The Florida Senate

COMMITTEE MEETING EXPANDED AGENDA

HEALTH POLICY
Senator Bean, Chair
Senator Sobel, Vice Chair

MEETING DATE: Tuesday, March 25, 2014
TIME: 2:00 —5:00 p.m.
PLACE: *Pat Thomas Committee Room,* 412 Knott Building

MEMBERS: Senator Bean, Chair; Senator Sobel, Vice Chair; Senators Brandes, Braynon, Flores, Galvano, Garcia, Grimsley, and Joyner

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
1	**SB 1276** Grimsley	Trauma Service Areas; Requiring the Department of Health to provide an annual report assessing the trauma system; revising factors for the department to consider when conducting the assessment; limiting the total number of trauma centers for each trauma service area; revising application requirements for the department to consider when selecting a hospital to be recognized as a trauma center; requiring the department to redesignate certain hospitals as Level II trauma centers, etc. HP 03/25/2014 AP	
2	**SB 1354** Grimsley (Similar H 1001)	Health Care; Revising contract requirements for managed care programs; prohibiting retroactive denial of claims in certain circumstances; establishing a process for providers to override certain treatment restrictions; requiring insurers to post preferred provider information on a website, etc. HP 03/25/2014 BI	
3	**CS/SB 1150** Commerce and Tourism / Bean (Similar H 1223)	Medical Tourism; Requiring Enterprise Florida, Inc., to collaborate with the Department of Economic Opportunity to market this state as a health care destination; requiring the Division of Tourism Marketing to include in its 4-year plan a discussion of the promotion of medical tourism; requiring the plan to promote national and international awareness of the qualifications, scope of services, and specialized expertise of health care providers in this state, to promote national and international awareness of certain business opportunities to attract practitioners to destinations in this state, and to include an initiative to showcase qualified health care providers, etc. CM 03/17/2014 Fav/CS HP 03/25/2014 AP	

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
4	**SB 1352** Grimsley (Compare CS/CS/H 819, H 7071, S 1066)	Health Care Practitioners; Expanding who may prescribe brand drugs under the prescription drug program when medically necessary; excepting controlled substances prescribed by an advanced practice registered nurse from the disqualifications for continued certification or licensure as a deputy or state pilot; authorizing an advanced practice registered nurse to prescribe, dispense, administer, or order drugs in accordance with a specified formulary, if such formulary is established; requiring the Board of Nursing to appoint a committee to determine whether such a formulary is needed and specifying the membership of the committee, etc. HP 03/25/2014 JU RC	
5	**SB 1086** Flores (Identical H 447)	Optional Medical Payments for Prenatal Care; Revising eligibility criteria for a pregnant woman to qualify for medical assistance payments, etc. HP 03/25/2014 AHS AP	
6	**SB 1134** Detert (Similar H 1195)	Home Medical Equipment; Exempting medical practices owned by allopathic, osteopathic, or chiropractic physicians, as well as medical practices owned by physicians and certain family members of such physicians, which sell or rent home medical equipment or services from the requirement that they be licensed as home medical equipment providers, etc. HP 03/25/2014 AHS AP	
7	**SB 1192** Sobel (Similar H 995)	Palliative Care; Creating the Palliative Care and Quality of Life Interdisciplinary Advisory Council; requiring the department to establish a palliative care consumer and professional information and education program; requiring certain health care practitioners to provide certain patients information about palliative care and information about facilities that offer palliative care; requiring certain health care facilities to comply with palliative care measures ordered by a patient's health care practitioner, etc. HP 03/25/2014 AHS AP	

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
8	**SB 1066** Grimsley (Similar CS/CS/H 819, Compare S 1352)	Department of Health; Authorizing the Department of Highway Safety and Motor Vehicles to provide reproductions of specified records to the Department of Health under certain circumstances; clarifying duties of the Department of Health to maintain the confidentiality of patient records that it obtains under subpoena pursuant to an investigation; authorizing licensees under investigation to inspect or receive copies of patient records connected with the investigation, subject to certain conditions; requiring the department to establish a toll-free telephone number for public reporting of certain complaints, etc. HP 03/25/2014 TR AP	
9	**SB 1254** Grimsley (Compare H 7105)	Health Care Services Rulemaking; Removing certain rulemaking authority relating to health care services; amending provisions relating to home medical equipment providers; requiring that the emergency management plan include criteria relating to the maintenance of patient equipment and supply lists, etc. HP 03/25/2014 RC	
10	**CS/SB 836** Regulated Industries / Bean (Similar H 687, Compare H 689)	Medical Gas; Requiring a person or establishment located inside or outside the state which intends to distribute medical gas within or into this state to obtain an applicable permit before operating; requiring the Department of Business and Professional Regulation to establish the form and content of an application; setting the minimum requirements for the storage and handling of medical gas; authorizing the department to require a facility that engages in wholesale distribution to undergo an inspection, etc. RI 03/06/2014 Fav/CS HP 03/25/2014	
11	**SB 282** Garcia (Similar H 7, Compare H 869)	Florida Kidcare Program; Clarifying that undocumented immigrants are excluded from eligibility; providing eligibility for optional payments for medical assistance and related services for certain lawfully residing children; clarifying that undocumented immigrants are excluded from eligibility for optional Medicaid payments or related services, etc. HP 03/25/2014 AHS AP	

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
12	**SB 572** Sobel (Identical H 499)	Use of a Tanning Facility by a Minor; Citing this act as the "Preventing Youth Cancer Act"; revising the age of a minor prohibited from using a tanning device at a tanning facility; prohibiting a minor of any age from using a tanning device; providing an exception if a health care provider prescribes tanning sessions for a minor to treat a medical condition and the tanning facility has on file a statement signed by the minor's parent or guardian, etc. HP 03/25/2014 CJ RC	
13	**SB 584** Lee (Similar CS/H 301)	Medical Examiners; Clarifying the circumstances under which a case must be referred to the district medical examiner for an investigation and determination of cause of death; prohibiting medical examiners from charging user fees for specified services involving a determination of cause of death, etc. HP 03/11/2014 Temporarily Postponed HP 03/25/2014 CA	
14	**SB 1412** Joyner (Identical H 339)	Closing the Gap Grant Program; Adding a requirement for project proposals under the grant program to address racial and ethnic disparities in morbidity and mortality rates relating to sickle cell disease, etc. HP 03/25/2014 AHS AP	
	Other Related Meeting Documents		

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Health Policy

BILL:	SB 1276
INTRODUCER:	Senator Grimsley
SUBJECT:	Trauma Service Areas
DATE:	March 21, 2014
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Stovall	HP	**Pre-meeting**
2.			AP	

I. Summary:

SB 1276 revises the selection and allocation of trauma centers, emphasizing performance related to quality standards. It requires the Department of Health (DOH) to conduct an annual assessment of the state trauma system and report to the Governor and the Legislature by February 1 of each year. Several factors are enumerated for inclusion in the assessment as well as consideration of the performance of the trauma system compared to specific standards for access and quality.

The bill reduces the number of trauma service areas (TSA) enumerated in statute from 19 to 18.[1] The total number of trauma centers statewide is limited to 33 and a specific number of trauma centers is allocated to each TSA, ranging from one to three trauma centers per TSA.[2] Any new Level I or Level II trauma centers must be located 10 miles or more from an existing Level I or II trauma center.

The DOH is directed to select which hospitals are to be recognized as trauma centers based on documentation of the hospital's ability to meet established quality standards. The bill strikes language allowing hospitals to protest DOH decisions based on the DOH's preliminary or in-depth reviews of applications.[3]

Finally, the DOH is required to redesignate a hospital as a Level II trauma center within 30 days after the request for redesignation if the hospital has operated continuously as a Level II trauma center for a 12-month period; is in operation on July 1, 2014; meets statutory requirements regarding quality of care and patient outcomes; and if resignation would not cause the total number of trauma centers in the TSA to exceed the number designated in s. 395.402, F.S.

[1] By eliminating current TSA 17 and moving Charlotte County in TSA 13 and Collier County into TSA 15.
[2] TSAs 2, 3, 4, 7, 11, 12, 14, and 15 are assigned one trauma center; TSAs 5, 6, 10, 13, and 16 are assigned two trauma centers; and TSAs 1, 8, 9, 17, and 18 are assigned three trauma centers.
[3] This would not affect a hospital's ability to protest final DOH action under the provisions of ch. 120, F.S.

II. Present Situation:

The regulation of trauma centers in Florida is established under part II of ch. 395, F.S. Trauma centers treat individuals who have incurred single or multiple injuries because of blunt or penetrating means or burns, and who require immediate medical intervention or treatment. Currently, there are 27 verified and provisional trauma centers in the state.[4]

Trauma centers in Florida are divided into several categories including Level I, Level II, and Pediatric trauma centers.

- A Level I trauma center is defined as a trauma center that:
  - Has formal research and education programs for the enhancement of trauma care; is verified by the DOH to be in substantial compliance with Level I trauma center and pediatric trauma center standards; and has been approved by the DOH to operate as a Level I trauma center;
  - Serves as a resource facility to Level II trauma centers, pediatric trauma centers, and general hospitals through shared outreach, education, and quality improvement activities; and
  - Participates in an inclusive system of trauma care, including providing leadership, system evaluation, and quality improvement activities.[5]
- A Level II trauma center is defined as a trauma center that:
  - Is verified by the DOH to be in substantial compliance with Level II trauma center standards and has been approved by the DOH to operate as a Level II trauma center or is designated pursuant to s. 395.4025(14);
  - Serves as a resource facility to general hospitals through shared outreach, education, and quality improvement activities; and
  - Participates in an inclusive system of trauma care.[6]
- A Pediatric trauma center is defined as a hospital that is verified by the DOH to be in substantial compliance with pediatric trauma center standards and has been approved by the DOH to operate as a pediatric trauma center.[7,8]

Trauma Center Apportionment

Pursuant to s. 395.402, F.S., Florida is divided into 19 "trauma service areas." A trauma service area is determined based on population density and an ability to respond to a specified number of patients in a trauma center environment. For purposes of medical response time, the trauma service area should have at least one Level I or Level II trauma center, and the DOH is required to allocate, by rule, the number of trauma centers for each trauma service area. There cannot be more than 44 trauma centers in the state.

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[4] *See* http://www.floridahealth.gov/licensing-and-regulation/trauma-system/_documents/%20traumacenterlisting2014.pdf, last visited on Mar. 18, 2014.
[5] Section 395.4001(6), F.S.
[6] Section 395.4001(7), F.S.
[7] Section 395.4001(8), F.S.
[8] For Level I, Level II, and pediatric trauma center standards *see* http://www.floridahealth.gov/licensing-and-regulation/trauma-system/_documents/%20traumacntrstandpamphlet150-9-2009rev1-14-10.pdf, last visited on Mar. 21, 2014.

On November 30, 2012, the Florida First District Court of Appeal upheld a circuit court ruling which invalidated DOH Rule 64J-2.010, F.A.C.[9] The rule mirrored exactly the allocation of trauma service areas in s. 395.402(4), F.S., even though the statute required the DOH to review the assignment of counties to trauma service areas annually. In its opinion the court stated that the trauma statutes were substantially amended in 2004 but the rule remained unchanged since 1992. As such, the rule continued to implement the outdated provisions of these statutes.[10] In response to this ruling, the DOH began a series of 12 workshops to gather input from the public in order to rewrite Rule 64J-2.010, F.A.C. When these workshops concluded, the DOH published a new proposed rule[11] using the input from these workshops and the final report of the American College of Surgeons Committee on Trauma Systems consultation team.[12] The DOH then initiated negotiated rulemaking which took place on January 23, 2014, in order to allow "an opportunity for interested parties to come together and discuss the draft rule text directly with each other."[13] After the public comment period, the DOH was in a position to certify the proposed rule but received rule challenge petitions in early March 2014.[14] The rule challenges are scheduled to be heard by the Department of Administrative Hearings between March 31 and April 11, 2014.[15]

Trauma Center Approval

Section 395.4025, F.S., provides a scheduled application process and specific trauma center selection criteria. Standards for verification and approval are based on national guidelines established by the American College of Surgeons.[16] Standards for verification and approval as a pediatric center are developed in conjunction with Children's Medical Services.

Acute care hospitals that submit a Letter of Intent to the DOH by October 1 are eligible to submit a trauma center application by April 1.[17] Once an applicant hospital receives the DOH's notification letter of provisional status designation, the hospital may begin operation as a provisional trauma center. During the provisional phase, the DOH conducts an in-depth review of the hospital's application. An onsite visit is conducted by an out-of-state survey team to verify compliance with the *Trauma Center Standards, DH Pamphlet 150-9*.[18] Based on the

[9] *Department of Health v. Bayfront Medical Center, Inc.*, (Fla. App. 1 Dist., 2012), (on file with Health Policy Committee)
[10] Id., p. 5
[11] Available at https://www.flrules.org/gateway/RuleNo.asp?title=Trauma&ID=64J-2.010, last visited on Mar. 18, 2014.
[12] Available at http://www.floridahealth.gov/licensing-and-regulation/trauma-system/_documents/fl-report-final-5-6-13.pdf. Last visited on Mar. 18, 2014.
[13] DOH press release, Dec. 20, 2013, available at http://newsroom.doh.state.fl.us/wp-content/uploads/newsroom/2013/05/122013-Trauma-Rulemaking-Negotiation.pdf, last visited on Mar. 18, 2014.
[14] Email from Gary Landry, Legislative Planning Office Manager, DOH (on file with Senate Health Policy Committee)
[15] Id.
[16] The ACS requirements for Level I, Level II, and pediatric trauma centers are available at: http://www.facs.org/trauma/verifivisitoutcomes.html, last visited on Mar. 21, 2013.
[17] The required criteria included in the application package is outlined in the department's *Trauma Center Standards, DH Pamphlet 150-9*, in accordance with s. 395.401(2), F.S., and is incorporated by reference in Rule 64J-2.011, F.A.C. The criteria is based on the American College of Surgeons (ACS) national guidelines entitled -- *Hospital and Prehospital Resources for Optimal Care of the Injured Patient.* See DOH analysis of SB 1276, (on file with Senate Health Policy Committee).
[18] Available at http://www.floridahealth.gov/licensing-and-regulation/trauma-system/_documents/%20traumacntrstandpamphlet150-9-2009rev1-14-10.pdf, last visited on Mar. 18, 2014.

recommendations from the out-of-state survey team, the DOH makes the decision to approve or deny the hospital to operate as a verified trauma center.[19]

Hospitals verified by the DOH receive a seven year certificate. A verified trauma center that intends to renew its verification must submit a renewal application form to the DOH at least 14 months prior to the expiration of the certificate. All renewing verified trauma centers receive an onsite visit by an out-of-state survey team after the DOH's receipt of the completed renewal form. Hospitals that have been verified by the DOH to be in compliance with the requirements of s. 395.4025, F.S., are approved to operate as a verified trauma center.[20]

In 2013, the Legislature passed ch. 2013-153, L.O.F., which created an exception to the standard process of verifying new trauma centers for certain Level II trauma centers. As amended, s. 395.4025(14), F.S., requires that a hospital must be designated by the DOH as a Level II trauma center if the hospital:

- Is located in a TSA with a population greater than 600,000 persons and a population density of less than 225 persons per square mile;
- Is located in a county with no verified trauma centers;
- Is located at least 15 miles or 20 minutes away from the nearest verified trauma center; and
- Has a valid certificate of trauma center verification from the American College of Surgeons.

III. Effect of Proposed Changes:

Section 1 of the bill amends s. 395.402, F.S., to:

- Require the DOH to conduct an annual assessment of the state trauma system which must be reported to the Governor, the President of the Senate, the Speaker of the House of Representatives, and the substantive legislative committees by February 1 of each year. The DOH must determine whether the existing trauma system is effective in providing trauma care uniformly throughout the state and, when creating the assessment, is required to:
  - Review the number and level of trauma centers needed for each trauma service area to provide an integrated trauma system statewide;
  - Identify criteria used for determining the number and level of trauma centers needed to serve the population in a defined TSA or region;
  - Evaluate the level of integration of the trauma system planning with interagency regional emergency and disaster planning and identify any action needed to reduce duplication of planning efforts and to promote effective responses to mass casualty events;
  - Report the amounts, sources, and uses of financial support for the trauma system;
  - Make recommendations regarding the distribution of state funds for trauma centers; and
  - Consider:
    - Recommendations submitted by regional trauma agencies;
    - Stakeholder recommendations; and
    - The performance of the trauma system compared to specific standards for access and quality;[21]
- Modify the existing TSAs to:

[19] Id.
[20] Id.
[21] These specific standards are not specified in the bill or in statute and would likely need to be determined by the DOH.

- Eliminate TSA 17[22] and place Collier County in TSA 15 along with Glades, Hendry, and Lee Counties; and,
- Move Charlotte County from TSA 15 to TSA 13;

- Designate a statewide total of 33 trauma centers, reduced from a maximum of 44, so that each TSA is granted a specific maximum number of allowed trauma centers.[23] The trauma centers are allocated so that:
  - TSAs 2, 3, 4, 7, 11, 12, 14, and 15 may have only one trauma center;
  - TSAs 5, 6, 10, 13, and 16 may have up to two trauma centers; and
  - TSAs 1, 8, 9, 17, and 18 may have up to three trauma centers;
- Prohibit approval of a new Level I or Level II trauma center if located less than 10 miles from an existing Level I or Level II trauma center;
- Strike language requiring the DOH to review the assignment of counties to TSAs; and
- Strike outdated provisions and make other technical changes.

Section 2 of the bill amends s. 395.4025, F.S., to:

- Require the DOH to select which hospitals to recognize as trauma centers based on documentation of the hospital's ability to meet established quality standards;[24]
- Strike language that allows a hospital to protest a decision made by the DOH based on the DOH's preliminary or in-depth review of applications or on the recommendations of the site visit review team and which requires the DOH to hold a hearing as provided in ch. 120, F.S.[25]
- Require the DOH to redesignate a hospital as a Level II trauma center if:
  - The hospital has operated continuously as a Level II trauma center for a 12-month period;
  - The hospital is in operation on July 1, 2014;
  - The hospital meets statutory requirements regarding quality of care and patient outcomes designated in s. 395.4025(5) and (6), F.S.;[26] and
  - Redesignation would not cause the total number of trauma centers in the TSA to exceed the number designated in s. 395.402, F.S.
- Strike outdated language, conform to changes made to s. 395.402, F.S., in the bill and make other technical changes.

Section 3 of the bill establishes an effective date of July 1, 2014.

[22] Consisting solely of Collier County.
[23] No TSA currently has more trauma centers than the limits placed on them by the bill. TSAs 1, 5, 6, 9, and 13are under their limits by 1 trauma center and TSA 8 is under its limit by 2 trauma centers.
[24] *See supra* n. 18.
[25] This would not affect a hospital's ability to protest final DOH action under the provisions of ch. 120, F.S.
[26] Subsection (5) requires an out-of-state review to team visit all provisional trauma centers between Oct. 1 and June 1 of each year, requires the DOH to develop a survey instrument for the reviewers to use, and requires that hospitals being considered meet all the requirements of a trauma center and be located in a TSA that has need for a trauma center. Subsection (6) requires the DOH to select trauma centers by July 1 based on the recommendations of the review team unless the hospital requests an extension of their provisional status and submits a corrective plan of action to the DOH.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

SB 1276 may have an indeterminate fiscal impact on existing and provisional trauma centers, as well as potential trauma center applicants, due to the revisions made to the manner in which trauma centers are allocated among the TSAs.

C. Government Sector Impact:

The DOH may incur indeterminate costs associated with producing the annual assessment of the state trauma system required in the bill and for adopting new rules to implement the changes made by the bill.

VI. Technical Deficiencies:

Lines 212 and 213 of the bill refer to the allocation of trauma centers to TSAs "under s. 395.402(4)", however those allocations are made in s. 395.402(5), F.S.

VII. Related Issues:

Lines 207-213 of the bill allow the DOH to grant an applicant additional time if the applicant is unable to meet all the necessary requirements and if "at the time of application the number of applicants in the service area in which the applicant is located is equal to or less than the service area allocation." The DOH states that this provision should include current trauma centers and, as such, should read "the number of trauma centers and applicants in the service area…"[27]

[27] See supra n. 13

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 395.402 and 395.4025.

IX. Additional Information:

A. Committee Substitute – Statement of Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.

This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.

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LEGISLATIVE ACTION

Senate . House

. . . . .

The Committee on Health Policy (Grimsley) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause and insert:

Section 1. Paragraphs (k), (l), (m), (n), and (o) of subsection (1) of section 395.401, Florida Statutes, are redesignated as paragraphs (l), (m), (n), (o), and (p), respectively, and paragraph (k) is added to that subsection, to read:

395.401 Trauma services system plans; approval of trauma

centers and pediatric trauma centers; procedures; renewal.—

(1)

(k) No hospital operating a trauma center may charge a trauma activation fee greater than $15,000. This paragraph expires on July 1, 2015.

Section 2. Subsection (5) is added to section 395.402, Florida Statutes, to read:

395.402 Trauma service areas; number and location of trauma centers.—

(5) No later than October 1, 2014, the department must convene the Florida Trauma System Plan Advisory Council in order to review the Trauma System Consultation Report issued by the American College of Surgeons Committee on Trauma dated February 2-5, 2013. Based on this review, the advisory council must submit recommendations, including recommended statutory changes, to the President of the Senate and the Speaker of the House of Representatives by February 1, 2015.

Section 3. Present subsections (8) through (12) of section 395.4025, Florida Statutes, are redesignated as subsections (7) through (11), respectively, paragraph (d) of subsection (2), and present subsection (7) of that section are amended, present subsections (13) and (14) of that section are redesignated as subsections (12) and (13), respectively, and amended, and a new subsections (14) and (15) are added to that section, to read:

395.4025 Trauma centers; selection; quality assurance; records.—

(2)

(d)1. Notwithstanding other provisions in this section, the department may grant up to an additional 18 months to a hospital

applicant that is unable to meet all requirements as provided in paragraph (c) at the time of application if the number of applicants in the service area in which the applicant is located is equal to or less than the service area allocation, as provided by rule of the department. An applicant that is granted additional time under ~~pursuant to~~ this paragraph shall submit a plan for departmental approval which includes timelines and activities that the applicant proposes to complete in order to meet application requirements. An ~~Any~~ applicant that demonstrates an ongoing effort to complete the activities within the timelines outlined in the plan shall be included in the number of trauma centers at such time that the department has conducted a provisional review of the application and has determined that the application is complete and that the hospital has the critical elements required for a trauma center.

2. Timeframes provided in subsections (1)-(7) ~~(8)~~ shall be stayed until the department determines that the application is complete and that the hospital has the critical elements required for a trauma center.

~~(7) Any hospital that wishes to protest a decision made by the department based on the department's preliminary or in-depth review of applications or on the recommendations of the site visit review team pursuant to this section shall proceed as provided in chapter 120. Hearings held under this subsection shall be conducted in the same manner as provided in ss. 120.569 and 120.57. Cases filed under chapter 120 may combine all disputes between parties.~~

(12) ~~(13)~~ The department may adopt, by rule, the procedures and process by which it will select trauma centers. Such

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procedures and process must be used in annually selecting trauma centers and must be consistent with subsections (1)-(7) ~~(8)~~ except in those situations in which it is in the best interest of, and mutually agreed to by, all applicants within a service area and the department to reduce the timeframes.

(13) ~~(14)~~ Notwithstanding the procedures established pursuant to subsections (1)-(12) ~~through (13)~~, hospitals located in areas with limited access to trauma center services shall be designated by the department as Level II trauma centers based on documentation of a valid certificate of trauma center verification from the American College of Surgeons. Areas with limited access to trauma center services are defined by the following criteria:

(a) The hospital is located in a trauma service area with a population greater than 600,000 persons but a population density of less than 225 persons per square mile;

(b) The hospital is located in a county with no verified trauma center; and

(c) The hospital is located at least 15 miles or 20 minutes travel time by ground transport from the nearest verified trauma center.

(14) If a hospital has operated continuously as a Level II trauma center for a consecutive 12-month period and is in operation on July 1, 2014, the department shall within 30 days after a request by the hospital, verify or designate such a hospital as a Level II trauma center if such hospital has met the requirements of subsections (5) and (6) with regard to quality of care and patient outcomes. A hospital that meets the requirements of this section shall be eligible for renewal of

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the 7-year approval period as provided in subsection (6).

(15) The department may not verify, designate, or provisionally approve any hospital to operate as a trauma center through the procedures established in subsections (1)-(13). This subsection expires July 1, 2015.

Section 4. This act shall take effect July 1, 2014.

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

And the title is amended as follows:

Delete everything before the enacting clause and insert:

A bill to be entitled

An act relating to trauma service centers; amending s. 395.401; restricting trauma service fees to $15,000 until July 1, 2015; amending s. 395.402; requiring the Department of Health to convene the Trauma System Plan Advisory Council by October 1, 2014; requiring the Trauma System Plan Advisory Council to review the Trauma System Consultation Report and make recommendations to the Legislature by February 1, 2015; amending s. 395.4025; deleting a provision relating to the procedure for protesting an application decision by the department; conforming cross-references; requiring the department to redesignate certain hospitals as Level II trauma centers; restricting the department from verifying designating, or provisionally approving hospitals as trauma centers until July 1, 2015; providing an effective date.

By Senator Grimsley

21-01447-14 20141276__

A bill to be entitled

An act relating to trauma service areas; amending s. 395.402, F.S.; requiring the Department of Health to provide an annual report assessing the trauma system; revising factors for the department to consider when conducting the assessment; limiting the total number of trauma centers for each trauma service area; deleting a provision that limits the total trauma areas allowed in the state; reconfiguring certain trauma service areas; amending s. 395.4025, F.S.; revising application requirements for the department to consider when selecting a hospital to be recognized as a trauma center; deleting a provision relating to the procedure for protesting an application decision by the department; conforming cross-references; requiring the department to redesignate certain hospitals as Level II trauma centers; providing an exception; providing an effective date.

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

Section 1. Section 395.402, Florida Statutes, is amended to read:

395.402 Trauma service areas; number and location of trauma centers.—

(1) The Legislature recognizes the need for a statewide, cohesive, uniform, and integrated trauma system. Within the trauma service areas, Level I and Level II trauma centers shall each be capable of annually treating a minimum of 1,000 and 500

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

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patients, respectively, with an injury severity score (ISS) of 9 or greater. Level II trauma centers in counties with a population of more than 500,000 shall have the capacity to care for 1,000 patients per year.

(2) Trauma service areas as defined in this section are to be used by ~~utilized until~~ the Department of Health to complete ~~completes~~ an annual assessment of the trauma system. This assessment shall be reported ~~and reports its finding~~ to the Governor, the President of the Senate, the Speaker of the House of Representatives, and the substantive legislative committees~~.~~ ~~The report shall be submitted~~ by February 1 of each year~~, 2005~~. The department shall review the existing trauma system and determine whether it is effective in providing trauma care uniformly throughout the state. The assessment shall:

~~(a) Consider aligning trauma service areas within the trauma region boundaries as established in July 2004.~~

(a) ~~(b)~~ Review the number and level of trauma centers needed for each trauma service area to provide a statewide integrated trauma system.

(b) ~~(c)~~ Identify ~~Establish~~ criteria used for determining the number and level of trauma centers needed to serve the population in a defined trauma service area or region.

~~(d) Consider including criteria within trauma center approval standards based upon the number of trauma victims served within a service area.~~

(c) ~~(c)~~ Evaluate the level of integration of ~~Review the Regional Domestic Security Task Force structure and determine whether integrating the~~ trauma system planning with interagency regional emergency and disaster planning ~~efforts is feasible~~ and

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

identify any action needed to reduce duplication of planning efforts and to promote effective response to mass casualty events ~~between the two entities~~.

(d) ~~(f)~~ Report the amounts, sources, and uses of financial support for the trauma system ~~Make recommendations regarding a continued revenue source which shall include a local participation requirement~~.

(e) ~~(g)~~ Make recommendations regarding the ~~a formula for the~~ distribution of state funds ~~identified~~ for trauma centers ~~which shall address incentives for new centers where needed and the need to maintain effective trauma care in areas served by existing centers, with consideration for the volume of trauma patients served, and the amount of charity care provided~~.

(3) In conducting the annual ~~such~~ assessment ~~and subsequent annual reviews~~, the department shall consider:

(a) ~~The~~ Recommendations ~~made as part of the regional trauma system plans~~ submitted by regional trauma agencies.

(b) Stakeholder recommendations.

(c) The performance of the trauma system compared to specific standards for access and quality ~~geographical composition of an area to ensure rapid access to trauma care by patients~~.

~~(d) Historical patterns of patient referral and transfer in an area.~~

~~(e) Inventories of available trauma care resources, including professional medical staff.~~

~~(f) Population growth characteristics.~~

~~(g) Transportation capabilities, including ground and air transport.~~

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~~(h) Medically appropriate ground and air travel times.~~

~~(i) Recommendations of the Regional Domestic Security Task Force.~~

~~(j) The actual number of trauma victims currently being served by each trauma center.~~

~~(k) Other appropriate criteria.~~

~~(4) Annually thereafter, the department shall review the assignment of the 67 counties to trauma service areas, in addition to the requirements of paragraphs (2)(b)-(g) and subsection (3). County assignments are made for the purpose of developing a system of trauma centers. Revisions made by the department shall take into consideration the recommendations made as part of the regional trauma system plans approved by the department and the recommendations made as part of the state trauma system plan. In cases where a trauma service area is located within the boundaries of more than one trauma region, the trauma service area's needs, response capability, and system requirements shall be considered by each trauma region served by that trauma service area in its regional system plan. Until the department completes the February 2005 assessment, the assignment of counties shall remain as established in this section.~~

(4) ~~(a)~~ The following trauma service areas are hereby established:

(a) ~~1.~~ Trauma service area 1 shall consist of Escambia, Okaloosa, Santa Rosa, and Walton Counties.

(b) ~~2.~~ Trauma service area 2 shall consist of Bay, Gulf, Holmes, and Washington Counties.

(c) ~~3.~~ Trauma service area 3 shall consist of Calhoun,

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Franklin, Gadsden, Jackson, Jefferson, Leon, Liberty, Madison, Taylor, and Wakulla Counties.

(d) ~~4.~~ Trauma service area 4 shall consist of Alachua, Bradford, Columbia, Dixie, Gilchrist, Hamilton, Lafayette, Levy, Putnam, Suwannee, and Union Counties.

(e) ~~5.~~ Trauma service area 5 shall consist of Baker, Clay, Duval, Nassau, and St. Johns Counties.

(f) ~~6.~~ Trauma service area 6 shall consist of Citrus, Hernando, and Marion Counties.

(g) ~~7.~~ Trauma service area 7 shall consist of Flagler and Volusia Counties.

(h) ~~8.~~ Trauma service area 8 shall consist of Lake, Orange, Osceola, Seminole, and Sumter Counties.

(i) ~~9.~~ Trauma service area 9 shall consist of Pasco and Pinellas Counties.

(j) ~~10.~~ Trauma service area 10 shall consist of Hillsborough County.

(k) ~~11.~~ Trauma service area 11 shall consist of Hardee, Highlands, and Polk Counties.

(l) ~~12.~~ Trauma service area 12 shall consist of Brevard and Indian River Counties.

(m) ~~13.~~ Trauma service area 13 shall consist of Charlotte, DeSoto, Manatee, and Sarasota Counties.

(n) ~~14.~~ Trauma service area 14 shall consist of Martin, Okeechobee, and St. Lucie Counties.

(o) ~~15.~~ Trauma service area 15 shall consist of Collier, ~~Charlotte,~~ Glades, Hendry, and Lee Counties.

(p) ~~16.~~ Trauma service area 16 shall consist of Palm Beach County.

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~~17. Trauma service area 17 shall consist of Collier County.~~

(q) ~~18.~~ Trauma service area 17 ~~18~~ shall consist of Broward County.

(r) ~~19.~~ Trauma service area 18 ~~19~~ shall consist of Miami-Dade and Monroe Counties.

(5) ~~(b) Each trauma service area should have at least one Level I or Level II trauma center. The department shall allocate, by rule,~~ The total number of trauma centers, including both Level I and Level II trauma centers, permitted in ~~needed for~~ each trauma service area is limited as follows: one center in areas 2, 3, 4, 7, 11, 12, 14, and 15; two centers in areas 5, 6, 10, 13, and 16; and three centers in areas 1, 8, 9, 17, and 18. An area may not have more than 3 centers. An additional Level I or Level II center may not be approved if located less than 10 miles from an existing Level I or Level II center.

~~(c) There shall be no more than a total of 44 trauma centers in the state.~~

Section 2. Present subsections (8) through (12) of section 395.4025, Florida Statutes, are redesignated as subsections (7) through (11), respectively, subsection (1), paragraphs (c) and (d) of subsection (2), and present subsection (7) of that section are amended, present subsections (13) and (14) of that section are redesignated as subsections (12) and (13), respectively, and amended, and a new subsection (14) is added to that section, to read:

395.4025 Trauma centers; selection; quality assurance; records.—

(1) ~~For purposes of developing a system of trauma centers, the department shall use the 19 trauma service areas established~~

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~~in s. 395.402. Within each service area and based on the state trauma system plan, the local or regional trauma services system plan, and recommendations of the local or regional trauma agency, the department shall establish the approximate number of trauma centers needed to ensure reasonable access to high-quality trauma services.~~ The department shall select those hospitals that are to be recognized as trauma centers, based on documentation of the hospital's ability to meet established quality standards.

(2)

(c) In order to be considered by the department, applications from those hospitals seeking selection as trauma centers, including those current verified trauma centers that seek a change ~~or redesignation~~ in approval status as a trauma center, must be received by the department no later than the close of business on April 1. The department shall conduct a provisional review of each application for the purpose of determining that the hospital's application is complete and that the hospital has the critical elements required for a trauma center. This ~~critical~~ review will be based on trauma center standards and shall determine ~~include, but not be limited to, a review of~~ whether the hospital has:

1. Equipment and physical facilities necessary to provide trauma services.

2. Personnel in sufficient numbers and with proper qualifications to provide trauma services.

3. An effective quality assurance process.

4. Submitted written confirmation by the local or regional trauma agency that the hospital applying to become a trauma

center is consistent with the plan of the local or regional trauma agency, as approved by the department, if such agency exists.

(d)1. Notwithstanding other provisions in this section, the department may grant up to an additional 18 months to a hospital applicant that is unable to meet all requirements as provided in paragraph (c) at the time of application if the number of applicants in the service area in which the applicant is located is equal to or less than the service area allocation, under s. 395.402(4) ~~as provided by rule of the department~~. An applicant that is granted additional time under ~~pursuant to~~ this paragraph shall submit a plan for departmental approval which includes timelines and activities that the applicant proposes to complete in order to meet application requirements. An ~~Any~~ applicant that demonstrates an ongoing effort to complete the activities within the timelines outlined in the plan shall be included in the number of trauma centers at such time that the department has conducted a provisional review of the application and has determined that the application is complete and that the hospital has the critical elements required for a trauma center.

2. Timeframes provided in subsections (1)-(7) ~~(8)~~ shall be stayed until the department determines that the application is complete and that the hospital has the critical elements required for a trauma center.

~~(7) Any hospital that wishes to protest a decision made by the department based on the department's preliminary or in-depth review of applications or on the recommendations of the site visit review team pursuant to this section shall proceed as provided in chapter 120. Hearings held under this subsection~~

~~shall be conducted in the same manner as provided in ss. 120.569 and 120.57. Cases filed under chapter 120 may combine all disputes between parties.~~

(12)~~(13)~~ The department may adopt, by rule, the procedures and process by which it will select trauma centers. Such procedures and process must be used in annually selecting trauma centers and must be consistent with subsections (1)-(7) ~~(8)~~ except in those situations in which it is in the best interest of, and mutually agreed to by, all applicants within a service area and the department to reduce the timeframes.

(13)~~(14)~~ Notwithstanding the procedures established pursuant to subsections (1)-(12) ~~through (13)~~, hospitals located in areas with limited access to trauma center services shall be designated by the department as Level II trauma centers based on documentation of a valid certificate of trauma center verification from the American College of Surgeons. Areas with limited access to trauma center services are defined by the following criteria:

(a) The hospital is located in a trauma service area with a population greater than 600,000 persons but a population density of less than 225 persons per square mile;

(b) The hospital is located in a county with no verified trauma center; and

(c) The hospital is located at least 15 miles or 20 minutes travel time by ground transport from the nearest verified trauma center.

(14) If a hospital has operated continuously as a Level II trauma center for a consecutive 12-month period and is in operation on July 1, 2014, the department shall within 30 days

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after a request by the hospital, redesignate such a hospital as a Level II trauma center if such hospital has met the requirements of subsections (5) and (6) with regard to quality of care and patient outcomes. The department shall designate any such hospital as a Level II trauma center if the redesignation of the hospital does not cause the total number of trauma centers in the trauma service area to exceed the number specified in s. 395.402(5). A hospital that meets the requirements of this section shall be eligible for renewal of the 7-year approval period as provided in subsection (6).

Section 3. This act shall take effect July 1, 2014.

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The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Health Policy

BILL:	SB 1354
INTRODUCER:	Senator Grimsley
SUBJECT:	Health Care
DATE:	March 22, 2014
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Lloyd	Stovall	HP	**Pre-meeting**
2.			BI	

I. Summary:

SB 1354 revises the managed care accountability contract provisions for the statewide Managed Medical Assistance (MMA) contracts under the Statewide Medicaid Managed Care Program (SMMC). It requires plans that establish prescribed drug formularies to offer a range of therapeutic options with at least two products in each therapeutic class. Managed care plans under MMA must also cover any drugs newly approved by the United States Food and Drug Administration (FDA) until the Medicaid Pharmaceutical and Therapeutics Committee can review the drug for inclusion in the formulary. If a drug on a Medicaid managed care plan's formulary is removed or changed, the plan must allow an enrollee to continue that drug if the provider submits a written request that demonstrates the drug is medically necessary and the enrollee meets clinical criteria to receive the drug.

The bill requires MMA managed care plans, health insurers, managed care organizations, and health maintenance organizations and any pharmacy benefit manager under contract with these insurers, to use a standardized prior authorization form adopted by the Financial Services Commission (commission). The form is to be adopted by January 15, 2015. All prior authorization requests for medical procedures, course of treatment, and prescriptions must be submitted using the same standardized two page form. A form submitted by a provider is deemed approved unless the issuer responds otherwise within two business days.

Managed care plans, health maintenance organizations and insurers, including Medicaid plans, that restrict medications by a step-therapy or fail-first protocol are required to have a clear and convenient process to request an override of the protocol. An override must be granted within 24 hours for certain situations where the prescribing provider believes the drug under the step-therapy or fail-first protocol has been or likely will be ineffective or will cause or will likely cause an adverse reaction. If the provider allows the patient to enter the step-therapy or fail-first protocol, the duration of the process may not exceed an amount deemed appropriate by the provider and if the provider deems it ineffective, the patient is entitled to receive the recommended course of treatment without override approval.

For insurance contracts for reduced rates of payment under s. 627.6471, F.S., the bill requires insurers to post a link on their website's homepage to a list of preferred providers. Changes to that list must be updated within 24 hours.

The bill has an indeterminate, but likely significant, fiscal impact.

II. Present Situation:

Medicaid

Medicaid is a joint federal and state funded program that provides health care for low income Floridians. The program is administered by the AHCA and financed with federal and state funds. Over 3.3 million Floridians are currently enrolled in Medicaid and the program's estimated expenditures for Fiscal Year 2012-2013 were approximately $21 billion.[1] The statutory authority for the Medicaid program is contained in ch. 409, F.S.

Statewide Medicaid Managed Care

In 2011, the Legislature passed HB 7107[2] creating the Statewide Medicaid Managed Care (SMMC) program as part IV of ch. 409, F.S. The SMMC program requires the AHCA to create an integrated managed care program for Medicaid enrollees that incorporates all of the minimum benefits for the delivery of primary and acute care under the Managed Medical Assistance component (MMA).[3] Final approval by the federal government of the 1915(b) Medicaid waiver for the MMA component of SMMC program was received on June 14, 2013.[4] The AHCA has recently begun the waiver renewal process for the period of July 1, 2014 through June 30, 2017.[5]

The Agency is in the process of implementing the MMA component of SMMC program through which most Medicaid recipients will receive their health care services. The first regional roll-out begins May 1, 2014, and the last is scheduled for August 1, 2014. During the implementation, existing Medicaid managed care plans will continue until the region they serve transitions to the MMA program.

The AHCA's contracts with the current Medicaid managed care plans allow the plans to develop their own preferred drug list (PDL) and prior authorization processes, including step-therapy and fail-first criteria, which must be approved by the AHCA.[6] Current managed care plans also have

[1] Agency for Health Care Administration, *Florida Medicaid*, http://ahca.myflorida.com/Medicaid/index.shtml (last visited Nov. 26, 2013).
[2] *See* ch. 2011-134, L.O.F.
[3] Health and Human Services Committee, Fla. House of Representatives, *PCS HHSC 11-01 Staff Analysis*, p.25, (Mar. 25, 2011).
[4] *See* Correspondence between Agency for Health Care Administration and the Centers for Medicare and Medicaid Services, http://ahca.myflorida.com/Medicaid/statewide_mc/pdf/mma/06-14-2013_Appproval_Letter.pdf (last visited Nov. 21, 2013).
[5] Agency for Health Care Administration, *Managed Medical Assistance - Federal Authorities*, http://ahca.myflorida.com/Medicaid/statewide_mc/index.shtml#FCA (last visited Nov. 21, 2013).
[6] Agency for Health Care Administration, *2014 Agency Bill Analysis - SB 1354* (Feb. 21, 2014), p. 2, on file with the Senate Health Policy.

the ability to deny claims for enrollees who were later determined to be ineligible at the time of service despite having issued a prior authorization.[7]

For the first year of the MMA transition, the Agency is requiring the MMA plans to use the Medicaid PDL. After the first year, the MMA plans may develop a plan-specific PDL for the Agency's consideration, if requested by the Agency at that time.[8]

Patient Protection and Affordable Care Act

In March 2010, the Congress passed and the President signed the Patient Protection and Affordable Care Act (PPACA).[9] Among its changes to the United States health care system are requirements for health insurers to make coverage available to all individuals and employers. Qualifying coverage may be obtained through an employer, the federal or state exchanges created under PPACA, or private individual or group coverage meeting the minimum essential benefits coverage standard. Florida did not establish its own state exchange under PPACA.

