EXCEPTIONS.—

(e) Personnel employed directly or under contract with the Department of Corrections in an inmate substance abuse program ~~who have direct contact with unmarried inmates under the age of 18 or with inmates who are developmentally disabled~~ are exempt from the fingerprinting and background check requirements of this section unless they have direct contact with unmarried inmates under the age of 18 or with inmates who are developmentally disabled.

(f) Service provider personnel who request an exemption from disqualification must submit the request within 30 days after being notified of the disqualification. If 5 years or more have elapsed since the most recent disqualifying offense, service provider personnel may work with adults with substance use disorders under the supervision of a qualified professional licensed under chapter 490 or chapter 491 or a master's level certified addiction professional until the agency makes a final determination regarding the request for an exemption from disqualification ~~Upon notification of the disqualification, the service provider shall comply with requirements regarding exclusion from employment in s. 435.06~~.

(4) EXEMPTIONS FROM DISQUALIFICATION.—

(b) Since rehabilitated substance abuse impaired persons are effective in the successful treatment and rehabilitation of individuals with substance use disorders ~~substance abuse~~

~~impaired adolescents~~, for service providers which treat adolescents 13 years of age and older, service provider personnel whose background checks indicate crimes under s. 817.563, s. 893.13, or s. 893.147 may be exempted from disqualification from employment pursuant to this paragraph.

Section 8. Subsection (7) of section 456.072, Florida Statutes, is amended to read:

456.072 Grounds for discipline; penalties; enforcement.—

(7) Notwithstanding subsection (2), upon a finding that a physician has prescribed or dispensed a controlled substance, or caused a controlled substance to be prescribed or dispensed, in a manner that violates the standard of practice set forth in s. 458.331(1)(q) or (t), s. 459.015(1)(t) or (x), s. 461.013(1)(o) or (s), or s. 466.028(1)(p) or (x), or that an advanced registered nurse practitioner has prescribed or dispensed a controlled substance, or caused a controlled substance to be prescribed or dispensed in a manner that violates the standard of practice set forth in s. 464.018(1)(n) or s. 464.018(1)(p)6., the physician or advanced registered nurse practitioner shall be suspended for a period of not less than 6 months and pay a fine of not less than $10,000 per count. Repeated violations shall result in increased penalties.

Section 9. Section 456.44, Florida Statutes, is amended to read:

456.44 Controlled substance prescribing.—

(1) DEFINITIONS.— As used in this section, the term:

(a) "Addiction medicine specialist" means a board-certified psychiatrist with a subspecialty certification in addiction medicine or who is eligible for such subspecialty certification in addiction medicine, an addiction medicine physician certified or eligible for certification by the American Society of Addiction Medicine, or an osteopathic physician who holds a certificate of added qualification in Addiction Medicine through the American Osteopathic Association.

(b) "Adverse incident" means any incident set forth in s. 458.351(4)(a)-(e) or s. 459.026(4)(a)-(e).

(c) "Board-certified pain management physician" means a physician who possesses board certification in pain medicine by the American Board of Pain Medicine, board certification by the American Board of Interventional Pain Physicians, or board certification or subcertification in pain management or pain medicine by a specialty board recognized by the American Association of Physician Specialists or the American Board of Medical Specialties or an osteopathic physician who holds a certificate in Pain Management by the American Osteopathic Association.

(d) "Board eligible" means successful completion of an anesthesia, physical medicine and rehabilitation, rheumatology, or neurology residency program approved by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association for a period of 6 years from successful completion of such residency program.

(e) "Chronic nonmalignant pain" means 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.

(f) "Mental health addiction facility" means a facility licensed under chapter 394 or chapter 397.

(g) "Registrant" means a physician, physician assistant, or advanced registered nurse practitioner who meets the requirements of subsection (2).

(2) REGISTRATION. ~~Effective January 1, 2012,~~ A physician licensed under chapter 458, chapter 459, chapter 461, or chapter 466, a physician assistant licensed under chapter 458 or chapter 459, or an advanced registered nurse practitioner certified under part I of chapter 464 who prescribes any controlled substance, listed in Schedule II, Schedule III, or Schedule IV as defined in s. 893.03, for the treatment of chronic nonmalignant pain, must:

(a) Designate himself or herself as a controlled substance prescribing practitioner on his or her ~~the physician's~~ practitioner profile.

(b) Comply with the requirements of this section and applicable board rules.

(3) STANDARDS OF PRACTICE.—The standards of practice in this section do not supersede the level of care, skill, and treatment recognized in general law related to health care licensure.

(a) A complete medical history and a physical examination must be conducted before beginning any treatment and must be documented in the medical record. The exact components of the physical examination shall be left to the judgment of the registrant ~~clinician~~ who is expected to perform a physical examination proportionate to the diagnosis that justifies a treatment. The medical record must, at a minimum, document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, a review of previous medical records, previous diagnostic studies, and history of alcohol and substance abuse. The medical record shall also document the presence of one or more recognized medical indications for the use of a controlled substance. Each registrant must develop a written plan for assessing each patient's risk of aberrant drug-related behavior, which may include patient drug testing. Registrants must assess each patient's risk for aberrant drug-related behavior and monitor that risk on an ongoing basis in accordance with the plan.

(b) Each registrant must develop a written individualized treatment plan for each patient. The treatment plan shall state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and shall indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the registrant ~~physician~~ shall adjust drug therapy to

the individual medical needs of each patient. Other treatment modalities, including a rehabilitation program, shall be considered depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment. The interdisciplinary nature of the treatment plan shall be documented.

(c) The registrant ~~physician~~ shall discuss the risks and benefits of the use of controlled substances, including the risks of abuse and addiction, as well as physical dependence and its consequences, with the patient, persons designated by the patient, or the patient's surrogate or guardian if the patient is incompetent. The registrant ~~physician~~ shall use a written controlled substance agreement between the registrant ~~physician~~ and the patient outlining the patient's responsibilities, including, but not limited to:

1. Number and frequency of controlled substance prescriptions and refills.

2. Patient compliance and reasons for which drug therapy may be discontinued, such as a violation of the agreement.

3. An agreement that controlled substances for the treatment of chronic nonmalignant pain shall be prescribed by a single treating registrant ~~physician~~ unless otherwise authorized by the treating registrant ~~physician~~ and documented in the medical record.

(d) The patient shall be seen by the registrant ~~physician~~ at regular intervals, not to exceed 3 months, to assess the

efficacy of treatment, ensure that controlled substance therapy remains indicated, evaluate the patient's progress toward treatment objectives, consider adverse drug effects, and review the etiology of the pain. Continuation or modification of therapy shall depend on the registrant's ~~physician's~~ evaluation of the patient's progress. If treatment goals are not being achieved, despite medication adjustments, the registrant ~~physician~~ shall reevaluate the appropriateness of continued treatment. The registrant ~~physician~~ shall monitor patient compliance in medication usage, related treatment plans, controlled substance agreements, and indications of substance abuse or diversion at a minimum of 3-month intervals.

(e) The registrant ~~physician~~ shall refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention shall be given to those patients who are at risk for misusing their medications and those whose living arrangements pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder requires extra care, monitoring, and documentation and requires consultation with or referral to an addiction medicine specialist or psychiatrist.

(f) A registrant ~~physician registered under this section~~ must maintain accurate, current, and complete records that are accessible and readily available for review and comply with the requirements of this section, the applicable practice act, and

applicable board rules. The medical records must include, but are not limited to:

1. The complete medical history and a physical examination, including history of drug abuse or dependence.

2. Diagnostic, therapeutic, and laboratory results.

3. Evaluations and consultations.

4. Treatment objectives.

5. Discussion of risks and benefits.

6. Treatments.

7. Medications, including date, type, dosage, and quantity prescribed.

8. Instructions and agreements.

9. Periodic reviews.

10. Results of any drug testing.

11. A photocopy of the patient's government-issued photo identification.

12. If a written prescription for a controlled substance is given to the patient, a duplicate of the prescription.

13. The registrant's ~~physician's~~ full name presented in a legible manner.

(g) A registrant shall immediately refer patients with signs or symptoms of substance ~~abuse shall be immediately referred~~ to a board-certified pain management physician, an addiction medicine specialist, or a mental health addiction facility as it pertains to drug abuse or addiction unless the registrant is a physician who is board-certified or board-

eligible in pain management. Throughout the period of time before receiving the consultant's report, a prescribing registrant ~~physician~~ shall clearly and completely document medical justification for continued treatment with controlled substances and those steps taken to ensure medically appropriate use of controlled substances by the patient. Upon receipt of the consultant's written report, the prescribing registrant ~~physician~~ shall incorporate the consultant's recommendations for continuing, modifying, or discontinuing controlled substance therapy. The resulting changes in treatment shall be specifically documented in the patient's medical record. Evidence or behavioral indications of diversion shall be followed by discontinuation of controlled substance therapy, and the patient shall be discharged, and all results of testing and actions taken by the registrant ~~physician~~ shall be documented in the patient's medical record.

This subsection does not apply to a board-eligible or board-certified anesthesiologist, physiatrist, rheumatologist, or neurologist, or to a board-certified physician who has surgical privileges at a hospital or ambulatory surgery center and primarily provides surgical services. This subsection does not apply to a board-eligible or board-certified medical specialist who has also completed a fellowship in pain medicine approved by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association, or who is board eligible or

board certified in pain medicine by the American Board of Pain Medicine or a board approved by the American Board of Medical Specialties or the American Osteopathic Association and performs interventional pain procedures of the type routinely billed using surgical codes. This subsection does not apply to a registrant, physician, advanced registered nurse practitioner, or physician assistant who prescribes medically necessary controlled substances for a patient during an inpatient stay in a hospital licensed under chapter 395.

Section 10. Paragraph (b) of subsection (2) of section 458.3265, Florida Statutes, is amended to read:

458.3265 Pain-management clinics.—

(2) PHYSICIAN RESPONSIBILITIES.—These responsibilities apply to any physician who provides professional services in a pain-management clinic that is required to be registered in subsection (1).

(b) Only ~~a person may not dispense any medication on the premises of a registered pain-management clinic unless he or she is~~ a physician licensed under this chapter or chapter 459 may dispense medication or prescribe a controlled substance regulated under chapter 893 on the premises of a registered pain-management clinic.

Section 11. Paragraph (b) of subsection (2) of section 459.0137, Florida Statutes, is amended to read:

459.0137 Pain-management clinics.—

(2) PHYSICIAN RESPONSIBILITIES.—These responsibilities apply to any osteopathic physician who provides professional services in a pain-management clinic that is required to be registered in subsection (1).

(b) Only ~~a person may not dispense any medication on the premises of a registered pain-management clinic unless he or she is~~ a physician licensed under this chapter or chapter 458 may dispense medication or prescribe a controlled substance regulated under chapter 893 on the premises of a registered pain-management clinic.

Section 12. Paragraph (e) of subsection (4) of section 458.347, Florida Statutes, is amended, and paragraph (c) of subsection (9) of that section is republished, to read:

458.347 Physician assistants.—

(4) PERFORMANCE OF PHYSICIAN ASSISTANTS.—

(e) A supervisory physician may delegate to a fully licensed physician assistant the authority to prescribe or dispense any medication used in the supervisory physician's practice unless such medication is listed on the formulary created pursuant to paragraph (f). A fully licensed physician assistant may only prescribe or dispense such medication under the following circumstances:

1. A physician assistant must clearly identify to the patient that he or she is a physician assistant. Furthermore, the physician assistant must inform the patient that the patient

has the right to see the physician prior to any prescription being prescribed or dispensed by the physician assistant.

2. The supervisory physician must notify the department of his or her intent to delegate, on a department-approved form, before delegating such authority and notify the department of any change in prescriptive privileges of the physician assistant. Authority to dispense may be delegated only by a supervising physician who is registered as a dispensing practitioner in compliance with s. 465.0276.

3. The physician assistant must file with the department a signed affidavit that he or she has completed a minimum of 10 continuing medical education hours in the specialty practice in which the physician assistant has prescriptive privileges with each licensure renewal application. Three of the 10 hours must consist of a continuing education course on the safe and effective prescribing of controlled substance medications 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 I Credit or designated by the American Academy of Physician Assistants as a Category 1 Credit.

4. The department may issue a prescriber number to the physician assistant granting authority for the prescribing of medicinal drugs authorized within this paragraph upon completion of the foregoing requirements. The physician assistant shall not be required to independently register pursuant to s. 465.0276.

5. The prescription must be written in a form that complies with chapter 499 and must contain, in addition to the supervisory physician's name, address, and telephone number, the physician assistant's prescriber number. Unless it is a drug or drug sample dispensed by the physician assistant, the prescription must be filled in a pharmacy permitted under chapter 465 and must be dispensed in that pharmacy by a pharmacist licensed under chapter 465. The appearance of the prescriber number creates a presumption that the physician assistant is authorized to prescribe the medicinal drug and the prescription is valid.

6. The physician assistant must note the prescription or dispensing of medication in the appropriate medical record.

(9) COUNCIL ON PHYSICIAN ASSISTANTS.—The Council on Physician Assistants is created within the department.

(c) The council shall:

1. Recommend to the department the licensure of physician assistants.

2. Develop all rules regulating the use of physician assistants by physicians under this chapter and chapter 459, except for rules relating to the formulary developed under paragraph (4)(f). The council shall also develop rules to ensure that the continuity of supervision is maintained in each practice setting. The boards shall consider adopting a proposed rule developed by the council at the regularly scheduled meeting immediately following the submission of the proposed rule by the

council. A proposed rule submitted by the council may not be adopted by either board unless both boards have accepted and approved the identical language contained in the proposed rule. The language of all proposed rules submitted by the council must be approved by both boards pursuant to each respective board's guidelines and standards regarding the adoption of proposed rules. If either board rejects the council's proposed rule, that board must specify its objection to the council with particularity and include any recommendations it may have for the modification of the proposed rule.

3. Make recommendations to the boards regarding all matters relating to physician assistants.

4. Address concerns and problems of practicing physician assistants in order to improve safety in the clinical practices of licensed physician assistants.

Section 13. Effective January 1, 2017, paragraph (f) of subsection (4) of section 458.347, Florida Statutes, is amended to read:

458.347 Physician assistants.—

(4) PERFORMANCE OF PHYSICIAN ASSISTANTS.—

(f)1. The council shall establish a formulary of medicinal drugs that a fully licensed physician assistant having prescribing authority under this section or s. 459.022 may not prescribe. The formulary must include ~~controlled substances as defined in chapter 893,~~ general anesthetics~~,~~ and radiographic contrast materials, and must limit the prescription of Schedule

II controlled substances as defined in s. 893.03 to a 7-day supply. The formulary must also restrict the prescribing of psychiatric mental health controlled substances for children under 18 years of age.

2. In establishing the formulary, the council shall consult with a pharmacist licensed under chapter 465, but not licensed under this chapter or chapter 459, who shall be selected by the State Surgeon General.

3. Only the council shall add to, delete from, or modify the formulary. Any person who requests an addition, deletion, or modification of a medicinal drug listed on such formulary has the burden of proof to show cause why such addition, deletion, or modification should be made.

4. The boards shall adopt the formulary required by this paragraph, and each addition, deletion, or modification to the formulary, by rule. Notwithstanding any provision of chapter 120 to the contrary, the formulary rule shall be effective 60 days after the date it is filed with the Secretary of State. Upon adoption of the formulary, the department shall mail a copy of such formulary to each fully licensed physician assistant having prescribing authority under this section or s. 459.022, and to each pharmacy licensed by the state. The boards shall establish, by rule, a fee not to exceed $200 to fund the provisions of this paragraph and paragraph (e).

Section 14. Subsection (2) of section 464.003, Florida Statutes, is amended to read:

464.003 Definitions.—As used in this part, the term:

(2) "Advanced or specialized nursing practice" means, in addition to the practice of professional nursing, the performance of advanced-level nursing acts approved by the board which, by virtue of postbasic specialized education, training, and experience, are appropriately performed by an advanced registered nurse practitioner. Within the context of advanced or specialized nursing practice, the advanced registered nurse practitioner may perform acts of nursing diagnosis and nursing treatment of alterations of the health status. The advanced registered nurse practitioner may also perform acts of medical diagnosis and treatment, prescription, and operation as authorized within the framework of an established supervisory protocol ~~which are identified and approved by a joint committee composed of three members appointed by the Board of Nursing, two of whom must be advanced registered nurse practitioners; three members appointed by the Board of Medicine, two of whom must have had work experience with advanced registered nurse practitioners; and the State Surgeon General or the State Surgeon General's designee. Each committee member appointed by a board shall be appointed to a term of 4 years unless a shorter term is required to establish or maintain staggered terms. The Board of Nursing shall adopt rules authorizing the performance of any such acts approved by the joint committee. Unless otherwise specified by the joint committee, such acts must be performed under the general supervision of a practitioner~~

~~licensed under chapter 458, chapter 459, or chapter 466 within the framework of standing protocols which identify the medical acts to be performed and the conditions for their performance.~~ The department may, by rule, require that a copy of the protocol be filed with the department along with the notice required by s. 458.348.

Section 15. Subsection (6) is added to section 464.012, Florida Statutes, to read:

464.012 Certification of advanced registered nurse practitioners; fees; controlled substance prescribing.—

(1) Any nurse desiring to be certified as an advanced registered nurse practitioner shall apply to the department and submit proof that he or she holds a current license to practice professional nursing and that he or she meets one or more of the following requirements as determined by the board:

(a) Satisfactory completion of a formal postbasic educational program of at least one academic year, the primary purpose of which is to prepare nurses for advanced or specialized practice.

(b) Certification by an appropriate specialty board. Such certification shall be required for initial state certification and any recertification as a registered nurse anesthetist or nurse midwife. The board may by rule provide for provisional state certification of graduate nurse anesthetists and nurse midwives for a period of time determined to be appropriate for

preparing for and passing the national certification examination.

(c) Graduation from a program leading to a master's degree in a nursing clinical specialty area with preparation in specialized practitioner skills. For applicants graduating on or after October 1, 1998, graduation from a master's degree program shall be required for initial certification as a nurse practitioner under paragraph (4)(c). For applicants graduating on or after October 1, 2001, graduation from a master's degree program shall be required for initial certification as a registered nurse anesthetist under paragraph (4)(a).

(2) The board shall provide by rule the appropriate requirements for advanced registered nurse practitioners in the categories of certified registered nurse anesthetist, certified nurse midwife, and nurse practitioner.

(3) An advanced registered nurse practitioner shall perform those functions authorized in this section within the framework of an established protocol that is filed with the board upon biennial license renewal and within 30 days after entering into a supervisory relationship with a physician or changes to the protocol. The board shall review the protocol to ensure compliance with applicable regulatory standards for protocols. The board shall refer to the department licensees submitting protocols that are not compliant with the regulatory standards for protocols. A practitioner currently licensed under chapter 458, chapter 459, or chapter 466 shall maintain

supervision for directing the specific course of medical treatment. Within the established framework, an advanced registered nurse practitioner may:

(a) Monitor and alter drug therapies.

(b) Initiate appropriate therapies for certain conditions.

(c) Perform additional functions as may be determined by rule in accordance with s. 464.003(2).

(d) Order diagnostic tests and physical and occupational therapy.

(4) In addition to the general functions specified in subsection (3), an advanced registered nurse practitioner may perform the following acts within his or her specialty:

(a) The certified registered nurse anesthetist may, to the extent authorized by established protocol approved by the medical staff of the facility in which the anesthetic service is performed, perform any or all of the following:

1. Determine the health status of the patient as it relates to the risk factors and to the anesthetic management of the patient through the performance of the general functions.

2. Based on history, physical assessment, and supplemental laboratory results, determine, with the consent of the responsible physician, the appropriate type of anesthesia within the framework of the protocol.

3. Order under the protocol preanesthetic medication.

4. Perform under the protocol procedures commonly used to render the patient insensible to pain during the performance of

surgical, obstetrical, therapeutic, or diagnostic clinical procedures. These procedures include ordering and administering regional, spinal, and general anesthesia; inhalation agents and techniques; intravenous agents and techniques; and techniques of hypnosis.

5. Order or perform monitoring procedures indicated as pertinent to the anesthetic health care management of the patient.

6. Support life functions during anesthesia health care, including induction and intubation procedures, the use of appropriate mechanical supportive devices, and the management of fluid, electrolyte, and blood component balances.

7. Recognize and take appropriate corrective action for abnormal patient responses to anesthesia, adjunctive medication, or other forms of therapy.

8. Recognize and treat a cardiac arrhythmia while the patient is under anesthetic care.

9. Participate in management of the patient while in the postanesthesia recovery area, including ordering the administration of fluids and drugs.

10. Place special peripheral and central venous and arterial lines for blood sampling and monitoring as appropriate.

(b) The certified nurse midwife may, to the extent authorized by an established protocol which has been approved by the medical staff of the health care facility in which the midwifery services are performed, or approved by the nurse

midwife's physician backup when the delivery is performed in a patient's home, perform any or all of the following:

1. Perform superficial minor surgical procedures.

2. Manage the patient during labor and delivery to include amniotomy, episiotomy, and repair.

3. Order, initiate, and perform appropriate anesthetic procedures.

4. Perform postpartum examination.

5. Order appropriate medications.

6. Provide family-planning services and well-woman care.

7. Manage the medical care of the normal obstetrical patient and the initial care of a newborn patient.

(c) The nurse practitioner may perform any or all of the following acts within the framework of established protocol:

1. Manage selected medical problems.

2. Order physical and occupational therapy.

3. Initiate, monitor, or alter therapies for certain uncomplicated acute illnesses.

4. Monitor and manage patients with stable chronic diseases.

5. Establish behavioral problems and diagnosis and make treatment recommendations.

(5) The board shall certify, and the department shall issue a certificate to, any nurse meeting the qualifications in this section. The board shall establish an application fee not to exceed $100 and a biennial renewal fee not to exceed $50. The

board is authorized to adopt such other rules as are necessary to implement the provisions of this section.

(6)(a) The board shall establish a committee to recommend a formulary of controlled substances that an advanced registered nurse practitioner may not prescribe or may prescribe only for specific uses or in limited quantities. The committee must consist of three advanced registered nurse practitioners licensed under this section, recommended by the Board of Nursing; three physicians licensed under chapter 458 or chapter 459 who have work experience with advanced registered nurse practitioners, recommended by the Board of Medicine; and a pharmacist licensed under chapter 465 who holds a Doctor of Pharmacy degree, recommended by the Board of Pharmacy. The committee may recommend an evidence-based formulary applicable to all advanced registered nurse practitioners which is limited by specialty certification, is limited to approved uses of controlled substances, or is subject to other similar restrictions the committee finds are necessary to protect the health, safety, and welfare of the public. The formulary must restrict the prescribing of psychiatric mental health controlled substances for children under 18 years of age to advanced registered nurse practitioners who also are psychiatric nurses as defined in s. 394.455. The formulary must also limit the prescribing of Schedule II controlled substances as defined in s. 893.03 to a 7-day supply, except that such restriction does not apply to controlled substances that are psychiatric

768 medications prescribed by psychiatric nurses as defined in s.
769 394.455.
770 (b) The board shall adopt by rule the recommended
771 formulary and any revisions to the formulary which it finds are
772 supported by evidence-based clinical findings presented by the
773 Board of Medicine, the Board of Osteopathic Medicine, or the
774 Board of Dentistry.
775 (c) The formulary required under this subsection does not
776 apply to a controlled substance that is dispensed for
777 administration pursuant to an order, including an order for
778 medication authorized by subparagraph (4)(a)3., subparagraph
779 (4)(a)4., or subparagraph (4)(a)9.
780 (d) The board shall adopt the committee's initial
781 recommendation no later October 31, 2016.
782 Section 16. Effective January 1, 2017, subsection (3) of
783 section 464.012, Florida Statutes, as amended by this act, is
784 amended to read:
785 464.012 Certification of advanced registered nurse
786 practitioners; fees; controlled substance prescribing.—
787 (3) An advanced registered nurse practitioner shall
788 perform those functions authorized in this section within the
789 framework of an established protocol that is filed with the
790 board upon biennial license renewal and within 30 days after
791 entering into a supervisory relationship with a physician or
792 changes to the protocol. The board shall review the protocol to
793 ensure compliance with applicable regulatory standards for

protocols. The board shall refer to the department licensees submitting protocols that are not compliant with the regulatory standards for protocols. A practitioner currently licensed under chapter 458, chapter 459, or chapter 466 shall maintain supervision for directing the specific course of medical treatment. Within the established framework, an advanced registered nurse practitioner may:

(a) Prescribe, dispense, administer, or order any drug; however, an advanced registered nurse practitioner may only prescribe or dispense a controlled substance as defined in s. 893.03 if the advanced registered nurse practitioner has graduated from a program leading to a master's or doctoral degree in a clinical nursing specialty area with training in specialized practitioner skills. ~~Monitor and alter drug therapies.~~

(b) Initiate appropriate therapies for certain conditions.

(c) Perform additional functions as may be determined by rule in accordance with s. 464.003(2).

(d) Order diagnostic tests and physical and occupational therapy.

Section 17. Subsection (3) of section 464.013, Florida Statutes, is amended to read:

464.013 Renewal of license or certificate.—

(3) The board shall by rule prescribe up to 30 hours of continuing education biennially as a condition for renewal of a license or certificate.

(a) A nurse who is certified by a health care specialty program accredited by the National Commission for Certifying Agencies or the Accreditation Board for Specialty Nursing Certification is exempt from continuing education requirements. The criteria for programs must ~~shall~~ be approved by the board.

(b) Notwithstanding the exemption in paragraph (a), as part of the maximum 30 hours of continuing education hours required under this subsection, advanced registered nurse practitioners certified under s. 464.012 must complete at least 3 hours of continuing education on the safe and effective prescription of controlled substances. Such continuing education courses must be 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, or the American Association of Nurse Practitioners and may be offered in a distance-learning format.

Section 18. Paragraph (p) is added to subsection (1) of section 464.018, Florida Statutes, and subsection (2) of that section is republished, to read:

464.018 Disciplinary actions.—

(1) The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2):

(p) For an advanced registered nurse practitioner:

1. Presigning blank prescription forms.

2. Prescribing for office use any medicinal drug appearing on Schedule II in chapter 893.

3. Prescribing, ordering, dispensing, administering, supplying, selling, or giving a drug that is an amphetamine or a sympathomimetic amine drug, or a compound designated in s. 893.03(2) as a Schedule II controlled substance, to or for any person except for:

a. The treatment of narcolepsy; hyperkinesis; behavioral syndrome in children characterized by the developmentally inappropriate symptoms of moderate to severe distractibility, short attention span, hyperactivity, emotional lability, and impulsivity; or drug-induced brain dysfunction.

b. The differential diagnostic psychiatric evaluation of depression or the treatment of depression shown to be refractory to other therapeutic modalities.

c. The clinical investigation of the effects of such drugs or compounds when an investigative protocol is submitted to, reviewed by, and approved by the department before such investigation is begun.

4. Prescribing, ordering, dispensing, administering, supplying, selling, or giving growth hormones, testosterone or its analogs, human chorionic gonadotropin (HCG), or other hormones for the purpose of muscle building or to enhance athletic performance. As used in this subparagraph, the term "muscle building" does not include the treatment of injured muscle. A prescription written for the drug products identified

in this subparagraph may be dispensed by a pharmacist with the presumption that the prescription is for legitimate medical use.

5. Promoting or advertising on any prescription form a community pharmacy unless the form also states: "This prescription may be filled at any pharmacy of your choice."

6. Prescribing, dispensing, administering, mixing, or otherwise preparing a legend drug, including a controlled substance, other than in the course of his or her professional practice. For the purposes of this subparagraph, it is legally presumed that prescribing, dispensing, administering, mixing, or otherwise preparing legend drugs, including all controlled substances, inappropriately or in excessive or inappropriate quantities is not in the best interest of the patient and is not in the course of the advanced registered nurse practitioner's professional practice, without regard to his or her intent.

7. Prescribing, dispensing, or administering a medicinal drug appearing on any schedule set forth in chapter 893 to himself or herself, except a drug prescribed, dispensed, or administered to the advanced registered nurse practitioner by another practitioner authorized to prescribe, dispense, or administer medicinal drugs.

8. Prescribing, ordering, dispensing, administering, supplying, selling, or giving amygdalin (laetrile) to any person.

9. Dispensing a substance designated in s. 893.03(2) or (3) as a substance controlled in Schedule II or Schedule III, respectively, in violation of s. 465.0276.

10. Promoting or advertising through any communication medium the use, sale, or dispensing of a substance designated in s. 893.03 as a controlled substance.

(2) The board may enter an order denying licensure or imposing any of the penalties in s. 456.072(2) against any applicant for licensure or licensee who is found guilty of violating any provision of subsection (1) of this section or who is found guilty of violating any provision of s. 456.072(1).

Section 19. Subsection (21) of section 893.02, Florida Statutes, is amended to read:

893.02 Definitions.—The following words and phrases as used in this chapter shall have the following meanings, unless the context otherwise requires:

(21) "Practitioner" means a physician licensed under ~~pursuant to~~ chapter 458, a dentist licensed under ~~pursuant to~~ chapter 466, a veterinarian licensed under ~~pursuant to~~ chapter 474, an osteopathic physician licensed under ~~pursuant to~~ chapter 459, an advanced registered nurse practitioner certified under chapter 464, a naturopath licensed under ~~pursuant to~~ chapter 462, a certified optometrist licensed under ~~pursuant to~~ chapter 463, or a podiatric physician licensed under ~~pursuant to~~ chapter 461, or a physician assistant licensed under chapter 458 or

chapter 459, provided such practitioner holds a valid federal controlled substance registry number.

Section 20. Paragraph (n) of subsection (1) of section 948.03, Florida Statutes, is amended to read:

948.03 Terms and conditions of probation.—

(1) The court shall determine the terms and conditions of probation. Conditions specified in this section do not require oral pronouncement at the time of sentencing and may be considered standard conditions of probation. These conditions may include among them the following, that the probationer or offender in community control shall:

(n) Be prohibited from using intoxicants to excess or possessing any drugs or narcotics unless prescribed by a physician, advanced registered nurse practitioner, or physician assistant. The probationer or community controllee may ~~shall~~ not knowingly visit places where intoxicants, drugs, or other dangerous substances are unlawfully sold, dispensed, or used.

Section 21. Paragraph (a) of subsection (1) and subsection (2) of section 458.348, Florida Statutes, are amended to read:

458.348 Formal supervisory relationships, standing orders, and established protocols; notice; standards.—

(1) NOTICE.—

(a) When a physician enters into a formal supervisory relationship or standing orders with an emergency medical technician or paramedic licensed pursuant to s. 401.27, which relationship or orders contemplate the performance of medical

acts, or when a physician enters into an established protocol with an advanced registered nurse practitioner, which protocol contemplates the performance of medical ~~acts identified and approved by the joint committee pursuant to s. 464.003(2) or~~ acts set forth in s. 464.012(3) and (4), the physician shall submit notice to the board. The notice shall contain a statement in substantially the following form:

I, ...(name and professional license number of physician)..., of ...(address of physician)... have hereby entered into a formal supervisory relationship, standing orders, or an established protocol with ...(number of persons)... emergency medical technician(s), ...(number of persons)... paramedic(s), or ...(number of persons)... advanced registered nurse practitioner(s).

(2) ESTABLISHMENT OF STANDARDS BY JOINT COMMITTEE.—The joint committee ~~created under s. 464.003(2)~~ shall determine minimum standards for the content of established protocols pursuant to which an advanced registered nurse practitioner may perform medical acts ~~identified and approved by the joint committee pursuant to s. 464.003(2)~~ or acts set forth in s. 464.012(3) and (4) and shall determine minimum standards for supervision of such acts by the physician, unless the joint committee determines that any act set forth in s. 464.012(3) or (4) is not a medical act. Such standards shall be based on risk

to the patient and acceptable standards of medical care and shall take into account the special problems of medically underserved areas. The standards developed by the joint committee shall be adopted as rules by the Board of Nursing and the Board of Medicine for purposes of carrying out their responsibilities pursuant to part I of chapter 464 and this chapter, respectively, but neither board shall have disciplinary powers over the licensees of the other board.

Section 22. Paragraph (a) of subsection (1) of section 459.025, Florida Statutes, is amended to read:

459.025 Formal supervisory relationships, standing orders, and established protocols; notice; standards.—

(1) NOTICE.—

(a) When an osteopathic physician enters into a formal supervisory relationship or standing orders with an emergency medical technician or paramedic licensed pursuant to s. 401.27, which relationship or orders contemplate the performance of medical acts, or when an osteopathic physician enters into an established protocol with an advanced registered nurse practitioner, which protocol contemplates the performance of medical acts ~~identified and approved by the joint committee pursuant to s. 464.003(2)~~ or acts set forth in s. 464.012(3) and (4), the osteopathic physician shall submit notice to the board. The notice must contain a statement in substantially the following form:

I, ...(name and professional license number of osteopathic physician)..., of ...(address of osteopathic physician)... have hereby entered into a formal supervisory relationship, standing orders, or an established protocol with ...(number of persons)... emergency medical technician(s), ...(number of persons)... paramedic(s), or ...(number of persons)... advanced registered nurse practitioner(s).

Section 23. For the purpose of incorporating the amendment made by this act to section 456.072, Florida Statutes, in a reference thereto, subsection (10) of section 458.331, Florida Statutes, is reenacted to read:

458.331 Grounds for disciplinary action; action by the board and department.—

(10) A probable cause panel convened to consider disciplinary action against a physician assistant alleged to have violated s. 456.072 or this section must include one physician assistant. The physician assistant must hold a valid license to practice as a physician assistant in this state and be appointed to the panel by the Council of Physician Assistants. The physician assistant may hear only cases involving disciplinary actions against a physician assistant. If the appointed physician assistant is not present at the disciplinary hearing, the panel may consider the matter and vote on the case in the absence of the physician assistant. The training requirements set forth in s. 458.307(4) do not apply to

the appointed physician assistant. Rules need not be adopted to implement this subsection.

Section 24. For the purpose of incorporating the amendment made by this act to section 456.072, Florida Statutes, in a reference thereto, paragraph (g) of subsection (7) of section 458.347, Florida Statutes, is reenacted to read:

458.347 Physician assistants.—

(7) PHYSICIAN ASSISTANT LICENSURE.—

(g) The Board of Medicine may impose any of the penalties authorized under ss. 456.072 and 458.331(2) upon a physician assistant if the physician assistant or the supervising physician has been found guilty of or is being investigated for any act that constitutes a violation of this chapter or chapter 456.

Section 25. For the purpose of incorporating the amendment made by this act to section 456.072, Florida Statutes, in a reference thereto, subsection (10) of section 459.015, Florida Statutes, is reenacted to read:

459.015 Grounds for disciplinary action; action by the board and department.—

(10) A probable cause panel convened to consider disciplinary action against a physician assistant alleged to have violated s. 456.072 or this section must include one physician assistant. The physician assistant must hold a valid license to practice as a physician assistant in this state and be appointed to the panel by the Council of Physician

Assistants. The physician assistant may hear only cases involving disciplinary actions against a physician assistant. If the appointed physician assistant is not present at the disciplinary hearing, the panel may consider the matter and vote on the case in the absence of the physician assistant. The training requirements set forth in s. 458.307(4) do not apply to the appointed physician assistant. Rules need not be adopted to implement this subsection.

Section 26. For the purpose of incorporating the amendment made by this act to section 456.072, Florida Statutes, in a reference thereto, paragraph (f) of subsection (7) of section 459.022, Florida Statutes, is reenacted to read:

459.022 Physician assistants.—

(7) PHYSICIAN ASSISTANT LICENSURE.—

(f) The Board of Osteopathic Medicine may impose any of the penalties authorized under ss. 456.072 and 459.015(2) upon a physician assistant if the physician assistant or the supervising physician has been found guilty of or is being investigated for any act that constitutes a violation of this chapter or chapter 456.

Section 27. For the purpose of incorporating the amendment made by this act to section 456.072, Florida Statutes, in a reference thereto, subsection (5) of section 465.0158, Florida Statutes, is reenacted to read:

465.0158 Nonresident sterile compounding permit.—

(5) In accordance with this chapter, the board may deny, revoke, or suspend the permit of; fine; or reprimand a permittee for:

(a) Failure to comply with this section;

(b) A violation listed under s. 456.0635, s. 456.065, or s. 456.072, except s. 456.072(1)(s) or (1)(u);

(c) A violation under s. 465.0156(5); or

(d) A violation listed under s. 465.016.

Section 28. For the purpose of incorporating the amendment made by this act to section 456.44, Florida Statutes, in a reference thereto, paragraph (mm) of subsection (1) of section 456.072, Florida Statutes, is reenacted to read:

456.072 Grounds for discipline; penalties; enforcement.—

(1) The following acts shall constitute grounds for which the disciplinary actions specified in subsection (2) may be taken:

(mm) Failure to comply with controlled substance prescribing requirements of s. 456.44.

Section 29. For the purpose of incorporating the amendment made by this act to section 456.44, Florida Statutes, in a reference thereto, section 466.02751, Florida Statutes, is reenacted to read:

466.02751 Establishment of practitioner profile for designation as a controlled substance prescribing practitioner.—The Department of Health shall establish a practitioner profile for dentists licensed under this chapter for a practitioner's

designation as a controlled substance prescribing practitioner as provided in s. 456.44.

Section 30. For the purpose of incorporating the amendment made by this act to section 458.347, Florida Statutes, in a reference thereto, section 458.303, Florida Statutes, is reenacted to read:

458.303 Provisions not applicable to other practitioners; exceptions, etc.—

(1) The provisions of ss. 458.301, 458.305, 458.307, 458.309, 458.311, 458.313, 458.315, 458.317, 458.319, 458.321, 458.327, 458.329, 458.331, 458.337, 458.339, 458.341, 458.343, 458.345, 458.347, and this section shall have no application to:

(a) Other duly licensed health care practitioners acting within their scope of practice authorized by statute.

(b) Any physician lawfully licensed in another state or territory or foreign country, when meeting duly licensed physicians of this state in consultation.

(c) Commissioned medical officers of the Armed Forces of the United States and of the Public Health Service of the United States while on active duty and while acting within the scope of their military or public health responsibilities.

(d) Any person while actually serving without salary or professional fees on the resident medical staff of a hospital in this state, subject to the provisions of s. 458.321.

(e) Any person furnishing medical assistance in case of an emergency.

(f) The domestic administration of recognized family remedies.

(g) The practice of the religious tenets of any church in this state.

(h) Any person or manufacturer who, without the use of drugs or medicine, mechanically fits or sells lenses, artificial eyes or limbs, or other apparatus or appliances or is engaged in the mechanical examination of eyes for the purpose of constructing or adjusting spectacles, eyeglasses, or lenses.

(2) Nothing in s. 458.301, s. 458.305, s. 458.307, s. 458.309, s. 458.311, s. 458.313, s. 458.319, s. 458.321, s. 458.327, s. 458.329, s. 458.331, s. 458.337, s. 458.339, s. 458.341, s. 458.343, s. 458.345, s. 458.347, or this section shall be construed to prohibit any service rendered by a registered nurse or a licensed practical nurse, if such service is rendered under the direct supervision and control of a licensed physician who provides specific direction for any service to be performed and gives final approval to all services performed. Further, nothing in this or any other chapter shall be construed to prohibit any service rendered by a medical assistant in accordance with the provisions of s. 458.3485.

Section 31. For the purpose of incorporating the amendment made by this act to section 458.347, Florida Statutes, in a reference thereto, paragraph (b) of subsection (7) of section 458.3475, Florida Statutes, is reenacted to read:

458.3475 Anesthesiologist assistants.—

(7) ANESTHESIOLOGIST AND ANESTHESIOLOGIST ASSISTANT TO ADVISE THE BOARD.—

(b) In addition to its other duties and responsibilities as prescribed by law, the board shall:

1. Recommend to the department the licensure of anesthesiologist assistants.

2. Develop all rules regulating the use of anesthesiologist assistants by qualified anesthesiologists under this chapter and chapter 459, except for rules relating to the formulary developed under s. 458.347(4)(f). The board shall also develop rules to ensure that the continuity of supervision is maintained in each practice setting. The boards shall consider adopting a proposed rule at the regularly scheduled meeting immediately following the submission of the proposed rule. A proposed rule may not be adopted by either board unless both boards have accepted and approved the identical language contained in the proposed rule. The language of all proposed rules must be approved by both boards pursuant to each respective board's guidelines and standards regarding the adoption of proposed rules.

3. Address concerns and problems of practicing anesthesiologist assistants to improve safety in the clinical practices of licensed anesthesiologist assistants.

Section 32. For the purpose of incorporating the amendment made by this act to section 458.347, Florida Statutes, in references thereto, paragraph (e) of subsection (4) and

paragraph (c) of subsection (9) of section 459.022, Florida Statutes, are reenacted to read:

459.022 Physician assistants.—

(4) PERFORMANCE OF PHYSICIAN ASSISTANTS.—

(e) A supervisory physician may delegate to a fully licensed physician assistant the authority to prescribe or dispense any medication used in the supervisory physician's practice unless such medication is listed on the formulary created pursuant to s. 458.347. A fully licensed physician assistant may only prescribe or dispense such medication under the following circumstances:

1. A physician assistant must clearly identify to the patient that she or he is a physician assistant. Furthermore, the physician assistant must inform the patient that the patient has the right to see the physician prior to any prescription being prescribed or dispensed by the physician assistant.

2. The supervisory physician must notify the department of her or his intent to delegate, on a department-approved form, before delegating such authority and notify the department of any change in prescriptive privileges of the physician assistant. Authority to dispense may be delegated only by a supervisory physician who is registered as a dispensing practitioner in compliance with s. 465.0276.

3. The physician assistant must file with the department a signed affidavit that she or he has completed a minimum of 10 continuing medical education hours in the specialty practice in

which the physician assistant has prescriptive privileges with each licensure renewal application.

4. The department may issue a prescriber number to the physician assistant granting authority for the prescribing of medicinal drugs authorized within this paragraph upon completion of the foregoing requirements. The physician assistant shall not be required to independently register pursuant to s. 465.0276.

5. The prescription must be written in a form that complies with chapter 499 and must contain, in addition to the supervisory physician's name, address, and telephone number, the physician assistant's prescriber number. Unless it is a drug or drug sample dispensed by the physician assistant, the prescription must be filled in a pharmacy permitted under chapter 465, and must be dispensed in that pharmacy by a pharmacist licensed under chapter 465. The appearance of the prescriber number creates a presumption that the physician assistant is authorized to prescribe the medicinal drug and the prescription is valid.

6. The physician assistant must note the prescription or dispensing of medication in the appropriate medical record.

(9) COUNCIL ON PHYSICIAN ASSISTANTS.—The Council on Physician Assistants is created within the department.

(c) The council shall:

1. Recommend to the department the licensure of physician assistants.

2. Develop all rules regulating the use of physician assistants by physicians under chapter 458 and this chapter, except for rules relating to the formulary developed under s. 458.347. The council shall also develop rules to ensure that the continuity of supervision is maintained in each practice setting. The boards shall consider adopting a proposed rule developed by the council at the regularly scheduled meeting immediately following the submission of the proposed rule by the council. A proposed rule submitted by the council may not be adopted by either board unless both boards have accepted and approved the identical language contained in the proposed rule. The language of all proposed rules submitted by the council must be approved by both boards pursuant to each respective board's guidelines and standards regarding the adoption of proposed rules. If either board rejects the council's proposed rule, that board must specify its objection to the council with particularity and include any recommendations it may have for the modification of the proposed rule.

3. Make recommendations to the boards regarding all matters relating to physician assistants.

4. Address concerns and problems of practicing physician assistants in order to improve safety in the clinical practices of licensed physician assistants.

Section 33. For the purpose of incorporating the amendment made by this act to section 458.347, Florida Statutes, in a

reference thereto, paragraph (b) of subsection (7) of section 459.023, Florida Statutes, is reenacted to read:

459.023 Anesthesiologist assistants.—

(7) ANESTHESIOLOGIST AND ANESTHESIOLOGIST ASSISTANT TO ADVISE THE BOARD.—

(b) In addition to its other duties and responsibilities as prescribed by law, the board shall:

1. Recommend to the department the licensure of anesthesiologist assistants.

2. Develop all rules regulating the use of anesthesiologist assistants by qualified anesthesiologists under this chapter and chapter 458, except for rules relating to the formulary developed under s. 458.347(4)(f). The board shall also develop rules to ensure that the continuity of supervision is maintained in each practice setting. The boards shall consider adopting a proposed rule at the regularly scheduled meeting immediately following the submission of the proposed rule. A proposed rule may not be adopted by either board unless both boards have accepted and approved the identical language contained in the proposed rule. The language of all proposed rules must be approved by both boards pursuant to each respective board's guidelines and standards regarding the adoption of proposed rules.

3. Address concerns and problems of practicing anesthesiologist assistants to improve safety in the clinical practices of licensed anesthesiologist assistants.

Section 34. For the purpose of incorporating the amendment made by this act to section 464.003, Florida Statutes, in a reference thereto, paragraph (c) of subsection (3) of section 464.012, Florida Statutes, is reenacted to read:

464.012 Certification of advanced registered nurse practitioners; fees.—

(3) An advanced registered nurse practitioner shall perform those functions authorized in this section within the framework of an established protocol that is filed with the board upon biennial license renewal and within 30 days after entering into a supervisory relationship with a physician or changes to the protocol. The board shall review the protocol to ensure compliance with applicable regulatory standards for protocols. The board shall refer to the department licensees submitting protocols that are not compliant with the regulatory standards for protocols. A practitioner currently licensed under chapter 458, chapter 459, or chapter 466 shall maintain supervision for directing the specific course of medical treatment. Within the established framework, an advanced registered nurse practitioner may:

(c) Perform additional functions as may be determined by rule in accordance with s. 464.003(2).

Section 35. For the purpose of incorporating the amendment made by this act to section 464.012, Florida Statutes, in a reference thereto, paragraph (a) of subsection (1) of section 456.041, Florida Statutes, is reenacted to read:

456.041 Practitioner profile; creation.—

(1)(a) The Department of Health shall compile the information submitted pursuant to s. 456.039 into a practitioner profile of the applicant submitting the information, except that the Department of Health shall develop a format to compile uniformly any information submitted under s. 456.039(4)(b). Beginning July 1, 2001, the Department of Health may compile the information submitted pursuant to s. 456.0391 into a practitioner profile of the applicant submitting the information. The protocol submitted pursuant to s. 464.012(3) must be included in the practitioner profile of the advanced registered nurse practitioner.

Section 36. For the purpose of incorporating the amendment made by this act to section 464.012, Florida Statutes, in references thereto, subsections (1) and (2) of section 458.348, Florida Statutes, are reenacted to read:

458.348 Formal supervisory relationships, standing orders, and established protocols; notice; standards.—

(1) NOTICE.—

(a) When a physician enters into a formal supervisory relationship or standing orders with an emergency medical technician or paramedic licensed pursuant to s. 401.27, which relationship or orders contemplate the performance of medical acts, or when a physician enters into an established protocol with an advanced registered nurse practitioner, which protocol contemplates the performance of medical acts identified and

approved by the joint committee pursuant to s. 464.003(2) or acts set forth in s. 464.012(3) and (4), the physician shall submit notice to the board. The notice shall contain a statement in substantially the following form:

I, ...(name and professional license number of physician)..., of ...(address of physician)... have hereby entered into a formal supervisory relationship, standing orders, or an established protocol with ...(number of persons)... emergency medical technician(s), ...(number of persons)... paramedic(s), or ...(number of persons)... advanced registered nurse practitioner(s).

(b) Notice shall be filed within 30 days of entering into the relationship, orders, or protocol. Notice also shall be provided within 30 days after the physician has terminated any such relationship, orders, or protocol.

(2) ESTABLISHMENT OF STANDARDS BY JOINT COMMITTEE.—The joint committee created under s. 464.003(2) shall determine minimum standards for the content of established protocols pursuant to which an advanced registered nurse practitioner may perform medical acts identified and approved by the joint committee pursuant to s. 464.003(2) or acts set forth in s. 464.012(3) and (4) and shall determine minimum standards for supervision of such acts by the physician, unless the joint committee determines that any act set forth in s. 464.012(3) or (4) is not a medical act. Such standards shall be based on risk to the patient and acceptable standards of medical care and

shall take into account the special problems of medically underserved areas. The standards developed by the joint committee shall be adopted as rules by the Board of Nursing and the Board of Medicine for purposes of carrying out their responsibilities pursuant to part I of chapter 464 and this chapter, respectively, but neither board shall have disciplinary powers over the licensees of the other board.

Section 37. For the purpose of incorporating the amendment made by this act to section 464.013, Florida Statutes, in a reference thereto, subsection (7) of section 464.0205, Florida Statutes, is reenacted to read:

464.0205 Retired volunteer nurse certificate.—

(7) The retired volunteer nurse certificate shall be valid for 2 years, and a certificateholder may reapply for a certificate so long as the certificateholder continues to meet the eligibility requirements of this section. Any legislatively mandated continuing education on specific topics must be completed by the certificateholder prior to renewal; otherwise, the provisions of s. 464.013 do not apply.

Section 38. For the purpose of incorporating the amendment made by this act to section 464.018, Florida Statutes, in a reference thereto, subsection (11) of section 320.0848, Florida Statutes, is reenacted to read:

320.0848 Persons who have disabilities; issuance of disabled parking permits; temporary permits; permits for certain

providers of transportation services to persons who have disabilities.—

(11) A violation of this section is grounds for disciplinary action under s. 458.331, s. 459.015, s. 460.413, s. 461.013, s. 463.016, or s. 464.018, as applicable.