Premium credits and other cost sharing subsidies are available to United States citizens and legal immigrants within certain income limits for qualified coverage purchased through the exchange. Premium credits are set on a sliding scare based on a percentage of the federal poverty level and reduce the out of pocket costs incurred by individuals and families.[10]

Federal regulations for PPACA also govern an enrollee's coverage bought through the exchanges and for non-grandfathered plans.[11] If an enrollee's coverage bought with advance premium tax credit for a qualified health plan (QHP)[12] is terminated for non-payment of premium for example, the regulations provide the enrollee a 3-month grace period before cancellation of coverage.[13] During the grace period, the insurer must pay claims for services rendered in the first month but may pend claims for the second and third months.[14] If coverage is ultimately terminated, the termination date is the last day of the first month of the grace period and the insurer may not recoup any claims paid during the first month of the grace period.

The federal regulations do not impact those enrollees who are not enrolled in an exchange plan or are not receiving a subsidy. The grace period for these individuals remains at the length required under s. 627.608. F.S., which varies by the length of the premium payment interval. Cancellation of coverage is effective the first day of the grace period if payment is not received.

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[7] *Id.*
[8] *Id.*
[9] P.L. 111-148. On March 30, 2010, PPACA was amended by P.L. 111-152, the Health Care and Education Reconciliation Act of 2010.
[10] Centers for Medicare and Medicaid Services, *Health Insurance Marketplace - Will I Qualify for Lower Costs on Monthly Premiums?* https://www.healthcare.gov/will-i-qualify-to-save-on-monthly-premiums/ (last visited Mar. 22, 2014).
[11] Certain plans received "grandfather status" under PPACA. A grandfathered health plan is a plan that existed on March 23, 2010, and had at least one person continuously covered for one year. Some consumer protections elements do not apply to grandfathered plans.
[12] A "qualified health plan" is an insurance plan certified by the applicable Health Insurance Marketplace, provides the essential health benefits, established limits on cost sharing and meets other requirements. *See* https://www.healthcare.gov/glossary/qualified-health-plan/ for more information on qualified health plans.
[13] 45 CFR 156.270 and 45 CFR 430.
[14] 45 CFR 156.270.

Step-Therapy or Fail-First Protocols

Step-therapy or fail-first protocols for prescription medication coverage requires a member to try a certain drug, usually a generic alternative, before receiving coverage for another drug, usually a branded, more expensive product. Utilization management pharmacy benefit programs were first introduced in the 1980s and became popular with the implementation of tiered co-payment formularies.[15] Step therapy is usually applied to a certain drug class with the goal of encouraging generic drug use and decreasing costs without compromising the quality of care.[16] Many step-therapy programs incorporate edits into the system to recognize members through prior claims who have previously received a first step drug so claims for a second step drug are not rejected, but automatically covered.

One outcome of step-therapy programs; however, has been that enrollees who have had a claim rejected, do not have a later claim for a later medication in that same class.[17] The process for notifying the patient and prescriber of a step-therapy claim rejection and the resubmission of an alternate medication varies by issuer.

Prior Authorization for Health Care Services

Insurers may require prior authorization for certain services as a cost control and quality measure. Florida has waived requirements for prior authorization for certain services and requires direct access within specified guidelines for certain services such as dermatology.[18] State law currently does not provide a specific standard form or review timeline for a prior authorization process for health care services covered by an insurer, managed care plan or health maintenance organization. Prior authorization is never required for any emergency procedure. Each insurer has established its own prior authorization process and form based on the situation and the type of authorization, such service, course of treatment, or prescription. The state has mandated a standard health claims processing form be adopted by the commission and used under s. 627.647, F.S., by all hospitals and a separate form by all physicians, dentists and pharmacists.

The National Council for Prescription Drug Programs, a non-profit, stakeholder group proposed in July 2013, new uniform electronic prior authorization (ePA) standards. The new ePA electronic prescribing standard provides for a two-way, real-time exchange of information for insurers and prescribers.[19]

Federal regulations for the Medicaid and Children's Health Insurance Program both require that managed care plans have written policies and procedures for initial and continuing authorization

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[15] Patrick P. Gleason, PharmD, FCCP, BCPS, *Assessing Step-Therapy Programs: A Step in the Right Direction*, www.amcp.org, Journal of Managed Care Pharmacy, p. 274, http://www.amcp.org/data/jmcp/273-75.pdf (April 2007, Vol. 13, No. 3)(last visited Mar. 23, 2014).
[16] *Id*.
[17] Gleason, *supra*, note 15 at 273-274.
[18] *See* s. 641.31(33), F.S. Provides direct access to dermatologists for up to 5 visits and testing annually.
[19] Press Release, National Council for Prescription Drug Programs, *New Uniform Electronic Prior Authorization Standard Supplants the Need for Legislation (*March 6, 2014) on file in the Senate Health Policy Committee.

decisions that ensure timely access to care for enrollees with serious and chronic conditions.[20] Both regulations establish that prior authorization decisions may not exceed 14 calendar days following receipt of the request, with a possible extension up to 14 additional calendar days if requested by the enrollee or provider or there is a need for additional information.

For Medicaid, an expedited authorization process is also provided that does not exceed 3 working days with the ability to extend up to 14 calendar days upon enrollee request, or if the managed care plan justifies a need for additional information and that the extension is in the enrollee's benefit.[21]

The Children's Health Insurance Program's regulation provides a deferral to any existing state law on the authorization of health services, if applicable.[22]

Preferred Provider Listings

Individuals enrolled in plans licensed under s. 627.6471, F.S., known as a "Preferred Provider Organization" or PPO plans, incur different out of pocket costs based on whether the provider is in-network. These out of pocket costs can be significant to the consumer. For example, in the standard PPO Option Group Plan for state employees, the enrollee would pay a small copayment for a physician office visit with an in-network provider after the enrollee had met any calendar year deductible, but would incur 40 percent of the costs with an out of network provider for the same service.[23] The state group PPO provider, Florida Blue, does provide a list of providers on its website.

Federal regulations require QHPs on the exchanges to make its provider directory available online and to potential enrollees in hard copy, upon request.[24] Further guidance from the federal Centers for Medicare and Medicaid Services (CMS) via a draft guidance letter indicates that QHPs must provide a link from the federal marketplace to their network directly where the consumer can view an up-to-date provider directory. CMS requires the directory to include the location, contact information, specialty, medical group, any institutional affiliations for each provider and whether the provider is accepting new patients.[25]

III. Effect of Proposed Changes:

Medicaid Managed Care Program (Section 1)

Section 1 modifies s. 409.967, F.S., and requires a Medicaid managed care plan that establishes a prescribed drug formulary or a PDL must provide a broad range of therapeutic options for the treatment of disease consistent with the outpatient population. At least two products in each

[20] *See* 42 CFR 438.210 (Medicaid) and 42 CFR 495 (Children's Health Insurance Program).
[21] 42 CFR 438.210.
[22] 42 CFR 457.495(d)(2).
[23] Florida Blue, 2014 Benefits, State Employees' PPO Plan, on file with the Senate Health Policy Committee.
[24] 45 CFR 156.235(b).
[25] Center for Consumer Information and Insurance Oversight, Centers for Medicare and Medicaid Services, *Draft 2015 Letter to Issuers in the Federally-Facilitated Marketplace* (Feb. 4, 2014), pg. 47, http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/draft-issuer-letter-2-4-2014.pdf (last visited Mar. 23, 2014).

therapeutic class must be included, if feasible. The AHCA indicates it will be required to amend its existing Medicaid contracts to ensure compliance.[26]

The managed care plan must also provide coverage through prior authorization for any new drug approved by the Food and Drug Administration until the Medicaid Pharmaceutical and Therapeutics Committee (committee) can review the drug for inclusion on the formulary. The timing of the committee meeting must comply with s. 409.91195, F.S., which requires at least quarterly meetings.

If a managed care plan removes a drug from a plan's formulary, the bill requires the managed care plan to continue the enrollee's receipt of the drug if the provider submits a written request that the drug is medically necessary and meets clinical criteria.

Prior Authorization Requirements (Sections 1, 3, and 7)

Health plans, health insurers, and health maintenance organizations, including those participating under SMMC will be required, upon adoption by the commission after January 1, 2015, to use a new, standardized prior authorization form for obtaining approval for a medical procedure, course of treatment, or prescription drug benefits. A pharmacy benefit manager under contract with a managed care plan must also comply with this requirement. The form shall be available electronically from the commission and on the managed care plan's website. A prior authorization request completed on the standardized form will be deemed approved upon receipt by the managed care plan unless the managed care plan responds within two business days.

SB 1354 adds the prior authorization provisions to existing s. 409.967, F.S., and creates two new sections, ss. 627.6465 and 641.393, F.S.

Step-Therapies or Fail-First Protocols (Sections 1, 4, and 8)

If medications for the treatment of a medical condition are restricted for use through a step-therapy or fail-first protocol by a SMMC plan, an insurer, or a health maintenance organization, the prescribing provider must have access to a clear and convenient process to request an override. An override must be granted within 24 hours if the prescribing provider believes that:

- Based on sound clinical evidence, the preferred treatment required under step-therapy or fail-first protocol has been ineffective in the patient's disease or medical condition; or,
- Based on sound clinical evidence or medical and scientific evidence, the preferred treatment required under the step-therapy or fail-first protocol:
  - Is expected or likely to be ineffective based on known relevant physical or mental characteristics of the enrollee and known characteristics of the drug regimen; or
  - Will cause or will likely cause an adverse reaction or other physical harm to the patient.

If the patient does enroll in the step-therapy or fail-first protocol, the duration of the process may not exceed a period deemed appropriate by the provider. If the provider finds the treatment ineffective, the bill provides that the patient is entitled to receive the recommended course of

[26] *See supra,* note 6.

treatment without requiring the provider to seek an override of the step-therapy or fail-first protocol.

To add the provisions on step-therapy and fail-first protocol for the SMMC program, s. 409.967, F.S., is amended and two new sections, ss. 627.6466 and 641.394, F.S., are created to apply the provisions to insurers and health maintenance organizations.

Payment of Claims (Sections 2 and 6)

Health insurers under s. 627.6131, F.S., and health maintenance organizations under s. 641.3155, F.S., are prohibited from retroactively denying claims because of insurer ineligibility if the insurer:

- Verified the eligibility of the insured at time of treatment and provided an authorization number or
- Provided the insured with an identification card as provided in s. 627.642(3), F.S., that at the time of service identifies the insured as eligible to receive services.

Reduced Rate Insurance Contracts - Provider Listings (Section 5)

For contracts for reduced rates of payment, s. 627.6471, F.S., is modified and insurers must post a link on their website's homepage to a list of preferred providers. Changes to that provider list must be updated within 24 hours.

The bill has an effective date of July 1, 2014.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Individuals and employers with private insurance coverage may see an increase in premium costs related to the step-therapy or fail-first process and the prior authorization provisions. These measures are used by insurers today as utilization management and cost control tools and might impact some current policies and procedures of insurers.

Consumers may see more timely authorization for certain services, course of treatment, or prescriptions ordered by their health care providers. Health care providers and their patients may also experience less of a burden receiving a brand drug under the step-therapy or fail-first guidelines as patients are provided a statutory mechanism for bypassing step one, if certain indicators are present.

Insurers under s. 627.6471, F.S., have an additional administrative impact complying with posting a list of preferred providers to their website and reflecting changes within 24 hours.

C. Government Sector Impact:

The fiscal impact to Medicaid is indeterminate at this time. The bill may increase the cost of providing a prescribed drug to Medicaid enrollees because it makes changes to the step-therapy and fail-first requirements for plan enrollees and requires that any drug prescribed or recommended by a provider be approved and reimbursed.

The AHCA would also need to modify existing Medicaid managed care contracts to incorporate the revised step-therapy and formulary requirements.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 409.967, 627.6131, 627.6471, and 641.3155.

This bill creates the following sections of the Florida Statutes: 627.6465, 627.6466, 641.393, and 641.394.

IX. Additional Information:

A. Committee Substitute – Statement of Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.

This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.

By Senator Grimsley

21-01230-14 20141354__

A bill to be entitled

An act relating to health care; amending s. 409.967, F.S.; revising contract requirements for managed care programs; providing requirements for plans establishing a drug formulary or list; requiring the use of a standardized form; establishing a process for providers to override certain treatment restrictions; amending s. 627.6131, F.S.; prohibiting retroactive denial of claims in certain circumstances; creating s. 627.6465, F.S.; requiring the use of a standardized form; requiring the commission to adopt rules to prescribe the form; providing requirements for the form; providing requirements for the availability and submission of the form; creating s. 627.6466, F.S.; establishing a process for providers to override certain treatment restrictions; providing requirements for approval of such overrides; providing an exception to the override process in certain circumstances; amending s. 627.6471, F.S.; requiring insurers to post preferred provider information on a website; amending s. 641.3155, F.S.; prohibiting retroactive denial of claims in certain circumstances; creating s. 641.393, F.S.; requiring the use of a standardized form; providing requirements for the availability and submission of the form; creating s. 641.394, F.S.; establishing a process for providers to override certain treatment restrictions; providing requirements for approval of such overrides; providing an exception to the override process in certain circumstances;

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21-01230-14 20141354__

providing an effective date.

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

Section 1. Paragraph (c) of subsection (2) of section 409.967, Florida Statutes, is amended to read:

409.967 Managed care plan accountability.—

(2) The agency shall establish such contract requirements as are necessary for the operation of the statewide managed care program. In addition to any other provisions the agency may deem necessary, the contract must require:

(c) *Access.*—

1. The agency shall establish specific standards for the number, type, and regional distribution of providers in managed care plan networks to ensure access to care for both adults and children. Each plan must maintain a regionwide network of providers in sufficient numbers to meet the access standards for specific medical services for all recipients enrolled in the plan. The exclusive use of mail-order pharmacies may not be sufficient to meet network access standards. Consistent with the standards established by the agency, provider networks may include providers located outside the region. A plan may contract with a new hospital facility before the date the hospital becomes operational if the hospital has commenced construction, will be licensed and operational by January 1, 2013, and a final order has issued in any civil or administrative challenge. Each plan shall establish and maintain an accurate and complete electronic database of contracted providers, including information about licensure or

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

registration, locations and hours of operation, specialty credentials and other certifications, specific performance indicators, and such other information as the agency deems necessary. The database must be available online to ~~both~~ the agency and the public and have the capability of comparing ~~to compare~~ the availability of providers to network adequacy standards and to accept and display feedback from each provider's patients. Each plan shall submit quarterly reports to the agency identifying the number of enrollees assigned to each primary care provider.

2.a. If establishing a prescribed drug formulary or preferred drug list, a managed care plan shall:

(I) Provide a broad range of therapeutic options for the treatment of disease states consistent with the general needs of an outpatient population. If feasible, the formulary or preferred drug list must include at least two products in a therapeutic class.

(II) Include coverage through prior authorization for each new drug approved by the United States Food and Drug Administration until the Medicaid Pharmaceutical and Therapeutics Committee reviews such drug for inclusion on the formulary. The timing of the formulary review must comply with s. 409.91195.

b. Each managed care plan shall ~~must~~ publish any prescribed drug formulary or preferred drug list on the plan's website in a manner that is accessible to and searchable by enrollees and providers. The plan shall ~~must~~ update the list within 24 hours after making a change. ~~Each plan must ensure that the prior authorization process for prescribed drugs is readily accessible~~

~~to health care providers, including posting appropriate contact information on its website and providing timely responses to providers.~~

c. If a prescription drug on a plan's formulary is removed or changed, the managed care plan shall permit an enrollee who was receiving the drug to continue to receive the drug if the provider submits a written request that demonstrates that the drug is medically necessary and the enrollee meets clinical criteria to receive the drug.

d. For enrollees ~~Medicaid recipients~~ diagnosed with hemophilia who have been prescribed anti-hemophilic-factor replacement products, the agency shall provide for those products and hemophilia overlay services through the agency's hemophilia disease management program.

3.a. Notwithstanding any other law, in order to establish uniformity in the submission of prior authorization forms, after January 1, 2015, a managed care plan shall use only the standardized prior authorization form adopted by the Financial Services Commission pursuant to s. 627.6465 for obtaining prior authorization for a medical procedure, course of treatment, or prescription drug benefits. If a managed care plan contracts with a pharmacy benefits manager to perform prior authorization services for prescription drug benefits, the pharmacy benefits manager shall use and accept the standardized prior authorization form. The form shall be made available electronically by the commission and on the managed care plan's website. The prescribing provider may submit the completed form electronically to the managed care plan.

b. A completed prior authorization request submitted by a

health care provider using the standardized prior authorization form required under sub-subparagraph a. is deemed approved upon receipt by the managed care plan unless the managed care plan responds within 2 business days.

c. Managed care plans, and their fiscal agents or intermediaries, must accept prior authorization requests for any service electronically.

4. If medications for the treatment of a medical condition are restricted for use by a managed care plan by a step-therapy or fail-first protocol, the prescribing provider must have access to a clear and convenient process to request an override of the protocol from the managed care plan. The managed care plan shall grant an override of the protocol within 24 hours if:

a. The prescribing provider believes that, based on sound clinical evidence, the preferred treatment required under the step-therapy or fail-first protocol has been ineffective in the treatment of the enrollee's disease or medical condition; or

b. The prescribing provider believes that, based on sound clinical evidence or medical and scientific evidence, the preferred treatment required under the step-therapy or fail-first protocol:

(I) Is expected or likely to be ineffective based on known relevant physical or mental characteristics of the enrollee and known characteristics of the drug regimen; or

(II) Will cause or will likely cause an adverse reaction or other physical harm to the enrollee.

If the prescribing provider allows the enrollee to enter the step-therapy or fail-first protocol recommended by the managed

care plan, the duration of the step-therapy or fail-first protocol may not exceed a period deemed appropriate by the provider. If the prescribing provider deems the treatment clinically ineffective, the enrollee is entitled to receive the recommended course of therapy without requiring the prescribing provider to seek approval for an override of the step-therapy or fail-first protocol.

Section 2. Subsection (11) of section 627.6131, Florida Statutes, is amended to read:

627.6131 Payment of claims.—

(11)(a) A health insurer may not retroactively deny a claim because of insured ineligibility more than 1 year after the date of payment of the claim.

(b) A health insurer that has verified the eligibility of an insured at the time of treatment and has provided an authorization number may not retroactively deny a claim because of insured ineligibility.

(c) A health insurer that has provided the insured with an identification card as provided in s. 627.642(3) which at the time of service identifies the insured as eligible to receive services may not retroactively deny a claim because of insured ineligibility.

Section 3. Section 627.6465, Florida Statutes, is created to read:

627.6465 Prior authorization.—

(1) Notwithstanding any other law, in order to establish uniformity in the submission of prior authorization forms, after January 1, 2015, a health insurance issuer, managed care plan as defined in s. 409.901, or health maintenance organization as

defined in s. 641.19 shall use only the standardized prior authorization form adopted by the Financial Services Commission for obtaining prior authorization for a medical procedure, course of treatment, or prescription drug benefits. If a health insurance issuer, managed care plan, or health maintenance organization contracts with a pharmacy benefits manager to perform prior authorization services for prescription drug benefits, the pharmacy benefits manager shall use and accept the standardized prior authorization form. The commission shall adopt rules prescribing the prior authorization form on or before January 1, 2015, and may consult with health insurance issuers or other organizations as necessary in the development of the form. The form may not exceed two pages in length, excluding any instructions or guiding documentation. The form shall be made available electronically by the commission and on the website of the health insurance issuer, managed care plan, or health maintenance organization. The prescribing provider may submit the completed form electronically to the health benefit plan. The adoption of the form by the commission does not constitute a determination that affects the substantial interests of a party under chapter 120.

(2) A completed prior authorization request submitted by a prescribing provider using the standardized prior authorization form required under subsection (1) is deemed approved upon receipt by the health insurance issuer unless the health insurance issuer responds within 2 business days.

Section 4. Section 627.6466, Florida Statutes, is created to read:

627.6466 Fail-first protocols.—If medications for the

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

treatment of a medical condition are restricted for use by an insurer by a step-therapy or fail-first protocol, the prescribing provider shall have access to a clear and convenient process to request an override of the protocol from the health benefit plan or health insurance issuer. The plan or issuer shall grant an override of the protocol within 24 hours if:

(1) The prescribing provider believes that, based on sound clinical evidence, the preferred treatment required under the step-therapy or fail-first protocol has been ineffective in the treatment of the insured's disease or medical condition; or

(2) The prescribing provider believes that, based on sound clinical evidence or medical and scientific evidence, the preferred treatment required under the step-therapy or fail-first protocol:

(a) Is expected or likely to be ineffective based on known relevant physical or mental characteristics of the insured and known characteristics of the drug regimen; or

(b) Will cause or is likely to cause an adverse reaction or other physical harm to the insured.

If the prescribing provider allows the patient to enter the step-therapy or fail-first protocol recommended by the insurer, the duration of the step-therapy or fail-first protocol may not exceed a period deemed appropriate by the provider. If the prescribing provider deems the treatment clinically ineffective, the patient is entitled to receive the recommended course of therapy without requiring the prescribing provider to seek approval for an override of the step-therapy or fail-first protocol.

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

Section 5. Subsection (2) of section 627.6471, Florida Statutes, is amended to read:

627.6471 Contracts for reduced rates of payment; limitations; coinsurance and deductibles.—

(2) An ~~Any~~ insurer issuing a policy of health insurance in this state~~,~~ which ~~insurance~~ includes coverage for the services of a preferred provider~~,~~ shall ~~must~~ provide each policyholder and certificateholder with a current list of preferred providers, shall ~~and must~~ make the list available for public inspection during regular business hours at the principal office of the insurer within the state, and shall post a link to the list of preferred providers on the home page of the insurer's website. Changes to the list of preferred providers must be reflected on the insurer's website within 24 hours.

Section 6. Subsection (10) of section 641.3155, Florida Statutes, is amended to read:

641.3155 Prompt payment of claims.—

(10)(a) A health maintenance organization may not retroactively deny a claim because of subscriber ineligibility more than 1 year after the date of payment of the claim.

(b) A health maintenance organization that has verified the eligibility of a subscriber at the time of treatment and has provided an authorization number may not retroactively deny a claim because of subscriber ineligibility.

(c) A health maintenance organization that has provided the subscriber with an identification card as provided in s. 627.642(3) which at the time of service identifies the subscriber as eligible to receive services may not retroactively deny a claim because of subscriber ineligibility.

Section 7. Section 641.393, Florida Statutes, is created to read:

641.393 Prior authorization.—

(1) Notwithstanding any other law, in order to establish uniformity in the submission of prior authorization forms, after January 1, 2015, a health maintenance organization shall use only the standardized prior authorization form adopted by the Financial Services Commission pursuant to s. 627.6465 for obtaining prior authorization for a medical procedure, course of treatment, or prescription drug benefits. If a health maintenance organization contracts with a pharmacy benefits manager to perform prior authorization services for prescription drug benefits, the pharmacy benefits manager must use and accept the standardized prior authorization form. The form shall be made available electronically by the commission and on the website of the health insurance issuer, managed care plan, or health maintenance organization. The health care provider may submit the completed form electronically to the health benefit plan.

(2) A completed prior authorization request submitted by a health care provider using the standardized prior authorization form required under subsection (1) is deemed approved upon receipt by the health maintenance organization unless the health maintenance organization responds within 2 business days.

Section 8. Section 641.394, Florida Statutes, is created to read:

641.394 Fail-first protocols.—If medications for the treatment of a medical condition are restricted for use by a health maintenance organization by a step-therapy or fail-first

protocol, the prescribing provider shall have access to a clear and convenient process to request an override of the protocol from the health maintenance organization. The health maintenance organization shall grant an override of the protocol within 24 hours if:

(1) The prescribing provider believes that, based on sound clinical evidence, the preferred treatment required under the step-therapy or fail-first protocol has been ineffective in the treatment of the insured's disease or medical condition; or

(2) The prescribing provider believes that, based on sound clinical evidence or medical and scientific evidence, the preferred treatment required under the step-therapy or fail-first protocol:

(a) Is expected or likely to be ineffective based on known relevant physical or mental characteristics of the insured and known characteristics of the drug regimen; or

(b) Will cause or is likely to cause an adverse reaction or other physical harm to the insured.

If the prescribing provider allows the patient to enter the step-therapy or fail-first protocol recommended by the health maintenance organization, the duration of the step-therapy or fail-first protocol may not exceed a period deemed appropriate by the provider. If the prescribing provider deems the treatment clinically ineffective, the patient is entitled to receive the recommended course of therapy without requiring the prescribing provider to seek approval for an override of the step-therapy or fail-first protocol.

Section 9. This act shall take effect July 1, 2014.

From: Wendy Viciana <wviciana@hotmail.com>
Sent: Friday, March 21, 2014 9:31 AM
To: GEORGIADES.CELIA
Subject: Support SB 1354

Importance: High

Dear Ms. Celia Georgiades,

Thank you for taking my call this morning. I would like to personally ask that the FL Senate Health Policy Chair, Senator Aaron Bean, and its members, carefully review and support the Step Therapy Bill, SB1354 (Grimsley, which is on the agenda, at their next meeting this coming Tuesday, March 25th.
This is an important bill for patients because it allows doctors to provide the most clinically appropriate medical care without HMOs making healthcare decisions based solely on cost.
As a constituent and a cancer survivor, I want to be able to make a difference in the lives of cancer patients and their families that need the best medical care that is available without cost being an issue.

Thank you for your attention to this matter and for forwarding this request to Senator Bean.

Sincerely,

Wendy Viciana

By e-mail

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Health Policy

BILL:	CS/SB 1150
INTRODUCER:	Commerce and Tourism Committee and Senator Bean
SUBJECT:	Medical Tourism
DATE:	March 20, 2014 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Askey	Hrdlicka	CM	**Fav/CS**
2.	Looke	Stovall	HP	**Pre-meeting**
3.			AP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 1150 directs Enterprise Florida, Inc., (EFI) and the Florida Tourism Industry Marketing Corporation (Visit Florida) to promote medical tourism and market the state as a healthcare destination.

Visit Florida is required to include medical tourism in the 4-year marketing plan and showcase Florida providers. The bill also requires Visit Florida to create a matching grant program for local and regional economic development organizations to create targeted medical tourism marketing initiatives.

The bill allocates from the appropriation for Visit Florida in the General Appropriations Act (GAA) $3.5 million annually for the development and implementation of the medical tourism marketing plan and $1.5 million annually for the matching grant program.

II. Present Situation:

Medical Tourism

Medical tourism is a term used to describe the act of traveling to receive medical treatment. Traditionally, the term meant to travel across international boundaries but consumer travel across state lines, referred to as domestic medical tourism, has become more common. Medical tourism can include both sophisticated treatments, such as cardiac surgery and orthopedics, as well as

elective or routine procedures for dental care or cosmetic surgeries. The industry has "medical tourism facilitators" that market medical tourism "models" to consumers. These facilitators are comparable to travel agents and present legal uncertainties in the interaction between facilitators and providers.

Medical tourism occurs for a variety of reasons including the globalization of healthcare services and increases in geriatric populations in the United States and Europe. Consumer preference in medical care will depend on factors that a consumer normally applies when purchasing a good. These factors can include cost, income, substitutions, or complimentary goods. Due to the size and scope of the healthcare industry, there is no one "trend" in medical tourism.

A recent report by the National Institute for Health Research found that outward medical tourism[1] had increased in the United Kingdom while inward medical tourism[2] remained reasonably steady.[3] The results from this report also highlighted several other factors that made general "trends" in medical tourism difficult to define. The report found that:

- Economic implications of medical tourism are not uniform;
- The medical tourism industry is almost entirely unregulated and there are potential risks to the consumer;
- Existing information is variable and there is no authoritative source of information;
- Medical tourists are a heterogeneous group of all ages and a range of socio-demographic groups;
- Tourists lack information and appear to make uninformed decisions without considering all associated risks;
- Tourists seem to make use of informal treatment-based or cultural networks to make their decisions;
- Patients are travelling to further or "new" markets in medical tourism; and
- Cost is never a sole motivator and often not the primary motivation for seeking treatment abroad.[4]

Additionally, the report concluded that more research was needed to:

- Better understand the health and social outcomes of treatment for those who travel for medical treatment;
- Generate more robust data that better capture the size and flows of medical tourism;
- Gather more information on patients including their origins, procedures, and outcomes;
- Allow for the development of better economic costing; and,
- Explore the issues of clinical relationships and networks.[5]

[1] Traveling from the UK to another country.
[2] Traveling from another country to the UK.
[3] National Institute for Health Research, *Implications for the NHS of inward and outward medical tourism; a policy and economic analysis using literature review and mixed-methods approaches* (February 2014), p. 28, available at: http://www.journalslibrary.nihr.ac.uk/hsdr/volume-2/issue-2 (Last visited Mar. 20, 2014).
[4] *Id*. at pp. 115-119
[5] *Id*. at pp. 119 and 120

Medical tourism can have political obstacles as well. While inward medical tourism is seen as an opportunity for economic growth, outward medical tourism has been criticized as an admission of domestic healthcare policy failure.[6]

Medical tourism is often presented as a way to lower costs for medical treatment. Cost savings is an incentive for some employers to adopt domestic medical tourism practices within the United States. Changes to healthcare law in the United States have brought medical treatment cost disparities into the spotlight. In May 2013, NPR reported on data released by the Federal Department of Health and Human Services on hospital charges for treatment of Medicare patients.[7] NPR reported that there were large differences in the costs of the 100 most common treatments that require hospitalization. Differences occurred across states and hospitals miles from each other. The differences in cost ranged in multiples of 5 to 40. Similar reports produced supporting examples including a joint replacement procedure that cost $297,000 at Centinela Hospital and $84,000 at St. John's Health Center, two California hospitals about 12 miles apart.[8] The reports suggest similar levels of disparity in costs to private insurers and uninsured patients.

Healthcare in Florida

Florida is the fourth largest state in terms of population with an estimated 19.5 million people. According to a report by the Wall Street Journal, Florida paid an average of $7,156 per person on healthcare in 2009.[9] The largest portions of that amount was spent on hospital care ($2,207) and physician/clinical services ($1,950). The U.S. average for the same time period was $6,815 per person. In Florida there are currently licensed: 301 hospitals,[10] 1,987 health care clinics,[11] 45,939 medical doctors, 10,445 dentists, 203,648 registered nurses, 20,850 pharmacists, and various other licensed practitioners totaling 863,270.[12]

Tourism in Florida

Visit Florida is the state's public/private partnership for tourism marketing. Enterprise Florida, Inc., contracts with Visit Florida to promote Florida as a tourist destination. EFI's Division of Tourism Marketing supports Visit Florida in its activities. Visit Florida is also required to adopt a 4-year tourism marketing plan.[13] According to Visit Florida, tourism in Florida was responsible for 91.5 million tourists in 2012 who spent more than $71.8 billion, generated 23 percent of the

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[6]The Economist, *Médecine avec frontiers: Why health care has failed to globalize* (February 15, 2014), available at: http://www.economist.com/news/international/21596563-why-health-care-has-failed-globalise-m-decine-avec-fronti-res (Last visited Mar. 20, 2014).
[7] NPR, *Government Data Reveals Wild Disparity in Health Care Costs* (May 8, 2013), available at: http://www.npr.org/templates/story/story.php?storyId=182337915 (Last visited March 20, 2014).
[8] Christian Science Monitor, *New report reveals stunning disparities in health-care costs* (May 8, 2013), available at: http://www.csmonitor.com/Business/2013/0508/New-report-reveals-stunning-disparities-in-health-care-costs (Last visited Mar. 20, 2014).
[9]The Wall Street Journal, *Health-Care Costs: A State-by-State Comparison* (April 8, 2013), available at: http://online.wsj.com/news/articles/SB10001424127887323884304578328173966380066 (Last visited Mar. 20, 2014).
[10]Florida Agency for Health Care Administration, available at: http://www.floridahealthfinder.gov/facilitylocator/ListFacilities.aspx (Last visited Mar. 20, 2014).
[11] *Id*.
[12] Florida Dept. of Health, Division of Medical Quality Assurance, *Annual Report and Long Range Plan: FY 2012-2013*, (Dec. 31, 2013).
[13] Section 288.923(4), F.S., sets forth the plan requirements.

state's sales tax revenue and employed more than one million Floridians.[14] The Fiscal Year 2013-2014 General Appropriations Act appropriated over $63 million to Visit Florida.[15] Visit Florida raises matching funds from the private sector, and in 2012 raised more than $108.6 million.[16]

III. Effect of Proposed Changes:

Section 1 amends s. 288.901, F.S., to direct EFI to market the state as a health care destination and to promote quality health care services in Florida.

Section 2 amends s. 288.923, F.S., to include the promotion of medical tourism as a part of Visit Florida's 4-year tourism marketing plan.

Section 3 creates s. 288.924, F.S., to set forth requirements for a medical tourism marketing plan and create a matching grant program to support local medical tourism marketing.

The bill requires Visit Florida to include specific initiatives to advance Florida as a healthcare destination within the 4-year marketing plan. The marketing plan must:

- Promote national and international awareness of the qualifications, scope of services, and specialized healthcare expertise of providers in Florida;
- Promote national and international awareness of medical conferences, training, and other business opportunities to attract medical practitioners to the state; and
- Include an initiative that showcases select qualified providers offering bundled healthcare packages and support services.

The showcased providers must be selected through a solicitation of proposals from licensed providers for plans. The plans should include available services, provider qualifications, logistic arrangements, and other services and amenities to be provided to patients and their families. Single proposals may include offers made through a network of providers.

Visit Florida shall assess the qualifications and credentials of providers submitting proposals. To the extent funding is available, all qualified providers must be selected to be showcased.

To be qualified for showcasing, a provider must:

- Ensure that all providers in a proposal have full, active, and unencumbered Florida licenses;
- Have accreditation that is not conditional or provisional from a nationally recognized accrediting body;
- Be recognized as a Cancer Center of Excellence[17] or have a current national or international recognition in a specialty area; and,
- Meet other criteria established by Visit Florida in collaboration with the Florida Agency for Health Care Administration and the Department of Health.

[14]Visit Florida, available at: http://www.visitflorida.com/en-us/about-visit-florida.html (Last visited Mar. 20, 2014).
[15] Fiscal Year 2013-14 General Appropriations Act, Line Item 2228, ch. 2013-40, L.O.F.
[16]Visit Florida, available at: http://www.visitflorida.com/en-us/about-visit-florida.html (Last visited Mar. 12, 2014).
[17] Section 381.925, F.S.

Visit Florida is also required to create a matching grant program to provide funding to local or regional economic development organizations for targeted medical tourism marketing initiatives. The initiatives must promote Florida as a destination for healthcare services. Providers involved in the local initiative must meet the criteria specified for qualified providers in the showcase. The local or regional economic development organization must show an ability to involve a variety of businesses to collaboratively welcome and support patients and their families who travel to Florida for medical services. The cash or in-kind services available from the local or regional economic development board must be at least equal to the amount of state financial support.

The bill requires $3.5 million of the funds appropriated in the GAA to Visit Florida to be allocated annually for the development and implementation of the medical tourism marketing plan. An additional $1.5 million must be allocated annually for the matching grant program.

Section 4 provides an effective date of July 1, 2014.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

CS/SB 1150 may have an indeterminate positive fiscal impact on the private sector medical and support industries that are being promoted under the provisions of the bill.

C. Government Sector Impact:

The bill requires that $5 million be appropriated from the GAA for the programs established by the bill.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 288.901 and 288.923.

This bill creates section 288.924 of the Florida Statutes.

IX. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Committee on Commerce and Tourism on March 17, 2014:
The committee substitute requires that Visit Florida also include promoting medical conferences, training, and other business opportunities to attract medical practitioners to the state in the 4-year tourism marketing plan. The committee substitute removes the application deadline and requirement of equal division of funds related to the matching grant program.

B. Amendments:

None.

This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.

386528

LEGISLATIVE ACTION

Senate . House

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The Committee on Health Policy (Bean) recommended the following:

Senate Amendment (with title amendment)

Before line 30
insert:

Section 1. Paragraph (b) of subsection (2) of section 288.0001, Florida Statutes, is amended to read:

288.0001 Economic Development Programs Evaluation.—The Office of Economic and Demographic Research and the Office of Program Policy Analysis and Government Accountability (OPPAGA) shall develop and present to the Governor, the President of the Senate, the Speaker of the House of Representatives, and the

386528

chairs of the legislative appropriations committees the Economic Development Programs Evaluation.

(2) The Office of Economic and Demographic Research and OPPAGA shall provide a detailed analysis of economic development programs as provided in the following schedule:

(b) By January 1, 2015, and every 3 years thereafter, an analysis of the following:

1. The entertainment industry financial incentive program established under s. 288.1254.

2. The entertainment industry sales tax exemption program established under s. 288.1258.

3. VISIT Florida and its programs established or funded under ss. 288.122, 288.1226, 288.12265, ~~and~~ 288.124, and 288.924.

4. The Florida Sports Foundation and related programs established under ss. 288.1162, 288.11621, 288.1166, 288.1167, 288.1168, 288.1169, and 288.1171.

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

And the title is amended as follows:

Between lines 2 and 3

insert:

288.0001, F.S.; providing for an evaluation; amending s.

By the Committee on Commerce and Tourism; and Senator Bean

577-02742A-14 20141150c1

A bill to be entitled

An act relating to medical tourism; amending s. 288.901, F.S.; requiring Enterprise Florida, Inc., to collaborate with the Department of Economic Opportunity to market this state as a health care destination; amending s. 288.923, F.S.; requiring the Division of Tourism Marketing to include in its 4-year plan a discussion of the promotion of medical tourism; creating s. 288.924, F.S.; requiring the plan to promote national and international awareness of the qualifications, scope of services, and specialized expertise of health care providers in this state, to promote national and international awareness of certain business opportunities to attract practitioners to destinations in this state, and to include an initiative to showcase qualified health care providers; requiring a specified amount of funds appropriated to the Florida Tourism Industry Marketing Corporation to be allocated for the medical tourism marketing plan; requiring the Florida Tourism Industry Marketing Corporation to create a matching grant program; specifying criteria for the grant program; requiring that a specified amount of funds appropriated to the Florida Tourism Industry Marketing Corporation be allocated for the grant program; providing an effective date.

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

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

577-02742A-14 20141150c1

Section 1. Subsection (2) of section 288.901, Florida Statutes, is amended to read:

288.901 Enterprise Florida, Inc.—

(2) PURPOSES.—Enterprise Florida, Inc., shall act as the economic development organization for the state, using ~~utilizing~~ private sector and public sector expertise in collaboration with the department to:

(a) Increase private investment in Florida;

(b) Advance international and domestic trade opportunities;

(c) Market the state both as a probusiness location for new investment and as an unparalleled tourist destination;

(d) Revitalize Florida's space and aerospace industries, and promote emerging complementary industries;

(e) Promote opportunities for minority-owned businesses;

(f) Assist and market professional and amateur sport teams and sporting events in Florida; ~~and~~

(g) Assist, promote, and enhance economic opportunities in this state's rural and urban communities; and

(h) Market the state as a health care destination by using the medical tourism initiatives as described in s. 288.924 to promote quality health care services in this state.

Section 2. Paragraph (c) of subsection (4) of section 288.923, Florida Statutes, is amended to read:

288.923 Division of Tourism Marketing; definitions; responsibilities.—

(4) The division's responsibilities and duties include, but are not limited to:

(c) Developing a 4-year marketing plan.

1. At a minimum, the marketing plan shall discuss the

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

following:

a. Continuation of overall tourism growth in this state.

b. Expansion to new or under-represented tourist markets.

c. Maintenance of traditional and loyal tourist markets.

d. Coordination of efforts with county destination marketing organizations, other local government marketing groups, privately owned attractions and destinations, and other private sector partners to create a seamless, four-season advertising campaign for the state and its regions.

e. Development of innovative techniques or promotions to build repeat visitation by targeted segments of the tourist population.

f. Consideration of innovative sources of state funding for tourism marketing.

g. Promotion of nature-based tourism and heritage tourism.

h. Promotion of medical tourism, as provided under s. 288.924.

i.~~h.~~ Development of a component to address emergency response to natural and manmade disasters from a marketing standpoint.

2. The plan shall be annual in construction and ongoing in nature. Any annual revisions of the plan shall carry forward the concepts of the remaining 3-year portion of the plan and consider a continuum portion to preserve the 4-year timeframe of the plan. The plan also shall include recommendations for specific performance standards and measurable outcomes for the division and direct-support organization. The department, in consultation with the board of directors of Enterprise Florida, Inc., shall base the actual performance metrics on these

recommendations.

3. The 4-year marketing plan shall be developed in collaboration with the Florida Tourism Industry Marketing Corporation. The plan shall be annually reviewed and approved by the board of directors of Enterprise Florida, Inc.

Section 3. Section 288.924, Florida Statutes, is created to read:

288.924 Medical tourism.—

(1) MEDICAL TOURISM MARKETING PLAN.—The Division of Tourism Marketing shall include within the 4-year marketing plan required under s. 288.923(4)(c) specific initiatives to advance this state as a destination for quality health care services. The plan must:

(a) Promote national and international awareness of the qualifications, scope of services, and specialized expertise of health care providers throughout this state;

(b) Promote national and international awareness of medical-related conferences, training, or other business opportunities to attract practitioners from the medical field to destinations in this state; and

(c) Include an initiative that showcases selected, qualified providers offering bundled packages of health care and support services for defined care episodes. The selection of providers to be showcased must be conducted through a solicitation of proposals from Florida hospitals and other licensed providers for plans that describe available services, provider qualifications, and special arrangements for food, lodging, transportation, or other support services and amenities that may be provided to visiting patients and their families. A

single health care provider may submit a proposal describing the available health care services that will be offered through a network of multiple providers and explaining any support services or other amenities associated with the care episode. The Florida Tourism Industry Marketing Corporation shall assess the qualifications and credentials of providers submitting proposals. To the extent funding is available, all qualified providers shall be selected to be showcased in the initiative. To be qualified, a health care provider must:

1. Have a full, active, and unencumbered Florida license and ensure that all health care providers participating in the proposal have full, active, and unencumbered Florida licenses;

2. Have a current accreditation that is not conditional or provisional from a nationally recognized accrediting body;

3. Be recognized as a Cancer Center of Excellence under s. 381.925 or have a current national or international recognition in another specialty area, if such recognition is given through a specific qualifying process; and

4. Meet other criteria as determined by the Florida Tourism Industry Marketing Corporation in collaboration with the Agency for Health Care Administration and the Department of Health.