Section 39. For the purpose of incorporating the amendment made by this act to section 464.018, Florida Statutes, in a reference thereto, subsection (2) of section 464.008, Florida Statutes, is reenacted to read:

464.008 Licensure by examination.—

(2) Each applicant who passes the examination and provides proof of meeting the educational requirements specified in subsection (1) shall, unless denied pursuant to s. 464.018, be entitled to licensure as a registered professional nurse or a licensed practical nurse, whichever is applicable.

Section 40. For the purpose of incorporating the amendment made by this act to section 464.018, Florida Statutes, in a reference thereto, subsection (5) of section 464.009, Florida Statutes, is reenacted to read:

464.009 Licensure by endorsement.—

(5) The department shall not issue a license by endorsement to any applicant who is under investigation in another state, jurisdiction, or territory of the United States for an act which would constitute a violation of this part or chapter 456 until such time as the investigation is complete, at which time the provisions of s. 464.018 shall apply.

Section 41. For the purpose of incorporating the amendment made by this act to section 464.018, Florida Statutes, in references thereto, paragraph (b) of subsection (1), subsection (3), and paragraph (b) of subsection (4) of section 464.0205, Florida Statutes, are reenacted to read:

464.0205 Retired volunteer nurse certificate.—

(1) Any retired practical or registered nurse desiring to serve indigent, underserved, or critical need populations in this state may apply to the department for a retired volunteer nurse certificate by providing:

(b) Verification that the applicant had been licensed to practice nursing in any jurisdiction in the United States for at least 10 years, had retired or plans to retire, intends to practice nursing only pursuant to the limitations provided by the retired volunteer nurse certificate, and has not committed any act that would constitute a violation under s. 464.018(1).

(3) The board may deny a retired volunteer nurse certificate to any applicant who has committed, or who is under investigation or prosecution for, any act that would constitute a ground for disciplinary action under s. 464.018.

(4) A retired volunteer nurse receiving certification from the board shall:

(b) Comply with the minimum standards of practice for nurses and be subject to disciplinary action for violations of s. 464.018, except that the scope of practice for certified

volunteers shall be limited to primary and preventive health care, or as further defined by board rule.

Section 42. For the purpose of incorporating the amendment made by this act to section 893.02, Florida Statutes, in a reference thereto, section 775.051, Florida Statutes, is reenacted to read:

775.051 Voluntary intoxication; not a defense; evidence not admissible for certain purposes; exception.—Voluntary intoxication resulting from the consumption, injection, or other use of alcohol or other controlled substance as described in chapter 893 is not a defense to any offense proscribed by law. Evidence of a defendant's voluntary intoxication is not admissible to show that the defendant lacked the specific intent to commit an offense and is not admissible to show that the defendant was insane at the time of the offense, except when the consumption, injection, or use of a controlled substance under chapter 893 was pursuant to a lawful prescription issued to the defendant by a practitioner as defined in s. 893.02.

Section 43. For the purpose of incorporating the amendment made by this act to section 948.03, Florida Statutes, in a reference thereto, paragraph (a) of subsection (3) of section 944.17, Florida Statutes, is reenacted to read:

944.17 Commitments and classification; transfers.—

(3)(a) Notwithstanding the provisions of s. 948.03, only those persons who are convicted and sentenced in circuit court to a cumulative sentence of incarceration for 1 year or more,

whether sentence is imposed in the same or separate circuits, may be received by the department into the state correctional system. Such persons shall be delivered to the custody of the department at such reception and classification centers as shall be provided for this purpose.

Section 44. For the purpose of incorporating the amendment made by this act to section 948.03, Florida Statutes, in a reference thereto, subsection (8) of section 948.001, Florida Statutes, is reenacted to read:

948.001 Definitions.—As used in this chapter, the term:

(8) "Probation" means a form of community supervision requiring specified contacts with parole and probation officers and other terms and conditions as provided in s. 948.03.

Section 45. For the purpose of incorporating the amendment made by this act to section 948.03, Florida Statutes, in a reference thereto, paragraph (e) of subsection (1) of section 948.101, Florida Statutes, is reenacted to read:

948.101 Terms and conditions of community control.—

(1) The court shall determine the terms and conditions of community control. Conditions specified in this subsection do not require oral pronouncement at the time of sentencing and may be considered standard conditions of community control. The court shall require intensive supervision and surveillance for an offender placed into community control, which may include, but is not limited to:

(e) The standard conditions of probation set forth in s. 948.03.

Section 46. Except as otherwise expressly provided in this act, this act shall take effect upon becoming a law.

T I T L E A M E N D M E N T

Remove everything before the enacting clause and insert:

A bill to be entitled

An act relating to behavioral health workforce; amending s. 110.12315, F.S.; expanding the categories of persons who may prescribe brand name drugs under the prescription drug program when medically necessary; amending ss. 310.071, 310.073, and 310.081, F.S.; exempting controlled substances prescribed by an advanced registered nurse practitioner or a physician assistant from the disqualifications for certification or licensure, and for continued certification or licensure, as a deputy pilot or state pilot; amending s. 394.453, F.S.; revising legislative intent; amending s. 394.467, F.S.; authorizing procedures for recommending admission of a patient to a treatment facility; amending s. 397.451, F.S.; revising provisions relating to exemptions from disqualification for certain service provider personnel; amending s. 456.072, F.S.; providing

mandatory administrative penalties for certain violations relating to prescribing or dispensing a controlled substance; amending s. 456.44, F.S.; providing a definition; deleting an obsolete date; requiring advanced registered nurse practitioners and physician assistants who prescribe controlled substances for certain pain to make a certain designation, comply with registration requirements, and follow specified standards of practice; providing applicability; amending ss. 458.3265 and 459.0137, F.S.; limiting the authority to prescribe a controlled substance in a pain-management clinic only to a physician licensed under chapter 458 or chapter 459, F.S.; amending s. 458.347, F.S.; revising the required continuing education requirements for a physician assistant; requiring that a specified formulary limit the prescription of certain controlled substances by physician assistants as of a specified date; amending s. 464.003, F.S.; redefining the term "advanced or specialized nursing practice"; deleting the joint committee established in the definition; amending s. 464.012, F.S.; requiring the Board of Nursing to establish a committee to recommend a formulary of controlled substances that may not be prescribed, or may be prescribed only on a limited basis, by an advanced registered nurse practitioner; specifying the

membership of the committee; providing parameters for the formulary; requiring that the formulary be adopted by board rule; specifying the process for amending the formulary and imposing a burden of proof; limiting the formulary's application in certain instances; requiring the board to adopt the committee's initial recommendations by a specified date; authorizing an advanced registered nurse practitioner to prescribe, dispense, administer, or order drugs, including certain controlled substances under certain circumstances, as of a specified date; amending s. 464.013, F.S.; revising continuing education requirements for renewal of a license or certificate; amending s. 464.018, F.S.; specifying acts that constitute grounds for denial of a license or for disciplinary action against an advanced registered nurse practitioner; amending s. 893.02, F.S.; redefining the term "practitioner" to include advanced registered nurse practitioners and physician assistants under the Florida Comprehensive Drug Abuse Prevention and Control Act for the purpose of prescribing controlled substances if a certain requirement is met; amending s. 948.03, F.S.; providing that possession of drugs or narcotics prescribed by an advanced registered nurse practitioner or a physician assistant does not violate

a prohibition relating to the possession of drugs or narcotics during probation; amending ss. 458.348 and 459.025, F.S.; conforming provisions to changes made by the act; reenacting ss. 458.331(10) and 459.015(10), F.S., relating to probable cause panels convened to consider disciplinary action against a physician assistant; ss. 458.347(7)(g) and 459.022(7)(f), F.S., relating to penalties imposed by the Board of Medicine and the Board of Osteopathic Medicine, respectively, upon a physician assistant; and s. 465.0158(5)(b), F.S., relating to nonresident sterile compounding permits, to incorporate the amendment made by the act to s. 456.072, F.S., in references thereto; reenacting ss. 456.072(1)(mm), F.S., relating to penalties for failure to comply with controlled substance prescribing requirements, and 466.02751, F.S., relating to establishment of a practitioner profile for dentists licensed under chapter 466, F.S., for designation as a controlled substance prescribing practitioner, to incorporate the amendment made by the act to s. 456.44, F.S., in references thereto; reenacting s. 458.303, F.S., relating to applicability of licensing provisions to certain health care practitioners; ss. 458.3475(7)(b) and 459.023(7)(b), F.S., relating to licensing and supervision of anesthesiologist assistants; s.

459.022(4)(e) and (9)(c), F.S., relating to licensing and supervision of physician assistants, to incorporate the amendment made by the act to s. 458.347, F.S., in references thereto; reenacting s. 464.012(3)(c), F.S., relating to authorization for a advanced registered nurse practitioner to perform certain functions, to incorporate the amendment made by the act to s. 464.003, F.S., in a reference thereto; reenacting ss. 456.041(1)(a) and 458.348(1) and (2), F.S., relating to a practitioner profile and notice of a supervisory relationship to incorporate the amendment made by the act to s. 464.012, F.S., in references thereto; reenacting s. 464.0205(7), F.S., relating to certification as a retired volunteer nurse to incorporate the amendment made by the act to s. 464.013, F.S., in a reference thereto; reenacting ss. 320.0848(11), 464.008(2), 464.009(5), and 464.0205(1)(b), (3), and (4)(b), F.S., relating to violations of provisions for disability parking, licensure or certification as a practical or registered nurse to incorporate the amendment made by the act to s. 464.018, F.S., in references thereto; reenacting s. 775.051, F.S., relating to admissible evidence of insanity to incorporate the amendment made by the act to s. 893.02, F.S., in a reference thereto; reenacting ss. 944.17(3)(a), 948.001(8), and

948.101(1)(e), F.S., relating to commitment of prisoners to state penitentiary, the definition of the term "probationer," and conditions of probation, to incorporate the amendment made by the act to s. 948.03, F.S., in references thereto; providing effective dates.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1151 Parentage
SPONSOR(S): Richardson and others
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee		Tuszynski	O'Callaghan
2) Civil Justice Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

A preplanned adoption arrangement is an arrangement in which a volunteer mother enters into an agreement with an intended mother and father for adoption of an unborn child carried by the volunteer mother.

Artificial insemination is a form of assisted reproductive technology that allows the introduction of donor sperm either via intracervical or intrauterine insemination into a woman's body. In-vitro insemination is a form of assisted reproductive technology in which eggs are removed from a woman's body (or donor eggs are used), mixed with sperm to create embryos, and then placed into the woman's body.

A gestational surrogacy contract is a binding and enforceable agreement between a commissioning couple and a gestational surrogate. The commissioning couple is the intended mother and father of a child who will be conceived by means of assisted reproductive technology using the eggs or sperm of at least one of the intended parents. The gestational surrogate is defined as a woman who contracts to become pregnant by means of assisted reproductive technology without the use of an egg from her body.

HB 1151 makes multiple changes in statute to provide same-sex married couples with mechanisms to establish parentage.

The bill amends s. 63.213, F.S., relating to preplanned adoption agreements to change language referring to the intended adoptive parents to gender-neutral descriptors and phrases.

The bill amends s. 742.11, F.S., relating to the presumed status of a child conceived by means of artificial or in-vitro insemination or donated eggs or pre-embryos. In this section "husband and wife" has been changed to "mother and her spouse" in relation to the woman carrying the child and her spouse, and also changes "husband and wife" to "spouses," elsewhere in the section.

The bill amends s. 742.13, F.S., to change the definition of "commissioning couple" to mean the intended parents, instead of the intended mother and father. The definition for "intended parents" is also added to that section to mean parents whose consent for artificial or in-vitro insemination using donated sperm or eggs and gestational surrogacy is established under s. 742.11 or s. 742.15, F.S., respectively, and persons defined as intended parents under s. 63.213, F.S.

The bill amends s. 742.15, F.S., relating to gestation surrogacy contracts by making it clear that a physician must determine that neither intended parent can physically gestate to term, or gestate a pregnancy without causing harm to the intended parent, or gestate without causing risk to the fetus. This language clarifies that, in a same-sex marriage in which each partner is a woman, the couple cannot use a surrogate unless neither woman can gestate a pregnancy.

The bill also amends s. 742.14, F.S., relating to the donation of eggs, sperm, or pre-embryos, by changing the term "father" to "donor" and fixing a cross reference; and amends s. 742.16, F.S., relating to the expedited affirmation of parental status for gestational surrogacy, by removing the notice requirement for anyone claiming paternity, and instead making the notice requirement applicable to any party claiming to be a genetic or intended parent unless such rights are relinquished pursuant to s. 742.14, F.S.

The bill could have an indeterminate, negative fiscal impact on DOH for the cost of processing birth certificates due to same-sex married couples having a mechanism to establish parentage..

The bill provides that it will take effect upon becoming law.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Marital Presumption of Parentage

All states have a statute or common law rule that presumes children born during the marriage, absent any agreements between parties at childbirth, are the biological children of the husband.[1] This marital presumption protects parents and children.[2] Historically, without genetic testing to prove that the husband was not the child's biological parent, raising the issue of legitimacy could harm the child (and the reputation of the child's mother), but would not resolve the question.[3] The advent of genetic testing has changes this; user-friendly, relatively inexpensive tests are now available.[4] These tests will exclude men who could not possibly be a child's genetic parent and establish with great certainty whether a particular man is a child's biological father.[5]

In recent years, same-sex couples have begun to adopt children, bear children from in-vitro fertilization, and "blended" families consisting of multiple parents and stepparents are more commonplace. However, state statutes relating to parentage have not kept pace with the changing structure of the American family.

Preplanned Adoption

A preplanned adoption arrangement is an arrangement in which a volunteer mother enters into an agreement with an intended mother and father for adoption of an unborn child carried by the volunteer mother.[6] A preplanned adoption agreement must include, but need not be limited to, the following terms:

- The volunteer mother agrees to become pregnant by the fertility technique specified in the agreement, to bear the child, and to terminate any parental rights and responsibilities through a written consent executed at the same time as the preplanned adoption agreement, subject to the volunteer mother's 48 hour right of rescission;[7]
- The volunteer mother agrees to submit to a reasonable medical evaluation and treatment and adhere to medical instructions about her prenatal health;[8]
- The volunteer mother acknowledges that she will assume parental rights and responsibilities if the intended mother and father terminate the agreement prior to final transfer of custody or if the preplanned adoption is not approved by the court;[9]
- That an intended father who is also a biological father acknowledges that he is aware that he will assume parental rights and responsibilities if the agreement is terminated for any reason or not approved by the court;[10]

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[1] Paula Roberts, Truth and consequences: Part II: Questioning the paternity of Marital Children, 37 Fam. L.Q. 55, 56 n.2 (2003) (referring to the rule as "one of the strongest and most persuasive presumptions known to the law").
[2] Id.
[3] Id.
[4] Id.
[5] Id.
[6] See s. 63.213(6)(h), F.S.
[7] S. 63.213(2)(a), F.S.
[8] S. 63.213(2)(b), F.S.
[9] S. 63.213(2)(c), F.S.
[10] S. 63.213(2)(d), F.S.

- The intended mother and father acknowledge they may not receive custody or parental rights if the volunteer mother terminates the agreement or rescinds her consent within 48 hours of birth;[11]
- The intended mother and father may agree to pay all reasonable legal, medical, psychological or psychiatric expenses of the volunteer mother related to the preplanned adoption agreement, and may also agree to pay reasonable living expenses and lost wages due to the pregnancy and birth, as well as reasonable compensation for inconvenience, discomfort, and medical risk, but no other compensation may be made;[12]
- The intended mother and father agree to accept custody and to assert full parental rights and responsibilities immediately upon birth, regardless of any impairment;[13]
- The intended mother and father must have the right to specify the blood and tissue typing tests to be performed if the agreement specifies that at least one of them is intended to be the biological parent;[14] and
- The agreement may be terminated at any time by any party.[15]

Artificial or In-vitro Insemination

Both artificial insemination and in-vitro insemination are methods to attempt pregnancy without natural insemination through sexual intercourse. Artificial insemination is a form of assisted reproductive technology that allows the introduction of donor sperm either via intracervical or intrauterine insemination into a woman's body. In-vitro insemination is a form of assisted reproductive technology in which eggs are removed from a woman's body (or donor eggs are used), mixed with sperm to create embryos, and then placed into the woman's body.[16]

Section 742.11, F.S., states that any child born within wedlock who has been conceived by either of these means, using donated eggs or sperm, is irrebuttably presumed to be the child of the husband and wife, provided they have both consented in writing to the artificial or in-vitro insemination and the use of donated eggs or pre-embryos, except in the case of gestational surrogacy.

Gestational Surrogacy Contract

A gestational surrogacy contract is a binding and enforceable agreement between a commissioning couple and a gestational surrogate.[17] The "commissioning couple" is defined to be intended mother and father of a child who will be conceived by means of assisted reproductive technology using the eggs or sperm of at least one of the intended parties.[18] The "gestational surrogate" is defined as a woman who contracts to become pregnant by means of assisted reproductive technology without the use of an egg from her body.

The contract may be entered into only when, within reasonable medical certainty as determined by licensed physician, the:[19]

- Commissioning mother cannot physically gestate a pregnancy to term;
- Gestation will cause a risk to the physical health of the commissioning mother; or
- Gestation will cause risk to the health of the fetus.

[11] S. 63.213(2)(e), F.S.
[12] S. 63.213(2)(f), F.S.
[13] S. 63.213(2)(g), F.S.
[14] S. 63.213(2)(h), F.S.
[15] S. 63.213(2)(i), F.S.
[16] U.S. National Library of Medicine, MedlinePlus Health Topics, Assisted Reproductive Technology, *accessible at*: https://www.nlm.nih.gov/medlineplus/assistedreproductivetechnology.html (last accessed 01/20/16).
[17] S. 742.15(1), F.S.
[18] S. 742.13(2), F.S.
[19] S. 742.15(2), F.S.

The contract must include the following provisions:[20]

- The commissioning couple agrees that the gestational surrogate shall be the sole source of consent with respect to clinical intervention and management of the pregnancy;
- The gestational surrogate agrees to submit to reasonable medical evaluation and treatment and to adhere to reasonable medical instructions about her prenatal health;
- The gestational surrogate agrees to relinquish any parental rights upon the child's birth, and proceed with affirmation of parental status proceedings, unless it is determined that neither of the commissioning couple is the genetic parent of the child;
- The commissioning couple agrees to accept custody of and to assume full parental rights and responsibilities upon the child's birth, regardless of any impairment; and
- The gestational surrogate agrees to assume parental rights and responsibilities for the child if it is determined that neither of the commissioning couple is the genetic parent of the child.

The contract may allow the commissioning couple to pay only reasonable living, legal, medical, psychological, and psychiatric expenses of the gestational surrogate that are directly related to pre-natal, intrapartal, and postpartal periods.[21]

Effect of Proposed Changes

Preplanned adoption

The bill amends s. 63.213, F.S., relating to preplanned adoption agreements to change language referring to the intended adoptive parents to gender-neutral descriptors and phrases. The bill also clarifies that the 48-hour right of rescission belongs to the genetic mother of the child in a preplanned adoption. This change allows for all married couples, including same-sex married couples, to enter into preplanned adoption agreements.

Artificial or In-vitro Insemination

The bill amends s. 742.11, F.S., relating to the presumed status of a child conceived by means of artificial or in-vitro insemination or donated eggs or pre-embryos. In this section "husband and wife" has been changed to "mother and her spouse" in relation to the woman carrying the child and her spouse, and also changes "husband and wife" to "spouses," elsewhere in the section. This language recognizes same-sex married couples and their ability to use assisted reproductive technology to create a family.

Gestational Surrogacy Contract

The bill amends s. 742.13, F.S., to change the definition of "commissioning couple" to mean the intended parents, instead of the intended mother and father. The definition for "intended parents" is also added to that section to mean parents whose consent for artificial or in-vitro insemination using donated sperm or eggs and gestational surrogacy is established under s. 742.11 or s. 742.15, F.S., respectively, and persons defined as intended parents under s. 63.213, F.S.

The bill amends s. 742.15, F.S., relating to gestation surrogacy contracts by making it clear that a physician must determine that neither intended parent can physically gestate to term, gestate a pregnancy without causing harm to the intended parent, or gestate without causing risk to the fetus. This language clarifies that, in a same-sex marriage in which each partner is a woman, the couple cannot use a surrogate unless neither woman can gestate a pregnancy.

[20] S. 742.15(3), F.S.
[21] S. 742.15(4), F.S.

The bill also:

- Amends s. 742.14, F.S., relating to the donation of eggs, sperm, or pre-embryos by changing the term "father" to "donor" and fixing a cross reference; and
- Amends s. 742.16, F.S., relating to the expedited affirmation of parental status for gestational surrogacy by removing the notice requirement for anyone claiming paternity, and instead making the notice requirement applicable to any party claiming to be a genetic or intended parent unless such rights are relinquished pursuant to s. 742.14, F.S.

The bill provides that it takes effect upon becoming law.

B. SECTION DIRECTORY:

Section 1: Amends s. 63.213, F.S., relating to preplanned adoption agreements.
Section 2: Amends s. 742.11, F.S., relating to presumed status of child conceived by means of artificial or in vitro insemination or donated eggs or pre-embryos.
Section 3: Amends s. 742.13, F.S., relating to definitions.
Section 4: Amends s. 742.14, F.S., relating to donation of eggs, sperm, or pre-embryos.
Section 5: Amends s. 742.15, F.S., relating to gestational surrogacy contracts.
Section 6: Amends s. 742. 16, F.S., relating to expedited affirmation of parental status for gestational surrogacy.
Section 7: Provides the bill will take effect upon becoming law.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   This bill could create an indeterminate, negative fiscal impact on DOH related to the cost of any additional birth certificate processing through the Bureau of Vital Statistics.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The bill references s. 752.11, F.S., on line 167, which does not appear germane to this bill. This is likely a scrivener's error meant to reference s. 742.11, F.S., which this bill amends.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to parentage; amending s. 63.213, F.S.; revising terminology relating to parents; amending ss. 742.11 and 742.13, F.S.; revising terminology relating to married couples; amending ss. 742.14 and 742.15, F.S.; revising terminology relating to parents; making technical changes; amending s. 742.16, F.S.; revising to whom notice of hearing must be given on a petition for expedited affirmation of parental status; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Paragraph (b) of subsection (1), paragraphs (a) and (c) through (h) of subsection (2), subsections (4) and (5), and paragraphs (d) through (i) of subsection (6) of section 63.213, Florida Statutes, are amended to read:

63.213 Preplanned adoption agreement.—

(1) Individuals may enter into a preplanned adoption arrangement as specified in this section, but such arrangement may not in any way:

(b) Constitute consent of a mother to place her biological child for adoption until 48 hours after the birth of the child and unless the court making the custody determination or approving the adoption determines that the mother was aware of her right to rescind within the 48-hour period after the birth

of the child but chose not to rescind such consent. The volunteer mother's right to rescind her consent in a preplanned adoption applies only when she is the genetic mother of the child ~~is genetically related to her~~.

(2) A preplanned adoption agreement must include, but need not be limited to, the following terms:

(a) That the volunteer mother agrees to become pregnant by the fertility technique specified in the agreement, to bear the child, and to terminate any parental rights and responsibilities to the child she might have through a written consent executed at the same time as the preplanned adoption agreement, subject to a right of rescission by the volunteer mother any time within 48 hours after the birth of the child, if the volunteer mother is the genetic mother of ~~genetically related to~~ the child.

(c) That the volunteer mother acknowledges that she is aware that she will assume parental rights and responsibilities for the child born to her as otherwise provided by law for a mother if the intended parents ~~father and intended mother~~ terminate the agreement before final transfer of custody is completed, if a court determines that a parent clearly specified by the preplanned adoption agreement to be the biological parent is not the biological parent, or if the preplanned adoption is not approved by the court pursuant to the Florida Adoption Act.

(d) That an intended parent ~~father~~ who is also the biological parent ~~father~~ acknowledges that the parent ~~he~~ is aware that the parent ~~he~~ will assume parental rights and

responsibilities for the child as otherwise provided by law for a biological parent ~~father~~ if the agreement is terminated for any reason by any party before final transfer of custody is completed or if the planned adoption is not approved by the court pursuant to the Florida Adoption Act.

(e) That the intended parents ~~father and intended mother~~ acknowledge that they may not receive custody or the parental rights under the agreement if the volunteer mother terminates the agreement or if the volunteer mother rescinds her consent to place her child for adoption within 48 hours after the birth of the child, if the volunteer mother is the genetic mother of ~~genetically related to~~ the child.

(f) That the intended parents ~~father and intended mother~~ may agree to pay all reasonable legal, medical, psychological, or psychiatric expenses of the volunteer mother related to the preplanned adoption arrangement and may agree to pay the reasonable living expenses of the volunteer mother and her wages lost due to the pregnancy and birth ~~of the volunteer mother~~ and reasonable compensation to the volunteer mother for inconvenience, discomfort, and medical risk. No other compensation, whether in cash or in kind, shall be made pursuant to a preplanned adoption arrangement.

(g) That the intended parents ~~father and intended mother~~ agree to accept custody of and to assert full parental rights and responsibilities for the child immediately upon the child's birth, regardless of any impairment to the child.

(h) That the intended parents ~~father and intended mother shall~~ have the right to specify the blood and tissue typing tests to be performed if the agreement specifies that at least one of them is intended to be the biological parent of the child.

(4) An attorney who represents the ~~an~~ intended parents ~~father and intended mother~~ or any other attorney with whom that attorney is associated may ~~shall~~ not represent simultaneously a female who is or proposes to be a volunteer mother in any matter relating to a preplanned adoption agreement or preplanned adoption arrangement.

(5) Payment to agents, finders, and intermediaries, including attorneys and physicians, as a finder's fee for finding volunteer mothers or matching a volunteer mother and intended parents ~~father and intended mother~~ is prohibited. Doctors, psychologists, attorneys, and other professionals may receive reasonable compensation for their professional services, such as providing medical services and procedures, legal advice in structuring and negotiating a preplanned adoption agreement, or counseling.

(6) As used in this section, the term:

(d) "Intended parents ~~father~~" means a married couple ~~male~~ who, as evidenced by a preplanned adoption agreement, intends to assert the parental rights and responsibilities for a child conceived through a fertility technique, regardless of whether the child is biologically related to both parents or either

parent ~~the male~~.

~~(c) "Intended mother" means a female who, as evidenced by a preplanned adoption agreement, intends to assert the parental rights and responsibilities for a child conceived through a fertility technique, regardless of whether the child is biologically related to the female.~~

(e) ~~(f)~~ "Party" means the intended father, the intended mother, the volunteer mother, or the volunteer mother's spouse ~~husband~~, if she has a spouse ~~husband~~.

(f) ~~(g)~~ "Preplanned adoption agreement" means a written agreement among the parties that specifies the intent of the parties as to their rights and responsibilities in the preplanned adoption arrangement, consistent with ~~the provisions of~~ this section.

(g) ~~(h)~~ "Preplanned adoption arrangement" means the arrangement through which the parties enter into an agreement for the volunteer mother to bear the child, for payment by the intended parents ~~father and intended mother~~ of the expenses allowed by this section, for the intended parents ~~father and intended mother~~ to assert full parental rights and responsibilities to the child if consent to adoption is not rescinded after birth by a volunteer mother who is the genetic mother of ~~genetically related to~~ the child, and for the volunteer mother to terminate, subject to any right of rescission, all her parental rights and responsibilities to the child in favor of the intended parents ~~father and intended~~

~~mother~~.

(h) ~~(i)~~ "Volunteer mother" means a female at least 18 years of age who voluntarily agrees, subject to a right of rescission if she is the genetic mother of the ~~it is her biological~~ child, that if she should become pregnant pursuant to a preplanned adoption arrangement, she will terminate her parental rights and responsibilities to the child in favor of the intended parents ~~father and intended mother~~.

Section 2. Section 742.11, Florida Statutes, is amended to read:

742.11 Presumed status of child conceived by means of artificial or in vitro insemination or donated eggs or preembryos.—

(1) Except in the case of gestational surrogacy, any child born within wedlock who has been conceived by the means of artificial or in vitro insemination is irrebuttably presumed to be the child of the mother and her spouse ~~husband and wife~~, provided that both spouses ~~husband and wife~~ have consented in writing to the artificial or in vitro insemination.

(2) Except in the case of gestational surrogacy, any child born within wedlock who has been conceived by means of donated eggs or preembryos shall be irrebuttably presumed to be the child of the recipient gestating woman and her spouse ~~husband~~, provided that both spouses ~~parties~~ have consented in writing to the use of donated eggs or preembryos.

Section 3. Subsection (2) of section 742.13, Florida

Statutes, is amended, subsections (10) through (15) are renumbered as subsections (11) through (16), respectively, and a new subsection (10) is added to that section, to read:

742.13 Definitions.—As used in ss. 742.11-742.17, the term:

(2) "Commissioning couple" means the intended parents ~~mother and father~~ of a child who will be conceived by means of assisted reproductive technology using the eggs or sperm of at least one of the intended parents.

(10) "Intended parents" means parents whose consent is established under s. 752.11 or s. 742.15 and persons defined as intended parents under s. 63.213.

Section 4. Section 742.14, Florida Statutes, is amended to read:

742.14 Donation of eggs, sperm, or preembryos.—The donor of any egg, sperm, or preembryo, other than the commissioning couple or a donor ~~father~~ who has executed a preplanned adoption agreement under s. 63.213 ~~63.212~~, shall relinquish all maternal or paternal rights and obligations with respect to the donation or the resulting children. Only reasonable compensation directly related to the donation of eggs, sperm, and preembryos shall be permitted.

Section 5. Subsection (2) of section 742.15, Florida Statutes, is amended to read:

742.15 Gestational surrogacy contract.—

(2) The commissioning couple shall enter into a contract

with a gestational surrogate only when, within reasonable medical certainty as determined by a physician licensed under chapter 458 or chapter 459:

(a) Neither intended parent can ~~The commissioning mother cannot~~ physically gestate a pregnancy to term;

(b) Neither intended parent can physically gestate a pregnancy without causing ~~The gestation will cause~~ a risk to the physical health of the intended parent ~~commissioning mother~~; or

(c) Neither intended parent can physically gestate a pregnancy without causing ~~The gestation will cause~~ a risk to the health of the fetus.

Section 6. Paragraph (c) of subsection (4) of section 742.16, Florida Statutes, is amended to read:

742.16 Expedited affirmation of parental status for gestational surrogacy.—

(4) Notice of the hearing shall be given by the commissioning couple to:

(c) Any party claiming to be a genetic or intended parent unless such rights are relinquished pursuant to s. 742.14 ~~paternity~~.

Section 7. This act shall take effect upon becoming a law.

Amendment No.

COMMITTEE/SUBCOMMITTEE ACTION	
ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Committee/Subcommittee hearing bill: Health Quality Subcommittee

Representative Richardson offered the following:

Amendment (with title amendment)

Remove everything after the enacting clause and insert:

Section 1. Section 382.015, Florida Statutes, is amended to read:

382.015 New certificates of live birth; duty of clerks of court and department.—The clerk of the court in which any proceeding for adoption, annulment of an adoption, affirmation of parental status, or determination of parentage ~~paternity~~ is to be registered, shall within 30 days after the final disposition, forward to the department a certified copy of the court order, or a report of the proceedings upon a form to be furnished by the department, together with sufficient information to identify the original birth certificate and to

enable the preparation of a new birth certificate. The clerk of the court shall implement a monitoring and quality control plan to ensure that all judicial determinations of parentage ~~paternity~~ are reported to the department in compliance with this section. The department shall track parentage ~~paternity~~ determinations reported monthly by county, monitor compliance with the 30-day timeframe, and report the data to the clerks of the court quarterly.

(1) ADOPTION AND ANNULMENT OF ADOPTION.—

(a) Upon receipt of the report or certified copy of an adoption decree, together with the information necessary to identify the original certificate of live birth, and establish a new certificate, the department shall prepare and file a new birth certificate, absent objection by the court decreeing the adoption, the adoptive parents, or the adoptee if of legal age. The certificate must ~~shall~~ bear the same file number as the original birth certificate. All names and identifying information relating to the adoptive parents entered on the new certificate shall refer to the adoptive parents, but nothing in the certificate shall refer to or designate the parents as being adoptive. All other items not affected by adoption shall be copied as on the original certificate, including the date of registration and filing.

(b) Upon receipt of the report or certified copy of an annulment-of-adoption decree, together with the sufficient information to identify the original certificate of live birth,

the department shall, if a new certificate of birth was filed following an adoption report or decree, remove the new certificate and restore the original certificate to its original place in the files, and the certificate so removed shall be sealed by the department.

(c) Upon receipt of a report or certified copy of an adoption decree or annulment-of-adoption decree for a person born in another state, the department shall forward the report or decree to the state of the registrant's birth. If the adoptee was born in Canada, the department shall send a copy of the report or decree to the appropriate birth registration authority in Canada.

(2) DETERMINATION OF PARENTAGE ~~PATERNITY~~.—Upon receipt of the report, a certified copy of a final decree of determination of parentage ~~paternity~~, or a certified copy of a final judgment of dissolution of marriage which requires the former spouse ~~husband~~ to pay child support for the child, together with sufficient information to identify the original certificate of live birth, the department shall prepare and file a new birth certificate, which must ~~shall~~ bear the same file number as the original birth certificate. The registrant's name shall be entered as decreed by the court or as reflected in the final judgment or support order. The names and identifying information of the parents shall be entered as of the date of the registrant's birth.

(3) AFFIRMATION OF PARENTAL STATUS.—Upon receipt of an order of affirmation of parental status issued pursuant to s. 742.16, together with sufficient information to identify the original certificate of live birth, the department shall prepare and file a new birth certificate which must ~~shall~~ bear the same file number as the original birth certificate. The names and identifying information of the registrant's parents entered on the new certificate shall be the commissioning couple, but the new certificate may not make reference to or designate the parents as the commissioning couple.

(4) SUBSTITUTION OF NEW CERTIFICATE OF BIRTH FOR ORIGINAL.—When a new certificate of birth is prepared, the department shall substitute the new certificate of birth for the original certificate on file. All copies of the original certificate of live birth in the custody of a local registrar or other state custodian of vital records shall be forwarded to the State Registrar. Thereafter, when a certified copy of the certificate of birth or portion thereof is issued, it must ~~shall~~ be a copy of the new certificate of birth or portion thereof, except when a court order requires issuance of a certified copy of the original certificate of birth. In an adoption, change in parentage ~~paternity~~, affirmation of parental status, undetermined parentage, or court-ordered substitution, the department shall place the original certificate of birth and all papers pertaining thereto under seal, not to be broken except by

order of a court of competent jurisdiction or as otherwise provided by law.

(5) FORM.—Except for certificates of foreign birth which are registered as provided in s. 382.017, and delayed certificates of birth which are registered as provided in ss. 382.019 and 382.0195, all original, new, or amended certificates of live birth must ~~shall~~ be identical in form, regardless of the marital status of the parents or the fact that the registrant is adopted or of undetermined parentage.

(6) RULES.—The department shall adopt and enforce ~~all~~ rules necessary to implement ~~for carrying out the provisions of~~ this section.

Section 2. Subsection (2) and paragraphs (a) and (b) of subsection (3) of section 382.013, Florida Statutes, are amended to read:

382.013 Birth registration.—A certificate for each live birth that occurs in this state shall be filed within 5 days after such birth with the local registrar of the district in which the birth occurred and shall be registered by the local registrar if the certificate has been completed and filed in accordance with this chapter and adopted rules. The information regarding registered births shall be used for comparison with information in the state case registry, as defined in chapter 61.

(2) PARENTAGE ~~PATERNITY~~.—

(a) If the mother is married at the time of birth, the name of the spouse must ~~husband shall~~ be entered on the birth certificate as a parent ~~the father~~ of the child, unless parentage ~~paternity~~ has been determined otherwise by a court of competent jurisdiction.

(b) Notwithstanding paragraph (a), if the spouse ~~husband~~ of the mother dies while the mother is pregnant but before the birth of the child, the name of the deceased spouse must ~~husband shall~~ be entered on the birth certificate as a parent ~~the father~~ of the child, unless parentage ~~paternity~~ has been determined otherwise by a court of competent jurisdiction.

(c) If the mother is not married at the time of the birth, the name of the father may not be entered on the birth certificate without the execution of an affidavit signed by both the mother and the person to be named as the father. The facility shall give notice orally or through the use of video or audio equipment, and in writing, of the alternatives to, the legal consequences of, and the rights, including, if one parent is a minor, any rights afforded due to minority status, and responsibilities that arise from signing an acknowledgment of paternity, as well as information provided by the Title IV-D agency established pursuant to s. 409.2557, regarding the benefits of voluntary establishment of parentage ~~paternity~~. Upon request of the mother and the person to be named as the father, the facility shall assist in the execution of the affidavit, a notarized voluntary acknowledgment of parentage ~~paternity~~, or a

voluntary acknowledgment of parentage ~~paternity~~ that is witnessed by two individuals and signed under penalty of perjury as specified by s. 92.525(2).

(d) If the parentage ~~paternity~~ of the child is determined by a court of competent jurisdiction as provided under s. 382.015 or there is a final judgment of dissolution of marriage which requires the former spouse ~~husband~~ to pay child support for the child, the name of the former spouse ~~father~~ and the surname of the child shall be entered on the certificate in accordance with the finding and order of the court. If the court fails to specify a surname for the child, the surname must ~~shall~~ be entered in accordance with subsection (3).

(e) If the parentage ~~paternity~~ of the child is determined pursuant to s. 409.256, the name of the father and the surname of the child must ~~shall~~ be entered on the certificate in accordance with the finding and order of the Department of Revenue.

(f) If the parents ~~mother and father~~ marry each other at any time after the child's birth, upon receipt of a marriage license that identifies any such child, the department shall amend the certificate with regard to the parents' marital status as though the parents were married at the time of birth.

(g) If the father is not named on the certificate, no other information about the father shall be entered on the certificate.

(3) NAME OF CHILD.—

(a) If the mother is married at the time of birth, the mother and spouse ~~father~~ whose names are entered on the birth certificate shall select the given names and surname of the child if both parents have custody of the child, otherwise the parent who has custody shall select the child's name.

(b) If the parents ~~mother and father~~ whose names are entered on the birth certificate disagree on the surname of the child and both parents have custody of the child, the surname selected by each parent ~~the father and the surname selected by the mother~~ shall both be entered on the birth certificate, separated by a hyphen, with the selected names entered in alphabetical order. If the parents disagree on the selection of a given name, the given name may not be entered on the certificate until a joint agreement that lists the agreed upon given name and is notarized by both parents is submitted to the department, or until a given name is selected by a court.

Section 3. Section 742.011, Florida Statutes, is amended to read:

742.011 Determination of parentage ~~paternity~~ proceedings; jurisdiction.—Any woman who is pregnant or has a child, any spouse of a woman who is pregnant or has a child, any man who has reason to believe that he is the father of a child, or any child may bring proceedings in the circuit court, in chancery, to determine the parentage ~~paternity~~ of the child when parentage ~~paternity~~ has not been established by law or otherwise.

Section 4. Section 742.091, Florida Statutes, is amended to read:

742.091 Marriage of parents.—If the ~~mother of any child born out of wedlock and the~~ reputed parents of a child ~~father shall~~ at any time after its birth intermarry, the child shall in all respects be deemed and held to be the child of the spouses ~~husband and wife~~, as though born within wedlock, and upon the payment of all costs and attorney fees as determined by the court, the cause shall be dismissed and the bond provided for in s. 742.021 is ~~shall be~~ void. The record of the proceedings in such cases shall be sealed against public inspection in the interests of the child.

Section 5. Section 742.105, Florida Statutes, is amended to read:

742.105 Effect of a determination of parentage ~~paternity~~ from a foreign jurisdiction.—A final order of parentage ~~paternity~~ entered in a foreign jurisdiction, whether resulting from a voluntary acknowledgment or an administrative or judicial process, or an affidavit acknowledging paternity signed in any other state according to its procedures, must ~~shall~~ be given the same legal effect as if such final order was entered or affidavit was signed pursuant to this chapter. In any proceeding in this state, a certified copy of the final order of parentage ~~paternity~~ from a foreign jurisdiction is ~~shall be~~ conclusive evidence of parentage ~~paternity~~.

Section 6. Section 742.11, Florida Statutes, is amended to read:

742.11 Presumed status of child conceived by means of artificial or in vitro insemination or donated eggs or preembryos.—

(1) Except in the case of gestational surrogacy, any child born within wedlock who has been conceived by the means of artificial or in vitro insemination is irrebuttably presumed to be the child of the spouses ~~husband and wife~~, provided that both spouses ~~husband and wife~~ have consented in writing to the artificial or in vitro insemination.

(2) Except in the case of gestational surrogacy, any child born within wedlock who has been conceived by means of donated eggs or preembryos shall be irrebuttably presumed to be the child of the recipient gestating woman and her spouse ~~husband~~, provided that both parties have consented in writing to the use of donated eggs or preembryos.

Section 7. Subsection (2) of section 742.13, Florida Statutes, is amended to read:

742.13 Definitions.—As used in ss. 742.11-742.17, the term:

(2) "Commissioning couple" means the intended parents ~~mother and father~~ of a child who will be conceived by means of assisted reproductive technology using the eggs or sperm of at least one of the intended parents.

Section 8. This act shall take effect July 1, 2016.

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249 **T I T L E A M E N D M E N T**

250 Remove everything before the enacting clause and insert:

251 A bill to be entitled

252 An act relating to parentage; amending s. 382.015, F.S.;

253 requiring the Department of Health to prepare, file, and issue a

254 new birth certificate under specified circumstances; requiring

255 the new birth certificate to bear a specified reference;

256 amending ss. 382.013, 742.011, 742.091, 742.105, 742.11, and

257 742.13, F.S.; conforming provisions to changes made by the act;

258 providing an effective date.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1211 Drugs, Devices, and Cosmetics
SPONSOR(S): Plakon
TIED BILLS: **IDEN./SIM. BILLS:** SB 1604

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee		Langston	O'Callaghan
2) Government Operations Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

The U.S. Food and Drug Administration (FDA) regulates the manufacture of prescription drugs, which typically includes making drugs (preparation, deriving, compounding, propagation, processing, producing, or fabrication) on a large scale for marketing and distribution of the product for unidentified patients. Generally, state boards of pharmacy continue to have primary responsibility for oversight and regulation of the practice of pharmacy, however, the FDA also regulates, and in some cases preempts state action, through the Drug Quality and Security Act (DQSA) and federal Food, Drug, and Cosmetic Act (FDCA). The DQSA created a national uniform standard with preemption of state pedigree laws that previously existed in 29 states, including Florida. In lieu of conflicting pedigree requirements from state to state, the DQSA creates an interoperable, electronic system for the tracing of drugs at the package level as they are distributed in the United States.

Part I of ch. 499, F.S., requires the Department of Business and Professional Regulation (DBPR) to regulate drugs, devices, and cosmetics. These regulations oversee various entities in the distribution chain, such as prescription drug manufacturers and prescription drug wholesale distributors, and relate to the distribution of prescription drugs into and within Florida.

The FDA prohibits adulterated or misbranded cosmetic products from being sold to consumers and enforces cosmetic product labeling requirements. Unlike drugs, cosmetic products are not subject to safety inspections and premarket approval. However, the FDA encourages cosmetic manufacturers to voluntarily submit information on facilities, products, and ingredients, which provides the FDA with post-market product information and assists in the assessment of product safety. DBPR's Division of Drugs, Devices, and Cosmetics (Division) regulates cosmetics that are manufactured and repackaged in Florida. Cosmetic manufacturers must hold an active cosmetic manufacturer permit issued by the Division. In addition, each product produced or repackaged by such manufacturers is required to be registered with the Division. A certificate of free sale (COFS) is a document issued by a regulatory agency containing information about a product's regulatory or marketing status. The Division offers these for cosmetic products.

HB 1211 amends several provisions of ch. 499, F.S., to bring it into conformity with the DQSA. The bill substantially revises the definition section of s. 499.003, F.S., to incorporate definitions of terms from the DQSA, delete terms made obsolete by the DQSA, and address the removal of federally preempted portions of ch. 499, F.S.

The bill eases the renewal requirements for wholesale distributor permits by reducing the information required to be provided in initial application and renewals. Additionally, it clarifies the entities that are required to be permitted as wholesale distributors in Florida and removes current bond requirement for wholesale distributors. The bill establishes a nonresident prescription drug repackager permit for those entities that repackage prescription drugs outside of Florida and distribute those prescription drugs into Florida.

The bill removes the requirement that Florida cosmetic manufacturers register cosmetic products with the Division. As such, cosmetic manufacturers located in Florida will no longer be required to register cosmetic products with the Division. In lieu of mandatory registration, the bill provides for a voluntary product registration which is limited to those entities that are legally authorized to manufacture, package, repackage or relabel the products in Florida. Additionally, the bill limits DBPR's ability to issue COFSs to issuance of certificates to those cosmetic products that voluntarily register with the Division.

The bill authorizes DBPR to adopt rules to issue remedial, non-disciplinary citations to entities for alleged violations of the provisions of ch. 499, F.S.

The bill has a significant negative fiscal impact on the Department of Business and Professional Regulation and no fiscal impact on local governments.

The bill provides an effective date of July 1, 2016.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

The Pharmaceutical Supply Chain

The drug that a patient gets from the pharmacy changes hands many times between when it was manufactured and when the pharmacist dispenses it to the patient; during that time, there are potential opportunities for the drug to be mishandled, diverted, or substituted with a counterfeit.[1] The pharmaceutical supply chain begins with the ingredients a manufacturer uses to make a drug, carries through the manufacturing process, and continues through the distribution system of wholesalers, warehouses, and transportation to the dispensing retail and institutional pharmacies, to the patient receiving the drug.[2]

In April 2013, the Director of the U.S. Food and Drug Administration's (FDA) Center for Drug Evaluation and Research described the pharmaceutical supply chain as follows:

> [T]he increasingly complex drug supply chain, from raw source materials to finished products for consumers, presents multiple opportunities for the product to be contaminated, diverted, or otherwise adulterated. Our efforts to secure the supply chain include minimizing risks that arise anywhere along the supply chain continuum, from sourcing a product's ingredients through the overseeing of a product's manufacture, storage, transit, sale, and distribution. A breach at any point in this continuum could lead to dangerous and even deadly outcomes for patients.[3]

Participants in the Pharmaceutical Supply Chain

A manufacturer produces the drug product and is usually the entity that submits the application to the FDA for approval to market the product or that holds the approval. A wholesale distributor receives the drug from the manufacturer and sells the drug to "persons other than a consumer or patient."[4] Generally, there are three types of wholesale distributors:

- A primary wholesale distributor obtains the drug products directly from the manufacturer and sells them to other wholesalers or dispensers.[5]
- An authorized distributor of record (ADR) is a wholesale distributor that has a relationship with a manufacturer that is ongoing, defined in regulations as including a written agreement specifying which products it will distribute and for which time period.[6]

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[1] Susan Thaul, *Pharmaceutical Supply Chain Security*, Congressional Research Service (October 31, 2013) p. 1, *available at* http://www.ncsl.org/documents/statefed/health/CRS-PharmSupChSec2013.pdf (last visited January 22, 2016)
[2] Id.
[3] Statement of Janet Woodcock, Director, Center for Drug Evaluation and Research, Food and Drug Administration, Department of Health and Human Services, before the Subcommittee on Health, Committee on Energy and Commerce, U.S. House of Representatives, hearing on "Securing Our Nation's Prescription Drug Supply Chain," April 25, 2013, http://www.fda.gov/NewsEvents/Testimony/ucm349186.htm (last visited January 22, 2016)
[4] 21 C.F.R. § 203.3.
[5] . The three largest primary wholesale distributors accounted for 85% of U.S. pharmaceutical wholesaling revenue. *After Heparin: Protecting Consumers from the Risks of Substandard and Counterfeit Drugs*, Pew Health Group, (July 12, 2011), http://www.pewtrusts.org/en/research-and-analysis/reports/2011/07/12/after-heparin-protecting-consumers-from-the-risks-of-substandard-and-counterfeit-drugs (last visited January 22, 2016); see also, Adam Fein, *Trends and top distributors in the pharmaceuticals sector*," in MDM Market Leaders 2012: Top Pharmaceuticals Distributors, (2013), http://www.mdm.com/2012-mdm-market-leaders-top-pharmaceuticals-distributors (last visited January 22, 2016)
[6] 21 C.F.R. § 203.3.

- A secondary wholesale distributor is a wholesale distributor that acquire drug products from a wholesale distributor, not directly from the manufacturer.[7]

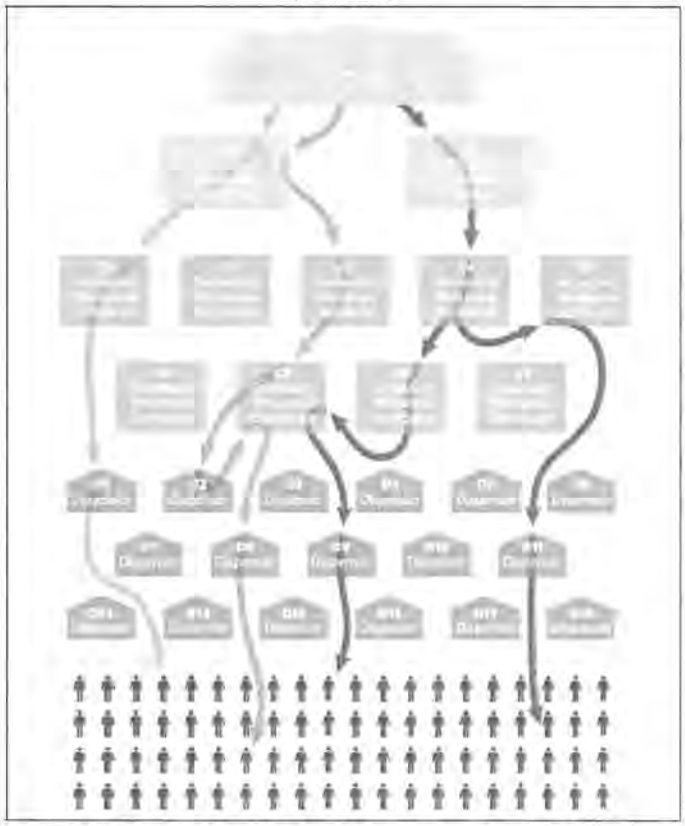
Also within the supply chain, a repackager removes a drug from its container and places it in another, usually smaller, container for sale to a distributor or dispenser.[8] Additionally, a third-party logistics provider takes temporary physical possession of the drug, but does not assume ownership of the drug.[9]

At the end of the supply chain, a dispenser provides the drug to the patient. A dispenser can be an independent, community pharmacy; a retail chain pharmacy; a hospital or health care facility; or doctor's office.[10]

A manufacturer may sell directly to a dispenser, however, typically it sells to a primary wholesale distributor, who in turn sells directly to a dispenser or may sell to a secondary wholesale distributor, who then sells the drug to the dispenser.[11] A dispenser may return certain drugs to the wholesaler who has the option to sell it to a dispenser, a wholesaler, or return it to the manufacturer.[12] Interspersed throughout the chain may be third-party logistics providers who transport or warehouse the drug under contract to the manufacturer, distributor, or dispenser.[13]

Figure 1. Downstream Pharmaceutical Supply Chain

(for illustration)



Source: Prepared by CRS.

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[7] *Supra*, note 1 at 4.
[8] U.S. Pharmacopeia, *Packaging Practice—Repackaging a Single Solid Oral Drug Product into a Unit-Dose Container*, http://www.pharmacopeia.cn/v29240/usp29nf24s0_c1146.html (last visited January 22, 2016); and Florida Department of Business and Professional Regulation, *Prescription Drug Repackager*, http://www.myfloridalicense.com/dbpr/ddc/PrescriptionDrugRepackager.html (last visited January 22, 2016).
[9] *Supra*, note 1 at 4.
[10] Id.
[11] Id. at 5.
[12] Id.
[13] Id.
[14] Id. at 6.

Since its passage in 1938, the federal Food, Drug, and Cosmetic Act (FDCA), has addressed and indirectly influences the pharmaceutical supply chain; Congress has made focused attempts at improving supply chain security by amending the FDCA.

Federal Regulation of the Pharmaceutical Supply Chain

The FDA regulates the manufacture of prescription drugs, which typically includes making drugs (preparation, deriving, compounding, propagation, processing, producing, or fabrication) on a large scale for marketing and distribution of the product for unidentified patients. Generally, state boards of pharmacy continue to have primary responsibility for oversight and regulation of the practice of pharmacy, however, the FDA also regulates, and in some cases preempts state action, through the Drug Quality and Security Act (DQSA) and the FDCA.

Drug Quality and Security Act (DQSA)

Previously, under the Prescription Drug Marketing Act,[15] the wholesale distribution of prescription drugs was monitored through the use of a pedigree to prevent the introduction and retail sale of substandard, ineffective, and counterfeit drugs in the pharmaceutical supply chain.[16] The DQSA amended the FDCA to create a national track-and-trace system to monitor the movement of drugs through the pharmaceutical supply chain. The DQSA created a national uniform standard with preemption of state pedigree laws[17] that previously existed in 29 states, including Florida.[18] In lieu of conflicting pedigree requirements from state to state, the DQSA creates an interoperable, electronic system for the tracing of drugs at the package level as they are distributed in the United States.

The system, which will be implemented over a ten year span, will facilitate the exchange of information at the individual package level about where a drug has been in the supply chain.[19] The new system created by the DQSA:

- Enables verification of the legitimacy of the drug product identifier down to the package level;
- Enhances detection and notification of illegitimate products in the drug supply chain; and
- Facilitates more efficient recalls of drug products.[20]

Among key provisions implemented over the next 10 years are requirements for:

- *Product identification*: Manufacturers and repackagers must put a unique product identifier on certain prescription drug packages, for example, using a bar code that can be easily read electronically.

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[15] 21 U.S.C. § 353(e)(1)(A) and 21 C.F.R. part 203.
[16] U.S. Food and Druga Administration, *CPG Sec. 160.900 Prescription Drug Marketing Act -- Pedigree Requirements under 21 CFR Part 203*, http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm073857.htm (last visited January 22, 2016).
[17] A drug pedigree is a statement of origin that identifies each prior sale, purchase, or trade of a drug, including the date of those transactions and the names and addresses of all parties to them. Under the pedigree requirement, each person who is engaged in the wholesale distribution of a prescription drug in interstate commerce, who is not the manufacturer or an authorized distributor of record for that drug, must provide to the person who receives the drug a pedigree for that drug.
[18] In 2011, the National Alliance for Model State Drug Laws (NAMSDL) identified 20 states with pedigree-related statutes; NAMSDL, Drug Pedigree Requirements for Pharmacies and Wholesalers: State Statutes, July 2011, and 16 states with pedigree-related regulations, NAMSDL, *Drug Pedigree Requirements for Pharmacies and Wholesalers: State Regulations*, (July 2011). 29 states have laws or regulations that go "beyond the federal PDMA standards." Testimony of Elizabeth A. Gallenagh, Vice President, Government Affairs and General Counsel, Healthcare Distribution Management Association, before the U.S. House Energy and Commerce Committee, Subcommittee on Health, April 25, 2013.
[19] U.S. Food and Druga Administration, *Drug Supply Chain Security Act (DSCSA)*, http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ (last visited January 21, 2016).
[20] Id.

- *Product tracing*: Manufacturers, wholesaler drug distributors, repackagers, and many dispensers in the drug supply chain must provide information about a drug and who handled it each time it is sold in the U.S. market.
- *Product verification*: Manufacturers, wholesaler drug distributors, repackagers, and many dispensers must establish systems and processes to be able to verify the product identifier on certain prescription drug packages.
- *Detection and response*: Manufacturers, wholesaler drug distributors, repackagers, and many dispensers must quarantine and promptly investigate a drug that has been identified as suspect, meaning that it may be counterfeit, unapproved, or potentially dangerous.
- *Notification*: Manufacturers, wholesaler drug distributors, repackagers, and many dispensers must establish systems and processes to notify FDA and other stakeholders if an illegitimate drug is found.[21]

Additionally, the DQSA established uniform national licensing standards for pharmaceutical wholesale distributors and preempts state laws, regulations, and requirements regarding wholesale distributor licensure that are inconsistent with, less stringent than, directly related to, or covered by the standards established by the DQSA. States will continue to license wholesale distributors, but they will be required to do so utilizing the federal standards established.[22]

Regulation of Drugs, Devices, and Cosmetics in Florida

Part I of ch. 499, F.S., requires the Department of Business and Professional Regulation (DBPR) to regulate drugs, devices, and cosmetics.[23] Most of the regulations relate to the distribution of prescription drugs into and within Florida. In particular, the regulations require various entities in the distribution chain, such as prescription drug manufacturers and prescription drug wholesale distributors, to obtain permits. In total, Florida has 17 distinct permits for these entities.[24]

Among many other provisions, the chapter provides for:

- Criminal prohibitions against distribution of contraband and misbranded prescription drugs;
- Regulation of the advertising and labeling of drugs, devices, and cosmetics;
- Permits for manufacturing and distributing drugs, devices, and cosmetics;
- Regulation of the wholesale distribution of prescription drugs with pedigree papers;
- Regulation of the provision of drug samples;
- The Cancer Drug Donation Program; and
- Numerous enforcement avenues for DBPR, including seizure and condemnation of drugs, devices, and cosmetics.

Many of these regulations have been significantly strengthened in recent years, including more stringent requirements to obtain a wholesale distributor permit, requiring, among other items, a posting of a bond and extensive background information for various employees of the wholesale distributor;[25] more thorough documentation requirements for the distribution of prescription drugs, including broader

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[21] Id.
[22] States will continue to license wholesale distributors, but they will be required to do so utilizing the federal standards established.
[23] S. 27, ch. 2010-161, Law of Fla., shifted responsibility for operation and enforcement of the Florida Drugs, Devices, and Cosmetics Act from the Department of Health to the Department of Business and Professional Regulation.
[24] A permit is required for a prescription drug manufacturer; a prescription drug repackager; a nonresident prescription drug manufacturer; a prescription drug wholesale distributor; an out-of-state prescription drug wholesale distributor; a retail pharmacy drug wholesale distributor; a restricted prescription drug distributor; a complimentary drug distributor; a freight forwarder; a veterinary prescription drug retail establishment; a veterinary prescription drug wholesale distributor; a limited prescription drug veterinary wholesale distributor; an over-the-counter drug manufacturer; a device manufacturer; a cosmetic manufacturer; a third party logistics provider; or a health care clinic establishment. S. 499.01(1), F.S.
[25] S. 499.01(2)(d), F.S. (requiring a bond of $100,000 or other means of equivalent security) and s. 499.012(8) and (9), F.S. (requiring, in addition to other information, place of residence for the past 7 years, fingerprints, photograph taken within 30 days, and name, address, occupation, and date and place of birth of each member of the person's immediate family who is 18 years of age or older).

application of the pedigree paper[26] to most wholesale distributions;[27] enhanced criminal penalties for, among other things, distribution of contraband prescription drugs;[28] and stronger departmental enforcement authority to protect the prescription drug supply chain.[29]

Permitting

An application for a permit or to renew a permit for a prescription drug wholesale distributor or an out-of-state prescription drug wholesale distributor must include:

- Certain personal identification and contact information;
- Estimates, in total dollar volume of prescription drug sales and purchases;
- Financial information;
- Information about the property on which the business is located;
- Information related to out-of-state licenses;
- Employee information, including fingerprints;
- Any other relevant information that DBPR requires, including, but not limited to, any information related to whether the applicant satisfies the definition of a primary wholesale distributor or a secondary wholesale distributor; and
- Documentation of the credentialing policies and procedures.

For an applicant that is a secondary wholesale distributor, the permit application must contain each of the following:

- A personal background information statement containing the background information and fingerprints each person named as the manager of the establishment, each designated representative, and each affiliated party of the applicant;
- If any of the five largest shareholders of the corporation seeking the permit is a corporation, the name, address, and title of each corporate officer and director of each such corporation; the name and address of such corporation; the name of such corporation's resident agent, such corporation's resident agent's address, and such corporation's state of its incorporation; and the name and address of each shareholder of such corporation that owns 5 percent or more of the stock of such corporation;
- The name and address of all financial institutions in which the applicant has an account which is used to pay for the operation of the establishment or to pay for drugs purchased for the establishment, together with the names of all persons that are authorized signatories on such accounts;
- The sources of all funds and the amounts of such funds used to purchase or finance purchases of prescription drugs or to finance the premises on which the establishment is to be located; and
- If any of the funds identified were borrowed, copies of all promissory notes or loans used to obtain such funds.[30]

Pedigree Papers

Florida law required, until preempted by the DQSA, that each person who is engaged in the wholesale distribution of a prescription drug must, prior to or simultaneous with each wholesale distribution,

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[26] A pedigree paper is a record that documents the movement of drugs, devices or cosmetics through the chain of commerce. A pedigree paper must provide a complete audit trail from a person's receipt or acquisition to sale or other disposition of the product or component. Rule 61N-1.012(1)(a), F.A.C.

[27] S. 499.01212, F.S. ("Each person who is engaged in the wholesale distribution of a prescription drug must, prior to or simultaneous with each wholesale distribution, provide a pedigree paper to the person who receives the drug.")

[28] S. 499.0051(6), F.S. (imposing a second degree felony for "a person who is knowingly in actual or constructive possession of any amount of contraband prescription drugs, who knowingly sells or delivers, or who possesses with intent to sell or deliver any amount of contraband prescription drugs").

[29] S. 499.0051(12) and (13), F.S.

[30] S. 499.012(8)(g), F.S.

provide a pedigree paper to the person who receives the drug.[31] For the wholesale distribution of a prescription drug within the normal distribution chain, a pedigree paper was required to contain:

- The statement: "This wholesale distributor purchased the specific unit of the prescription drug directly from the manufacturer."
- The manufacturer's national drug code identifier and the name and address of the wholesale distributor and the purchaser of the prescription drug.
- The name of the prescription drug as it appears on the label.
- The quantity, dosage form, and strength of the prescription drug.[32]

For all other wholesale distributions of prescription drugs, the pedigree paper was required to contain:

- The quantity, dosage form, and strength of the prescription drugs.
- The lot numbers of the prescription drugs.
- The name and address of each owner of the prescription drug and his or her signature.
- Shipping information, including the name and address of each person certifying delivery or receipt of the prescription drug.
- An invoice number, a shipping document number, or another number uniquely identifying the transaction.
- A certification that the recipient wholesale distributor has authenticated the pedigree papers.
- The unique serialization of the prescription drug, if the manufacturer or repackager has uniquely serialized the individual prescription drug unit.
- The name, address, telephone number, and, if available, e-mail contact information of each wholesale distributor involved in the chain of the prescription drug's custody.[33]

Non-Disciplinary Citations

DBPR may bring an enforcement action, including the issuance of Notices of Violations and Administrative Complaints, against entities that have violated the provisions of ch. 499, F.S., that are not harmful or unsafe to the public health, such as changing ownership and continuing to operate without notifying DBPR. However, DBPR does not currently have the authority to issue such citations under ch. 499, F.S. DBPR does have this authority for the other professions it regulates under ch. 455, F.S. (Business and Professional Regulation); similarly, the Department of Health has this authority under ch. 456, F.S. (Health Professions and Occupations).

Federal Regulation of Cosmetics

In the United States more than 8 billion cosmetics are sold annually which results in over $60 billion in annual sales.[34] FDA's definition of cosmetics covers a broad range of products. For regulatory purposes, the term includes products for the eyes, face, nails, hair, skin, and mouth, which may be in the form of products such as makeup, polish, hair dyes, fragrances, deodorants, shave gel, oral care, lotions, bath products, and products for infants and children.[35]

The FDA regulates cosmetics under the authority of the FDCA and the Fair Packaging and Labeling Act (FPLA). The FDCA prohibits the adulteration and misbranding of cosmetics and the introduction,

[31] S. 499.01212(1), F.S.
[32] S. 499.01212(2)(a), F.S.
[33] S. 499.01212(2)(b), F.S.
[34] Statement of Michael Landa, Director, Center for Food Safety and Applied Nutrition, Food and Drug Administration, Department of Health and Human Services, before the Subcommittee on Health, Committee on Energy and Commerce, U.S. House of Representatives, hearing on "Examining the Current State of Cosmetics," March 27, 2012, http://www.fda.gov/NewsEvents/Testimony/ucm297215.htm (last visited January 22, 2016).
[35] 21 C.F.R. §720.4(c)(12) (1992).

receipt, and delivery of adulterated or misbranded cosmetics into interstate commerce.[36] A cosmetic is considered to be adulterated if it contains a substance that may cause injury to users under the conditions of use prescribed on the product's labeling or if it contains a soiled or decomposed substance.[37] A cosmetic is considered to be misbranded if its labeling is false or misleading, if it does not bear the required labeling information, if the container is made or filled in a deceptive manner, or if it does not comply with child resistant packaging requirements.[38] The FDA is authorized to take action against a cosmetic on the market if a product is found to be adulterated or misbranded, as well as companies and individuals who market such products.[39] However, the FDA does not have the authority to require a manufacturer to recall a cosmetic product from the marketplace, although the agency has general regulations on voluntary recalls.[40]

Voluntary Regulations

The FDA's legal authority over cosmetics is less comprehensive than other products it regulates, such as drugs and medical devices, with respect to mandatory product approval, regulation, and registration. The FDA does not impose registration requirements on cosmetic manufacturers, but it allows cosmetic manufactures to follow voluntary registration regulations. These voluntary regulations include facility registration, reporting of product's ingredients, and reporting of adverse reactions to products.

Voluntary cosmetic regulation compliance is managed electronically through the FDA's Voluntary Cosmetic Registration Program (VCRP). The VCRP is an electronic reporting system for manufacturers, packers, and distributors of cosmetic products that are distributed commercially in the United States.[41] Voluntary submission to the VCRP provides the FDA with information on cosmetic businesses and products, which helps support product safety review processes.[42] As of December 2015, there are 2,970 active online accounts, 1,473 registered establishments, and 45,103 product formulations on file with the VCRP.[43]

Labeling

The FPLA requires that packages and their labels provide consumers with accurate information about the quantity of contents to prevent consumer deception.[44] FPLA regulations require cosmetic product labels to disclose:[45]

- Identification of the product;
- Net quantity of contents in terms of weight, measure, or numerical count;
- Material facts about product and its use, such as directions for safe use;
- Name and place of business of the product's manufacturer, packer, or distributor;
- Warning and caution statements for products that are required to bear such statements by the FDCA and FDA regulations; and
- A list of ingredients in descending order of predominance.

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[36] Amalia Corby-Edwards, *FDA Regulation of Cosmetics and Personal Care Products*, Congressional Research Service, July 9, 2012, available at http://asbcouncil.org/sites/default/files/library/docs/crs_report_fda_regulation_of_cosmetics_and_personal_care_products.pdf (last visited January 22, 2016).
[37] Id.
[38] Id.
[39] U.S. FOOD AND DRUG ADMINISTRATION, *FDA Authority over Cosmetics*, March 20, 2014, http://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm074162.htm (last visited December 10, 2015).
[40] *Supra*, note 36.
[41] U.S. FOOD AND DRUG ADMINISTRATION, *Voluntary Cosmetic Registration Program*, http://www.fda.gov/Cosmetics/RegistrationProgram/default.htm (last visited December 10, 2015).
[42] Information from the VCRP is used by the Cosmetic Ingredient Review, an industry funded organization, to assess ingredient safety and determine priorities for ingredient safety review. *Id.*
[43] U.S. FOOD AND DRUG ADMINISTRATION, *Registration Reports*, http://www.fda.gov/Cosmetics/RegistrationProgram/RegistrationReports/default.htm (last visited December 9, 2015).
[44] 15 U.S.C. § 1451-1460 (2009).
[45] *Supra*, note 34.

Product Ingredients

The FDA is not statutorily authorized to approve a premarket cosmetic product. Therefore, manufactures are responsible for verifying the safety of their products before they are sold to consumers. FDA regulations prohibit or restrict the use of 10 types of ingredients in cosmetic products including chloroform, bithioniol, methylene chloride, and mercury-containing compounds[46] and require warning statements on the labels of certain types of cosmetics. Manufacturers must remove dangerous products from the market once a safety concern emerges. The FDA can pursue enforcement actions against such products or against firms or individuals who violate the law.[47] In general, except for color additives and those ingredients that are prohibited or restricted by regulation, a manufacturer may use any ingredient in the formulation of a cosmetic, provided that the:[48]

- Ingredient and the finished cosmetic are safe under labeled or customary conditions of use;
- Product is properly labeled; and
- Use of the ingredient does not otherwise cause the cosmetic to be adulterated or misbranded under the laws that FDA enforces.

Florida Cosmetic Regulation

DBPR's Division of Drugs, Devices, and Cosmetics (Division) regulates Florida cosmetic manufacturers and registers cosmetic products manufactured or repackaged in Florida.

Manufacturer Permit

Cosmetic manufacturers physically located in Florida must obtain a cosmetic manufacturer permit through the Division.[49] Manufacture in this context means the preparation, deriving, compounding, propagation, processing, producing, or fabrication of any cosmetic.[50] Cosmetic manufacturers also repackage products by changing the container, wrapper, or label of a product, which may include altering the quantity of a product into different containers.[51] A person that only labels or changes the label of a cosmetic, but does not open the container sealed by the manufacturer of the product, is exempt from obtaining a permit.[52]

Applicants for a cosmetic manufacturer permit must complete and submit an application, pass an onsite inspection,[53] and pay a fee. Applicants must pay a fee of $800 for a biennial permit and a one-time pre-permit inspection fee of $150.[54] As of November 2014, there were 125 establishments with Division issued cosmetic manufacturer permits.[55]

Division regulations provide guidelines for cosmetic manufacturers to ensure cosmetic product safety and quality and compliance with FDA laws and regulations. The regulations provide that: [56]

- Manufacturers must assure that personnel do not contribute to contamination or adulteration of

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[46] U.S. FOOD AND DRUG ADMINISTRATION, *Prohibited and Restricted Ingredients*, http://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm127406.htm (last visited December 10, 2015).
[47] *Supra*, note 34.
[48] *Supra*, note 39.
[49] S. 499.01(2)(o), F.S.
[50] FLORIDA DEP'T OF BUSINESS AND PROFESSIONAL REGULATION, *Cosmetic Manufacturer,* http://www.myfloridalicense.com/dbpr/ddc/CosmeticManufacturer.html (last visited December 11, 2015).
[51] Id.
[52] *Supra*, note 49.
[53] If the applicant also holds an Over-the-Counter Drug Manufacturer or Prescription Drug Manufacturer permit at the same time an inspection is not required. *Supra*, note 50
[54] *Supra*, note 50.
[55] Letter from the Director of the Division of Drugs, Devices, and Cosmetics to a representative of the Florida Cosmetic Manufacturers Coalition on November 26, 2014. (on file with Health Quality Subcommittee staff).
[56] Rule 61N-1.010, F.A.C.

the product;
- Any facility used for the manufacture, processing, packaging, or labeling of a cosmetic shall be of suitable size and construction to produce a product that is not adulterated or misbranded;
- Any facility and equipment used in the manufacture, processing, packaging, or labeling of a cosmetic shall be maintained in a clean and sanitary condition;
- Components, containers, and closures shall not be reactive, additive, or absorptive so as to alter the safety or purity of the cosmetic;
- Container closure systems shall provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the cosmetic product; and
- An appropriate identification or tracking system should be in place to facilitate a rapid and effective recall or market withdrawal.

Registration of Products

Cosmetics manufactured, packaged, repackaged, labeled or relabeled in Florida must be registered with the Division.[57] Products that are both a cosmetic and a drug must be registered as a drug.[58] Registration of cosmetic products requires a manufacturer to submit a detailed Division application, a copy of the product labels, and a fee for each product.[59] The application includes the following information:

- Manufacturer's contact and address information, type of ownership, and operating hours;
- Name of product as shown on label;
- Identification of the product, if it is for professional use only;
- Manufacturer of the product, including its name, city, and state;
- Identical cosmetic products information; and
- Signed affidavit section.[60]

New cosmetic products must be registered prior to sale. If a manufacturer has existing registered products, its registered product list must be updated through the formal application process to include any new products.[61] The registration and biennial renewal fee for each cosmetic product is $30.

Manufacturers often produce similar products or slightly alter products from an outside manufacturer; for example, they may use a different brand name, container, or scent for an almost identical product. In these instances, for registration purposes, the product is not considered separate and distinct. The process for "identical products" requires submission of an application and a $15 fee and biennial renewal fee for each additional size, quantity, color, flavor, and scent of a registered cosmetic product.[62]

The Division reviews applicants' product labels to determine compliance with the requirements of the FDCA.[63] The Division reviews the ingredients of the cosmetic to determine if the ingredients are approved for use in cosmetics or otherwise safe for cosmetic products.[64] Division pharmacists or drug inspectors review products that may contain ingredients that are prohibited or may change the

[57] S. 499.015(1)(a), F.S.
[58] Rule 61N-1.016(1)(a), F.A.C.
[59] S. 499.015, F.S.
[60] FLORIDA DEP'T OF BUSINESS AND PROFESSIONAL REGULATION, *Application for Product Registration-Cosmetics Form No.: DBPR-DDC-228*, available at http://www.myfloridalicense.com/DBPR/ddc/documents/Product_Registration_Cosmetic_App-228.pdf (last visited December 14, 2015).
[61] Rule 61N-1.016(4)(b), F.A.C.
[62] Rule 61N-1.016(1)(b), F.A.C.
[63] Rule 61N-1.009, F.A.C.
[64] Florida Department of Business and Professional Regulation, 2016 Legislative Bill Analysis SB 176, September 29, 2015. (SB 176 is identical to HB 261, analysis is on file with Health Quality Subcommittee staff).

classification of the product to a drug.[65] Currently, there are 13,024 active cosmetic product registrations with the Division.[66]

Inspection and Investigation of Cosmetic Manufacturers

Passing an onsite inspection is a prerequisite to issuance of a Cosmetic Manufacturer permit, unless the applicant also holds an Over-the-Counter Drug Manufacturer or Prescription Drug Manufacturer permit at the same address.[67] Additionally, once a permit has been issued to a cosmetic manufacturer, it is subject to inspection and investigation, whether announced or unannounced, by the Division and the Department of Law Enforcement.[68]

Certificates of Free Sale

Manufacturers exporting products from the United States are often asked by foreign customers or foreign governments to supply a certificate of free sale (COFS) to ensure that products are in compliance with FDA laws and regulations. A COFS is a document issued by a regulatory agency containing information about a product's regulatory or marketing status.[69] A COFS verifies that products being exported are freely marketed without restriction and are approved for sale in the United States and Florida.[70]

A COFS can be issued by a federal, state, city office or a non-governmental association such as a Chamber of Commerce. The Division, when requested by a cosmetic manufacturer, issues a COFS for a registered cosmetic product that is to be exported to another country.[71] Enterprise Florida will prepare a COFS for firms involved in the exporting of products manufactured in, or distributed from Florida for a fee of $20.00.[72]

Effect of the Bill

Alignment of Ch. 499, F.S., with the DQSA

HB 1211 amends several provisions of ch. 499, F.S., to bring it into conformity with the DQSA's amendments to the FDCA.

Definitions

The bill substantially revises the definition section of s. 499.003, F.S., to incorporate definitions of terms from the DQSA, delete terms made obsolete by the DQSA, and address the removal of federally preempted portions of ch. 499, F.S. Of note, the bill substantially revises the definition of wholesale distribution and removes the definitions for primary and secondary distribution as well as what it means to distribute in order to comply with the DQSA.

Preemption of Pedigree law

The bill remove references to Florida's pedigree requirements throughout ch. 499, F.S. Additionally, where appropriate, the bill replaces the references to "pedigree papers" with references to "transaction

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[65] *Supra*, note 55.
[66] *Supra*, note 64.
[67] *Supra*, note 50.
[68] S. 499.051(1), F.S.; Rule 61N-1.019(1)-(3), F.A.C.
[69] U.S. FOOD AND DRUG ADMINISTRATION, *FDA Export Certificate,* December 18, 2014, http://www.fda.gov/RegulatoryInformation/Guidances/ucm125789.htm, (last visited December 15, 2015).
[70] Enterprise Florida, *Certificate of Free Sale*, available at https://www.enterpriseflorida.com/wp-content/uploads/certificate-of-free-sale-flyer.pdf (last visited December 14, 2015).
[71] Rule 61N-1.017, F.A.C.
[72] *Supra*, note 70.

history, transaction information, or transaction statement" to account for the DQSA's preemption of Florida's pedigree law and the requirements for the new tracking and tracing program under the DQSA.

Permits and Permitting

The bill eases the renewal requirements for wholesale distributor permits by reducing the information required to be provided in the initial application and renewals. Additionally, it clarifies the entities that are required to be permitted as wholesale distributors in Florida and removes current bond requirement for wholesale distributors. It conforms the wholesale distributor bond requirement of the DQSA, allowing wholesale distributors with annual sales of $10,000,000 or less to provide proof of $25,000 bond or other equivalent security.

The bill clarifies when the Division can issue a prescription drug manufacturer permit to a nuclear pharmacy and a retail pharmacy wholesale distributor permit to a community pharmacy.

The bill removes the requirement that repackagers comply with the same requirements as wholesale distributors and requires repackagers to comply with requirements applicable to prescription drug manufacturers to comport to the provisions of the DQSA.

The bill establishes a nonresident prescription drug repackager permit for those entities that repackage prescription drugs outside of Florida and distribute those prescription drugs into Florida. The nonresident prescription drug repackager must comply with manufacture requirements to be permitted, comply with all state and federal good manufacturing practices, and be registered with the federal government.

The bill requires nonresident prescription drug manufacturers to comply with the Florida requirements for prescription drug manufacturers and allows DBPR to issue a virtual nonresident prescription drug manufacturing permit to entities outside of Florida that manufacture prescription drugs but do not actually make or take physical possession of the prescription drugs. DBPR may adopt rules exempting the nonresident virtual manufacturers from certain establishment, security and storage requirements.

Cosmetic Product Registration

The bill removes the requirement that Florida cosmetic manufacturers register cosmetic products with the Division. As such, cosmetic manufacturers located in Florida will no longer be required to register cosmetic products with the Division. In lieu of mandatory registration, the bill provides for a voluntary product registration which is limited to those entities that are legally authorized to manufacture, package, repackage or relabel the products in Florida.

The bill requires product registrations issued after July 1, 2016, to expire on the same date as the manufacturing permit of the manufacturer that manufactures the product. This will ensure that both the product registration and permit renewals will be on the same schedule.

Certificate of Free Sale

The bill limits DBPR's ability to issue COFSs to issuance of certificates to those cosmetic products that voluntarily register with the Division. While COFSs would not be available from the Division for unregistered cosmetic products, they would continue to be available from other entities for exported cosmetic products, including Enterprise Florida.

Non-Disciplinary Citations

The bill authorizes DBPR to adopt rules to issue remedial, non-disciplinary citations to entities for alleged violations of the provisions of ch. 499, F.S. These citations may be issued, within 12 months of the occurrence, for violations that do not pose a substantial threat to the public health, safety, and

welfare. The subject of the citation must be given the option to refuse the citation and have the allegations investigated pursuant to the provisions of s. 499.051, F.S., relating to investigations. The citation becomes a non-disciplinary final order if not timely disputed. DBPR is authorized to recover investigatory costs as part of the citation and adopt rules to designate the monetary assessments and other remedial measures that must be taken as a result of a citation.

B. SECTION DIRECTORY:

Section 1: Amends s. 499.003, F.S., relating to definitions of terms used in this part.
Section 2: Amends s. 499.005, F.S., relating to prohibited acts.
Section 3: Amends s. 499.0051, F.S., relating to criminal acts.
Section 4: Amends s. 499.006, F.S., related to adulterated drug or device.
Section 5: Amends s. 499.01, F.S., relating to permits.
Section 6: Amends s. 499.012, F.S., relating to permit application requirements.
Section 7: Amends s. 499.01201, F.S., relating to Agency for Health Care Administration review and use of statute and rule violation or compliance data.
Section 8: Amends s. 499.0121, F.S., relating to storage and handling of prescription drugs.
Section 9: Amends s. 499.015, F.S., relating to registration of drugs, devices, and cosmetics; issuance of certificates of free sale.
Section 10: Amends s. 499.03, F.S., relating to possession of certain drugs without prescriptions unlawful; exemptions and exceptions.
Section 11: Amends s. 499.05, F.S., relating to rules.
Section 12: Amends s. 499.051, F.S., relating to inspections and investigations.
Section 13: Amends s. 499.066, F.S., relating to penalties; remedies.
Section 14: Amends s. 499.82, F.S., relating to definitions.
Section 15: Amends s. 499.89, F.S., relating to recordkeeping.
Section 16: Repeals s. 499.01212, F.S.
Section 17: Amends s. 409.9201, F.S., related to Medicaid fraud.
Section 18: Amends s. 794.075, F.S., relating to sexual predators; erectile dysfunction drugs.
Section 19: Amends s. 921.0022, F.S., relating to criminal punishment code; offense severity ranking chart.
Section 20: Provides an effective date.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   The Division will experience a decrease in revenues, of approximately $208,180, annually, associated with no longer receiving payment of fees for cosmetic product registration and product registration renewal by creating a voluntary registration scheme.[73]

   There are 13,024 current, active registered cosmetic products. Product registrations are renewed biennially. The Division's biennial renewal fees from the 13,024 products are approximately $330,465 (or $165,232.50 annually). The bill would reduce the Division's revenue from these fees and the revenue reductions would increase the Division fund's anticipated deficit.[74]

2. Expenditures:

   The Division will save $579 annually in postage from changes to the process for renewal of permits.

[73] Department of Business and Professional Regulation, Agency Analysis for 2016 HB 1211
[74] Department of Business and Professional Regulation, Agency Analysis for 2016 HB 261

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Cost savings associated with renewal of permits could results in an estimated annual savings of $225,379 to the industry each year and an estimated saving of $1,105 per year per permittee.[75]

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

None.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

DBPR is authorized to adopt rules to:

- Set permitting renewal schedules;
- Determine violations of ch. 499, F.S., for which non-disciplinary citations may be issued;
- Determine the monetary assessment and other remedial measures that an entity issued a non-disciplinary citation must comply with to satisfy the citation; and
- Provide for the issuance of virtual prescription drug manufacturer (resident & nonresident) permits, including rules pertaining to establishment, security and storage.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

[75] *Supra*, note 73.

A bill to be entitled

An act relating to drugs, devices, and cosmetics; amending s. 499.003, F.S.; providing, revising, and deleting definitions for purposes of the Florida Drug and Cosmetic Act; amending s. 499.005, F.S.; revising prohibited acts related to the distribution of prescription drugs; conforming a cross-reference; amending s. 499.0051, F.S.; prohibiting the distribution of prescription drugs without delivering a transaction history, transaction information, and transaction statement; providing penalties; deleting provisions and revising terminology related to pedigree papers, to conform to changes made by the act; amending s. 499.006, F.S.; conforming provisions; amending s. 499.01, F.S.; requiring nonresident prescription drug repackagers to obtain an operating permit; authorizing a manufacturer to engage in the wholesale distribution of prescription drugs; providing for the issuance of virtual prescription drug manufacturer permits and virtual nonresident prescription drug manufacturer permits to certain persons; providing exceptions from certain virtual manufacturer requirements; requiring a nonresident prescription drug repackager permit for certain persons; deleting surety bond requirements for prescription drug wholesale distributors; requiring

that certain persons obtain an out-of-state prescription drug wholesale distributor permit; requiring certain third party logistic providers to be licensed; requiring research and development labeling on certain prescription drug active pharmaceutical ingredient packaging; requiring certain manufacturers to create and maintain certain records; requiring certain prescription drug distributors to provide certain information to health care entities for which they repackage prescription drugs; amending s. 499.012, F.S.; providing for issuance of a prescription drug manufacturer permit or retail pharmacy drug wholesale distributor permit when an applicant at the same address is a licensed nuclear pharmacy or community pharmacy; providing for the expiration of deficient permit applications; requiring trade secret information submitted by an applicant to be maintained as a trade secret; authorizing the quadrennial renewal of permits; providing for calculation of fees for such permit renewals; revising procedures and application requirements for permit renewals; providing for late renewal fees; allowing a permittee who submits a renewal application to continue operations; removing certain application requirements for renewal of a permit; requiring bonds or other surety of a specified amount; requiring proof

of inspection of establishments used in wholesale distribution; authorizing the Department of Business and Professional Regulation to contract for the collection of electronic fingerprints under certain circumstances; providing information that may be submitted in lieu of certain application requirements for specified permits and certifications; removing provisions relating to annual renewal and expiration of permits; conforming cross-references; amending s. 499.01201, F.S.; conforming provisions; amending s. 499.0121, F.S.; revising prescription drug recordkeeping requirements; requiring inventories and records of transactions for active pharmaceutical ingredients; conforming provisions; amending s. 499.015, F.S.; removing cosmetics from registration requirements; authorizing voluntary registration of cosmetics; providing application and fee requirements for cosmetics; restricting those persons who may register a product with the department; providing for the expiration, renewal, and issuance of certain product registrations; providing for product registration fees; amending ss. 499.03, 499.05, and 499.051, F.S.; conforming provisions to changes made by the act; amending s. 499.066, F.S.; authorizing the issuance of nondisciplinary citations; authorizing the department to adopt rules designating violations for

which a citation may be issued; authorizing the department to recover investigative costs pursuant to the citation; specifying a time limitation for issuance of a citation; providing for service of a citation; amending s. 499.82, F.S.; revising the definition of "wholesale distribution" for purposes of medical gas requirements; amending s. 499.89, F.S.; conforming provisions; repealing s. 499.01212, F.S., relating to pedigree papers; amending ss. 409.9201, 794.075, and 921.0022, F.S.; conforming provisions to changes made by the act; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 499.003, Florida Statutes, is amended to read:

499.003 Definitions of terms used in this part.—As used in this part, the term:

(1) "Active pharmaceutical ingredient" includes any substance or mixture of substances intended, represented, or labeled for use in drug manufacturing that furnishes or is intended to furnish, in a finished dosage form, any pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, therapy, or prevention of disease in humans or other animals, or to affect the structure or any function of the body of humans or animals.

(2)~~(1)~~ "Advertisement" means any representation disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or which is likely to induce, directly or indirectly, the purchase of drugs, devices, or cosmetics.

(3) "Affiliate" means a business entity that has a relationship with another business entity in which, directly or indirectly:

(a) The business entity controls, or has the power to control, the other business entity; or

(b) A third party controls, or has the power to control, both business entities.

~~(2) "Affiliated group" means an affiliated group as defined by s. 1504 of the Internal Revenue Code of 1986, as amended, which is composed of chain drug entities, including at least 50 retail pharmacies, warehouses, or repackagers, which are members of the same affiliated group. The affiliated group must disclose the names of all its members to the department.~~

(4)~~(3)~~ "Affiliated party" means:

(a) A director, officer, trustee, partner, or committee member of a permittee or applicant or a subsidiary or service corporation of the permittee or applicant;

(b) A person who, directly or indirectly, manages, controls, or oversees the operation of a permittee or applicant, regardless of whether such person is a partner, shareholder, manager, member, officer, director, independent contractor, or

employee of the permittee or applicant;

(c) A person who has filed or is required to file a personal information statement pursuant to s. 499.012(9) or is required to be identified in an application for a permit or to renew a permit pursuant to s. 499.012(8); or

(d) The five largest natural shareholders that own at least 5 percent of the permittee or applicant.

(5) ~~(4)~~ "Applicant" means a person applying for a permit or certification under this part.

~~(5) "Authenticate" means to affirmatively verify upon receipt of a prescription drug that each transaction listed on the pedigree paper has occurred.~~

~~(a) A wholesale distributor is not required to open a sealed, medical convenience kit to authenticate a pedigree paper for a prescription drug contained within the kit.~~

~~(b) Authentication of a prescription drug included in a sealed, medical convenience kit shall be limited to verifying the transaction and pedigree information received.~~

(6) "Certificate of free sale" means a document prepared by the department which certifies a drug, device, or cosmetic, that is registered with the department, as one that can be legally sold in the state.

(7) "Chain pharmacy warehouse" means a ~~wholesale~~ distributor permitted pursuant to s. 499.01 that maintains a physical location for prescription drugs that functions solely as a central warehouse to perform intracompany transfers of such

drugs between members of an affiliate ~~to a member of its affiliated group~~.

(8) "Closed pharmacy" means a pharmacy that is licensed under chapter 465 and purchases prescription drugs for use by a limited patient population and not for wholesale distribution or sale to the public. The term does not include retail pharmacies.

(9) "Color" includes black, white, and intermediate grays.

(10) "Color additive" means, with the exception of any material that has been or hereafter is exempt under the federal act, a material that:

(a) Is a dye pigment, or other substance, made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity from a vegetable, animal, mineral, or other source; or

(b) When added or applied to a drug or cosmetic or to the human body, or any part thereof, is capable alone, or through reaction with other substances, of imparting color thereto.

(11) "Contraband prescription drug" means any adulterated drug, as defined in s. 499.006, any counterfeit drug, as defined in this section, and also means any prescription drug for which a transaction history, transaction information, or transaction statement ~~pedigree paper~~ does not exist, or for which the transaction history, transaction information, or transaction statement ~~pedigree paper~~ in existence has been forged, counterfeited, falsely created, or contains any altered, false,

or misrepresented matter.

(12) "Cosmetic" means an article, with the exception of soap, that is:

(a) Intended to be rubbed, poured, sprinkled, or sprayed on; introduced into; or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance; or

(b) Intended for use as a component of any such article.

(13) "Counterfeit drug," "counterfeit device," or "counterfeit cosmetic" means a drug, device, or cosmetic which, or the container, seal, or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug, device, or cosmetic manufacturer, processor, packer, or distributor other than the person that in fact manufactured, processed, packed, or distributed that drug, device, or cosmetic and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, that other drug, device, or cosmetic manufacturer, processor, packer, or distributor.

(14) "Department" means the Department of Business and Professional Regulation.

(15) "Device" means any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including its components, parts, or accessories, which is:

(a) Recognized in the current edition of the United States Pharmacopoeia and National Formulary, or any supplement thereof,

(b) Intended for use in the diagnosis, cure, mitigation, treatment, therapy, or prevention of disease in humans or other animals, or

(c) Intended to affect the structure or any function of the body of humans or other animals,

and that does not achieve any of its principal intended purposes through chemical action within or on the body of humans or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

(16) "Distribute" or "distribution" means sale, purchase, trade, delivery, handling, storage, or receipt ~~to sell; offer to sell; give away; transfer, whether by passage of title, physical movement, or both; deliver; or offer to deliver~~. The term does not mean to administer or dispense ~~and does not include the billing and invoicing activities that commonly follow a wholesale distribution transaction~~.

~~(17) "Drop shipment" means the sale of a prescription drug from a manufacturer to a wholesale distributor, where the wholesale distributor takes title to, but not possession of, the prescription drug, and the manufacturer of the prescription drug ships the prescription drug directly to a chain pharmacy warehouse or a person authorized by law to purchase prescription drugs for the purpose of administering or dispensing the drug,~~

~~as defined in s. 465.003.~~

(17)~~(18)~~ "Drug" means an article that is:

(a) Recognized in the current edition of the United States Pharmacopoeia and National Formulary, official Homeopathic Pharmacopoeia of the United States, or any supplement to any of those publications;

(b) Intended for use in the diagnosis, cure, mitigation, treatment, therapy, or prevention of disease in humans or other animals;

(c) Intended to affect the structure or any function of the body of humans or other animals; or

(d) Intended for use as a component of any article specified in paragraph (a), paragraph (b), or paragraph (c), and includes active pharmaceutical ingredients, but does not include devices or their nondrug components, parts, or accessories. ~~For purposes of this paragraph, an "active pharmaceutical ingredient" includes any substance or mixture of substances intended, represented, or labeled for use in drug manufacturing that furnishes or is intended to furnish, in a finished dosage form, any pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, therapy, or prevention of disease in humans or other animals, or to affect the structure or any function of the body of humans or other animals.~~

(18)~~(19)~~ "Establishment" means a place of business which is at one general physical location and may extend to one or

more contiguous suites, units, floors, or buildings operated and controlled exclusively by entities under common operation and control. Where multiple buildings are under common exclusive ownership, operation, and control, an intervening thoroughfare does not affect the contiguous nature of the buildings. For purposes of permitting, each suite, unit, floor, or building must be identified in the most recent permit application.

(19) ~~(20)~~ "Federal act" means the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. ss. 301 et seq.; 52 Stat. 1040 et seq.

(20) ~~(21)~~ "Freight forwarder" means a person who receives prescription drugs which are owned by another person and designated by that person for export, and exports those prescription drugs.

(21) ~~(22)~~ "Health care entity" means a closed pharmacy or any person, organization, or business entity that provides diagnostic, medical, surgical, or dental treatment or care, or chronic or rehabilitative care, but does not include any wholesale distributor or retail pharmacy licensed under state law to deal in prescription drugs. However, a blood establishment is a health care entity that may engage in the wholesale distribution of prescription drugs under s. 499.01(2)(h)1.c. ~~499.01(2)(g)1.c.~~

(22) ~~(23)~~ "Health care facility" means a health care facility licensed under chapter 395.

(23) ~~(24)~~ "Hospice" means a corporation licensed under part IV of chapter 400.

(24)~~(25)~~ "Hospital" means a facility as defined in s. 395.002 and licensed under chapter 395.

(25)~~(26)~~ "Immediate container" does not include package liners.

(26)~~(27)~~ "Label" means a display of written, printed, or graphic matter upon the immediate container of any drug, device, or cosmetic. A requirement made by or under authority of this part or rules adopted under this part that any word, statement, or other information appear on the label is not complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any, of the retail package of such drug, device, or cosmetic or is easily legible through the outside container or wrapper.

(27)~~(28)~~ "Labeling" means all labels and other written, printed, or graphic matters:

(a) Upon a drug, device, or cosmetic, or any of its containers or wrappers; or

(b) Accompanying or related to such drug, device, or cosmetic.

(28)~~(29)~~ "Manufacture" means the preparation, deriving, compounding, propagation, processing, producing, or fabrication of any drug, device, or cosmetic.

(29)~~(30)~~ "Manufacturer" means:

(a) A person who holds a New Drug Application, an Abbreviated New Drug Application, a Biologics License Application, or a New Animal Drug Application approved under the

federal act or a license issued under s. 351 of the Public Health Service Act, 42 U.S.C. s. 262, for such drug or biologics, or if such drug or biologics is not the subject of an approved application or license, the person who manufactured the drug or biologics ~~prepares, derives, manufactures, or produces a drug, device, or cosmetic~~;

(b) A co-licensed partner of the person described in paragraph (a) who obtains the drug or biologics directly from a person described in paragraph (a), paragraph (c), or this paragraph ~~The holder or holders of a New Drug Application (NDA), an Abbreviated New Drug Application (ANDA), a Biologics License Application (BLA), or a New Animal Drug Application (NADA), provided such application has become effective or is otherwise approved consistent with s. 499.023~~;

(c) An affiliate of a person described in paragraph (a), paragraph (b), or this paragraph that receives the drug or biologics directly from a person described in paragraph (a), paragraph (b), or this paragraph ~~A private label distributor for whom the private label distributor's prescription drugs are originally manufactured and labeled for the distributor and have not been repackaged~~; or

(d) A person that manufactures a device or a cosmetic. ~~A person registered under the federal act as a manufacturer of a prescription drug, who is described in paragraph (a), paragraph (b), or paragraph (c), who has entered into a written agreement with another prescription drug manufacturer that authorizes~~

~~either manufacturer to distribute the prescription drug identified in the agreement as the manufacturer of that drug consistent with the federal act and its implementing regulations;~~

~~(e) A member of an affiliated group that includes, but is not limited to, persons described in paragraph (a), paragraph (b), paragraph (c), or paragraph (d), which member distributes prescription drugs, whether or not obtaining title to the drugs, only for the manufacturer of the drugs who is also a member of the affiliated group. As used in this paragraph, the term "affiliated group" means an affiliated group as defined in s. 1504 of the Internal Revenue Code of 1986, as amended. The manufacturer must disclose the names of all of its affiliated group members to the department; or~~

~~(f) A person permitted as a third-party logistics provider, only while providing warehousing, distribution, or other logistics services on behalf of a person described in paragraph (a), paragraph (b), paragraph (c), paragraph (d), or paragraph (e).~~

The term does not include a pharmacy that is operating in compliance with pharmacy practice standards as defined in chapter 465 and rules adopted under that chapter.

(30)~~(31)~~ "Medical convenience kit" means packages or units that contain combination products as defined in 21 C.F.R. s. 3.2(e)(2).

(31) ~~(32)~~ "Medical gas" means any liquefied or vaporized gas that is a prescription drug, whether alone or in combination with other gases, and as defined in the federal act.

(32) ~~(33)~~ "New drug" means:

(a) Any drug the composition of which is such that the drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling of that drug; or

(b) Any drug the composition of which is such that the drug, as a result of investigations to determine its safety and effectiveness for use under certain conditions, has been recognized for use under such conditions, but which drug has not, other than in those investigations, been used to a material extent or for a material time under such conditions.

~~(34) "Normal distribution chain" means a wholesale distribution of a prescription drug in which the wholesale distributor or its wholly owned subsidiary purchases and receives the specific unit of the prescription drug directly from the manufacturer and distributes the prescription drug directly, or through up to two intracompany transfers, to a chain pharmacy warehouse or a person authorized by law to purchase prescription drugs for the purpose of administering or dispensing the drug, as defined in s. 465.003. For purposes of this subsection, the term "intracompany" means any transaction~~

~~or transfer between any parent, division, or subsidiary wholly owned by a corporate entity.~~

(33)~~(35)~~ "Nursing home" means a facility licensed under part II of chapter 400.

(34)~~(36)~~ "Official compendium" means the current edition of the official United States Pharmacopoeia and National Formulary, or any supplement thereto.

~~(37) "Pedigree paper" means a document in written or electronic form approved by the department which contains information required by s. 499.01212 regarding the sale and distribution of any given prescription drug.~~

(35)~~(38)~~ "Permittee" means any person holding a permit issued under this chapter ~~pursuant to s. 499.012~~.

(36)~~(39)~~ "Person" means any individual, child, joint venture, syndicate, fiduciary, partnership, corporation, division of a corporation, firm, trust, business trust, company, estate, public or private institution, association, organization, group, city, county, city and county, political subdivision of this state, other governmental agency within this state, and any representative, agent, or agency of any of the foregoing, or any other group or combination of the foregoing.

(37)~~(40)~~ "Pharmacist" means a person licensed under chapter 465.

(38)~~(41)~~ "Pharmacy" means an entity licensed under chapter 465.