(2) ALLOCATION OF FUNDS FOR MARKETING PLAN.—Annually, at least $3.5 million of the funds appropriated in the General Appropriations Act to the Florida Tourism Industry Marketing Corporation shall be allocated for the development and implementation of the medical tourism marketing plan.

(3) MEDICAL TOURISM MATCHING GRANTS.—The Florida Tourism Industry Marketing Corporation shall create a matching grant program to provide funding to local or regional economic

development organizations for targeted medical tourism marketing initiatives. The initiatives must promote and advance Florida as a destination for quality health care services. Selection of recipients of a matching grant shall be based on the following criteria:

(a) The providers involved in the local initiative must meet the criteria specified in subsection (1).

(b) The local or regional economic development organization must demonstrate an ability to involve a variety of businesses in a collaborative effort to welcome and support patients and their families who travel to this state to obtain medical services.

(c) The cash or in-kind services available from the local or regional economic development organization must be at least equal to the amount of available state financial support.

(4) ALLOCATION OF FUNDS FOR MATCHING GRANTS.—Annually, at least $1.5 million of the funds appropriated in the General Appropriations Act to the Florida Tourism Industry Marketing Corporation shall be allocated for the matching grant program.

Section 4. This act shall take effect July 1, 2014.

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Health Policy

BILL:	SB 1352
INTRODUCER:	Senator Grimsley
SUBJECT:	Health Care Practitioners
DATE:	March 25, 2014
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Peterson	Stovall	HP	**Pre-meeting**
2.			JU	
3.			RC	

I. Summary:

SB 1352 amends laws governing advanced registered nurse practitioners (ARNP) to:

- Authorize an ARNP to prescribe controlled substances, subject to a negative formulary, if any, adopted by a committee appointed by the Board of Nursing (BON).
- Change "advanced registered nurse practitioner" to "advanced practice registered nurse" throughout the statutes, thereby adopting the title recommended in the Consensus Model for APRN Regulation.
- Add grounds for discipline of an ARNP related to prescribing that are the same as apply to other health care practitioners who have prescribing authority.
- Require an ARNP to comply with statutes applicable to other health care practitioners who prescribe controlled substance for the treatment of chronic nonmalignant pain.
- Add "advanced practice registered nurse" to all sections of law that reference controlled substances prescribed by a physician.
- Prohibit the unauthorized use of the title "Certified Nurse Practitioner" or related abbreviations and provide penalties.

The bill amends part I of ch. 394, F.S., the Florida Mental Health Act, to:

- Revise the credentials for registered nurses who are authorized to perform specified acts under the Florida Mental Health Act. Specifically, the bill requires national advanced practice certification as a psychiatric-mental health advanced practice registered nurse (PMH-APRN), requiring advanced practice certification in lieu of 2 years clinical experience as is currently required.
- Change "psychiatric nurse" to "psychiatric-mental health advanced practice registered nurse" throughout the act.
- Authorize PMH-APRNs to examine and approve releases of patients admitted to a receiving facility for involuntary examination.

The bill revises health care practitioner continuing education (CE) requirements to:

- Eliminate the HIV continuing education requirement for all health care practitioners who are required to complete the class.
- Require domestic violence and medical errors continuing education one time, prior to first renewal for all affected health care practitioners.
- Eliminate all CE requirements for certified nursing assistants (CNA).

Finally, the bill:

- Revises the Patient Self-Referral Act of 1992 to allow referrals for designated health services at an entity in which the health care provider owns stock that is publicly traded.
- Clarifies that fees charged for written or typed medical records must be the same regardless of format or medium.
- Removes language related to certification of medical assistants.

II. Present Situation:

Advanced Practice Registered Nurses

The term "advanced practice registered nurse" (APRN) refers in general terms to a group of licensed registered nurses who have advanced education and clinical training and who serve as primary care providers in a broad range of acute care and outpatient settings.[1] Licensure or certification as an APRN is contingent upon completion of an accredited graduate-level education program and passage of a national certification examination.[2] The titles given to APRNs vary from state-to-state. In Florida, the generic licensure title is "advanced registered nurse practitioner."[3] The National Council of State Boards of Nursing encourages states to use the title APRN.[4] Within the titles of APRN, there are four general categories: nurse practitioner, nurse midwife, registered nurse anesthetist, and clinical nurse specialist. Within these categories there may be subspecialties based on the APRN's training, the patients to be served, or the conditions to be treated by the APRN. Florida recognizes three types of APRN: the certified nurse practitioner (CNP), certified registered nurse anesthetist (CRNA), and the certified nurse midwife (CNM).[5]

Regulation of Advanced Registered Nurse Practitioners in Florida

Chapter 464, F.S., governs the licensure and regulation of nurses in Florida. Nurses are licensed by the Department of Health (DOH) and are regulated by the BON.[6]

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[1] *See, e.g.* Institute of Medicine, *The Future of Nursing, Leading Change, Advancing Health*, 23 (2011), *available at* http://www.nap.edu/download.php?record_id=12956 (last visited March 26, 2014).
[2] National Council of State Boards of Nursing *Model for Uniform National Advanced Practice Registered Nurse (APRN) Regulation: A Handbook for Legislators*, 2, *available at* https://www.ncsbn.org/2276.htm (last visited March 20, 2014).
[3] *See, e.g.* s.464.003(3), F.S.
[4] *The Consensus Model for APRN Regulation, Licensure, Accreditation, Certification and Education*, 9 (July 7, 2008), *available at* https://www.ncsbn.org/2276.htm (last visited March 20, 2014).
[5] Section 464.003(3), F.S. Florida certifies clinical nurse specialists as a category distinct from advanced registered nurse practitioners. (*See* ss. 464.003(7) and 464.0115, F.S.)
[6] The BON is comprised of 13 members appointed by the Governor and confirmed by the Senate who serve 4 year terms. Seven of the 13 members must be nurses who reside in Florida and have been engaged in the practice of professional nursing for at least 4 years. Of those seven members, one must be an advanced registered nurse practitioner, one a nurse educator at

Applicants for an RN[7] or LPN [8] license must submit an application form to the DOH, pay a fee, submit information for a criminal background check, and pass a licensure exam.[9] The exam used by the DOH is the National Council Licensure Examination (NCLEX), developed by the National Council of State Boards of Nursing.

In order to practice advanced or specialized nursing,[10] a person must be certified as an ARNP.[11] To be certified as an ARNP, a nurse must hold a current RN license and submit proof to the BON that he or she meets one of the following requirements:[12]

- Satisfactory completion of a formal post basic educational program of specialized or advanced nursing practice;
- Certification by an appropriate specialty board;[13]
- Completion of a master's degree program in the appropriate clinical.

Advanced or specialized nursing acts, as authorized by statute, may only be performed under protocol of a supervising physician. Within the established framework of the protocol, an ARNP may:[14]

- Monitor and alter drug therapies.
- Initiate appropriate therapies for certain conditions.
- Order diagnostic tests and physical and occupational therapy.

The statute further describes additional acts that may be performed within an ARNP's specialty certification (CRNA, CNW, and CNP).[15] According to the BON:

> The scope of practice for all categories of ARNPs shall include those functions which the ARNP has been educated to perform including the monitoring and altering of drug

an approved nursing program, and one a nurse executive. Three members of the BON must be licensed practical nurses (LPN) who reside in the state and have engaged in the practice of practical nursing for at least 4 years. The remaining three members must be Florida residents who have never been licensed as nurses and are in no way connected to the practice of nursing, any health care facility, agency, or insurer. Additionally, one member must be 60 years of age or older. (*See* s. 464.004(2), F.S.)

[7] Practice of professional nursing.

[8] Practice of practical nursing.

[9] Section 464.008, F.S.

[10] "Advanced specialized nursing practice" is defined as the performance of advanced-level nursing acts approved by the BON which, by virtue of postbasic specialized education, training and experience, are appropriately performed by an advanced registered nurse practitioner. (s. 464.003(2), F.S.)

[11] Section 464.003(3), F.S.

[12] Section 464.012(1), F.S.

[13] Specialty boards expressly recognized by the BON include: Council on Certification of Nurse Anesthetists, or Council on Recertification of Nurse Anesthetists; American College of Nurse Midwives; American Nurses Association (American Nurses Credentialing Center); National Certification Corporation for OB/GYN, Neonatal Nursing Specialties; National Board of Pediatric Nurse Practitioners and Associates; National Board for Certification of Hospice and Palliative Nurses; American Academy of Nurse Practitioners; Oncology Nursing Certification Corporation; American Association of Critical-Care Nurses Adult Acute Care Nurse Practitioner Certification. (Rule 64B9-4.002(2), F.A.C.)

[14] Section 464.012(3), F.S.

[15] Section 464.012(4), F.S.

therapies, and initiation of appropriate therapies according to the established protocol and consistent with the practice setting.[16]

In addition and also under physician protocol, an ARNP may perform those *medical* acts authorized by a joint committee of representatives of the Board of Medicine and the BON appointed by the State Surgeon General. Acts approved by the joint committee must be authorized by rule adopted by the BON to become part of an ARNP's scope of practice.[17]

The joint committee was also given responsibility for determining minimum standards for the content of established protocols pursuant to which an ARNP performs the approved medical acts.[18] Rules of the BON and the Board of Medicine require the protocol to contain information related to the duties of both the physician and the ARNP, treatments that may be initiated and for what conditions, drug therapies that may be initiated by the ARNP as determined by patient condition and ARNP judgment, and specific conditions requiring direct evaluation or consultation.[19]

Florida does not allow ARNPs to prescribe controlled substances.[20] Florida is currently the only state in the nation that does not allow ARNPs to prescribe controlled substances.[21]

ARNPs must meet financial responsibility requirements, as determined by rule of the BON, and the practitioner profiling requirements.[22] The BON requires 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 in the same amounts payable to the ARNP.[23]

Nurse Workforce Data

In 2012, there were approximately 110,200 certified nurse practitioners (CNPs), 35,200 certified registered nurse anesthetists (CRNAs), 6,000 certified nurse midwives (CNMs), and 2,711,000 registered nurses (RNs) employed in the U.S.[24] During Fiscal Year 2012–2013, Florida had 17,958 advanced registered nurse practitioners with an active certificate authorizing practice in the state.[25] The Florida Center for Nursing reports that over 30 percent of Florida's ARNPs are

[16] Rule 64B9-4.010, F.A.C.
[17] The committee has not met since 1999 and no medical acts have been approved pursuant to this statute. (E-mail from Paul Runk, Florida Department of Health (Feb.20, 2014) (on file with the Senate Health Policy Committee).
[18] Section 458.348(2), F.S.
[19] Rules 64B9-4.010 and 64B8-35.002, F.A.C.
[20] Sections 893.02(21) and 893.05(1), F.S.
[21] Drug Enforcement Agency, *Mid-Level Practitioners Authorization by State* (March 2014), *available at* http://www.deadiversion.usdoj.gov/drugreg/practioners/mlp_by_state.pdf (last visited March 19, 2014).
[22] Sections 456.0391 and 456.041, F.S.
[23] Rule 64B9-4.002(5), F.A.C.
[24] U.S. Department of Labor, Bureau of Labor Statistics, *Employment Projections*, http://data.bls.gov/projections/occupationProj (last visited on March 18, 2014).
[25] Florida Department of Health, Division of Medical Quality Assurance, *Annual Report and Long Range Plan FY 2012-2013*, 9, *available at* http://www.floridahealth.gov/licensing-and-regulation/reports-and-publications/_documents/annual-report-12-13.pdf (last visited March 18, 2014). The total reflects In-State Active and Out-of-State Active licensees. "In-State Active" means the licensed practitioner has a Florida mailing address and is authorized to practice. "Out-of-State Active" means the licensed practitioner has an out-of-state mailing address and is authorized to practice.

51 to 60 years old, meaning there will be a large sector of Florida's advanced practice nursing workforce retiring in the near future.[26]

Florida Mental Health Act

In 1971, the Legislature created part I of ch. 394, F.S., the "Florida Mental Health Act," also known as the Baker Act, to address mental health needs in the state. The Baker Act is a civil commitment law which provides a process for the involuntary examination and subsequent involuntary placement (commitment) of a person for either inpatient or outpatient treatment of a mental, emotional, or behavioral disorder.

The Department of Children and Families (DCF) administers this law through receiving facilities, which are public or private facilities that are designated by the DCF to receive and hold involuntary patients under emergency conditions for psychiatric evaluation and to provide short-term treatment.[27] A patient who requires further treatment may be transported to a treatment facility. Treatment facilities designated by the DCF are state-owned, state-operated, or state-supported hospitals which provide extended treatment and hospitalization beyond what is provided in a receiving facility.[28]

An involuntary examination may be initiated by court order; law enforcement; or certificate executed by a physician, clinical psychologist, psychiatric nurse, mental health counselor, marriage and family therapist, or clinical social worker stating that he or she examined the person within the preceding 48 hours and the person appears to meet the criteria for involuntary examination.[29] A psychiatric nurse is defined as an RN who has a master's degree or a doctorate in psychiatric nursing and 2 years of post-master's clinical experience under the supervision of a physician.[30] A patient must be examined within 72 hours of arrival and may be released only with the approval of a psychiatrist, clinical psychologist, or emergency room physician with experience in the diagnosis and treatment of mental and nervous disorders.[31]

The Patient Self-Referral Act of 1992

Section 455.053, F.S., is "The Patient Self-Referral Act of 1992." The act addresses the issue of the referral of patients by a health care provider for services or treatments when the referring health care provider has a financial interest in the service or treatment to be provided, which could result in a conflict of interest or the potential for inappropriate referrals for financial gain.[32] Federal[33] and state laws both generally prohibit self-referrals while providing certain exceptions. The exception in Florida law currently distinguishes between referrals for the provision of

[26] Florida Center for Nursing, *Presentation on Florida's Nurse Workforce*, 13 (Nov. 6, 2013), *available at:* http://myfloridahouse.gov/Sections/Documents/loaddoc.aspx?PublicationType=Committees&CommitteeId=2786&Session=2014&DocumentType=Meeting Packets&FileName=schcwi 11-6-13.pdf (last visited March 18, 2014).
[27] Section 394.455(26), F.S.
[28] Section 394.455(32), F.S.
[29] Section 394.463(2)(a), F.S.
[30] Section 394.455(23), F.S.
[31] Section 394.463(2)(f), F.S.
[32] Comm. On Health Regulation, The Florida Senate, *Referrals Between Health Care Providers in the Delivery of Radiation Therapy Services*, 1, 4 (Issue Brief 2012-218) (Sept. 2011).
[33] 42 U.S.C. 1395nn.

designated health services and the referral for any other health care item or service in which the health care provider has an interest.[34] Designated health services include clinical laboratory services, physical therapy services, comprehensive rehabilitative services, diagnostic–imaging services, and radiation therapy services.[35]

Health Care Practitioner Continuing Education

Florida law generally requires health care practitioners to complete continuing education as a condition of licensure and/or re-licensure. Some requirements are general obligations to complete a number of hours in subject areas determined by the relevant regulatory board.[36] For example, CNAs are required by statute to complete 12 hours of in-service training annually.[37] By rule of the BON, every 2 years, the in-service training hours must include at least the following areas:[38]

- Bloodborne Pathogens, Infection Control
- Domestic Violence
- Medical Record Documentation and Legal Aspects Appropriate to Nursing Assistants
- Resident Rights
- Communication with cognitively impaired clients
- CPR skills

Other continuing education requirements are expressly created in statute. Examples of these are as follows:

- Practitioners licensed or certified under ch. 458, F.S. (Allopathic Medicine), ch. 459, F.S. (Osteopathic Medicine), part I of ch. 464, F.S. (Nursing), ch. 466, F.S. (Dentistry and Dental Hygiene), ch. 467, F.S. (Midwifery), ch. 490, F.S. (Psychological Services), or ch. 491, F.S. (Clinical, Counseling, and Psychotherapy Services), must complete a 2-hour continuing education course on domestic violence as part of every third biennial-re-licensure or re-certification (once every 6 years).[39]
- All health care practitioners regulated by the DOH or a board must complete a course related to prevention of medical errors at initial licensure and biennial renewals thereafter.[40]
- Practitioners licensed or certified under ch. 457, F.S. (Acupuncture), ch. 458, F.S. (Allopathic Medicine), ch. 459, F.S. (Osteopathic Medicine), ch. 460, F.S. (Chiropractic Medicine), ch. 461, F.S., (Podiatric Medicine), ch. 463, F.S. (Optometry), part I of ch. 464, F.S. (Nursing), ch, 465, F.S. (Pharmacy), ch. 466, F.S. (Dentistry and Dental Hygiene), parts II, III, V, and X of ch.468, F.S. (Nursing Home Administration; Occupational Therapy; Respiratory Therapy; and Dietetics and Nutrition), are required to complete a course on HIV/AIDS one time, no later than first renewal.[41]

[34] Section 456.053(5), F.S.
[35] Section 456.053(3)(c), F.S.
[36] *See, e.g.* s. 456.013(6), F.S.
[37] Section 464.203(7), F.S.
[38] Rule 64B9-15.011(2), F.A.C.
[39] Section 456.031(1), F.S.
[40] Section 456.013(7), F.S.
[41] Section 456.033, F.S.

Medical Assistants

Current law creates a definition of "medical assistant" and describes the duties a medical assistant may undertake under the direct supervision and responsibility of a licensed physician. These limited duties include certain basic office and laboratory procedures, assisting with first aid, taking vital signs, and performing aseptic procedures, among others. The law says that a medical assistant may be certified by the American Association of Medical Assistants or as a Registered Medical Assistant by the American Medical Technologist, but the law does not require certification as a condition of performing the specified duties. There are other agencies that certify medical assistants that are not recognized in law.[42]

III. Effect of Proposed Changes:

ARNP/APRN Regulation

SB 1352 amends laws governing ARNPs to:

- Change "advanced registered nurse practitioner" to "advanced practice registered nurse" throughout the statutes, thereby adopting the title recommended in the APRN Regulation Consensus Model. **(Sections 25 – 104 contain only APRN title conforming changes and no substantive changes.)**
- Authorize APRNs to prescribe controlled substances under physician protocol, unless the drug is on a negative formulary prohibiting or otherwise limiting its use. The BON will appoint a committee consisting of at least three APRNs, two physicians, and a pharmacist recommended by the Surgeon General to adopt a formulary, if determined necessary to protect the public. The formulary may include drugs that may not be prescribed, or prescribed only for specific uses or subject to specific limitations. The committee may recommend a formulary applicable to all APRNs, limited by specialty certification, limited to approved uses of controlled substances, or other similar limitations the committee deems appropriate to protect the public health, safety, and welfare. The BON must adopt a recommended formulary by rule, with rulemaking initiated no later than October 1, 2014. A person requesting subsequent changes to the formulary bears the burden to show why the change should be made. The BON must post notice of any proposed, pending, or adopted changes to the formulary. The procedural requirements of this section track the requirements in current law applicable to the physician assistant formulary.[43] **(Section 19)**
- Revise the term "practitioner" under the Florida Comprehensive Drug Abuse Prevention and Control Act (ch. 893, F.S.) to include APRNs, as is necessary to authorize controlled substance prescribing. **(Section 23)**
- Add grounds for discipline of an APRN related to prescribing that are the same as apply to other health care practitioners who have prescribing authority, including enhanced penalties for prescribing, dispensing, mixing, or otherwise preparing a legend drug, including a controlled substance, other than in the course of the APRN's professional practice, or doing so inappropriately or in excessive or inappropriate amounts. **(Sections 14 and 21)**

[42] *See, e.g.* The American Registry of Medical Assistants, http://arma-cert.org/ (last visited March 17, 2014).
[43] *See* s. 458.347(4)(f), F.S.

- Require an APRN to comply with all statutes applicable to other health care practitioners who prescribe controlled substances to treat chronic nonmalignant pain. This includes:
  - Registration as a prescribing practitioner.
  - Complying with the specified standards of practice related to physical examination and medical history, treatment plans, communication of risks and benefits of treatment, follow up visits, referrals, records, and suspected addiction referrals. **(Section 15)**
- Add "advanced practice registered nurse" to all sections of law that reference controlled substances prescribed by a physician.
  - Prescribing brand drugs under the state prescription drug program. **(Section 1)**
  - Excepting controlled substances prescribed by an APRN from the disqualifications for continued certification or licensure as a deputy or state pilot. **(Sections 2, 3, and 4)**
  - Prohibiting substance abuse service providers from denying access to services to a person who takes medications prescribed by an APRN. **(Section 8)**
- Adds "Certified Nurse Practitioner" and related abbreviations to the list of titles and abbreviations that cannot be used without valid certification. A violation is a first degree misdemeanor, which is punishable by up to one year in jail or a fine of $1,000. **(Section 20)**

Florida Mental Health Act

The bill amends part I of ch. 394, F.S., the Florida Mental Health Act, to:

- Revise the credentials for registered nurses who are authorized to perform specified acts under the Florida Mental Health Act. Specifically, the bill requires national advanced practice certification as a Psychiatric-Mental Health Advanced Practice Registered Nurse in lieu of the 2 years clinical experience, required in the act today of psychiatric nurses. **(Section 6)**
- Change "Psychiatric Nurse" to "Psychiatric-Mental Health Advanced Practice Registered Nurse" (PMH-APRN) throughout the act. **(Sections 7 and 8)**
- Authorize PMH-APRNs to examine and approve releases of patients admitted to a receiving facility for involuntary examination. **(Section 7)**

Health Care Practitioner Continuing Education

The bill revises health care practitioner CE requirements to:

- Require domestic violence continuing education and medical errors prevention training one time, prior to first renewal for all practitioners. **(Sections 9 and 10)**
- Eliminate the HIV CE requirement for all practitioners who are required to take a course. While the bill repeals the section of law in ch. 456, F.S., which establishes the requirement as a condition of health practitioner licensure, it does not affect any HIV education required of as a condition of employment in specified settings.[44] **(Sections 5 and 11)**
- Eliminate all CE requirements for CNAs. **(Section 22)**

Miscellaneous Provisions

Finally, the bill:

[44] *See* ss. 381.0035, F.S. and 400.506((8), F.S.

- Revises the Patient Self-Referral Act of 1992 to allow referrals for designated health services at an entity in which the health care provider owns registered securities that are purchased on a national exchange or in the over-the-counter market and issued by a publicly held corporation whose shares are traded on the exchange or market and whose corporate assets exceed $50 million. The public corporation does not loan funds or guarantee a loan for an investor who is in a position to make referrals if the loan is used to obtain the investment interest. The effect of the bill is to extend to health care providers who refer patients to designated health services the exemption for an ownership interest of publicly-traded stock that currently applies to health care providers who refer patients to all other health care services. This is consistent with federal law. **(Section 12)**
- Clarifies that fees charged for written or typed medical records must be the same regardless of format or medium. This language is consistent with a rule proposed by the Board of Medicine amending Rule 64B8-10.003, F.A.C., relating to costs of reproducing medical records.[45] **(Section 13)**
- Removes language related to certification of medical assistants. **(Section 17)**
- Removes obsolete language related to physician office supervision. (**Sections 16 and 18)**

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Health care providers may experience efficiencies in operations if APRNs are no longer required to locate and obtain the signature of a physician to prescribe a controlled substance the APRN has determined necessary for the treatment of a patient.

Health care practitioners will experience savings in time and expenses related to the continuing education requirements that are eliminated or made less frequent.

[45] The Board of Medicine's rulemaking has been ongoing since October 2012 and involved multiple public hearings. On March 7, 2014, the board provided notice of another public hearing on April 4, 2014.

C. Government Sector Impact:

The DOH indicates that it will incur non-recurring costs for rulemaking to conform to the revisions related to continuing education, which can be absorbed by current budget authority. The DOH will incur an indeterminate non-recurring cost to staff activities of the drug formulary committee.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 110.12315, 310.071, 310.073, 310.081, 381.0035, 394.455, 394.463, 397.501, 456.013, 456.031, 456.033, 456.053, 456.057, 456.072, 456.44, 458.348, 458.3485, 459.025, 464.012, 464.015, 464.018, 464.203, 893.02, 948.03, 39.303, 39.304, 90.503, 112.0455, 121.0515, 252.515, 381.00315, 381.00593, 383.141, 390.0111, 390.012, 394.4574, 394.4655, 394.467, 395.0191, 395.602, 395.605, 397.311, 397.405, 397.427, 400.021, 400.0255, 400.172, 400.211, 400.462, 400.487, 400.506, 401.445, 409.905, 409.908, 409.9081, 409.9122, 409.973, 429.26, 429.918, 440.102, 456.0391, 456.0392, 456.041, 456.048, 458.3265, 458.331, 459.0137, 459.015, 464.003, 464.004, 464.016, 464.0205, 467.003, 480.0475, 483.041, 483.801, 486.021, 490.012, 491.0057, 491.012, 493.6108, 626.9707, 627.357, 627.6471, 627.6472, 627.736, 633.412, 641.3923, 641.495, 744.331, 744.703, 766.102, 766.103, 766.1115, 766.1116, 794.08, 943.13, 945.603, 1002.20, 1002.42, 1006.062, 1009.65, 1009.66, and 1009.67.

IX. Additional Information:

A. Committee Substitute – Statement of Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.

This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.

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LEGISLATIVE ACTION

Senate . House

. . . . .

The Committee on Health Policy (Grimsley) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause and insert:

Section 1. Subsection (3) 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:

(3) The Department of Management Services 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 health care practitioner ~~physician~~ 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 of Management Services.

Section 2. Paragraph (c) of subsection (1) of section 310.071, Florida Statutes, is amended 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

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tolerance for any controlled substance regulated under chapter 893 unless that individual is under the care of a physician or advanced practice registered nurse and that controlled substance was prescribed by that physician or advanced practice registered nurse. 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.

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 or advanced practice registered nurse and that controlled substance was prescribed by that physician or advanced practice registered nurse. To maintain eligibility as a licensed state pilot, each

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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 or advanced practice registered nurse and that controlled substance was prescribed by that physician or advanced practice registered nurse. 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

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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. Subsections (23) and (33) of section 394.455, Florida Statutes, are amended to read:

394.455 Definitions.—As used in this part, unless the context clearly requires otherwise, the term:

(23) "Psychiatric-mental health advanced practice registered ~~Psychiatric~~ nurse" means a registered nurse certified ~~licensed~~ under s. 464.012 ~~part I of chapter 464~~ who has a master's degree or a doctorate in psychiatric nursing and holds a national advanced practice certification as a psychiatric-mental health advanced practice nurse ~~2 years of post-master's clinical experience under the supervision of a physician~~.

(33) "Service provider" means any public or private receiving facility, an entity under contract with the Department of Children and Families ~~Family Services~~ to provide mental health services, a clinical psychologist, a clinical social worker, a marriage and family therapist, a mental health counselor, a physician, a psychiatric-mental health advanced practice registered ~~psychiatric~~ nurse ~~as defined in subsection (23)~~, or a community mental health center or clinic as defined in this part.

Section 6. Paragraphs (a) and (f) of subsection (2) of section 394.463, Florida Statutes, are amended to read:

394.463 Involuntary examination.—

(2) INVOLUNTARY EXAMINATION.—

(a) An involuntary examination may be initiated by any one of the following means:

1. A court may enter an ex parte order stating that a person appears to meet the criteria for involuntary examination, giving the findings on which that conclusion is based. The ex parte order for involuntary examination must be based on sworn testimony, written or oral. If other less restrictive means are not available, such as voluntary appearance for outpatient evaluation, a law enforcement officer, or other designated agent of the court, shall take the person into custody and deliver him or her to the nearest receiving facility for involuntary examination. The order of the court shall be made a part of the patient's clinical record. A ~~No~~ fee may not ~~shall~~ be charged for the filing of an order under this subsection. Any receiving facility accepting the patient based on this order must send a copy of the order to the Agency for Health Care Administration on the next working day. The order shall be valid only until executed or, if not executed, for the period specified in the order itself. If no time limit is specified in the order, the order shall be valid for 7 days after the date that the order was signed.

2. A law enforcement officer shall take a person who appears to meet the criteria for involuntary examination into custody and deliver the person or have him or her delivered to the nearest receiving facility for examination. The officer

shall execute a written report detailing the circumstances under which the person was taken into custody, and the report shall be made a part of the patient's clinical record. Any receiving facility accepting the patient based on this report must send a copy of the report to the Agency for Health Care Administration on the next working day.

3. A physician, clinical psychologist, psychiatric nurse, mental health counselor, marriage and family therapist, or clinical social worker may execute a certificate stating that he or she has examined a person within the preceding 48 hours and finds that the person appears to meet the criteria for involuntary examination and stating the observations upon which that conclusion is based. If other less restrictive means are not available, such as voluntary appearance for outpatient evaluation, a law enforcement officer shall take the person named in the certificate into custody and deliver him or her to the nearest receiving facility for involuntary examination. The law enforcement officer shall execute a written report detailing the circumstances under which the person was taken into custody. The report and certificate shall be made a part of the patient's clinical record. Any receiving facility accepting the patient based on this certificate must send a copy of the certificate to the Agency for Health Care Administration on the next working day.

(f) A patient shall be examined by a physician or clinical psychologist 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, a clinical psychologist, or a psychiatric-mental health advanced practice registered nurse or, if the receiving facility is a hospital, the release may also be approved by 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. However, a patient may not be held in a receiving facility for involuntary examination longer than 72 hours.

Section 7. Paragraph (a) of subsection (2) of section 397.501, Florida Statutes, is amended to read:

397.501 Rights of individuals.—Individuals receiving substance abuse services from any service provider are guaranteed protection of the rights specified in this section, unless otherwise expressly provided, and service providers must ensure the protection of such rights.

(2) RIGHT TO NONDISCRIMINATORY SERVICES.—

(a) Service providers may not deny an individual access to substance abuse services solely on the basis of race, gender, ethnicity, age, sexual preference, human immunodeficiency virus status, prior service departures against medical advice, disability, or number of relapse episodes. Service providers may not deny an individual who takes medication prescribed by a physician or an advanced practice registered nurse access to substance abuse services solely on that basis. Service providers who receive state funds to provide substance abuse services may not, if space and sufficient state resources are available, deny access to services based solely on inability to pay.

Section 8. Subsection (5) of section 456.053, Florida Statutes, is amended to read:

456.053 Financial arrangements between referring health care providers and providers of health care services.—

(5) PROHIBITED REFERRALS AND CLAIMS FOR PAYMENT.—Except as provided in this section:

(a) A health care provider may not refer a patient for the provision of designated health services to an entity in which the health care provider is an investor or has an investment interest unless:

1. The provider's investment interest is in registered securities purchased on a national exchange or in the over-the-counter market and issued by a publicly held corporation whose:

a. Shares are traded on a national exchange or in the over-the-counter market; and

b. Total assets at the end of the corporation's most recent fiscal quarter exceeded $50 million.

2. The publicly held corporation does not loan funds to or guarantee a loan for an investor who is in a position to make referrals to the entity or corporation if the investor uses any part of such loan to obtain the investment interest.

(b) A health care provider may not refer a patient for the provision of any other health care item or service to an entity in which the health care provider is an investor unless:

1. The provider's investment interest is in registered securities purchased on a national exchange or over-the-counter market and issued by a publicly held corporation whose:

a. ~~Whose~~ Shares are traded on a national exchange or on the over-the-counter market; and

b. ~~Whose~~ Total assets at the end of the corporation's most recent fiscal quarter exceeded $50 million; or

2. With respect to an entity other than a publicly held corporation described in subparagraph 1., and a referring provider's investment interest in such entity, each of the following requirements is ~~are~~ met:

a. No more than 50 percent of the value of the investment interests are held by investors who are in a position to make referrals to the entity.

b. The terms under which an investment interest is offered to an investor who is in a position to make referrals to the entity are no different from the terms offered to investors who are not in a position to make such referrals.

c. The terms under which an investment interest is offered to an investor who is in a position to make referrals to the entity are not related to the previous or expected volume of referrals from that investor to the entity.

d. There is no requirement that an investor make referrals or be in a position to make referrals to the entity as a condition for becoming or remaining an investor.

3. With respect to either such entity or publicly held corporation:

a. The entity or corporation does not loan funds to or guarantee a loan for an investor who is in a position to make referrals to the entity or corporation if the investor uses any part of such loan to obtain the investment interest.

b. The amount distributed to an investor representing a return on the investment interest is directly proportional to the amount of the capital investment, including the fair market

value of any preoperational services rendered, invested in the entity or corporation by that investor.

(c) ~~4.~~ Each board and, in the case of hospitals, the Agency for Health Care Administration~~,~~ shall encourage the use by licensees of the declaratory statement procedure to determine the applicability of this section or any rule adopted pursuant to this section as it applies solely to the licensee. Boards shall submit to the Agency for Health Care Administration the name of any entity in which a provider investment interest has been approved pursuant to this section.

(d) ~~(c)~~ A ~~No~~ claim for payment may not be presented by an entity to any individual, third-party payor, or other entity for a service furnished pursuant to a referral prohibited under this section.

(e) ~~(d)~~ If an entity collects any amount that was billed in violation of this section, the entity shall refund such amount on a timely basis to the payor or individual, whichever is applicable.

(f) ~~(e)~~ A ~~Any~~ person who ~~that~~ presents or causes to be presented a bill or a claim for service that such person knows or should know is for a service for which payment may not be made under paragraph (d) ~~(c)~~, or for which a refund has not been made under paragraph (e) ~~(d)~~, shall be subject to a civil penalty of not more than $15,000 for each such service to be imposed and collected by the appropriate board.

(g) ~~(f)~~ Any health care provider or other entity that enters into an arrangement or scheme, such as a cross-referral arrangement, which the physician or entity knows or should know has a principal purpose of assuring referrals by the physician

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to a particular entity which, if the physician directly made referrals to such entity, would be in violation of this section, shall be subject to a civil penalty of not more than $100,000 for each such circumvention arrangement or scheme to be imposed and collected by the appropriate board.

(h) ~~(g)~~ A violation of this section by a health care provider shall constitute grounds for disciplinary action to be taken by the applicable board pursuant to s. 458.331(2), s. 459.015(2), s. 460.413(2), s. 461.013(2), s. 463.016(2), or s. 466.028(2). Any hospital licensed under chapter 395 found in violation of this section shall be subject to s. 395.0185(2).

(i) ~~(h)~~ A ~~Any~~ hospital licensed under chapter 395 may not discriminate ~~that discriminates~~ against or otherwise penalize ~~penalizes~~ a health care provider for compliance with this act.

(j) ~~(i)~~ ~~The provision of~~ Paragraph (a) does ~~shall~~ not apply to referrals to the offices of radiation therapy centers managed by an entity or subsidiary or general partner thereof, which performed radiation therapy services at those same offices before ~~prior to~~ April 1, 1991, or ~~and shall not apply also~~ to referrals for radiation therapy to be performed at no more than one additional office of any entity qualifying for the foregoing exception which, before ~~prior to~~ February 1, 1992, had a binding purchase contract on and a nonrefundable deposit paid for a linear accelerator to be used at the additional office. The physical site of the radiation treatment centers affected by this provision may be relocated as a result of the following factors: acts of God; fire; strike; accident; war; eminent domain actions by any governmental body; or refusal by the lessor to renew a lease. A relocation for the foregoing reasons

is limited to relocation of an existing facility to a replacement location within the county of the existing facility upon written notification to the Office of Licensure and Certification.

(k) ~~(j)~~ A health care provider who meets the requirements of paragraph (a), paragraph ~~paragraphs~~ (b), or paragraph (j) ~~and (i)~~ must disclose his or her investment interest to his or her patients as provided in s. 456.052.

Section 9. Subsection (17) of section 456.057, Florida Statutes, is amended to read:

456.057 Ownership and control of patient records; report or copies of records to be furnished; disclosure of information.—

(17) A health care practitioner or records owner furnishing copies of reports or records or making the reports or records available for digital scanning pursuant to this section shall charge no more than the actual cost of copying, including reasonable staff time, or the amount specified in administrative rule by the appropriate board, or the department when there is no board. The rates charged for reproduction of written or typed medical records must be the same regardless of format or medium.

Section 10. 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 or advanced practice registered nurse 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), s.

464.018(1)(p)6., or s. 466.028(1)(p) or (x), the physician or advanced practice registered nurse 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 11. 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 or an advanced practice registered nurse 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 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 practitioner ~~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 practitioner ~~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 practitioner ~~physician~~ shall use a written controlled substance agreement between the practitioner ~~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 practitioner ~~physician~~ unless otherwise authorized by the treating practitioner ~~physician~~ and documented in the medical record.

(d) The patient shall be seen by the practitioner ~~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 practitioner's ~~physician's~~ evaluation of the patient's progress. If treatment goals are not being achieved, despite medication adjustments, the practitioner ~~physician~~ shall reevaluate the appropriateness of continued treatment. The practitioner ~~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 practitioner ~~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 practitioner ~~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 practitioner'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 practitioner 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 practitioner ~~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 practitioner ~~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 practitioner ~~physician~~ shall be documented in the patient's medical record.

This subsection does not apply to a board-eligible or board-

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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 physician or advanced practice registered nurse who prescribes medically necessary controlled substances for a patient during an inpatient stay in a hospital licensed under chapter 395.

Section 12. Subsections (1), (2), and (4) 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 practice registered nurse ~~practitioner~~, which

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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 practice registered nurse(s) ~~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; STANDARDS.—The joint committee created under s. 464.003(2) shall determine minimum standards for the content of established protocols pursuant to which an advanced practice 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.

(4) SUPERVISORY RELATIONSHIPS IN MEDICAL OFFICE SETTINGS.—A physician who supervises an advanced practice registered nurse ~~practitioner~~ or physician assistant at a medical office other than the physician's primary practice location, where the advanced practice registered nurse ~~practitioner~~ or physician assistant is not under the onsite supervision of a supervising physician, must comply with the standards set forth in this subsection. For the purpose of this subsection, a physician's "primary practice location" means the address reflected on the physician's profile published pursuant to s. 456.041.

(a) A physician who is engaged in providing primary health care services may not supervise more than four offices in addition to the physician's primary practice location. For the purpose of this subsection, "primary health care" means health care services that are commonly provided to patients without referral from another practitioner, including obstetrical and gynecological services, and excludes practices providing primarily dermatologic and skin care services, which include aesthetic skin care services.

(b) A physician who is engaged in providing specialty health care services may not supervise more than two offices in addition to the physician's primary practice location. For the

purpose of this subsection, "specialty health care" means health care services that are commonly provided to patients with a referral from another practitioner and excludes practices providing primarily dermatologic and skin care services, which include aesthetic skin care services.

(c) A physician who supervises an advanced practice registered nurse ~~practitioner~~ or physician assistant at a medical office other than the physician's primary practice location, where the advanced practice registered nurse ~~practitioner~~ or physician assistant is not under the onsite supervision of a supervising physician and the services offered at the office are primarily dermatologic or skin care services, which include aesthetic skin care services other than plastic surgery, must comply with the standards listed in subparagraphs 1.-4. Notwithstanding s. 458.347(4)(e)6., a physician supervising a physician assistant pursuant to this paragraph may not be required to review and cosign charts or medical records prepared by such physician assistant.

1. The physician shall submit to the board the addresses of all offices where he or she is supervising an advanced practice registered nurse ~~practitioner~~ or a physician's assistant which are not the physician's primary practice location.

2. The physician must be board certified or board eligible in dermatology or plastic surgery as recognized by the board pursuant to s. 458.3312.

3. All such offices that are not the physician's primary place of practice must be within 25 miles of the physician's primary place of practice or in a county that is contiguous to the county of the physician's primary place of practice.

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However, the distance between any of the offices may not exceed 75 miles.

4. The physician may supervise only one office other than the physician's primary place of practice ~~except that until July 1, 2011, the physician may supervise up to two medical offices other than the physician's primary place of practice if the addresses of the offices are submitted to the board before July 1, 2006. Effective July 1, 2011, the physician may supervise only one office other than the physician's primary place of practice, regardless of when the addresses of the offices were submitted to the board~~.

(d) A physician who supervises an office in addition to the physician's primary practice location must conspicuously post in each of the physician's offices a current schedule of the regular hours when the physician is present in that office and the hours when the office is open while the physician is not present.

(e) This subsection does not apply to health care services provided in facilities licensed under chapter 395 or in conjunction with a college of medicine, a college of nursing, an accredited graduate medical program, or a nursing education program; not-for-profit, family-planning clinics that are not licensed pursuant to chapter 390; rural and federally qualified health centers; health care services provided in a nursing home licensed under part II of chapter 400, an assisted living facility licensed under part I of chapter 429, a continuing care facility licensed under chapter 651, or a retirement community consisting of independent living units and a licensed nursing home or assisted living facility; anesthesia services provided

in accordance with law; health care services provided in a designated rural health clinic; health care services provided to persons enrolled in a program designed to maintain elderly persons and persons with disabilities in a home or community-based setting; university primary care student health centers; school health clinics; or health care services provided in federal, state, or local government facilities. Subsection (3) and this subsection do not apply to offices at which the exclusive service being performed is laser hair removal by an advanced practice registered nurse ~~practitioner~~ or physician assistant.

Section 13. Subsection (3) of section 458.3485, Florida Statutes, is amended to read:

458.3485 Medical assistant.—

~~(3) CERTIFICATION.—Medical assistants may be certified by the American Association of Medical Assistants or as a Registered Medical Assistant by the American Medical Technologists.~~

Section 14. Subsections (1) and (3) of section 459.025, Florida Statutes, are 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 practice registered nurse

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~~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 practice registered nurse(s) ~~nurse practitioner(s)~~.