(39)~~(42)~~ "Prepackaged drug product" means a drug that

originally was in finished packaged form sealed by a manufacturer and that is placed in a properly labeled container by a pharmacy or practitioner authorized to dispense pursuant to chapter 465 for the purpose of dispensing in the establishment in which the prepackaging occurred.

(40) ~~(43)~~ "Prescription drug" means a prescription, medicinal, or legend drug, including, but not limited to, finished dosage forms or active pharmaceutical ingredients subject to, defined by, or described by s. 503(b) of the federal act or s. 465.003(8), s. 499.007(13), subsection (31) ~~(32)~~, or subsection (47) ~~(52)~~, except that an active pharmaceutical ingredient is a prescription drug only if substantially all finished dosage forms in which it may be lawfully dispensed or administered in this state are also prescription drugs.

(41) ~~(44)~~ "Prescription drug label" means any display of written, printed, or graphic matter upon the immediate container of any prescription drug before it is dispensed ~~prior to its dispensing~~ to an individual patient pursuant to a prescription of a practitioner authorized by law to prescribe.

(42) ~~(45)~~ "Prescription label" means any display of written, printed, or graphic matter upon the immediate container of any prescription drug dispensed pursuant to a prescription of a practitioner authorized by law to prescribe.

~~(46) "Primary wholesale distributor" means any wholesale distributor that:~~

~~(a) Purchased 90 percent or more of the total dollar~~

~~volume of its purchases of prescription drugs directly from manufacturers in the previous year; and~~

~~(b)1. Directly purchased prescription drugs from not fewer than 50 different prescription drug manufacturers in the previous year; or~~

~~2. Has, or the affiliated group, as defined in s. 1504 of the Internal Revenue Code, of which the wholesale distributor is a member has, not fewer than 250 employees.~~

~~(c) For purposes of this subsection, "directly from manufacturers" means:~~

~~1. Purchases made by the wholesale distributor directly from the manufacturer of prescription drugs; and~~

~~2. Transfers from a member of an affiliated group, as defined in s. 1504 of the Internal Revenue Code, of which the wholesale distributor is a member, if:~~

~~a. The affiliated group purchases 90 percent or more of the total dollar volume of its purchases of prescription drugs from the manufacturer in the previous year; and~~

~~b. The wholesale distributor discloses to the department the names of all members of the affiliated group of which the wholesale distributor is a member and the affiliated group agrees in writing to provide records on prescription drug purchases by the members of the affiliated group not later than 48 hours after the department requests access to such records, regardless of the location where the records are stored.~~

(43) ~~(47)~~ "Proprietary drug," or "OTC drug," means a patent

or over-the-counter drug in its unbroken, original package, which drug is sold to the public by, or under the authority of, the manufacturer or primary distributor thereof, is not misbranded under the provisions of this part, and can be purchased without a prescription.

(44) ~~(48)~~ "Repackage" includes repacking or otherwise changing the container, wrapper, or labeling to further the distribution of the drug, device, or cosmetic.

(45) ~~(49)~~ "Repackager" means a person who repackages. The term excludes pharmacies that are operating in compliance with pharmacy practice standards as defined in chapter 465 and rules adopted under that chapter.

(46) ~~(50)~~ "Retail pharmacy" means a community pharmacy licensed under chapter 465 that purchases prescription drugs at fair market prices and provides prescription services to the public.

~~(51) "Secondary wholesale distributor" means a wholesale distributor that is not a primary wholesale distributor.~~

(47) ~~(52)~~ "Veterinary prescription drug" means a prescription drug intended solely for veterinary use. The label of the drug must bear the statement, "Caution: Federal law restricts this drug to sale by or on the order of a licensed veterinarian."

(48) ~~(53)~~ "Wholesale distribution" means the distribution of a prescription drug to a person ~~drugs to persons~~ other than a consumer or patient, or the receipt of a prescription drug by a

person other than the consumer or patient, but does not include:

(a) Any of the following activities, which is not a violation of s. 499.005(21) if such activity is conducted in accordance with s. 499.01(2)(h) ~~499.01(2)(g)~~:

1. The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a prescription drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of that organization.

2. The distribution ~~sale, purchase, or trade~~ of a prescription drug or an offer to distribute ~~sell, purchase, or trade~~ a prescription drug by a charitable organization described in s. 501(c)(3) of the Internal Revenue Code of 1986, as amended and revised, to a nonprofit affiliate of the organization to the extent otherwise permitted by law.

3. The distribution ~~sale, purchase, or trade~~ of a prescription drug ~~or an offer to sell, purchase, or trade a prescription drug~~ among hospitals or other health care entities that are under common control. For purposes of this subparagraph, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, by voting rights, by contract, or otherwise.

4. The distribution ~~sale, purchase, trade, or other transfer~~ of a prescription drug from or for any federal, state, or local government agency or any entity eligible to purchase

prescription drugs at public health services prices pursuant to Pub. L. No. 102-585, s. 602 to a contract provider or its subcontractor for eligible patients of the agency or entity under the following conditions:

a. The agency or entity must obtain written authorization for the distribution ~~sale, purchase, trade, or other transfer~~ of a prescription drug under this subparagraph from the Secretary of Business and Professional Regulation or his or her designee.

b. The contract provider or subcontractor must be authorized by law to administer or dispense prescription drugs.

c. In the case of a subcontractor, the agency or entity must be a party to and execute the subcontract.

d. The contract provider and subcontractor must maintain and produce immediately for inspection all records of movement or transfer of all the prescription drugs belonging to the agency or entity, including, but not limited to, the records of receipt and disposition of prescription drugs. Each contractor and subcontractor dispensing or administering these drugs must maintain and produce records documenting the dispensing or administration. Records that are required to be maintained include, but are not limited to, a perpetual inventory itemizing drugs received and drugs dispensed by prescription number or administered by patient identifier, which must be submitted to the agency or entity quarterly.

e. The contract provider or subcontractor may administer or dispense the prescription drugs only to the eligible patients

of the agency or entity or must return the prescription drugs for or to the agency or entity. The contract provider or subcontractor must require proof from each person seeking to fill a prescription or obtain treatment that the person is an eligible patient of the agency or entity and must, at a minimum, maintain a copy of this proof as part of the records of the contractor or subcontractor required under sub-subparagraph d.

f. In addition to the departmental inspection authority set forth in s. 499.051, the establishment of the contract provider and subcontractor and all records pertaining to prescription drugs subject to this subparagraph shall be subject to inspection by the agency or entity. All records relating to prescription drugs of a manufacturer under this subparagraph shall be subject to audit by the manufacturer of those drugs, without identifying individual patient information.

(b) Any of the following activities, which is not a violation of s. 499.005(21) if such activity is conducted in accordance with rules established by the department:

1. The distribution ~~sale, purchase, or trade~~ of a prescription drug among federal, state, or local government health care entities that are under common control and are authorized to purchase such prescription drug.

2. The distribution ~~sale, purchase, or trade~~ of a prescription drug or ~~an~~ offer to distribute ~~sell, purchase, or trade~~ a prescription drug for emergency medical reasons, which may include~~. For purposes of this subparagraph, The term~~

~~"emergency medical reasons" includes~~ transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage. For purposes of this subparagraph, a drug shortage not caused by a public health emergency does not constitute an emergency medical reason.

3. The distribution ~~transfer~~ of a prescription drug acquired by a medical director on behalf of a licensed emergency medical services provider to that emergency medical services provider and its transport vehicles for use in accordance with the provider's license under chapter 401.

~~4. The revocation of a sale or the return of a prescription drug to the person's prescription drug wholesale supplier.~~

4.~~5.~~ The donation of a prescription drug by a health care entity to a charitable organization that has been granted an exemption under s. 501(c)(3) of the Internal Revenue Code of 1986, as amended, and that is authorized to possess prescription drugs.

5.~~6.~~ The distribution ~~transfer~~ of a prescription drug by a person authorized to purchase or receive prescription drugs to a person licensed or permitted to handle reverse distributions or destruction under the laws of the jurisdiction in which the person handling the reverse distribution or destruction receives the drug.

6.~~7.~~ The distribution ~~transfer~~ of a prescription drug by a hospital or other health care entity to a person licensed under

this part to repackage prescription drugs for the purpose of repackaging the prescription drug for use by that hospital, or other health care entity and other health care entities that are under common control, if ownership of the prescription drugs remains with the hospital or other health care entity at all times. In addition to the recordkeeping requirements of s. 499.0121(6), the hospital or health care entity that distributes ~~transfers~~ prescription drugs pursuant to this subparagraph must reconcile all drugs distributed ~~transferred~~ and returned and resolve any discrepancies in a timely manner.

(c) Intracompany distribution of any drug between members of an affiliate or within a manufacturer.

(d) The distribution of a prescription drug by the manufacturer of the prescription drug.

(e) ~~(c)~~ The distribution of prescription drug samples by manufacturers' representatives or distributors' representatives conducted in accordance with s. 499.028.

(f) The distribution of a prescription drug by a third-party logistics provider permitted or licensed pursuant to and operating in compliance with the laws of this state and federal law if such third-party logistics provider does not take ownership of the prescription drug.

(g) The distribution of a prescription drug, or an offer to distribute a prescription drug by a repackager registered as a drug establishment with the United States Food and Drug Administration that has taken ownership or possession of the

prescription drug and repacks it in accordance with this part.

(h) The purchase or other acquisition by a dispenser, hospital, or other health care entity of a prescription drug for use by such dispenser, hospital, or other health care entity.

(i) The distribution of a prescription drug by a hospital or other health care entity, or by a wholesale distributor or manufacturer operating at the direction of the hospital or other health care entity, to a repackager for the purpose of repackaging the prescription drug for use by that hospital, or other health care entity and other health care entities that are under common control, if ownership of the prescription drug remains with the hospital or other health care entity at all times.

(j) ~~(d)~~ The distribution ~~sale, purchase, or trade~~ of blood and blood components intended for transfusion. As used in this paragraph, the term "blood" means whole blood collected from a single donor and processed for transfusion or further manufacturing, and the term "blood components" means that part of the blood separated by physical or mechanical means.

(k) ~~(e)~~ The lawful dispensing of a prescription drug in accordance with chapter 465.

(l) ~~(f)~~ The distribution ~~sale, purchase, or trade~~ of a prescription drug between pharmacies as a result of a sale, transfer, merger, or consolidation of all or part of the business of the pharmacies from or with another pharmacy, whether accomplished as a purchase and sale of stock or of

business assets.

(m) The distribution of minimal quantities of prescription drugs by a licensed retail pharmacy to a licensed practitioner for office use in compliance with chapter 465 and rules adopted thereunder.

(n) The distribution of an intravenous prescription drug that, by its formulation, is intended for the replenishment of fluids and electrolytes, such as sodium, chloride, and potassium or calories, such as dextrose and amino acids.

(o) The distribution of an intravenous prescription drug used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions.

(p) The distribution of a prescription drug that is intended for irrigation or sterile water, whether intended for such purposes or for injection.

(q) The distribution of an exempt medical convenience kit pursuant to 21 U.S.C. s. 353(e)(4)(M).

(r) A common carrier that transports a prescription drug, if the common carrier does not take ownership of the prescription drug.

(s) Saleable drug returns when conducted by a dispenser.

(t) Facilitating the distribution of a prescription drug by providing solely administrative services, including processing of orders and payments.

(u) The distribution by a charitable organization described in s. 501(c)(3) of the Internal Revenue Code of

prescription drugs donated to or supplied at a reduced price to the charitable organization to:

1. A licensed health care practitioner, as defined in s. 456.001, who is authorized under the appropriate practice act to prescribe and administer prescription drugs;

2. A health care clinic establishment permitted pursuant to chapter 499; or

3. The Department of Health or the licensed medical director of a government agency health care entity, authorized to possess prescription drugs, for storage and use in the treatment of persons in need of emergency medical services, including controlling communicable diseases or providing protection from unsafe conditions that pose an imminent threat to public health,

if the distributor and the receiving entity receive no direct or indirect financial benefit other than tax benefits related to charitable contributions. Distributions under this section that involve controlled substances must comply with all state and federal regulations pertaining to the handling of controlled substances.

(v) The distribution of medical gas pursuant to part III of this chapter.

(49) ~~(54)~~ "Wholesale distributor" means a ~~any~~ person, other than a manufacturer, a manufacturer's co-licensed partner, a third-party logistics provider, or a repackager, who is engaged

in wholesale distribution ~~of prescription drugs in or into this state, including, but not limited to, manufacturers; repackagers; own-label distributors; jobbers; private-label distributors; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; exporters; retail pharmacies; and the agents thereof that conduct wholesale distributions~~.

Section 2. Subsections (21), (28), and (29) of section 499.005, Florida Statutes, are amended to read:

499.005 Prohibited acts.—It is unlawful for a person to perform or cause the performance of any of the following acts in this state:

(21) The wholesale distribution of any prescription drug that was:

(a) Purchased by a public or private hospital or other health care entity; or

(b) Donated or supplied at a reduced price to a charitable organization,

unless the wholesale distribution of the prescription drug is authorized in s. 499.01(2)(h)1.c. ~~499.01(2)(g)1.c.~~

(28) Failure to acquire or deliver a transaction history, transaction information, or transaction statement ~~pedigree paper~~ as required under this part and rules adopted under this part.

~~(29) The receipt of a prescription drug pursuant to a~~

~~wholesale distribution without having previously received or simultaneously receiving a pedigree paper that was attested to as accurate and complete by the wholesale distributor as required under this part.~~

Section 3. Subsections (4) through (17) of section 499.0051, Florida Statutes, are renumbered as subsections (3) through (16), respectively, and subsections (1) and (2), present subsection (3), paragraphs (h) and (i) of present subsection (12), and paragraph (d) of present subsection (13) of that section are amended, to read:

499.0051 Criminal acts.—

(1) FAILURE TO MAINTAIN OR DELIVER TRANSACTION HISTORY, TRANSACTION INFORMATION, OR TRANSACTION STATEMENT ~~PEDIGREE PAPERS~~.—

(a) A person~~, other than a manufacturer,~~ engaged in the ~~wholesale~~ distribution of prescription drugs who fails to deliver to another person a complete and accurate transaction history, transaction information, or transaction statement ~~pedigree papers~~ concerning a prescription drug or contraband prescription drug, as required by this chapter and rules adopted under this chapter, before ~~prior to~~, or simultaneous with, the transfer of the prescription drug or contraband prescription drug to another person commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(b) A person engaged in the ~~wholesale~~ distribution of prescription drugs who fails to acquire a complete and accurate

transaction history, transaction information, or transaction statement ~~pedigree papers~~ concerning a prescription drug or contraband prescription drug, as required by this chapter and rules adopted under this chapter, before ~~prior to~~, or simultaneous with, the receipt of the prescription drug or contraband prescription drug from another person commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(c) Any person who knowingly destroys, alters, conceals, or fails to maintain a complete and accurate transaction history, transaction information, or transaction statement ~~pedigree papers~~ concerning any prescription drug or contraband prescription drug, as required by this chapter and rules adopted under this chapter, in his or her possession commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

~~(2) FAILURE TO AUTHENTICATE PEDIGREE PAPERS.—Effective July 1, 2006:~~

~~(a) A person engaged in the wholesale distribution of prescription drugs who is in possession of pedigree papers concerning prescription drugs or contraband prescription drugs and who fails to authenticate the matters contained in the pedigree papers and who nevertheless attempts to further distribute prescription drugs or contraband prescription drugs commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.~~

~~(b) A person in possession of pedigree papers concerning prescription drugs or contraband prescription drugs who falsely swears or certifies that he or she has authenticated the matters contained in the pedigree papers commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.~~

(2)~~(3)~~ KNOWING FORGERY OF TRANSACTION HISTORY, TRANSACTION INFORMATION, OR TRANSACTION STATEMENT ~~PEDIGREE PAPERS~~.—A person who knowingly forges, counterfeits, or falsely creates any transaction history, transaction information, or transaction statement ~~pedigree paper~~; who falsely represents any factual matter contained on any transaction history, transaction information, or transaction statement ~~pedigree paper~~; or who knowingly omits to record material information required to be recorded in a transaction history, transaction information, or transaction statement ~~pedigree paper~~, commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(11)~~(12)~~ ADULTERATED AND MISBRANDED DRUGS; FALSE ADVERTISEMENT; FAILURE TO MAINTAIN RECORDS RELATING TO DRUGS.—Any person who violates any of the following provisions commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083; but, if the violation is committed after a conviction of such person under this subsection has become final, such person commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083, or as

otherwise provided in this part:

(h) The failure to maintain records related to a drug as required by this part and rules adopted under this part, except for transaction histories, transaction information, or transaction statements ~~pedigree papers~~, invoices, or shipping documents related to prescription drugs.

(i) The possession of any drug in violation of this part, except if the violation relates to a deficiency in transaction histories, transaction information, or transaction statements ~~pedigree papers~~.

(12) ~~(13)~~ REFUSAL TO ALLOW INSPECTION; SELLING, PURCHASING, OR TRADING DRUG SAMPLES; FAILURE TO MAINTAIN RECORDS RELATING TO PRESCRIPTION DRUGS.—Any person who violates any of the following provisions commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, or as otherwise provided in this part:

(d) The failure to receive, maintain, or provide invoices and shipping documents~~, other than pedigree papers,~~ if applicable, related to the distribution of a prescription drug.

Section 4. Subsection (10) of section 499.006, Florida Statutes, is amended to read:

499.006 Adulterated drug or device.—A drug or device is adulterated:

(10) If it is a prescription drug for which the required transaction history, transaction information, or transaction statement ~~pedigree paper~~ is nonexistent, fraudulent, or

incomplete under the requirements of this part or applicable rules, or that has been purchased, held, sold, or distributed at any time by a person not authorized under federal or state law to do so; or

Section 5. Section 499.01, Florida Statutes, is amended to read:

499.01 Permits.—

(1) Before ~~Prior to~~ operating, a permit is required for each person and establishment that intends to operate as:

(a) A prescription drug manufacturer;

(b) A prescription drug repackager;

(c) A nonresident prescription drug manufacturer;

(d) A nonresident prescription drug repackager;

(e) ~~(d)~~ A prescription drug wholesale distributor;

(f) ~~(e)~~ An out-of-state prescription drug wholesale distributor;

(g) ~~(f)~~ A retail pharmacy drug wholesale distributor;

(h) ~~(g)~~ A restricted prescription drug distributor;

(i) ~~(h)~~ A complimentary drug distributor;

(j) ~~(i)~~ A freight forwarder;

(k) ~~(j)~~ A veterinary prescription drug retail establishment;

(l) ~~(k)~~ A veterinary prescription drug wholesale distributor;

(m) ~~(l)~~ A limited prescription drug veterinary wholesale distributor;

(n) ~~(m)~~ An over-the-counter drug manufacturer;

(o) ~~(n)~~ A device manufacturer;

(p) ~~(o)~~ A cosmetic manufacturer;

(q) ~~(p)~~ A third party logistics provider; or

(r) ~~(q)~~ A health care clinic establishment.

(2) The following permits are established:

(a) Prescription drug manufacturer permit.—A prescription drug manufacturer permit is required for any person that is a manufacturer of a prescription drug and that manufactures or distributes such prescription drugs in this state.

1. A person that operates an establishment permitted as a prescription drug manufacturer may engage in wholesale distribution of prescription drugs for which the person is the manufacturer ~~manufactured at that establishment~~ and must comply with s. 499.0121 and all other ~~of the~~ provisions of this part~~,~~ ~~except s. 499.01212,~~ and ~~the~~ rules adopted under this part~~,~~ ~~except s. 499.01212, which apply to a wholesale distributor~~. The department shall adopt rules for issuing a virtual prescription drug manufacturer permit to a person who engages in the manufacture of prescription drugs but does not make or take physical possession of any prescription drugs. The rules adopted by the department under this section may exempt virtual manufacturers from certain establishment, security, and storage requirements set forth in s. 499.0121.

2. A prescription drug manufacturer must comply with all appropriate state and federal good manufacturing practices.

3. A blood establishment, as defined in s. 381.06014, operating in a manner consistent with the provisions of 21 C.F.R. parts 211 and 600-640, and manufacturing only the prescription drugs described in s. 499.003(48)(j) ~~499.003(53)(d)~~ is not required to be permitted as a prescription drug manufacturer under this paragraph or to register products under s. 499.015.

(b) Prescription drug repackager permit.—A prescription drug repackager permit is required for any person that repackages a prescription drug in this state.

1. A person that operates an establishment permitted as a prescription drug repackager may engage in ~~wholesale~~ distribution of prescription drugs repackaged at that establishment and must comply with all of the provisions of this part and the rules adopted under this part that apply to a prescription drug manufacturer ~~wholesale distributor~~.

2. A prescription drug repackager must comply with all appropriate state and federal good manufacturing practices.

(c) Nonresident prescription drug manufacturer permit.—A nonresident prescription drug manufacturer permit is required for any person that is a manufacturer of prescription drugs, unless permitted as a third party logistics provider, located outside of this state or outside the United States and that engages in the ~~wholesale~~ distribution in this state of such prescription drugs. Each such manufacturer must be permitted by the department and comply with all of the provisions required of

a prescription drug manufacturer ~~wholesale distributor~~ under this part~~, except s. 499.01212~~. The department shall adopt rules for issuing a virtual nonresident prescription drug manufacturer permit to a person who engages in the manufacture of prescription drugs but does not make or take physical possession of any prescription drugs. The rules adopted by the department under this section may exempt virtual nonresident manufacturers from certain establishment, security, and storage requirements set forth in s. 499.0121.

1. A person that distributes prescription drugs for which the person is not the manufacturer must also obtain an out-of-state prescription drug wholesale distributor permit or third party logistics provider permit pursuant to this section to engage in the ~~wholesale~~ distribution of such prescription drugs when required by this part. This subparagraph does not apply to a manufacturer that distributes prescription drugs only for the manufacturer of the prescription drugs where both manufacturers are affiliates ~~as defined in s. 499.003(30)(c)~~.

2. Any such person must comply with the licensing or permitting requirements of the jurisdiction in which the establishment is located and the federal act, and any prescription drug distributed ~~product wholesaled~~ into this state must comply with this part. If a person intends to import prescription drugs from a foreign country into this state, the nonresident prescription drug manufacturer must provide to the department a list identifying each prescription drug it intends

to import and document approval by the United States Food and Drug Administration for such importation.

(d) Nonresident prescription drug repackager permit.—A nonresident prescription drug repackager permit is required for any person located outside of this state, but within the United States or its territories, that repackages prescription drugs and engages in the distribution of such prescription drugs into this state.

1. A nonresident prescription drug repackager must comply with all of the provisions of this section and the rules adopted under this section that apply to a prescription drug manufacturer.

2. A nonresident prescription drug repackager must be permitted by the department and comply with all appropriate state and federal good manufacturing practices.

3. A nonresident prescription drug repackager must be registered as a drug establishment with the United States Food and Drug Administration.

(e) ~~(d)~~ Prescription drug wholesale distributor permit.—A prescription drug wholesale distributor permit is required for any person who is a wholesale distributor of prescription drugs and that ~~may engage in the~~ wholesale distributes such ~~distribution of~~ prescription drugs in this state. ~~A prescription drug wholesale distributor that applies to the department for a new permit or the renewal of a permit must submit a bond of $100,000, or other equivalent means of security acceptable to~~

~~the department, such as an irrevocable letter of credit or a deposit in a trust account or financial institution, payable to the Professional Regulation Trust Fund. The purpose of the bond is to secure payment of any administrative penalties imposed by the department and any fees and costs incurred by the department regarding that permit which are authorized under state law and which the permittee fails to pay 30 days after the fine or costs become final. The department may make a claim against such bond or security until 1 year after the permittee's license ceases to be valid or until 60 days after any administrative or legal proceeding authorized in this part which involves the permittee is concluded, including any appeal, whichever occurs later.~~ The department may adopt rules for issuing a prescription drug wholesale distributor-broker permit to a person who engages in the wholesale distribution of prescription drugs and does not take physical possession of any prescription drugs.

(f) ~~(e)~~ Out-of-state prescription drug wholesale distributor permit.—An out-of-state prescription drug wholesale distributor permit is required for any person that is a wholesale distributor located outside this state, but within the United States or its territories, which engages in the wholesale distribution of prescription drugs into this state ~~and which must be permitted by the department and comply with all the provisions required of a wholesale distributor under this part~~. ~~An out-of-state prescription drug wholesale distributor that applies to the department for a new permit or the renewal of a~~

~~permit must submit a bond of $100,000, or other equivalent means of security acceptable to the department, such as an irrevocable letter of credit or a deposit in a trust account or financial institution, payable to the Professional Regulation Trust Fund. The purpose of the bond is to secure payment of any administrative penalties imposed by the department and any fees and costs incurred by the department regarding that permit which are authorized under state law and which the permittee fails to pay 30 days after the fine or costs become final. The department may make a claim against such bond or security until 1 year after the permittee's license ceases to be valid or until 60 days after any administrative or legal proceeding authorized in this part which involves the permittee is concluded, including any appeal, whichever occurs later.~~ The out-of-state prescription drug wholesale distributor must maintain at all times a license or permit to engage in the wholesale distribution of prescription drugs in compliance with laws of the state in which it is a resident. If the state from which the wholesale distributor distributes prescription drugs does not require a license to engage in the wholesale distribution of prescription drugs, the distributor must be licensed as a wholesale distributor as required by the federal act.

(g) ~~(f)~~ Retail pharmacy drug wholesale distributor permit.—A retail pharmacy drug wholesale distributor is a retail pharmacy engaged in wholesale distribution of prescription drugs within this state under the following conditions:

1. The pharmacy must obtain a retail pharmacy drug wholesale distributor permit pursuant to this part and ~~the~~ rules adopted under this part.

2. The wholesale distribution activity does not exceed 30 percent of the total annual purchases of prescription drugs. If the wholesale distribution activity exceeds the 30-percent maximum, the pharmacy must obtain a prescription drug wholesale distributor permit.

3. The transfer of prescription drugs that appear in any schedule contained in chapter 893 is subject to chapter 893 and the federal Comprehensive Drug Abuse Prevention and Control Act of 1970.

4. The transfer is between a retail pharmacy and another retail pharmacy, or a Modified Class II institutional pharmacy, or a health care practitioner licensed in this state and authorized by law to dispense or prescribe prescription drugs.

5. All records of sales of prescription drugs subject to this section must be maintained separate and distinct from other records and comply with the recordkeeping requirements of this part.

(h) ~~(g)~~ Restricted prescription drug distributor permit.—

1. A restricted prescription drug distributor permit is required for:

a. Any person located in this state who engages in the distribution of a prescription drug, which distribution is not considered "wholesale distribution" under s. 499.003(48)(a)

~~499.003(53)(a)~~.

b. Any person located in this state who engages in the receipt or distribution of a prescription drug in this state for the purpose of processing its return or its destruction if such person is not the person initiating the return, the prescription drug wholesale supplier of the person initiating the return, or the manufacturer of the drug.

c. A blood establishment located in this state which collects blood and blood components only from volunteer donors as defined in s. 381.06014 or pursuant to an authorized practitioner's order for medical treatment or therapy and engages in the wholesale distribution of a prescription drug not described in s. 499.003(48)(j) ~~499.003(53)(d)~~ to a health care entity. A mobile blood unit operated by a blood establishment permitted under this sub-subparagraph is not required to be separately permitted. The health care entity receiving a prescription drug distributed under this sub-subparagraph must be licensed as a closed pharmacy or provide health care services at that establishment. The blood establishment must operate in accordance with s. 381.06014 and may distribute only:

(I) Prescription drugs indicated for a bleeding or clotting disorder or anemia;

(II) Blood-collection containers approved under s. 505 of the federal act;

(III) Drugs that are blood derivatives, or a recombinant or synthetic form of a blood derivative;

(IV) Prescription drugs that are identified in rules adopted by the department and that are essential to services performed or provided by blood establishments and authorized for distribution by blood establishments under federal law; or

(V) To the extent authorized by federal law, drugs necessary to collect blood or blood components from volunteer blood donors; for blood establishment personnel to perform therapeutic procedures under the direction and supervision of a licensed physician; and to diagnose, treat, manage, and prevent any reaction of a volunteer blood donor or a patient undergoing a therapeutic procedure performed under the direction and supervision of a licensed physician,

as long as all of the health care services provided by the blood establishment are related to its activities as a registered blood establishment or the health care services consist of collecting, processing, storing, or administering human hematopoietic stem cells or progenitor cells or performing diagnostic testing of specimens if such specimens are tested together with specimens undergoing routine donor testing. The blood establishment may purchase and possess the drugs described in this sub-subparagraph without a health care clinic establishment permit.

2. Storage, handling, and recordkeeping of these distributions by a person required to be permitted as a restricted prescription drug distributor must be in accordance

with the requirements for wholesale distributors under s. 499.0121~~, but not those set forth in s. 499.01212 if the distribution occurs pursuant to sub-subparagraph 1.a. or sub-subparagraph 1.b~~.

3. A person who applies for a permit as a restricted prescription drug distributor, or for the renewal of such a permit, must provide to the department the information required under s. 499.012.

4. The department may adopt rules regarding the distribution of prescription drugs by hospitals, health care entities, charitable organizations, other persons not involved in wholesale distribution, and blood establishments, which rules are necessary for the protection of the public health, safety, and welfare.

(i)~~(h)~~ Complimentary drug distributor permit.—A complimentary drug distributor permit is required for any person that engages in the distribution of a complimentary drug, subject to the requirements of s. 499.028.

(j)~~(i)~~ Freight forwarder permit.—A freight forwarder permit is required for any person that engages in the distribution of a prescription drug as a freight forwarder unless the person is a common carrier. The storage, handling, and recordkeeping of such distributions must comply with the requirements for wholesale distributors under s. 499.0121~~, but not those set forth in s. 499.01212~~. A freight forwarder must provide the source of the prescription drugs with a validated

airway bill, bill of lading, or other appropriate documentation to evidence the exportation of the product.

(k) ~~(j)~~ Veterinary prescription drug retail establishment permit.—A veterinary prescription drug retail establishment permit is required for any person that sells veterinary prescription drugs to the public but does not include a pharmacy licensed under chapter 465.

1. The sale to the public must be based on a valid written order from a veterinarian licensed in this state who has a valid client-veterinarian relationship with the purchaser's animal.

2. Veterinary prescription drugs may not be sold in excess of the amount clearly indicated on the order or beyond the date indicated on the order.

3. An order may not be valid for more than 1 year.

4. A veterinary prescription drug retail establishment may not purchase, sell, trade, or possess human prescription drugs or any controlled substance as defined in chapter 893.

5. A veterinary prescription drug retail establishment must sell a veterinary prescription drug in the original, sealed manufacturer's container with all labeling intact and legible. The department may adopt by rule additional labeling requirements for the sale of a veterinary prescription drug.

6. A veterinary prescription drug retail establishment must comply with all of the wholesale distribution requirements of s. 499.0121.

7. Prescription drugs sold by a veterinary prescription

drug retail establishment pursuant to a practitioner's order may not be returned into the retail establishment's inventory.

(l) ~~(k)~~ Veterinary prescription drug wholesale distributor permit.—A veterinary prescription drug wholesale distributor permit is required for any person that engages in the distribution of veterinary prescription drugs in or into this state. A veterinary prescription drug wholesale distributor that also distributes prescription drugs subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act which it did not manufacture must obtain a permit as a prescription drug wholesale distributor, an out-of-state prescription drug wholesale distributor, or a limited prescription drug veterinary wholesale distributor in lieu of the veterinary prescription drug wholesale distributor permit. A veterinary prescription drug wholesale distributor must comply with the requirements for wholesale distributors under s. 499.0121~~, but not those set forth in s. 499.01212~~.

(m) ~~(l)~~ Limited prescription drug veterinary wholesale distributor permit.—Unless engaging in the activities of and permitted as a prescription drug manufacturer, nonresident prescription drug manufacturer, prescription drug wholesale distributor, or out-of-state prescription drug wholesale distributor, a limited prescription drug veterinary wholesale distributor permit is required for any person that engages in the distribution in or into this state of veterinary prescription drugs and prescription drugs subject to, defined

by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act under the following conditions:

1. The person is engaged in the business of wholesaling prescription and veterinary prescription drugs to persons:

a. Licensed as veterinarians practicing on a full-time basis;

b. Regularly and lawfully engaged in instruction in veterinary medicine;

c. Regularly and lawfully engaged in law enforcement activities;

d. For use in research not involving clinical use; or

e. For use in chemical analysis or physical testing or for purposes of instruction in law enforcement activities, research, or testing.

2. No more than 30 percent of total annual prescription drug sales may be prescription drugs approved for human use which are subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act.

3. The person does not distribute in any jurisdiction prescription drugs subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act to any person who is authorized to sell, distribute, purchase, trade, or use these drugs on or for humans.

4. A limited prescription drug veterinary wholesale distributor that applies to the department for a new permit or the renewal of a permit must submit a bond of $20,000, or other

equivalent means of security acceptable to the department, such as an irrevocable letter of credit or a deposit in a trust account or financial institution, payable to the Professional Regulation Trust Fund. The purpose of the bond is to secure payment of any administrative penalties imposed by the department and any fees and costs incurred by the department regarding that permit which are authorized under state law and which the permittee fails to pay 30 days after the fine or costs become final. The department may make a claim against such bond or security until 1 year after the permittee's license ceases to be valid or until 60 days after any administrative or legal proceeding authorized in this part which involves the permittee is concluded, including any appeal, whichever occurs later.

5. A limited prescription drug veterinary wholesale distributor must maintain at all times a license or permit to engage in the wholesale distribution of prescription drugs in compliance with laws of the state in which it is a resident.

6. A limited prescription drug veterinary wholesale distributor must comply with the requirements for wholesale distributors under s. ~~ss.~~ 499.0121 ~~and 499.01212, except that a limited prescription drug veterinary wholesale distributor is not required to provide a pedigree paper as required by s. 499.01212 upon the wholesale distribution of a prescription drug to a veterinarian~~.

7. A limited prescription drug veterinary wholesale distributor may not return to inventory for subsequent wholesale

distribution any prescription drug subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act which has been returned by a veterinarian.

8. A limited prescription drug veterinary wholesale distributor permit is not required for an intracompany sale or transfer of a prescription drug from an out-of-state establishment that is duly licensed to engage in the wholesale distribution of prescription drugs in its state of residence to a licensed limited prescription drug veterinary wholesale distributor in this state if both wholesale distributors conduct wholesale distributions of prescription drugs under the same business name. The recordkeeping requirements of s. ~~ss.~~ 499.0121(6) ~~and 499.01212~~ must be followed for this transaction.

(n) ~~(m)~~ Over-the-counter drug manufacturer permit.—An over-the-counter drug manufacturer permit is required for any person that engages in the manufacture or repackaging of an over-the-counter drug.

1. An over-the-counter drug manufacturer may not possess or purchase prescription drugs.

2. A pharmacy is exempt from obtaining an over-the-counter drug manufacturer permit if it is operating in compliance with pharmacy practice standards as defined in chapter 465 and ~~the~~ rules adopted under that chapter.

3. An over-the-counter drug manufacturer must comply with all appropriate state and federal good manufacturing practices.

(o) ~~(n)~~ Device manufacturer permit.—

1. A device manufacturer permit is required for any person that engages in the manufacture, repackaging, or assembly of medical devices for human use in this state, except that a permit is not required if:

a. The person is engaged only in manufacturing, repackaging, or assembling a medical device pursuant to a practitioner's order for a specific patient; or

b. The person does not manufacture, repackage, or assemble any medical devices or components for such devices, except those devices or components which are exempt from registration pursuant to s. 499.015(8).

2. A manufacturer or repackager of medical devices in this state must comply with all appropriate state and federal good manufacturing practices and quality system rules.

3. The department shall adopt rules related to storage, handling, and recordkeeping requirements for manufacturers of medical devices for human use.

(p) ~~(o)~~ Cosmetic manufacturer permit.—A cosmetic manufacturer permit is required for any person that manufactures or repackages cosmetics in this state. A person that only labels or changes the labeling of a cosmetic but does not open the container sealed by the manufacturer of the product is exempt from obtaining a permit under this paragraph.

(q) ~~(p)~~ Third party logistics provider permit.—A third party logistics provider permit is required for any person that contracts with a prescription drug wholesale distributor or

prescription drug manufacturer to provide warehousing, distribution, or other logistics services on behalf of a manufacturer, ~~or~~ wholesale distributor, or dispenser, but who does not take title to the prescription drug or have responsibility to direct the sale or disposition of the prescription drug. A third party logistics provider located outside of this state, must be licensed in the state or territory from which the prescription drug is distributed by the third party logistics provider. If the state or territory from which the third party logistics provider originates does not require a license to operate as a third party logistics provider, the third party logistic provider must be licensed as a third party logistics provider as required by the federal act. Each third party logistics provider permittee shall comply with s. ~~the requirements for wholesale distributors under ss.~~ 499.0121 ~~and 499.01212, with the exception of those wholesale distributions described in s. 499.01212(3)(a),~~ and other rules that the department requires.

(r) ~~(q)~~ Health care clinic establishment permit. ~~Effective January 1, 2009,~~ A health care clinic establishment permit is required for the purchase of a prescription drug by a place of business at one general physical location that provides health care or veterinary services, which is owned and operated by a business entity that has been issued a federal employer tax identification number. For the purpose of this paragraph, the term "qualifying practitioner" means a licensed health care

practitioner defined in s. 456.001, or a veterinarian licensed under chapter 474, who is authorized under the appropriate practice act to prescribe and administer a prescription drug.

1. An establishment must provide, as part of the application required under s. 499.012, designation of a qualifying practitioner who will be responsible for complying with all legal and regulatory requirements related to the purchase, recordkeeping, storage, and handling of the prescription drugs. In addition, the designated qualifying practitioner shall be the practitioner whose name, establishment address, and license number is used on all distribution documents for prescription drugs purchased or returned by the health care clinic establishment. Upon initial appointment of a qualifying practitioner, the qualifying practitioner and the health care clinic establishment shall notify the department on a form furnished by the department within 10 days after such employment. In addition, the qualifying practitioner and health care clinic establishment shall notify the department within 10 days after any subsequent change.

2. The health care clinic establishment must employ a qualifying practitioner at each establishment.

3. In addition to the remedies and penalties provided in this part, a violation of this chapter by the health care clinic establishment or qualifying practitioner constitutes grounds for discipline of the qualifying practitioner by the appropriate regulatory board.

4. The purchase of prescription drugs by the health care clinic establishment is prohibited during any period of time when the establishment does not comply with this paragraph.

5. A health care clinic establishment permit is not a pharmacy permit or otherwise subject to chapter 465. A health care clinic establishment that meets the criteria of a modified Class II institutional pharmacy under s. 465.019 is not eligible to be permitted under this paragraph.

6. This paragraph does not apply to the purchase of a prescription drug by a licensed practitioner under his or her license.

(3) A nonresident prescription drug manufacturer permit is not required for a manufacturer to distribute a prescription drug active pharmaceutical ingredient that it manufactures to a prescription drug manufacturer permitted in this state ~~in limited quantities~~ intended for research and development and not for resale or human use other than lawful clinical trials and biostudies authorized and regulated by federal law. A manufacturer claiming to be exempt from the permit requirements of this subsection and the prescription drug manufacturer purchasing and receiving the active pharmaceutical ingredient shall comply with the recordkeeping requirements of s. 499.0121(6)~~, but not the requirements of s. 499.01212~~. The prescription drug manufacturer purchasing and receiving the active pharmaceutical ingredient shall maintain on file a record of the FDA registration number; if available, the out-of-state

license, permit, or registration number; and, if available, a copy of the most current FDA inspection report, for all manufacturers from whom they purchase active pharmaceutical ingredients under this section. ~~The department shall define the term "limited quantities" by rule, and may include the allowable number of transactions within a given period of time and the amount of prescription drugs distributed into the state for purposes of this exemption.~~ The failure to comply with the requirements of this subsection, or rules adopted by the department to administer this subsection, for the purchase of prescription drug active pharmaceutical ingredients is a violation of s. 499.005(14), and a knowing failure is a violation of s. 499.0051(4).

(a) The immediate package or container of a prescription drug active pharmaceutical ingredient distributed into the state that is intended for research and development under this subsection shall bear a label prominently displaying the statement: "Caution: Research and Development Only—Not for Manufacturing, Compounding, or Resale."

(b) A prescription drug manufacturer that obtains a prescription drug active pharmaceutical ingredient under this subsection for use in clinical trials and or biostudies authorized and regulated by federal law must create and maintain records detailing the specific clinical trials or biostudies for which the prescription drug active pharmaceutical ingredient was obtained.

(4)(a) A permit issued under this part is not required to distribute a prescription drug active pharmaceutical ingredient from an establishment located in the United States to an establishment located in this state permitted as a prescription drug manufacturer under this part for use by the recipient in preparing, deriving, processing, producing, or fabricating a prescription drug finished dosage form at the establishment in this state where the product is received under an approved and otherwise valid New Drug Approval Application, Abbreviated New Drug Application, New Animal Drug Application, or Therapeutic Biologic Application, provided that the application, active pharmaceutical ingredient, or finished dosage form has not been withdrawn or removed from the market in this country for public health reasons.

1. Any distributor claiming exemption from permitting requirements pursuant to this paragraph shall maintain a license, permit, or registration to engage in the wholesale distribution of prescription drugs under the laws of the state from which the product is distributed. If the state from which the prescription drugs are distributed does not require a license to engage in the wholesale distribution of prescription drugs, the distributor must be licensed as a wholesale distributor as required by the federal act.

2. Any distributor claiming exemption from permitting requirements pursuant to this paragraph and the prescription drug manufacturer purchasing and receiving the active

pharmaceutical ingredient shall comply with the recordkeeping requirements of s. 499.0121(6)~~, but not the requirements of s. 499.01212~~.

(b) A permit issued under this part is not required to distribute ~~limited quantities of~~ a prescription drug that has not been repackaged from an establishment located in the United States to an establishment located in this state permitted as a prescription drug manufacturer under this part for research and development or to a holder of a letter of exemption issued by the department under s. 499.03(4) for research, teaching, or testing. ~~The department shall define "limited quantities" by rule and may include the allowable number of transactions within a given period of time and the amounts of prescription drugs distributed into the state for purposes of this exemption.~~

1. Any distributor claiming exemption from permitting requirements pursuant to this paragraph shall maintain a license, permit, or registration to engage in the wholesale distribution of prescription drugs under the laws of the state from which the product is distributed. If the state from which the prescription drugs are distributed does not require a license to engage in the wholesale distribution of prescription drugs, the distributor must be licensed as a wholesale distributor as required by the federal act.

2. All purchasers and recipients of any prescription drugs distributed pursuant to this paragraph shall ensure that the products are not resold or used, directly or indirectly, on

humans except in lawful clinical trials and biostudies authorized and regulated by federal law.

3. Any distributor claiming exemption from permitting requirements pursuant to this paragraph, and the purchaser and recipient of the prescription drug, shall comply with the recordkeeping requirements of s. 499.0121(6)~~, but not the requirements of s. 499.01212~~.

4. The immediate package or container of any active pharmaceutical ingredient distributed into the state that is intended for teaching, testing, research, and development shall bear a label prominently displaying the statement: "Caution: Research, Teaching, or Testing Only - Not for Manufacturing, Compounding, or Resale."

(c) An out-of-state prescription drug wholesale distributor permit is not required for an intracompany sale or transfer of a prescription drug from an out-of-state establishment that is duly licensed as a prescription drug wholesale distributor in its state of residence to a licensed prescription drug wholesale distributor in this state, if both wholesale distributors conduct wholesale distributions of prescription drugs under the same business name. The recordkeeping requirements of s. ~~ss.~~ 499.0121(6) ~~and 499.01212~~ must be followed for such transactions.

(d) Persons receiving prescription drugs from a source claimed to be exempt from permitting requirements under this subsection shall maintain on file:

1. A record of the FDA establishment registration number, if any;

2. The resident state or federal license, registration, or permit that authorizes the source to distribute prescription drugs ~~drug wholesale distribution license, permit, or registration number~~; and

3. A copy of the most recent resident state or FDA inspection report, for all distributors and establishments from whom they purchase or receive prescription drugs under this subsection.

(e) All persons claiming exemption from permitting requirements pursuant to this subsection who engage in the distribution of prescription drugs within or into the state are subject to this part, including ss. 499.005 and 499.0051, and shall make available, within 48 hours, to the department on request all records related to any prescription drugs distributed under this subsection, including those records described in s. 499.051(4), regardless of the location where the records are stored.

(f) A person purchasing and receiving a prescription drug from a person claimed to be exempt from licensing requirements pursuant to this subsection shall report to the department in writing within 14 days after receiving any product that is misbranded or adulterated or that fails to meet minimum standards set forth in the official compendium or state or federal good manufacturing practices for identity, purity,

potency, or sterility, regardless of whether the product is thereafter rehabilitated, quarantined, returned, or destroyed.

(g) The department may adopt rules to administer this subsection which are necessary for the protection of the public health, safety, and welfare. Failure to comply with the requirements of this subsection, or rules adopted by the department to administer this subsection, is a violation of s. 499.005(14), and a knowing failure is a violation of s. 499.0051(4).

(h) This subsection does not relieve any person from any requirement prescribed by law with respect to controlled substances as defined in the applicable federal and state laws.

(5) A prescription drug repackager permit issued under this part is not required for a restricted prescription drug distributor permitholder that is a health care entity to repackage prescription drugs in this state for its own use or for distribution to hospitals or other health care entities in the state for their own use, pursuant to s. 499.003(48)(a)3. ~~499.003(53)(a)3.~~, if:

(a) The prescription drug distributor notifies the department, in writing, of its intention to engage in repackaging under this exemption, 30 days before engaging in the repackaging of prescription drugs at the permitted establishment;

(b) The prescription drug distributor is under common control with the hospitals or other health care entities to

which the prescription drug distributor is distributing prescription drugs. As used in this paragraph, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, contract, or otherwise;

(c) The prescription drug distributor repackages the prescription drugs in accordance with current state and federal good manufacturing practices; and

(d) The prescription drug distributor labels the prescription drug it repackages in accordance with state and federal laws and rules.

The prescription drug distributor is exempt from the product registration requirements of s. 499.015 with regard to the prescription drugs that it repackages and distributes under this subsection. A prescription drug distributor that repackages and distributes prescription drugs under this subsection to a not-for-profit rural hospital, as defined in s. 395.602, is not required to comply with paragraph (c) or paragraph (d), but must provide to each health care entity for which it repackages, for each prescription drug that is repackaged and distributed, the information required by department rule for labeling prescription drugs. The prescription drug distributor shall also provide the additional current packaging and label information for the prescription drug by hard copy or by electronic means.

Section 6. Section 499.012, Florida Statutes, is amended

to read:

499.012 Permit application requirements.—

(1)(a) A permit issued pursuant to this part may be issued only to a natural person who is at least 18 years of age or to an applicant that is not a natural person if each person who, directly or indirectly, manages, controls, or oversees the operation of that applicant is at least 18 years of age.

(b) An establishment that is a place of residence may not receive a permit and may not operate under this part.

(c) A person that applies for or renews a permit to manufacture or distribute prescription drugs may not use a name identical to the name used by any other establishment or licensed person authorized to purchase prescription drugs in this state, except that a restricted drug distributor permit issued to a health care entity will be issued in the name in which the institutional pharmacy permit is issued and a retail pharmacy drug wholesale distributor will be issued a permit in the name of its retail pharmacy permit.

(d) A permit for a prescription drug manufacturer, prescription drug repackager, prescription drug wholesale distributor, limited prescription drug veterinary wholesale distributor, or retail pharmacy drug wholesale distributor may not be issued to the address of a health care entity or to a pharmacy licensed under chapter 465, except as provided in this paragraph. The department may issue a prescription drug manufacturer permit to an applicant at the same address as a

licensed nuclear pharmacy, which is a health care entity, even if the nuclear pharmacy holds a special sterile compounding permit under chapter 465, for the purpose of manufacturing prescription drugs used in positron emission tomography or other radiopharmaceuticals, as listed in a rule adopted by the department pursuant to this paragraph. The purpose of this exemption is to assure availability of state-of-the-art pharmaceuticals that would pose a significant danger to the public health if manufactured at a separate establishment address from the nuclear pharmacy from which the prescription drugs are dispensed. The department may also issue a retail pharmacy drug wholesale distributor permit to the address of a community pharmacy licensed under chapter 465, even if the community pharmacy holds a special sterile compounding permit under chapter 465, as long as the community pharmacy ~~which~~ does not meet the definition of a closed pharmacy in s. 499.003.

(e) A county or municipality may not issue an occupational license for ~~any licensing period beginning on or after October 1, 2003, for~~ any establishment that requires a permit pursuant to this part, unless the establishment exhibits a current permit issued by the department for the establishment. Upon presentation of the requisite permit issued by the department, an occupational license may be issued by the municipality or county in which application is made. The department shall furnish to local agencies responsible for issuing occupational licenses a current list of all establishments licensed pursuant

to this part.

(2) Notwithstanding subsection (6), a permitted person in good standing may change the type of permit issued to that person by completing a new application for the requested permit, paying the amount of the difference in the permit fees if the fee for the new permit is more than the fee for the original permit, and meeting the applicable permitting conditions for the new permit type. The new permit expires on the expiration date of the original permit being changed; however, a new permit for a prescription drug wholesale distributor, an out-of-state prescription drug wholesale distributor, or a retail pharmacy drug wholesale distributor shall expire on the expiration date of the original permit or 1 year after the date of issuance of the new permit, whichever is earlier. A refund may not be issued if the fee for the new permit is less than the fee that was paid for the original permit.