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

(3) SUPERVISORY RELATIONSHIPS IN MEDICAL OFFICE SETTINGS.—An osteopathic physician who supervises an advanced practice registered nurse ~~practitioner~~ or physician assistant at a medical office other than the osteopathic physician's primary practice location, where the advanced practice registered nurse ~~practitioner~~ or physician assistant is not under the onsite supervision of a supervising osteopathic physician, must comply with the standards set forth in this subsection. For the purpose of this subsection, an osteopathic physician's "primary practice location" means the address reflected on the physician's profile

published pursuant to s. 456.041.

(a) An osteopathic physician who is engaged in providing primary health care services may not supervise more than four offices in addition to the osteopathic physician's primary practice location. For the purpose of this subsection, "primary health care" means health care services that are commonly provided to patients without referral from another practitioner, including obstetrical and gynecological services, and excludes practices providing primarily dermatologic and skin care services, which include aesthetic skin care services.

(b) An osteopathic physician who is engaged in providing specialty health care services may not supervise more than two offices in addition to the osteopathic physician's primary practice location. For the purpose of this subsection, "specialty health care" means health care services that are commonly provided to patients with a referral from another practitioner and excludes practices providing primarily dermatologic and skin care services, which include aesthetic skin care services.

(c) An osteopathic physician who supervises an advanced practice registered nurse ~~practitioner~~ or physician assistant at a medical office other than the osteopathic physician's primary practice location, where the advanced practice registered nurse ~~practitioner~~ or physician assistant is not under the onsite supervision of a supervising osteopathic physician and the services offered at the office are primarily dermatologic or skin care services, which include aesthetic skin care services other than plastic surgery, must comply with the standards listed in subparagraphs 1.-4. Notwithstanding s.

459.022(4)(e)6., an osteopathic physician supervising a physician assistant pursuant to this paragraph may not be required to review and cosign charts or medical records prepared by such physician assistant.

1. The osteopathic physician shall submit to the Board of Osteopathic Medicine the addresses of all offices where he or she is supervising or has a protocol with an advanced practice registered nurse ~~practitioner~~ or a physician's assistant which are not the osteopathic physician's primary practice location.

2. The osteopathic physician must be board certified or board eligible in dermatology or plastic surgery as recognized by the Board of Osteopathic Medicine pursuant to s. 459.0152.

3. All such offices that are not the osteopathic physician's primary place of practice must be within 25 miles of the osteopathic physician's primary place of practice or in a county that is contiguous to the county of the osteopathic physician's primary place of practice. However, the distance between any of the offices may not exceed 75 miles.

4. The osteopathic physician may supervise only one office other than the osteopathic physician's primary place of practice ~~except that until July 1, 2011, the osteopathic physician may supervise up to two medical offices other than the osteopathic physician's primary place of practice if the addresses of the offices are submitted to the Board of Osteopathic Medicine before July 1, 2006. Effective July 1, 2011, the osteopathic physician may supervise only one office other than the osteopathic physician's primary place of practice, regardless of when the addresses of the offices were submitted to the Board of Osteopathic Medicine~~.

(d) An osteopathic physician who supervises an office in addition to the osteopathic physician's primary practice location must conspicuously post in each of the osteopathic physician's offices a current schedule of the regular hours when the osteopathic physician is present in that office and the hours when the office is open while the osteopathic physician is not present.

(e) This subsection does not apply to health care services provided in facilities licensed under chapter 395 or in conjunction with a college of medicine or college of nursing or an accredited graduate medical or nursing education program; offices where the only service being performed is hair removal by an advanced practice registered nurse ~~practitioner~~ or physician assistant; not-for-profit, family-planning clinics that are not licensed pursuant to chapter 390; rural and federally qualified health centers; health care services provided in a nursing home licensed under part II of chapter 400, an assisted living facility licensed under part I of chapter 429, a continuing care facility licensed under chapter 651, or a retirement community consisting of independent living units and either a licensed nursing home or assisted living facility; anesthesia services provided in accordance with law; health care services provided in a designated rural health clinic; health care services provided to persons enrolled in a program designed to maintain elderly persons and persons with disabilities in a home or community-based setting; university primary care student health centers; school health clinics; or health care services provided in federal, state, or local government facilities.

Section 15. Section 464.012, Florida Statutes, is amended to read:

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

(1) Any nurse desiring to be certified as an advanced practice 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

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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 practice registered nurses ~~nurse practitioners~~ in the categories of certified registered nurse anesthetist, certified nurse midwife, and certified nurse practitioner.

(3) An advanced practice 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 practice registered nurse ~~practitioner~~ may:

(a) Prescribe, dispense, administer, or order drugs. As used in this paragraph, the term "drugs" includes controlled substances.

(b) ~~(a)~~ Monitor and alter drug therapies.

(c) ~~(b)~~ Initiate appropriate therapies for certain conditions.

(d) ~~(c)~~ Perform additional functions as may be determined by

rule in accordance with s. 464.003(2).

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

(4) In addition to the general functions specified in subsection (3), an advanced practice 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 certified 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 appoint a committee to recommend whether a formulary of controlled substances that an advanced practice registered nurse may not prescribe or may prescribe only for specific uses or subject to specific limitations is necessary to protect the health, safety, and welfare of the public. The committee shall consist of at least three advanced practice registered nurses, including a certified registered nurse anesthetist, a certified nurse midwife, and a certified nurse practitioner; at least two physicians recommended by the Board of Medicine, and one physician recommended by the Board of Osteopathic Medicine, who have had work experience with advanced

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practice registered nurses; and a pharmacist licensed under chapter 465, but not licensed under chapter 458, chapter 459, or this chapter, who shall be selected by the State Surgeon General. The committee may recommend a formulary applicable to all advanced practice registered nurses, limited by specialty certification, limited to approved uses of controlled substances, or subject to other similar restriction it deems necessary to protect the health, safety, and welfare of the public.

(b) The board shall adopt any formulary required under this subsection by rule. Only the board may add to, delete from, or modify the formulary. A person who requests the addition, deletion, or modification of a controlled substance listed on the formulary has the burden of proof to show cause why the change should be made. The board shall post notice of any proposed, pending, or adopted changes to the formulary on its website.

(c) The board shall initiate rulemaking, if required to implement the committee's initial recommendation, no later than October 1, 2014.

Section 16. Present subsections (8) through (10) of section 464.015, Florida Statutes, are renumbered as subsections (9) through (11), respectively, and amended, and a new subsection (8) is added to that section, to read:

464.015 Titles and abbreviations; restrictions; penalty.—

(8) Only persons who hold valid certificates to practice as certified nurse practitioners in this state may use the title "Certified Nurse Practitioner" and use the abbreviations "C.N.P." and "nurse practitioner."

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(9)~~(8)~~ Only persons who hold valid certificates to practice as advanced practice registered nurses ~~nurse practitioners~~ in this state may use the title "Advanced Practice Registered Nurse ~~Practitioner~~" and the abbreviation "A.P.R.N." ~~"A.R.N.P."~~

(10)~~(9)~~ A person may not practice or advertise as, or assume the title of, registered nurse, licensed practical nurse, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, or advanced practice registered nurse ~~practitioner~~ or use the abbreviation "R.N.," "L.P.N.," "C.N.S.," "C.R.N.A.," "C.N.M.," "C.N.P.," or "A.P.R.N." ~~"A.R.N.P."~~ or take any other action that would lead the public to believe that person was certified as such or is performing nursing services pursuant to the exception set forth in s. 464.022(8), unless that person is licensed or certified to practice as such.

(11)~~(10)~~ A violation of this section is a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

Section 17. Paragraph (p) is added to subsection (1) of section 464.018, Florida Statutes, 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 only an advanced practice registered nurse:

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

sympathomimetic amine drug, or a compound designated pursuant to chapter 893 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, 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. For the purposes of this subsection, the term "muscle building" does not include the treatment of injured muscle. A prescription written for the drug products listed above may be dispensed by the pharmacist with the presumption that the prescription is for legitimate medical use.

5. Promoting or advertising on any prescription form of 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 paragraph, it shall be 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 practice registered nurse's professional practice, without regard to his or her intent.

7. Prescribing, dispensing, or administering a medicinal drug appearing on a schedule set forth in chapter 893 to himself or herself, except a drug prescribed, dispensed, or administered to the advanced practice registered nurse 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 controlled substance listed in Schedule II or Schedule III of chapter 893 in violation of s. 465.0276.

10. Promoting or advertising through any communication medium the use, sale, or dispensing of a controlled substance appearing on a schedule in chapter 893.

Section 18. 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 pursuant to

chapter 458, a dentist licensed pursuant to chapter 466, a veterinarian licensed pursuant to chapter 474, an osteopathic physician licensed pursuant to chapter 459, an advanced practice registered nurse certified pursuant to chapter 464, a naturopath licensed pursuant to chapter 462, a certified optometrist licensed pursuant to chapter 463, or a podiatric physician licensed pursuant to chapter 461, provided such practitioner holds a valid federal controlled substance registry number.

Section 19. 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 or advanced practice registered nurse. 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 20. Subsections (3) and (4) of section 39.303, Florida Statutes, are amended to read:

39.303 Child protection teams; services; eligible cases.—The Children's Medical Services Program in the Department of Health shall develop, maintain, and coordinate the services of one or more multidisciplinary child protection teams in each of

the service districts of the Department of Children and Family Services. Such teams may be composed of appropriate representatives of school districts and appropriate health, mental health, social service, legal service, and law enforcement agencies. The Legislature finds that optimal coordination of child protection teams and sexual abuse treatment programs requires collaboration between the Department of Health and the Department of Children and Family Services. The two departments shall maintain an interagency agreement that establishes protocols for oversight and operations of child protection teams and sexual abuse treatment programs. The State Surgeon General and the Deputy Secretary for Children's Medical Services, in consultation with the Secretary of Children and Family Services, shall maintain the responsibility for the screening, employment, and, if necessary, the termination of child protection team medical directors, at headquarters and in the 15 districts. Child protection team medical directors shall be responsible for oversight of the teams in the districts.

(3) All abuse and neglect cases transmitted for investigation to a district by the hotline must be simultaneously transmitted to the Department of Health child protection team for review. For the purpose of determining whether face-to-face medical evaluation by a child protection team is necessary, all cases transmitted to the child protection team which meet the criteria in subsection (2) must be timely reviewed by:

(a) A physician licensed under chapter 458 or chapter 459 who holds board certification in pediatrics and is a member of a child protection team;

(b) A physician licensed under chapter 458 or chapter 459 who holds board certification in a specialty other than pediatrics, who may complete the review only when working under the direction of a physician licensed under chapter 458 or chapter 459 who holds board certification in pediatrics and is a member of a child protection team;

(c) An advanced practice registered nurse ~~practitioner~~ licensed under chapter 464 who has a specialty ~~speciality~~ in pediatrics or family medicine and is a member of a child protection team;

(d) A physician assistant licensed under chapter 458 or chapter 459, who may complete the review only when working under the supervision of a physician licensed under chapter 458 or chapter 459 who holds board certification in pediatrics and is a member of a child protection team; or

(e) A registered nurse licensed under chapter 464, who may complete the review only when working under the direct supervision of a physician licensed under chapter 458 or chapter 459 who holds certification in pediatrics and is a member of a child protection team.

(4) A face-to-face medical evaluation by a child protection team is not necessary when:

(a) The child was examined for the alleged abuse or neglect by a physician who is not a member of the child protection team, and a consultation between the child protection team board-certified pediatrician, advanced practice registered nurse ~~practitioner~~, physician assistant working under the supervision of a child protection team board-certified pediatrician, or registered nurse working under the direct supervision of a child

protection team board-certified pediatrician, and the examining physician concludes that a further medical evaluation is unnecessary;

(b) The child protective investigator, with supervisory approval, has determined, after conducting a child safety assessment, that there are no indications of injuries as described in paragraphs (2)(a)-(h) as reported; or

(c) The child protection team board-certified pediatrician, as authorized in subsection (3), determines that a medical evaluation is not required.

Notwithstanding paragraphs (a), (b), and (c), a child protection team pediatrician, as authorized in subsection (3), may determine that a face-to-face medical evaluation is necessary.

Section 21. Paragraph (b) of subsection (1) of section 39.304, Florida Statutes, is amended to read:

39.304 Photographs, medical examinations, X rays, and medical treatment of abused, abandoned, or neglected child.—

(1)

(b) If the areas of trauma visible on a child indicate a need for a medical examination, or if the child verbally complains or otherwise exhibits distress as a result of injury through suspected child abuse, abandonment, or neglect, or is alleged to have been sexually abused, the person required to investigate may cause the child to be referred for diagnosis to a licensed physician or an emergency department in a hospital without the consent of the child's parents or legal custodian. Such examination may be performed by any licensed physician or an advanced <u>practice</u> registered nurse ~~practitioner~~ licensed

pursuant to part I of chapter 464. Any licensed physician, or advanced practice registered nurse ~~practitioner~~ licensed pursuant to part I of chapter 464, who has reasonable cause to suspect that an injury was the result of child abuse, abandonment, or neglect may authorize a radiological examination to be performed on the child without the consent of the child's parent or legal custodian.

Section 22. Paragraph (a) of subsection (1) of section 90.503, Florida Statutes, is amended to read:

90.503 Psychotherapist-patient privilege.—

(1) For purposes of this section:

(a) A "psychotherapist" is:

1. A person authorized to practice medicine in any state or nation, or reasonably believed by the patient so to be, who is engaged in the diagnosis or treatment of a mental or emotional condition, including alcoholism and other drug addiction;

2. A person licensed or certified as a psychologist under the laws of any state or nation, who is engaged primarily in the diagnosis or treatment of a mental or emotional condition, including alcoholism and other drug addiction;

3. A person licensed or certified as a clinical social worker, marriage and family therapist, or mental health counselor under the laws of this state, who is engaged primarily in the diagnosis or treatment of a mental or emotional condition, including alcoholism and other drug addiction;

4. Treatment personnel of facilities licensed by the state pursuant to chapter 394, chapter 395, or chapter 397, of facilities designated by the Department of Children and Families ~~Family Services~~ pursuant to chapter 394 as treatment facilities,

or of facilities defined as community mental health centers pursuant to s. 394.907(1), who are engaged primarily in the diagnosis or treatment of a mental or emotional condition, including alcoholism and other drug addiction; or

5. An advanced practice registered nurse ~~practitioner~~ certified under s. 464.012, whose primary scope of practice is the diagnosis or treatment of mental or emotional conditions, including chemical abuse, and limited only to actions performed in accordance with part I of chapter 464.

Section 23. Paragraph (e) of subsection (8) of section 112.0455, Florida Statutes, is amended to read:

112.0455 Drug-Free Workplace Act.—

(8) PROCEDURES AND EMPLOYEE PROTECTION.—All specimen collection and testing for drugs under this section shall be performed in accordance with the following procedures:

(e) A specimen for a drug test may be taken or collected by any of the following persons:

1. A physician, a physician's assistant, a registered professional nurse, a licensed practical nurse, an advanced practice registered ~~a~~ nurse ~~practitioner~~, or a certified paramedic who is present at the scene of an accident for the purpose of rendering emergency medical service or treatment.

2. A qualified person employed by a licensed laboratory.

Section 24. Subsection (3) of section 121.0515, Florida Statutes, is amended to read:

121.0515 Special Risk Class.—

(3) CRITERIA.—A member, to be designated as a special risk member, must meet the following criteria:

(a) Effective October 1, 1978, the member must be employed

as a law enforcement officer and be certified, or required to be certified, in compliance with s. 943.1395; however, sheriffs and elected police chiefs are excluded from meeting the certification requirements of this paragraph. In addition, the member's duties and responsibilities must include the pursuit, apprehension, and arrest of law violators or suspected law violators; or as of July 1, 1982, the member must be an active member of a bomb disposal unit whose primary responsibility is the location, handling, and disposal of explosive devices; or the member must be the supervisor or command officer of a member or members who have such responsibilities. Administrative support personnel, including, but not limited to, those whose primary duties and responsibilities are in accounting, purchasing, legal, and personnel, are not included;

(b) Effective October 1, 1978, the member must be employed as a firefighter and be certified, or required to be certified, in compliance with s. 633.408 and be employed solely within the fire department of a local government employer or an agency of state government with firefighting responsibilities. In addition, the member's duties and responsibilities must include on-the-scene fighting of fires; as of October 1, 2001, fire prevention or firefighter training; as of October 1, 2001, direct supervision of firefighting units, fire prevention, or firefighter training; or as of July 1, 2001, aerial firefighting surveillance performed by fixed-wing aircraft pilots employed by the Florida Forest Service of the Department of Agriculture and Consumer Services; or the member must be the supervisor or command officer of a member or members who have such responsibilities. Administrative support personnel, including,

but not limited to, those whose primary duties and responsibilities are in accounting, purchasing, legal, and personnel, are not included. All periods of creditable service in fire prevention or firefighter training, or as the supervisor or command officer of a member or members who have such responsibilities, and for which the employer paid the special risk contribution rate, are included;

(c) Effective October 1, 1978, the member must be employed as a correctional officer and be certified, or required to be certified, in compliance with s. 943.1395. In addition, the member's primary duties and responsibilities must be the custody, and physical restraint when necessary, of prisoners or inmates within a prison, jail, or other criminal detention facility, or while on work detail outside the facility, or while being transported; or as of July 1, 1984, the member must be the supervisor or command officer of a member or members who have such responsibilities. Administrative support personnel, including, but not limited to, those whose primary duties and responsibilities are in accounting, purchasing, legal, and personnel, are not included; however, wardens and assistant wardens, as defined by rule, are included;

(d) Effective October 1, 1999, the member must be employed by a licensed Advance Life Support (ALS) or Basic Life Support (BLS) employer as an emergency medical technician or a paramedic and be certified in compliance with s. 401.27. In addition, the member's primary duties and responsibilities must include on-the-scene emergency medical care or as of October 1, 2001, direct supervision of emergency medical technicians or paramedics, or the member must be the supervisor or command

officer of one or more members who have such responsibility. Administrative support personnel, including, but not limited to, those whose primary responsibilities are in accounting, purchasing, legal, and personnel, are not included;

(e) Effective January 1, 2001, the member must be employed as a community-based correctional probation officer and be certified, or required to be certified, in compliance with s. 943.1395. In addition, the member's primary duties and responsibilities must be the supervised custody, surveillance, control, investigation, and counseling of assigned inmates, probationers, parolees, or community controllees within the community; or the member must be the supervisor of a member or members who have such responsibilities. Administrative support personnel, including, but not limited to, those whose primary duties and responsibilities are in accounting, purchasing, legal services, and personnel management, are not included; however, probation and parole circuit and deputy circuit administrators are included;

(f) Effective January 1, 2001, the member must be employed in one of the following classes and must spend at least 75 percent of his or her time performing duties which involve contact with patients or inmates in a correctional or forensic facility or institution:

1. Dietitian (class codes 5203 and 5204);
2. Public health nutrition consultant (class code 5224);
3. Psychological specialist (class codes 5230 and 5231);
4. Psychologist (class code 5234);
5. Senior psychologist (class codes 5237 and 5238);
6. Regional mental health consultant (class code 5240);

7. Psychological Services Director—DCF (class code 5242);

8. Pharmacist (class codes 5245 and 5246);

9. Senior pharmacist (class codes 5248 and 5249);

10. Dentist (class code 5266);

11. Senior dentist (class code 5269);

12. Registered nurse (class codes 5290 and 5291);

13. Senior registered nurse (class codes 5292 and 5293);

14. Registered nurse specialist (class codes 5294 and 5295);

15. Clinical associate (class codes 5298 and 5299);

16. Advanced practice registered nurse ~~practitioner~~ (class codes 5297 and 5300);

17. Advanced practice registered nurse ~~practitioner~~ specialist (class codes 5304 and 5305);

18. Registered nurse supervisor (class codes 5306 and 5307);

19. Senior registered nurse supervisor (class codes 5308 and 5309);

20. Registered nursing consultant (class codes 5312 and 5313);

21. Quality management program supervisor (class code 5314);

22. Executive nursing director (class codes 5320 and 5321);

23. Speech and hearing therapist (class code 5406); or

24. Pharmacy manager (class code 5251);

(g) Effective July 1, 2001, the member must be employed as a youth custody officer and be certified, or required to be certified, in compliance with s. 943.1395. In addition, the member’s primary duties and responsibilities must be the

supervised custody, surveillance, control, investigation, apprehension, arrest, and counseling of assigned juveniles within the community;

(h) Effective October 1, 2005, through June 30, 2008, the member must be employed by a law enforcement agency or medical examiner's office in a forensic discipline recognized by the International Association for Identification and must qualify for active membership in the International Association for Identification. The member's primary duties and responsibilities must include the collection, examination, preservation, documentation, preparation, or analysis of physical evidence or testimony, or both, or the member must be the direct supervisor, quality management supervisor, or command officer of one or more individuals with such responsibility. Administrative support personnel, including, but not limited to, those whose primary responsibilities are clerical or in accounting, purchasing, legal, and personnel, are not included;

(i) Effective July 1, 2008, the member must be employed by the Department of Law Enforcement in the crime laboratory or by the Division of State Fire Marshal in the forensic laboratory in one of the following classes:

1. Forensic technologist (class code 8459);

2. Crime laboratory technician (class code 8461);

3. Crime laboratory analyst (class code 8463);

4. Senior crime laboratory analyst (class code 8464);

5. Crime laboratory analyst supervisor (class code 8466);

6. Forensic chief (class code 9602); or

7. Forensic services quality manager (class code 9603);

(j) Effective July 1, 2008, the member must be employed by

a local government law enforcement agency or medical examiner's office and must spend at least 65 percent of his or her time performing duties that involve the collection, examination, preservation, documentation, preparation, or analysis of human tissues or fluids or physical evidence having potential biological, chemical, or radiological hazard or contamination, or use chemicals, processes, or materials that may have carcinogenic or health-damaging properties in the analysis of such evidence, or the member must be the direct supervisor of one or more individuals having such responsibility. If a special risk member changes to another position within the same agency, he or she must submit a complete application as provided in paragraph (4)(a); or

(k) The member must have already qualified for and be actively participating in special risk membership under paragraph (a), paragraph (b), or paragraph (c), must have suffered a qualifying injury as defined in this paragraph, must not be receiving disability retirement benefits as provided in s. 121.091(4), and must satisfy the requirements of this paragraph.

1. The ability to qualify for the class of membership defined in paragraph (2)(i) occurs when two licensed medical physicians, one of whom is a primary treating physician of the member, certify the existence of the physical injury and medical condition that constitute a qualifying injury as defined in this paragraph and that the member has reached maximum medical improvement after August 1, 2008. The certifications from the licensed medical physicians must include, at a minimum, that the injury to the special risk member has resulted in a physical

loss, or loss of use, of at least two of the following: left arm, right arm, left leg, or right leg; and:

a. That this physical loss or loss of use is total and permanent, except if the loss of use is due to a physical injury to the member's brain, in which event the loss of use is permanent with at least 75 percent loss of motor function with respect to each arm or leg affected.

b. That this physical loss or loss of use renders the member physically unable to perform the essential job functions of his or her special risk position.

c. That, notwithstanding this physical loss or loss of use, the individual can perform the essential job functions required by the member's new position, as provided in subparagraph 3.

d. That use of artificial limbs is not possible or does not alter the member's ability to perform the essential job functions of the member's position.

e. That the physical loss or loss of use is a direct result of a physical injury and not a result of any mental, psychological, or emotional injury.

2. For the purposes of this paragraph, "qualifying injury" means an injury sustained in the line of duty, as certified by the member's employing agency, by a special risk member that does not result in total and permanent disability as defined in s. 121.091(4)(b). An injury is a qualifying injury if the injury is a physical injury to the member's physical body resulting in a physical loss, or loss of use, of at least two of the following: left arm, right arm, left leg, or right leg. Notwithstanding any other provision of this section, an injury that would otherwise qualify as a qualifying injury is not

considered a qualifying injury if and when the member ceases employment with the employer for whom he or she was providing special risk services on the date the injury occurred.

3. The new position, as described in sub-subparagraph 1.c., that is required for qualification as a special risk member under this paragraph is not required to be a position with essential job functions that entitle an individual to special risk membership. Whether a new position as described in sub-subparagraph 1.c. exists and is available to the special risk member is a decision to be made solely by the employer in accordance with its hiring practices and applicable law.

4. This paragraph does not grant or create additional rights for any individual to continued employment or to be hired or rehired by his or her employer that are not already provided within the Florida Statutes, the State Constitution, the Americans with Disabilities Act, if applicable, or any other applicable state or federal law.

Section 25. Paragraph (a) of subsection (3) of section 252.515, Florida Statutes, is amended to read:

252.515 Postdisaster Relief Assistance Act; immunity from civil liability.—

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

(a) "Emergency first responder" means:

1. A physician licensed under chapter 458.

2. An osteopathic physician licensed under chapter 459.

3. A chiropractic physician licensed under chapter 460.

4. A podiatric physician licensed under chapter 461.

5. A dentist licensed under chapter 466.

6. An advanced <u>practice</u> registered nurse ~~practitioner~~

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certified under s. 464.012.

7. A physician assistant licensed under s. 458.347 or s. 459.022.

8. A worker employed by a public or private hospital in the state.

9. A paramedic as defined in s. 401.23(17).

10. An emergency medical technician as defined in s. 401.23(11).

11. A firefighter as defined in s. 633.102.

12. A law enforcement officer as defined in s. 943.10.

13. A member of the Florida National Guard.

14. Any other personnel designated as emergency personnel by the Governor pursuant to a declared emergency.

Section 26. Paragraph (b) of subsection (1) of section 381.00315, Florida Statutes, is amended to read:

381.00315 Public health advisories; public health emergencies; quarantines.—The State Health Officer is responsible for declaring public health emergencies and quarantines and issuing public health advisories.

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

(b) "Public health emergency" means any occurrence, or threat thereof, whether natural or manmade ~~man made~~, which results or may result in substantial injury or harm to the public health from infectious disease, chemical agents, nuclear agents, biological toxins, or situations involving mass casualties or natural disasters. Before ~~Prior to~~ declaring a public health emergency, the State Health Officer shall, to the extent possible, consult with the Governor and shall notify the Chief of Domestic Security. The declaration of a public health

emergency shall continue until the State Health Officer finds that the threat or danger has been dealt with to the extent that the emergency conditions no longer exist and he or she terminates the declaration. However, a declaration of a public health emergency may not continue for longer than 60 days unless the Governor concurs in the renewal of the declaration. The State Health Officer, upon declaration of a public health emergency, may take actions that are necessary to protect the public health. Such actions include, but are not limited to:

1. Directing manufacturers of prescription drugs or over-the-counter drugs who are permitted under chapter 499 and wholesalers of prescription drugs located in this state who are permitted under chapter 499 to give priority to the shipping of specified drugs to pharmacies and health care providers within geographic areas that have been identified by the State Health Officer. The State Health Officer must identify the drugs to be shipped. Manufacturers and wholesalers located in the state must respond to the State Health Officer's priority shipping directive before shipping the specified drugs.

2. Notwithstanding chapters 465 and 499 and rules adopted thereunder, directing pharmacists employed by the department to compound bulk prescription drugs and provide these bulk prescription drugs to physicians and nurses of county health departments or any qualified person authorized by the State Health Officer for administration to persons as part of a prophylactic or treatment regimen.

3. Notwithstanding s. 456.036, temporarily reactivating the inactive license of the following health care practitioners, when such practitioners are needed to respond to the public

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health emergency: physicians licensed under chapter 458 or chapter 459; physician assistants licensed under chapter 458 or chapter 459; licensed practical nurses, registered nurses, and advanced practice registered nurses certified ~~nurse practitioners licensed~~ under part I of chapter 464; respiratory therapists licensed under part V of chapter 468; and emergency medical technicians and paramedics certified under part III of chapter 401. Only those health care practitioners specified in this paragraph who possess an unencumbered inactive license and who request that such license be reactivated are eligible for reactivation. An inactive license that is reactivated under this paragraph shall return to inactive status when the public health emergency ends or before ~~prior to~~ the end of the public health emergency if the State Health Officer determines that the health care practitioner is no longer needed to provide services during the public health emergency. Such licenses may only be reactivated for a period not to exceed 90 days without meeting the requirements of s. 456.036 or chapter 401, as applicable.

4. Ordering an individual to be examined, tested, vaccinated, treated, or quarantined for communicable diseases that have significant morbidity or mortality and present a severe danger to public health. Individuals who are unable or unwilling to be examined, tested, vaccinated, or treated for reasons of health, religion, or conscience may be subjected to quarantine.

a. Examination, testing, vaccination, or treatment may be performed by any qualified person authorized by the State Health Officer.

b. If the individual poses a danger to the public health,

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the State Health Officer may subject the individual to quarantine. If there is no practical method to quarantine the individual, the State Health Officer may use any means necessary to vaccinate or treat the individual.

Any order of the State Health Officer given to effectuate this paragraph shall be immediately enforceable by a law enforcement officer under s. 381.0012.

Section 27. Subsection (3) of section 381.00593, Florida Statutes, is amended to read:

381.00593 Public school volunteer health care practitioner program.—

(3) For purposes of this section, the term "health care practitioner" means a physician licensed under chapter 458; an osteopathic physician licensed under chapter 459; a chiropractic physician licensed under chapter 460; a podiatric physician licensed under chapter 461; an optometrist licensed under chapter 463; an advanced practice registered nurse ~~practitioner~~, registered nurse, or licensed practical nurse licensed under part I of chapter 464; a pharmacist licensed under chapter 465; a dentist or dental hygienist licensed under chapter 466; a midwife licensed under chapter 467; a speech-language pathologist or audiologist licensed under part I of chapter 468; a dietitian/nutritionist licensed under part X of chapter 468; or a physical therapist licensed under chapter 486.

Section 28. Paragraph (c) of subsection (1) of section 383.141, Florida Statutes, is amended to read:

383.141 Prenatally diagnosed conditions; patient to be provided information; definitions; information clearinghouse;

advisory council.—

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

(c) "Health care provider" means a practitioner licensed or registered under chapter 458 or chapter 459 or an advanced practice registered nurse ~~practitioner~~ certified under chapter 464.

Section 29. Paragraph (a) of subsection (3) of section 390.0111, Florida Statutes, is amended to read:

390.0111 Termination of pregnancies.—

(3) CONSENTS REQUIRED.—A termination of pregnancy may not be performed or induced except with the voluntary and informed written consent of the pregnant woman or, in the case of a mental incompetent, the voluntary and informed written consent of her court-appointed guardian.

(a) Except in the case of a medical emergency, consent to a termination of pregnancy is voluntary and informed only if:

1. The physician who is to perform the procedure, or the referring physician, has, at a minimum, orally, in person, informed the woman of:

a. The nature and risks of undergoing or not undergoing the proposed procedure that a reasonable patient would consider material to making a knowing and willful decision of whether to terminate a pregnancy.

b. The probable gestational age of the fetus, verified by an ultrasound, at the time the termination of pregnancy is to be performed.

(I) The ultrasound must be performed by the physician who is to perform the abortion or by a person having documented evidence that he or she has completed a course in the operation

of ultrasound equipment as prescribed by rule and who is working in conjunction with the physician.

(II) The person performing the ultrasound must offer the woman the opportunity to view the live ultrasound images and hear an explanation of them. If the woman accepts the opportunity to view the images and hear the explanation, a physician or a registered nurse, licensed practical nurse, advanced practice registered nurse ~~practitioner~~, or physician assistant working in conjunction with the physician must contemporaneously review and explain the images to the woman before the woman gives informed consent to having an abortion procedure performed.

(III) The woman has a right to decline to view and hear the explanation of the live ultrasound images after she is informed of her right and offered an opportunity to view the images and hear the explanation. If the woman declines, the woman shall complete a form acknowledging that she was offered an opportunity to view and hear the explanation of the images but that she declined that opportunity. The form must also indicate that the woman's decision was not based on any undue influence from any person to discourage her from viewing the images or hearing the explanation and that she declined of her own free will.

(IV) Unless requested by the woman, the person performing the ultrasound may not offer the opportunity to view the images and hear the explanation and the explanation may not be given if, at the time the woman schedules or arrives for her appointment to obtain an abortion, a copy of a restraining order, police report, medical record, or other court order or

documentation is presented which provides evidence that the woman is obtaining the abortion because the woman is a victim of rape, incest, domestic violence, or human trafficking or that the woman has been diagnosed as having a condition that, on the basis of a physician's good faith clinical judgment, would create a serious risk of substantial and irreversible impairment of a major bodily function if the woman delayed terminating her pregnancy.

c. The medical risks to the woman and fetus of carrying the pregnancy to term.

2. Printed materials prepared and provided by the department have been provided to the pregnant woman, if she chooses to view these materials, including:

a. A description of the fetus, including a description of the various stages of development.

b. A list of entities that offer alternatives to terminating the pregnancy.

c. Detailed information on the availability of medical assistance benefits for prenatal care, childbirth, and neonatal care.

3. The woman acknowledges in writing, before the termination of pregnancy, that the information required to be provided under this subsection has been provided.

~~Nothing in~~ This paragraph is not intended to prohibit a physician from providing any additional information that ~~which~~ the physician deems material to the woman's informed decision to terminate her pregnancy.

Section 30. Paragraphs (c), (e), and (f) of subsection (3)

of section 390.012, Florida Statutes, are amended to read:

390.012 Powers of agency; rules; disposal of fetal remains.—

(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 who has admitting privileges at a licensed hospital 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 practice 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.

(e) Rules relating to the abortion procedure. At a minimum,

these rules shall require:

1. That a physician, registered nurse, licensed practical nurse, advanced practice registered nurse ~~practitioner~~, or physician assistant is available to all patients throughout the abortion procedure.

2. Standards for the safe conduct of abortion procedures that conform to obstetric standards in keeping with established standards of care regarding the estimation of fetal age as defined in rule.

3. Appropriate use of general and local anesthesia, analgesia, and sedation if ordered by the physician.

4. Appropriate precautions, such as the establishment of intravenous access at least for patients undergoing post-first trimester abortions.

5. Appropriate monitoring of the vital signs and other defined signs and markers of the patient's status throughout the abortion procedure and during the recovery period until the patient's condition is deemed to be stable in the recovery room.

(f) Rules that prescribe minimum recovery room standards. At a minimum, these rules shall require that:

1. Postprocedure recovery rooms are supervised and staffed to meet the patients' needs.

2. Immediate postprocedure care 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.

4. A registered nurse, licensed practical nurse, advanced

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practice 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 remains on the premises of the abortion clinic until all patients are discharged.

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.

6. A physician discusses Rho(D) immune globulin with each patient for whom it is indicated and 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, a refusal form approved by the agency shall be signed by the patient and a witness and included in the medical record.

7. Written instructions with regard to postabortion coitus, signs of possible problems, and general aftercare are given to each patient. Each patient shall have specific written instructions regarding access to medical care for complications, including a telephone number to call for medical emergencies.

8. There is a specified minimum length of time that a patient remains in the recovery room by type of abortion procedure and duration of gestation.

9. The physician ensures that a registered nurse, licensed practical nurse, advanced practice 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.

10. Equipment and services are readily accessible to provide appropriate emergency resuscitative and life support procedures pending the transfer of the patient or viable fetus to the hospital.

Section 31. Paragraph (a) of subsection (2) of section 394.4574, Florida Statutes, is amended to read:

394.4574 Department responsibilities for a mental health resident who resides in an assisted living facility that holds a limited mental health license.—

(2) The department must ensure that:

(a) A mental health resident has been assessed by a psychiatrist, clinical psychologist, clinical social worker, or psychiatric-mental health advanced practice registered ~~psychiatric~~ nurse, or an individual who is supervised by one of these professionals, and determined to be appropriate to reside in an assisted living facility. The documentation must be provided to the administrator of the facility within 30 days after the mental health resident has been admitted to the facility. An evaluation completed upon discharge from a state mental hospital meets the requirements of this subsection related to appropriateness for placement as a mental health resident if it was completed within 90 days before ~~prior to~~ admission to the facility.

Section 32. Subsection (2) of section 394.4655, Florida Statutes, is amended to read:

394.4655 Involuntary outpatient placement.—

(2) INVOLUNTARY OUTPATIENT PLACEMENT.—

(a)1. A patient who is being recommended for involuntary

outpatient placement by the administrator of the receiving facility where the patient has been examined may be retained by the facility after adherence to the notice 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 outpatient placement are met. However, in a county having 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-mental health advanced practice registered ~~psychiatric~~ nurse. Any second opinion authorized in this subparagraph may be conducted through a face-to-face examination, in person or by electronic means. Such recommendation must be entered on an involuntary outpatient placement certificate that authorizes the receiving facility to retain the patient pending completion of a hearing. The certificate shall be made a part of the patient's clinical record.

2. If the patient has been stabilized and no longer meets the criteria for involuntary examination pursuant to s. 394.463(1), the patient must be released from the receiving facility while awaiting the hearing for involuntary outpatient placement. Before filing a petition for involuntary outpatient treatment, the administrator of a receiving facility or a designated department representative must identify the service

provider that will have primary responsibility for service provision under an order for involuntary outpatient placement, unless the person is otherwise participating in outpatient psychiatric treatment and is not in need of public financing for that treatment, in which case the individual, if eligible, may be ordered to involuntary treatment pursuant to the existing psychiatric treatment relationship.

3. The service provider shall prepare a written proposed treatment plan in consultation with the patient or the patient's guardian advocate, if appointed, for the court's consideration for inclusion in the involuntary outpatient placement order. The service provider shall also provide a copy of the proposed treatment plan to the patient and the administrator of the receiving facility. The treatment plan must specify the nature and extent of the patient's mental illness, address the reduction of symptoms that necessitate involuntary outpatient placement, and include measurable goals and objectives for the services and treatment that are provided to treat the person's mental illness and assist the person in living and functioning in the community or to prevent a relapse or deterioration. Service providers may select and supervise other individuals to implement specific aspects of the treatment plan. The services in the treatment plan must be deemed clinically appropriate by a physician, clinical psychologist, psychiatric-mental health advanced practice registered ~~psychiatric~~ nurse, mental health counselor, marriage and family therapist, or clinical social worker who consults with, or is employed or contracted by, the service provider. The service provider must certify to the court in the proposed treatment plan whether sufficient services for

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improvement and stabilization are currently available and whether the service provider agrees to provide those services. If the service provider certifies that the services in the proposed treatment plan are not available, the petitioner may not file the petition.

(b) If a patient in involuntary inpatient placement meets the criteria for involuntary outpatient placement, the administrator of the treatment facility may, before the expiration of the period during which the treatment facility is authorized to retain the patient, recommend involuntary outpatient placement. 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 outpatient placement are met. However, in a county having 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-mental health advanced practice registered ~~psychiatric~~ nurse. Any second opinion authorized in this subparagraph may be conducted through a face-to-face examination, in person or by electronic means. Such recommendation must be entered on an involuntary outpatient placement certificate, and the certificate must be made a part of the patient's clinical record.

(c)1. The administrator of the treatment facility shall provide a copy of the involuntary outpatient placement

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certificate and a copy of the state mental health discharge form to a department representative in the county where the patient will be residing. For persons who are leaving a state mental health treatment facility, the petition for involuntary outpatient placement must be filed in the county where the patient will be residing.

2. The service provider that will have primary responsibility for service provision shall be identified by the designated department representative before ~~prior to~~ the order for involuntary outpatient placement and must, before ~~prior to~~ filing a petition for involuntary outpatient placement, certify to the court whether the services recommended in the patient's discharge plan are available in the local community and whether the service provider agrees to provide those services. The service provider must develop with the patient, or the patient's guardian advocate, if appointed, a treatment or service plan that addresses the needs identified in the discharge plan. The plan must be deemed to be clinically appropriate by a physician, clinical psychologist, psychiatric-mental health advanced practice registered ~~psychiatric~~ nurse, mental health counselor, marriage and family therapist, or clinical social worker, as defined in this chapter, who consults with, or is employed or contracted by, the service provider.

3. If the service provider certifies that the services in the proposed treatment or service plan are not available, the petitioner may not file the petition.

Section 33. 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-mental health advanced practice registered ~~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 34. Paragraphs (a) and (b) of subsection (2) and subsection (4) of section 395.0191, Florida Statutes, are amended to read:

395.0191 Staff membership and clinical privileges.—

(2)(a) Each licensed facility shall establish rules and procedures for consideration of an application for clinical

privileges submitted by an advanced practice registered nurse ~~practitioner~~ licensed and certified under part I of chapter 464, in accordance with the provisions of this section. A ~~No~~ licensed facility may not ~~shall~~ deny such application solely because the applicant is licensed under part I of chapter 464 or because the applicant is not a participant in the Florida Birth-Related Neurological Injury Compensation Plan.

(b) An advanced practice registered nurse ~~practitioner~~ who is certified as a registered nurse anesthetist licensed under part I of chapter 464 shall administer anesthesia under the onsite medical direction of a professional licensed under chapter 458, chapter 459, or chapter 466, and in accordance with an established protocol approved by the medical staff. The medical direction shall specifically address the needs of the individual patient.

(4) This section does not ~~Nothing herein shall~~ restrict ~~in any way~~ the authority of the medical staff of a licensed facility to review for approval or disapproval all applications for appointment and reappointment to all categories of staff and to make recommendations on each applicant to the governing board, including the delineation of privileges to be granted in each case. In making such recommendations and in the delineation of privileges, each applicant shall be considered individually pursuant to criteria for a doctor licensed under chapter 458, chapter 459, chapter 461, or chapter 466, ~~or~~ for an advanced practice registered nurse ~~practitioner~~ licensed and certified under part I of chapter 464, or for a psychologist licensed under chapter 490, as applicable. The applicant’s eligibility for staff membership or clinical privileges shall be determined

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by the applicant's background, experience, health, training, and demonstrated competency; the applicant's adherence to applicable professional ethics; the applicant's reputation; and the applicant's ability to work with others and by such other elements as determined by the governing board, consistent with this part.