(3)(a) A written application for a permit or to renew a permit must be filed with the department on forms furnished by the department. The department shall establish, by rule, the form and content of the application to obtain or renew a permit. The applicant must submit to the department with the application a statement that swears or affirms that the information is true and correct.

(b) Upon a determination that 2 years have elapsed since the department notified an applicant for permit, certification, or product registration of a deficiency in the application and

that the applicant has failed to cure the deficiency, the application shall expire. The determination regarding the 2-year lapse of time shall be based on documentation that the department notified the applicant of the deficiency in accordance with s. 120.60.

(c) Information submitted by an applicant on an application required pursuant to this subsection which is a trade secret, as defined in s. 812.081, shall be maintained by the department as trade secret information pursuant to s. 499.051(7).

(4)(a) Except for a permit for a prescription drug wholesale distributor or an out-of-state prescription drug wholesale distributor, an application for a permit must include:

1. The name, full business address, and telephone number of the applicant;

2. All trade or business names used by the applicant;

3. The address, telephone numbers, and the names of contact persons for each facility used by the applicant for the storage, handling, and distribution of prescription drugs;

4. The type of ownership or operation, such as a partnership, corporation, or sole proprietorship; and

5. The names of the owner and the operator of the establishment, including:

a. If an individual, the name of the individual;

b. If a partnership, the name of each partner and the name of the partnership;

c. If a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the state of incorporation;

d. If a sole proprietorship, the full name of the sole proprietor and the name of the business entity;

e. If a limited liability company, the name of each member, the name of each manager, the name of the limited liability company, and the name of the state in which the limited liability company was organized; and

f. Any other relevant information that the department requires.

(b) Upon approval of the application by the department and payment of the required fee, the department shall issue a permit to the applicant, if the applicant meets the requirements of this part and rules adopted under this part.

(c) Any change in information required under paragraph (a) must be submitted to the department before the change occurs.

(d) The department shall consider, at a minimum, the following factors in reviewing the qualifications of persons to be permitted under this part:

1. The applicant's having been found guilty, regardless of adjudication, in a court of this state or other jurisdiction, of a violation of a law that directly relates to a drug, device, or cosmetic. A plea of nolo contendere constitutes a finding of guilt for purposes of this subparagraph.

2. The applicant's having been disciplined by a regulatory

agency in any state for any offense that would constitute a violation of this part.

3. Any felony conviction of the applicant under a federal, state, or local law;

4. The applicant's past experience in manufacturing or distributing drugs, devices, or cosmetics;

5. The furnishing by the applicant of false or fraudulent material in any application made in connection with manufacturing or distributing drugs, devices, or cosmetics;

6. Suspension or revocation by a federal, state, or local government of any permit currently or previously held by the applicant for the manufacture or distribution of any drugs, devices, or cosmetics;

7. Compliance with permitting requirements under any previously granted permits;

8. Compliance with requirements to maintain or make available to the state permitting authority or to federal, state, or local law enforcement officials those records required under this section; and

9. Any other factors or qualifications the department considers relevant to and consistent with the public health and safety.

(5) ~~Except for a permit for a prescription drug wholesale distributor or an out-of-state prescription drug wholesale distributor:~~

(a) The department shall adopt rules for the biennial

renewal of permits; however, the department may issue up to a 4-year permit to selected permittees notwithstanding any other provision of law. Fees for such renewal may not exceed the fee caps set forth in s. 499.041 on an annualized basis as authorized by law.

(b) The department shall renew a permit upon receipt of the renewal application and renewal fee if the applicant meets the requirements established under this part and ~~the~~ rules adopted under this part.

(c) At least 90 days before the expiration date of a permit, the department shall forward a permit renewal notification to the permittee at the mailing address of the permitted establishment on file with the department. The permit renewal notification must state conspicuously the date on which the permit for the establishment will expire and that the establishment may not operate unless the permit for the establishment is renewed timely. ~~A permit, unless sooner suspended or revoked, automatically expires 2 years after the last day of the anniversary month in which the permit was originally issued.~~

(d) A permit issued under this part may be renewed by making application for renewal on forms furnished by the department and paying the appropriate fees.

1. If a prescription drug wholesale distributor or an out-of-state prescription drug wholesale distributor renewal application and fee are submitted and postmarked later than 45

days before the expiration date of the permit, the permit may be renewed only upon payment of a late renewal fee of $100, plus the required renewal fee.

2. If any other ~~a~~ renewal application and fee are submitted and postmarked after the expiration date of the permit, the permit may be renewed only upon payment of a late renewal delinquent fee of $100, plus the required renewal fee, not later than 60 days after the expiration date.

3. A permittee who submits a renewal application in accordance with this paragraph may continue to operate under its permit, unless the permit is suspended or revoked, until final disposition of the renewal application.

4.~~(d)~~ Failure to renew a permit in accordance with this section precludes any future renewal of that permit. If a permit issued pursuant to this part has expired and cannot be renewed, before an establishment may engage in activities that require a permit under this part, the establishment must submit an application for a new permit, pay the applicable application fee, the initial permit fee, and all applicable penalties, and be issued a new permit by the department.

(6) A permit issued by the department is nontransferable. Each permit is valid only for the person or governmental unit to which it is issued and is not subject to sale, assignment, or other transfer, voluntarily or involuntarily; nor is a permit valid for any establishment other than the establishment for which it was originally issued.

(a) A person permitted under this part must notify the department before making a change of address. The department shall set a change of location fee not to exceed $100.

(b)1. An application for a new permit is required when a majority of the ownership or controlling interest of a permitted establishment is transferred or assigned or when a lessee agrees to undertake or provide services to the extent that legal liability for operation of the establishment will rest with the lessee. The application for the new permit must be made before the date of the sale, transfer, assignment, or lease.

2. A permittee that is authorized to distribute prescription drugs may transfer such drugs to the new owner or lessee under subparagraph 1. only after the new owner or lessee has been approved for a permit to distribute prescription drugs.

(c) If an establishment permitted under this part closes, the owner must notify the department in writing before the effective date of closure and must:

1. Return the permit to the department;

2. If the permittee is authorized to distribute prescription drugs, indicate the disposition of such drugs, including the name, address, and inventory, and provide the name and address of a person to contact regarding access to records that are required to be maintained under this part. Transfer of ownership of prescription drugs may be made only to persons authorized to possess prescription drugs under this part.

The department may revoke the permit of any person that fails to comply with the requirements of this subsection.

(7) A permit must be posted in a conspicuous place on the licensed premises.

(8) An application for a permit or to renew a permit for a prescription drug wholesale distributor or an out-of-state prescription drug wholesale distributor submitted to the department must include:

(a) The name, full business address, and telephone number of the applicant.

(b) All trade or business names used by the applicant.

(c) The address, telephone numbers, and the names of contact persons for each facility used by the applicant for the storage, handling, and distribution of prescription drugs.

(d) The type of ownership or operation, such as a partnership, corporation, or sole proprietorship.

(e) The names of the owner and the operator of the establishment, including:

1. If an individual, the name of the individual.

2. If a partnership, the name of each partner and the name of the partnership.

3. If a corporation:

a. The name, address, and title of each corporate officer and director.

b. The name and address of the corporation, resident agent of the corporation, the resident agent's address, and the

corporation's state of incorporation.

c. The name and address of each shareholder of the corporation that owns 5 percent or more of the outstanding stock of the corporation.

4. If a sole proprietorship, the full name of the sole proprietor and the name of the business entity.

5. If a limited liability company:

a. The name and address of each member.

b. The name and address of each manager.

c. The name and address of the limited liability company, the resident agent of the limited liability company, and the name of the state in which the limited liability company was organized.

(f) If applicable, the name and address of each affiliate of ~~member of the affiliated group of which~~ the applicant ~~is a member~~.

(g) ~~1.~~ The applicant's gross annual receipts attributable to prescription drug wholesale distribution activities for the previous tax year. ~~For an application for a new permit, the estimated annual dollar volume of prescription drug sales of the applicant, the estimated annual percentage of the applicant's total company sales that are prescription drugs, the applicant's estimated annual total dollar volume of purchases of prescription drugs, and the applicant's estimated annual total dollar volume of prescription drug purchases directly from manufacturers.~~

~~2. For an application to renew a permit, the total dollar volume of prescription drug sales in the previous year, the total dollar volume of prescription drug sales made in the previous 6 months, the percentage of total company sales that were prescription drugs in the previous year, the total dollar volume of purchases of prescription drugs in the previous year, and the total dollar volume of prescription drug purchases directly from manufacturers in the previous year.~~

~~Such portions of the information required pursuant to this paragraph which are a trade secret, as defined in s. 812.081, shall be maintained by the department as trade secret information is required to be maintained under s. 499.051.~~

(h) The tax year of the applicant.

(i) A copy of the deed for the property on which applicant's establishment is located, if the establishment is owned by the applicant, or a copy of the applicant's lease for the property on which applicant's establishment is located that has an original term of not less than 1 calendar year, if the establishment is not owned by the applicant.

(j) A list of all licenses and permits issued to the applicant by any other state which authorize the applicant to purchase or possess prescription drugs.

(k) The name of the manager of the establishment that is applying for the permit or to renew the permit, the next four highest ranking employees responsible for prescription drug

wholesale operations for the establishment, and the name of all affiliated parties for the establishment, together with the personal information statement and fingerprints required pursuant to subsection (9) for each of such persons.

(l) The name of each of the applicant's designated representatives as required by subsection (15) ~~(16)~~, together with the personal information statement and fingerprints required pursuant to subsection (9) for each such person.

(m) Evidence of a surety bond in this state or any other state in the United States in the amount of $100,000. If the annual gross receipts of the applicant's previous tax year is $10 million or less, evidence of a surety bond in the amount of $25,000. The specific language of the surety bond must include the State of Florida as a beneficiary, payable to the Professional Regulation Trust Fund. In lieu of the surety bond, the applicant may provide other equivalent security, such as an irrevocable letter of credit or a deposit in a trust account or financial institution, that includes the State of Florida as a beneficiary, payable to the Professional Regulation Trust Fund. The purpose of the bond or other security is to secure payment of any administrative penalties imposed by the department and any fees and costs incurred by the department regarding that permit which are authorized under state law and which the permittee fails to pay 30 days after the fine or costs become final. The department may make a claim against such bond or security until 1 year after the permittee's license ceases to be

valid or until 60 days after any administrative or legal proceeding authorized in this part which involves the permittee is concluded, including any appeal, whichever occurs later. ~~For an applicant that is a secondary wholesale distributor, each of the following:~~

~~1. A personal background information statement containing the background information and fingerprints required pursuant to subsection (9) for each person named in the applicant's response to paragraphs (k) and (l) and for each affiliated party of the applicant.~~

~~2. If any of the five largest shareholders of the corporation seeking the permit is a corporation, the name, address, and title of each corporate officer and director of each such corporation; the name and address of such corporation; the name of such corporation's resident agent, such corporation's resident agent's address, and such corporation's state of its incorporation; and the name and address of each shareholder of such corporation that owns 5 percent or more of the stock of such corporation.~~

~~3. The name and address of all financial institutions in which the applicant has an account which is used to pay for the operation of the establishment or to pay for drugs purchased for the establishment, together with the names of all persons that are authorized signatories on such accounts. The portions of the information required pursuant to this subparagraph which are a trade secret, as defined in s. 812.081, shall be maintained by~~

~~the department as trade secret information is required to be maintained under s. 499.051.~~

~~4. The sources of all funds and the amounts of such funds used to purchase or finance purchases of prescription drugs or to finance the premises on which the establishment is to be located.~~

~~5. If any of the funds identified in subparagraph 4. were borrowed, copies of all promissory notes or loans used to obtain such funds.~~

(n) For establishments used in wholesale distribution, proof of an inspection conducted by the department, the United States Food and Drug Administration, or another governmental entity charged with the regulation of good manufacturing practices related to wholesale distribution of prescription drugs, within timeframes set forth by the department in departmental rules, which demonstrates substantial compliance with current good manufacturing practices applicable to wholesale distribution of prescription drugs. The department may recognize another state's inspection of a wholesale distributor located in that state if such state's laws are deemed to be substantially equivalent to the law of this state by the department. The department may accept an inspection by a third-party accreditation or inspection service which meets the criteria set forth in department rule.

(o) ~~(n)~~ Any other relevant information that the department requires~~, including, but not limited to, any information related~~

~~to whether the applicant satisfies the definition of a primary wholesale distributor or a secondary wholesale distributor~~.

(p)~~(o)~~ Documentation of the credentialing policies and procedures required by s. 499.0121(15).

(9)(a) Each person required by subsection (8) or subsection (15) to provide a personal information statement and fingerprints shall provide the following information to the department on forms prescribed by the department:

1. The person's places of residence for the past 7 years.

2. The person's date and place of birth.

3. The person's occupations, positions of employment, and offices held during the past 7 years.

4. The principal business and address of any business, corporation, or other organization in which each such office of the person was held or in which each such occupation or position of employment was carried on.

5. Whether the person has been, during the past 7 years, the subject of any proceeding for the revocation of any license and, if so, the nature of the proceeding and the disposition of the proceeding.

6. Whether, during the past 7 years, the person has been enjoined, temporarily or permanently, by a court of competent jurisdiction from violating any federal or state law regulating the possession, control, or distribution of prescription drugs, together with details concerning any such event.

7. A description of any involvement by the person with any

business, including any investments, other than the ownership of stock in a publicly traded company or mutual fund, during the past 4 ~~7~~ years, which manufactured, administered, prescribed, distributed, or stored pharmaceutical products and any lawsuits in which such businesses were named as a party.

8. A description of any felony criminal offense of which the person, as an adult, was found guilty, regardless of whether adjudication of guilt was withheld or whether the person pled guilty or nolo contendere. A criminal offense committed in another jurisdiction which would have been a felony in this state must be reported. If the person indicates that a criminal conviction is under appeal and submits a copy of the notice of appeal of that criminal offense, the applicant must, within 15 days after the disposition of the appeal, submit to the department a copy of the final written order of disposition.

9. A photograph of the person taken in the previous 180 ~~30~~ days.

10. A set of fingerprints for the person on a form and under procedures specified by the department, together with payment of an amount equal to the costs incurred by the department for the criminal record check of the person.

11. The name, address, occupation, and date and place of birth for each member of the person's immediate family who is 18 years of age or older. As used in this subparagraph, the term "member of the person's immediate family" includes the person's spouse, children, parents, siblings, the spouses of the person's

children, and the spouses of the person's siblings.

12. Any other relevant information that the department requires.

(b) The information required pursuant to paragraph (a) shall be provided under oath.

(c) The department shall submit the fingerprints provided by a person for initial licensure to the Department of Law Enforcement for a statewide criminal record check and for forwarding to the Federal Bureau of Investigation for a national criminal record check of the person. The department shall submit the fingerprints provided by a person as a part of a renewal application to the Department of Law Enforcement for a statewide criminal record check, and for forwarding to the Federal Bureau of Investigation for a national criminal record check, for the initial renewal of a permit after January 1, 2004; for any subsequent renewal of a permit, the department shall submit the required information for a statewide and national criminal record check of the person. Any person who as a part of an initial permit application or initial permit renewal after January 1, 2004, submits to the department a set of fingerprints required for the criminal record check required in this paragraph are ~~shall~~ not ~~be~~ required to provide a subsequent set of fingerprints for a criminal record check to the department, if the person has undergone a criminal record check as a condition of the issuance of an initial permit or the initial renewal of a permit of an applicant after January 1, 2004. The

department is authorized to contract with private vendors, or enter into interagency agreements, to collect electronic fingerprints where fingerprints are required for registration, certification, or the licensure process or where criminal history record checks are required.

(d) For purposes of applying for renewal of a permit under subsection (8) or certification under subsection (16), a person may submit the following in lieu of satisfying the requirements of paragraphs (a), (b), and (c):

1. A photograph of the individual taken within 180 days; and

2. A copy of the personal information statement form most recently submitted to the department and a certification under oath, on a form specified by the department, that the individual has reviewed the previously submitted personal information statement form and that the information contained therein remains unchanged.

(10) The department may deny an application for a permit or refuse to renew a permit for a prescription drug wholesale distributor or an out-of-state prescription drug wholesale distributor if:

(a) The applicant has not met the requirements for the permit.

(b) The management, officers, or directors of the applicant or any affiliated party are found by the department to be incompetent or untrustworthy.

(c) The applicant is so lacking in experience in managing a wholesale distributor as to make the issuance of the proposed permit hazardous to the public health.

(d) The applicant is so lacking in experience in managing a wholesale distributor as to jeopardize the reasonable promise of successful operation of the wholesale distributor.

(e) The applicant is lacking in experience in the distribution of prescription drugs.

(f) The applicant's past experience in manufacturing or distributing prescription drugs indicates that the applicant poses a public health risk.

(g) The applicant is affiliated directly or indirectly through ownership, control, or other business relations, with any person or persons whose business operations are or have been detrimental to the public health.

(h) The applicant, or any affiliated party, has been found guilty of or has pleaded guilty or nolo contendere to any felony or crime punishable by imprisonment for 1 year or more under the laws of the United States, any state, or any other country, regardless of whether adjudication of guilt was withheld.

(i) The applicant or any affiliated party has been charged with a felony in a state or federal court and the disposition of that charge is pending during the application review or renewal review period.

(j) The applicant has furnished false or fraudulent information or material in any application made in this state or

any other state in connection with obtaining a permit or license to manufacture or distribute drugs, devices, or cosmetics.

(k) That a federal, state, or local government permit currently or previously held by the applicant, or any affiliated party, for the manufacture or distribution of any drugs, devices, or cosmetics has been disciplined, suspended, or revoked and has not been reinstated.

(l) The applicant does not possess the financial or physical resources to operate in compliance with the permit being sought, this chapter, and the rules adopted under this chapter.

(m) The applicant or any affiliated party receives, directly or indirectly, financial support and assistance from a person who was an affiliated party of a permittee whose permit was subject to discipline or was suspended or revoked, other than through the ownership of stock in a publicly traded company or a mutual fund.

(n) The applicant or any affiliated party receives, directly or indirectly, financial support and assistance from a person who has been found guilty of any violation of this part or chapter 465, chapter 501, or chapter 893, any rules adopted under this part or those chapters, any federal or state drug law, or any felony where the underlying facts related to drugs, regardless of whether the person has been pardoned, had her or his civil rights restored, or had adjudication withheld, other than through the ownership of stock in a publicly traded company

or a mutual fund.

(o) The applicant for renewal of a permit under s. 499.01(2)(e) or (f) ~~499.01(2)(d) or (e)~~ has not actively engaged in the wholesale distribution of prescription drugs, as demonstrated by the regular and systematic distribution of prescription drugs throughout the year as evidenced by not fewer than 12 wholesale distributions in the previous year and not fewer than three wholesale distributions in the previous 6 months.

(p) Information obtained in response to s. 499.01(2)(e) or (f) ~~499.01(2)(d) or (e)~~ demonstrates it would not be in the best interest of the public health, safety, and welfare to issue a permit.

(q) The applicant does not possess the financial standing and business experience for the successful operation of the applicant.

(r) The applicant or any affiliated party has failed to comply with the requirements for manufacturing or distributing prescription drugs under this part, similar federal laws, similar laws in other states, or the rules adopted under such laws.

(11) Upon approval of the application by the department and payment of the required fee, the department shall issue or renew a prescription drug wholesale distributor or an out-of-state prescription drug wholesale distributor permit to the applicant.

~~(12) For a permit for a prescription drug wholesale distributor or an out-of-state prescription drug wholesale distributor:~~

~~(a) The department shall adopt rules for the annual renewal of permits. At least 90 days before the expiration of a permit, the department shall forward a permit renewal notification and renewal application to the prescription drug wholesale distributor or out-of-state prescription drug wholesale distributor at the mailing address of the permitted establishment on file with the department. The permit renewal notification must state conspicuously the date on which the permit for the establishment will expire and that the establishment may not operate unless the permit for the establishment is renewed timely.~~

~~(b) A permit, unless sooner suspended or revoked, automatically expires 1 year after the last day of the anniversary month in which the permit was originally issued. A permit may be renewed by making application for renewal on forms furnished by the department and paying the appropriate fees. If a renewal application and fee are submitted and postmarked after 45 days prior to the expiration date of the permit, the permit may be renewed only upon payment of a late renewal fee of $100, plus the required renewal fee. A permittee that has submitted a renewal application in accordance with this paragraph may continue to operate under its permit, unless the permit is suspended or revoked, until final disposition of the renewal~~

~~application.~~

~~(c) Failure to renew a permit in accordance with this section precludes any future renewal of that permit. If a permit issued pursuant to this section has expired and cannot be renewed, before an establishment may engage in activities that require a permit under this part, the establishment must submit an application for a new permit; pay the applicable application fee, initial permit fee, and all applicable penalties; and be issued a new permit by the department.~~

(12) ~~(13)~~ A person that engages in wholesale distribution of prescription drugs in this state must have a wholesale distributor's permit issued by the department, except as noted in this section. Each establishment must be separately permitted except as noted in this subsection.

(a) A separate establishment permit is not required when a permitted prescription drug wholesale distributor consigns a prescription drug to a pharmacy that is permitted under chapter 465 and located in this state, provided that:

1. The consignor wholesale distributor notifies the department in writing of the contract to consign prescription drugs to a pharmacy along with the identity and location of each consignee pharmacy;

2. The pharmacy maintains its permit under chapter 465;

3. The consignor wholesale distributor, which has no legal authority to dispense prescription drugs, complies with all wholesale distribution requirements of s. ~~ss.~~ 499.0121 ~~and~~

~~499.01212~~ with respect to the consigned drugs and maintains records documenting the transfer of title or other completion of the wholesale distribution of the consigned prescription drugs;

4. The distribution of the prescription drug is otherwise lawful under this chapter and other applicable law;

5. Open packages containing prescription drugs within a pharmacy are the responsibility of the pharmacy, regardless of how the drugs are titled; and

6. The pharmacy dispenses the consigned prescription drug in accordance with the limitations of its permit under chapter 465 or returns the consigned prescription drug to the consignor wholesale distributor. In addition, a person who holds title to prescription drugs may transfer the drugs to a person permitted or licensed to handle the reverse distribution or destruction of drugs. Any other distribution by and means of the consigned prescription drug by any person, not limited to the consignor wholesale distributor or consignee pharmacy, to any other person is prohibited.

(b) A wholesale distributor's permit is not required for the one-time transfer of title of a pharmacy's lawfully acquired prescription drug inventory by a pharmacy with a valid permit issued under chapter 465 to a consignor prescription drug wholesale distributor, permitted under this chapter, in accordance with a written consignment agreement between the pharmacy and that wholesale distributor if the permitted pharmacy and the permitted prescription drug wholesale

distributor comply with all of the provisions of paragraph (a) and the prescription drugs continue to be within the permitted pharmacy's inventory for dispensing in accordance with the limitations of the pharmacy permit under chapter 465. A consignor drug wholesale distributor may not use the pharmacy as a wholesale distributor through which it distributes the prescription drugs to other pharmacies. Nothing in this section is intended to prevent a wholesale distributor from obtaining this inventory in the event of nonpayment by the pharmacy.

(c) A separate establishment permit is not required when a permitted prescription drug wholesale distributor operates temporary transit storage facilities for the sole purpose of storage, for up to 16 hours, of a delivery of prescription drugs when the wholesale distributor was temporarily unable to complete the delivery to the recipient.

(d) The department shall require information from each wholesale distributor as part of the permit and renewal of such permit, as required under this section.

(13) ~~(14)~~ Personnel employed in wholesale distribution must have appropriate education and experience to enable them to perform their duties in compliance with state permitting requirements.

(14) ~~(15)~~ The name of a permittee or establishment on a prescription drug wholesale distributor permit or an out-of-state prescription drug wholesale distributor permit may not include any indicia of attainment of any educational degree, any

indicia that the permittee or establishment possesses a professional license, or any name or abbreviation that the department determines is likely to cause confusion or mistake or that the department determines is deceptive, including that of any other entity authorized to purchase prescription drugs.

(15) ~~(16)~~ (a) Each establishment that is issued an initial or renewal permit as a prescription drug wholesale distributor or an out-of-state prescription drug wholesale distributor must designate in writing to the department at least one natural person to serve as the designated representative of the wholesale distributor. Such person must have an active certification as a designated representative from the department.

(b) To be certified as a designated representative, a natural person must:

1. Submit an application on a form furnished by the department and pay the appropriate fees.

2. Be at least 18 years of age.

3. Have at least 2 years of verifiable full-time:

a. Work experience in a pharmacy licensed in this state or another state, where the person's responsibilities included, but were not limited to, recordkeeping for prescription drugs;

b. Managerial experience with a prescription drug wholesale distributor licensed in this state or in another state; or

c. Managerial experience with the United States Armed

Forces, where the person's responsibilities included, but were not limited to, recordkeeping, warehousing, distributing, or other logistics services pertaining to prescription drugs.

4. Receive a passing score of at least 75 percent on an examination given by the department regarding federal laws governing distribution of prescription drugs and this part and the rules adopted by the department governing the wholesale distribution of prescription drugs. This requirement shall be effective 1 year after the results of the initial examination are mailed to the persons that took the examination. The department shall offer such examinations at least four times each calendar year.

5. Provide the department with a personal information statement and fingerprints pursuant to subsection (9).

(c) The department may deny an application for certification as a designated representative or may suspend or revoke a certification of a designated representative pursuant to s. 499.067.

(d) A designated representative:

1. Must be actively involved in and aware of the actual daily operation of the wholesale distributor.

2. Must be employed full time in a managerial position by the wholesale distributor.

3. Must be physically present at the establishment during normal business hours, except for time periods when absent due to illness, family illness or death, scheduled vacation, or

other authorized absence.

4. May serve as a designated representative for only one wholesale distributor at any one time.

(e) A wholesale distributor must notify the department when a designated representative leaves the employ of the wholesale distributor. Such notice must be provided to the department within 10 business days after the last day of designated representative's employment with the wholesale distributor.

(f) A wholesale distributor may not operate under a prescription drug wholesale distributor permit or an out-of-state prescription drug wholesale distributor permit for more than 10 business days after the designated representative leaves the employ of the wholesale distributor, unless the wholesale distributor employs another designated representative and notifies the department within 10 business days of the identity of the new designated representative.

Section 7. Section 499.01201, Florida Statutes, is amended to read:

499.01201 Agency for Health Care Administration review and use of statute and rule violation or compliance data.—Notwithstanding any other provision ~~provisions~~ of law ~~to the contrary~~, the Agency for Health Care Administration may not:

(1) Review or use any violation or alleged violation of s. 499.0121(6) ~~or s. 499.01212~~, or any rules adopted under that section ~~those sections~~, as a ground for denying or withholding

any payment of a Medicaid reimbursement to a pharmacy licensed under chapter 465; or

(2) Review or use compliance with s. 499.0121(6) ~~or s. 499.01212~~, or any rules adopted under that section ~~those sections~~, as the subject of any audit of Medicaid-related records held by a pharmacy licensed under chapter 465.

Section 8. Paragraph (d) of subsection (4) and subsection (6) of section 499.0121, Florida Statutes, are amended to read:

499.0121 Storage and handling of prescription drugs; recordkeeping.—The department shall adopt rules to implement this section as necessary to protect the public health, safety, and welfare. Such rules shall include, but not be limited to, requirements for the storage and handling of prescription drugs and for the establishment and maintenance of prescription drug distribution records.

(4) EXAMINATION OF MATERIALS AND RECORDS.—

(d) Upon receipt, a wholesale distributor must review records required under this section for the acquisition of prescription drugs for accuracy and completeness, considering the total facts and circumstances surrounding the transactions and the wholesale distributors involved. ~~This includes authenticating each transaction listed on a pedigree paper, as defined in s. 499.003(37).~~

(6) RECORDKEEPING.—The department shall adopt rules that require keeping such records of prescription drugs, including active pharmaceutical ingredients, as are necessary for the

protection of the public health.

(a) ~~Wholesale~~ Distributors of prescription drugs and active pharmaceutical ingredients must establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs and active pharmaceutical ingredients. These records must provide a complete audit trail from receipt to sale or other disposition, be readily retrievable for inspection, and include, at a minimum, the following information:

1. The source of the prescription drugs or active pharmaceutical ingredients, including the name and principal address of the seller or transferor, and the address of the location from which the prescription drugs were shipped;

2. The name, principal address, and state license permit or registration number of the person authorized to purchase prescription drugs or active pharmaceutical ingredients;

3. The name, strength, dosage form, and quantity of the prescription drugs received and distributed or disposed of;

4. The dates of receipt and distribution or other disposition of the prescription drugs or active pharmaceutical ingredients; and

5. Any financial documentation supporting the transaction.

(b) Inventories and records must be made available for inspection and photocopying by authorized federal, state, or local officials for a period of 2 years following disposition of the drugs or 3 years after the creation of the records,

whichever period is longer.

(c) Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means must be readily available for authorized inspection during the retention period. Records that are kept at a central location outside of this state and that are not electronically retrievable must be made available for inspection within 2 working days after a request by an authorized official of a federal, state, or local law enforcement agency. Records that are maintained at a central location within this state must be maintained at an establishment that is permitted pursuant to this part and must be readily available.

(d) Each manufacturer or repackager of medical devices, over-the-counter drugs, or cosmetics must maintain records that include the name and principal address of the seller or transferor of the product, the address of the location from which the product was shipped, the date of the transaction, the name and quantity of the product involved, and the name and principal address of the person who purchased the product.

~~(e) When pedigree papers are required by this part, a wholesale distributor must maintain the pedigree papers separate and distinct from other records required under this part.~~

Section 9. Subsections (1), (3), (4), and (6) of section 499.015, Florida Statutes, are amended to read:

499.015 Registration of drugs, devices, and cosmetics;

issuance of certificates of free sale.—

(1)(a) Except for those persons exempted from the definition of manufacturer in s. 499.003, any person who manufactures, packages, repackages, labels, or relabels a drug or a~~,~~ device~~, or cosmetic~~ in this state must register such drug or~~,~~ device~~, or cosmetic~~ biennially with the department; pay a fee in accordance with the fee schedule provided by s. 499.041; and comply with this section. The registrant must list each separate and distinct drug or~~,~~ device~~, or cosmetic~~ at the time of registration.

(b) Any person who manufactures, packages, repackages, labels, or relabels a cosmetic in this state may voluntarily register such cosmetic biennially with the department. A person registering a cosmetic must submit a completed application to register the cosmetic, pay a fee in accordance with the fee schedule provided by s. 499.041, comply with the provisions of this section, and must list each separate and distinct cosmetic at the time of registration.

(c)~~(b)~~ The department may not register any product that does not comply with the Federal Food, Drug, and Cosmetic Act, as amended, or Title 21 C.F.R. Registration of a product by the department does not mean that the product does in fact comply with all provisions of the Federal Food, Drug, and Cosmetic Act, as amended.

(d) A person may not register a product with the department if that person is not legally authorized to

manufacture, package, repackage, label, or relabel the product in this state.

(3) Except for those persons exempted from the definition of manufacturer in s. 499.003, a person may not sell any product that he or she has failed to register in conformity with this section. Such failure to register subjects such drug or~~,~~ device~~, or cosmetic product~~ to seizure and condemnation as provided in s. 499.062, and subjects such person to the penalties and remedies provided in this part.

(4) Unless a registration is renewed, it expires 2 years after the last day of the month in which it was issued. Any product registration issued or renewed on or after July 1, 2016, shall expire on the same date as the manufacturer or repackager permit of the person seeking to register the product. If the first product registration issued to a person on or after July 1, 2016, expires less than 366 days after issuance, the fee for product registration shall be $15. If the first product registration issued to a person on or after July 1, 2016, expires more than 365 days after issuance, the fee for product registration shall be $30. The department may issue a stop-sale notice or order against a person that is subject to the requirements of this section and that fails to comply with this section within 31 days after the date the registration expires. The notice or order shall prohibit such person from selling or causing to be sold any drugs, devices, or cosmetics covered by this part until he or she complies with the requirements of this

section.

(6) The department may only issue a certificate of free sale for any product that is ~~required to be~~ registered under this part.

Section 10. Subsection (1) of section 499.03, Florida Statutes, is amended to read:

499.03 Possession of certain drugs without prescriptions unlawful; exemptions and exceptions.—

(1) A person may not possess, or possess with intent to sell, dispense, or deliver, any habit-forming, toxic, harmful, or new drug subject to s. 499.003(32) ~~499.003(33)~~, or prescription drug as defined in s. 499.003(40) ~~499.003(43)~~, unless the possession of the drug has been obtained by a valid prescription of a practitioner licensed by law to prescribe the drug. However, this section does not apply to the delivery of such drugs to persons included in any of the classes named in this subsection, or to the agents or employees of such persons, for use in the usual course of their businesses or practices or in the performance of their official duties, as the case may be; nor does this section apply to the possession of such drugs by those persons or their agents or employees for such use:

(a) A licensed pharmacist or any person under the licensed pharmacist's supervision while acting within the scope of the licensed pharmacist's practice;

(b) A licensed practitioner authorized by law to prescribe prescription drugs or any person under the licensed

practitioner's supervision while acting within the scope of the licensed practitioner's practice;

(c) A qualified person who uses prescription drugs for lawful research, teaching, or testing, and not for resale;

(d) A licensed hospital or other institution that procures such drugs for lawful administration or dispensing by practitioners;

(e) An officer or employee of a federal, state, or local government; or

(f) A person that holds a valid permit issued by the department pursuant to this part which authorizes that person to possess prescription drugs.

Section 11. Paragraphs (i) through (p) of subsection (1) of section 499.05, Florida Statutes, are amended to read:

499.05 Rules.—

(1) The department shall adopt rules to implement and enforce this chapter with respect to:

(i) Additional conditions that qualify as an emergency medical reason under s. 499.003(48)(b)2. ~~499.003(53)(b)2.~~ or s. 499.82.

~~(j) Procedures and forms relating to the pedigree paper requirement of s. 499.01212.~~

(j)~~(k)~~ The protection of the public health, safety, and welfare regarding good manufacturing practices that manufacturers and repackagers must follow to ensure the safety of the products.

(k) ~~(l)~~ Information required from each retail establishment pursuant to s. 499.012(3) or s. 499.83(2)(c), including requirements for prescriptions or orders.

(l) ~~(m)~~ The recordkeeping, storage, and handling with respect to each of the distributions of prescription drugs specified in s. 499.003(48)(a)-(v) ~~499.003(53)(a)-(d)~~ or s. 499.82(14).

~~(n) Alternatives to compliance with s. 499.01212 for a prescription drug in the inventory of a permitted prescription drug wholesale distributor as of June 30, 2006, and the return of a prescription drug purchased prior to July 1, 2006. The department may specify time limits for such alternatives.~~

(m) ~~(o)~~ Wholesale distributor reporting requirements of s. 499.0121(14).

(n) ~~(p)~~ Wholesale distributor credentialing and distribution requirements of s. 499.0121(15).

Section 12. Subsection (7) of section 499.051, Florida Statutes, is amended to read:

499.051 Inspections and investigations.—

(7) The complaint and all information obtained pursuant to the investigation by the department are confidential and exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution until the investigation and the enforcement action are completed. However, trade secret information contained therein as defined by s. 812.081(1)(c) shall remain confidential and exempt from the provisions of s. 119.07(1) and s. 24(a), Art. I

of the State Constitution, as long as the information is retained by the department. This subsection does not prohibit the department from using such information for regulatory or enforcement proceedings under this chapter or from providing such information to any law enforcement agency or any other regulatory agency. However, the receiving agency shall keep such records confidential and exempt as provided in this subsection. ~~In addition, this subsection is not intended to prevent compliance with the provisions of s. 499.01212, and the pedigree papers required in that section shall not be deemed a trade secret.~~

Section 13. Subsection (8) is added to section 499.066, Florida Statutes, to read:

499.066 Penalties; remedies.—In addition to other penalties and other enforcement provisions:

(8)(a) The department shall adopt rules to permit the issuance of remedial, nondisciplinary citations. A citation shall be issued to the person alleged to have committed a violation and contain the person's name, address, and license number, if applicable, a brief factual statement, the sections of the law allegedly violated, and the monetary assessment and or other remedial measures imposed. The citation must clearly state that the person may choose, in lieu of accepting the citation, to have the department rescind the citation and conduct an investigation pursuant to s. 499.051. If the person does not dispute the matter in the citation with the department

within 30 days after the citation is served, the citation becomes a final order and does not constitute discipline.

(b) The department shall adopt rules designating violations for which a citation may be issued. The rules shall designate as citable those violations for which there is no substantial threat to the public health, safety, or welfare.

(c) The department is entitled to recover the costs of investigation, in addition to any penalty provided according to department rule, as part of the penalty levied pursuant to the citation.

(d) A citation must be issued within 12 months after the filing of the complaint that is the basis for the citation.

(e) Service of a citation may be made by personal service or certified mail, restricted delivery, to the person at the person's last known address of record with the department or to the person's Florida registered agent.

(f) The department has authority to, and shall adopt rules to, designate those violations for which a person is subject to the issuance of a citation and designate the monetary assessments and or other remedial measures that must be taken for those violations. The department has continuous authority to amend its rules adopted pursuant to this section.

Section 14. Subsection (14) of section 499.82, Florida Statutes, is amended to read:

499.82 Definitions.—As used in this part, the term:

(14) "Wholesale distribution" means the distribution of

medical gas to a person other than a consumer or patient. Wholesale distribution of medical gases does not include:

(a) The sale, purchase, or trade of a medical gas; an offer to sell, purchase, or trade a medical gas; or the dispensing of a medical gas pursuant to a prescription;

(b) Activities exempt from the definition of wholesale distribution in s. 499.003; or

(c) The sale, purchase, or trade of a medical gas or an offer to sell, purchase, or trade a medical gas for emergency medical reasons~~; or~~

~~(d) Other transactions excluded from the definition of wholesale distribution under the federal act or regulations implemented under the federal act related to medical gas~~.

Section 15. Subsection (4) of section 499.89, Florida Statutes, is amended to read:

499.89 Recordkeeping.—

~~(4) A pedigree paper is not required for distributing or dispensing medical gas.~~

Section 16. Section 499.01212, Florida Statutes, is repealed.

Section 17. Paragraph (a) of subsection (1) of section 409.9201, Florida Statutes, is amended to read:

409.9201 Medicaid fraud.—

(1) As used in this section, the term:

(a) "Prescription drug" means any drug, including, but not limited to, finished dosage forms or active ingredients that are

subject to, defined in, or described in s. 503(b) of the Federal Food, Drug, and Cosmetic Act or in s. 465.003(8), s. 499.003(47) ~~499.003(52)~~, s. 499.007(13), or s. 499.82(10).

The value of individual items of the legend drugs or goods or services involved in distinct transactions committed during a single scheme or course of conduct, whether involving a single person or several persons, may be aggregated when determining the punishment for the offense.

Section 18. Subsection (1) of section 794.075, Florida Statutes, is amended to read:

794.075 Sexual predators; erectile dysfunction drugs.—

(1) A person may not possess a prescription drug, as defined in s. 499.003(40) ~~499.003(43)~~, for the purpose of treating erectile dysfunction if the person is designated as a sexual predator under s. 775.21.

Section 19. Paragraphs (d) and (f) of subsection (3) of section 921.0022, Florida Statutes, are amended to read:

921.0022 Criminal Punishment Code; offense severity ranking chart.—

(3) OFFENSE SEVERITY RANKING CHART

(d) LEVEL 4

Florida Statute	Felony Degree	Description

316.1935(3)(a)	2nd	Driving at high speed or with wanton disregard for safety while fleeing or attempting to elude law enforcement officer who is in a patrol vehicle with siren and lights activated.
499.0051(1)	3rd	Failure to maintain or deliver transaction history, transaction information, or transaction statements ~~pedigree papers~~.
~~499.0051(2)~~	~~3rd~~	~~Failure to authenticate pedigree papers.~~
499.0051(5) ~~499.0051(6)~~	2nd	Knowing sale or delivery, or possession with intent to sell, contraband prescription drugs.
517.07(1)	3rd	Failure to register securities.
517.12(1)	3rd	Failure of dealer, associated person, or issuer of securities to register.

784.07(2)(b)	3rd	Battery of law enforcement officer, firefighter, etc.
784.074(1)(c)	3rd	Battery of sexually violent predators facility staff.
784.075	3rd	Battery on detention or commitment facility staff.
784.078	3rd	Battery of facility employee by throwing, tossing, or expelling certain fluids or materials.
784.08(2)(c)	3rd	Battery on a person 65 years of age or older.
784.081(3)	3rd	Battery on specified official or employee.
784.082(3)	3rd	Battery by detained person on visitor or other detainee.
784.083(3)	3rd	Battery on code inspector.
784.085	3rd	Battery of child by throwing, tossing, projecting, or

			expelling certain fluids or materials.
2613			
	787.03(1)	3rd	Interference with custody; wrongly takes minor from appointed guardian.
2614			
	787.04(2)	3rd	Take, entice, or remove child beyond state limits with criminal intent pending custody proceedings.
2615			
	787.04(3)	3rd	Carrying child beyond state lines with criminal intent to avoid producing child at custody hearing or delivering to designated person.
2616			
	787.07	3rd	Human smuggling.
2617			
	790.115(1)	3rd	Exhibiting firearm or weapon within 1,000 feet of a school.
2618			
	790.115(2)(b)	3rd	Possessing electric weapon or device, destructive device, or other weapon on school

		property.
790.115(2)(c)	3rd	Possessing firearm on school property.
800.04(7)(c)	3rd	Lewd or lascivious exhibition; offender less than 18 years.
810.02(4)(a)	3rd	Burglary, or attempted burglary, of an unoccupied structure; unarmed; no assault or battery.
810.02(4)(b)	3rd	Burglary, or attempted burglary, of an unoccupied conveyance; unarmed; no assault or battery.
810.06	3rd	Burglary; possession of tools.
810.08(2)(c)	3rd	Trespass on property, armed with firearm or dangerous weapon.
812.014(2)(c)3.	3rd	Grand theft, 3rd degree $10,000 or more but less than $20,000.

812.014 (2)(c)4.-10.	3rd	Grand theft, 3rd degree, a will, firearm, motor vehicle, livestock, etc.
812.0195(2)	3rd	Dealing in stolen property by use of the Internet; property stolen $300 or more.
817.563(1)	3rd	Sell or deliver substance other than controlled substance agreed upon, excluding s. 893.03(5) drugs.
817.568(2)(a)	3rd	Fraudulent use of personal identification information.
817.625(2)(a)	3rd	Fraudulent use of scanning device or reencoder.
828.125(1)	2nd	Kill, maim, or cause great bodily harm or permanent breeding disability to any registered horse or cattle.
837.02(1)	3rd	Perjury in official

		proceedings.
837.021(1)	3rd	Make contradictory statements in official proceedings.
838.022	3rd	Official misconduct.
839.13(2)(a)	3rd	Falsifying records of an individual in the care and custody of a state agency.
839.13(2)(c)	3rd	Falsifying records of the Department of Children and Families.
843.021	3rd	Possession of a concealed handcuff key by a person in custody.
843.025	3rd	Deprive law enforcement, correctional, or correctional probation officer of means of protection or communication.
843.15(1)(a)	3rd	Failure to appear while on bail for felony (bond estreature or

		bond jumping).
847.0135(5)(c)	3rd	Lewd or lascivious exhibition using computer; offender less than 18 years.
874.05(1)(a)	3rd	Encouraging or recruiting another to join a criminal gang.
893.13(2)(a)1.	2nd	Purchase of cocaine (or other s. 893.03(1)(a), (b), or (d), (2)(a), (2)(b), or (2)(c)4. drugs).
914.14(2)	3rd	Witnesses accepting bribes.
914.22(1)	3rd	Force, threaten, etc., witness, victim, or informant.
914.23(2)	3rd	Retaliation against a witness, victim, or informant, no bodily injury.
918.12	3rd	Tampering with jurors.

Florida Statute	Felony Degree	Description
934.215	3rd	Use of two-way communications device to facilitate commission of a crime.

(f) LEVEL 6

Florida Statute	Felony Degree	Description
316.027(2)(b)	2nd	Leaving the scene of a crash involving serious bodily injury.
316.193(2)(b)	3rd	Felony DUI, 4th or subsequent conviction.
400.9935(4)(c)	2nd	Operating a clinic, or offering services requiring licensure, without a license.
499.0051(2) ~~499.0051(3)~~	2nd	Knowing forgery of transaction history, transaction information, or transaction statement ~~pedigree papers~~.
499.0051(3)	2nd	Knowing purchase or receipt of

~~499.0051(4)~~		prescription drug from unauthorized person.
499.0051(4) ~~499.0051(5)~~	2nd	Knowing sale or transfer of prescription drug to unauthorized person.
775.0875(1)	3rd	Taking firearm from law enforcement officer.
784.021(1)(a)	3rd	Aggravated assault; deadly weapon without intent to kill.
784.021(1)(b)	3rd	Aggravated assault; intent to commit felony.
784.041	3rd	Felony battery; domestic battery by strangulation.
784.048(3)	3rd	Aggravated stalking; credible threat.
784.048(5)	3rd	Aggravated stalking of person under 16.
784.07(2)(c)	2nd	Aggravated assault on law

		enforcement officer.
784.074(1)(b)	2nd	Aggravated assault on sexually violent predators facility staff.
784.08(2)(b)	2nd	Aggravated assault on a person 65 years of age or older.
784.081(2)	2nd	Aggravated assault on specified official or employee.
784.082(2)	2nd	Aggravated assault by detained person on visitor or other detainee.
784.083(2)	2nd	Aggravated assault on code inspector.
787.02(2)	3rd	False imprisonment; restraining with purpose other than those in s. 787.01.
790.115(2)(d)	2nd	Discharging firearm or weapon on school property.

790.161(2)	2nd	Make, possess, or throw destructive device with intent to do bodily harm or damage property.
790.164(1)	2nd	False report of deadly explosive, weapon of mass destruction, or act of arson or violence to state property.
790.19	2nd	Shooting or throwing deadly missiles into dwellings, vessels, or vehicles.
794.011(8)(a)	3rd	Solicitation of minor to participate in sexual activity by custodial adult.
794.05(1)	2nd	Unlawful sexual activity with specified minor.
800.04(5)(d)	3rd	Lewd or lascivious molestation; victim 12 years of age or older but less than 16 years of age; offender less than 18 years.

800.04(6)(b)	2nd	Lewd or lascivious conduct; offender 18 years of age or older.
806.031(2)	2nd	Arson resulting in great bodily harm to firefighter or any other person.
810.02(3)(c)	2nd	Burglary of occupied structure; unarmed; no assault or battery.
810.145(8)(b)	2nd	Video voyeurism; certain minor victims; 2nd or subsequent offense.
812.014(2)(b)1.	2nd	Property stolen $20,000 or more, but less than $100,000, grand theft in 2nd degree.
812.014(6)	2nd	Theft; property stolen $3,000 or more; coordination of others.
812.015(9)(a)	2nd	Retail theft; property stolen $300 or more; second or subsequent conviction.

812.015(9)(b)	2nd	Retail theft; property stolen $3,000 or more; coordination of others.
812.13(2)(c)	2nd	Robbery, no firearm or other weapon (strong-arm robbery).
817.4821(5)	2nd	Possess cloning paraphernalia with intent to create cloned cellular telephones.
825.102(1)	3rd	Abuse of an elderly person or disabled adult.
825.102(3)(c)	3rd	Neglect of an elderly person or disabled adult.
825.1025(3)	3rd	Lewd or lascivious molestation of an elderly person or disabled adult.
825.103(3)(c)	3rd	Exploiting an elderly person or disabled adult and property is valued at less than $10,000.

827.03(2)(c)	3rd	Abuse of a child.
827.03(2)(d)	3rd	Neglect of a child.
827.071(2) & (3)	2nd	Use or induce a child in a sexual performance, or promote or direct such performance.
836.05	2nd	Threats; extortion.
836.10	2nd	Written threats to kill or do bodily injury.
843.12	3rd	Aids or assists person to escape.
847.011	3rd	Distributing, offering to distribute, or possessing with intent to distribute obscene materials depicting minors.
847.012	3rd	Knowingly using a minor in the production of materials harmful to minors.
847.0135(2)	3rd	Facilitates sexual conduct of

			or with a minor or the visual depiction of such conduct.
2700			
	914.23	2nd	Retaliation against a witness, victim, or informant, with bodily injury.
2701			
	944.35(3)(a)2.	3rd	Committing malicious battery upon or inflicting cruel or inhuman treatment on an inmate or offender on community supervision, resulting in great bodily harm.
2702			
	944.40	2nd	Escapes.
2703			
	944.46	3rd	Harboring, concealing, aiding escaped prisoners.
2704			
	944.47(1)(a)5.	2nd	Introduction of contraband (firearm, weapon, or explosive) into correctional facility.
2705			
	951.22(1)	3rd	Intoxicating drug, firearm, or weapon introduced into county facility.

Section 20. This act shall take effect July 1, 2016.