Section 35. Subsection (3) of section 395.602, Florida Statutes, is amended to read:

395.602 Rural hospitals.—

(3) USE OF FUNDS.—It is the intent of the Legislature that funds as appropriated shall be used ~~utilized~~ by the department for the purpose of increasing the number of primary care physicians, physician assistants, certified nurse midwives, certified nurse practitioners, and nurses in rural areas, either through the Medical Education Reimbursement and Loan Repayment Program as defined by s. 1009.65 or through a federal loan repayment program which requires state matching funds. The department may use funds appropriated for the Medical Education Reimbursement and Loan Repayment Program as matching funds for federal loan repayment programs for health care personnel, such as that authorized in Pub. L. No. 100-177, s. 203. If the department receives federal matching funds, the department shall only implement the federal program. Reimbursement through either program shall be limited to:

(a) Primary care physicians, physician assistants, certified nurse midwives, certified nurse practitioners, and nurses employed by or affiliated with rural hospitals, as defined in this act; and

(b) Primary care physicians, physician assistants,

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certified nurse midwives, certified nurse practitioners, and nurses employed by or affiliated with rural area health education centers, as defined in this section. These personnel shall practice:

1. In a county with a population density of no greater than 100 persons per square mile; or

2. Within the boundaries of a hospital tax district which encompasses a population of no greater than 100 persons per square mile.

If the department administers a federal loan repayment program, priority shall be given to obligating state and federal matching funds pursuant to paragraphs (a) and (b). The department may use federal matching funds in other health workforce shortage areas and medically underserved areas in the state for loan repayment programs for primary care physicians, physician assistants, certified nurse midwives, certified nurse practitioners, and nurses who are employed by publicly financed health care programs that serve medically indigent persons.

Section 36. Paragraphs (b) and (c) of subsection (8) of section 395.605, Florida Statutes, are amended to read:

395.605 Emergency care hospitals.—

(8)

(b) All patients shall be under the care of a physician or under the care of an advanced practice registered ~~a~~ nurse ~~practitioner~~ or a physician assistant supervised by a physician.

(c) A physician, an advanced practice registered nurse ~~practitioner~~, or a physician assistant shall be on duty at all times, or a physician shall be on call and available within 30

minutes at all times.

Section 37. Subsection (26) of section 397.311, Florida Statutes, is amended to read:

397.311 Definitions.—As used in this chapter, except part VIII, the term:

(26) "Qualified professional" means a physician or a physician assistant licensed under chapter 458 or chapter 459; a professional licensed under chapter 490 or chapter 491; an advanced practice registered nurse ~~practitioner~~ having a specialty in psychiatry licensed under part I of chapter 464; or a person who is certified through a department-recognized certification process for substance abuse treatment services and who holds, at a minimum, a bachelor's degree. A person who is certified in substance abuse treatment services by a state-recognized certification process in another state at the time of employment with a licensed substance abuse provider in this state may perform the functions of a qualified professional as defined in this chapter but must meet certification requirements contained in this subsection no later than 1 year after his or her date of employment.

Section 38. Section 397.405, Florida Statutes, is amended to read:

397.405 Exemptions from licensure.—The following are exempt from the licensing provisions of this chapter:

(1) A hospital or hospital-based component licensed under chapter 395.

(2) A nursing home facility as defined in s. 400.021.

(3) A substance abuse education program established pursuant to s. 1003.42.

(4) A facility or institution operated by the Federal Government.

(5) A physician or physician assistant licensed under chapter 458 or chapter 459.

(6) A psychologist licensed under chapter 490.

(7) A social worker, marriage and family therapist, or mental health counselor licensed under chapter 491.

(8) A legally cognizable church or nonprofit religious organization or denomination providing substance abuse services, including prevention services, which are solely religious, spiritual, or ecclesiastical in nature. A church or nonprofit religious organization or denomination providing any of the licensed service components itemized under s. 397.311(18) is not exempt from substance abuse licensure but retains its exemption with respect to all services which are solely religious, spiritual, or ecclesiastical in nature.

(9) Facilities licensed under chapter 393 which, in addition to providing services to persons with developmental disabilities, also provide services to persons developmentally at risk as a consequence of exposure to alcohol or other legal or illegal drugs while in utero.

(10) DUI education and screening services provided pursuant to ss. 316.192, 316.193, 322.095, 322.271, and 322.291. Persons or entities providing treatment services must be licensed under this chapter unless exempted from licensing as provided in this section.

(11) A facility licensed under s. 394.875 as a crisis stabilization unit.

The exemptions from licensure in this section do not apply to any service provider that receives an appropriation, grant, or contract from the state to operate as a service provider as defined in this chapter or to any substance abuse program regulated pursuant to s. 397.406. Furthermore, this chapter may not be construed to limit the practice of a physician or physician assistant licensed under chapter 458 or chapter 459, a psychologist licensed under chapter 490, a psychotherapist licensed under chapter 491, or an advanced practice registered nurse ~~practitioner~~ licensed under part I of chapter 464, who provides substance abuse treatment, so long as the physician, physician assistant, psychologist, psychotherapist, or advanced practice registered nurse ~~practitioner~~ does not represent to the public that he or she is a licensed service provider and does not provide services to individuals pursuant to part V of this chapter. Failure to comply with any requirement necessary to maintain an exempt status under this section is a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

Section 39. Subsections (5), (9), and (10) of section 397.427, Florida Statutes, are amended to read:

397.427 Medication-assisted treatment service providers; rehabilitation program; needs assessment and provision of services; persons authorized to issue takeout medication; unlawful operation; penalty.—

(5) Notwithstanding s. 465.019(2), a physician assistant, a registered nurse, an advanced practice registered nurse ~~practitioner~~, or a licensed practical nurse working for a licensed service provider may deliver takeout medication for

opiate treatment to persons enrolled in a maintenance treatment program for medication-assisted treatment for opiate addiction if:

(a) The medication-assisted treatment program for opiate addiction has an appropriate valid permit issued pursuant to rules adopted by the Board of Pharmacy.~~;~~

(b) The medication for treatment of opiate addiction has been delivered pursuant to a valid prescription written by the program's physician licensed pursuant to chapter 458 or chapter 459.~~;~~

(c) The medication for treatment of opiate addiction which is ordered appears on a formulary and is prepackaged and prelabeled with dosage instructions and distributed from a source authorized under chapter 499.~~;~~

(d) Each licensed provider adopts written protocols which provide for supervision of the physician assistant, registered nurse, advanced practice registered nurse ~~practitioner~~, or licensed practical nurse by a physician licensed pursuant to chapter 458 or chapter 459 and for the procedures by which patients' medications may be delivered by the physician assistant, registered nurse, advanced practice registered nurse ~~practitioner~~, or licensed practical nurse. Such protocols shall be signed by the supervising physician and either the administering registered nurse, the advanced practice registered nurse ~~practitioner~~, or the licensed practical nurse.

(e) Each licensed service provider maintains and has available for inspection by representatives of the Board of Pharmacy all medical records and patient care protocols, including records of medications delivered to patients, in

accordance with the board.

(9) A physician assistant, a registered nurse, an advanced practice registered nurse ~~practitioner~~, or a licensed practical nurse working for a licensed service provider may deliver medication as prescribed by rule if:

(a) The service provider is authorized to provide medication-assisted treatment;

(b) The medication has been administered pursuant to a valid prescription written by the program's physician who is licensed under chapter 458 or chapter 459; and

(c) The medication ordered appears on a formulary or meets federal requirements for medication-assisted treatment.

(10) Each licensed service provider that provides medication-assisted treatment must adopt written protocols as specified by the department and in accordance with federally required rules, regulations, or procedures. The protocol shall provide for the supervision of the physician assistant, registered nurse, advanced practice registered nurse ~~practitioner~~, or licensed practical nurse working under the supervision of a physician who is licensed under chapter 458 or chapter 459. The protocol must specify how the medication will be used in conjunction with counseling or psychosocial treatment and that the services provided will be included on the treatment plan. The protocol must specify the procedures by which medication-assisted treatment may be administered by the physician assistant, registered nurse, advanced practice registered nurse ~~practitioner~~, or licensed practical nurse. These protocols shall be signed by the supervising physician and the administering physician assistant, registered nurse,

advanced practice registered nurse ~~practitioner~~, or licensed practical nurse.

Section 40. Subsection (8) of section 400.021, Florida Statutes, is amended to read:

400.021 Definitions.—When used in this part, unless the context otherwise requires, the term:

(8) "Geriatric outpatient clinic" means a site for providing outpatient health care to persons 60 years of age or older, which is staffed by a registered nurse, a physician assistant, or a licensed practical nurse under the direct supervision of a registered nurse, advanced practice registered nurse ~~practitioner~~, physician assistant, or physician.

Section 41. Subsection (3) of section 400.0255, Florida Statutes, is amended to read:

400.0255 Resident transfer or discharge; requirements and procedures; hearings.—

(3) When a discharge or transfer is initiated by the nursing home, the nursing home administrator employed by the nursing home that is discharging or transferring the resident, or an individual employed by the nursing home who is designated by the nursing home administrator to act on behalf of the administration, must sign the notice of discharge or transfer. Any notice indicating a medical reason for transfer or discharge must either be signed by the resident's attending physician or the medical director of the facility, or include an attached written order for the discharge or transfer. The notice or the order must be signed by the resident's physician, medical director, treating physician, advanced practice registered nurse ~~practitioner~~, or physician assistant.

Section 42. Subsection (3) of section 400.172, Florida Statutes, is amended to read:

400.172 Respite care provided in nursing home facilities.—

(3) A prospective respite care resident must provide medical information from a physician, physician assistant, or advanced practice registered nurse ~~practitioner~~ and any other information provided by the primary caregiver required by the facility before or when the person is admitted to receive respite care. The medical information must include a physician's order for respite care and proof of a physical examination by a licensed physician, physician assistant, or advanced practice registered nurse ~~practitioner~~. The physician's order and physical examination may be used to provide intermittent respite care for up to 12 months after the date the order is written.

Section 43. Subsection (3) of section 400.462, Florida Statutes, is amended to read:

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

(3) "Advanced practice registered nurse ~~practitioner~~" means a person licensed in this state to practice professional nursing and certified in advanced or specialized nursing practice, as defined in s. 464.003.

Section 44. Section 400.487, Florida Statutes, is amended to read:

400.487 Home health service agreements; physician's, physician assistant's, and advanced practice registered nurse's ~~nurse practitioner's~~ treatment orders; patient assessment; establishment and review of plan of care; provision of services; orders not to resuscitate.—

(1) Services provided by a home health agency must be

covered by an agreement between the home health agency and the patient or the patient's legal representative specifying the home health services to be provided, the rates or charges for services paid with private funds, and the sources of payment, which may include Medicare, Medicaid, private insurance, personal funds, or a combination thereof. A home health agency providing skilled care must make an assessment of the patient's needs within 48 hours after the start of services.

(2) When required by the provisions of chapter 464; part I, part III, or part V of chapter 468; or chapter 486, the attending physician, physician assistant, or advanced practice registered nurse ~~practitioner~~, acting within his or her respective scope of practice, shall establish treatment orders for a patient who is to receive skilled care. The treatment orders must be signed by the physician, physician assistant, or advanced practice registered nurse ~~practitioner~~ before a claim for payment for the skilled services is submitted by the home health agency. If the claim is submitted to a managed care organization, the treatment orders must be signed within the time allowed under the provider agreement. The treatment orders shall be reviewed, as frequently as the patient's illness requires, by the physician, physician assistant, or advanced practice registered nurse ~~practitioner~~ in consultation with the home health agency.

(3) A home health agency shall arrange for supervisory visits by a registered nurse to the home of a patient receiving home health aide services in accordance with the patient's direction, approval, and agreement to pay the charge for the visits.

(4) Each patient has the right to be informed of and to participate in the planning of his or her care. Each patient must be provided, upon request, a copy of the plan of care established and maintained for that patient by the home health agency.

(5) When nursing services are ordered, the home health agency to which a patient has been admitted for care must provide the initial admission visit, all service evaluation visits, and the discharge visit by a direct employee. Services provided by others under contractual arrangements to a home health agency must be monitored and managed by the admitting home health agency. The admitting home health agency is fully responsible for ensuring that all care provided through its employees or contract staff is delivered in accordance with this part and applicable rules.

(6) The skilled care services provided by a home health agency, directly or under contract, must be supervised and coordinated in accordance with the plan of care.

(7) Home health agency personnel may withhold or withdraw cardiopulmonary resuscitation if presented with an order not to resuscitate executed pursuant to s. 401.45. The agency shall adopt rules providing for the implementation of such orders. Home health personnel and agencies may ~~shall~~ not be subject to criminal prosecution or civil liability, nor be considered to have engaged in negligent or unprofessional conduct, for withholding or withdrawing cardiopulmonary resuscitation pursuant to such an order and rules adopted by the agency.

Section 45. Paragraph (a) of subsection (13) of section 400.506, Florida Statutes, is amended to read:

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400.506 Licensure of nurse registries; requirements; penalties.—

(13) All persons referred for contract in private residences by a nurse registry must comply with the following requirements for a plan of treatment:

(a) When, in accordance with the privileges and restrictions imposed upon a nurse under part I of chapter 464, the delivery of care to a patient is under the direction or supervision of a physician or when a physician is responsible for the medical care of the patient, a medical plan of treatment must be established for each patient receiving care or treatment provided by a licensed nurse in the home. The original medical plan of treatment must be timely signed by the physician, physician assistant, or advanced practice registered nurse ~~practitioner~~, acting within his or her respective scope of practice, and reviewed in consultation with the licensed nurse at least every 2 months. Any additional order or change in orders must be obtained from the physician, physician assistant, or advanced practice registered nurse ~~practitioner~~ and reduced to writing and timely signed by the physician, physician assistant, or advanced practice registered nurse ~~practitioner~~. The delivery of care under a medical plan of treatment must be substantiated by the appropriate nursing notes or documentation made by the nurse in compliance with nursing practices established under part I of chapter 464.

Section 46. Subsections (1) and (2) of section 401.445, Florida Statutes, are amended to read:

401.445 Emergency examination and treatment of incapacitated persons.—

(1) ~~No~~ Recovery is not ~~shall be~~ allowed in any court in this state against any emergency medical technician, paramedic, or physician as defined in this chapter, any advanced practice registered nurse ~~practitioner~~ certified under s. 464.012, or any physician assistant licensed under s. 458.347 or s. 459.022, or any person acting under the direct medical supervision of a physician, in an action brought for examining or treating a patient without his or her informed consent if:

(a) The patient at the time of examination or treatment is intoxicated, under the influence of drugs, or otherwise incapable of providing informed consent as provided in s. 766.103;

(b) The patient at the time of examination or treatment is experiencing an emergency medical condition; and

(c) The patient would reasonably, under all the surrounding circumstances, undergo such examination, treatment, or procedure if he or she were advised by the emergency medical technician, paramedic, physician, advanced practice registered nurse ~~practitioner~~, or physician assistant in accordance with s. 766.103(3).

Examination and treatment provided under this subsection shall be limited to reasonable examination of the patient to determine the medical condition of the patient and treatment reasonably necessary to alleviate the emergency medical condition or to stabilize the patient.

(2) In examining and treating a person who is apparently intoxicated, under the influence of drugs, or otherwise incapable of providing informed consent, the emergency medical

technician, paramedic, physician, advanced practice registered nurse ~~practitioner~~, or physician assistant, or any person acting under the direct medical supervision of a physician, shall proceed wherever possible with the consent of the person. If the person reasonably appears to be incapacitated and refuses his or her consent, the person may be examined, treated, or taken to a hospital or other appropriate treatment resource if he or she is in need of emergency attention, without his or her consent, but unreasonable force may ~~shall~~ not be used.

Section 47. Subsections (1) and (11) of section 409.905, Florida Statutes, are amended to read:

409.905 Mandatory Medicaid services.—The agency may make payments for the following services, which are required of the state by Title XIX of the Social Security Act, furnished by Medicaid providers to recipients who are determined to be eligible on the dates on which the services were provided. Any service under this section shall be provided only when medically necessary and in accordance with state and federal law. Mandatory services rendered by providers in mobile units to Medicaid recipients may be restricted by the agency. Nothing in this section shall be construed to prevent or limit the agency from adjusting fees, reimbursement rates, lengths of stay, number of visits, number of services, or any other adjustments necessary to comply with the availability of moneys and any limitations or directions provided for in the General Appropriations Act or chapter 216.

(1) ADVANCED PRACTICE REGISTERED NURSE ~~PRACTITIONER~~ SERVICES.—The agency shall pay for services provided to a recipient by a certified ~~licensed~~ advanced practice registered

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nurse ~~practitioner~~ who has, if required under s. 464.012(3), a current protocol ~~valid collaboration agreement~~ with a licensed physician on file with the Department of Health or who provides anesthesia services in accordance with established protocol required by state law and approved by the medical staff of the facility in which the anesthetic service is performed. Reimbursement for such services must be provided in an amount that equals not less than 80 percent of the reimbursement to a physician who provides the same services, unless otherwise provided for in the General Appropriations Act.

(11) RURAL HEALTH CLINIC SERVICES.—The agency shall pay for outpatient primary health care services for a recipient provided by a clinic certified by and participating in the Medicare program which is located in a federally designated, rural, medically underserved area and has on its staff one or more certified ~~licensed~~ primary care nurse practitioners or physician assistants, and a licensed staff supervising physician or a consulting supervising physician.

Section 48. Paragraph (a) of subsection (3) and subsection (7) of section 409.908, Florida Statutes, are amended to read:

409.908 Reimbursement of Medicaid providers.—Subject to specific appropriations, the agency shall reimburse Medicaid providers, in accordance with state and federal law, according to methodologies set forth in the rules of the agency and in policy manuals and handbooks incorporated by reference therein. These methodologies may include fee schedules, reimbursement methods based on cost reporting, negotiated fees, competitive bidding pursuant to s. 287.057, and other mechanisms the agency considers efficient and effective for purchasing services or

goods on behalf of recipients. If a provider is reimbursed based on cost reporting and submits a cost report late and that cost report would have been used to set a lower reimbursement rate for a rate semester, then the provider's rate for that semester shall be retroactively calculated using the new cost report, and full payment at the recalculated rate shall be effected retroactively. Medicare-granted extensions for filing cost reports, if applicable, shall also apply to Medicaid cost reports. Payment for Medicaid compensable services made on behalf of Medicaid eligible persons is subject to the availability of moneys and any limitations or directions provided for in the General Appropriations Act or chapter 216. Further, nothing in this section shall be construed to prevent or limit the agency from adjusting fees, reimbursement rates, lengths of stay, number of visits, or number of services, or making any other adjustments necessary to comply with the availability of moneys and any limitations or directions provided for in the General Appropriations Act, provided the adjustment is consistent with legislative intent.

(3) Subject to any limitations or directions provided for in the General Appropriations Act, the following Medicaid services and goods may be reimbursed on a fee-for-service basis. For each allowable service or goods furnished in accordance with Medicaid rules, policy manuals, handbooks, and state and federal law, the payment shall be the amount billed by the provider, the provider's usual and customary charge, or the maximum allowable fee established by the agency, whichever amount is less, with the exception of those services or goods for which the agency makes payment using a methodology based on capitation rates,

average costs, or negotiated fees.

(a) Advanced practice registered nurse ~~practitioner~~ services.

(7) A provider of family planning services shall be reimbursed the lesser of the amount billed by the provider or an all-inclusive amount per type of visit for physicians and advanced practice registered nurses ~~nurse practitioners~~, as established by the agency in a fee schedule.

Section 49. Subsection (2) of section 409.9081, Florida Statutes, is amended to read:

409.9081 Copayments.—

(2) The agency shall, subject to federal regulations and any directions or limitations provided for in the General Appropriations Act, require copayments for the following additional services: hospital inpatient, laboratory and X-ray services, transportation services, home health care services, community mental health services, rural health services, federally qualified health clinic services, and advanced practice registered nurse ~~practitioner~~ services. The agency may only establish copayments for prescribed drugs or for any other federally authorized service if such copayment is specifically provided for in the General Appropriations Act or other law.

Section 50. Subsection (11) of section 409.9122, Florida Statutes, is amended to read:

409.9122 Mandatory Medicaid managed care enrollment; programs and procedures.—

(11) A managed care plan that has a Medicaid contract shall at least annually review each primary care physician’s active patient load and shall ensure that additional Medicaid

recipients are not assigned to physicians who have a total active patient load of more than 3,000 patients. As used in this subsection, the term "active patient" means a patient who is seen by the same primary care physician, or by a physician assistant or advanced practice registered nurse ~~practitioner~~ under the supervision of the primary care physician, at least three times within a calendar year. Each primary care physician shall annually certify to the managed care plan whether or not his or her patient load exceeds the limits established under this subsection and the managed care plan shall accept such certification on face value as compliance with this subsection. The agency shall accept the managed care plan's representations that it is in compliance with this subsection based on the certification of its primary care physicians, unless the agency has an objective indication that access to primary care is being compromised, such as receiving complaints or grievances relating to access to care. If the agency determines that an objective indication exists that access to primary care is being compromised, it may verify the patient load certifications submitted by the managed care plan's primary care physicians and that the managed care plan is not assigning Medicaid recipients to primary care physicians who have an active patient load of more than 3,000 patients. This subsection expires October 1, 2014.

Section 51. Paragraph (a) of subsection (1) of section 409.973, Florida Statutes, is amended to read:

409.973 Benefits.—

(1) MINIMUM BENEFITS.—Managed care plans shall cover, at a minimum, the following services:

(a) Advanced practice registered nurse ~~practitioner~~ services.

Section 52. Subsections (2), (4), (5), and (6) of section 429.26, Florida Statutes, are amended to read:

429.26 Appropriateness of placements; examinations of residents.—

(2) A physician, physician assistant, or advanced practice registered nurse ~~practitioner~~ who is employed by an assisted living facility to provide an initial examination for admission purposes may not have financial interest in the facility.

(4) If possible, each resident shall have been examined by a licensed physician, a licensed physician assistant, or a certified advanced practice registered ~~licensed~~ nurse ~~practitioner~~ within 60 days before admission to the facility. The signed and completed medical examination report shall be submitted to the owner or administrator of the facility who shall use the information contained therein to assist in the determination of the appropriateness of the resident's admission and continued stay in the facility. The medical examination report shall become a permanent part of the record of the resident at the facility and shall be made available to the agency during inspection or upon request. An assessment that has been completed through the Comprehensive Assessment and Review for Long-Term Care Services (CARES) Program fulfills the requirements for a medical examination under this subsection and s. 429.07(3)(b)6.

(5) Except as provided in s. 429.07, if a medical examination has not been completed within 60 days before the admission of the resident to the facility, a licensed physician,

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licensed physician assistant, or certified advanced practice registered ~~licensed~~ nurse ~~practitioner~~ shall examine the resident and complete a medical examination form provided by the agency within 30 days following the admission to the facility to enable the facility owner or administrator to determine the appropriateness of the admission. The medical examination form shall become a permanent part of the record of the resident at the facility and shall be made available to the agency during inspection by the agency or upon request.

(6) Any resident accepted in a facility and placed by the department or the Department of Children and Families ~~Family Services~~ shall have been examined by medical personnel within 30 days before placement in the facility. The examination shall include an assessment of the appropriateness of placement in a facility. The findings of this examination shall be recorded on the examination form provided by the agency. The completed form shall accompany the resident and shall be submitted to the facility owner or administrator. Additionally, in the case of a mental health resident, the Department of Children and Families ~~Family Services~~ must provide documentation that the individual has been assessed by a psychiatrist, clinical psychologist, clinical social worker, or psychiatric-mental health advanced practice registered ~~psychiatric~~ nurse, or an individual who is supervised by one of these professionals, and determined to be appropriate to reside in an assisted living facility. The documentation must be in the facility within 30 days after the mental health resident has been admitted to the facility. An evaluation completed upon discharge from a state mental hospital meets the requirements of this subsection related to

appropriateness for placement as a mental health resident providing it was completed within 90 days before ~~prior to~~ admission to the facility. The applicable department shall provide to the facility administrator any information about the resident that would help the administrator meet his or her responsibilities under subsection (1). Further, department personnel shall explain to the facility operator any special needs of the resident and advise the operator whom to call should problems arise. The applicable department shall advise and assist the facility administrator where the special needs of residents who are recipients of optional state supplementation require such assistance.

Section 53. Paragraph (a) of subsection (2) and paragraph (a) of subsection (7) of section 429.918, Florida Statutes, are amended to read:

429.918 Licensure designation as a specialized Alzheimer's services adult day care center.—

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

(a) "ADRD participant" means a participant who has a documented diagnosis of Alzheimer's disease or a dementia-related disorder (ADRD) from a licensed physician, licensed physician assistant, or a licensed advanced practice registered nurse ~~practitioner~~.

(7)(a) An ADRD participant admitted to an adult day care center having a license designated under this section, or the caregiver when applicable, must:

1. Require ongoing supervision to maintain the highest level of medical or custodial functioning and have a demonstrated need for a responsible party to oversee his or her

care.

2. Not actively demonstrate aggressive behavior that places himself, herself, or others at risk of harm.

3. Provide the following medical documentation signed by a licensed physician, licensed physician assistant, or ~~a~~ licensed advanced practice registered nurse ~~practitioner~~:

a. Any physical, health, or emotional conditions that require medical care.

b. A listing of the ADRD participant's current prescribed and over-the-counter medications and dosages, diet restrictions, mobility restrictions, and other physical limitations.

4. Provide documentation signed by a health care provider licensed in this state which indicates that the ADRD participant is free of the communicable form of tuberculosis and free of signs and symptoms of other communicable diseases.

Section 54. Paragraph (e) of subsection (5) of section 440.102, Florida Statutes, is amended to read:

440.102 Drug-free workplace program requirements.—The following provisions apply to a drug-free workplace program implemented pursuant to law or to rules adopted by the Agency for Health Care Administration:

(5) PROCEDURES AND EMPLOYEE PROTECTION.—All specimen collection and testing for drugs under this section shall be performed in accordance with the following procedures:

(e) A specimen for a drug test may be taken or collected by any of the following persons:

1. A physician, a physician assistant, a registered professional nurse, a licensed practical nurse, or an advanced practice registered ~~a~~ nurse ~~practitioner~~ or a certified

paramedic who is present at the scene of an accident for the purpose of rendering emergency medical service or treatment.

2. A qualified person employed by a licensed or certified laboratory as described in subsection (9).

Section 55. Section 456.0391, Florida Statutes, is amended to read:

456.0391 Advanced practice registered nurses ~~nurse practitioners~~; information required for certification.—

(1)(a) Each person who applies for initial certification under s. 464.012 must, at the time of application, and each person certified under s. 464.012 who applies for certification renewal must, in conjunction with the renewal of such certification and under procedures adopted by the Department of Health, and in addition to any other information that may be required from the applicant, furnish the following information to the Department of Health:

1. The name of each school or training program that the applicant has attended, with the months and years of attendance and the month and year of graduation, and a description of all graduate professional education completed by the applicant, excluding any coursework taken to satisfy continuing education requirements.

2. The name of each location at which the applicant practices.

3. The address at which the applicant will primarily conduct his or her practice.

4. Any certification or designation that the applicant has received from a specialty or certification board that is recognized or approved by the regulatory board or department to

which the applicant is applying.

5. The year that the applicant received initial certification and began practicing the profession in any jurisdiction and the year that the applicant received initial certification in this state.

6. Any appointment which the applicant currently holds to the faculty of a school related to the profession and an indication as to whether the applicant has had the responsibility for graduate education within the most recent 10 years.

7. A description of any criminal offense of which the applicant has been found guilty, regardless of whether adjudication of guilt was withheld, or to which the applicant has pled guilty or nolo contendere. A criminal offense committed in another jurisdiction which would have been a felony or misdemeanor if committed in this state must be reported. If the applicant indicates that a criminal offense is under appeal and submits a copy of the notice for appeal of that criminal offense, the department must state that the criminal offense is under appeal if the criminal offense is reported in the applicant's profile. If the applicant indicates to the department that a criminal offense is under appeal, 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.

8. A description of any final disciplinary action taken within the previous 10 years against the applicant by a licensing or regulatory body in any jurisdiction, by a specialty board that is recognized by the board or department, or by a

licensed hospital, health maintenance organization, prepaid health clinic, ambulatory surgical center, or nursing home. Disciplinary action includes resignation from or nonrenewal of staff membership or the restriction of privileges at a licensed hospital, health maintenance organization, prepaid health clinic, ambulatory surgical center, or nursing home taken in lieu of or in settlement of a pending disciplinary case related to competence or character. If the applicant indicates that the disciplinary action is under appeal and submits a copy of the document initiating an appeal of the disciplinary action, the department must state that the disciplinary action is under appeal if the disciplinary action is reported in the applicant's profile.

(b) In addition to the information required under paragraph (a), each applicant for initial certification or certification renewal must provide the information required of licensees pursuant to s. 456.049.

(2) The Department of Health shall send a notice to each person certified under s. 464.012 at the certificateholder's last known address of record regarding the requirements for information to be submitted by advanced practice registered nurses ~~nurse practitioners~~ pursuant to this section in conjunction with the renewal of such certificate.

(3) Each person certified under s. 464.012 who has submitted information pursuant to subsection (1) must update that information in writing by notifying the Department of Health within 45 days after the occurrence of an event or the attainment of a status that is required to be reported by subsection (1). Failure to comply with the requirements of this

subsection to update and submit information constitutes a ground for disciplinary action under chapter 464 and s. 456.072(1)(k). For failure to comply with the requirements of this subsection to update and submit information, the department or board, as appropriate, may:

(a) Refuse to issue a certificate to any person applying for initial certification who fails to submit and update the required information.

(b) Issue a citation to any certificateholder who fails to submit and update the required information and may fine the certificateholder up to $50 for each day that the certificateholder is not in compliance with this subsection. The citation must clearly state that the certificateholder may choose, in lieu of accepting the citation, to follow the procedure under s. 456.073. If the certificateholder disputes the matter in the citation, the procedures set forth in s. 456.073 must be followed. However, if the certificateholder 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 constitutes discipline. Service of a citation may be made by personal service or certified mail, restricted delivery, to the subject at the certificateholder's last known address.

(4)(a) An applicant for initial certification under s. 464.012 must submit a set of fingerprints to the Department of Health on a form and under procedures specified by the department, along with payment in an amount equal to the costs incurred by the Department of Health for a national criminal history check of the applicant.

(b) An applicant for renewed certification who has not previously submitted a set of fingerprints to the Department of Health for purposes of certification must submit a set of fingerprints to the department as a condition of the initial renewal of his or her certificate after the effective date of this section. The applicant must submit the fingerprints on a form and under procedures specified by the department, along with payment in an amount equal to the costs incurred by the Department of Health for a national criminal history check. For subsequent renewals, the applicant for renewed certification must only submit information necessary to conduct a statewide criminal history check, along with payment in an amount equal to the costs incurred by the Department of Health for a statewide criminal history check.

(c)1. The Department of Health shall submit the fingerprints provided by an applicant for initial certification to the Florida Department of Law Enforcement for a statewide criminal history check, and the Florida Department of Law Enforcement shall forward the fingerprints to the Federal Bureau of Investigation for a national criminal history check of the applicant.

2. The department shall submit the fingerprints provided by an applicant for the initial renewal of certification to the Florida Department of Law Enforcement for a statewide criminal history check, and the Florida Department of Law Enforcement shall forward the fingerprints to the Federal Bureau of Investigation for a national criminal history check for the initial renewal of the applicant’s certificate after the effective date of this section.

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3. For any subsequent renewal of the applicant's certificate, the department shall submit the required information for a statewide criminal history check of the applicant to the Florida Department of Law Enforcement.

(d) Any applicant for initial certification or renewal of certification as an advanced practice registered nurse ~~practitioner~~ who submits to the Department of Health a set of fingerprints and information required for the criminal history check required under this section may ~~shall~~ not be required to provide a subsequent set of fingerprints or other duplicate information required for a criminal history check to the Agency for Health Care Administration, the Department of Juvenile Justice, or the Department of Children and Families ~~Family Services~~ for employment or licensure with such agency or department, if the applicant has undergone a criminal history check as a condition of initial certification or renewal of certification as an advanced practice registered nurse ~~practitioner~~ with the Department of Health, notwithstanding any other provision of law to the contrary. In lieu of such duplicate submission, the Agency for Health Care Administration, the Department of Juvenile Justice, and the Department of Children and Families ~~Family Services~~ shall obtain criminal history information for employment or licensure of persons certified under s. 464.012 by such agency or department from the Department of Health's health care practitioner credentialing system.

(5) Each person who is required to submit information pursuant to this section may submit additional information to the Department of Health. Such information may include, but is

not limited to:

(a) Information regarding publications in peer-reviewed professional literature within the previous 10 years.

(b) Information regarding professional or community service activities or awards.

(c) Languages, other than English, used by the applicant to communicate with patients or clients and identification of any translating service that may be available at the place where the applicant primarily conducts his or her practice.

(d) An indication of whether the person participates in the Medicaid program.

Section 56. Subsection (2) of section 456.0392, Florida Statutes, is amended to read:

456.0392 Prescription labeling.—

(2) A prescription for a drug ~~that is not listed as a controlled substance in chapter 893~~ which is written by an advanced practice registered nurse ~~practitioner~~ certified under s. 464.012 is presumed, subject to rebuttal, to be valid and within the parameters of the prescriptive authority delegated by a practitioner licensed under chapter 458, chapter 459, or chapter 466.

Section 57. Paragraph (a) of subsection (1) and subsection (6) of section 456.041, Florida Statutes, are amended 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 practice registered nurse ~~practitioner~~.

(6) The Department of Health shall provide in each practitioner profile for every physician or advanced practice registered nurse ~~practitioner~~ terminated for cause from participating in the Medicaid program, pursuant to s. 409.913, or sanctioned by the Medicaid program a statement that the practitioner has been terminated from participating in the Florida Medicaid program or sanctioned by the Medicaid program.

Section 58. Subsection (1) of section 456.048, Florida Statutes, is amended to read:

456.048 Financial responsibility requirements for certain health care practitioners.—

(1) As a prerequisite for licensure or license renewal, the Board of Acupuncture, the Board of Chiropractic Medicine, the Board of Podiatric Medicine, and the Board of Dentistry shall, by rule, require that all health care practitioners licensed under the respective board, and the Board of Medicine and the Board of Osteopathic Medicine shall, by rule, require that all anesthesiologist assistants licensed pursuant to s. 458.3475 or s. 459.023, and the Board of Nursing shall, by rule, require that advanced practice registered nurses ~~nurse practitioners~~ certified under s. 464.012, and the department shall, by rule, require that midwives maintain medical malpractice insurance or provide proof of financial responsibility in an amount and in a

manner determined by the board or department to be sufficient to cover claims arising out of the rendering of or failure to render professional care and services in this state.

Section 59. Paragraph (c) 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).

(c) A physician, a physician assistant, or an advanced practice registered nurse ~~practitioner~~ must perform a physical examination of a patient on the same day that the physician prescribes a controlled substance to a patient at a pain-management clinic. If the physician prescribes more than a 72-hour dose of controlled substances for the treatment of chronic nonmalignant pain, the physician must document in the patient's record the reason for prescribing that quantity.

Section 60. Paragraph (dd) of subsection (1) of section 458.331, Florida Statutes, is amended to read:

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

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

(dd) Failing to supervise adequately the activities of those physician assistants, paramedics, emergency medical technicians, advanced practice registered nurses ~~nurse practitioners~~, or anesthesiologist assistants acting under the supervision of the physician.

Section 61. Paragraph (c) 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).

(c) An osteopathic physician, a physician assistant, or an advanced practice registered nurse ~~practitioner~~ must perform a physical examination of a patient on the same day that the physician prescribes a controlled substance to a patient at a pain-management clinic. If the osteopathic physician prescribes more than a 72-hour dose of controlled substances for the treatment of chronic nonmalignant pain, the osteopathic physician must document in the patient's record the reason for prescribing that quantity.

Section 62. Paragraph (hh) of subsection (1) of section 459.015, Florida Statutes, is amended to read:

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

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

(hh) Failing to supervise adequately the activities of those physician assistants, paramedics, emergency medical technicians, advanced practice registered nurses ~~nurse practitioners~~, anesthesiologist assistants, or other persons acting under the supervision of the osteopathic physician.

Section 63. Subsections (2) and (3) of section 464.003, Florida Statutes, are 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 practice registered nurse ~~practitioner~~. Within the context of advanced or specialized nursing practice, the advanced practice registered nurse ~~practitioner~~ may perform acts of nursing diagnosis and nursing treatment of alterations of the health status. The advanced practice registered nurse ~~practitioner~~ may also perform acts of medical diagnosis and treatment, prescription, and operation 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 or s. 459.025.

(3) "Advanced practice registered nurse ~~practitioner~~" means any person licensed in this state to practice professional nursing and certified in advanced or specialized nursing practice, including certified registered nurse anesthetists, certified nurse midwives, and certified nurse practitioners.

Section 64. Subsection (2) of section 464.004, Florida Statutes, is amended to read:

464.004 Board of Nursing; membership; appointment; terms.—

(2) Seven members of the board must be registered nurses who are residents of this state and who have been engaged in the practice of professional nursing for at least 4 years, including at least one advanced practice registered nurse ~~practitioner~~, one nurse educator member of an approved program, and one nurse executive. These seven board members should be representative of the diverse areas of practice within the nursing profession. In addition, three members of the board must be licensed practical nurses who are residents of this state and who have been actively engaged in the practice of practical nursing for at least 4 years before ~~prior to~~ their appointment. The remaining three members must be residents of the state who have never been licensed as nurses and who are in no way connected with the practice of nursing. No person may be appointed as a lay member who is in any way connected with, or has any financial interest in, any health care facility, agency, or insurer. At least one member of the board must be 60 years of age or older.

Section 65. Paragraph (a) of subsection (2) of section

464.016, Florida Statutes, is amended to read:

464.016 Violations and penalties.—

(2) Each of the following acts constitutes a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083:

(a) Using the name or title "Nurse," "Registered Nurse," "Licensed Practical Nurse," "Clinical Nurse Specialist," "Certified Registered Nurse Anesthetist," "Certified Nurse Midwife," "Certified Nurse Practitioner," "Advanced Practice Registered Nurse ~~Practitioner~~," or any other name or title which implies that a person was licensed or certified as same, unless such person is duly licensed or certified.

Section 66. Paragraph (a) of subsection (4) of section 464.0205, Florida Statutes, is amended to read:

464.0205 Retired volunteer nurse certificate.—

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

(a) Work under the direct supervision of the director of a county health department, a physician working under a limited license issued pursuant to s. 458.317 or s. 459.0075, a physician licensed under chapter 458 or chapter 459, an advanced practice registered nurse ~~practitioner~~ certified under s. 464.012, or a registered nurse licensed under s. 464.008 or s. 464.009.

Section 67. Subsection (2) of section 467.003, Florida Statutes, is amended to read:

467.003 Definitions.—As used in this chapter, unless the context otherwise requires:

(2) "Certified nurse midwife" means a person who is

licensed as an advanced practice registered nurse ~~practitioner~~ under part I of chapter 464 and who is certified to practice midwifery by the American College of Nurse Midwives.

Section 68. Subsection (1) of section 480.0475, Florida Statutes, is amended to read:

480.0475 Massage establishments; prohibited practices.—

(1) A person may not operate a massage establishment between the hours of midnight and 5 a.m. This subsection does not apply to a massage establishment:

(a) Located on the premises of a health care facility as defined in s. 408.07; a health care clinic as defined in s. 400.9905(4); a hotel, motel, or bed and breakfast inn, as those terms are defined in s. 509.242; a timeshare property as defined in s. 721.05; a public airport as defined in s. 330.27; or a pari-mutuel facility as defined in s. 550.002;

(b) In which every massage performed between the hours of midnight and 5 a.m. is performed by a massage therapist acting under the prescription of a physician or physician assistant licensed under chapter 458, an osteopathic physician or physician assistant licensed under chapter 459, a chiropractic physician licensed under chapter 460, a podiatric physician licensed under chapter 461, an advanced practice registered nurse ~~practitioner~~ licensed under part I of chapter 464, or a dentist licensed under chapter 466; or

(c) Operating during a special event if the county or municipality in which the establishment operates has approved such operation during the special event.

Section 69. Subsection (7) of section 483.041, Florida Statutes, is amended to read:

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

(7) "Licensed practitioner" means a physician licensed under chapter 458, chapter 459, chapter 460, or chapter 461; a certified optometrist licensed under chapter 463; a dentist licensed under chapter 466; a person licensed under chapter 462; or an advanced practice registered nurse ~~practitioner~~ licensed under part I of chapter 464; or a duly licensed practitioner from another state licensed under similar statutes who orders examinations on materials or specimens for nonresidents of the State of Florida, but who reside in the same state as the requesting licensed practitioner.

Section 70. Subsection (5) of section 483.801, Florida Statutes, is amended to read:

483.801 Exemptions.—This part applies to all clinical laboratories and clinical laboratory personnel within this state, except:

(5) Advanced practice registered nurses certified ~~nurse practitioners licensed~~ under part I of chapter 464 who perform provider-performed microscopy procedures (PPMP) in an exclusive-use laboratory setting.

Section 71. Paragraph (a) of subsection (11) of section 486.021, Florida Statutes, is amended to read:

486.021 Definitions.—In this chapter, unless the context otherwise requires, the term:

(11) "Practice of physical therapy" means the performance of physical therapy assessments and the treatment of any disability, injury, disease, or other health condition of human beings, or the prevention of such disability, injury, disease, or other condition of health, and rehabilitation as related

thereto by the use of the physical, chemical, and other properties of air; electricity; exercise; massage; the performance of acupuncture only upon compliance with the criteria set forth by the Board of Medicine, when no penetration of the skin occurs; the use of radiant energy, including ultraviolet, visible, and infrared rays; ultrasound; water; the use of apparatus and equipment in the application of the foregoing or related thereto; the performance of tests of neuromuscular functions as an aid to the diagnosis or treatment of any human condition; or the performance of electromyography as an aid to the diagnosis of any human condition only upon compliance with the criteria set forth by the Board of Medicine.

(a) A physical therapist may implement a plan of treatment developed by the physical therapist for a patient or provided for a patient by a practitioner of record or by an advanced practice registered nurse ~~practitioner~~ licensed under s. 464.012. The physical therapist shall refer the patient to or consult with a practitioner of record if the patient's condition is found to be outside the scope of physical therapy. If physical therapy treatment for a patient is required beyond 21 days for a condition not previously assessed by a practitioner of record, the physical therapist shall obtain a practitioner of record who will review and sign the plan. For purposes of this paragraph, a health care practitioner licensed under chapter 458, chapter 459, chapter 460, chapter 461, or chapter 466 and engaged in active practice is eligible to serve as a practitioner of record.