COMMITTEE/SUBCOMMITTEE AMENDMENT

Bill No. HB 1211 (2016)

Amendment No. 1

COMMITTEE/SUBCOMMITTEE ACTION		
ADOPTED	__	(Y/N)
ADOPTED AS AMENDED	__	(Y/N)
ADOPTED W/O OBJECTION	__	(Y/N)
FAILED TO ADOPT	__	(Y/N)
WITHDRAWN	__	(Y/N)
OTHER	_____	

Committee/Subcommittee hearing bill: Health Quality Subcommittee

Representative Plakon offered the following:

Amendment (with title amendment)

Remove lines 2364-2422 and insert:

Section 9. Subsection (4) of section 499.015, Florida Statutes, is amended to read:

499.015 Registration of drugs, devices, and cosmetics; issuance of certificates of free sale.—

(4) Unless a registration is renewed, it expires 2 years after the last day of the month in which it was issued. Any product registration issued or renewed on or after July 1, 2016, shall expire on the same date as the manufacturer or repackager permit of the person seeking to register the product. If the first product registration issued to a person on or after July 1, 2016, expires less than 366 days after issuance, the fee for

product registration shall be $15. If the first product registration issued to a person on or after July 1, 2016, expires more than 365 days after issuance, the fee for product registration shall be $30. The department may issue a stop-sale notice or order against a person that is subject to the requirements of this section and that fails to comply with this section within 31 days after the date the registration expires. The notice or order shall prohibit such person from selling or causing to be sold any drugs, devices, or cosmetics covered by this part until he or she complies with the requirements of this section.

T I T L E A M E N D M E N T

Remove lines 67-74 and insert:

499.015, F.S.; providing for the expiration, renewal, and issuance of certain product registrations; providing for product registration fees; amending ss. 499.03, 499.05, and

Amendment No. 2

COMMITTEE/SUBCOMMITTEE ACTION

ADOPTED	____	(Y/N)
ADOPTED AS AMENDED	____	(Y/N)
ADOPTED W/O OBJECTION	____	(Y/N)
FAILED TO ADOPT	____	(Y/N)
WITHDRAWN	____	(Y/N)
OTHER		

Committee/Subcommittee hearing bill: Health Quality Subcommittee

Representative Plakon offered the following:

Amendment (with title amendment)

Remove lines 2584-2707 and insert:

Section 18. Paragraph (b) of subsection (1) of section 499.067, Florida Statutes, is amended to read:

499.067 Denial, suspension, or revocation of permit, certification, or registration.—

(1)

(b) The department may deny an application for a permit or certification, or suspend or revoke a permit or certification, if the department finds that:

1. The applicant is not of good moral character or that it would be a danger or not in the best interest of the public

health, safety, and welfare if the applicant were issued a permit or certification.

2. The applicant has not met the requirements for the permit or certification.

3. The applicant is not eligible for a permit or certification for any of the reasons enumerated in s. 499.012.

4. The applicant, permittee, or person certified under s. 499.012(15) ~~s. 499.012(16)~~ demonstrates any of the conditions enumerated in s. 499.012.

5. The applicant, permittee, or person certified under s. 499.012(15) ~~s. 499.012(16)~~ has committed any violation of this chapter.

Section 19. Subsection (1) of section 794.075, Florida Statutes, is amended to read:

794.075 Sexual predators; erectile dysfunction drugs.—

(1) A person may not possess a prescription drug, as defined in s. 499.003(40) ~~499.003(43)~~, for the purpose of treating erectile dysfunction if the person is designated as a sexual predator under s. 775.21.

Section 20. Paragraphs (d), (f), (i), and (j) of subsection (3) of section 921.0022, Florida Statutes, are amended to read:

921.0022 Criminal Punishment Code; offense severity ranking chart.—

(3) OFFENSE SEVERITY RANKING CHART

(d) LEVEL 4

Florida Statute	Felony Degree	Description
316.1935(3)(a)	2nd	Driving at high speed or with wanton disregard for safety while fleeing or attempting to elude law enforcement officer who is in a patrol vehicle with siren and lights activated.
499.0051(1)	3rd	Failure to maintain or deliver transaction history, transaction information, or transaction statements ~~pedigree papers~~.
~~499.0051(2)~~	~~3rd~~	~~Failure to authenticate pedigree papers.~~
499.0051(5) ~~499.0051(6)~~	2nd	Knowing sale or delivery, or possession with intent to sell, contraband prescription drugs.
517.07(1)	3rd	Failure to register securities.

517.12(1)	3rd	Failure of dealer, associated person, or issuer of securities to register.
784.07(2)(b)	3rd	Battery of law enforcement officer, firefighter, etc.
784.074(1)(c)	3rd	Battery of sexually violent predators facility staff.
784.075	3rd	Battery on detention or commitment facility staff.
784.078	3rd	Battery of facility employee by throwing, tossing, or expelling certain fluids or materials.
784.08(2)(c)	3rd	Battery on a person 65 years of age or older.
784.081(3)	3rd	Battery on specified official or employee.
784.082(3)	3rd	Battery by detained person on visitor or other detainee.

784.083(3)	3rd	Battery on code inspector.
784.085	3rd	Battery of child by throwing, tossing, projecting, or expelling certain fluids or materials.
787.03(1)	3rd	Interference with custody; wrongly takes minor from appointed guardian.
787.04(2)	3rd	Take, entice, or remove child beyond state limits with criminal intent pending custody proceedings.
787.04(3)	3rd	Carrying child beyond state lines with criminal intent to avoid producing child at custody hearing or delivering to designated person.
787.07	3rd	Human smuggling.
790.115(1)	3rd	Exhibiting firearm or weapon within 1,000 feet of a school.

790.115(2)(b)	3rd	Possessing electric weapon or device, destructive device, or other weapon on school property.
790.115(2)(c)	3rd	Possessing firearm on school property.
800.04(7)(c)	3rd	Lewd or lascivious exhibition; offender less than 18 years.
810.02(4)(a)	3rd	Burglary, or attempted burglary, of an unoccupied structure; unarmed; no assault or battery.
810.02(4)(b)	3rd	Burglary, or attempted burglary, of an unoccupied conveyance; unarmed; no assault or battery.
810.06	3rd	Burglary; possession of tools.
810.08(2)(c)	3rd	Trespass on property, armed with firearm or dangerous weapon.
812.014(2)(c)3.	3rd	Grand theft, 3rd degree $10,000 or more but less than $20,000.

812.014 (2)(c)4.-10.	3rd	Grand theft, 3rd degree, a will, firearm, motor vehicle, livestock, etc.
812.0195(2)	3rd	Dealing in stolen property by use of the Internet; property stolen $300 or more.
817.563(1)	3rd	Sell or deliver substance other than controlled substance agreed upon, excluding s. 893.03(5) drugs.
817.568(2)(a)	3rd	Fraudulent use of personal identification information.
817.625(2)(a)	3rd	Fraudulent use of scanning device or reencoder.
828.125(1)	2nd	Kill, maim, or cause great bodily harm or permanent breeding disability to any registered horse or cattle.
837.02(1)	3rd	Perjury in official proceedings.

837.021(1)	3rd	Make contradictory statements in official proceedings.
838.022	3rd	Official misconduct.
839.13(2)(a)	3rd	Falsifying records of an individual in the care and custody of a state agency.
839.13(2)(c)	3rd	Falsifying records of the Department of Children and Families.
843.021	3rd	Possession of a concealed handcuff key by a person in custody.
843.025	3rd	Deprive law enforcement, correctional, or correctional probation officer of means of protection or communication.
843.15(1)(a)	3rd	Failure to appear while on bail for felony (bond estreature or bond jumping).

847.0135(5)(c)	3rd	Lewd or lascivious exhibition using computer; offender less than 18 years.
874.05(1)(a)	3rd	Encouraging or recruiting another to join a criminal gang.
893.13(2)(a)1.	2nd	Purchase of cocaine (or other s. 893.03(1)(a), (b), or (d), (2)(a), (2)(b), or (2)(c)4. drugs).
914.14(2)	3rd	Witnesses accepting bribes.
914.22(1)	3rd	Force, threaten, etc., witness, victim, or informant.
914.23(2)	3rd	Retaliation against a witness, victim, or informant, no bodily injury.
918.12	3rd	Tampering with jurors.
934.215	3rd	Use of two-way communications device to facilitate commission

of a crime.

(f) LEVEL 6

Florida Statute	Felony Degree	Description
316.027(2)(b)	2nd	Leaving the scene of a crash involving serious bodily injury.
316.193(2)(b)	3rd	Felony DUI, 4th or subsequent conviction.
400.9935(4)(c)	2nd	Operating a clinic, or offering services requiring licensure, without a license.
499.0051(2) ~~499.0051(3)~~	2nd	Knowing forgery of transaction history, transaction information, or transaction statement ~~pedigree papers~~.
499.0051(3) ~~499.0051(4)~~	2nd	Knowing purchase or receipt of prescription drug from unauthorized person.

499.0051(4) ~~499.0051(5)~~	2nd	Knowing sale or transfer of prescription drug to unauthorized person.
775.0875(1)	3rd	Taking firearm from law enforcement officer.
784.021(1)(a)	3rd	Aggravated assault; deadly weapon without intent to kill.
784.021(1)(b)	3rd	Aggravated assault; intent to commit felony.
784.041	3rd	Felony battery; domestic battery by strangulation.
784.048(3)	3rd	Aggravated stalking; credible threat.
784.048(5)	3rd	Aggravated stalking of person under 16.
784.07(2)(c)	2nd	Aggravated assault on law enforcement officer.

784.074(1)(b)	2nd	Aggravated assault on sexually violent predators facility staff.
784.08(2)(b)	2nd	Aggravated assault on a person 65 years of age or older.
784.081(2)	2nd	Aggravated assault on specified official or employee.
784.082(2)	2nd	Aggravated assault by detained person on visitor or other detainee.
784.083(2)	2nd	Aggravated assault on code inspector.
787.02(2)	3rd	False imprisonment; restraining with purpose other than those in s. 787.01.
790.115(2)(d)	2nd	Discharging firearm or weapon on school property.
790.161(2)	2nd	Make, possess, or throw destructive device with intent

		to do bodily harm or damage property.
790.164(1)	2nd	False report of deadly explosive, weapon of mass destruction, or act of arson or violence to state property.
790.19	2nd	Shooting or throwing deadly missiles into dwellings, vessels, or vehicles.
794.011(8)(a)	3rd	Solicitation of minor to participate in sexual activity by custodial adult.
794.05(1)	2nd	Unlawful sexual activity with specified minor.
800.04(5)(d)	3rd	Lewd or lascivious molestation; victim 12 years of age or older but less than 16 years of age; offender less than 18 years.
800.04(6)(b)	2nd	Lewd or lascivious conduct; offender 18 years of age or

		older.
806.031(2)	2nd	Arson resulting in great bodily harm to firefighter or any other person.
810.02(3)(c)	2nd	Burglary of occupied structure; unarmed; no assault or battery.
810.145(8)(b)	2nd	Video voyeurism; certain minor victims; 2nd or subsequent offense.
812.014(2)(b)1.	2nd	Property stolen $20,000 or more, but less than $100,000, grand theft in 2nd degree.
812.014(6)	2nd	Theft; property stolen $3,000 or more; coordination of others.
812.015(9)(a)	2nd	Retail theft; property stolen $300 or more; second or subsequent conviction.
812.015(9)(b)	2nd	Retail theft; property stolen $3,000 or more; coordination of

		others.
812.13(2)(c)	2nd	Robbery, no firearm or other weapon (strong-arm robbery).
817.4821(5)	2nd	Possess cloning paraphernalia with intent to create cloned cellular telephones.
825.102(1)	3rd	Abuse of an elderly person or disabled adult.
825.102(3)(c)	3rd	Neglect of an elderly person or disabled adult.
825.1025(3)	3rd	Lewd or lascivious molestation of an elderly person or disabled adult.
825.103(3)(c)	3rd	Exploiting an elderly person or disabled adult and property is valued at less than $10,000.
827.03(2)(c)	3rd	Abuse of a child.
827.03(2)(d)	3rd	Neglect of a child.

827.071(2) & (3)	2nd	Use or induce a child in a sexual performance, or promote or direct such performance.
836.05	2nd	Threats; extortion.
836.10	2nd	Written threats to kill or do bodily injury.
843.12	3rd	Aids or assists person to escape.
847.011	3rd	Distributing, offering to distribute, or possessing with intent to distribute obscene materials depicting minors.
847.012	3rd	Knowingly using a minor in the production of materials harmful to minors.
847.0135(2)	3rd	Facilitates sexual conduct of or with a minor or the visual depiction of such conduct.

914.23	2nd	Retaliation against a witness, victim, or informant, with bodily injury.
944.35(3)(a)2.	3rd	Committing malicious battery upon or inflicting cruel or inhuman treatment on an inmate or offender on community supervision, resulting in great bodily harm.
944.40	2nd	Escapes.
944.46	3rd	Harboring, concealing, aiding escaped prisoners.
944.47(1)(a)5.	2nd	Introduction of contraband (firearm, weapon, or explosive) into correctional facility.
951.22(1)	3rd	Intoxicating drug, firearm, or weapon introduced into county facility.

(i) LEVEL 9

Florida Statute	Felony Degree	Description
316.193 (3)(c)3.b.	1st	DUI manslaughter; failing to render aid or give information.
327.35 (3)(c)3.b.	1st	BUI manslaughter; failing to render aid or give information.
409.920 (2)(b)1.c.	1st	Medicaid provider fraud; $50,000 or more.
499.0051(8) ~~499.0051(9)~~	1st	Knowing sale or purchase of contraband prescription drugs resulting in great bodily harm.
560.123(8)(b)3.	1st	Failure to report currency or payment instruments totaling or exceeding $100,000 by money transmitter.
560.125(5)(c)	1st	Money transmitter business

			by unauthorized person, currency, or payment instruments totaling or exceeding $100,000.
163			
	655.50(10)(b)3.	1st	Failure to report financial transactions totaling or exceeding $100,000 by financial institution.
164			
	775.0844	1st	Aggravated white collar crime.
165			
	782.04(1)	1st	Attempt, conspire, or solicit to commit premeditated murder.
166			
	782.04(3)	1st,PBL	Accomplice to murder in connection with arson, sexual battery, robbery, burglary, aggravated fleeing or eluding with serious bodily injury or death, and other specified

felonies.

782.051(1)	1st	Attempted felony murder while perpetrating or attempting to perpetrate a felony enumerated in s. 782.04(3).
782.07(2)	1st	Aggravated manslaughter of an elderly person or disabled adult.
787.01(1)(a)1.	1st,PBL	Kidnapping; hold for ransom or reward or as a shield or hostage.
787.01(1)(a)2.	1st,PBL	Kidnapping with intent to commit or facilitate commission of any felony.
787.01(1)(a)4.	1st,PBL	Kidnapping with intent to interfere with performance of any

			governmental or political function.
787.02(3)(a)		1st,PBL	False imprisonment; child under age 13; perpetrator also commits aggravated child abuse, sexual battery, or lewd or lascivious battery, molestation, conduct, or exhibition.
787.06(3)(c)1.		1st	Human trafficking for labor and services of an unauthorized alien child.
787.06(3)(d)		1st	Human trafficking using coercion for commercial sexual activity of an unauthorized adult alien.
787.06(3)(f)1.		1st,PBL	Human trafficking for commercial sexual activity by the transfer or transport of any child from

			outside Florida to within the state.
790.161	1st	Attempted capital destructive device offense.	
790.166(2)	1st,PBL	Possessing, selling, using, or attempting to use a weapon of mass destruction.	
794.011(2)	1st	Attempted sexual battery; victim less than 12 years of age.	
794.011(2)	Life	Sexual battery; offender younger than 18 years and commits sexual battery on a person less than 12 years.	
794.011(4)(a)	1st,PBL	Sexual battery, certain circumstances; victim 12 years of age or older but younger than 18 years;	

			offender 18 years or older.
794.011(4)(b)		1st	Sexual battery, certain circumstances; victim and offender 18 years of age or older.
794.011(4)(c)		1st	Sexual battery, certain circumstances; victim 12 years of age or older; offender younger than 18 years.
794.011(4)(d)		1st,PBL	Sexual battery, certain circumstances; victim 12 years of age or older; prior conviction for specified sex offenses.
794.011(8)(b)		1st,PBL	Sexual battery; engage in sexual conduct with minor 12 to 18 years by person in familial or custodial

			authority.
794.08(2)	1st	Female genital mutilation; victim younger than 18 years of age.	
800.04(5)(b)	Life	Lewd or lascivious molestation; victim less than 12 years; offender 18 years or older.	
812.13(2)(a)	1st,PBL	Robbery with firearm or other deadly weapon.	
812.133(2)(a)	1st,PBL	Carjacking; firearm or other deadly weapon.	
812.135(2)(b)	1st	Home-invasion robbery with weapon.	
817.535(3)(b)	1st	Filing false lien or other unauthorized document; second or subsequent offense; property owner is	

			a public officer or employee.
191			
	817.535(4)(a)2.	1st	Filing false claim or other unauthorized document; defendant is incarcerated or under supervision.
192			
	817.535(5)(b)	1st	Filing false lien or other unauthorized document; second or subsequent offense; owner of the property incurs financial loss as a result of the false instrument.
193			
	817.568(7)	2nd, PBL	Fraudulent use of personal identification information of an individual under the age of 18 by his or her parent, legal guardian, or person exercising custodial authority.
194			
	827.03(2)(a)	1st	Aggravated child abuse.
195			

847.0145(1)	1st	Selling, or otherwise transferring custody or control, of a minor.
847.0145(2)	1st	Purchasing, or otherwise obtaining custody or control, of a minor.
859.01	1st	Poisoning or introducing bacteria, radioactive materials, viruses, or chemical compounds into food, drink, medicine, or water with intent to kill or injure another person.
893.135	1st	Attempted capital trafficking offense.
893.135(1)(a)3.	1st	Trafficking in cannabis, more than 10,000 lbs.
893.135 (1)(b)1.c.	1st	Trafficking in cocaine, more than 400 grams, less than 150 kilograms.

893.135 (1)(c)1.c.	1st	Trafficking in illegal drugs, more than 28 grams, less than 30 kilograms.
893.135 (1)(c)2.d.	1st	Trafficking in hydrocodone, 200 grams or more, less than 30 kilograms.
893.135 (1)(c)3.d.	1st	Trafficking in oxycodone, 100 grams or more, less than 30 kilograms.
893.135 (1)(d)1.c.	1st	Trafficking in phencyclidine, more than 400 grams.
893.135 (1)(e)1.c.	1st	Trafficking in methaqualone, more than 25 kilograms.
893.135 (1)(f)1.c.	1st	Trafficking in amphetamine, more than 200 grams.
893.135 (1)(h)1.c.	1st	Trafficking in gamma-hydroxybutyric acid (GHB), 10 kilograms or more.
893.135	1st	Trafficking in 1,4-

(1)(j)1.c.		Butanediol, 10 kilograms or more.
893.135 (1)(k)2.c.	1st	Trafficking in Phenethylamines, 400 grams or more.
896.101(5)(c)	1st	Money laundering, financial instruments totaling or exceeding $100,000.
896.104(4)(a)3.	1st	Structuring transactions to evade reporting or registration requirements, financial transactions totaling or exceeding $100,000.

(j) LEVEL 10

Florida Statute	Felony Degree	Description
499.0051(9) ~~499.0051(10)~~	1st	Knowing sale or purchase of contraband prescription drugs resulting in death.

782.04(2)	1st,PBL	Unlawful killing of human; act is homicide, unpremeditated.
782.07(3)	1st	Aggravated manslaughter of a child.
787.01(1)(a)3.	1st,PBL	Kidnapping; inflict bodily harm upon or terrorize victim.
787.01(3)(a)	Life	Kidnapping; child under age 13, perpetrator also commits aggravated child abuse, sexual battery, or lewd or lascivious battery, molestation, conduct, or exhibition.
787.06(3)(g)	Life	Human trafficking for commercial sexual activity of a child under the age of 18 or mentally defective or incapacitated person.

787.06(4)(a)	Life	Selling or buying of minors into human trafficking.
794.011(3)	Life	Sexual battery; victim 12 years or older, offender uses or threatens to use deadly weapon or physical force to cause serious injury.
812.135(2)(a)	1st,PBL	Home-invasion robbery with firearm or other deadly weapon.
876.32	1st	Treason against the state.

Section 21. This act shall take effect July 1, 2016

T I T L E A M E N D M E N T

Remove line 88 and insert:
499.067, 794.075, and 921.0022, F.S.; conforming provisions to

Amendment No. 3

COMMITTEE/SUBCOMMITTEE ACTION	
ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Committee/Subcommittee hearing bill: Health Quality Subcommittee

Representative Plakon offered the following:

Amendment (with directory and title amendments)

Between lines 2363 and 2364, insert:

(15) DUE DILIGENCE OF PURCHASERS.—

(b) A wholesale distributor must take reasonable measures to identify its customers, understand the normal and expected transactions conducted by those customers, and identify those transactions that are suspicious in nature. A wholesale distributor must establish internal policies and procedures for identifying suspicious orders and preventing suspicious transactions. A wholesale distributor must assess orders for greater than 7,500 ~~5,000~~ unit doses of any one controlled substance in any one month to determine whether the purchase is reasonable. In making such assessments, a wholesale distributor

may consider the purchasing entity's clinical business needs, location, and population served, in addition to other factors established in the distributor's policies and procedures. A wholesale distributor must report to the department any regulated transaction involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance that the regulated person believes may indicate that the listed chemical will be used in violation of the law. The wholesale distributor shall maintain records that document the report submitted to the department in compliance with this paragraph.

D I R E C T O R Y A M E N D M E N T

Remove lines 2295-2296 and insert:

Section 8. Paragraph (d) of subsection (4), subsection (6), and paragraph (b) of subsection (15) of section 499.0121, Florida Statutes, are amended to read:

T I T L E A M E N D M E N T

Remove line 66 and insert:

ingredients; requiring a wholesale distributor to perform an assessment of orders over a certain number of unit doses of a controlled substance; conforming provisions; amending s.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1277 Licensure of Foreign-Trained Physicians
SPONSOR(S): Campbell
TIED BILLS: **IDEN./SIM. BILLS:** SB 1626

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee		Siples	O'Callaghan
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

The Department of Health (DOH), in conjunction with the Board of Medicine (board), oversees the licensure and regulation of allopathic physicians in this state, pursuant to ch. 458, F.S. Florida law prescribes the minimum standards an applicant for licensure must meet to be licensed as a physician.

For licensure by examination, an applicant must meet minimum medical education and postgraduate training standards, as well as achieve an acceptable score on a board-approved national licensing examination. Licensure by endorsement is available to an individual who is licensed in another state or U.S. territory for a specified period of time, and who can demonstrate compliance with the minimum medical education and postgraduate training standards, as well as a passing score on a board-approved national licensing examination.

The bill provides an alternative option for graduates of foreign medical schools to meet the education and training requirements for licensure as a physician. The bill allows a graduate of an allopathic foreign medical school listed in the World Directory of Medical Schools that has not been certified by the state, pursuant to s. 458.314, F.S., to apply for licensure. The World Directory of Medical Schools is a world-wide directory of medical schools that was jointly developed by the World Federation for Medical Education and the Foundation for Advancement of International Medical Education and Research, in collaboration with the World Health Organization and the University of Copenhagen. The applicant must also demonstrate that he or she is proficient in English, has completed a board-approved residency or fellowship of at least one year, and has held an active physician license and practiced medicine in a foreign jurisdiction for at least the 10 years immediately preceding the date of application for licensure.

The bill also provides that a foreign medical school graduate, who applies for licensure pursuant to its provisions, may meet the licensure examination requirement by achieving a passing score on an examination that the board determines is substantially equivalent to, or more stringent than, the United States Medical Licensing Examination (USMLE).

The bill provides that the board may certify an applicant for licensure who meets the education and training requirements, as well as any other licensure requirements, with a condition, limitation, or restriction, including a probationary period, a scope of practice limitation, or a supervision requirement, to be imposed by the DOH, for a duration specified by the board.

The bill may have an indeterminate, negative fiscal impact on the DOH and no fiscal impact on local governments.

The effective date of the bill is July 1, 2016.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Licensure and Regulation of Physicians

Chapter 458, F.S., provides for the licensure and regulation of the practice of medicine by the Florida Board of Medicine (board) in conjunction the Department of Health (DOH). The chapter provides, among other things, licensure requirements by examination for medical school graduates and licensure by endorsement requirements.

Licensure by Examination

An individual seeking to be licensed by examination as a medical doctor, must meet the following requirements:[1]

- Pay an application fee;[2]
- Be at least 21 years of age;
- Be of good moral character;
- Has not committed an act or offense that would constitute the basis for disciplining a physician, pursuant to s. 458.331, F.S.;
- Complete 2 years of post-secondary education which includes, at a minimum, courses in fields such as anatomy, biology, and chemistry prior to entering medical school;
- Meets one of the following medical education and postgraduate training requirements:
    - Is a graduate of an allopathic medical school recognized and approved by an accrediting agency recognized by the U.S. Office of Education or recognized by an appropriate governmental body of a U.S. territorial jurisdiction, and has completed at least one year of approved residency training;
    - Is a graduate of an allopathic foreign medical school registered with the World Health Organization and certified pursuant to statute as meeting the standards required to accredit U.S. medical schools, and has completed at least one year of approved residency training; or
    - Is a graduate of an allopathic foreign medical school that has not been certified pursuant to statute; has an active, valid certificate issued by the Educational Commission for Foreign Medical Graduates (ECFMG),[3] has passed that commission's examination; and has completed an approved residency or fellowship of at least 2 years in one specialty area;
- Has submitted to a background screening by the DOH; and
- Has obtained a passing score on:
    - The United States Medical Licensing Examination (USMLE);
    - A combination of the USMLE, the examination of the Federation of State Medical Boards of the United States, Inc. (FLEX), or the examination of the National Board of Medical Examiners up to the year 2000; or

[1] Section 458.311(1), F.S.
[2] Pursuant to r. 64B8-3.002(5), F.A.C., the application fee for a person desiring to be licensed as a physician by examination is $500. The applicant must pay an initial license fee of $429. Section 766.314(4), F.S., assesses a fee to be paid with at time of an initial license to finance the Florida Birth-Related Neurological Injury Compensation Plan. The current assessment amount is $250.
[3] A graduate of a foreign medical school does not need to present an ECFMG certification or pass its exam if the graduate received his or bachelor's degree from an accredited U.S. college or university, studied at a medical school recognized by the World Health Organization, and has completed all but the internship or social service requirements, has passed parts I and II of the National Board Medical Examiners licensing examination or the ECFMG equivalent examination. (Section 458.311, F.S.)

- The Special Purpose Examination of the Federation of State Medical Boards of the United States (SPEX), if the applicant was licensed on the basis of a state board examination, is currently licensed in at least one other jurisdiction of the United States or Canada, and has practiced for a period of at least 10 years.

Licensure by Endorsement

An individual who holds an active license to practice medicine in another jurisdiction may seek licensure by endorsement to practice medicine in Florida.[4] The applicant must meet the same requirements for licensure by examination. To qualify for licensure by endorsement, the applicant must also submit evidence of the licensed active practice of medicine in another jurisdiction for at least 2 of the preceding 4 years, or evidence of successful completion of either a board-approved postgraduate training program within 2 years preceding filing of an application or a board-approved clinical competency examination within the year preceding the filing of an application for licensure.

When the board determines that any applicant for licensure by endorsement has failed to meet, to the board's satisfaction, each of the appropriate requirements for licensure by endorsement, it may enter an order requiring one or more of the following terms:

- Refusal to certify to the DOH an application for licensure, certification, or registration;
- Certification to the DOH of an application for licensure, certification, or registration with restrictions on the scope of practice of the licensee; or
- Certification to the DOH of an application for licensure, certification, or registration with placement of the physician on probation for a period of time and subject to such conditions as the board may specify, including, but not limited to, requiring the physician to submit to treatment, attend continuing education courses, submit to reexamination, or work under the supervision of another physician.

Certification of Foreign Educational Institutions

Section 458.314, F.S., authorizes the DOH to develop standards and a process by which a foreign medical school may be certified as meeting standards comparable to those required for the accreditation of a U.S. medical school. A graduate of a foreign medical school certified as meeting the DOH's standards is eligible for licensure as a medical doctor after obtaining a passing score on a medical licensure examination, demonstrating proficiency in English, and successfully completing one year of graduate training in an approved program.[5] In determining whether a foreign medical school is to be certified, the DOH will evaluate several areas, including governance, administration, curriculum, admissions, class size, and the availability of resources, such as faculty and budget.[6]

World Directory of Medical Schools

The World Directory of Medical Schools (world directory) is a world-wide database of medical schools jointly developed by the World Federation for Medical Education and the Foundation for Advancement of International Medical Education and Research (FAIMER), in collaboration with the World Health Organization and the University of Copenhagen.[7] The data contained in the world directory was derived from the University of Copenhagen's Avicenna Directory, which was the successor of the World Health Organization's World Directory of Medical Schools, and the International Medical Education Directory compiled by FAIMER. [8] The information provided in the International Medical Education Directory was

[4] Section 458.313, F.S.
[5] Rule 64B8-15, F.A.C. Prior to being admitted to an approved residency program, the Accreditation Council for Graduate Medical Education must verify that the foreign medical graduate has been certified by the ECFMG.
[6] *See generally* Rule 64B8-15, F.A.C.
[7] World Directory of Medical Schools, *About the World Directory*, *available at* http://www.wdoms.org/about/ (last visited Jan. 13, 2016).
[8] World Directory of Medical Schools, *History of the World Directory of Medical Schools*, *available at* http://www.wdoms.org/history/ (last visited Jan. 13, 2016). The Avicenna Directory is managed by the World Federation for Medical Education.

derived from data collected by the ECFMG throughout its history of evaluating the medical credentials of graduates of foreign medical schools.

The world directory defines a "medical school" as an educational institution that provides a complete or full program leading to a basic medical qualification that permits the holder to obtain a license to practice as a medical doctor or physician.[9]

The database provides basic details about each medical school, such as contact information, operational status, the year instruction began, the percentage of clinical training and access to clinical facilities, curriculum duration, prerequisite education, and language of instruction, if available. However, being listed in the directory does not denote any recognition, accreditation, or endorsement by the world directory or the organizations producing the world directory.[10]

Effective June 30, 2015, the ECFMG uses the world directory to determine eligibility for certification of foreign medical graduates by its organization.[11] If a foreign medical school meets the ECFMG requirements, the school's profile contains a notation of such and its graduates are eligible to apply for ECFMG certification and the USMLE. However, if the medical school is not listed in the world directory or it is listed but its profile does not have the ECFMG notation, its students are ineligible to apply for ECFMG certification and the USMLE.

Effect of the Proposed Changes

All applicants for licensure as a physician must meet minimum medical educational standards by graduating from an accredited or government approved medical school and successfully completing postgraduate training requirements. The bill provides an additional option that graduates of foreign medical schools may use to meet the education requirements for licensure by examination. To qualify for licensure as a physician by examination, the bill allows a graduate of an allopathic foreign medical school listed in the World Directory of Medical Schools that has not been certified by the state, pursuant to s. 458.314, F.S., to qualify for licensure, if the applicant meets the following:

- Demonstrates competency in English by obtaining a satisfactory score on an approved test, if the foreign medical school provides instruction in a language other than English;
- Has completed a board-approved residency or fellowship of at least 1 year in one specialty area, which counts towards the regular or subspecialty certification by a board recognized and certified by the American Board of Medical Specialties; and
- Has held an active physician license and has practiced medicine in a foreign jurisdiction for at least 10 years immediately preceding the date of application.

All licensure applicants must achieve a passing score on a board-approved licensure examination. The bill allows applicants who apply pursuant to this provision to meet the examination requirement by obtaining a passing score on an examination determined by the board to be substantially equivalent to, or more stringent than, the USMLE.

The bill permits the DOH to impose a condition, limitation, or restriction, including but not limited to, a probationary period of practice, a scope of practice limitation, or a supervision requirement for any applicant certified by the board to be licensed pursuant to the provisions of the bill, for a duration specified by the board.

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[9] *Supra* note 1.

[10] World Directory of Medical Schools, *Search the World Directory, available at* https://search.wdoms.org/ (last visited on Jan. 13, 2016).

[11] Educational Commission for Foreign Medical Graduates, *Update: World Directory of Medical Schools Replaces International Medical Education Directory for Purposes of Determining Eligibility for ECFMG Certification and USMLE*, (June 30, 2015), *available at* http://www.ecfmg.org/news/2015/06/30/update-world-directory-of-medical-schools-replaces-international-medical-education-directory-for-purposes-of-determining-eligibility-for-ecfmg-certification-and-usmle/ (last visited Jan. 13, 2016).

The bill provides an effective date of July 1, 2016.

B. SECTION DIRECTORY:

Section 1. Amends s. 458.311, F.S., relating to licensure by examination; requirements; fees.
Section 2. Provides an effective date of July 1, 2016.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   The bill may have an indeterminate, positive fiscal impact on the DOH. The DOH may collect application, licensure, and renewal fees from additional individuals that may be eligible to apply for licensure.

2. Expenditures:

   The bill may have an indeterminate, insignificant fiscal impact on the DOH. The DOH may experience a recurring workload increase as additional individuals may be eligible to apply for licensure. The DOH may need to update its licensure software to include the additional educational qualifications.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

For foreign trained physicians intending to become licensed in Florida, this bill may result in cost savings associated with no longer having to take the USMLE or FLEX to become licensed if the foreign trained physician meets the new licensure criteria provided in the bill.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to licensure of foreign-trained physicians; amending s. 458.311, F.S.; establishing licensure requirements for certain foreign-trained physicians; authorizing the Board of Medicine to impose licensure restrictions, limitations, or conditions on certain foreign-trained physicians; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Paragraphs (f) and (h) of subsection (1) and subsection (7) of section 458.311, Florida Statutes, are amended to read:

458.311 Licensure by examination; requirements; fees.—

(1) Any person desiring to be licensed as a physician, who does not hold a valid license in any state, shall apply to the department on forms furnished by the department. The department shall license each applicant who the board certifies:

(f) Meets one of the following medical education and postgraduate training requirements:

1.a. Is a graduate of an allopathic medical school or allopathic college recognized and approved by an accrediting agency recognized by the United States Office of Education or is a graduate of an allopathic medical school or allopathic college within a territorial jurisdiction of the United States

recognized by the accrediting agency of the governmental body of that jurisdiction;

b. If the language of instruction of the medical school is other than English, has demonstrated competency in English through presentation of a satisfactory grade on the Test of Spoken English of the Educational Testing Service or a similar test approved by rule of the board; and

c. Has completed an approved residency of at least 1 year.

2.a. Is a graduate of an allopathic foreign medical school registered with the World Health Organization and certified pursuant to s. 458.314 as having met the standards required to accredit medical schools in the United States or reasonably comparable standards;

b. If the language of instruction of the foreign medical school is other than English, has demonstrated competency in English through presentation of the Educational Commission for Foreign Medical Graduates English proficiency certificate or by a satisfactory grade on the Test of Spoken English of the Educational Testing Service or a similar test approved by rule of the board; and

c. Has completed an approved residency of at least 1 year.

3.a. Is a graduate of an allopathic foreign medical school which has not been certified pursuant to s. 458.314;

b. Has had his or her medical credentials evaluated by the Educational Commission for Foreign Medical Graduates, holds an active, valid certificate issued by that commission, and has

passed the examination utilized by that commission; and

c. Has completed an approved residency of at least 1 year; however, after October 1, 1992, the applicant shall have completed an approved residency or fellowship of at least 2 years in one specialty area. However, to be acceptable, the fellowship experience and training must be counted toward regular or subspecialty certification by a board recognized and certified by the American Board of Medical Specialties.

4.a. Is a graduate of an allopathic foreign medical school listed in the World Directory of Medical Schools produced as a joint venture of the World Federation for Medical Education and the Foundation for Advancement of International Medical Education and Research, in collaboration with the World Health Organization, and accredited by an accrediting agency recognized by the governmental body of the foreign jurisdiction, but which is not certified pursuant to s. 458.314;

b. If the language of instruction of the foreign medical school is other than English, has demonstrated competency in English through presentation of a satisfactory grade on the Test of Spoken English of the Educational Testing Service or a similar test approved by rule of the board;

c. Has completed a board-approved residency or fellowship of at least 1 year in one specialty area, which must be counted toward regular or subspecialty certification by a board recognized and certified by the American Board of Medical Specialties; and

d. Has held an active physician license and practiced medicine in a foreign jurisdiction for at least the 10 years immediately preceding the application for licensure under this section.

(h) Has obtained a passing score, as established by rule of the board, on the licensure examination of the United States Medical Licensing Examination (USMLE); or a combination of the United States Medical Licensing Examination (USMLE), the examination of the Federation of State Medical Boards of the United States, Inc. (FLEX), or the examination of the National Board of Medical Examiners up to the year 2000; or for the purpose of examination of any applicant who was licensed on the basis of a state board examination and who is currently licensed in at least one other jurisdiction of the United States or Canada, and who has practiced pursuant to such licensure for a period of at least 10 years, use of the Special Purpose Examination of the Federation of State Medical Boards of the United States (SPEX) upon receipt of a passing score as established by rule of the board. An applicant meeting the medical education and postgraduate training requirements in subparagraph (f)4. may meet the examination requirement of this paragraph by obtaining a passing score on an examination determined by the board to be substantially equivalent to, or more stringent than, the United States Medical Licensing Examination (USMLE). However, for the purpose of examination of any applicant who was licensed on the basis of a state board

examination prior to 1974, who is currently licensed in at least three other jurisdictions of the United States or Canada, and who has practiced pursuant to such licensure for a period of at least 20 years, this paragraph does not apply.

(7) Upon certification by the board, the department shall impose conditions, limitations, or restrictions on a license if the applicant is on probation in another jurisdiction for an act which would constitute a violation of this chapter. The board may certify an applicant for licensure who has met the medical education and postgraduate training requirements under subparagraph (1)(f)4. and all other licensure requirements with a condition, limitation, or restriction, including, but not limited to, a probationary period of practice, a scope of practice limitation, or a supervision requirement, which shall be imposed by the department for a duration specified by the board.

Section 2. This act shall take effect July 1, 2016.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1313 Low-THC Cannabis
SPONSOR(S): Brodeur
TIED BILLS: None **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee		O'Callaghan	O'Callaghan
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

In 2014, the Legislature enacted the Compassionate Medical Cannabis Act (CMCA) to authorize dispensing organizations approved by the Department of Health (DOH) to manufacture, possess, sell, and dispense low-THC cannabis for medical use by patients suffering from cancer or a physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms. A physician may only order low-THC cannabis for medical use if the patient is a permanent resident of Florida, no other satisfactory alternative treatment option exists, the physician has determined that the risks of ordering the low-THC cannabis are reasonable in light of the potential benefit for the patient, and the physician has obtained voluntary informed consent to such treatment.

Under the CMCA, an applicant for approval as a dispensing organization has to meet certain criteria to be selected by DOH and DOH may select only five dispensing organizations in the state to grow, process, and dispense low-THC cannabis. Although there is specific criteria that must be met before DOH may approve an applicant as a dispensing organization, the CMCA does not include regulatory standards for the operation, security, and safety of dispensing organizations or the growing, processing, testing, packaging, labeling, dispensing, or transportation of low-THC cannabis.

The bill creates new regulatory standards for dispensing organizations, including standards for the growing, processing, testing, packaging, labeling, dispensing, and transportation of low-THC cannabis. The bill also provides DOH with greater regulatory oversight by authorizing DOH to perform inspections, create a patient and caregiver registration card system, assess fees and take disciplinary action, and create standards for laboratories testing low-THC cannabis.

The bill also increases the criteria a physician must meet to be eligible to order low-THC cannabis for a patient by requiring the physician to specialize in certain practice areas and specifying the length of time the physician must have treated the patient. The bill also limits a physician's order to a 30-day supply of low-THC cannabis. The bill prohibits a physician ordering low-THC cannabis from being employed by a dispensing organization and authorizes the appropriate regulatory board to take disciplinary action against a physician who orders low-THC cannabis and receives compensation from a dispensing organization related to the order.

The bill has an indeterminate negative fiscal impact on DOH and no fiscal impact on local governments.

The bill takes effect July 1, 2016.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Marijuana, also called cannabis, has been used for a variety of health conditions for at least 3,000 years.[1] Currently, the U.S. Food and Drug Administration (FDA) hasn't approved the use of cannabis to treat any health condition due to the lack of research to show that the benefits of using cannabis outweigh the risks.[2] However, based on the scientific study of cannabinoids, which are chemicals contained in cannabis, the FDA has approved two synthetic prescription drugs that contain certain cannabinoids.[3]

Although there are more than 100 cannabinoids in a marijuana plant, the two main cannabinoids of medical interest are delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD). THC is a mind-altering chemical that increases appetite and reduces nausea and may also decrease pain, inflammation, and muscle control problems. CBD is a chemical that does not affect the mind or behavior, but may be useful in reducing pain and inflammation, controlling epileptic seizures, and possibly treating mental illness and addictions.[4]

Research on the Medical Use of Cannabis

During the course of drug development, a typical compound is found to have some medical benefit and then extensive tests are undertaken to determine its safety and proper dosage for medical use.[5] In contrast, marijuana has been widely used in the United States for decades. In 2014, just over 49% of the U.S. population over 12 years old had tried marijuana or hashish at least once and just over 10% were current users.[6] The data on the adverse effects of marijuana are more extensive than the data on its effectiveness.[7] Clinical studies of marijuana are difficult to conduct as researchers interested in clinical studies of marijuana face a series of barriers, research funds are limited, and there is a daunting thicket of federal and state regulations to be negotiated.[8] In fact, recently, there has been an exponential rise in the use of marijuana compared to the rise in scientific knowledge of its benefits or adverse effects because some states have allowed the public or patients to access marijuana while the federal government continues to limit scientific and clinical investigators' access to marijuana for research.[9]

In 1999, the Institute of Medicine published a study based on a comprehensive review of existing scientific data and clinical studies pertaining to the medical value of marijuana.[10] The study concluded that there is potential therapeutic value of cannabinoid drugs, primarily THC, for pain relief, control of

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[1] U.S. Department of Health & Human Services, National Center for Complementary and Integrative Health, *Medical Marijuana, available at* https://nccih.nih.gov/health/marijuana (last visited on December 27, 2015).
[2] U.S. Department of Health & Human Services, National Center for Complementary and Integrative Health, *What is medical marijuana?, available at* http://www.drugabuse.gov/publications/drugfacts/marijuana-medicine (last visited on December 27, 2015).
[3] *Id.*
[4] *Id.*
[5] Institute of Medicine, *Marijuana and Medicine: Assessing the Science Base*, The National Academies Press, 1999, available at http://www.nap.edu/catalog/6376/marijuana-and-medicine-assessing-the-science-base (last visited on December 27, 2015).
[6] Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality, *Results from the 2014 National Survey on Drug Use and Health: Detailed Tables, available at* http://www.samhsa.gov/data/population-data-nsduh/reports (last visited on December 27, 2015).
[7] *Supra* note 5 at 137.
[8] *Id.*
[9] Friedman, Daniel, M.D., Devinsky, Orrin, M.D., *Cannabinoids in the Treatment of Epilepsy*, NEW ENG. J. MED., September 10, 2015, on file with the Health Quality Subcommittee.
[10] *Supra* note 5 at 179.

nausea and vomiting, and appetite stimulation.[11] The study reports that smoked marijuana, however, is a crude THC delivery system that also delivers harmful substances.[12]

The Institute of Medicine's study, which warned that smoking marijuana is harmful, was corroborated by a study published in the New England Journal of Medicine in 2014.[13] The 2014 study further warned that long-term marijuana use can lead to addiction and that adolescents have an increased vulnerability to adverse long-term outcomes from marijuana use.[14] Specifically, the study found that, as compared with persons who begin to use marijuana in adulthood, those who begin in adolescence are approximately 2 to 4 times as likely to have symptoms of cannabis dependence within 2 years after first use.[15] The study also found that cannabis-based treatment with THC may have irreversible effects on brain development in adolescents as the brain's endocannabinoid system undergoes development in childhood and adolescence.[16]

More recently, a study published in 2015 in the Journal of the American Medical Association found that there is moderate-quality evidence to support the use of cannabinoids for the treatment of chronic pain and spasticity and that there is low-quality evidence suggesting that cannabinoids are associated with improvements in nausea and vomiting due to chemotherapy, weight gain in HIV infection, sleep disorders, and Tourette syndrome.[17]

Despite the uncertainty of the efficacy of marijuana on various medical conditions, there has recently been much interest in the use of marijuana, especially the compound CBD, to treat epilepsy.[18] A few factors contributing to the interest of the public, media, and researchers in such treatment are that new anti-seizure drugs have not substantially reduced the proportion of patients with medically refractory seizures, the side effects of such drugs continue to have negative side effects to the central nervous system and affect quality of life, and there appears to be some evidence-based efficacy of such treatment based on case stories and limited preclinical and clinical studies.[19]

Federal Regulation of Cannabis

The Federal Controlled Substances Act[20] lists cannabis as a Schedule 1 drug, meaning it has a high potential for abuse, has no currently accepted medical use, and has a lack of accepted safety for use under medical supervision.[21] The Federal Controlled Substances Act imposes penalties on those who possess, sell, distribute, dispense, and use cannabis.[22] A first misdemeanor offense for possession of cannabis in any amount can result in a $1,000 fine and up to a year in prison, climbing for subsequent offenses to as much as $5,000 and three years.[23] Selling and cultivating cannabis are subject to even greater penalties.[24]

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[11] *Id.*
[12] *Id.*
[13] Volkow, N.D., Baler, R.D., Compton, W.M. and Weiss, S.R., *Adverse Health Effects of Marijuana Use*, NEW ENG. J. MED., June 5, 2014, *available at* dfaf.org/assets/docs/Adverse%20health%20effects.pdf (last visited on December 27, 2015).
[14] *Id.* at 2219.
[15] *Id.* at 2220.
[16] *Id.* at 2219.
[17] American Medical Association, *Cannabinoids for Medical Use: A Systematic Review and Meta-analysis*, JAMA, June 2015, on file with the Health Quality Subcommittee.
[18] *Supra* note 9 at 1048.
[19] *Supra* note 9 at 1048, 1052-1053, and 1056.
[20] 21 U.S.C. ss. 801-971.
[21] 21 U.S.C. s. 812.
[22] 21 U.S.C. ss. 841-65.
[23] 21 U.S.C. s. 844.
[24] 21 U.S.C. ss. 841-65.

In August of 2013, the United States Department of Justice (USDOJ) issued a publication entitled "Smart on Crime: Reforming the Criminal Justice System for the 21st Century."[25] This document details the federal government's changing stance on low-level drug crimes announcing a "change in Department of Justice charging policies so that certain people who have committed low-level, nonviolent drug offenses, who have no ties to large-scale organizations, gangs, or cartels will no longer be charged with offenses that impose draconian mandatory minimum sentences. Under the revised policy, these people would instead receive sentences better suited to their individual conduct rather than excessive prison terms more appropriate for violent criminals or drug kingpins."[26]

On August 29, 2013, United States Deputy Attorney General James Cole issued a memorandum to federal attorneys that appeared to relax the federal government's cannabis-related offense enforcement policies.[27] The memo stated that the USDOJ was committed to using its limited investigative and prosecutorial resources to address the most significant threats in the most effective, consistent, and rational ways, and outlined eight areas of enforcement priorities.[28] These enforcement priorities focused on offenses that would result in cannabis being distributed to minors, cannabis sale revenues going to criminal gangs or other similar organizations, and cannabis being grown on public lands.[29] The memo indicated that outside of the listed enforcement priorities, the federal government would not enforce federal cannabis-related laws in states that have legalized the drug and that have a robust regulatory scheme in place.[30]

In 2014, Congress enacted the Consolidated and Further Continuing Appropriations Act of 2015 (Appropriations Act of 2015). Section 538 of the Appropriations Act of 2015 prohibits the USDOJ from expending any funds in connection with the enforcement of any law that interferes with a state's ability to implement its own state law that authorizes the use, distribution, possession, or cultivation of medical marijuana.[31] Despite this prohibition in the Appropriations Act of 2015, the USDOJ has continued to take some enforcement measures against medical cannabis dispensaries. However, in October 2015, the United States District Court for the Northern District of California held that section 538 plainly on its face prohibits the Department of Justice from taking such action.[32] Congress recently re-enacted the prohibition in section 542 of the Consolidated Appropriations Act of 2016.[33]

Regulation of Cannabis in Other States

Currently, 23 states[34] and the District of Columbia have comprehensive laws that permit and regulate the use of cannabis for medicinal purposes.[35] While these laws vary widely, most specify the medical conditions a patient must be diagnosed with to be eligible to use cannabis for treatment, allow a caregiver to assist with such treatment, require the registration of the patient and caregiver and a

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[25] U.S. Department of Justice, *Smart on Crime: Reforming the Criminal Justice System for the 21st Century, available at* http://www.justice.gov/ag/smart-on-crime.pdf. (last visited on December 27, 2015).
[26] *Id.*
[27] U.S. Department of Justice, *Guidance Regarding Marijuana Enforcement*, August 29, 2014, *available at* http://www.justice.gov/iso/opa/resources/3052013829132756857467.pdf (last visited on December 27, 2015).
[28] *Id.*
[29] *Id.*
[30] *Id.*
[31] Pub. L. 113-235 (2014).
[32] *U.S. v. Marin Alliance for Medical Marijuana*, 2015 WL 6123062 (N.D. Cal. Oct. 19, 2015).
[33] Pub. L. 114-113 (2015).
[34] These states include: Alaska, Arizona, California, Colorado, Connecticut, Delaware, Hawaii, Illinois, Maine, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, Oregon, Rhode Island, Vermont, and Washington. California was the first to establish a medical marijuana program in 1996 and New York was the most recent state to pass medical marijuana legislation which took effect in July 2014. National Conference of State Legislatures, *State Medical Marijuana Laws, available at* http://www.ncsl.org/issues-research/health/state-medical-marijuana-laws.aspx (last visited on December 27, 2015).
[35] According to the National Conference of State Legislatures, 17 other states allow the use of low-THC cannabis for medical use or allow a legal defense for such use, including Florida. National Conference of State Legislatures, *State Medical Marijuana Laws, available at* http://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx (last visited on December 27, 2015).

registration ID card to be issued to the patient and caregiver, restrict where cannabis can be used, and provide standards pertaining to the growing, processing, packaging, transport, and dispensing of medical cannabis.