Section 72. Paragraph (d) of subsection (1) of section 490.012, Florida Statutes, is amended to read:

490.012 Violations; penalties; injunction.—

(1)

(d) No person shall hold herself or himself out by any title or description incorporating the word, or a permutation of the word, "psychotherapy" unless such person holds a valid, active license under chapter 458, chapter 459, chapter 490, or chapter 491, or such person is certified as an advanced practice registered nurse ~~practitioner~~, pursuant to s. 464.012, who has been determined by the Board of Nursing as a specialist in psychiatric mental health.

Section 73. Subsection (1) of section 491.0057, Florida Statutes, is amended to read:

491.0057 Dual licensure as a marriage and family therapist.—The department shall license as a marriage and family therapist any person who demonstrates to the board that he or she:

(1) Holds a valid, active license as a psychologist under chapter 490 or as a clinical social worker or mental health counselor under this chapter, or is certified under s. 464.012 as an advanced practice registered nurse ~~practitioner~~ who has been determined by the Board of Nursing as a specialist in psychiatric mental health.

Section 74. Paragraph (d) of subsection (1) and subsection (2) of section 491.012, Florida Statutes, are amended to read:

491.012 Violations; penalty; injunction.—

(1) It is unlawful and a violation of this chapter for any person to:

(d) Use the terms psychotherapist, sex therapist, or juvenile sexual offender therapist unless such person is

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licensed pursuant to this chapter or chapter 490, or is certified under s. 464.012 as an advanced practice registered nurse ~~practitioner~~ who has been determined by the Board of Nursing as a specialist in psychiatric mental health and the use of such terms is within the scope of her or his practice based on education, training, and licensure.

(2) It is unlawful and a violation of this chapter for any person to describe her or his services using the following terms or any derivative thereof, unless such person holds a valid, active license under this chapter or chapter 490, or is certified under s. 464.012 as an advanced practice registered nurse ~~practitioner~~ who has been determined by the Board of Nursing as a specialist in psychiatric mental health and the use of such terms is within the scope of her or his practice based on education, training, and licensure:

(a) "Psychotherapy."

(b) "Sex therapy."

(c) "Sex counseling."

(d) "Clinical social work."

(e) "Psychiatric social work."

(f) "Marriage and family therapy."

(g) "Marriage and family counseling."

(h) "Marriage counseling."

(i) "Family counseling."

(j) "Mental health counseling."

Section 75. Subsection (2) of section 493.6108, Florida Statutes, is amended to read:

493.6108 Investigation of applicants by Department of Agriculture and Consumer Services.—

(2) In addition to subsection (1), the department shall make an investigation of the general physical fitness of the Class "G" applicant to bear a weapon or firearm. Determination of physical fitness shall be certified by a physician or physician assistant currently licensed pursuant to chapter 458, chapter 459, or any similar law of another state or authorized to act as a licensed physician by a federal agency or department or by an advanced practice registered nurse ~~practitioner~~ currently licensed pursuant to chapter 464. Such certification shall be submitted on a form provided by the department.

Section 76. Subsection (1) of section 626.9707, Florida Statutes, is amended to read:

626.9707 Disability insurance; discrimination on basis of sickle-cell trait prohibited.—

(1) An ~~No~~ insurer authorized to transact insurance in this state may not ~~shall~~ refuse to issue and deliver in this state any policy of disability insurance, whether such policy is defined as individual, group, blanket, franchise, industrial, or otherwise, which is currently being issued for delivery in this state and which affords benefits and coverage for any medical treatment or service authorized and permitted to be furnished by a hospital, clinic, health clinic, neighborhood health clinic, health maintenance organization, physician, physician's assistant, advanced practice registered nurse ~~practitioner~~, or medical service facility or personnel solely because the person to be insured has the sickle-cell trait.

Section 77. Paragraph (b) of subsection (1) of section 627.357, Florida Statutes, is amended to read:

627.357 Medical malpractice self-insurance.—

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

(b) "Health care provider" means any:

1. Hospital licensed under chapter 395.

2. Physician licensed, or physician assistant licensed, under chapter 458.

3. Osteopathic physician or physician assistant licensed under chapter 459.

4. Podiatric physician licensed under chapter 461.

5. Health maintenance organization certificated under part I of chapter 641.

6. Ambulatory surgical center licensed under chapter 395.

7. Chiropractic physician licensed under chapter 460.

8. Psychologist licensed under chapter 490.

9. Optometrist licensed under chapter 463.

10. Dentist licensed under chapter 466.

11. Pharmacist licensed under chapter 465.

12. Registered nurse, licensed practical nurse, or advanced practice registered nurse ~~practitioner~~ licensed or registered under part I of chapter 464.

13. Other medical facility.

14. Professional association, partnership, corporation, joint venture, or other association established by the individuals set forth in subparagraphs 2., 3., 4., 7., 8., 9., 10., 11., and 12. for professional activity.

Section 78. Subsection (6) of section 627.6471, Florida Statutes, is amended to read:

627.6471 Contracts for reduced rates of payment; limitations; coinsurance and deductibles.—

(6) If psychotherapeutic services are covered by a policy

issued by the insurer, the insurer shall provide eligibility criteria for each group of health care providers licensed under chapter 458, chapter 459, chapter 490, or chapter 491, which include psychotherapy within the scope of their practice as provided by law, or for any person who is certified as an advanced practice registered nurse ~~practitioner~~ in psychiatric mental health under s. 464.012. When psychotherapeutic services are covered, eligibility criteria shall be established by the insurer to be included in the insurer's criteria for selection of network providers. The insurer may not discriminate against a health care provider by excluding such practitioner from its provider network solely on the basis of the practitioner's license.

Section 79. Subsections (15) and (17) of section 627.6472, Florida Statutes, are amended to read:

627.6472 Exclusive provider organizations.—

(15) If psychotherapeutic services are covered by a policy issued by the insurer, the insurer shall provide eligibility criteria for all groups of health care providers licensed under chapter 458, chapter 459, chapter 490, or chapter 491, which include psychotherapy within the scope of their practice as provided by law, or for any person who is certified as an advanced practice registered nurse ~~practitioner~~ in psychiatric mental health under s. 464.012. When psychotherapeutic services are covered, eligibility criteria shall be established by the insurer to be included in the insurer's criteria for selection of network providers. The insurer may not discriminate against a health care provider by excluding such practitioner from its provider network solely on the basis of the practitioner's

license.

(17) An exclusive provider organization may ~~shall~~ not discriminate with respect to participation as to any advanced practice registered nurse ~~practitioner~~ licensed and certified pursuant to s. 464.012, who is acting within the scope of such license and certification, solely on the basis of such license or certification. This subsection may ~~shall~~ not be construed to prohibit a plan from including providers only to the extent necessary to meet the needs of the plan's enrollees or from establishing any measure designed to maintain quality and control costs consistent with the responsibilities of the plan.

Section 80. Paragraph (a) of subsection (1) of section 627.736, Florida Statutes, is amended to read:

627.736 Required personal injury protection benefits; exclusions; priority; claims.—

(1) REQUIRED BENEFITS.—An insurance policy complying with the security requirements of s. 627.733 must provide personal injury protection to the named insured, relatives residing in the same household, persons operating the insured motor vehicle, passengers in the motor vehicle, and other persons struck by the motor vehicle and suffering bodily injury while not an occupant of a self-propelled vehicle, subject to subsection (2) and paragraph (4)(e), to a limit of $10,000 in medical and disability benefits and $5,000 in death benefits resulting from bodily injury, sickness, disease, or death arising out of the ownership, maintenance, or use of a motor vehicle as follows:

(a) *Medical benefits.*—Eighty percent of all reasonable expenses for medically necessary medical, surgical, X-ray, dental, and rehabilitative services, including prosthetic

devices and medically necessary ambulance, hospital, and nursing services if the individual receives initial services and care pursuant to subparagraph 1. within 14 days after the motor vehicle accident. The medical benefits provide reimbursement only for:

1. Initial services and care that are lawfully provided, supervised, ordered, or prescribed by a physician licensed under chapter 458 or chapter 459, a dentist licensed under chapter 466, or a chiropractic physician licensed under chapter 460 or that are provided in a hospital or in a facility that owns, or is wholly owned by, a hospital. Initial services and care may also be provided by a person or entity licensed under part III of chapter 401 which provides emergency transportation and treatment.

2. Upon referral by a provider described in subparagraph 1., followup services and care consistent with the underlying medical diagnosis rendered pursuant to subparagraph 1. which may be provided, supervised, ordered, or prescribed only by a physician licensed under chapter 458 or chapter 459, a chiropractic physician licensed under chapter 460, a dentist licensed under chapter 466, or, to the extent permitted by applicable law and under the supervision of such physician, osteopathic physician, chiropractic physician, or dentist, by a physician assistant licensed under chapter 458 or chapter 459 or an advanced practice registered nurse ~~practitioner~~ licensed under chapter 464. Followup services and care may also be provided by the following persons or entities:

a. A hospital or ambulatory surgical center licensed under chapter 395.

b. An entity wholly owned by one or more physicians licensed under chapter 458 or chapter 459, chiropractic physicians licensed under chapter 460, or dentists licensed under chapter 466 or by such practitioners and the spouse, parent, child, or sibling of such practitioners.

c. An entity that owns or is wholly owned, directly or indirectly, by a hospital or hospitals.

d. A physical therapist licensed under chapter 486, based upon a referral by a provider described in this subparagraph.

e. A health care clinic licensed under part X of chapter 400 which is accredited by an accrediting organization whose standards incorporate comparable regulations required by this state, or

(I) Has a medical director licensed under chapter 458, chapter 459, or chapter 460;

(II) Has been continuously licensed for more than 3 years or is a publicly traded corporation that issues securities traded on an exchange registered with the United States Securities and Exchange Commission as a national securities exchange; and

(III) Provides at least four of the following medical specialties:

(A) General medicine.

(B) Radiography.

(C) Orthopedic medicine.

(D) Physical medicine.

(E) Physical therapy.

(F) Physical rehabilitation.

(G) Prescribing or dispensing outpatient prescription

medication.

(H) Laboratory services.

3. Reimbursement for services and care provided in subparagraph 1. or subparagraph 2. up to $10,000 if a physician licensed under chapter 458 or chapter 459, a dentist licensed under chapter 466, a physician assistant licensed under chapter 458 or chapter 459, or an advanced practice registered nurse ~~practitioner~~ licensed under chapter 464 has determined that the injured person had an emergency medical condition.

4. Reimbursement for services and care provided in subparagraph 1. or subparagraph 2. is limited to $2,500 if a provider listed in subparagraph 1. or subparagraph 2. determines that the injured person did not have an emergency medical condition.

5. Medical benefits do not include massage as defined in s. 480.033 or acupuncture as defined in s. 457.102, regardless of the person, entity, or licensee providing massage or acupuncture, and a licensed massage therapist or licensed acupuncturist may not be reimbursed for medical benefits under this section.

6. The Financial Services Commission shall adopt by rule the form that must be used by an insurer and a health care provider specified in sub-subparagraph 2.b., sub-subparagraph 2.c., or sub-subparagraph 2.e. to document that the health care provider meets the criteria of this paragraph. Such rule must include a requirement for a sworn statement or affidavit.

Only insurers writing motor vehicle liability insurance in this state may provide the required benefits of this section, and

such insurer may not require the purchase of any other motor vehicle coverage other than the purchase of property damage liability coverage as required by s. 627.7275 as a condition for providing such benefits. Insurers may not require that property damage liability insurance in an amount greater than $10,000 be purchased in conjunction with personal injury protection. Such insurers shall make benefits and required property damage liability insurance coverage available through normal marketing channels. An insurer writing motor vehicle liability insurance in this state who fails to comply with such availability requirement as a general business practice violates part IX of chapter 626, and such violation constitutes an unfair method of competition or an unfair or deceptive act or practice involving the business of insurance. An insurer committing such violation is subject to the penalties provided under that part, as well as those provided elsewhere in the insurance code.

Section 81. Paragraph (e) of subsection (1) of section 633.412, Florida Statutes, is amended to read:

633.412 Firefighters; qualifications for certification.—

(1) A person applying for certification as a firefighter must:

(e) Be in good physical condition as determined by a medical examination given by a physician, surgeon, or physician assistant licensed to practice in the state pursuant to chapter 458; an osteopathic physician, surgeon, or physician assistant licensed to practice in the state pursuant to chapter 459; or an advanced <u>practice</u> registered nurse ~~practitioner~~ licensed to practice in the state pursuant to chapter 464. Such examination may include, but need not be limited to, the National Fire

Protection Association Standard 1582. A medical examination evidencing good physical condition shall be submitted to the division, on a form as provided by rule, before an individual is eligible for admission into a course under s. 633.408.

Section 82. Section 641.3923, Florida Statutes, is amended to read:

641.3923 Discrimination against providers prohibited.—A health maintenance organization may ~~shall~~ not discriminate with respect to participation as to any advanced practice registered nurse ~~practitioner~~ licensed and certified pursuant to s. 464.012, who is acting within the scope of such license and certification, solely on the basis of such license or certification. This section may ~~shall~~ not be construed to prohibit a plan from including providers only to the extent necessary to meet the needs of the plan's enrollees or from establishing any measure designed to maintain quality and control costs consistent with the responsibilities of the plan.

Section 83. Subsection (8) of section 641.495, Florida Statutes, is amended to read:

641.495 Requirements for issuance and maintenance of certificate.—

(8) Each organization's contracts, certificates, and subscriber handbooks shall contain a provision, if applicable, disclosing that, for certain types of described medical procedures, services may be provided by physician assistants, certified nurse practitioners, or other individuals who are not licensed physicians.

Section 84. Paragraph (a) of subsection (3) of section 744.331, Florida Statutes, is amended to read:

744.331 Procedures to determine incapacity.—

(3) EXAMINING COMMITTEE.—

(a) Within 5 days after a petition for determination of incapacity has been filed, the court shall appoint an examining committee consisting of three members. One member must be a psychiatrist or other physician. The remaining members must be either a psychologist, gerontologist, another psychiatrist, or other physician, a registered nurse, advanced practice registered nurse ~~practitioner~~, licensed social worker, a person with an advanced degree in gerontology from an accredited institution of higher education, or other person who by knowledge, skill, experience, training, or education may, in the court's discretion, advise the court in the form of an expert opinion. One of three members of the committee must have knowledge of the type of incapacity alleged in the petition. Unless good cause is shown, the attending or family physician may not be appointed to the committee. If the attending or family physician is available for consultation, the committee must consult with the physician. Members of the examining committee may not be related to or associated with one another, with the petitioner, with counsel for the petitioner or the proposed guardian, or with the person alleged to be totally or partially incapacitated. A member may not be employed by any private or governmental agency that has custody of, or furnishes, services or subsidies, directly or indirectly, to the person or the family of the person alleged to be incapacitated or for whom a guardianship is sought. A petitioner may not serve as a member of the examining committee. Members of the examining committee must be able to communicate, either directly or

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through an interpreter, in the language that the alleged incapacitated person speaks or to communicate in a medium understandable to the alleged incapacitated person if she or he is able to communicate. The clerk of the court shall send notice of the appointment to each person appointed no later than 3 days after the court's appointment.

Section 85. Subsection (1) of section 744.703, Florida Statutes, is amended to read:

744.703 Office of public guardian; appointment, notification.—

(1) The executive director of the Statewide Public Guardianship Office, after consultation with the chief judge and other circuit judges within the judicial circuit and with appropriate advocacy groups and individuals and organizations who are knowledgeable about the needs of incapacitated persons, may establish, within a county in the judicial circuit or within the judicial circuit, one or more offices of public guardian and if so established, shall create a list of persons best qualified to serve as the public guardian, who have been investigated pursuant to s. 744.3135. The public guardian must have knowledge of the legal process and knowledge of social services available to meet the needs of incapacitated persons. The public guardian shall maintain a staff or contract with professionally qualified individuals to carry out the guardianship functions, including an attorney who has experience in probate areas and another person who has a master's degree in social work, or a gerontologist, psychologist, registered nurse, or advanced practice registered nurse ~~practitioner~~. A public guardian that is a nonprofit corporate guardian under s. 744.309(5) must

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receive tax-exempt status from the United States Internal Revenue Service.

Section 86. Subsection (6) of section 766.102, Florida Statutes, is amended to read:

766.102 Medical negligence; standards of recovery; expert witness.—

(6) A physician licensed under chapter 458 or chapter 459 who qualifies as an expert witness under subsection (5) and who, by reason of active clinical practice or instruction of students, has knowledge of the applicable standard of care for nurses, certified nurse practitioners, certified registered nurse anesthetists, certified registered nurse midwives, physician assistants, or other medical support staff may give expert testimony in a medical negligence action with respect to the standard of care of such medical support staff.

Section 87. Subsection (3) of section 766.103, Florida Statutes, is amended to read:

766.103 Florida Medical Consent Law.—

(3) ~~No~~ Recovery is not ~~shall be~~ allowed in any court in this state against any physician licensed under chapter 458, osteopathic physician licensed under chapter 459, chiropractic physician licensed under chapter 460, podiatric physician licensed under chapter 461, dentist licensed under chapter 466, advanced practice registered nurse ~~practitioner~~ certified under s. 464.012, or physician assistant licensed under s. 458.347 or s. 459.022 in an action brought for treating, examining, or operating on a patient without his or her informed consent when:

(a)1. The action of the physician, osteopathic physician, chiropractic physician, podiatric physician, dentist, advanced

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practice registered nurse ~~practitioner~~, or physician assistant in obtaining the consent of the patient or another person authorized to give consent for the patient was in accordance with an accepted standard of medical practice among members of the medical profession with similar training and experience in the same or similar medical community as that of the person treating, examining, or operating on the patient for whom the consent is obtained; and

2. A reasonable individual, from the information provided by the physician, osteopathic physician, chiropractic physician, podiatric physician, dentist, advanced practice registered nurse ~~practitioner~~, or physician assistant, under the circumstances, would have a general understanding of the procedure, the medically acceptable alternative procedures or treatments, and the substantial risks and hazards inherent in the proposed treatment or procedures, which are recognized among other physicians, osteopathic physicians, chiropractic physicians, podiatric physicians, or dentists in the same or similar community who perform similar treatments or procedures; or

(b) The patient would reasonably, under all the surrounding circumstances, have undergone such treatment or procedure had he or she been advised by the physician, osteopathic physician, chiropractic physician, podiatric physician, dentist, advanced practice registered nurse ~~practitioner~~, or physician assistant in accordance with the provisions of paragraph (a).

Section 88. Paragraph (d) of subsection (3) of section 766.1115, Florida Statutes, is amended to read:

766.1115 Health care providers; creation of agency relationship with governmental contractors.—

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

(d) "Health care provider" or "provider" means:

1. A birth center licensed under chapter 383.

2. An ambulatory surgical center licensed under chapter 395.

3. A hospital licensed under chapter 395.

4. A physician or physician assistant licensed under chapter 458.

5. An osteopathic physician or osteopathic physician assistant licensed under chapter 459.

6. A chiropractic physician licensed under chapter 460.

7. A podiatric physician licensed under chapter 461.

8. A registered nurse, nurse midwife, licensed practical nurse, or advanced practice registered nurse ~~practitioner~~ licensed or registered under part I of chapter 464 or any facility which employs nurses licensed or registered under part I of chapter 464 to supply all or part of the care delivered under this section.

9. A midwife licensed under chapter 467.

10. A health maintenance organization certificated under part I of chapter 641.

11. A health care professional association and its employees or a corporate medical group and its employees.

12. Any other medical facility the primary purpose of which is to deliver human medical diagnostic services or which delivers nonsurgical human medical treatment, and which includes an office maintained by a provider.

13. A dentist or dental hygienist licensed under chapter 466.

14. A free clinic that delivers only medical diagnostic services or nonsurgical medical treatment free of charge to all low-income recipients.

15. Any other health care professional, practitioner, provider, or facility under contract with a governmental contractor, including a student enrolled in an accredited program that prepares the student for licensure as any one of the professionals listed in subparagraphs 4.-9.

The term includes any nonprofit corporation qualified as exempt from federal income taxation under s. 501(a) of the Internal Revenue Code, and described in s. 501(c) of the Internal Revenue Code, which delivers health care services provided by licensed professionals listed in this paragraph, any federally funded community health center, and any volunteer corporation or volunteer health care provider that delivers health care services.

Section 89. Subsection (1) of section 766.1116, Florida Statutes, is amended to read:

766.1116 Health care practitioner; waiver of license renewal fees and continuing education requirements.—

(1) As used in this section, the term "health care practitioner" means a physician or physician assistant licensed under chapter 458; an osteopathic physician or physician assistant licensed under chapter 459; a chiropractic physician licensed under chapter 460; a podiatric physician licensed under chapter 461; an advanced <u>practice</u> registered nurse ~~practitioner~~, registered nurse, or licensed practical nurse licensed under part I of chapter 464; a dentist or dental hygienist licensed

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under chapter 466; or a midwife licensed under chapter 467, who participates as a health care provider under s. 766.1115.

Section 90. Subsection (5) of section 794.08, Florida Statutes, is amended to read:

794.08 Female genital mutilation.—

(5) This section does not apply to procedures performed by or under the direction of a physician licensed under chapter 458, an osteopathic physician licensed under chapter 459, a registered nurse licensed under part I of chapter 464, a practical nurse licensed under part I of chapter 464, an advanced practice registered nurse ~~practitioner~~ licensed under part I of chapter 464, a midwife licensed under chapter 467, or a physician assistant licensed under chapter 458 or chapter 459 when necessary to preserve the physical health of a female person. This section also does not apply to any autopsy or limited dissection conducted pursuant to chapter 406.

Section 91. Subsection (6) of section 943.13, Florida Statutes, is amended to read:

943.13 Officers' minimum qualifications for employment or appointment.—On or after October 1, 1984, any person employed or appointed as a full-time, part-time, or auxiliary law enforcement officer or correctional officer; on or after October 1, 1986, any person employed as a full-time, part-time, or auxiliary correctional probation officer; and on or after October 1, 1986, any person employed as a full-time, part-time, or auxiliary correctional officer by a private entity under contract to the Department of Corrections, to a county commission, or to the Department of Management Services shall:

(6) Have passed a physical examination by a licensed

physician, physician assistant, or certified advanced practice registered nurse ~~practitioner~~, based on specifications established by the commission. In order to be eligible for the presumption set forth in s. 112.18 while employed with an employing agency, a law enforcement officer, correctional officer, or correctional probation officer must have successfully passed the physical examination required by this subsection upon entering into service as a law enforcement officer, correctional officer, or correctional probation officer with the employing agency, which examination must have failed to reveal any evidence of tuberculosis, heart disease, or hypertension. A law enforcement officer, correctional officer, or correctional probation officer may not use a physical examination from a former employing agency for purposes of claiming the presumption set forth in s. 112.18 against the current employing agency.

Section 92. Subsection (2) of section 945.603, Florida Statutes, is amended to read:

945.603 Powers and duties of authority.—The purpose of the authority is to assist in the delivery of health care services for inmates in the Department of Corrections by advising the Secretary of Corrections on the professional conduct of primary, convalescent, dental, and mental health care and the management of costs consistent with quality care, by advising the Governor and the Legislature on the status of the Department of Corrections' health care delivery system, and by assuring that adequate standards of physical and mental health care for inmates are maintained at all Department of Corrections institutions. For this purpose, the authority has the authority

to:

(2) Review and make recommendations regarding health care for the delivery of health care services including, but not limited to, acute hospital-based services and facilities, primary and tertiary care services, ancillary and clinical services, dental services, mental health services, intake and screening services, medical transportation services, and the use of advanced practice registered nurse ~~practitioner~~ and physician assistant personnel to act as physician extenders as these relate to inmates in the Department of Corrections.

Section 93. Paragraph (i) of subsection (3) of section 1002.20, Florida Statutes, is amended to read:

1002.20 K-12 student and parent rights.—Parents of public school students must receive accurate and timely information regarding their child's academic progress and must be informed of ways they can help their child to succeed in school. K-12 students and their parents are afforded numerous statutory rights including, but not limited to, the following:

(3) HEALTH ISSUES.—

(i) *Epinephrine use and supply.*—

1. A student who has experienced or is at risk for life-threatening allergic reactions may carry an epinephrine auto-injector and self-administer epinephrine by auto-injector while in school, participating in school-sponsored activities, or in transit to or from school or school-sponsored activities if the school has been provided with parental and physician authorization. The State Board of Education, in cooperation with the Department of Health, shall adopt rules for such use of epinephrine auto-injectors that shall include provisions to

protect the safety of all students from the misuse or abuse of auto-injectors. A school district, county health department, public-private partner, and their employees and volunteers shall be indemnified by the parent of a student authorized to carry an epinephrine auto-injector for any and all liability with respect to the student's use of an epinephrine auto-injector pursuant to this paragraph.

2. A public school may purchase from a wholesale distributor as defined in s. 499.003 and maintain in a locked, secure location on its premises a supply of epinephrine auto-injectors for use if a student is having an anaphylactic reaction. The participating school district shall adopt a protocol developed by a licensed physician for the administration by school personnel who are trained to recognize an anaphylactic reaction and to administer an epinephrine auto-injection. The supply of epinephrine auto-injectors may be provided to and used by a student authorized to self-administer epinephrine by auto-injector under subparagraph 1. or trained school personnel.

3. The school district and its employees and agents, including the physician who provides the standing protocol for school epinephrine auto-injectors, are not liable for any injury arising from the use of an epinephrine auto-injector administered by trained school personnel who follow the adopted protocol and whose professional opinion is that the student is having an anaphylactic reaction:

a. Unless the trained school personnel's action is willful and wanton;

b. Notwithstanding that the parents or guardians of the

student to whom the epinephrine is administered have not been provided notice or have not signed a statement acknowledging that the school district is not liable; and

c. Regardless of whether authorization has been given by the student's parents or guardians or by the student's physician, physician's assistant, or advanced practice registered nurse ~~practitioner~~.

Section 94. Paragraph (b) of subsection (17) of section 1002.42, Florida Statutes, is amended to read:

1002.42 Private schools.—

(17) EPINEPHRINE SUPPLY.—

(b) The private school and its employees and agents, including the physician who provides the standing protocol for school epinephrine auto-injectors, are not liable for any injury arising from the use of an epinephrine auto-injector administered by trained school personnel who follow the adopted protocol and whose professional opinion is that the student is having an anaphylactic reaction:

1. Unless the trained school personnel's action is willful and wanton;

2. Notwithstanding that the parents or guardians of the student to whom the epinephrine is administered have not been provided notice or have not signed a statement acknowledging that the school district is not liable; and

3. Regardless of whether authorization has been given by the student's parents or guardians or by the student's physician, physician's assistant, or advanced practice registered nurse ~~practitioner~~.

Section 95. Subsections (4) and (5) of section 1006.062,

Florida Statutes, are amended to read:

1006.062 Administration of medication and provision of medical services by district school board personnel.—

(4) Nonmedical assistive personnel shall be allowed to perform health-related services upon successful completion of child-specific training by a registered nurse or advanced practice registered nurse ~~practitioner~~ licensed under chapter 464, a physician licensed pursuant to chapter 458 or chapter 459, or a physician assistant licensed pursuant to chapter 458 or chapter 459. All procedures shall be monitored periodically by a nurse, advanced practice registered nurse ~~practitioner~~, physician assistant, or physician, including, but not limited to:

(a) Intermittent clean catheterization.

(b) Gastrostomy tube feeding.

(c) Monitoring blood glucose.

(d) Administering emergency injectable medication.

(5) For all other invasive medical services not listed in this subsection, a registered nurse or advanced practice registered nurse ~~practitioner~~ licensed under chapter 464, a physician licensed pursuant to chapter 458 or chapter 459, or a physician assistant licensed pursuant to chapter 458 or chapter 459 shall determine if nonmedical district school board personnel shall be allowed to perform such service.

Section 96. Subsection (1) and paragraph (a) of subsection (2) of section 1009.65, Florida Statutes, are amended to read:

1009.65 Medical Education Reimbursement and Loan Repayment Program.—

(1) To encourage qualified medical professionals to

practice in underserved locations where there are shortages of such personnel, there is established the Medical Education Reimbursement and Loan Repayment Program. The function of the program is to make payments that offset loans and educational expenses incurred by students for studies leading to a medical or nursing degree, medical or nursing licensure, or advanced practice registered nurse ~~practitioner~~ certification or physician assistant licensure. The following licensed or certified health care professionals are eligible to participate in this program: medical doctors with primary care specialties, doctors of osteopathic medicine with primary care specialties, physician's assistants, licensed practical nurses and registered nurses, and advanced practice registered nurses ~~nurse practitioners~~ with primary care specialties such as certified nurse midwives. Primary care medical specialties for physicians include obstetrics, gynecology, general and family practice, internal medicine, pediatrics, and other specialties which may be identified by the Department of Health.

(2) From the funds available, the Department of Health shall make payments to selected medical professionals as follows:

(a) Up to $4,000 per year for licensed practical nurses and registered nurses, up to $10,000 per year for advanced practice registered nurses ~~nurse practitioners~~ and physician's assistants, and up to $20,000 per year for physicians. Penalties for noncompliance shall be the same as those in the National Health Services Corps Loan Repayment Program. Educational expenses include costs for tuition, matriculation, registration, books, laboratory and other fees, other educational costs, and

reasonable living expenses as determined by the Department of Health.

Section 97. Subsection (2) of section 1009.66, Florida Statutes, is amended to read:

1009.66 Nursing Student Loan Forgiveness Program.—

(2) To be eligible, a candidate must have graduated from an accredited or approved nursing program and have received a Florida license as a licensed practical nurse or a registered nurse or a Florida certificate as an advanced practice registered nurse ~~practitioner~~.

Section 98. Subsection (3) of section 1009.67, Florida Statutes, is amended to read:

1009.67 Nursing scholarship program.—

(3) A scholarship may be awarded for no more than 2 years, in an amount not to exceed $8,000 per year. However, registered nurses pursuing a graduate degree for a faculty position or to practice as an advanced practice registered nurse ~~practitioner~~ may receive up to $12,000 per year. These amounts shall be adjusted by the amount of increase or decrease in the Consumer Price Index for All Urban Consumers published by the United States Department of Commerce.

Section 99. This act shall take effect July 1, 2014.

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

And the title is amended as follows:

Delete everything before the enacting clause and insert:

A bill to be entitled

An act relating to health care practitioners; amending

s. 110.12315, F.S.; expanding who may prescribe brand drugs under the prescription drug program when medically necessary; amending ss. 310.071, 310.073, and 310.081, F.S.; excepting controlled substances prescribed by an advanced practice registered nurse from the disqualifications for continued certification or licensure as a deputy or state pilot; amending s. 394.455, F.S.; updating terminology to make reference to "psychiatric-mental health advanced practice registered nurse" instead of "psychiatric nurse"; requiring that such nurse hold a specified national certification; conforming a reference to the term; amending s. 394.463, F.S.; authorizing a psychiatric-mental health advanced practice registered nurse to approve the involuntary examination or release of a patient from a receiving facility; amending s. 397.501, F.S.; prohibiting service providers from denying access to substance abuse services to an individual who takes medications prescribed by an advanced practice registered nurse; amending s. 456.053, F.S.; providing an additional exception to prohibited referrals; amending s. 456.057, F.S.; requiring rates charged for copies of certain medical records to be the same regardless of format or medium; amending s. 456.072, F.S.; applying existing penalties for violations relating to the prescribing or dispensing of controlled substances to an advanced practice registered nurse; amending s. 456.44, F.S.; requiring advanced practice registered nurses who

prescribe controlled substances for certain pain to make a certain designation, comply with registration requirements, and follow specified standards of practice; amending s. 458.348, F.S.; deleting obsolete language regarding the number of offices a physician may supervise; conforming terminology; amending s. 458.3485, F.S.; deleting language relating to the certification and registration of medical assistants; amending s. 459.025; deleting obsolete language regarding the number of offices a physician may supervise; amending s. 464.012, F.S.; authorizing an advanced practice registered nurse to prescribe, dispense, administer, or order drugs in accordance with a specified formulary, if such formulary is established; requiring the Board of Nursing to appoint a committee to determine whether such a formulary is needed and specifying the membership of the committee; providing parameters for the recommendations of the committee; requiring that any formulary be adopted by board rule; specifying the process for amending the formulary and imposing a burden of proof; requiring notice of proposed, pending, or adopted changes; specifying a deadline for initiating any required rulemaking; conforming terminology; amending s. 464.015, F.S.; applying current provisions and criminal penalties relating to restrictions on the use of titles and abbreviations to certified nurse practitioners; conforming terminology; amending s. 464.018, F.S.; specifying acts that constitute grounds

for denial of a license for or disciplinary action against an advanced practice registered nurse who practices without specified supervision; amending s. 893.02, F.S.; redefining the term "practitioner" to include advanced practice registered nurses under the Florida Comprehensive Drug Abuse Prevention and Control Act; amending s. 948.03, F.S.; including drugs or narcotics prescribed by an advanced practice registered nurse in an exception relating to the possession of drugs or narcotics during probation; amending ss. 39.303, 39.304, 90.503, 112.0455, 121.0515, 252.515, 381.00315, 381.00593, 383.141, 390.0111, 390.012, 394.4574, 394.4655, 394.467, 395.0191, 395.602, 395.605, 397.311, 397.405, 397.427, 400.021, 400.0255, 400.172, 400.462, 400.487, 400.506, 401.445, 409.905, 409.908, 409.9081, 409.9122, 409.973, 429.26, 429.918, 440.102, 456.0391, 456.0392, 456.041, 456.048, 458.3265, 458.331, 459.0137, 459.015, 464.003, 464.004, 464.016, 464.0205, 467.003, 480.0475, 483.041, 483.801, 486.021, 490.012, 491.0057, 491.012, 493.6108, 626.9707, 627.357, 627.6471, 627.6472, 627.736, 633.412, 641.3923, 641.495, 744.331, 744.703, 766.102, 766.103, 766.1115, 766.1116, 794.08, 943.13, 945.603, 1002.20, 1002.42, 1006.062, 1009.65, 1009.66, and 1009.67; conforming terminology to changes made by the act; providing an effective date.

862596

LEGISLATIVE ACTION

Senate . House

. . . . .

The Committee on Health Policy (Grimsley) recommended the following:

Senate Amendment to Amendment (179338)

Delete line 162
and insert:
3. A physician, clinical psychologist, psychiatric-mental health advanced practice registered ~~psychiatric~~ nurse,

809346

LEGISLATIVE ACTION

Senate . House

. . . . .

The Committee on Health Policy (Brandes) recommended the following:

Senate Amendment to Amendment (179338) (with title amendment)

Between lines 1048 and 1049
insert:

Section 18. Subsection (3) of section 486.031, Florida Statutes, is amended to read:

486.031 Physical therapist; licensing requirements.—To be eligible for licensing as a physical therapist, an applicant must:

809346

(3)(a) Have been graduated from a school of physical therapy which has been approved for the educational preparation of physical therapists by the appropriate accrediting agency recognized by the Commission on Recognition of Postsecondary Accreditation or the United States Department of Education at the time of her or his graduation and have passed, to the satisfaction of the board, the American Registry Examination prior to 1971 or a national examination approved by the board to determine her or his fitness for practice as a physical therapist as hereinafter provided;

(b) Have received a diploma from a program in physical therapy in a foreign country and have educational credentials deemed equivalent to those required for the educational preparation of physical therapists in this country, as recognized by the board or by an appropriate agency ~~as~~ identified by the board, and have passed to the satisfaction of the board an examination to determine her or his fitness for practice as a physical therapist ~~as hereinafter provided~~; or

(c) Be entitled to licensure without examination as provided in s. 486.081.

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

And the title is amended as follows:

Between lines 3841 and 3842

insert:

486.031, F.S.; revising provisions relating to the recognition of physical therapy programs and educational credentials from foreign countries to meet requirements for licensing as a physical therapist;

809346

amending s.

565194

LEGISLATIVE ACTION

Senate . House

. . . . .

The Committee on Health Policy (Brandes) recommended the following:

Senate Amendment to Amendment (179338)

Between lines 958 and 959
insert:
(d) A formulary, if adopted pursuant to this subsection, shall not apply to drugs that are ordered as authorized in a protocol.

718228

LEGISLATIVE ACTION

Senate . House

. .

. .

. .

. .

The Committee on Health Policy (Brandes) recommended the following:

Senate Amendment (with title amendment)

Between lines 1204 and 1205
insert:

Section 23. Subsection (3) of section 486.031, Florida Statutes, is amended to read:

486.031 Physical therapist; licensing requirements.—To be eligible for licensing as a physical therapist, an applicant must:

(3)(a) Have been graduated from a school of physical

718228

therapy which has been approved for the educational preparation of physical therapists by the appropriate accrediting agency recognized by the Commission on Recognition of Postsecondary Accreditation or the United States Department of Education at the time of her or his graduation and have passed, to the satisfaction of the board, the American Registry Examination prior to 1971 or a national examination approved by the board to determine her or his fitness for practice as a physical therapist as hereinafter provided;

(b) Have received a diploma from a program in physical therapy in a foreign country and have educational credentials deemed equivalent to those required for the educational preparation of physical therapists in this country, as recognized by the board or by an appropriate agency ~~as~~ identified by the board, and have passed to the satisfaction of the board an examination to determine her or his fitness for practice as a physical therapist ~~as hereinafter provided~~; or

(c) Be entitled to licensure without examination as provided in s. 486.081.

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

And the title is amended as follows:

Between lines 72 and 73

insert:

amending s. 486.031, F.S.; revising provisions relating to the recognition of physical therapy programs and educational credentials from foreign countries to meet requirements for licensing as a physical therapist;

By Senator Grimsley

21-01201C-14 20141352__

A bill to be entitled

An act relating to health care practitioners; amending s. 110.12315, F.S.; expanding who may prescribe brand drugs under the prescription drug program when medically necessary; amending ss. 310.071, 310.073, and 310.081, F.S.; excepting controlled substances prescribed by an advanced practice registered nurse from the disqualifications for continued certification or licensure as a deputy or state pilot; amending s. 381.0035, F.S.; deleting a cross-reference to conform to changes made by the act; amending s. 394.455, F.S.; updating terminology to make reference to "psychiatric-mental health advanced practice registered nurse" instead of "psychiatric nurse"; requiring that such nurse hold a specified national certification; conforming a reference to the term; amending s. 394.463, F.S.; authorizing a psychiatric-mental health advanced practice registered nurse to approve the involuntary examination or release of a patient from a receiving facility; amending s. 397.501, F.S.; prohibiting service providers from denying access to substance abuse services to an individual who takes medications prescribed by an advanced practice registered nurse; amending ss. 456.013 and 456.031, F.S.; specifying a timeframe within which certain continuing education must be completed; repealing s. 456.033, F.S., relating to the continuing education requirement related to HIV and AIDS for specified licensees; amending s. 456.053,

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21-01201C-14 20141352__

F.S.; providing an additional exception to prohibited referrals; amending s. 456.057, F.S.; requiring rates charged for copies of certain medical records to be the same regardless of format or medium; amending s. 456.072, F.S.; applying existing penalties for violations relating to the prescribing or dispensing of controlled substances to an advanced practice registered nurse; amending s. 456.44, F.S.; requiring advanced practice registered nurses who prescribe controlled substances for certain pain to make a certain designation, comply with registration requirements, and follow specified standards of practice; amending s. 458.348, F.S.; deleting obsolete language regarding the number of offices a physician may supervise; conforming terminology; amending s. 458.3485, F.S.; deleting language relating to the certification and registration of medical assistants; amending s. 459.025; deleting obsolete language regarding the number of offices a physician may supervise; amending s. 464.012, F.S.; authorizing an advanced practice registered nurse to prescribe, dispense, administer, or order drugs in accordance with a specified formulary, if such formulary is established; requiring the Board of Nursing to appoint a committee to determine whether such a formulary is needed and specifying the membership of the committee; providing parameters for the recommendations of the committee; requiring that any formulary be adopted by board rule; specifying the process for amending the

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formulary and imposing a burden of proof; requiring notice of proposed, pending, or adopted changes; specifying a deadline for initiating any required rulemaking; conforming terminology; amending s. 464.015, F.S.; applying current provisions and criminal penalties relating to restrictions on the use of titles and abbreviations to certified nurse practitioners; conforming terminology; amending s. 464.018, F.S.; specifying acts that constitute grounds for denial of a license for or disciplinary action against an advanced practice registered nurse who practices without specified supervision; amending s. 464.203, F.S.; deleting a requirement that a certified nursing assistant receive annual inservice training; amending s. 893.02, F.S.; redefining the term "practitioner" to include advanced practice registered nurses under the Florida Comprehensive Drug Abuse Prevention and Control Act; amending s. 948.03, F.S.; including drugs or narcotics prescribed by an advanced practice registered nurse in an exception relating to the possession of drugs or narcotics during probation; amending ss. 39.303, 39.304, 90.503, 112.0455, 121.0515, 252.515, 381.00315, 381.00593, 383.141, 390.0111, 390.012, 394.4574, 394.4655, 394.467, 395.0191, 395.602, 395.605, 397.311, 397.405, 397.427, 400.021, 400.0255, 400.172, 400.211, 400.462, 400.487, 400.506, 401.445, 409.905, 409.908, 409.9081, 409.9122, 409.973, 429.26, 429.918, 440.102, 456.0391, 456.0392, 456.041, 456.048, 458.3265, 458.331,

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

459.0137, 459.015, 464.003, 464.004, 464.016, 464.0205, 467.003, 480.0475, 483.041, 483.801, 486.021, 490.012, 491.0057, 491.012, 493.6108, 626.9707, 627.357, 627.6471, 627.6472, 627.736, 633.412, 641.3923, 641.495, 744.331, 744.703, 766.102, 766.103, 766.1115, 766.1116, 794.08, 943.13, 945.603, 1002.20, 1002.42, 1006.062, 1009.65, 1009.66, and 1009.67; conforming terminology to changes made by the act; providing an effective date.