Patients' Use of Medical Cannabis

While nearly every state has a list of medical conditions for which the patient may be treated with medical cannabis, the particular conditions vary from state to state. Most states also provide a mechanism for the list of qualifying medical conditions to be expanded, usually by allowing a state agency or a board to add qualifying medical conditions to the list or by providing a physician with some discretion in determining whether such treatment would benefit the patient.[36] The most common qualifying conditions named[37] in the statutes of the states with comprehensive medical cannabis laws are:[38]

- Cancer- 22 states
- HIV/AIDS- 22 states
- Multiple sclerosis- 20 states
- Epilepsy- 20 states
- Glaucoma- 19 states
- Crohn's disease- 12 states
- Amyotrophic lateral sclerosis- 10 states
- Hepatitis C- 8 states
- Alzheimer's disease- 8 states

Most states require that at least one, but sometimes states require two, physicians to certify that the patient has a qualifying condition. Qualifying patients are usually required to be registered in an electronic registry and must be issued a registration ID card, usually from a state agency.[39]

Most states place general restrictions on where medical cannabis may be used. Typically, medical cannabis may not be used in public places, such as parks and on buses, or in areas where there are more stringent restrictions placed on the use of drugs, such as in or around schools or in prisons.[40]

There are two general methods by which patients can obtain medical cannabis. They must either self-cultivate the cannabis in their homes, or buy cannabis from specified points of sale or dispensaries. Regulations governing the amount of medical cannabis that may be grown or dispensed varies widely. For example, the amount of medical cannabis patients are allowed to have ranges from 1 ounce of usable[41] cannabis to 24 ounces of usable cannabis, depending on the state. Furthermore, the number of cannabis plants that patients are allowed to grow ranges from 2 mature marijuana plants to 18

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[36] For example, see the following state laws allowing an agency to approve other conditions: AS § 17.37.070 (Alaska), A.R.S. § 36-2801 (Arizona), C.R.S.A. Const. Art. 18, § 14 (Colorado), C.G.S.A. § 21a-408 (Connecticut), 16 Del.C. § 4902A (Delaware), HRS § 329-121 (Hawaii), 410 ILCS 130/10 (Illinois), M.C.L.A. 333.26423 (Michigan), M.S.A. §152.22 (Minnesota), N.R.S. 453A.050 (Nevada), N.H. Rev. Stat. §126-X:1 (New Hampshire), N.J.S.A. 24:6I-3 (New Jersey), N.M.S.A. 1978, § 26-2B-3 (New Mexico), O.R.S. § 475.302 (Oregon), and Gen. Laws 1956, § 21-28.6-3 (Rhode Island). For examples of states allowing for physician discretion in treating other conditions with medical cannabis, see M.G.L.A. 94C App. §1-2.

[37] These are diseases specified in states' statutes. The state statutes also included symptoms or conditions of diseases that could apply to several other diseases, such as cachexia or wasting syndrome, severe pain, severe nausea, seizures, or muscle spasms.

[38] Information based on research performed by Health Quality Subcommittee staff. The laws of each state are on file with the subcommittee.

[39] *Id.*

[40] For example, see N.R.S. 453A.322 (Nevada), N.J.S.A. 18A:40-12.22 (New Jersey), 5 CCR 1006-2:12 (Colorado), and West's Ann.Cal.Health & Safety Code § 11362.768 (California).

[41] "Usable cannabis" generally means the seeds, leaves, buds, and flowers of the cannabis plant and any mixture or preparation thereof, but does not include the stalks and roots of the plant or the weight of any non-cannabis ingredients combined with cannabis. For example, see 410 ILCS 130/10 (Illinois) and OAR 333-008-0010 (Oregon).

seedling marijuana plants. At least 10 states limit the amount of medical cannabis that may be ordered by specifying the number of days or months of a supply a physician may order.[42]

Caregivers

Caregivers are generally allowed to purchase or grow cannabis for the patient, be in possession of a specified quantity of cannabis, and aid the patient in using cannabis, but are strictly prohibited from using cannabis themselves. Some states may also require the caregiver to be at least 21[43] and may prohibit the caregiver from being the patient's physician.[44] Like the patient receiving treatment, the caregiver is usually required to be registered and have a registration ID card, typically issued by a state agency.[45]

Quality and Safety Standards

States vary in their regulations of entities that grow, process, transport, and dispense medical cannabis. However, most states with comprehensive medical cannabis laws require such entities to meet certain standards to ensure the quality and safety of the medical cannabis and standards to ensure the security of the facilities possessing the medical cannabis. For example, some states require a state agency to establish and enforce standards for laboratory testing of medical cannabis.[46] States may also require certain packaging and labeling standards for medical cannabis, including the requirement for packaging to meet the standards under the United States Poison Prevention Packaging Act.[47] States' security measures may require facilities that grow, process, transport, and dispense medical cannabis to implement an inventory tracking system that tracks the cannabis from "seed-to-sale."[48]

Florida's Cannabis Laws

Criminal Law

Florida's drug control laws are set forth in ch. 893, F.S., entitled the Florida Comprehensive Drug Abuse Prevention and Control Act (Drug Control Act).[49] The Drug Control Act classifies controlled substances into five categories, ranging from Schedule I to Schedule V.[50] Cannabis is currently a Schedule I controlled substance,[51] which means it has a high potential for abuse, it has no currently accepted medical use in treatment in the United States, and its use under medical supervision does not meet accepted safety standards.[52] Cannabis is defined as:

> All parts of any plant of the genus Cannabis, whether growing or not; the seeds thereof; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant or its seeds or resin. The term does not

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[42] *See* C.G.S.A. §21a-4089 (Connecticut), 410 ILCS 130/10 (Illinois), MD Code, Health-General, § 13-3301 (Maryland), M.G.L.A. 94C App. §1-2 (Massachusetts), M.S.A. § 152.29 (Minnesota), N.R.S. 453A.200 (Nevada), N.H. Rev. Stat. § 126-X:8 (New Hampshire), N.J.S.A. 24:6I-10 (New Jersey), N.M.S.A. 1978, § 26-2B-3 (New Mexico), and McKinney's Public Health Law § 3362 (New York).

[43] See, for example, 22 M.R.S.A. § 2423-A (Maine), 105 CMR 725.020 (Massachusetts), and Gen.Laws 1956, § 44-67-2 (Rhode Island).

[44] For an example of a law prohibiting a physician from being a caregiver, see the definition of "primary caregiver" in C.R.S.A. § 25-1.5-106 (Colorado).

[45] *Supra* note 38.

[46] *See* HRS § 329D-8 (Hawaii), N.R.S. 453A.368 (Nevada), and West's RCWA 69.50.348 (Washington).

[47] *See* C.R.S.A. § 12-43.3-104(Colorado) and Haw. Admin. Rules (HAR) § 11-850-92 (Hawaii).

[48] *See* C.R.S.A. § 35-61-105.5 (Colorado), OAR 333-064-0100 (Oregon), and West's RCWA 69.51A.250 (Washington- effective July 1, 2016).

[49] s. 893.01, F.S.

[50] s. 893.03, F.S.

[51] s. 893.03(1)(c)7., F.S.

[52] s. 893.03(1), F.S.

include "low-THC cannabis," as defined in s. 381.986, if manufactured, possessed, sold, purchased, delivered, distributed, or dispensed, in conformance with s. 381.986.[53]

The Drug Control Act contains a variety of provisions criminalizing behavior related to cannabis:

- Section 893.13, F.S., makes it a crime to sell, manufacture, deliver, purchase, or possess cannabis. The penalties for these offenses range from first degree misdemeanors to second degree felonies.[54]
- Section 893.135(1)(a), F.S., makes it a first degree felony[55] to traffic in cannabis, i.e., to possess, sell, purchase, manufacture, deliver, or import more than 25 pounds of cannabis or 300 or more cannabis plants. Depending on the amount of cannabis or cannabis plants trafficked, mandatory minimum sentences of three to 15 years and fines of $25,000 to $200,000 apply to a conviction.[56]
- Section 893.147, F.S., makes it a crime to possess, use, deliver, manufacture, transport, or sell drug paraphernalia.[57] The penalties for these offenses range from first degree misdemeanors to second degree felonies.[58]

Medical Necessity Defense

Florida courts have held that persons charged with offenses based on the possession, use, or manufacture of marijuana may use the medical necessity defense, which requires a defendant to prove that:

- He or she did not intentionally bring about the circumstance which precipitated the unlawful act;
- He or she could not accomplish the same objective using a less offensive alternative; and
- The evil sought to be avoided was more heinous than the unlawful act.[59]

In *Jenks v. State,*[60] the defendants, a married couple, suffered from uncontrollable nausea due to AIDS treatment and had testimony from their physician that they could find no effective alternative treatment. The defendants tried cannabis, and after finding that it successfully treated their symptoms, decided to grow two cannabis plants.[61] They were subsequently charged with manufacturing and possession of drug paraphernalia. Under these facts, the First District Court of Appeal found that "section 893.03 does not preclude the defense of medical necessity" and that the defendants met the criteria for the medical necessity defense.[62] The court ordered the defendants to be acquitted.[63]

Seven years after the *Jenks* decision, the First District Court of Appeal again recognized the medical necessity defense in *Sowell v. State.*[64] More recently, the State Attorney's Office in the Twelfth Judicial

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[53] s. 893.02(3), F.S.

[54] A first degree misdemeanor is punishable by up to one year in county jail and a $1,000 fine; a third degree felony is punishable by up to five years imprisonment and a $5,000 fine; and a second degree felony is punishable by up to 15 years imprisonment and a $10,000 fine. ss. 775.082 and 775.083, F.S.

[55] A first degree felony is punishable by up to 30 years imprisonment and a $10,000 fine. ss. 775.082 and 775.083, F.S.

[56] s. 893.13(1)(a), F.S.

[57] Drug paraphernalia is defined in s. 893.145, F.S., as:

> All equipment, products, and materials of any kind which are used, intended for use, or designed for use in the planting, propagating, cultivating, growing, harvesting, manufacturing, compounding, converting, producing, processing, preparing, testing, analyzing, packaging, repackaging, storing, containing, concealing, transporting, injecting, ingesting, inhaling, or otherwise introducing into the human body a controlled substance in violation of ch. 893, F.S., or s. 877.111, F.S.

[58] s. 893.147, F.S.

[59] *Jenks v. State*, 582 So.2d 676, 679 (Fla. 1st DCA 1991), *rev. denied,* 589 So.2d 292 (Fla. 1991).

[60] 582 So.2d 676 (Fla. 1st DCA 1991).

[61] *Id.*

[62] *Id.*

[63] *Id.*

[64] 739 So.2d 333 (Fla. 1st DCA 1998).

Circuit cited the medical necessity defense as the rationale for not prosecuting a person arrested for cultivating a small amount of cannabis in his home for his wife's medical use.[65]

Compassionate Medical Cannabis Act of 2014

The Compassionate Medical Cannabis Act of 2014[66] (CMCA) legalized a low tetrahydrocannabinol (THC) and high cannabidiol (CBD) form of cannabis (low-THC cannabis)[67] for the medical use[68] by patients suffering from cancer or a physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms.

The CMCA provides that a Florida licensed allopathic or osteopathic physician who has completed certain training[69] and has examined and is treating such a patient may order low-THC cannabis for that patient to treat the disease, disorder, or condition or to alleviate its symptoms, if no other satisfactory alternative treatment options exist for the patient. To meet the requirements of the CMCA, each of the following conditions must be satisfied:

- The patient must be a permanent resident of Florida.
- The physician must determine that the risks of ordering low-THC cannabis are reasonable in light of the potential benefit for that patient.[70]
- The physician must register as the orderer of low-THC cannabis for the patient on the compassionate use registry (registry) maintained by the Department of Health (DOH) and must update the registry to reflect the contents of the order.
- The physician must maintain a patient treatment plan and must submit the plan quarterly to the University of Florida College of Pharmacy.
- The physician must obtain the voluntary informed consent of the patient or the patient's legal guardian to treatment with low-THC cannabis.[71]

Under the CMCA, DOH was required to approve five dispensing organizations by January 1, 2015, with one dispensing organization in each of the following regions: northwest Florida, northeast Florida, central Florida, southeast Florida, and southwest Florida.[72] To be approved as a dispensing organization, an applicant must establish that it:

- Possesses a certificate of registration issued by the Department of Agriculture and Consumer Services for the cultivation of more than 400,000 plants;
- Is operated by a nurseryman;
- Has been operating as a registered nursery in this state for at least 30 continuous years;

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[65] *Interdepartmental Memorandum*, State Attorney's Office for the Twelfth Judicial Circuit of Florida, SAO Case # 13CF007016AM, April 2, 2013, on file with the Health Quality Subcommittee.

[66] *See* ch. 2014-157, L.O.F., and s. 381.986, F.S.

[67] The act defines "low-THC cannabis," as the dried flowers of the plant *Cannabis* which contain 0.8 percent or less of tetrahydrocannabinol and more than 10 percent of cannabidiol weight for weight, or the seeds, resin, or any compound, manufacture, salt, derivative, mixture, or preparation of the plant or its seeds or resin. *See* s. 381.986(1)(b), F.S.

[68] Section 381.986(1)(c), F.S., defines "medical use" as "administration of the ordered amount of low-THC cannabis. The term does not include the possession, use, or administration by smoking. The term also does not include the transfer of low-THC cannabis to a person other than the qualified patient for whom it was ordered or the qualified patient's legal representative on behalf of the qualified patient." Section 381.986(1)(e), F.S., defines "smoking" as "burning or igniting a substance and inhaling the smoke. Smoking does not include the use of a vaporizer."

[69] Section 381.986(4), F.S., requires such physicians to successfully complete an 8-hour course and examination offered by the Florida Medical Association or the Florida Osteopathic Medical Association which encompasses the clinical indications for the appropriate use of low-THC cannabis, appropriate delivery mechanisms, contraindications for such use, and the state and federal laws governing its ordering, dispensing, and processing

[70] If a patient is younger than 18 years of age, a second physician must concur with this determination, and such determination must be documented in the patient's medical record. s. 381.986(2)(b), F.S.

[71] s. 381.986(2), F.S.

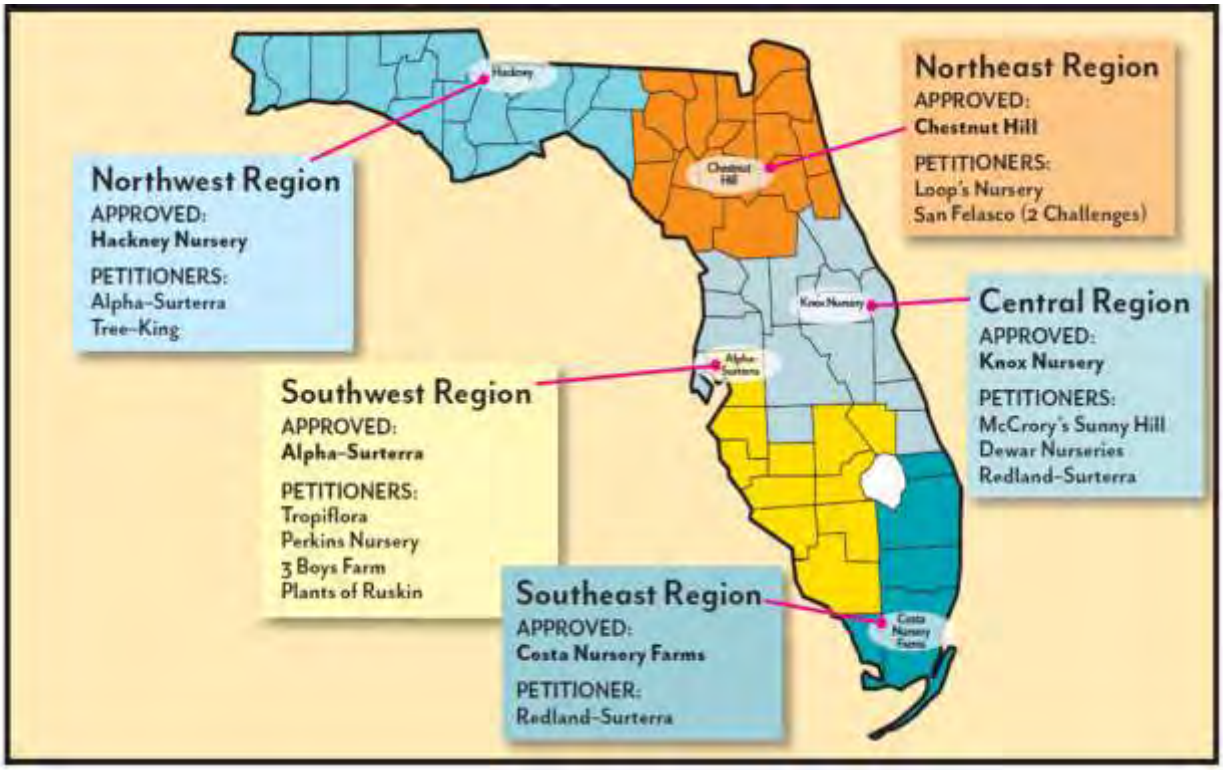
[72] s. 381.986(5)(b), F.S.

- Has the technical and technological ability to cultivate and produce low-THC cannabis;
- Employs a medical director, who must be a physician and have successfully completed a course and examination that encompasses appropriate safety procedures and knowledge of low-THC cannabis; and
- Other specified requirements.[73]

Implementation by DOH of the dispensing organization approval process was delayed due to litigation challenging proposed rules that addressed the initial application requirements for dispensing organizations, revocation of dispensing organization approval, and inspection and cultivation authorization procedures for dispensing organizations. Such litigation was resolved on May 27, 2015, with an order entered by the Division of Administrative Hearings holding that the challenged rules do not constitute an invalid exercise of delegated legislative authority.[74] Thereafter, the rules took effect on June 17, 2015.[75]

The application process to become a dispensing organization closed on July 8, 2015, with 28 applications received by DOH. On November 23, 2015, DOH announced the five approved dispensing organizations: Hackney Nursery in the northwest region, Chestnut Hill Tree Farm in the northeast region, Knox Nursery in the central region, Costa Nursery Farms in the southeast region, and Alpha Foliage in the southwest region. To date, 13 petitions[76] have been filed contesting DOH's approval of these five dispensing organizations.[77]

APPROVED DISPENSING ORGANIZATIONS AND PENDING CHALLENGES



SOURCE: Department of Health, Office of Compassionate Use.

[73] *Id.*
[74] *Baywood v.Nurseries Co., Inc. v. Dep't of Health,* Case No. 15-1694RP (Fla. DOAH May 27, 2015).
[75] Rule Chapter 64-4, F.A.C.
[76] A copy of each petition is available at http://www.floridahealth.gov/programs-and-services/office-of-compassionate-use/ (last visited on December 28, 2015).
[77] Chestnut Hill Tree Farm also filed a counter-petition to San Felasco Nurseries' challenge to the Chestnut Hill Tree Farm being approved as the northeast region dispensing organization. *Chestnut Hill Tree Farm, LLC v. San Felasco Nurseries, Inc.*, Case. No. 15-007276, (Fla. DOAH, Dec. 18, 2015).

The CMCA provides that it is a first degree misdemeanor for:

- A physician to order low-THC cannabis for a patient without a reasonable belief that the patient is suffering from a required condition; or
- Any person to fraudulently represent that he or she has a required condition to a physician for the purpose of being ordered low-THC cannabis.[78]

The CMCA specifies that notwithstanding ss. 893.13, 893.135, or 893.147, F.S., or any other law that:

- Qualified patients[79] and their legal representatives may purchase and possess low-THC cannabis up to the amount ordered for the patient's medical use.
- Approved dispensing organizations and their owners, managers, and employees may manufacture, possess, sell, deliver, distribute, dispense, and lawfully dispose of reasonable quantities, as established by DOH rule, of low-THC cannabis. Such dispensing organizations and their owners, managers, and employees are not subject to licensure or regulation under ch. 465, F.S., relating to pharmacies.[80]

The CMCA requires DOH to create a secure, electronic, and online registry for the registration of physicians and patients.[81] Physicians must register as the orderer of low-THC cannabis for a named patient on the registry and must update the registry to reflect the contents of the order.[82] The registry must prevent an active registration of a patient by multiple physicians and must be accessible to law enforcement agencies and to a dispensing organization to verify patient authorization for low-THC cannabis and to record the low-THC cannabis dispensed.[83]

Effect of Proposed Changes

This bill creates additional regulatory standards under the Compassionate Medical Cannabis Act (CMCA) for dispensing organizations approved by DOH to grow, process, transport, and dispense low-THC cannabis. Additionally, the bill strengthens the criteria for physicians to be able to order low-THC cannabis, the criteria for physicians to become medical directors of dispensing organizations, and DOH's responsibilities under the CMCA. The bill includes other measures to increase the accountability of those who have access to low-THC cannabis, to increase the safety and quality of the low-THC cannabis being dispensed, and to increase the security of premises and personnel in possession of low-THC cannabis.

Dispensing Organizations

Current law requires approved dispensing organizations to maintain compliance with certain criteria required to be met prior to their selection, but it does not provide standards specifically relating to the quality or safety of low-THC cannabis or the security of entities possessing or transporting low-THC cannabis. The bill establishes new quality and safety standards for growing, processing, transporting and dispensing low-THC cannabis and security standards for those entities performing such acts.

[78] s. 381.986(3), F.S.
[79] Section 381.986(1)(d), F.S., provides that a "qualified patient" is a Florida resident who has been added by a physician licensed under ch. 458, F.S. or ch. 459, F.S., to the compassionate use registry to receive low-THC cannabis from a dispensing organization.
[80] s. 381.986(7), F.S.
[81] s. 381.985(5)(a), F.S.
[82] s. 381.986(2)(c), F.S.
[83] s. 381.985(5)(a), F.S.

Growing Low-THC Cannabis

When growing low-THC cannabis, the bill provides that a dispensing organization may use pesticides determined by DOH to be safely applied to plants intended for human consumption and requires the dispensing organization to:

- Grow and process low-THC cannabis within an enclosed structure and in a room separate from any other plant;
- Inspect seeds and growing plants for plant pests that endanger or threaten the horticultural and agricultural interests of the state, notify the Department of Agriculture and Consumer Services within 10 calendar days of a determination that a plant is infested or infected by such plant pest, and implement and maintain phytosanitary policies and procedures; and
- Perform fumigation or treatment of plants or the removal and destruction of infested or infected plants in accordance with ch. 581, F.S., or any rules adopted thereunder.

Processing Low-THC Cannabis

When processing low-THC cannabis, a dispensing organization must:

- Process the low-THC cannabis in an enclosure separate from other plants or products;
- Package the low-THC cannabis in compliance with the United States Poison Prevention Packaging Act (15 U.S.C. §§1471-1477);[84]
- Package the low-THC cannabis in a receptacle that has a firmly affixed and legible label stating the following information:
    - The name of the dispensing organization.
    - The quantity of low-THC cannabis contained within.
    - The cannabinoid profile of the low-THC cannabis, including the THC level.
    - Any ingredient other than low-THC cannabis contained within.
    - The date the low-THC is dispensed.
    - The patient's name and registration identification number.
    - A statement that the product is for medical use and not for resale or transfer to another person.
    - A unique serial number that will match the product with the original batch of low-THC cannabis from which the product was made to facilitate necessary warnings or recalls by DOH.
    - A recommended "use by" date or expiration date; and
- Reserve two processed samples per each batch, retain such samples for at least one year, and make those samples available for testing.

Dispensing Low-THC Cannabis

The bill prohibits a dispensing organization from dispensing more than a 30-day supply of low-THC cannabis to a patient or the patient's caregiver or selling any other type of retail product other than the physician ordered low-THC cannabis or paraphernalia. The bill also requires the dispensing organization to:

- Have the dispensing organization employee dispensing the low-THC cannabis enter into the compassionate use registry his or her name or unique employee identifier;

[84] The Poison Prevention Packaging Act requires packaging to be designed or constructed in a manner to make it significantly difficult for children under five years of age to open within a reasonable time, and not difficult for normal adults to use properly. *See* U.S. Consumer Product Safety Commission, *Poison Prevention Packaging Act*, *available at* http://www.cpsc.gov/en/Regulations-Laws--Standards/Statutes/Poison-Prevention-Packaging-Act/ (last visited on December 29, 2015).

- Verify in the compassionate use registry that a physician has ordered low-THC cannabis or a specific type of paraphernalia for the patient;
- Verify the patient or patient's caregiver holds a valid and active registration card; and
- Record in the compassionate use registry the paraphernalia dispensed, if any, in addition to the other information required under current law to be recorded in the registry.

Safety and Security Measures

The bill also requires the dispensing organization to implement and maintain certain safety and security measures relating to its facilities and certain safety and quality measures for low-THC cannabis dispensed or transported by the dispensing organization. Specifically, the bill requires the dispensing organization to:

- Maintain a fully operational security alarm system;
- Maintain a video surveillance system that records continuously 24 hours per day and meets specific minimum criteria;
- Retain video surveillance recordings for a minimum of 45 days, or longer upon the request of law enforcement;
- Enclose the perimeter of any buildings used in the cultivation, processing, or dispensing of low-THC cannabis with at least a six-foot high fence;
- Ensure that the outdoor premises of the dispensing organization has sufficient lighting from dusk until dawn;
- Dispense low-THC cannabis or paraphernalia only between the hours of 9 p.m. and 7 a.m., but allows the dispensing organization to perform all other operations 24 hours per day;
- Establish and maintain a tracking system approved by DOH that traces the low-THC cannabis from seed to sale, including key notification of events as determined by DOH;
- Store low-THC cannabis in secured, locked rooms or a vault;
- Have at least 2 employees of the dispensing organization or of a contracted security agency be on the dispensing organization premises at all times;
- Have all employees wear a photo identification badge at all times while on the premises;
- Have visitors wear a visitor's pass at all times while on the premises;
- Implement an alcohol and drug free workplace policy; and
- Report to local law enforcement within 24 hours of the dispensing organization being notified or becoming aware of the theft, diversion, or loss of low-THC cannabis.

To ensure the safe transport of low-THC cannabis to dispensing organization facilities, laboratories, or patients, the bill requires dispensing organizations to:

- Maintain a transportation manifest, which must be retained for at least one year;
- Ensure only vehicles in good-working order are used to transport low-THC cannabis;
- Lock low-THC cannabis in a separate compartment or container within the vehicle;
- Have at least two persons in a vehicle transporting low-THC cannabis and at least one person remain in the vehicle while the low-THC cannabis is being delivered; and
- Provide specific safety and security training to those employees transporting low-THC cannabis.

Physicians

Current law requires a physician to meet certain criteria, including additional training and education, to be qualified to order low-THC cannabis. The bill increases the qualification criteria and allows the physician to order paraphernalia for the administration of low-THC cannabis. "Paraphernalia" is defined by the bill as objects used, intended for use, or designed for use in preparing, storing, ingesting, inhaling, or otherwise introducing low-THC cannabis into the human body. The additional criteria in the bill require the physician to:

- Be board-certified as an oncologist, neurologist, or epileptologist or specialize in the treatment of cancer, epilepsy, or physical medical conditions that chronically produce symptoms of seizures or severe and persistent muscle spasms. When treating a patient who is a minor and a second physician's concurrence for treatment using low-THC cannabis is required, the second physician must also meet this criterion.
- Have treated the patient for cancer or a physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms for at least six months.
- Include in the registry the ordered amount of low-THC cannabis that will provide the patient with not more than a 30-day supply and any paraphernalia needed by the patient for the medical use of low-THC cannabis.

The bill prohibits a physician ordering low-THC cannabis from being employed as a medical director of a dispensing organization and provides that a physician who orders low-THC cannabis and receives compensation from a dispensing organization related to the ordering of low-THC cannabis may be subject to disciplinary action under the applicable practice act and under s. 456.072(1)(n), F.S.

The bill also increases the qualification criteria for medical directors of dispensing organizations by requiring the medical director to be board-certified as an oncologist, neurologist, or epileptologist or provide proof that he or she specializes in the treatment of cancer, epilepsy, or physical medical conditions that chronically produce symptoms of seizures or severe and persistent muscle spasms.

Testing Laboratories

Current law does not require the testing of low-THC cannabis by laboratories to ensure the composition of the low-THC cannabis to be dispensed complies with law or to ensure that it is safe. The bill requires a dispensing organization to contract with a laboratory approved by DOH for purposes of testing low-THC cannabis for compliance with the law and to detect any mold, bacteria, or other contaminant which may result in adverse effects to human health or the environment. The contract must require the laboratory to report to the dispensing organization, within 48 hours of a test, the cannabinoid composition of the product and whether the laboratory has detected any mold, bacteria, or other contaminant in the product which may result in adverse effects to human health or the environment.

The bill also creates an exemption from criminal law for DOH approved laboratories and their employees, allowing the laboratories and laboratory employees to possess, test, transport, and lawfully dispose of low-THC cannabis.

Department of Health

The bill grants DOH greater regulatory oversight of dispensing organizations by authorizing DOH to conduct inspections, set certain standards for laboratory testing of low-THC cannabis, establish a registration card system for patients and caregivers, and assess fines or take disciplinary action for certain violations. The bill also grants DOH authority to conduct additional acts to administer the CMCA. Specifically, the bill provides that DOH:

- May conduct announced or unannounced inspections of dispensing organizations to determine compliance with the law.
- Must inspect a dispensing organization upon complaint or notice provided to DOH that the dispensing organization has dispensed low-THC cannabis containing any mold, bacteria, or other contaminant that may cause or has caused an adverse effect to human health or the environment.
- Must conduct at least an annual inspection to evaluate dispensing organization records, personnel, equipment, processes, security measures, sanitation practices, and quality assurance practices.
- May inspect laboratories to ensure laboratories are using standardized procedures to test low-THC cannabis.

- May adopt standards for the approval of laboratories contracting with dispensing organizations, including standardized procedures, required equipment, and conflict of interest provisions.
- May enter into interagency agreements with the Department of Agriculture and Consumer Services, the Department of Business and Professional Regulation, the Department of Transportation, the Department of Highway Safety and Motor Vehicles, and the Agency for Health Care Administration, and such agencies are authorized to enter into an interagency agreement with DOH, to conduct inspections or perform other responsibilities assigned to DOH under the CMCA.
- Make a list of all approved dispensing organizations and qualified ordering physicians and medical directors publicly available on its website.
- May establish a system for issuing and renewing patient and caregiver registration cards, establish the circumstances under which the cards may be revoked by or must be returned to DOH, and establish fees to implement such system. DOH must require, at a minimum, the registration cards to:
    - State the name, address, and date of birth of the patient or caregiver.
    - Have a full-face, passport-style photograph of the patient or caregiver that has been taken within 90 days prior to registration.
    - Identify whether the cardholder is a patient or caregiver.
    - List a unique numerical identifier for the patient or caregiver that is matched to the identifier used for such person in DOH's compassionate use registry.
    - Provide the expiration date, which shall be from one year from the physician's initial order of low-THC cannabis.
    - For the caregiver, provide the name and unique numerical identifier of the patient the caregiver is assisting.
    - Be resistant to counterfeiting or tampering.
- Must create a schedule of violations in rule to impose reasonable fines not to exceed $10,000 on a licensee, and before assessing a fine must consider the severity of the violation, any actions taken by the licensee to correct the violation or to remedy complaints, and any previous violations.
- May suspend, revoke, or refuse to renew the license of a licensee for having a license, or the authority to practice any regulated profession or the authority to conduct any business, revoked, suspended, or otherwise acted against, including the denial of licensure by the licensing authority, for a violation that would constitute a violation under Florida law.
- May adopt rules necessary to implement the CMCA.

DOH is also responsible for overseeing a dispensing organization's advertising as the bill only allows a dispensing organization to use an insignia or logo approved by DOH.

The bill provides an effective date of July 1, 2016.

B. SECTION DIRECTORY:

Section 1. Amends s. 381.986, F.S., relating to compassionate use of low-THC cannabis.

Section 2. Provides an effective date of July 1, 2016.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

The bill will have an indeterminate positive fiscal impact on DOH associated with the collection of fees to administer the registration card system, should DOH create such a system. However, the

revenue generated by such fees should be offset by the costs associated with administration of the system.

DOH may also generate revenue from any fines assessed against dispensing organizations in violation of the CMCA.

2. Expenditures:

The bill will have an indeterminate negative fiscal impact on DOH associated with the resources needed to administer the registration card system. DOH will also incur minimal costs associated with rulemaking. DOH may also incur costs associated with inspections of dispensing organizations and laboratories.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

The bill does not appear to have any impact on local government revenues.

2. Expenditures:

The bill does not appear to have any impact on local government expenditures.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Dispensing organizations may incur costs associated with meeting the bill's new quality, safety, and security standards. It is indeterminate the extent to which approved dispensing organizations already meet such standards or the extent to which equipment will need to be purchased or personnel will need to be hired to meet the bill's requirements.

Dispensing organizations will also incur costs associated with contracting with testing laboratories. It is indeterminate the cost of such contractual services.

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:

DOH appears to have sufficient rulemaking authority to carry out its responsibilities under the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to low-THC cannabis for medical use; amending s. 381.986, F.S.; providing and revising definitions; revising requirements for physicians ordering low-THC cannabis; providing that a physician who orders low-THC cannabis and receives related compensation from a dispensing organization is subject to disciplinary action; revising requirements relating to physician education; requiring the Department of Health to include caregiver information in the online compassionate use registry; revising requirements for dispensing organizations; specifying duties and responsibilities of the department; authorizing an approved laboratory and its employees to possess, test, transport, and lawfully dispose of low-THC cannabis or paraphernalia in certain circumstances; exempting an approved dispensing organization and related persons from the Florida Drug and Cosmetic Act; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 381.986, Florida Statutes, is amended to read:

381.986 Compassionate use of low-THC cannabis.—

(1) DEFINITIONS.—As used in this section, the term:

(a) "Caregiver" means an individual who is 21 years of age or older, a permanent resident of the state, and registered with the department to assist a patient with the medical use of low-THC cannabis.

(b) ~~(a)~~ "Dispensing organization" means an organization approved by the department to cultivate, process, and dispense low-THC cannabis pursuant to this section.

(c) ~~(b)~~ "Low-THC cannabis" means a plant of the genus Cannabis, the dried flowers of which contain 0.8 percent or less of tetrahydrocannabinol and more than 10 percent of cannabidiol weight for weight; the seeds thereof; the resin extracted from any part of such plant; or any compound, manufacture, salt, derivative, mixture, or preparation of such plant or its seeds or resin that is dispensed only from a dispensing organization.

(d) ~~(c)~~ "Medical use" means administration of the ordered amount of low-THC cannabis. The term does not include the possession, use, or administration by smoking. The term also does not include the transfer of low-THC cannabis to a person other than the qualified patient for whom it was ordered, ~~or~~ the qualified patient's legal guardian if the guardian is a registered caregiver, or other registered caregiver ~~representative~~ on behalf of the qualified patient.

(e) "Paraphernalia" means objects used, intended for use, or designed for use in preparing, storing, ingesting, inhaling, or otherwise introducing low-THC cannabis into the human body.

(f) ~~(d)~~ "Qualified patient" means a permanent resident of

this state who has been added to the compassionate use registry by a physician licensed under chapter 458 or chapter 459 to receive low-THC cannabis from a dispensing organization.

(g) ~~(e)~~ "Smoking" means burning or igniting a substance and inhaling the smoke. Smoking does not include the use of a vaporizer.

(2) PHYSICIAN ORDERING. ~~Effective January 1, 2015,~~ A physician is authorized to ~~licensed under chapter 458 or chapter 459 who has examined and is treating a patient suffering from cancer or a physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms may~~ order ~~for the patient's medical use~~ low-THC cannabis to treat a patient suffering from cancer or a physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms; ~~such disease, disorder, or condition or to~~ order low-THC cannabis to alleviate symptoms of such disease, disorder, or condition, if no other satisfactory alternative treatment options exist for the ~~that~~ patient; or order paraphernalia for the medical use of low-THC cannabis, only if the physician ~~and all of the following conditions apply~~:

(a) Holds an active, unrestricted license as a physician under chapter 458 or an osteopathic physician under chapter 459;

(b) Is board-certified as an oncologist, neurologist, or epileptologist or specializes in the treatment of cancer, epilepsy, or physical medical conditions that chronically produce symptoms of seizures or severe and persistent muscle

spasms;

(c) Has treated the patient for cancer or a physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms for at least 3 months immediately preceding the patient's registration in the compassionate use registry;

(d) Has successfully completed the course and examination required under paragraph (4)(a);

(e) ~~(b)~~ Has determined ~~The physician determines~~ that the risks of treating the patient with ~~ordering~~ low-THC cannabis are reasonable in light of the potential benefit to the ~~for that~~ patient. If a patient is younger than 18 years of age, a second physician having a board certification or specialization described in paragraph (b) must concur with this determination, and such determination must be documented in the patient's medical record; ~~.~~

(f) ~~(c) The physician~~ Registers as the orderer of low-THC cannabis for the named patient on the compassionate use registry maintained by the department and updates the registry to reflect the contents of the order, including the amount of low-THC cannabis that will provide the patient with not more than a 30-day supply and any paraphernalia needed by the patient for the medical use of low-THC cannabis. The physician must also update the registry within 7 days after any change is made to the original order to reflect the change. The physician shall deactivate the patient's and caregiver's registration when

treatment is discontinued;~~.~~

(g) ~~(d) The physician~~ Maintains a patient treatment plan that includes the dose, route of administration, planned duration, and monitoring of the patient's symptoms and other indicators of tolerance or reaction to the low-THC cannabis;~~.~~

(h) ~~(e) The physician~~ Submits the patient treatment plan quarterly to the University of Florida College of Pharmacy for research on the safety and efficacy of low-THC cannabis on patients;~~.~~

(i) ~~(f) The physician~~ Obtains the voluntary informed consent of the patient or the patient's legal guardian to treatment with low-THC cannabis after sufficiently explaining the current state of knowledge in the medical community of the effectiveness of treatment of the patient's condition with low-THC cannabis, the medically acceptable alternatives, and the potential risks and side effects; and

(j) Is not a medical director employed by a dispensing organization.

~~(a) The patient is a permanent resident of this state.~~

(3) PENALTIES.—

(a) A physician commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083, if the physician orders low-THC cannabis or paraphernalia for a patient without a reasonable belief that the patient is suffering from:

1. Cancer or a physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle

spasms that can be treated with low-THC cannabis; or

2. Symptoms of cancer or a physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms that can be alleviated with low-THC cannabis.

(b) Any person who fraudulently represents that he or she has cancer or a physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms to a physician for the purpose of being ordered low-THC cannabis or paraphernalia by such physician commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(c) A physician who orders low-THC cannabis or paraphernalia and receives compensation from a dispensing organization related to the ordering of low-THC cannabis is subject to disciplinary action under the applicable practice act and s. 456.072(1)(n).

(4) PHYSICIAN EDUCATION.—

(a) Before ordering low-THC cannabis or paraphernalia for medical use by a patient in this state, the appropriate board shall require the ordering physician ~~licensed under chapter 458 or chapter 459~~ to successfully complete an 8-hour course and subsequent examination offered by the Florida Medical Association or the Florida Osteopathic Medical Association that encompasses the clinical indications for the appropriate use of low-THC cannabis, the appropriate delivery mechanisms, the

contraindications for such use, as well as the relevant state and federal laws governing the ordering, dispensing, and possessing of this substance. The ~~first~~ course and examination shall ~~be presented by October 1, 2014, and shall~~ be administered at least annually ~~thereafter~~. Successful completion of the course may be used by a physician to satisfy 8 hours of the continuing medical education requirements required by his or her respective board for licensure renewal. This course may be offered in a distance learning format.

(b) The appropriate board shall require the medical director of each dispensing organization to hold an active, unrestricted license as a physician under chapter 458 or an osteopathic physician under chapter 459 and be board-certified as an oncologist, neurologist, or epileptologist or provide proof that he or she specializes in the treatment of cancer, epilepsy, or physical medical conditions that chronically produce symptoms of seizures or severe and persistent muscle spasms. Additionally, the medical director must ~~approved under subsection (5) to~~ successfully complete a 2-hour course and subsequent examination offered by the Florida Medical Association or the Florida Osteopathic Medical Association that encompasses appropriate safety procedures and knowledge of low-THC cannabis.

(c) Successful completion of the course and examination specified in paragraph (a) is required for every physician who orders low-THC cannabis or paraphernalia each time such

physician renews his or her license. In addition, successful completion of the course and examination specified in paragraph (b) is required for the medical director of each dispensing organization each time such physician renews his or her license.

(d) A physician who fails to comply with this subsection and who orders low-THC cannabis or paraphernalia may be subject to disciplinary action under the applicable practice act and under s. 456.072(1)(k).

(5) DUTIES OF THE DEPARTMENT. ~~By January 1, 2015,~~ The department shall:

(a) Create and maintain a secure, electronic, and online compassionate use registry for the registration of physicians, ~~and~~ patients, and caregivers as provided under this section. The registry must be accessible to law enforcement agencies and to a dispensing organization ~~in order~~ to verify patient and caregiver authorization for low-THC cannabis and paraphernalia and record the low-THC cannabis and paraphernalia dispensed. The registry must prevent an active registration of a patient by multiple physicians.

(b) Authorize the establishment of five dispensing organizations to ensure reasonable statewide accessibility and availability as necessary for patients registered in the compassionate use registry and who are ordered low-THC cannabis or paraphernalia under this section, one in each of the following regions: northwest Florida, northeast Florida, central Florida, southeast Florida, and southwest Florida. The

department shall develop an application form and impose an initial application and biennial renewal fee that is sufficient to cover the costs of administering this section. An applicant for approval as a dispensing organization must be able to demonstrate:

1. The technical and technological ability to cultivate and produce low-THC cannabis. The applicant must possess a valid certificate of registration issued by the Department of Agriculture and Consumer Services pursuant to s. 581.131 that is issued for the cultivation of more than 400,000 plants, be operated by a nurseryman as defined in s. 581.011, and have been operated as a registered nursery in this state for at least 30 continuous years.

2. The ability to secure the premises, resources, and personnel necessary to operate as a dispensing organization.

3. The ability to maintain accountability of all raw materials, finished products, and any byproducts to prevent diversion or unlawful access to or possession of these substances.

4. An infrastructure reasonably located to dispense low-THC cannabis to registered patients statewide or regionally as determined by the department.

5. The financial ability to maintain operations for the duration of the 2-year approval cycle, including the provision of certified financials to the department. Upon approval, the applicant must post a $5 million performance bond.

6. That all owners and managers have been fingerprinted and have successfully passed a level 2 background screening pursuant to s. 435.04.

7. The employment of a medical director who meets the qualifications of paragraph (4)(b) ~~is a physician licensed under chapter 458 or chapter 459~~ to supervise the activities of the dispensing organization.

(c) Monitor physician registration and ordering of low-THC cannabis or paraphernalia for ordering practices that could facilitate unlawful diversion or misuse of low-THC cannabis and take disciplinary action as indicated.

~~(d) Adopt rules necessary to implement this section.~~

(6) DISPENSING ORGANIZATION.—An approved dispensing organization, at all times, must ~~shall~~ maintain compliance with the criteria demonstrated for selection and approval as a dispensing organization under subsection (5) and the criteria required in this subsection ~~at all times~~.

(a) When growing low-THC cannabis, a dispensing organization:

1. May use pesticides determined by the department, after consultation with the Department of Agriculture and Consumer Services, to be safely applied to plants intended for human consumption, but may not use pesticides designated as restricted-use pesticides pursuant to s. 487.042.

2. Must grow and process low-THC cannabis within an enclosed structure and in a room separate from any other plant.

3. Must inspect seeds and growing plants for plant pests that endanger or threaten the horticultural and agricultural interests of the state, notify the Department of Agriculture and Consumer Services within 10 calendar days after a determination that a plant is infested or infected by such plant pest, and implement and maintain phytosanitary policies and procedures.

4. Must perform fumigation or treatment of plants, or the removal and destruction of infested or infected plants, in accordance with chapter 581 and any rules adopted thereunder.

(b) When processing low-THC cannabis, a dispensing organization must:

1. Process the low-THC cannabis in an enclosure separate from other plants or products.

2. Package the low-THC cannabis in compliance with the United States Poison Prevention Packaging Act, 15 U.S.C. ss. 1471-1477.

3. Package the low-THC cannabis in a receptacle that has a firmly affixed and legible label stating the following information:

a. The name of the dispensing organization.

b. The quantity of low-THC cannabis contained in the receptacle.

c. The cannabinoid profile of the low-THC cannabis, including the THC level.

d. Any ingredient other than low-THC cannabis contained in the receptacle.

e. The date that the low-THC is dispensed.

f. The patient's name and registration identification number.

g. A statement that the low-THC cannabis is for medical use and not for resale or transfer to another person.

h. A unique serial number corresponding to the original batch of low-THC cannabis from which the low-THC cannabis contained in the receptacle was made, to facilitate necessary warnings or recalls by the department.

i. A recommended "use by" date or expiration date.

4. Reserve two processed samples from each batch, retain such samples for at least 1 year, and make such samples available for testing.

(c) When dispensing low-THC cannabis or paraphernalia, a dispensing organization:

1. May not dispense more than a 30-day supply of low-THC cannabis to a patient or the patient's caregiver.

2. Must have the dispensing organization's employee who dispenses the low-THC cannabis or paraphernalia enter into the compassionate use registry his or her name or unique employee identifier.

3. Must verify in the compassionate use registry that a physician has ordered the low-THC cannabis or a specific type of paraphernalia for the patient.

4. May not dispense or sell any other type of retail product, other than physician-ordered paraphernalia, while

dispensing low-THC cannabis.

5. Must ~~Before dispensing low-THC cannabis to a qualified patient, the dispensing organization shall~~ verify that the patient has an active registration in the compassionate use registry, the patient or patient's caregiver holds a valid and active registration card, the order presented matches the order contents as recorded in the registry, and the order has not already been filled.

6. Must, upon dispensing the low-THC cannabis, ~~the dispensing organization shall~~ record in the registry the date, time, quantity, and form of low-THC cannabis and any paraphernalia dispensed.

(d) To ensure the safety and security of its premises and any off-site storage facilities, and to maintain adequate controls against the diversion, theft, and loss of low-THC cannabis, a dispensing organization must:

1. Maintain a fully operational security alarm system that secures all entry points and perimeter windows and is equipped with motion detectors; pressure switches; and duress, panic, and hold-up alarms.

2. Maintain a video surveillance system that records continuously 24 hours each day and meets the following minimum criteria:

a. Cameras are fixed in a place that allows for the clear identification of persons and activities in controlled areas of the premises. Controlled areas include grow rooms, processing

rooms, storage rooms, disposal rooms or areas, and point-of-sale rooms.

b. Cameras are fixed in entrances and exits to the premises, which shall record from both indoor and outdoor, or ingress and egress, vantage points.

c. Recorded images must clearly and accurately display the time and date.

3. Retain video surveillance recordings for a minimum of 45 days or longer upon the request of a law enforcement agency.

4. Enclose the perimeter of any buildings used in cultivating, processing, or dispensing low-THC cannabis with a fence or wall at least 6 feet in height.

5. Ensure that the organization's outdoor premises have sufficient lighting from dusk until dawn.

6. Establish and maintain a tracking system approved by the department that traces the low-THC cannabis from seed to sale. The tracking system shall include notification of key events as determined by the department, including when low-THC cannabis seeds are planted, low-THC cannabis plants are harvested, low-THC cannabis plants are destroyed, low-THC cannabis is transported, low-THC cannabis is sold, or a theft, diversion, or loss of low-THC cannabis occurs.

7. Not dispense low-THC cannabis or paraphernalia between the hours of 9 p.m. and 7 a.m., but may perform all other operations 24 hours each day.

8. Store low-THC cannabis in a secured, locked room or a

vault.

9. Require at least two of its employees, or two employees of a security agency with whom it contracts, to be on the organization's premises at all times.

10. Require each employee to wear a photo identification badge at all times while on the premises.

11. Require each visitor to wear a visitor's pass at all times while on the premises.

12. Implement an alcohol and drug-free workplace policy.

13. Report to local law enforcement within 24 hours after it is notified or becomes aware of the theft, diversion, or loss of low-THC cannabis.

(e) To ensure the safe transport of low-THC cannabis to dispensing organization facilities, laboratories, or patients, the dispensing organization must:

1. Maintain a transportation manifest, which must be retained for at least 1 year.

2. Ensure only vehicles in good working order are used to transport low-THC cannabis.

3. Lock low-THC cannabis in a separate compartment or container within the vehicle.

4. Require at least two persons to be in a vehicle transporting low-THC cannabis, and require at least one person to remain in the vehicle while the low-THC cannabis is being delivered.

5. Provide specific safety and security training to

employees transporting or delivering low-THC cannabis.

(f) A dispensing organization may only use an insignia or logo approved by the department to advertise its product.