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

Section 1. Subsection (3) 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:

(3) The Department of Management Services 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 health care practitioner ~~physician~~ 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

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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 of Management Services.

Section 2. Paragraph (c) of subsection (1) of section 310.071, Florida Statutes, is amended 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 or advanced practice registered nurse and that controlled substance was prescribed by that physician or advanced practice registered nurse. 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.

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 or advanced practice registered nurse and that controlled substance was prescribed by that physician or advanced practice registered nurse. 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 or advanced practice registered nurse and that controlled substance was prescribed by that physician or advanced practice registered nurse. 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. Subsection (4) of section 381.0035, Florida Statutes, is amended to read:

381.0035 Educational course on HIV and AIDS; employees and clients of certain health care facilities.—

~~(4) This section does not apply to an employee who is subject to the requirements of s. 456.033.~~

Section 6. Subsections (23) and (33) of section 394.455, Florida Statutes, are amended to read:

394.455 Definitions.—As used in this part, unless the context clearly requires otherwise, the term:

(23) "Psychiatric-mental health advanced practice registered ~~Psychiatric~~ nurse" means a registered nurse certified ~~licensed~~ under s. 464.012 ~~part I of chapter 464~~ who has a master's degree or a doctorate in psychiatric nursing and holds a national advanced practice certification as a psychiatric-mental health advanced practice nurse ~~2 years of post-master's clinical experience under the supervision of a physician~~.

(33) "Service provider" means any public or private receiving facility, an entity under contract with the Department of Children and Families ~~Family Services~~ to provide mental health services, a clinical psychologist, a clinical social worker, a marriage and family therapist, a mental health counselor, a physician, a psychiatric-mental health advanced practice registered ~~psychiatric~~ nurse ~~as defined in subsection (23)~~, or a community mental health center or clinic as defined in this part.

Section 7. Paragraphs (a) and (f) of subsection (2) of section 394.463, Florida Statutes, are amended to read:

394.463 Involuntary examination.—

(2) INVOLUNTARY EXAMINATION.—

(a) An involuntary examination may be initiated by any one

of the following means:

1. A court may enter an ex parte order stating that a person appears to meet the criteria for involuntary examination, giving the findings on which that conclusion is based. The ex parte order for involuntary examination must be based on sworn testimony, written or oral. If other less restrictive means are not available, such as voluntary appearance for outpatient evaluation, a law enforcement officer, or other designated agent of the court, shall take the person into custody and deliver him or her to the nearest receiving facility for involuntary examination. The order of the court shall be made a part of the patient's clinical record. A ~~No~~ fee may not ~~shall~~ be charged for the filing of an order under this subsection. Any receiving facility accepting the patient based on this order must send a copy of the order to the Agency for Health Care Administration on the next working day. The order shall be valid only until executed or, if not executed, for the period specified in the order itself. If no time limit is specified in the order, the order shall be valid for 7 days after the date that the order was signed.

2. A law enforcement officer shall take a person who appears to meet the criteria for involuntary examination into custody and deliver the person or have him or her delivered to the nearest receiving facility for examination. The officer shall execute a written report detailing the circumstances under which the person was taken into custody, and the report shall be made a part of the patient's clinical record. Any receiving facility accepting the patient based on this report must send a copy of the report to the Agency for Health Care Administration

on the next working day.

3. A physician, clinical psychologist, psychiatric-mental health advanced practice registered ~~psychiatric~~ nurse, mental health counselor, marriage and family therapist, or clinical social worker may execute a certificate stating that he or she has examined a person within the preceding 48 hours and finds that the person appears to meet the criteria for involuntary examination and stating the observations upon which that conclusion is based. If other less restrictive means are not available, such as voluntary appearance for outpatient evaluation, a law enforcement officer shall take the person named in the certificate into custody and deliver him or her to the nearest receiving facility for involuntary examination. The law enforcement officer shall execute a written report detailing the circumstances under which the person was taken into custody. The report and certificate shall be made a part of the patient's clinical record. Any receiving facility accepting the patient based on this certificate must send a copy of the certificate to the Agency for Health Care Administration on the next working day.

(f) A patient shall be examined by a physician or clinical psychologist 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, a clinical psychologist, or a psychiatric-mental health advanced practice registered nurse or, if the receiving facility is a hospital, the release

may also be approved by 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. However, a patient may not be held in a receiving facility for involuntary examination longer than 72 hours.

Section 8. Paragraph (a) of subsection (2) of section 397.501, Florida Statutes, is amended to read:

397.501 Rights of individuals.—Individuals receiving substance abuse services from any service provider are guaranteed protection of the rights specified in this section, unless otherwise expressly provided, and service providers must ensure the protection of such rights.

(2) RIGHT TO NONDISCRIMINATORY SERVICES.—

(a) Service providers may not deny an individual access to substance abuse services solely on the basis of race, gender, ethnicity, age, sexual preference, human immunodeficiency virus status, prior service departures against medical advice, disability, or number of relapse episodes. Service providers may not deny an individual who takes medication prescribed by a physician or an advanced practice registered nurse access to substance abuse services solely on that basis. Service providers who receive state funds to provide substance abuse services may not, if space and sufficient state resources are available, deny access to services based solely on inability to pay.

Section 9. Subsection (7) of section 456.013, Florida Statutes, is amended to read:

456.013 Department; general licensing provisions.—

(7) The boards, or the department when there is no board,

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shall require the completion, no later than upon first renewal, of a 2-hour course relating to prevention of medical errors as part of relicensure or recertification ~~the licensure and renewal process~~. The 2-hour course shall count towards the total number of continuing education hours required for the profession. The course shall be approved by the board or department, as appropriate, and shall include a study of root-cause analysis, error reduction and prevention, and patient safety. In addition, the course approved by the Board of Medicine and the Board of Osteopathic Medicine shall include information relating to the five most misdiagnosed conditions during the previous biennium, as determined by the board. If the course is being offered by a facility licensed pursuant to chapter 395 for its employees, the board may approve up to 1 hour of the 2-hour course to be specifically related to error reduction and prevention methods used in that facility.

Section 10. Paragraphs (a) and (b) of subsection (1) of section 456.031, Florida Statutes, are amended to read:

456.031 Requirement for instruction on domestic violence.—

(1)(a) The appropriate board shall require each person licensed or certified under chapter 458, chapter 459, part I of chapter 464, chapter 466, chapter 467, chapter 490, or chapter 491 to complete a 2-hour continuing education course, approved by the board, on domestic violence, as defined in s. 741.28, no later than upon first renewal, as part of ~~every third biennial~~ relicensure or recertification. The course shall consist of information on the number of patients in that professional's practice who are likely to be victims of domestic violence and the number who are likely to be perpetrators of domestic

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violence, screening procedures for determining whether a patient has any history of being either a victim or a perpetrator of domestic violence, and instruction on how to provide such patients with information on, or how to refer such patients to, resources in the local community, such as domestic violence centers and other advocacy groups, that provide legal aid, shelter, victim counseling, batterer counseling, or child protection services.

(b) Each ~~such~~ licensee or certificateholder shall submit confirmation of having completed the ~~such~~ course required under paragraph (a), on a form provided by the board, when submitting fees for first ~~every third biennial~~ renewal.

Section 11. Section 456.033, Florida Statutes, is repealed.

Section 12. Subsection (5) of section 456.053, Florida Statutes, is amended to read:

456.053 Financial arrangements between referring health care providers and providers of health care services.—

(5) PROHIBITED REFERRALS AND CLAIMS FOR PAYMENT.—Except as provided in this section:

(a) A health care provider may not refer a patient for the provision of designated health services to an entity in which the health care provider is an investor or has an investment interest unless:

1. The provider's investment interest is in registered securities purchased on a national exchange or in the over-the-counter market and issued by a publicly held corporation whose:

a. Shares are traded on a national exchange or in the over-the-counter market; and

b. Total assets at the end of the corporation's most recent

fiscal quarter exceeded $50 million.

2. The publicly held corporation does not loan funds to or guarantee a loan for an investor who is in a position to make referrals to the entity or corporation if the investor uses any part of such loan to obtain the investment interest.

(b) A health care provider may not refer a patient for the provision of any other health care item or service to an entity in which the health care provider is an investor unless:

1. The provider's investment interest is in registered securities purchased on a national exchange or over-the-counter market and issued by a publicly held corporation whose:

a. ~~Whose~~ Shares are traded on a national exchange or on the over-the-counter market; and

b. ~~Whose~~ Total assets at the end of the corporation's most recent fiscal quarter exceeded $50 million; or

2. With respect to an entity other than a publicly held corporation described in subparagraph 1., and a referring provider's investment interest in such entity, each of the following requirements is ~~are~~ met:

a. No more than 50 percent of the value of the investment interests are held by investors who are in a position to make referrals to the entity.

b. The terms under which an investment interest is offered to an investor who is in a position to make referrals to the entity are no different from the terms offered to investors who are not in a position to make such referrals.

c. The terms under which an investment interest is offered to an investor who is in a position to make referrals to the entity are not related to the previous or expected volume of

referrals from that investor to the entity.

d. There is no requirement that an investor make referrals or be in a position to make referrals to the entity as a condition for becoming or remaining an investor.

3. With respect to either such entity or publicly held corporation:

a. The entity or corporation does not loan funds to or guarantee a loan for an investor who is in a position to make referrals to the entity or corporation if the investor uses any part of such loan to obtain the investment interest.

b. The amount distributed to an investor representing a return on the investment interest is directly proportional to the amount of the capital investment, including the fair market value of any preoperational services rendered, invested in the entity or corporation by that investor.

(c) ~~4.~~ Each board and, in the case of hospitals, the Agency for Health Care Administration~~,~~ shall encourage the use by licensees of the declaratory statement procedure to determine the applicability of this section or any rule adopted pursuant to this section as it applies solely to the licensee. Boards shall submit to the Agency for Health Care Administration the name of any entity in which a provider investment interest has been approved pursuant to this section.

(d) ~~(c)~~ A ~~No~~ claim for payment may not be presented by an entity to any individual, third-party payor, or other entity for a service furnished pursuant to a referral prohibited under this section.

(e) ~~(d)~~ If an entity collects any amount that was billed in violation of this section, the entity shall refund such amount

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on a timely basis to the payor or individual, whichever is applicable.

(f) ~~(e)~~ A ~~Any~~ person who ~~that~~ presents or causes to be presented a bill or a claim for service that such person knows or should know is for a service for which payment may not be made under paragraph (d) ~~(c)~~, or for which a refund has not been made under paragraph (e) ~~(d)~~, shall be subject to a civil penalty of not more than $15,000 for each such service to be imposed and collected by the appropriate board.

(g) ~~(f)~~ Any health care provider or other entity that enters into an arrangement or scheme, such as a cross-referral arrangement, which the physician or entity knows or should know has a principal purpose of assuring referrals by the physician to a particular entity which, if the physician directly made referrals to such entity, would be in violation of this section, shall be subject to a civil penalty of not more than $100,000 for each such circumvention arrangement or scheme to be imposed and collected by the appropriate board.

(h) ~~(g)~~ A violation of this section by a health care provider shall constitute grounds for disciplinary action to be taken by the applicable board pursuant to s. 458.331(2), s. 459.015(2), s. 460.413(2), s. 461.013(2), s. 463.016(2), or s. 466.028(2). Any hospital licensed under chapter 395 found in violation of this section shall be subject to s. 395.0185(2).

(i) ~~(h)~~ A ~~Any~~ hospital licensed under chapter 395 may not discriminate ~~that discriminates~~ against or otherwise penalize ~~penalizes~~ a health care provider for compliance with this act.

(j) ~~(i) The provision of~~ Paragraph (a) does ~~shall~~ not apply to referrals to the offices of radiation therapy centers managed

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by an entity or subsidiary or general partner thereof, which performed radiation therapy services at those same offices prior to April 1, 1991, or ~~and shall not apply also~~ to referrals for radiation therapy to be performed at no more than one additional office of any entity qualifying for the foregoing exception which, prior to February 1, 1992, had a binding purchase contract on and a nonrefundable deposit paid for a linear accelerator to be used at the additional office. The physical site of the radiation treatment centers affected by this provision may be relocated as a result of the following factors: acts of God; fire; strike; accident; war; eminent domain actions by any governmental body; or refusal by the lessor to renew a lease. A relocation for the foregoing reasons is limited to relocation of an existing facility to a replacement location within the county of the existing facility upon written notification to the Office of Licensure and Certification.

(k) ~~(j)~~ A health care provider who meets the requirements of paragraph (a), paragraph ~~paragraphs~~ (b), or paragraph (j) ~~and (i)~~ must disclose his or her investment interest to his or her patients as provided in s. 456.052.

Section 13. Subsection (17) of section 456.057, Florida Statutes, is amended to read:

456.057 Ownership and control of patient records; report or copies of records to be furnished; disclosure of information.—

(17) A health care practitioner or records owner furnishing copies of reports or records or making the reports or records available for digital scanning pursuant to this section shall charge no more than the actual cost of copying, including reasonable staff time, or the amount specified in administrative

rule by the appropriate board, or the department when there is no board. The rates charged for reproduction of written or typed medical records must be the same regardless of format or medium.

Section 14. 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 or advanced practice registered nurse 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), s. 464.018(1)(p)6., or s. 466.028(1)(p) or (x), the physician or advanced practice registered nurse 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 15. 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 or an advanced practice registered nurse 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 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,

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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 practitioner ~~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 practitioner ~~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 practitioner ~~physician~~ shall use a written controlled substance agreement between the practitioner ~~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 practitioner ~~physician~~ unless otherwise authorized by the treating practitioner ~~physician~~ and documented in the medical record.

(d) The patient shall be seen by the practitioner ~~physician~~

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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 practitioner's ~~physician's~~ evaluation of the patient's progress. If treatment goals are not being achieved, despite medication adjustments, the practitioner ~~physician~~ shall reevaluate the appropriateness of continued treatment. The practitioner ~~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 practitioner ~~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 practitioner ~~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 practitioner'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 practitioner 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 practitioner ~~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 practitioner ~~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 practitioner ~~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 physician or advanced practice registered nurse who prescribes medically necessary controlled substances for a patient during an inpatient stay in a hospital licensed under chapter 395.

Section 16. Subsections (1), (2), and (4) 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 practice 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 practice registered nurse(s) ~~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;

STANDARDS.—The joint committee created under s. 464.003(2) shall determine minimum standards for the content of established protocols pursuant to which an advanced practice 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.

(4) SUPERVISORY RELATIONSHIPS IN MEDICAL OFFICE SETTINGS.—A physician who supervises an advanced practice registered nurse ~~practitioner~~ or physician assistant at a medical office other than the physician's primary practice location, where the advanced practice registered nurse ~~practitioner~~ or physician assistant is not under the onsite supervision of a supervising physician, must comply with the standards set forth in this subsection. For the purpose of this subsection, a physician's "primary practice location" means the address reflected on the physician's profile published pursuant to s. 456.041.

(a) A physician who is engaged in providing primary health care services may not supervise more than four offices in

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addition to the physician's primary practice location. For the purpose of this subsection, "primary health care" means health care services that are commonly provided to patients without referral from another practitioner, including obstetrical and gynecological services, and excludes practices providing primarily dermatologic and skin care services, which include aesthetic skin care services.

(b) A physician who is engaged in providing specialty health care services may not supervise more than two offices in addition to the physician's primary practice location. For the purpose of this subsection, "specialty health care" means health care services that are commonly provided to patients with a referral from another practitioner and excludes practices providing primarily dermatologic and skin care services, which include aesthetic skin care services.

(c) A physician who supervises an advanced practice registered nurse ~~practitioner~~ or physician assistant at a medical office other than the physician's primary practice location, where the advanced practice registered nurse ~~practitioner~~ or physician assistant is not under the onsite supervision of a supervising physician and the services offered at the office are primarily dermatologic or skin care services, which include aesthetic skin care services other than plastic surgery, must comply with the standards listed in subparagraphs 1.-4. Notwithstanding s. 458.347(4)(e)6., a physician supervising a physician assistant pursuant to this paragraph may not be required to review and cosign charts or medical records prepared by such physician assistant.

1. The physician shall submit to the board the addresses of

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all offices where he or she is supervising an advanced practice registered nurse ~~practitioner~~ or a physician's assistant which are not the physician's primary practice location.

2. The physician must be board certified or board eligible in dermatology or plastic surgery as recognized by the board pursuant to s. 458.3312.

3. All such offices that are not the physician's primary place of practice must be within 25 miles of the physician's primary place of practice or in a county that is contiguous to the county of the physician's primary place of practice. However, the distance between any of the offices may not exceed 75 miles.

4. The physician may supervise only one office other than the physician's primary place of practice ~~except that until July 1, 2011, the physician may supervise up to two medical offices other than the physician's primary place of practice if the addresses of the offices are submitted to the board before July 1, 2006. Effective July 1, 2011, the physician may supervise only one office other than the physician's primary place of practice, regardless of when the addresses of the offices were submitted to the board~~.

(d) A physician who supervises an office in addition to the physician's primary practice location must conspicuously post in each of the physician's offices a current schedule of the regular hours when the physician is present in that office and the hours when the office is open while the physician is not present.

(e) This subsection does not apply to health care services provided in facilities licensed under chapter 395 or in

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conjunction with a college of medicine, a college of nursing, an accredited graduate medical program, or a nursing education program; not-for-profit, family-planning clinics that are not licensed pursuant to chapter 390; rural and federally qualified health centers; health care services provided in a nursing home licensed under part II of chapter 400, an assisted living facility licensed under part I of chapter 429, a continuing care facility licensed under chapter 651, or a retirement community consisting of independent living units and a licensed nursing home or assisted living facility; anesthesia services provided in accordance with law; health care services provided in a designated rural health clinic; health care services provided to persons enrolled in a program designed to maintain elderly persons and persons with disabilities in a home or community-based setting; university primary care student health centers; school health clinics; or health care services provided in federal, state, or local government facilities. Subsection (3) and this subsection do not apply to offices at which the exclusive service being performed is laser hair removal by an advanced practice registered nurse ~~practitioner~~ or physician assistant.

Section 17. Subsection (3) of section 458.3485, Florida Statutes, is amended to read:

458.3485 Medical assistant.—

~~(3) CERTIFICATION.—Medical assistants may be certified by the American Association of Medical Assistants or as a Registered Medical Assistant by the American Medical Technologists.~~

Section 18. Subsections (1) and (3) of section 459.025,

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Florida Statutes, are 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 practice 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 practice registered nurse(s) ~~nurse practitioner(s)~~.

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

(3) SUPERVISORY RELATIONSHIPS IN MEDICAL OFFICE SETTINGS.—An osteopathic physician who supervises an advanced practice registered nurse ~~practitioner~~ or physician assistant at a medical office other than the osteopathic physician's primary practice location, where the advanced practice registered nurse ~~practitioner~~ or physician assistant is not under the onsite supervision of a supervising osteopathic physician, must comply with the standards set forth in this subsection. For the purpose of this subsection, an osteopathic physician's "primary practice location" means the address reflected on the physician's profile published pursuant to s. 456.041.

(a) An osteopathic physician who is engaged in providing primary health care services may not supervise more than four offices in addition to the osteopathic physician's primary practice location. For the purpose of this subsection, "primary health care" means health care services that are commonly provided to patients without referral from another practitioner, including obstetrical and gynecological services, and excludes practices providing primarily dermatologic and skin care services, which include aesthetic skin care services.

(b) An osteopathic physician who is engaged in providing specialty health care services may not supervise more than two offices in addition to the osteopathic physician's primary practice location. For the purpose of this subsection, "specialty health care" means health care services that are commonly provided to patients with a referral from another practitioner and excludes practices providing primarily dermatologic and skin care services, which include aesthetic skin care services.

(c) An osteopathic physician who supervises an advanced practice registered nurse ~~practitioner~~ or physician assistant at a medical office other than the osteopathic physician's primary practice location, where the advanced practice registered nurse ~~practitioner~~ or physician assistant is not under the onsite supervision of a supervising osteopathic physician and the services offered at the office are primarily dermatologic or skin care services, which include aesthetic skin care services other than plastic surgery, must comply with the standards listed in subparagraphs 1.-4. Notwithstanding s. 459.022(4)(e)6., an osteopathic physician supervising a physician assistant pursuant to this paragraph may not be required to review and cosign charts or medical records prepared by such physician assistant.

1. The osteopathic physician shall submit to the Board of Osteopathic Medicine the addresses of all offices where he or she is supervising or has a protocol with an advanced practice registered nurse ~~practitioner~~ or a physician's assistant which are not the osteopathic physician's primary practice location.

2. The osteopathic physician must be board certified or board eligible in dermatology or plastic surgery as recognized by the Board of Osteopathic Medicine pursuant to s. 459.0152.

3. All such offices that are not the osteopathic physician's primary place of practice must be within 25 miles of the osteopathic physician's primary place of practice or in a county that is contiguous to the county of the osteopathic physician's primary place of practice. However, the distance between any of the offices may not exceed 75 miles.

4. The osteopathic physician may supervise only one office

other than the osteopathic physician's primary place of practice ~~except that until July 1, 2011, the osteopathic physician may supervise up to two medical offices other than the osteopathic physician's primary place of practice if the addresses of the offices are submitted to the Board of Osteopathic Medicine before July 1, 2006. Effective July 1, 2011, the osteopathic physician may supervise only one office other than the osteopathic physician's primary place of practice, regardless of when the addresses of the offices were submitted to the Board of Osteopathic Medicine~~.

(d) An osteopathic physician who supervises an office in addition to the osteopathic physician's primary practice location must conspicuously post in each of the osteopathic physician's offices a current schedule of the regular hours when the osteopathic physician is present in that office and the hours when the office is open while the osteopathic physician is not present.

(e) This subsection does not apply to health care services provided in facilities licensed under chapter 395 or in conjunction with a college of medicine or college of nursing or an accredited graduate medical or nursing education program; offices where the only service being performed is hair removal by an advanced practice registered nurse ~~practitioner~~ or physician assistant; not-for-profit, family-planning clinics that are not licensed pursuant to chapter 390; rural and federally qualified health centers; health care services provided in a nursing home licensed under part II of chapter 400, an assisted living facility licensed under part I of chapter 429, a continuing care facility licensed under chapter

651, or a retirement community consisting of independent living units and either a licensed nursing home or assisted living facility; anesthesia services provided in accordance with law; health care services provided in a designated rural health clinic; health care services provided to persons enrolled in a program designed to maintain elderly persons and persons with disabilities in a home or community-based setting; university primary care student health centers; school health clinics; or health care services provided in federal, state, or local government facilities.

Section 19. Section 464.012, Florida Statutes, is amended to read:

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

(1) Any nurse desiring to be certified as an advanced practice 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 practice registered nurses ~~nurse practitioners~~ in the categories of certified registered nurse anesthetist, certified nurse midwife, and certified nurse practitioner.

(3) An advanced practice 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 practice registered nurse ~~practitioner~~ may:

(a) Prescribe, dispense, administer, or order drugs. As used in this paragraph, the term "drugs" includes controlled substances.

(b) ~~(a)~~ Monitor and alter drug therapies.

(c) ~~(b)~~ Initiate appropriate therapies for certain conditions.

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

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

(4) In addition to the general functions specified in subsection (3), an advanced practice 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.

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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

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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 certified 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 appoint a committee to recommend

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whether a formulary of controlled substances that an advanced practice registered nurse may not prescribe or may prescribe only for specific uses or subject to specific limitations is necessary to protect the health, safety, and welfare of the public. The committee shall consist of at least three advanced practice registered nurses, including a certified registered nurse anesthetist, a certified nurse midwife, and a certified nurse practitioner; at least one physician recommended by the Board of Medicine, and one physician recommended by the Board of Osteopathic Medicine, who have had work experience with advanced practice registered nurses; and a pharmacist licensed under chapter 465, but not licensed under chapter 458, chapter 459, or this chapter, who shall be selected by the State Surgeon General. The committee may recommend a formulary applicable to all advanced practice registered nurses, limited by specialty certification, limited to approved uses of controlled substances, or subject to other similar restriction it deems necessary to protect the health, safety, and welfare of the public.

(b) The board shall adopt any formulary required under this subsection by rule. Only the board may add to, delete from, or modify the formulary. A person who requests the addition, deletion, or modification of a controlled substance listed on the formulary has the burden of proof to show cause why the change should be made. The board shall post notice of any proposed, pending, or adopted changes to the formulary on its website.

(c) The board shall initiate rulemaking, if required to implement the committee's initial recommendation, no later than

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October 1, 2014.

Section 20. Present subsections (8) through (10) of section 464.015, Florida Statutes, are renumbered as subsections (9) through (11), respectively, and amended, and a new subsection (8) is added to that section, to read:

464.015 Titles and abbreviations; restrictions; penalty.—

(8) Only persons who hold valid certificates to practice as certified nurse practitioners in this state may use the title "Certified Nurse Practitioner" and use the abbreviations "C.N.P." and "nurse practitioner."

(9) ~~(8)~~ Only persons who hold valid certificates to practice as advanced practice registered nurses ~~nurse practitioners~~ in this state may use the title "Advanced Practice Registered Nurse ~~Practitioner~~" and the abbreviation "A.P.R.N." ~~"A.R.N.P."~~

(10) ~~(9)~~ A person may not practice or advertise as, or assume the title of, registered nurse, licensed practical nurse, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, or advanced practice registered nurse ~~practitioner~~ or use the abbreviation "R.N.," "L.P.N.," "C.N.S.," "C.R.N.A.," "C.N.M.," "C.N.P.," or "A.P.R.N." ~~"A.R.N.P."~~ or take any other action that would lead the public to believe that person was certified as such or is performing nursing services pursuant to the exception set forth in s. 464.022(8), unless that person is licensed or certified to practice as such.

(11) ~~(10)~~ A violation of this section is a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

Section 21. Paragraphs (p) and (q) are added to subsection

(1) of section 464.018, Florida Statutes, 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 only an advanced practice registered nurse:

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 sympathomimetic amine drug, or a compound designated pursuant to chapter 893 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, 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. For the purposes of this subsection, the term "muscle building" does not include the treatment of injured muscle. A prescription written for the drug products listed above may be dispensed by the pharmacist with the presumption that the prescription is for legitimate medical use.

5. Promoting or advertising on any prescription form of 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 paragraph, it shall be 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 practice registered nurse's professional practice, without regard to his or her intent.

7. Prescribing, dispensing, or administering a medicinal drug appearing on a schedule set forth in chapter 893 to himself or herself, except a drug prescribed, dispensed, or administered to the advanced practice registered nurse 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 controlled substance listed in Schedule II

or Schedule III of chapter 893 in violation of s. 465.0276.

10. Promoting or advertising through any communication medium the use, sale, or dispensing of a controlled substance appearing on a schedule in chapter 893.

Section 22. Subsection (7) of section 464.203, Florida Statutes, is amended to read:

464.203 Certified nursing assistants; certification requirement.—

~~(7) A certified nursing assistant shall complete 12 hours of inservice training during each calendar year. The certified nursing assistant shall be responsible for maintaining documentation demonstrating compliance with these provisions. The Council on Certified Nursing Assistants, in accordance with s. 464.2085(2)(b), shall propose rules to implement this subsection.~~

Section 23. 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 pursuant to chapter 458, a dentist licensed pursuant to chapter 466, a veterinarian licensed pursuant to chapter 474, an osteopathic physician licensed pursuant to chapter 459, an advanced practice registered nurse certified pursuant to chapter 464, a naturopath licensed pursuant to chapter 462, a certified optometrist licensed pursuant to chapter 463, or a podiatric physician licensed pursuant to chapter 461, provided such practitioner holds a valid federal controlled substance registry number.

Section 24. 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 or advanced practice registered nurse. The probationer or community controllee shall not knowingly visit places where intoxicants, drugs, or other dangerous substances are unlawfully sold, dispensed, or used.

Section 25. Subsections (3) and (4) of section 39.303, Florida Statutes, are amended to read:

39.303 Child protection teams; services; eligible cases.—The Children's Medical Services Program in the Department of Health shall develop, maintain, and coordinate the services of one or more multidisciplinary child protection teams in each of the service districts of the Department of Children and Family Services. Such teams may be composed of appropriate representatives of school districts and appropriate health, mental health, social service, legal service, and law enforcement agencies. The Legislature finds that optimal coordination of child protection teams and sexual abuse treatment programs requires collaboration between the Department of Health and the Department of Children and Family Services.

The two departments shall maintain an interagency agreement that establishes protocols for oversight and operations of child protection teams and sexual abuse treatment programs. The State Surgeon General and the Deputy Secretary for Children's Medical Services, in consultation with the Secretary of Children and Family Services, shall maintain the responsibility for the screening, employment, and, if necessary, the termination of child protection team medical directors, at headquarters and in the 15 districts. Child protection team medical directors shall be responsible for oversight of the teams in the districts.

(3) All abuse and neglect cases transmitted for investigation to a district by the hotline must be simultaneously transmitted to the Department of Health child protection team for review. For the purpose of determining whether face-to-face medical evaluation by a child protection team is necessary, all cases transmitted to the child protection team which meet the criteria in subsection (2) must be timely reviewed by:

(a) A physician licensed under chapter 458 or chapter 459 who holds board certification in pediatrics and is a member of a child protection team;

(b) A physician licensed under chapter 458 or chapter 459 who holds board certification in a specialty other than pediatrics, who may complete the review only when working under the direction of a physician licensed under chapter 458 or chapter 459 who holds board certification in pediatrics and is a member of a child protection team;

(c) An advanced practice registered nurse ~~practitioner~~ licensed under chapter 464 who has a specialty ~~speciality~~ in

pediatrics or family medicine and is a member of a child protection team;

(d) A physician assistant licensed under chapter 458 or chapter 459, who may complete the review only when working under the supervision of a physician licensed under chapter 458 or chapter 459 who holds board certification in pediatrics and is a member of a child protection team; or

(e) A registered nurse licensed under chapter 464, who may complete the review only when working under the direct supervision of a physician licensed under chapter 458 or chapter 459 who holds certification in pediatrics and is a member of a child protection team.

(4) A face-to-face medical evaluation by a child protection team is not necessary when:

(a) The child was examined for the alleged abuse or neglect by a physician who is not a member of the child protection team, and a consultation between the child protection team board-certified pediatrician, advanced practice registered nurse ~~practitioner~~, physician assistant working under the supervision of a child protection team board-certified pediatrician, or registered nurse working under the direct supervision of a child protection team board-certified pediatrician, and the examining physician concludes that a further medical evaluation is unnecessary;

(b) The child protective investigator, with supervisory approval, has determined, after conducting a child safety assessment, that there are no indications of injuries as described in paragraphs (2)(a)-(h) as reported; or

(c) The child protection team board-certified pediatrician,

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as authorized in subsection (3), determines that a medical evaluation is not required.

Notwithstanding paragraphs (a), (b), and (c), a child protection team pediatrician, as authorized in subsection (3), may determine that a face-to-face medical evaluation is necessary.

Section 26. Paragraph (b) of subsection (1) of section 39.304, Florida Statutes, is amended to read:

39.304 Photographs, medical examinations, X rays, and medical treatment of abused, abandoned, or neglected child.—

(1)

(b) If the areas of trauma visible on a child indicate a need for a medical examination, or if the child verbally complains or otherwise exhibits distress as a result of injury through suspected child abuse, abandonment, or neglect, or is alleged to have been sexually abused, the person required to investigate may cause the child to be referred for diagnosis to a licensed physician or an emergency department in a hospital without the consent of the child's parents or legal custodian. Such examination may be performed by any licensed physician or an advanced practice registered nurse ~~practitioner~~ licensed pursuant to part I of chapter 464. Any licensed physician, or advanced practice registered nurse ~~practitioner~~ licensed pursuant to part I of chapter 464, who has reasonable cause to suspect that an injury was the result of child abuse, abandonment, or neglect may authorize a radiological examination to be performed on the child without the consent of the child's parent or legal custodian.

Section 27. Paragraph (a) of subsection (1) of section

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90.503, Florida Statutes, is amended to read:

90.503 Psychotherapist-patient privilege.—

(1) For purposes of this section:

(a) A "psychotherapist" is:

1. A person authorized to practice medicine in any state or nation, or reasonably believed by the patient so to be, who is engaged in the diagnosis or treatment of a mental or emotional condition, including alcoholism and other drug addiction;

2. A person licensed or certified as a psychologist under the laws of any state or nation, who is engaged primarily in the diagnosis or treatment of a mental or emotional condition, including alcoholism and other drug addiction;

3. A person licensed or certified as a clinical social worker, marriage and family therapist, or mental health counselor under the laws of this state, who is engaged primarily in the diagnosis or treatment of a mental or emotional condition, including alcoholism and other drug addiction;

4. Treatment personnel of facilities licensed by the state pursuant to chapter 394, chapter 395, or chapter 397, of facilities designated by the Department of Children and Families ~~Family Services~~ pursuant to chapter 394 as treatment facilities, or of facilities defined as community mental health centers pursuant to s. 394.907(1), who are engaged primarily in the diagnosis or treatment of a mental or emotional condition, including alcoholism and other drug addiction; or

5. An advanced practice registered nurse ~~practitioner~~ certified under s. 464.012, whose primary scope of practice is the diagnosis or treatment of mental or emotional conditions, including chemical abuse, and limited only to actions performed

in accordance with part I of chapter 464.

Section 28. Paragraph (e) of subsection (8) of section 112.0455, Florida Statutes, is amended to read:

112.0455 Drug-Free Workplace Act.—

(8) PROCEDURES AND EMPLOYEE PROTECTION.—All specimen collection and testing for drugs under this section shall be performed in accordance with the following procedures:

(e) A specimen for a drug test may be taken or collected by any of the following persons:

1. A physician, a physician's assistant, a registered professional nurse, a licensed practical nurse, an advanced practice registered ~~a~~ nurse ~~practitioner~~, or a certified paramedic who is present at the scene of an accident for the purpose of rendering emergency medical service or treatment.

2. A qualified person employed by a licensed laboratory.

Section 29. Subsection (3) of section 121.0515, Florida Statutes, is amended to read:

121.0515 Special Risk Class.—

(3) CRITERIA.—A member, to be designated as a special risk member, must meet the following criteria:

(a) Effective October 1, 1978, the member must be employed as a law enforcement officer and be certified, or required to be certified, in compliance with s. 943.1395; however, sheriffs and elected police chiefs are excluded from meeting the certification requirements of this paragraph. In addition, the member's duties and responsibilities must include the pursuit, apprehension, and arrest of law violators or suspected law violators; or as of July 1, 1982, the member must be an active member of a bomb disposal unit whose primary responsibility is

the location, handling, and disposal of explosive devices; or the member must be the supervisor or command officer of a member or members who have such responsibilities. Administrative support personnel, including, but not limited to, those whose primary duties and responsibilities are in accounting, purchasing, legal, and personnel, are not included;

(b) Effective October 1, 1978, the member must be employed as a firefighter and be certified, or required to be certified, in compliance with s. 633.408 and be employed solely within the fire department of a local government employer or an agency of state government with firefighting responsibilities. In addition, the member's duties and responsibilities must include on-the-scene fighting of fires; as of October 1, 2001, fire prevention or firefighter training; as of October 1, 2001, direct supervision of firefighting units, fire prevention, or firefighter training; or as of July 1, 2001, aerial firefighting surveillance performed by fixed-wing aircraft pilots employed by the Florida Forest Service of the Department of Agriculture and Consumer Services; or the member must be the supervisor or command officer of a member or members who have such responsibilities. Administrative support personnel, including, but not limited to, those whose primary duties and responsibilities are in accounting, purchasing, legal, and personnel, are not included. All periods of creditable service in fire prevention or firefighter training, or as the supervisor or command officer of a member or members who have such responsibilities, and for which the employer paid the special risk contribution rate, are included;

(c) Effective October 1, 1978, the member must be employed

as a correctional officer and be certified, or required to be certified, in compliance with s. 943.1395. In addition, the member's primary duties and responsibilities must be the custody, and physical restraint when necessary, of prisoners or inmates within a prison, jail, or other criminal detention facility, or while on work detail outside the facility, or while being transported; or as of July 1, 1984, the member must be the supervisor or command officer of a member or members who have such responsibilities. Administrative support personnel, including, but not limited to, those whose primary duties and responsibilities are in accounting, purchasing, legal, and personnel, are not included; however, wardens and assistant wardens, as defined by rule, are included;

(d) Effective October 1, 1999, the member must be employed by a licensed Advance Life Support (ALS) or Basic Life Support (BLS) employer as an emergency medical technician or a paramedic and be certified in compliance with s. 401.27. In addition, the member's primary duties and responsibilities must include on-the-scene emergency medical care or as of October 1, 2001, direct supervision of emergency medical technicians or paramedics, or the member must be the supervisor or command officer of one or more members who have such responsibility. Administrative support personnel, including, but not limited to, those whose primary responsibilities are in accounting, purchasing, legal, and personnel, are not included;

(e) Effective January 1, 2001, the member must be employed as a community-based correctional probation officer and be certified, or required to be certified, in compliance with s. 943.1395. In addition, the member's primary duties and

responsibilities must be the supervised custody, surveillance, control, investigation, and counseling of assigned inmates, probationers, parolees, or community controllees within the community; or the member must be the supervisor of a member or members who have such responsibilities. Administrative support personnel, including, but not limited to, those whose primary duties and responsibilities are in accounting, purchasing, legal services, and personnel management, are not included; however, probation and parole circuit and deputy circuit administrators are included;

(f) Effective January 1, 2001, the member must be employed in one of the following classes and must spend at least 75 percent of his or her time performing duties which involve contact with patients or inmates in a correctional or forensic facility or institution:

1. Dietitian (class codes 5203 and 5204);
2. Public health nutrition consultant (class code 5224);
3. Psychological specialist (class codes 5230 and 5231);
4. Psychologist (class code 5234);
5. Senior psychologist (class codes 5237 and 5238);
6. Regional mental health consultant (class code 5240);
7. Psychological Services Director—DCF (class code 5242);
8. Pharmacist (class codes 5245 and 5246);
9. Senior pharmacist (class codes 5248 and 5249);
10. Dentist (class code 5266);
11. Senior dentist (class code 5269);
12. Registered nurse (class codes 5290 and 5291);
13. Senior registered nurse (class codes 5292 and 5293);
14. Registered nurse specialist (class codes 5294 and

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5295);

15. Clinical associate (class codes 5298 and 5299);
16. Advanced practice registered nurse ~~practitioner~~ (class codes 5297 and 5300);
17. Advanced practice registered nurse ~~practitioner~~ specialist (class codes 5304 and 5305);
18. Registered nurse supervisor (class codes 5306 and 5307);
19. Senior registered nurse supervisor (class codes 5308 and 5309);
20. Registered nursing consultant (class codes 5312 and 5313);
21. Quality management program supervisor (class code 5314);
22. Executive nursing director (class codes 5320 and 5321);
23. Speech and hearing therapist (class code 5406); or
24. Pharmacy manager (class code 5251);

(g) Effective July 1, 2001, the member must be employed as a youth custody officer and be certified, or required to be certified, in compliance with s. 943.1395. In addition, the member's primary duties and responsibilities must be the supervised custody, surveillance, control, investigation, apprehension, arrest, and counseling of assigned juveniles within the community;

(h) Effective October 1, 2005, through June 30, 2008, the member must be employed by a law enforcement agency or medical examiner's office in a forensic discipline recognized by the International Association for Identification and must qualify for active membership in the International Association for

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Identification. The member's primary duties and responsibilities must include the collection, examination, preservation, documentation, preparation, or analysis of physical evidence or testimony, or both, or the member must be the direct supervisor, quality management supervisor, or command officer of one or more individuals with such responsibility. Administrative support personnel, including, but not limited to, those whose primary responsibilities are clerical or in accounting, purchasing, legal, and personnel, are not included;

(i) Effective July 1, 2008, the member must be employed by the Department of Law Enforcement in the crime laboratory or by the Division of State Fire Marshal in the forensic laboratory in one of the following classes:

1. Forensic technologist (class code 8459);

2. Crime laboratory technician (class code 8461);

3. Crime laboratory analyst (class code 8463);

4. Senior crime laboratory analyst (class code 8464);

5. Crime laboratory analyst supervisor (class code 8466);

6. Forensic chief (class code 9602); or

7. Forensic services quality manager (class code 9603);

(j) Effective July 1, 2008, the member must be employed by a local government law enforcement agency or medical examiner's office and must spend at least 65 percent of his or her time performing duties that involve the collection, examination, preservation, documentation, preparation, or analysis of human tissues or fluids or physical evidence having potential biological, chemical, or radiological hazard or contamination, or use chemicals, processes, or materials that may have carcinogenic or health-damaging properties in the analysis of

such evidence, or the member must be the direct supervisor of one or more individuals having such responsibility. If a special risk member changes to another position within the same agency, he or she must submit a complete application as provided in paragraph (4)(a); or

(k) The member must have already qualified for and be actively participating in special risk membership under paragraph (a), paragraph (b), or paragraph (c), must have suffered a qualifying injury as defined in this paragraph, must not be receiving disability retirement benefits as provided in s. 121.091(4), and must satisfy the requirements of this paragraph.

1. The ability to qualify for the class of membership defined in paragraph (2)(i) occurs when two licensed medical physicians, one of whom is a primary treating physician of the member, certify the existence of the physical injury and medical condition that constitute a qualifying injury as defined in this paragraph and that the member has reached maximum medical improvement after August 1, 2008. The certifications from the licensed medical physicians must include, at a minimum, that the injury to the special risk member has resulted in a physical loss, or loss of use, of at least two of the following: left arm, right arm, left leg, or right leg; and:

a. That this physical loss or loss of use is total and permanent, except if the loss of use is due to a physical injury to the member's brain, in which event the loss of use is permanent with at least 75 percent loss of motor function with respect to each arm or leg affected.

b. That this physical loss or loss of use renders the

member physically unable to perform the essential job functions of his or her special risk position.

c. That, notwithstanding this physical loss or loss of use, the individual can perform the essential job functions required by the member's new position, as provided in subparagraph 3.

d. That use of artificial limbs is not possible or does not alter the member's ability to perform the essential job functions of the member's position.

e. That the physical loss or loss of use is a direct result of a physical injury and not a result of any mental, psychological, or emotional injury.