(g) A dispensing organization must contract with a laboratory approved by the department for purposes of testing low-THC cannabis for compliance with this section and to detect any mold, bacteria, or other contaminant in the product that may result in adverse effects to human health or the environment. The contract must require the laboratory to report to the dispensing organization, within 48 hours after a test, the cannabinoid composition of the product and whether the laboratory has detected any mold, bacteria, or other contaminant in the product that may result in adverse effects to human health or the environment.

(7) DEPARTMENT AUTHORITY AND RESPONSIBILITIES.—

(a) The department:

1. May conduct announced or unannounced inspections of dispensing organizations to determine compliance with this section or rules adopted pursuant to this section.

2. Must inspect a dispensing organization upon complaint or notice provided to the department that the dispensing organization has dispensed low-THC cannabis containing any mold, bacteria, or other contaminant that may cause or has caused an adverse effect to human health or the environment.

3. Must conduct at least a biennial inspection of each dispensing organization to evaluate the dispensing

organization's records, personnel, equipment, processes, security measures, sanitation practices, and quality assurance practices.

(b) The department may inspect laboratories to ensure they are using standardized procedures to test low-THC cannabis.

(c) The department may adopt standards for the approval of laboratories contracting with dispensing organizations, including standardized procedures, required equipment, and conflict-of-interest provisions.

(d) The department may enter into interagency agreements with the Department of Agriculture and Consumer Services, the Department of Business and Professional Regulation, the Department of Transportation, the Department of Highway Safety and Motor Vehicles, and the Agency for Health Care Administration, and such agencies are authorized to enter into an interagency agreement with the department, to conduct inspections or perform other responsibilities assigned to the department under this section.

(e) The department must make a list of all approved dispensing organizations and qualified ordering physicians and medical directors publicly available on its website.

(f) The department may establish a system for issuing and renewing patient and caregiver registration cards, establish the circumstances under which the cards may be revoked by or must be returned to the department, and establish fees to implement such system. The department must require, at a minimum, the

registration cards to:

1. Provide the name, address, and date of birth of the patient or caregiver.

2. Have a full-face, passport-type, color photograph of the patient or caregiver taken within the 90 days immediately preceding registration.

3. Identify whether the cardholder is a patient or caregiver.

4. List a unique numeric identifier for the patient or caregiver that is matched to the identifier used for such person in the department's compassionate use registry.

5. Provide the expiration date, which shall be 1 year after the date of the physician's initial order of low-THC cannabis.

6. For the caregiver, provide the name and unique numeric identifier of the patient that the caregiver is assisting.

7. Be resistant to counterfeiting or tampering.

(g) The department must create a schedule of violations in rule to impose reasonable fines not to exceed $10,000 on a dispensing organization. In determining the amount of the fine to be levied for a violation, the department shall consider:

1. The severity of the violation.

2. Any actions taken by the dispensing organization to correct the violation or to remedy the complaint.

3. Any previous violations.

(h) The department may suspend, revoke, or refuse to renew

a dispensing organization's approval if the organization has had a license or authority to practice any regulated profession or the authority to conduct any business in any other state or country revoked, suspended, or otherwise acted against, including the denial of licensure by the licensing authority, for a violation that would constitute a violation under Florida law.

(i) The department may adopt rules necessary to implement this section.

(8) ~~(7)~~ EXCEPTIONS TO OTHER LAWS.—

(a) Notwithstanding s. 893.13, s. 893.135, s. 893.147, or any other provision of law, but subject to the requirements of this section, a qualified patient and the qualified patient's caregiver ~~legal representative~~ may purchase and possess for the patient's medical use up to the amount of low-THC cannabis ordered for the patient, but not more than a 30-day supply of low-THC cannabis.

(b) Notwithstanding s. 893.13, s. 893.135, s. 893.147, or any other provision of law, but subject to the requirements of this section, an approved dispensing organization and its owners, managers, and employees may manufacture, possess, sell, deliver, distribute, dispense, and lawfully dispose of reasonable quantities, as established by department rule, of low-THC cannabis. For purposes of this subsection, the terms "manufacture," "possession," "deliver," "distribute," and "dispense" have the same meanings as provided in s. 893.02.

(c) Notwithstanding s. 893.13, s. 893.135, s. 893.147, or any other provision of law, but subject to the requirements of this section, an approved laboratory and its employees may possess, test, transport, and lawfully dispose of low-THC cannabis or paraphernalia as provided by department rule.

(d) An approved dispensing organization and its owners, managers, and employees are not subject to licensure or regulation under chapter 465 or chapter 499 for manufacturing, possessing, selling, delivering, distributing, dispensing, or lawfully disposing of reasonable quantities, as established by department rule, of low-THC cannabis.

Section 2. This act shall take effect July 1, 2016.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1411 Termination of Pregnancies
SPONSOR(S): Burton and others
TIED BILLS: **IDEN./SIM. BILLS:** SB 1722

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee		McElroy	O'Callaghan
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

HB 1411 amends existing abortion clinic and fetal tissue disposal requirements, and creates a registration program for abortion referral and counseling agencies.

The bill requires clinics that perform only first trimester abortions to have either a written patient transfer agreement or the physician who performs the abortion to have admitting privileges with a hospital within a reasonable proximity to the clinic. Abortion clinics that perform abortions after the first trimester must have such a written agreement and all physicians who perform abortions in those clinics must have such admitting privileges.

The bill prohibits anyone from advertising, selling, purchasing, donating and transferring fetal remains obtained through an abortion, as well as offering to do any of the preceding acts.

The bill prohibits public funding for an organization that owns, operates, or is affiliated with a licensed abortion clinic but provides exemptions to this prohibition.

The bill requires the Agency for Health Care Administration (AHCA) to perform annual licensure inspections of all abortion clinics, including a review of at least 50% of the patient records generated since the last inspection.

The bill establishes the manner for disposal of fetal remains and clarifies the penalty for failing to do so.

The bill requires all abortion clinics to comply with the reporting requirements for the United States Standard Report of Induced Termination of Pregnancy adopted by the Centers for Disease Control and Prevention.

The bill requires AHCA to submit an annual report to the President of the Senate and the Speaker of the House of Representatives which summarizes all regulatory actions it has taken against abortion clinics and referral agencies during the prior year.

The bill requires abortion referral or counseling agencies to register with AHCA.

The bill removes an existing statutory license fee cap and requires AHCA to establish fees which may not be more than the costs incurred by AHCA in licensing and regulating abortion clinics.

The bill appears to have a negative fiscal impact on state government and may have an indeterminate, positive fiscal impact on local government.

The bill provides an effective date of January 1, 2017.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Federal Law on Abortion

Right to Abortion

In 1973, the foundation of modern abortion jurisprudence, *Roe v. Wade*[1], was decided by the U.S. Supreme Court. Using strict scrutiny, the Court determined that a woman's right to an abortion is part of a fundamental right to privacy guaranteed under the Due Process Clause of the Fourteenth Amendment of the U.S. Constitution. Further, the Court reasoned that state regulation limiting the exercise of this right must be justified by a compelling state interest, and must be narrowly drawn.[2] In 1992, the fundamental holding of *Roe* was upheld by the U.S. Supreme Court in *Planned Parenthood v. Casey*.[3]A

The Viability Standard

In *Roe v. Wade*, the U.S. Supreme Court established a rigid trimester framework dictating when, if ever, states can regulate abortion.[4] The Court held that states could not regulate abortions during the first trimester of pregnancy. With respect to the second trimester, the Court held that states could only enact regulations aimed at protecting the mother's health, not the fetus's life. Therefore, no ban on abortions is permitted during the second trimester. The state's interest in the life of the fetus becomes sufficiently compelling only at the beginning of the third trimester, allowing it to prohibit abortions. Even then, the Court requires states to permit an abortion in circumstances necessary to preserve the health or life of the mother.[5]

The current viability standard is set forth in *Planned Parenthood v. Casey*.[6] Recognizing that medical advancements in neonatal care can advance viability to a point somewhat earlier than the third trimester, the U.S. Supreme Court rejected the trimester framework and, instead, limited the states' ability to regulate abortion pre-viability. Thus, while upholding the underlying holding in *Roe*, which authorizes states to "[r]egulate, and even proscribe, abortion except where it is necessary, in appropriate medical judgment, for the preservation of the life or health of the mother[,]"[7] the Court determined that the line for this authority should be drawn at "viability," because "..... there may be some medical developments that affect the precise point of viability...but this is an imprecision with tolerable limits given that the medical community and all those who must apply its discoveries will continue to explore the matter."[8] Furthermore, the Court recognized that "in some broad sense, it might be said that a woman who fails to act before viability has consented to the State's intervention on behalf of the developing child."[9]

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[1] *Roe v. Wade*, 410 U.S. 113 (1973).
[2] Id.
[3] *Casey*, 505 U.S. 833 (1992).
[4] *Roe*, 410 U.S. 113 (1973).
[5] Id. at 164-165.
[6] *Casey*, 505. U.S. 833 (1992).
[7] *See Roe*, 410 U.S. at 164-65.
[8] *See Casey, 505 U.S.* at 870.
[9] Id.

Undue Burden

In *Planned Parenthood v. Casey*, the U.S. Supreme Court established the undue burden standard for determining whether a law places an impermissible obstacle to a woman's right to an abortion. The Court held that health regulations which impose undue burdens on the right to abortion are invalid.[10] State regulation imposes an "undue burden" on a woman's decision to have an abortion if it has the purpose or effect of placing a substantial obstacle in the path of the woman who seeks the abortion of a nonviable fetus.[11] However, not every law, which makes the right to an abortion more difficult to exercise, is an infringement of that right.[12]

The Hyde Amendment

The Hyde Amendment is a rider to the annual appropriations bill for the U.S. Departments of Labor and Education, which prevents Medicaid and any other programs under these departments from funding abortions, except in limited cases. The amendment is named after Rep. Henry J. Hyde (R-IL), who, as a freshman legislator, first offered the amendment.

The Hyde Amendment has been enacted into law in various forms since 1976. In 1980, the U.S. Supreme Court affirmed the constitutionality of the Hyde Amendment in *Harris v. McRae*.[13] In *Harris*, the Court determined that funding restrictions created by the Hyde Amendment did not violate the U.S. Constitution's Fifth Amendment and, therefore, did not contravene the liberty or equal protection guarantees of the Due Process Clause of the Fifth Amendment.[14] The Court opined that, although government may not place obstacles in the path of a woman's exercise of her freedom of choice, it need not remove those obstacles that are not created by the government (in this case indigence).[15] The Court further opined that, although Congress has opted to subsidize medically necessary services generally, but not certain medically necessary abortions, the Hyde Amendment leaves an indigent woman with at least the same range of choice in deciding whether to obtain a medically necessary abortion as she would have had if Congress had chosen to subsidize no health care costs at all.[16]

The current language of the Hyde Amendment, contained in the Consolidated Appropriations Act of 2016 is as follows:[17]

> SEC. 506.
> (a) None of the funds appropriated in this Act, and none of the funds in any trust fund to which funds are appropriated in this Act, shall be expended for any abortion.
>
> (b) None of the funds appropriated in this Act, and none of the funds in any trust fund to which funds are appropriated in this Act, shall be expended for health benefits coverage that includes coverage of abortion.
>
> (c) The term "health benefits coverage" means the package of services covered by a managed care provider or organization pursuant to a contract or other arrangement.

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[10] Id. at 878.
[11] Id. at 877
[12] Id. at 873.
[13] 448 U.S. 297 (1980). *See also Rust v. Sullivan*, 500 U.S. 173 (1991), and *Webster v. Reproductive Health Services*, 492 U.S. 490 (1989), upholding *Harris v. McRae*.
[14] *Harris*, 448 U.S. at 326-27.
[15] *Harris*, *Id.* at 316-17.
[16] *Id.*
[17] H.R.2029 — 114th Congress (2015-2016). https://www.congress.gov/bill/114th-congress/house-bill/2029/text (last visited on January 15, 2016).

SEC. 507
(a) The limitations established in the preceding section shall not apply to an abortion—

(1) if the pregnancy is the result of an act of rape or incest; or
(2) in the case where a woman suffers from a physical disorder, physical injury, or physical illness, including a life endangering physical condition caused by or arising from the pregnancy itself, that would, as certified by a physician, place the woman in danger of death unless an abortion is performed.

(b) Nothing in the preceding section shall be construed as prohibiting the expenditure by a State, locality, entity, or private person of State, local, or private funds (other than a State's or locality's contribution of Medicaid matching funds).

(c) Nothing in the preceding section shall be construed as restricting the ability of any managed care provider from offering abortion coverage or the ability of a State or locality to contract separately with such a provider for such coverage with State funds (other than a State's or locality's contribution of Medicaid matching funds).

(d) (1) None of the funds made available in this Act may be made available to a Federal agency or program, or to a State or local government, if such agency, program, or government subjects any institutional or individual health care entity to discrimination on the basis that the health care entity does not provide, pay for, provide coverage of, or refer for abortions.

(2) In this subsection, the term "health care entity" includes an individual physician or other health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan.

Fetal Tissue

The Secretary of the U.S. Department of Health and Human Services is authorized under federal statutory law to conduct or support research on the transplantation of human fetal tissue for therapeutic purposes.[18] The human fetal tissue used in the research may come from a spontaneous abortion, an induced abortion or a stillbirth.[19] However, before the fetal tissue may be used for research, informed consent must be obtained from:[20]

(1) **The woman electing to donate the fetal tissue** who must sign a written statement of consent declaring that the donated fetal tissue is for research, made without restriction as to who may be the recipients of the tissue, and that she has not been informed of the identity of any potential recipients.
(2) **The attending physician** who must sign a written statement declaring that the tissue has been donated in accordance to (1) and that full disclosure has been made as to the physician's interest, if any, in the research to be conducted with the tissue and of any known medical or privacy risks to the woman.

[18] 42 U.S. Code § 289g–1.
[19] Id.
[20] Id.

(a) If the fetal tissue has been obtained through an induced abortion the written statement must also attest that the physician obtained consent to the abortion prior to the consent for the donation of the tissue; that no alteration of the timing, method, or procedures used to terminate the pregnancy was made solely for the purposes of obtaining the tissue; and the abortion was performed in accordance with applicable State law.

(3) **The researcher** who must sign a written statement of consent declaring that he or she is aware that the tissue is human and that it has been donated as a result of an abortion or stillbirth; has provide this information to any individual performing research or receiving a transplant of the tissue; and, has had no part in any decisions as to the timing, method, or procedures used to terminate the pregnancy.

Federal statutory law prohibits certain transfers and uses of human fetal tissue. The purchase of fetal tissue is prohibited. As such, a person may not knowingly transfer fetal tissue for valuable consideration.[21] Directed donation for use in transplantation is also prohibited. This applies to a donation which is made pursuant to a promise that the fetal tissue will be transplanted in a specific individual, as well as for a donation in which the recipient has paid for the donor's abortion.[22] Finally, solicitation or acceptance of tissues from fetuses gestated for research is prohibited.[23] This includes fetal tissue that was donated related to a pregnancy that was deliberately initiated to provide tissue for research or fetal tissue that was gestated in the uterus of a nonhuman animal.[24] Violation of any of these prohibitions can result in fines and imprisonment of up to 10 years.[25]

Florida Law on Abortion

Right to Abortion

Florida affords greater privacy rights to its citizens than those provided under the U.S. Constitution. While the federal Constitution traditionally shields enumerated and implied individual liberties from state or federal intrusion, the federal Court has long held that the state constitutions may provide even greater protections.[26] In 1980, Florida amended its Constitution to include Article I, s. 23 which creates an express right to privacy:[27]

> Every natural person has the right to be let alone and free from governmental intrusion into the person's private life except as otherwise provided herein. This section shall not be construed to limit the public's right of access to public records and meetings as provided by law.

This amendment is an independent, freestanding constitutional provision which declares the fundamental right to privacy and provides greater privacy rights then those implied by the federal Constitution.[28]

The Florida Supreme Court has recognized Florida's constitutional right to privacy "is clearly implicated in a woman's decision whether or not to continue her pregnancy."[29] In *In re T.W.,* the Florida Supreme Court ruled that[30]:

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[21] Valuable consideration does not include reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue. 42 U.S. Code § 289g–2(a).
[22] 42 U.S. Code § 289g–2(b).
[23] 42 U.S. Code § 289g–2(c).
[24] Id.
[25] 42 U.S. Code § 289g–2(d).
[26] *In re T.W.*, 551 So.2d 1186, 1191 (Fla. 1989).
[27] Id.
[28] Id at 1191-1192.
[29] Id at 1192.

> [P]rior to the end of the first trimester, the abortion decision must be left to the woman and may not be significantly restricted by the state. Following this point, the state may impose significant restrictions only in the least intrusive manner designed to safeguard the health of the mother. Insignificant burdens during either period must substantially further important state interests....Under our Florida Constitution, the state's interest becomes compelling upon viability....Viability under Florida law occurs at that point in time when the fetus becomes capable of meaningful life outside the womb through standard medical procedures.

The court recognized that after viability, the state can regulate abortion in the interest of the unborn child if the mother's health is not in jeopardy.[31]

Abortion Regulation

In Florida, abortion is defined as the termination of a human pregnancy with an intention other than to produce a live birth or to remove a dead fetus.[32] An abortion must be performed by a physician[33] licensed under ch. 458, F.S., or ch. 459, F.S., or a physician practicing medicine or osteopathic medicine in the employment of the United States.[34]

The Agency for Health Care Administration (AHCA) licenses and regulates abortion clinics in the state, pursuant to ch. 390, F.S., and part II of ch. 408, F.S.[35] To become licensed an abortion clinic must pay a fee which may not be less than $70 or more than $500.[36]

The level of regulation which may be prescribed by AHCA is dependent upon the trimester in which the abortion is being performed.[37] However, all abortion clinics and physicians performing abortions are subject to the following requirements:

- An abortion may only be performed in a validly licensed hospital, abortion clinic, or in a physician's office;[38]
- An abortion clinic must be operated by a person with a valid and current license;[39]
- A third trimester abortion may only be performed in a hospital;[40]
- Proper medical care must be given and used for a fetus when an abortion is performed during viability;[41]
- Experimentation on a fetus is prohibited;[42]
- Except when there is a medical emergency, an abortion may only be performed after a patient has given voluntary and written informed consent;[43]
- Consent includes verification of the fetal age via ultrasound imaging;[44]

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[30] Id at 1193
[31] Id. at 1194.
[32] Section 390.011(1), F.S.
[33] Section 390.0111(2), F.S.
[34] Section 390.011(8), F.S.
[35] Section 408.802(3) provides for the applicability of the Health Care Licensing Procedures Act to abortion clinics.
[36] Section 390.014, F.S.
[37] Currently, only the third trimester is defined in statute. Pursuant to 59A-9.019, F.A.C., "trimester" is a 12-week period of pregnancy. "First trimester" is the first 12 weeks of pregnancy (the first 14 completed weeks from the last normal menstrual period); "Second trimester" is that portion of a pregnancy following the 12th week and extending through the 24th week of gestation; and "third trimester" is that portion of pregnancy beginning with the 25th week of gestation.
[38] Section 797.03 (1), F.S.
[39] Section 797.03 (2), F.S.
[40] Section 797.03(3), F.S. The violation of any of these provisions results in a second degree misdemeanor.
[41] Section 390.0111(4), F.S.
[42] Section 390.0111(6), F.S.
[43] Section 390.0111(3), F.S. A physician violating this provision is subject to disciplinary action.

- Fetal remains are to be disposed of in a sanitary and appropriate manner;[45] and
- Parental notice must be given 48 hours before performing an abortion on a minor,[46] unless waived by a parent or otherwise ordered by a judge.

Florida law permits only minimal regulation of clinics providing only first trimester abortions. AHCA is allowed to promulgate regulations which are comparable to rules that apply to all surgical procedures requiring approximately the same degree of skill and care as the performance of first trimester abortions.[47] These regulations consist of requiring first trimester abortions performed by a licensed physician at a licensed facility and minimal record-keeping requirements.[48] Several other regulations related to first trimester abortions have been held unconstitutional, including rules which required abortion clinics and the physicians who perform first trimester abortions to:[49]

- Maintain specified equipment in the clinic;
- Prepare a written pamphlet outlining post-operative treatment;
- Perform specified tests prior to the abortion procedure;
- Make available certain medications for post-operative treatment;
- Establish procedures to maintain proper sanitation; and
- Dispose of fetal remains in a nuisance-free manner.

AHCA has broader authority to establish rules for abortion clinics which perform abortions after the first trimester. This includes, among others, prescribing standards for: [50]

- Adequate private space for interviewing, counseling, and medical evaluations;
- Dressing rooms for staff and patients;
- Appropriate lavatory areas;
- Areas for pre-procedure hand-washing;
- Private procedure rooms;
- Adequate lighting and ventilation for procedures;
- Surgical or gynecological examination tables and other fixed equipment;
- Post-procedure recovery rooms that are equipped to meet the patients' needs;
- Emergency exits to accommodate a stretcher or gurney;
- Areas for cleaning and sterilizing instruments;
- Adequate areas for the secure storage of medical records and necessary equipment; and
- Conspicuous display of the clinic's license.

AHCA is also required to promulgate rules for clinics which perform abortions after the first trimester which require an abortion clinic to designate a medical director who is licensed to practice medicine in this state.[51] The medical director must have admitting privileges at a licensed hospital in this state or have a transfer agreement with a licensed hospital within reasonable proximity[52] of the clinic.[53]

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[44] Section 390.0111(3)(a)1.b., F.S.
[45] Section 390.0111(8), F.S. A person who improperly disposes of fetal remains commits a second degree misdemeanor.
[46] Section 390.01114(3), F.S. A physician who violates this provision is subject to disciplinary action.
[47] Section 390.012(2), F.S.
[48] *Florida Women's Medical Clinic, Inc. v. Smith*, 536 F.Supp. 1048 (S.D. Fla. 1982).
[49] Id.
[50] Section 390.012(3)(a)1., F.S. Rules related to abortion are found in ch. 59A-9, F.A.C.
[51] Section 390.012(3)(c), F.S.
[52] "Reasonable proximity" means a distance not to exceed thirty minutes transport time by emergency vehicle. 59A-9.019, F.A.C.,
[53] Section 390.012(3)(c), F.S.

AHCA has broad authority to inspect abortion clinics. These inspections must occur biennially and must be unannounced.[54] AHCA has the right to inspect all records of abortion clinics.[55] The exact number of records to be reviewed during the inspection is at the discretion of AHCA.

Both the Department of Health (DOH) and AHCA have authority to take licensure action against individuals and clinics that are in violation of statutes or rules.[56] Additionally, abortion clinics may be subject to criminal penalties for violation of statutes and rules.

Abortion Data Collection and Reporting Requirements

Currently facilities that perform terminations are required to submit a monthly report to AHCA containing the following:

- Number of abortions performed,
- Reason for performance; and
- Gestational age of the fetus.[57]

AHCA is required to keep this information in a central location from which statistical data can be drawn.[58] If the abortion is performed in a location other than a medical facility, the physician who performed the abortion is responsible for reporting the information to AHCA.[59] The reports are confidential and exempt from public records requirements.[60] Fines may be imposed for violations of the reporting requirements.[61]

The Centers for Disease Control and Prevention (CDC), compiles statistics voluntarily reported by the 50 states, the District of Columbia and New York City, related to termination of pregnancies to produce a national estimate.[62] The last national estimate was completed in 2012.[63] The CDC requests the following information from states in the U.S. Standard Report of Induced Termination of Pregnancy:

- Facility name (clinic or hospital);
- City, town or location;
- County;
- Hospital or clinic's patient identification number (used for querying for missing information without identifying the patient);
- Age;
- Marital status;
- Date of termination;
- Residence of patient;
- Ethnicity;
- Race;
- Education attainment;
- Date of last menses;
- Clinical estimate of gestation;

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[54] Section 408.811, F.S.
[55] Id.
[56] Section 390.018, F.S.
[57] Section 390.0112 (1), F.S.
[58] *Id.*
[59] Section 390.0112(2), F.S.
[60] Section S. 390.0112(3), F.S.
[61] Section 390.0112(4), F.S.
[62] *Abortion Surveillance- United States, 2012*, Surveillance Summaries, Centers for Disease Control and Prevention, November 27, 2015 / 64(SS10);1-40 http://www.cdc.gov/mmwr/preview/mmwrhtml/ss6410a1.htm?s_cid=ss6410a1_e (last visited on January 4, 2016).
[63] Id.

- Previous pregnancy history;
- Previous abortion history;
- Type of abortion procedure; and
- Name of attending physician and name of person completing report.[64]

The CDC uses this data to provide an annual Abortion Surveillance Report (ASR). The CDC notes that they receive data from some states, but not all.[65] Currently, Florida only reports the annual number of terminations that occur in the state,[66] and is therefore absent from all but three of the charts in the ASR.

Florida Abortion Statistics

In 2014, DOH reported that there were 220,138 live births in the state of Florida.[67] In the same year, AHCA reported that there were 72,073 abortion procedures performed in the state. Of those performed:[68]

- 65,902 were performed in the first trimester (12 weeks and under);
- 6,171 were performed in the second trimester (13 to 24 weeks); and
- None were performed in the third trimester (25 weeks and over).

The majority of the procedures (65,210) were elective.[69] The remainder of the abortions were performed due to:[70]

- Emotional or psychological health of the mother (76);
- Physical health of the mother that was not life endangering (158);
- Life endangering physical condition (69);
- Rape (749);
- Serious fetal genetic defect, deformity, or abnormality (560); and
- Social or economic reasons (5,115).

Florida's Application of the Hyde Amendment

In Florida, based on the Hyde Amendment, Medicaid reimburses for abortions for one of the following reasons:

- The woman suffers from a physical disorder, physical injury, or physical illness, including a life endangering physical condition caused or arising from the pregnancy itself, that would place the woman in danger of death unless an abortion is performed;
- When the pregnancy is the result of rape (sexual battery) as defined in s. 794.011, F.S.; or
- When the pregnancy is the result of incest as defined in s. 826.04, F.S.[71]

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[64] Centers for Disease Control, Handbook on the Reporting of Induced Termination of Pregnancy, www.cdc.gov/nchs/data/misc/hb_itop.pdf (last visited on January 4, 2016).
[65] *Abortion Surveillance- United States, 2012*, Surveillance Summaries, Centers for Disease Control and Prevention, November 27, 2015 / 64(SS10);1-40 http://www.cdc.gov/mmwr/preview/mmwrhtml/ss6410a1.htm?s_cid=ss6410a1_e (last visited on January 4, 2016).
[66] Id.
[67] Correspondence from the Department of Health to the House of Representatives Health Quality Subcommittee dated February 26, 2015, on file with Health Quality Subcommittee Staff.
[68] Reported Induced Terminations of Pregnancy (ITOP) by Reason, By Weeks of Gestation for Calendar Year 2014, AHCA, on file with the Health Quality Subcommittee Staff.
[69] Id.
[70] Id.
[71] Agency for Health Care Administration, *Florida Medicaid: Ambulatory Surgery Center Services Coverage and Limitations Handbook*, January 2005, *available at* http://www.baccinc.org/medi/CD_April_2005/Provider_Handbooks/Medicaid_Coverage_and_Limitations_Handbooks/Ambulatory_Surgical_Center_Updated_January_2005.pdf (last visited Mar. 17, 2011).

An Abortion Certification Form must be completed and signed by the physician who performed the abortion for the covered procedures. The form must be submitted with the facility claim, the physician's claim, and the anesthesiologist's claim. The physician must record the reason for the abortion in the physician's medical records for the recipient.[72]

Fetal Tissue

Florida law prohibits experimentation on any live fetus or infant either prior to or subsequent to an abortion unless it is necessary to preserve the life of such fetus or infant.[73] Florida law also prohibits anyone from advertising, selling, purchasing or otherwise transferring a human embryo for valuable consideration.[74] There is however no prohibition against the donation of a human embryo.

Chapter 390, F.S., contains two standards for the disposal of fetal tissue. Pursuant to s. 390.0111, F.S., all fetal remains must be disposed of in a sanitary and appropriate manner and in accordance with standard health practices established by DOH. Failure to dispose of fetal remains in accordance with department rules is a misdemeanor of the second degree.[75] Pursuant to s. 390.012, F.S., abortion clinics are required to dispose of fetal tissue in a competent and professional manner consistent with the manner in which other human tissue is disposed.[76] Failure to adhere to this requirement is a first degree misdemeanor.[77]

Abortion Referral or Counseling Agencies

An "abortion referral or counseling agency" is any person, group, or organization that provides advice or help to persons in obtaining abortions.[78] These entities may be funded publicly or privately and are prohibited from charging or accepting any referral fees from a physician, hospital, clinic, or other medical facility.[79] Abortion referral or counseling agencies are required to provide an individual with a full explanation of an abortion, including alternatives to this procedure.[80] If the individual is a minor, then this explanation must also be provided to the parent or guardian of the minor.[81]

Effect of Proposed Changes

The bill requires clinics that perform only first trimester abortions to have either a written patient transfer agreement or the physician who performs the abortion to have admitting privileges with a hospital within a reasonable proximity to the clinic. Abortion clinics that perform abortions after the first trimester must have such a written agreement and all physicians who perform abortions in those clinics must have such admitting privileges.

The bill prohibits anyone from advertising, selling, purchasing, donating and transferring fetal remains obtained through an abortion, as well as offering to do any of the preceding acts.

The bill prohibits a state agency, local governmental entity, or managed care plan providing services under part IV of chapter 409(Medicaid), F.S., from expending funds for the benefit of, pay funds to, or initiate or renew a contract with an organization that owns, operates, or is affiliated with a licensed abortion clinic. The bill provides exemptions to this prohibition if:

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[72] *Id.*
[73] Section 390.0111(6), F.S.
[74] Section 873.05, F.S. "Valuable consideration" does not include the reasonable costs associated with the removal, storage, and transportation of a human embryo.
[75] Section 390.0111(7), F.S.
[76] Section 390.012(7), F.S.
[77] Id.
[78] Section 390.025, F.S.
[79] Id.
[80] Id.
[81] Id.

- All abortions performed are due to rape or incest or are medically necessary to preserve the life of the pregnant woman;
- The funds must be expended to fulfill the terms of a contract entered into before July 1, 2016; or
- The funds must be expended as reimbursement for Medicaid services provided on a fee-for-service basis.

The bill requires AHCA to perform annual licensure inspections of all abortion clinics. AHCA is required to review at least 50% of the patient records generated since the last inspection. AHCA is also required to promptly investigate allegations that unlicensed abortions are being performed at a clinic.

Chapter 390, F.S., currently contains two methods, each with different standards and levels of penalties, for the disposal of fetal remains. The bill eliminates this potential conflict and requires disposal of fetal remains in a sanitary manner pursuant to s. 381.0098, F.S., rules adopted thereunder and rules adopted by AHCA under this provision.

The bill requires all abortion clinics, by January 1, 2017, to report to AHCA information consistent with the United States Standard Report of Induced Termination of Pregnancy adopted by the CDC. AHCA must submit this data to the CDC upon request.

The bill requires, beginning February 1, 2017, AHCA to submit an annual report to the President of the Senate and the Speaker of the House of Representatives which summarizes all regulatory actions taken by it against abortion clinics and referral or counseling agencies during the prior year.

The bill requires registration of abortion referral or counseling agencies. AHCA will set the registration fee which may not exceed the cost to administer the registration. Facilities licensed pursuant to chapters 390, 395, 400 and 408, F.S., are exempt from registering as well as health care clinics and health care practitioners defined in s. 456.001, F.S., if they refer less than 6 patients each month.

The bill removes the statutory license fee cap of not less than $70 and not more than $500 and requires AHCA to establish fees which may not be more than required to pay for the costs incurred by AHCA in licensing and regulating abortion clinics.

The bill defines gestation and trimester to provide clarification as to when the first, second and third trimesters begin and end.

Provides an effective date of July 1, 2016, or as otherwise specified in the bill.

B. SECTION DIRECTORY:

Section 1: Amending s. 390.011, F.S., relating to definitions.
Section 2: Amending s. 390.0111, F.S., relating to termination of pregnancies.
Section 3: Amending s. 390.0112, F.S., relating to termination of pregnancies and reporting.
Section 4: Amending s. 390.012, F.S., relating to powers of agency, rules and disposal of fetal remains.
Section 5: Amending s. 390.014, F.S., relating to licenses fees.
Section 6: Amending s. 390.025, F.S., relating to abortion referral or counseling agencies and penalties.
Section 7: Amending s. 873.05, F.S., relating to advertising or sale of human embryos prohibited.
Section 8: Provides an effective date of July 1, 2016.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   Fees related to the registration of abortion referral and counseling agencies which may not exceed costs incurred by AHCA in administering the registration of these providers.

2. Expenditures:

   The bill requires AHCA to perform annual licensure inspections of all abortion clinics, including a review at least 50% of the patient records generated since the last inspection. AHCA anticipates this will cause an increase in surveyor workload requiring an additional 0.50 full-time equivalent (FTE) nurse surveyor position. This position will require $3,569 in non-recurring funds and $53,651 in recurring funds.

   The bill prohibits public funding for an organization that owns, operates, or is affiliated with a licensed abortion clinic. This includes state agencies and managed care plans and may result in an indeterminate, positive fiscal impact.

   The bill requires AHCA to collect and report information consistent with the United States Standard Report of Induced Termination of Pregnancy adopted by the CDC. Changes will need to be made to AHCA's ITOP reporting system to be consistent with the bills reporting requirements. AHCA estimates nonrecurring programming and developer costs of $181,664 for the initial setup and $6,300 in recurring costs thereafter.

   The bill requires the registration of referral and counseling agencies. AHCA will incur costs administering this program. However, the bill authorizes AHCA to set and collect registration fees which should offset any costs it incurs in the administration of this program.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   The bill prohibits public funding for an organization that owns, operates, or is affiliated with a licensed abortion clinic. This applies to funding provided through local governmental entities and may result in an indeterminate, positive fiscal impact.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Abortion clinics may incur an indeterminate, negative fiscal impact associated with compliance with the bill's data reporting requirements.

The bill prohibits public funding for an organization that owns, operates, or is affiliated with a licensed abortion clinic. This applies to funding provided through local governmental entities, state agencies and managed care plans. This may result in an indeterminate, negative fiscal impact for clinics and associated business organizations.

Abortion referral and counseling agencies will incur a negative fiscal impact related to the bill's registration requirement.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not Applicable. This bill does not appear to require counties or municipalities to spend funds or take action requiring the expenditure of funds; reduce the authority that counties and municipalities have to raise revenue in the aggregate; or reduce the percentage of state tax shared with counties or municipalities.

2. Other:

The bill requires clinics which perform 1st trimester abortions only to have either a written patient transfer agreement with a hospital within a reasonable proximity or the physician who performs the abortion to have admitting privileges at a hospital within a reasonable proximity. State and federal law permit only minimal regulation of first trimester abortions. In Florida, these regulations consist of requiring first trimester abortions be performed by a licensed physician at a licensed facility and minimal record-keeping requirements. Previously enacted regulations which exceeded these minimal regulations were found to be unconstitutional.

The bill requires abortion clinics that perform abortions after the first trimester to have all physicians who perform abortions have admitting privileges at a hospital within a reasonable proximity to the clinic. Ten states have enacted similar laws which have been upheld in five states, including Texas. The Texas statute is currently under review by the United States Supreme Court.[82]

B. RULE-MAKING AUTHORITY:

AHCA currently has sufficient rule-making authority to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

[82] *Whole Woman's Health v. Cole*, 136 S.Ct. 499 (U.S. 2015).

A bill to be entitled

An act relating to termination of pregnancies; amending s. 390.011, F.S.; defining the term "gestation" and revising the term "third trimester"; amending s. 390.0111, F.S.; revising the requirements for disposal of fetal remains; revising the criminal punishment for failure to properly dispose of fetal remains; prohibiting state agencies, local governmental entities, and Medicaid managed care plans from expending or paying funds to or initiating or renewing contracts under certain circumstances with certain organizations that perform abortions; providing exceptions; amending s. 390.0112, F.S.; requiring directors of certain hospitals and physicians' offices and licensed abortion clinics to submit monthly reports to the Agency for Health Care Administration on a specified form; prohibiting the report from including personal identifying information; requiring the agency to submit certain data to the Centers for Disease Control and Prevention on a quarterly basis; amending s. 390.012, F.S.; requiring the agency to develop and enforce rules relating to license inspections and investigations of certain clinics; requiring the agency to adopt rules that require certain clinics to have written agreements with local hospitals for certain

contingencies; specifying that the rules must require physicians who perform abortions at a clinic that performs abortions in the first trimester of pregnancy to have admitting privileges at a hospital within reasonable proximity to the clinic; revising requirements for rules that prescribe minimum recovery room standards; revising requirements for the disposal of fetal remains; requiring the agency to submit an annual report to the Legislature; amending s. 390.014, F.S.; providing a different limitation on the amount of a fee; amending s. 390.025, F.S.; requiring certain organizations that provide abortion referral services or abortion counseling services to register with the agency, pay a specified fee, and include certain information in advertisements; requiring biennial renewal of a registration; providing exemptions from the registration requirement; requiring the agency to adopt rules; providing for the assessment of costs in certain circumstances; amending s. 873.05, F.S.; prohibiting an offer to purchase, sell, donate, or transfer fetal remains obtained from an abortion and the purchase, sale, donation, or transfer of such remains, excluding costs associated with certain transportation of remains; providing effective dates.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Present subsections (6) through (12) of section 390.011, Florida Statutes, are redesignated as subsections (7) through (13), respectively, a new subsection (6) is added to that section, and present subsection (11) of that section is amended, to read:

390.011 Definitions.—As used in this chapter, the term:

(6) "Gestation" means the development of a human embryo or fetus between fertilization and birth.

(12)~~(11)~~ "~~Third~~ Trimester" means one of the following three distinct periods of time in the duration of a pregnancy:

(a) "First trimester," which is the period of time from fertilization through the end of the 11th week of gestation.

(b) "Second trimester," which is the period of time from the beginning of the 12th week of gestation through the end of the 23rd week of gestation.

(c) "Third trimester," which is the period of time from the beginning of the 24th week of gestation through birth ~~the weeks of pregnancy after the 24th week of pregnancy~~.

Section 2. Subsection (7) of section 390.0111, Florida Statutes, is amended, and subsection (15) is added to that section, to read:

390.0111 Termination of pregnancies.—

(7) FETAL REMAINS.—Fetal remains shall be disposed of in a sanitary ~~and appropriate~~ manner pursuant to s. 381.0098 and rules adopted thereunder ~~and in accordance with standard health~~

~~practices, as provided by rule of the Department of Health~~. Failure to dispose of fetal remains in accordance with this subsection ~~department rules~~ is a misdemeanor of the first ~~second~~ degree, punishable as provided in s. 775.082 or s. 775.083.

(15) USE OF PUBLIC FUNDS RESTRICTED.—A state agency, a local governmental entity, or a managed care plan providing services under part IV of chapter 409 may not expend funds for the benefit of, pay funds to, or initiate or renew a contract with an organization that owns, operates, or is affiliated with one or more clinics that are licensed under this chapter and perform abortions unless one or more of the following applies:

(a) All abortions performed by such clinics are:

1. On fetuses that are conceived through rape or incest; or

2. Are medically necessary to preserve the life of the pregnant woman or to avert a serious risk of substantial and irreversible physical impairment of a major bodily function of the pregnant woman, other than a psychological condition.

(b) The funds must be expended to fulfill the terms of a contract entered into before July 1, 2016.

(c) The funds must be expended as reimbursement for Medicaid services provided on a fee-for-service basis.

Section 3. Subsection (1) of section 390.0112, Florida Statutes, is amended, present subsections (2), (3), and (4) of that section are redesignated as subsections (3), (4), and (5), respectively, and a new subsection (2) is added to that section,

to read:

390.0112 Termination of pregnancies; reporting.—

(1) The director of any medical facility in which abortions are performed, including a physician's office, ~~any pregnancy is terminated~~ shall submit a ~~monthly~~ report each month to the agency. The report may be submitted electronically, may not include personal identifying information, and must include:

(a) Until the agency begins collecting data under paragraph (e), the number of abortions performed.

(b) The reasons such abortions were performed.

(c) For each abortion, the period of gestation at the time the abortion was performed.

(d) ~~which contains the number of procedures performed, the reason for same, the period of gestation at the time such procedures were performed, and~~ The number of infants born alive or alive ~~during or~~ immediately after an attempted abortion.

(e) Beginning no later than January 1, 2017, information consistent with the United States Standard Report of Induced Termination of Pregnancy adopted by the Centers for Disease Control and Prevention.

(2) The agency shall keep ~~be responsible for keeping~~ such reports in a central location for the purpose of compiling and analyzing ~~place from which~~ statistical data and shall submit data reported pursuant to paragraph (1)(e) to the Division of Reproductive Health within the Centers for Disease Control and Prevention, as requested by the Centers for Disease Control and

Prevention ~~analysis can be made~~.

Section 4. Paragraph (c) of subsection (1), subsection (2), and paragraphs (c) and (f) of subsection (3) of section 390.012, Florida Statutes, are amended, present paragraphs (g) and (h) of subsection (3) are redesignated as paragraphs (h) and (i), respectively, a new paragraph (g) is added to that subsection, subsection (7) of that section is amended, and subsection (8) is added to that section, to read:

390.012 Powers of agency; rules; disposal of fetal remains.—

(1) The agency may develop and enforce rules pursuant to ss. 390.011-390.018 and part II of chapter 408 for the health, care, and treatment of persons in abortion clinics and for the safe operation of such clinics.

(c) The rules shall provide for:

1. The performance of pregnancy termination procedures only by a licensed physician.

2. The making, protection, and preservation of patient records, which shall be treated as medical records under chapter 458. When performing a license inspection of a clinic, the agency shall inspect at least 50 percent of patient records generated since the clinic's last license inspection.

3. Annual inspections by the agency of all clinics licensed under this chapter to ensure that such clinics are in compliance with this chapter and agency rules.

4. The prompt investigation of credible allegations of

abortions being performed at a clinic that is not licensed to perform such procedures.

(2) For clinics that perform abortions in the first trimester of pregnancy only, these rules must ~~shall~~ be comparable to rules that apply to all surgical procedures requiring approximately the same degree of skill and care as the performance of first trimester abortions and must require:

(a) Clinics to have a written patient transfer agreement with a hospital within reasonable proximity to the clinic which includes the transfer of the patient's medical records held by the clinic and the treating physician to the licensed hospital; or

(b) Physicians who perform abortions at the clinic to have admitting privileges at a hospital within reasonable proximity to the clinic.

(3) For clinics that perform or claim to perform abortions after the first trimester of pregnancy, the agency shall adopt rules pursuant to ss. 120.536(1) and 120.54 to implement the provisions of this chapter, including the following:

(c) Rules relating to abortion clinic personnel. At a minimum, these rules shall require that:

1. The abortion clinic designate a medical director who is licensed to practice medicine in this state, and all physicians who perform abortions in the clinic have ~~who has~~ admitting privileges at a ~~licensed~~ hospital within reasonable proximity to the clinic ~~in this state or has a transfer agreement with a~~

~~licensed hospital within reasonable proximity of the clinic~~.

2. If a physician is not present after an abortion is performed, a registered nurse, licensed practical nurse, advanced registered nurse practitioner, or physician assistant ~~shall~~ be present and remain at the clinic to provide postoperative monitoring and care until the patient is discharged.

3. Surgical assistants receive training in counseling, patient advocacy, and the specific responsibilities associated with the services the surgical assistants provide.

4. Volunteers receive training in the specific responsibilities associated with the services the volunteers provide, including counseling and patient advocacy as provided in the rules adopted by the director for different types of volunteers based on their responsibilities.

(f) Rules that prescribe minimum recovery room standards. At a minimum, these rules must ~~shall~~ require that:

1. Postprocedure recovery rooms be ~~are~~ supervised and staffed to meet the patients' needs.

2. Immediate postprocedure care consist ~~consists~~ of observation in a supervised recovery room for as long as the patient's condition warrants.

~~3. The clinic arranges hospitalization if any complication beyond the medical capability of the staff occurs or is suspected.~~

3.~~4.~~ A registered nurse, licensed practical nurse,

advanced registered nurse practitioner, or physician assistant who is trained in the management of the recovery area and is capable of providing basic cardiopulmonary resuscitation and related emergency procedures remain ~~remains~~ on the premises of the abortion clinic until all patients are discharged.

4.~~5.~~ A physician ~~shall~~ sign the discharge order and be readily accessible and available until the last patient is discharged to facilitate the transfer of emergency cases if hospitalization of the patient or viable fetus is necessary.

5.~~6.~~ A physician discuss ~~discusses~~ Rho(D) immune globulin with each patient for whom it is indicated and ensure ~~ensures~~ that it is offered to the patient in the immediate postoperative period or ~~that it~~ will be available to her within 72 hours after completion of the abortion procedure. If the patient refuses the Rho(D) immune globulin, she and a witness must sign a refusal form approved by the agency which must be ~~shall be signed by the patient and a witness and~~ included in the medical record.

6.~~7.~~ Written instructions with regard to postabortion coitus, signs of possible problems, and general aftercare which are specific to the patient be ~~are~~ given to each patient. The instructions must include information ~~Each patient shall have specific written instructions~~ regarding access to medical care for complications, including a telephone number for use in the event of a ~~to call for~~ medical emergency ~~emergencies~~.

7.~~8.~~ ~~There is~~ A ~~specified~~ minimum length of time be specified, by type of abortion procedure and duration of

gestation, during which ~~that~~ a patient must remain ~~remains~~ in the recovery room ~~by type of abortion procedure and duration of gestation~~.

8.~~9.~~ The physician ensure ~~ensures~~ that, with the patient's consent, a registered nurse, licensed practical nurse, advanced registered nurse practitioner, or physician assistant from the abortion clinic makes a good faith effort to contact the patient by telephone~~, with the patient's consent,~~ within 24 hours after surgery to assess the patient's recovery.

9.~~10.~~ Equipment and services be ~~are~~ readily accessible to provide appropriate emergency resuscitative and life support procedures pending the transfer of the patient or viable fetus to the hospital.

(g) Rules that require clinics to have a written patient transfer agreement with a hospital within reasonable proximity to the clinic which includes the transfer of the patient's medical records held by both the clinic and the treating physician.

(7) If an ~~any~~ owner, operator, or employee of an abortion clinic fails to dispose of fetal remains and tissue in a sanitary manner pursuant to s. 381.0098, rules adopted thereunder, and rules adopted by the agency pursuant to this section ~~consistent with the disposal of other human tissue in a competent professional manner~~, the license of such clinic may be suspended or revoked, and such person commits ~~is guilty of~~ a misdemeanor of the first degree, punishable as provided in s.

775.082 or s. 775.083.

(8) Beginning February 1, 2017, and annually thereafter, the agency shall submit a report to the President of the Senate and the Speaker of the House of Representatives which summarizes all regulatory actions taken during the prior year by the agency under this chapter.

Section 5. Subsection (3) of section 390.014, Florida Statutes, is amended to read:

390.014 Licenses; fees.—

(3) In accordance with s. 408.805, an applicant or licensee shall pay a fee for each license application submitted under this chapter and part II of chapter 408. The amount of the fee shall be established by rule and may not be more than required to pay for the costs incurred by the agency in administering this chapter ~~less than $70 or more than $500~~.

Section 6. Effective January 1, 2017, present subsection (3) of section 390.025, Florida Statutes, is amended, and new subsections (3), (4), and (5) are added to that section, to read:

390.025 Abortion referral or counseling agencies; penalties.—

(3) An abortion referral or counseling agency, as defined in subsection (1), shall register with the Agency for Health Care Administration. To register or renew a registration an applicant must pay an initial or renewal registration fee established by rule, which must not exceed the costs incurred by

the agency in administering this section. Registrants must include in any advertising materials the registration number issued by the agency and must renew their registration biennially.

(4) The following are exempt from the requirement to register pursuant to subsection (3):

(a) Facilities licensed pursuant to this chapter, chapter 395, chapter 400, or chapter 408;

(b) Facilities that are exempt from licensure as a clinic under s. 400.9905(4) and that refer five or fewer patients for abortions per month; and

(c) Health care practitioners, as defined in s. 456.001, who, in the course of their practice outside of a facility licensed pursuant to this chapter, chapter 395, chapter 400, or chapter 408, refer five or fewer patients for abortions each month.

(5) The agency shall adopt rules to administer this section and part II of chapter 408.

(6)~~(3)~~ Any person who violates the provisions of subsection (2) commits ~~this section is guilty of~~ a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083. In addition to any other penalties imposed pursuant to this chapter, the Agency for Health Care Administration may assess costs related to an investigation of violations of this section which results in a successful prosecution. Such costs may not include attorney fees.

Section 7. Section 873.05, Florida Statutes, is amended to read:

873.05 Advertising, purchase, ~~or~~ sale, or transfer of human embryos or fetal remains prohibited.—

(1) A ~~No~~ person may not ~~shall~~ knowingly advertise or offer to purchase or sell, or purchase, sell, or otherwise transfer, a ~~any~~ human embryo for valuable consideration.

~~(2)~~ As used in this subsection ~~section~~, the term "valuable consideration" does not include the reasonable costs associated with the removal, storage, and transportation of a human embryo.

(2) A person may not advertise or offer to purchase, sell, donate, or transfer, or purchase, sell, donate, or transfer, fetal remains obtained from an abortion, as defined in s. 390.011. This subsection does not prohibit the transportation or transfer of fetal remains for disposal pursuant to s. 381.0098 or rules adopted thereunder.

(3) A person who violates ~~the provisions of~~ this section commits ~~is guilty of~~ a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

Section 8. Except as otherwise expressly provided in this act, this act shall take effect July 1, 2016.