2. For the purposes of this paragraph, "qualifying injury" means an injury sustained in the line of duty, as certified by the member's employing agency, by a special risk member that does not result in total and permanent disability as defined in s. 121.091(4)(b). An injury is a qualifying injury if the injury is a physical injury to the member's physical body resulting in a physical loss, or loss of use, of at least two of the following: left arm, right arm, left leg, or right leg. Notwithstanding any other provision of this section, an injury that would otherwise qualify as a qualifying injury is not considered a qualifying injury if and when the member ceases employment with the employer for whom he or she was providing special risk services on the date the injury occurred.

3. The new position, as described in sub-subparagraph 1.c., that is required for qualification as a special risk member under this paragraph is not required to be a position with essential job functions that entitle an individual to special risk membership. Whether a new position as described in sub-

subparagraph 1.c. exists and is available to the special risk member is a decision to be made solely by the employer in accordance with its hiring practices and applicable law.

4. This paragraph does not grant or create additional rights for any individual to continued employment or to be hired or rehired by his or her employer that are not already provided within the Florida Statutes, the State Constitution, the Americans with Disabilities Act, if applicable, or any other applicable state or federal law.

Section 30. Paragraph (a) of subsection (3) of section 252.515, Florida Statutes, is amended to read:

252.515 Postdisaster Relief Assistance Act; immunity from civil liability.—

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

(a) "Emergency first responder" means:

1. A physician licensed under chapter 458.

2. An osteopathic physician licensed under chapter 459.

3. A chiropractic physician licensed under chapter 460.

4. A podiatric physician licensed under chapter 461.

5. A dentist licensed under chapter 466.

6. An advanced practice registered nurse ~~practitioner~~ certified under s. 464.012.

7. A physician assistant licensed under s. 458.347 or s. 459.022.

8. A worker employed by a public or private hospital in the state.

9. A paramedic as defined in s. 401.23(17).

10. An emergency medical technician as defined in s. 401.23(11).

11. A firefighter as defined in s. 633.102.

12. A law enforcement officer as defined in s. 943.10.

13. A member of the Florida National Guard.

14. Any other personnel designated as emergency personnel by the Governor pursuant to a declared emergency.

Section 31. Paragraph (b) of subsection (1) of section 381.00315, Florida Statutes, is amended to read:

381.00315 Public health advisories; public health emergencies; quarantines.—The State Health Officer is responsible for declaring public health emergencies and quarantines and issuing public health advisories.

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

(b) "Public health emergency" means any occurrence, or threat thereof, whether natural or manmade ~~man made~~, which results or may result in substantial injury or harm to the public health from infectious disease, chemical agents, nuclear agents, biological toxins, or situations involving mass casualties or natural disasters. Prior to declaring a public health emergency, the State Health Officer shall, to the extent possible, consult with the Governor and shall notify the Chief of Domestic Security. The declaration of a public health emergency shall continue until the State Health Officer finds that the threat or danger has been dealt with to the extent that the emergency conditions no longer exist and he or she terminates the declaration. However, a declaration of a public health emergency may not continue for longer than 60 days unless the Governor concurs in the renewal of the declaration. The State Health Officer, upon declaration of a public health emergency, may take actions that are necessary to protect the

public health. Such actions include, but are not limited to:

1. Directing manufacturers of prescription drugs or over-the-counter drugs who are permitted under chapter 499 and wholesalers of prescription drugs located in this state who are permitted under chapter 499 to give priority to the shipping of specified drugs to pharmacies and health care providers within geographic areas that have been identified by the State Health Officer. The State Health Officer must identify the drugs to be shipped. Manufacturers and wholesalers located in the state must respond to the State Health Officer's priority shipping directive before shipping the specified drugs.

2. Notwithstanding chapters 465 and 499 and rules adopted thereunder, directing pharmacists employed by the department to compound bulk prescription drugs and provide these bulk prescription drugs to physicians and nurses of county health departments or any qualified person authorized by the State Health Officer for administration to persons as part of a prophylactic or treatment regimen.

3. Notwithstanding s. 456.036, temporarily reactivating the inactive license of the following health care practitioners, when such practitioners are needed to respond to the public health emergency: physicians licensed under chapter 458 or chapter 459; physician assistants licensed under chapter 458 or chapter 459; licensed practical nurses, registered nurses, and advanced practice registered nurses certified ~~nurse practitioners licensed~~ under part I of chapter 464; respiratory therapists licensed under part V of chapter 468; and emergency medical technicians and paramedics certified under part III of chapter 401. Only those health care practitioners specified in

this paragraph who possess an unencumbered inactive license and who request that such license be reactivated are eligible for reactivation. An inactive license that is reactivated under this paragraph shall return to inactive status when the public health emergency ends or prior to the end of the public health emergency if the State Health Officer determines that the health care practitioner is no longer needed to provide services during the public health emergency. Such licenses may only be reactivated for a period not to exceed 90 days without meeting the requirements of s. 456.036 or chapter 401, as applicable.

4. Ordering an individual to be examined, tested, vaccinated, treated, or quarantined for communicable diseases that have significant morbidity or mortality and present a severe danger to public health. Individuals who are unable or unwilling to be examined, tested, vaccinated, or treated for reasons of health, religion, or conscience may be subjected to quarantine.

a. Examination, testing, vaccination, or treatment may be performed by any qualified person authorized by the State Health Officer.

b. If the individual poses a danger to the public health, the State Health Officer may subject the individual to quarantine. If there is no practical method to quarantine the individual, the State Health Officer may use any means necessary to vaccinate or treat the individual.

Any order of the State Health Officer given to effectuate this paragraph shall be immediately enforceable by a law enforcement officer under s. 381.0012.

Section 32. Subsection (3) of section 381.00593, Florida Statutes, is amended to read:

381.00593 Public school volunteer health care practitioner program.—

(3) For purposes of this section, the term "health care practitioner" means a physician licensed under chapter 458; an osteopathic physician licensed under chapter 459; a chiropractic physician licensed under chapter 460; a podiatric physician licensed under chapter 461; an optometrist licensed under chapter 463; an advanced practice registered nurse ~~practitioner~~, registered nurse, or licensed practical nurse licensed under part I of chapter 464; a pharmacist licensed under chapter 465; a dentist or dental hygienist licensed under chapter 466; a midwife licensed under chapter 467; a speech-language pathologist or audiologist licensed under part I of chapter 468; a dietitian/nutritionist licensed under part X of chapter 468; or a physical therapist licensed under chapter 486.

Section 33. Paragraph (c) of subsection (1) of section 383.141, Florida Statutes, is amended to read:

383.141 Prenatally diagnosed conditions; patient to be provided information; definitions; information clearinghouse; advisory council.—

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

(c) "Health care provider" means a practitioner licensed or registered under chapter 458 or chapter 459 or an advanced practice registered nurse ~~practitioner~~ certified under chapter 464.

Section 34. Paragraph (a) of subsection (3) of section 390.0111, Florida Statutes, is amended to read:

390.0111 Termination of pregnancies.—

(3) CONSENTS REQUIRED.—A termination of pregnancy may not be performed or induced except with the voluntary and informed written consent of the pregnant woman or, in the case of a mental incompetent, the voluntary and informed written consent of her court-appointed guardian.

(a) Except in the case of a medical emergency, consent to a termination of pregnancy is voluntary and informed only if:

1. The physician who is to perform the procedure, or the referring physician, has, at a minimum, orally, in person, informed the woman of:

a. The nature and risks of undergoing or not undergoing the proposed procedure that a reasonable patient would consider material to making a knowing and willful decision of whether to terminate a pregnancy.

b. The probable gestational age of the fetus, verified by an ultrasound, at the time the termination of pregnancy is to be performed.

(I) The ultrasound must be performed by the physician who is to perform the abortion or by a person having documented evidence that he or she has completed a course in the operation of ultrasound equipment as prescribed by rule and who is working in conjunction with the physician.

(II) The person performing the ultrasound must offer the woman the opportunity to view the live ultrasound images and hear an explanation of them. If the woman accepts the opportunity to view the images and hear the explanation, a physician or a registered nurse, licensed practical nurse, advanced practice registered nurse ~~practitioner~~, or physician

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assistant working in conjunction with the physician must contemporaneously review and explain the images to the woman before the woman gives informed consent to having an abortion procedure performed.

(III) The woman has a right to decline to view and hear the explanation of the live ultrasound images after she is informed of her right and offered an opportunity to view the images and hear the explanation. If the woman declines, the woman shall complete a form acknowledging that she was offered an opportunity to view and hear the explanation of the images but that she declined that opportunity. The form must also indicate that the woman's decision was not based on any undue influence from any person to discourage her from viewing the images or hearing the explanation and that she declined of her own free will.

(IV) Unless requested by the woman, the person performing the ultrasound may not offer the opportunity to view the images and hear the explanation and the explanation may not be given if, at the time the woman schedules or arrives for her appointment to obtain an abortion, a copy of a restraining order, police report, medical record, or other court order or documentation is presented which provides evidence that the woman is obtaining the abortion because the woman is a victim of rape, incest, domestic violence, or human trafficking or that the woman has been diagnosed as having a condition that, on the basis of a physician's good faith clinical judgment, would create a serious risk of substantial and irreversible impairment of a major bodily function if the woman delayed terminating her pregnancy.

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c. The medical risks to the woman and fetus of carrying the pregnancy to term.

2. Printed materials prepared and provided by the department have been provided to the pregnant woman, if she chooses to view these materials, including:

a. A description of the fetus, including a description of the various stages of development.

b. A list of entities that offer alternatives to terminating the pregnancy.

c. Detailed information on the availability of medical assistance benefits for prenatal care, childbirth, and neonatal care.

3. The woman acknowledges in writing, before the termination of pregnancy, that the information required to be provided under this subsection has been provided.

~~Nothing in~~ This paragraph is not intended to prohibit a physician from providing any additional information that ~~which~~ the physician deems material to the woman's informed decision to terminate her pregnancy.

Section 35. Paragraphs (c), (e), and (f) of subsection (3) of section 390.012, Florida Statutes, are amended to read:

390.012 Powers of agency; rules; disposal of fetal remains.—

(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 who has admitting privileges at a licensed hospital 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 practice 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.

(e) Rules relating to the abortion procedure. At a minimum, these rules shall require:

1. That a physician, registered nurse, licensed practical nurse, advanced practice registered nurse ~~practitioner~~, or physician assistant is available to all patients throughout the abortion procedure.

2. Standards for the safe conduct of abortion procedures that conform to obstetric standards in keeping with established standards of care regarding the estimation of fetal age as

defined in rule.

3. Appropriate use of general and local anesthesia, analgesia, and sedation if ordered by the physician.

4. Appropriate precautions, such as the establishment of intravenous access at least for patients undergoing post-first trimester abortions.

5. Appropriate monitoring of the vital signs and other defined signs and markers of the patient's status throughout the abortion procedure and during the recovery period until the patient's condition is deemed to be stable in the recovery room.

(f) Rules that prescribe minimum recovery room standards. At a minimum, these rules shall require that:

1. Postprocedure recovery rooms are supervised and staffed to meet the patients' needs.

2. Immediate postprocedure care 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.

4. A registered nurse, licensed practical nurse, advanced practice 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 remains on the premises of the abortion clinic until all patients are discharged.

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.

6. A physician discusses Rho(D) immune globulin with each patient for whom it is indicated and 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, a refusal form approved by the agency shall be signed by the patient and a witness and included in the medical record.

7. Written instructions with regard to postabortion coitus, signs of possible problems, and general aftercare are given to each patient. Each patient shall have specific written instructions regarding access to medical care for complications, including a telephone number to call for medical emergencies.

8. There is a specified minimum length of time that a patient remains in the recovery room by type of abortion procedure and duration of gestation.

9. The physician ensures that a registered nurse, licensed practical nurse, advanced practice 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.

10. Equipment and services are readily accessible to provide appropriate emergency resuscitative and life support procedures pending the transfer of the patient or viable fetus to the hospital.

Section 36. Paragraph (a) of subsection (2) of section 394.4574, Florida Statutes, is amended to read:

394.4574 Department responsibilities for a mental health

resident who resides in an assisted living facility that holds a limited mental health license.—

(2) The department must ensure that:

(a) A mental health resident has been assessed by a psychiatrist, clinical psychologist, clinical social worker, or psychiatric-mental health advanced practice registered ~~psychiatric~~ nurse, or an individual who is supervised by one of these professionals, and determined to be appropriate to reside in an assisted living facility. The documentation must be provided to the administrator of the facility within 30 days after the mental health resident has been admitted to the facility. An evaluation completed upon discharge from a state mental hospital meets the requirements of this subsection related to appropriateness for placement as a mental health resident if it was completed within 90 days prior to admission to the facility.

Section 37. Subsection (2) of section 394.4655, Florida Statutes, is amended to read:

394.4655 Involuntary outpatient placement.—

(2) INVOLUNTARY OUTPATIENT PLACEMENT.—

(a)1. A patient who is being recommended for involuntary outpatient placement by the administrator of the receiving facility where the patient has been examined may be retained by the facility after adherence to the notice 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 outpatient placement are met.

However, in a county having 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-mental health advanced practice registered ~~psychiatric~~ nurse. Any second opinion authorized in this subparagraph may be conducted through a face-to-face examination, in person or by electronic means. Such recommendation must be entered on an involuntary outpatient placement certificate that authorizes the receiving facility to retain the patient pending completion of a hearing. The certificate shall be made a part of the patient's clinical record.

2. If the patient has been stabilized and no longer meets the criteria for involuntary examination pursuant to s. 394.463(1), the patient must be released from the receiving facility while awaiting the hearing for involuntary outpatient placement. Before filing a petition for involuntary outpatient treatment, the administrator of a receiving facility or a designated department representative must identify the service provider that will have primary responsibility for service provision under an order for involuntary outpatient placement, unless the person is otherwise participating in outpatient psychiatric treatment and is not in need of public financing for that treatment, in which case the individual, if eligible, may be ordered to involuntary treatment pursuant to the existing psychiatric treatment relationship.

3. The service provider shall prepare a written proposed

treatment plan in consultation with the patient or the patient's guardian advocate, if appointed, for the court's consideration for inclusion in the involuntary outpatient placement order. The service provider shall also provide a copy of the proposed treatment plan to the patient and the administrator of the receiving facility. The treatment plan must specify the nature and extent of the patient's mental illness, address the reduction of symptoms that necessitate involuntary outpatient placement, and include measurable goals and objectives for the services and treatment that are provided to treat the person's mental illness and assist the person in living and functioning in the community or to prevent a relapse or deterioration. Service providers may select and supervise other individuals to implement specific aspects of the treatment plan. The services in the treatment plan must be deemed clinically appropriate by a physician, clinical psychologist, psychiatric-mental health advanced practice registered ~~psychiatric~~ nurse, mental health counselor, marriage and family therapist, or clinical social worker who consults with, or is employed or contracted by, the service provider. The service provider must certify to the court in the proposed treatment plan whether sufficient services for improvement and stabilization are currently available and whether the service provider agrees to provide those services. If the service provider certifies that the services in the proposed treatment plan are not available, the petitioner may not file the petition.

(b) If a patient in involuntary inpatient placement meets the criteria for involuntary outpatient placement, the administrator of the treatment facility may, before the

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expiration of the period during which the treatment facility is authorized to retain the patient, recommend involuntary outpatient placement. 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 outpatient placement are met. However, in a county having 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-mental health advanced practice registered ~~psychiatric~~ nurse. Any second opinion authorized in this subparagraph may be conducted through a face-to-face examination, in person or by electronic means. Such recommendation must be entered on an involuntary outpatient placement certificate, and the certificate must be made a part of the patient's clinical record.

(c)1. The administrator of the treatment facility shall provide a copy of the involuntary outpatient placement certificate and a copy of the state mental health discharge form to a department representative in the county where the patient will be residing. For persons who are leaving a state mental health treatment facility, the petition for involuntary outpatient placement must be filed in the county where the patient will be residing.

2. The service provider that will have primary responsibility for service provision shall be identified by the

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designated department representative prior to the order for involuntary outpatient placement and must, prior to filing a petition for involuntary outpatient placement, certify to the court whether the services recommended in the patient's discharge plan are available in the local community and whether the service provider agrees to provide those services. The service provider must develop with the patient, or the patient's guardian advocate, if appointed, a treatment or service plan that addresses the needs identified in the discharge plan. The plan must be deemed to be clinically appropriate by a physician, clinical psychologist, psychiatric-mental health advanced practice registered ~~psychiatric~~ nurse, mental health counselor, marriage and family therapist, or clinical social worker, as defined in this chapter, who consults with, or is employed or contracted by, the service provider.

3. If the service provider certifies that the services in the proposed treatment or service plan are not available, the petitioner may not file the petition.

Section 38. 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-mental health advanced practice registered ~~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 39. Paragraphs (a) and (b) of subsection (2) and subsection (4) of section 395.0191, Florida Statutes, are amended to read:

395.0191 Staff membership and clinical privileges.—

(2)(a) Each licensed facility shall establish rules and procedures for consideration of an application for clinical privileges submitted by an advanced practice registered nurse ~~practitioner~~ licensed and certified under part I of chapter 464, in accordance with the provisions of this section. A ~~No~~ licensed facility may not ~~shall~~ deny such application solely because the applicant is licensed under part I of chapter 464 or because the applicant is not a participant in the Florida Birth-Related Neurological Injury Compensation Plan.

(b) An advanced practice registered nurse ~~practitioner~~ who

is certified as a registered nurse anesthetist licensed under part I of chapter 464 shall administer anesthesia under the onsite medical direction of a professional licensed under chapter 458, chapter 459, or chapter 466, and in accordance with an established protocol approved by the medical staff. The medical direction shall specifically address the needs of the individual patient.

(4) This section does not ~~Nothing herein shall~~ restrict ~~in any way~~ the authority of the medical staff of a licensed facility to review for approval or disapproval all applications for appointment and reappointment to all categories of staff and to make recommendations on each applicant to the governing board, including the delineation of privileges to be granted in each case. In making such recommendations and in the delineation of privileges, each applicant shall be considered individually pursuant to criteria for a doctor licensed under chapter 458, chapter 459, chapter 461, or chapter 466, ~~or~~ for an advanced practice registered nurse ~~practitioner~~ licensed and certified under part I of chapter 464, or for a psychologist licensed under chapter 490, as applicable. The applicant's eligibility for staff membership or clinical privileges shall be determined by the applicant's background, experience, health, training, and demonstrated competency; the applicant's adherence to applicable professional ethics; the applicant's reputation; and the applicant's ability to work with others and by such other elements as determined by the governing board, consistent with this part.

Section 40. Subsection (3) of section 395.602, Florida Statutes, is amended to read:

395.602 Rural hospitals.—

(3) USE OF FUNDS.—It is the intent of the Legislature that funds as appropriated shall be used ~~utilized~~ by the department for the purpose of increasing the number of primary care physicians, physician assistants, certified nurse midwives, certified nurse practitioners, and nurses in rural areas, either through the Medical Education Reimbursement and Loan Repayment Program as defined by s. 1009.65 or through a federal loan repayment program which requires state matching funds. The department may use funds appropriated for the Medical Education Reimbursement and Loan Repayment Program as matching funds for federal loan repayment programs for health care personnel, such as that authorized in Pub. L. No. 100-177, s. 203. If the department receives federal matching funds, the department shall only implement the federal program. Reimbursement through either program shall be limited to:

(a) Primary care physicians, physician assistants, certified nurse midwives, certified nurse practitioners, and nurses employed by or affiliated with rural hospitals, as defined in this act; and

(b) Primary care physicians, physician assistants, certified nurse midwives, certified nurse practitioners, and nurses employed by or affiliated with rural area health education centers, as defined in this section. These personnel shall practice:

1. In a county with a population density of no greater than 100 persons per square mile; or

2. Within the boundaries of a hospital tax district which encompasses a population of no greater than 100 persons per

square mile.

If the department administers a federal loan repayment program, priority shall be given to obligating state and federal matching funds pursuant to paragraphs (a) and (b). The department may use federal matching funds in other health workforce shortage areas and medically underserved areas in the state for loan repayment programs for primary care physicians, physician assistants, certified nurse midwives, certified nurse practitioners, and nurses who are employed by publicly financed health care programs that serve medically indigent persons.

Section 41. Paragraphs (b) and (c) of subsection (8) of section 395.605, Florida Statutes, are amended to read:

395.605 Emergency care hospitals.—

(8)

(b) All patients shall be under the care of a physician or under the care of an advanced practice registered ~~a~~ nurse ~~practitioner~~ or a physician assistant supervised by a physician.

(c) A physician, an advanced practice registered nurse ~~practitioner~~, or a physician assistant shall be on duty at all times, or a physician shall be on call and available within 30 minutes at all times.

Section 42. Subsection (26) of section 397.311, Florida Statutes, is amended to read:

397.311 Definitions.—As used in this chapter, except part VIII, the term:

(26) "Qualified professional" means a physician or a physician assistant licensed under chapter 458 or chapter 459; a professional licensed under chapter 490 or chapter 491; an

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advanced practice registered nurse ~~practitioner~~ having a specialty in psychiatry licensed under part I of chapter 464; or a person who is certified through a department-recognized certification process for substance abuse treatment services and who holds, at a minimum, a bachelor's degree. A person who is certified in substance abuse treatment services by a state-recognized certification process in another state at the time of employment with a licensed substance abuse provider in this state may perform the functions of a qualified professional as defined in this chapter but must meet certification requirements contained in this subsection no later than 1 year after his or her date of employment.

Section 43. Section 397.405, Florida Statutes, is amended to read:

397.405 Exemptions from licensure.—The following are exempt from the licensing provisions of this chapter:

(1) A hospital or hospital-based component licensed under chapter 395.

(2) A nursing home facility as defined in s. 400.021.

(3) A substance abuse education program established pursuant to s. 1003.42.

(4) A facility or institution operated by the Federal Government.

(5) A physician or physician assistant licensed under chapter 458 or chapter 459.

(6) A psychologist licensed under chapter 490.

(7) A social worker, marriage and family therapist, or mental health counselor licensed under chapter 491.

(8) A legally cognizable church or nonprofit religious

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organization or denomination providing substance abuse services, including prevention services, which are solely religious, spiritual, or ecclesiastical in nature. A church or nonprofit religious organization or denomination providing any of the licensed service components itemized under s. 397.311(18) is not exempt from substance abuse licensure but retains its exemption with respect to all services which are solely religious, spiritual, or ecclesiastical in nature.

(9) Facilities licensed under chapter 393 which, in addition to providing services to persons with developmental disabilities, also provide services to persons developmentally at risk as a consequence of exposure to alcohol or other legal or illegal drugs while in utero.

(10) DUI education and screening services provided pursuant to ss. 316.192, 316.193, 322.095, 322.271, and 322.291. Persons or entities providing treatment services must be licensed under this chapter unless exempted from licensing as provided in this section.

(11) A facility licensed under s. 394.875 as a crisis stabilization unit.

The exemptions from licensure in this section do not apply to any service provider that receives an appropriation, grant, or contract from the state to operate as a service provider as defined in this chapter or to any substance abuse program regulated pursuant to s. 397.406. Furthermore, this chapter may not be construed to limit the practice of a physician or physician assistant licensed under chapter 458 or chapter 459, a psychologist licensed under chapter 490, a psychotherapist

licensed under chapter 491, or an advanced practice registered nurse ~~practitioner~~ licensed under part I of chapter 464, who provides substance abuse treatment, so long as the physician, physician assistant, psychologist, psychotherapist, or advanced practice registered nurse ~~practitioner~~ does not represent to the public that he or she is a licensed service provider and does not provide services to individuals pursuant to part V of this chapter. Failure to comply with any requirement necessary to maintain an exempt status under this section is a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

Section 44. Subsections (5), (9), and (10) of section 397.427, Florida Statutes, are amended to read:

397.427 Medication-assisted treatment service providers; rehabilitation program; needs assessment and provision of services; persons authorized to issue takeout medication; unlawful operation; penalty.—

(5) Notwithstanding s. 465.019(2), a physician assistant, a registered nurse, an advanced practice registered nurse ~~practitioner~~, or a licensed practical nurse working for a licensed service provider may deliver takeout medication for opiate treatment to persons enrolled in a maintenance treatment program for medication-assisted treatment for opiate addiction if:

(a) The medication-assisted treatment program for opiate addiction has an appropriate valid permit issued pursuant to rules adopted by the Board of Pharmacy.~~;~~

(b) The medication for treatment of opiate addiction has been delivered pursuant to a valid prescription written by the

program's physician licensed pursuant to chapter 458 or chapter 459.~~.~~

(c) The medication for treatment of opiate addiction which is ordered appears on a formulary and is prepackaged and prelabeled with dosage instructions and distributed from a source authorized under chapter 499.~~.~~

(d) Each licensed provider adopts written protocols which provide for supervision of the physician assistant, registered nurse, advanced practice registered nurse ~~practitioner~~, or licensed practical nurse by a physician licensed pursuant to chapter 458 or chapter 459 and for the procedures by which patients' medications may be delivered by the physician assistant, registered nurse, advanced practice registered nurse ~~practitioner~~, or licensed practical nurse. Such protocols shall be signed by the supervising physician and either the administering registered nurse, the advanced practice registered nurse ~~practitioner~~, or the licensed practical nurse.

(e) Each licensed service provider maintains and has available for inspection by representatives of the Board of Pharmacy all medical records and patient care protocols, including records of medications delivered to patients, in accordance with the board.

(9) A physician assistant, a registered nurse, an advanced practice registered nurse ~~practitioner~~, or a licensed practical nurse working for a licensed service provider may deliver medication as prescribed by rule if:

(a) The service provider is authorized to provide medication-assisted treatment;

(b) The medication has been administered pursuant to a

valid prescription written by the program's physician who is licensed under chapter 458 or chapter 459; and

(c) The medication ordered appears on a formulary or meets federal requirements for medication-assisted treatment.

(10) Each licensed service provider that provides medication-assisted treatment must adopt written protocols as specified by the department and in accordance with federally required rules, regulations, or procedures. The protocol shall provide for the supervision of the physician assistant, registered nurse, advanced practice registered nurse ~~practitioner~~, or licensed practical nurse working under the supervision of a physician who is licensed under chapter 458 or chapter 459. The protocol must specify how the medication will be used in conjunction with counseling or psychosocial treatment and that the services provided will be included on the treatment plan. The protocol must specify the procedures by which medication-assisted treatment may be administered by the physician assistant, registered nurse, advanced practice registered nurse ~~practitioner~~, or licensed practical nurse. These protocols shall be signed by the supervising physician and the administering physician assistant, registered nurse, advanced practice registered nurse ~~practitioner~~, or licensed practical nurse.

Section 45. Subsection (8) of section 400.021, Florida Statutes, is amended to read:

400.021 Definitions.—When used in this part, unless the context otherwise requires, the term:

(8) "Geriatric outpatient clinic" means a site for providing outpatient health care to persons 60 years of age or

older, which is staffed by a registered nurse, a physician assistant, or a licensed practical nurse under the direct supervision of a registered nurse, advanced practice registered nurse ~~practitioner~~, physician assistant, or physician.

Section 46. Subsection (3) of section 400.0255, Florida Statutes, is amended to read:

400.0255 Resident transfer or discharge; requirements and procedures; hearings.—

(3) When a discharge or transfer is initiated by the nursing home, the nursing home administrator employed by the nursing home that is discharging or transferring the resident, or an individual employed by the nursing home who is designated by the nursing home administrator to act on behalf of the administration, must sign the notice of discharge or transfer. Any notice indicating a medical reason for transfer or discharge must either be signed by the resident's attending physician or the medical director of the facility, or include an attached written order for the discharge or transfer. The notice or the order must be signed by the resident's physician, medical director, treating physician, advanced practice registered nurse ~~practitioner~~, or physician assistant.

Section 47. Subsection (3) of section 400.172, Florida Statutes, is amended to read:

400.172 Respite care provided in nursing home facilities.—

(3) A prospective respite care resident must provide medical information from a physician, physician assistant, or advanced practice registered nurse ~~practitioner~~ and any other information provided by the primary caregiver required by the facility before or when the person is admitted to receive

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respite care. The medical information must include a physician's order for respite care and proof of a physical examination by a licensed physician, physician assistant, or advanced practice registered nurse ~~practitioner~~. The physician's order and physical examination may be used to provide intermittent respite care for up to 12 months after the date the order is written.

Section 48. Subsection (4) of section 400.211, Florida Statutes, is amended to read:

400.211 Persons employed as nursing assistants; certification requirement.—

(4) When employed by a nursing home facility for a 12-month period or longer, a nursing assistant, to maintain certification, shall submit to a performance review every 12 months and must receive regular inservice education based on the outcome of such reviews. The inservice training must:

(a) Be sufficient to ensure the continuing competence of nursing assistants ~~and must meet the standard specified in s. 464.203(7)~~;

(b) Include, at a minimum:

1. Techniques for assisting with eating and proper feeding;

2. Principles of adequate nutrition and hydration;

3. Techniques for assisting and responding to the cognitively impaired resident or the resident with difficult behaviors;

4. Techniques for caring for the resident at the end-of-life; and

5. Recognizing changes that place a resident at risk for pressure ulcers and falls; and

(c) Address areas of weakness as determined in nursing

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assistant performance reviews and may address the special needs of residents as determined by the nursing home facility staff.

Costs associated with this training may not be reimbursed from additional Medicaid funding through interim rate adjustments.

Section 49. Subsection (3) of section 400.462, Florida Statutes, is amended to read:

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

(3) "Advanced practice registered nurse ~~practitioner~~" means a person licensed in this state to practice professional nursing and certified in advanced or specialized nursing practice, as defined in s. 464.003.

Section 50. Section 400.487, Florida Statutes, is amended to read:

400.487 Home health service agreements; physician's, physician assistant's, and advanced practice registered nurse's ~~nurse practitioner's~~ treatment orders; patient assessment; establishment and review of plan of care; provision of services; orders not to resuscitate.—

(1) Services provided by a home health agency must be covered by an agreement between the home health agency and the patient or the patient's legal representative specifying the home health services to be provided, the rates or charges for services paid with private funds, and the sources of payment, which may include Medicare, Medicaid, private insurance, personal funds, or a combination thereof. A home health agency providing skilled care must make an assessment of the patient's needs within 48 hours after the start of services.

(2) When required by the provisions of chapter 464; part I,

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part III, or part V of chapter 468; or chapter 486, the attending physician, physician assistant, or advanced practice registered nurse ~~practitioner~~, acting within his or her respective scope of practice, shall establish treatment orders for a patient who is to receive skilled care. The treatment orders must be signed by the physician, physician assistant, or advanced practice registered nurse ~~practitioner~~ before a claim for payment for the skilled services is submitted by the home health agency. If the claim is submitted to a managed care organization, the treatment orders must be signed within the time allowed under the provider agreement. The treatment orders shall be reviewed, as frequently as the patient's illness requires, by the physician, physician assistant, or advanced practice registered nurse ~~practitioner~~ in consultation with the home health agency.

(3) A home health agency shall arrange for supervisory visits by a registered nurse to the home of a patient receiving home health aide services in accordance with the patient's direction, approval, and agreement to pay the charge for the visits.

(4) Each patient has the right to be informed of and to participate in the planning of his or her care. Each patient must be provided, upon request, a copy of the plan of care established and maintained for that patient by the home health agency.

(5) When nursing services are ordered, the home health agency to which a patient has been admitted for care must provide the initial admission visit, all service evaluation visits, and the discharge visit by a direct employee. Services

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provided by others under contractual arrangements to a home health agency must be monitored and managed by the admitting home health agency. The admitting home health agency is fully responsible for ensuring that all care provided through its employees or contract staff is delivered in accordance with this part and applicable rules.

(6) The skilled care services provided by a home health agency, directly or under contract, must be supervised and coordinated in accordance with the plan of care.

(7) Home health agency personnel may withhold or withdraw cardiopulmonary resuscitation if presented with an order not to resuscitate executed pursuant to s. 401.45. The agency shall adopt rules providing for the implementation of such orders. Home health personnel and agencies shall not be subject to criminal prosecution or civil liability, nor be considered to have engaged in negligent or unprofessional conduct, for withholding or withdrawing cardiopulmonary resuscitation pursuant to such an order and rules adopted by the agency.

Section 51. Paragraph (a) of subsection (13) of section 400.506, Florida Statutes, is amended to read:

400.506 Licensure of nurse registries; requirements; penalties.—

(13) All persons referred for contract in private residences by a nurse registry must comply with the following requirements for a plan of treatment:

(a) When, in accordance with the privileges and restrictions imposed upon a nurse under part I of chapter 464, the delivery of care to a patient is under the direction or supervision of a physician or when a physician is responsible

for the medical care of the patient, a medical plan of treatment must be established for each patient receiving care or treatment provided by a licensed nurse in the home. The original medical plan of treatment must be timely signed by the physician, physician assistant, or advanced practice registered nurse ~~practitioner~~, acting within his or her respective scope of practice, and reviewed in consultation with the licensed nurse at least every 2 months. Any additional order or change in orders must be obtained from the physician, physician assistant, or advanced practice registered nurse ~~practitioner~~ and reduced to writing and timely signed by the physician, physician assistant, or advanced practice registered nurse ~~practitioner~~. The delivery of care under a medical plan of treatment must be substantiated by the appropriate nursing notes or documentation made by the nurse in compliance with nursing practices established under part I of chapter 464.

Section 52. Subsections (1) and (2) of section 401.445, Florida Statutes, are amended to read:

401.445 Emergency examination and treatment of incapacitated persons.—

(1) ~~No~~ Recovery is not ~~shall be~~ allowed in any court in this state against any emergency medical technician, paramedic, or physician as defined in this chapter, any advanced practice registered nurse ~~practitioner~~ certified under s. 464.012, or any physician assistant licensed under s. 458.347 or s. 459.022, or any person acting under the direct medical supervision of a physician, in an action brought for examining or treating a patient without his or her informed consent if:

(a) The patient at the time of examination or treatment is

intoxicated, under the influence of drugs, or otherwise incapable of providing informed consent as provided in s. 766.103;

(b) The patient at the time of examination or treatment is experiencing an emergency medical condition; and

(c) The patient would reasonably, under all the surrounding circumstances, undergo such examination, treatment, or procedure if he or she were advised by the emergency medical technician, paramedic, physician, advanced practice registered nurse ~~practitioner~~, or physician assistant in accordance with s. 766.103(3).

Examination and treatment provided under this subsection shall be limited to reasonable examination of the patient to determine the medical condition of the patient and treatment reasonably necessary to alleviate the emergency medical condition or to stabilize the patient.

(2) In examining and treating a person who is apparently intoxicated, under the influence of drugs, or otherwise incapable of providing informed consent, the emergency medical technician, paramedic, physician, advanced practice registered nurse ~~practitioner~~, or physician assistant, or any person acting under the direct medical supervision of a physician, shall proceed wherever possible with the consent of the person. If the person reasonably appears to be incapacitated and refuses his or her consent, the person may be examined, treated, or taken to a hospital or other appropriate treatment resource if he or she is in need of emergency attention, without his or her consent, but unreasonable force shall not be used.

Section 53. Subsections (1) and (11) of section 409.905, Florida Statutes, are amended to read:

409.905 Mandatory Medicaid services.—The agency may make payments for the following services, which are required of the state by Title XIX of the Social Security Act, furnished by Medicaid providers to recipients who are determined to be eligible on the dates on which the services were provided. Any service under this section shall be provided only when medically necessary and in accordance with state and federal law. Mandatory services rendered by providers in mobile units to Medicaid recipients may be restricted by the agency. Nothing in this section shall be construed to prevent or limit the agency from adjusting fees, reimbursement rates, lengths of stay, number of visits, number of services, or any other adjustments necessary to comply with the availability of moneys and any limitations or directions provided for in the General Appropriations Act or chapter 216.

(1) ADVANCED PRACTICE REGISTERED NURSE ~~PRACTITIONER~~ SERVICES.—The agency shall pay for services provided to a recipient by a certified ~~licensed~~ advanced practice registered nurse ~~practitioner~~ who has, if required under s. 464.012(3), a current protocol ~~valid collaboration agreement~~ with a licensed physician on file with the Department of Health or who provides anesthesia services in accordance with established protocol required by state law and approved by the medical staff of the facility in which the anesthetic service is performed. Reimbursement for such services must be provided in an amount that equals not less than 80 percent of the reimbursement to a physician who provides the same services, unless otherwise

provided for in the General Appropriations Act.

(11) RURAL HEALTH CLINIC SERVICES.—The agency shall pay for outpatient primary health care services for a recipient provided by a clinic certified by and participating in the Medicare program which is located in a federally designated, rural, medically underserved area and has on its staff one or more certified ~~licensed~~ primary care nurse practitioners or physician assistants, and a licensed staff supervising physician or a consulting supervising physician.

Section 54. Paragraph (a) of subsection (3) and subsection (7) of section 409.908, Florida Statutes, are amended to read:

409.908 Reimbursement of Medicaid providers.—Subject to specific appropriations, the agency shall reimburse Medicaid providers, in accordance with state and federal law, according to methodologies set forth in the rules of the agency and in policy manuals and handbooks incorporated by reference therein. These methodologies may include fee schedules, reimbursement methods based on cost reporting, negotiated fees, competitive bidding pursuant to s. 287.057, and other mechanisms the agency considers efficient and effective for purchasing services or goods on behalf of recipients. If a provider is reimbursed based on cost reporting and submits a cost report late and that cost report would have been used to set a lower reimbursement rate for a rate semester, then the provider's rate for that semester shall be retroactively calculated using the new cost report, and full payment at the recalculated rate shall be effected retroactively. Medicare-granted extensions for filing cost reports, if applicable, shall also apply to Medicaid cost reports. Payment for Medicaid compensable services made on

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behalf of Medicaid eligible persons is subject to the availability of moneys and any limitations or directions provided for in the General Appropriations Act or chapter 216. Further, nothing in this section shall be construed to prevent or limit the agency from adjusting fees, reimbursement rates, lengths of stay, number of visits, or number of services, or making any other adjustments necessary to comply with the availability of moneys and any limitations or directions provided for in the General Appropriations Act, provided the adjustment is consistent with legislative intent.

(3) Subject to any limitations or directions provided for in the General Appropriations Act, the following Medicaid services and goods may be reimbursed on a fee-for-service basis. For each allowable service or goods furnished in accordance with Medicaid rules, policy manuals, handbooks, and state and federal law, the payment shall be the amount billed by the provider, the provider's usual and customary charge, or the maximum allowable fee established by the agency, whichever amount is less, with the exception of those services or goods for which the agency makes payment using a methodology based on capitation rates, average costs, or negotiated fees.

(a) Advanced practice registered nurse ~~practitioner~~ services.

(7) A provider of family planning services shall be reimbursed the lesser of the amount billed by the provider or an all-inclusive amount per type of visit for physicians and advanced practice registered nurses ~~nurse practitioners~~, as established by the agency in a fee schedule.

Section 55. Subsection (2) of section 409.9081, Florida

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Statutes, is amended to read:

409.9081 Copayments.—

(2) The agency shall, subject to federal regulations and any directions or limitations provided for in the General Appropriations Act, require copayments for the following additional services: hospital inpatient, laboratory and X-ray services, transportation services, home health care services, community mental health services, rural health services, federally qualified health clinic services, and advanced practice registered nurse ~~practitioner~~ services. The agency may only establish copayments for prescribed drugs or for any other federally authorized service if such copayment is specifically provided for in the General Appropriations Act or other law.

Section 56. Subsection (11) of section 409.9122, Florida Statutes, is amended to read:

409.9122 Mandatory Medicaid managed care enrollment; programs and procedures.—

(11) A managed care plan that has a Medicaid contract shall at least annually review each primary care physician's active patient load and shall ensure that additional Medicaid recipients are not assigned to physicians who have a total active patient load of more than 3,000 patients. As used in this subsection, the term "active patient" means a patient who is seen by the same primary care physician, or by a physician assistant or advanced practice registered nurse ~~practitioner~~ under the supervision of the primary care physician, at least three times within a calendar year. Each primary care physician shall annually certify to the managed care plan whether or not his or her patient load exceeds the limits established under

this subsection and the managed care plan shall accept such certification on face value as compliance with this subsection. The agency shall accept the managed care plan's representations that it is in compliance with this subsection based on the certification of its primary care physicians, unless the agency has an objective indication that access to primary care is being compromised, such as receiving complaints or grievances relating to access to care. If the agency determines that an objective indication exists that access to primary care is being compromised, it may verify the patient load certifications submitted by the managed care plan's primary care physicians and that the managed care plan is not assigning Medicaid recipients to primary care physicians who have an active patient load of more than 3,000 patients. This subsection expires October 1, 2014.

Section 57. Paragraph (a) of subsection (1) of section 409.973, Florida Statutes, is amended to read:

409.973 Benefits.—

(1) MINIMUM BENEFITS.—Managed care plans shall cover, at a minimum, the following services:

(a) Advanced practice registered nurse ~~practitioner~~ services.

Section 58. Subsections (2), (4), (5), and (6) of section 429.26, Florida Statutes, are amended to read:

429.26 Appropriateness of placements; examinations of residents.—

(2) A physician, physician assistant, or advanced practice registered nurse ~~practitioner~~ who is employed by an assisted living facility to provide an initial examination for admission

purposes may not have financial interest in the facility.

(4) If possible, each resident shall have been examined by a licensed physician, a licensed physician assistant, or a certified advanced practice registered ~~licensed~~ nurse ~~practitioner~~ within 60 days before admission to the facility. The signed and completed medical examination report shall be submitted to the owner or administrator of the facility who shall use the information contained therein to assist in the determination of the appropriateness of the resident's admission and continued stay in the facility. The medical examination report shall become a permanent part of the record of the resident at the facility and shall be made available to the agency during inspection or upon request. An assessment that has been completed through the Comprehensive Assessment and Review for Long-Term Care Services (CARES) Program fulfills the requirements for a medical examination under this subsection and s. 429.07(3)(b)6.

(5) Except as provided in s. 429.07, if a medical examination has not been completed within 60 days before the admission of the resident to the facility, a licensed physician, licensed physician assistant, or certified advanced practice registered ~~licensed~~ nurse ~~practitioner~~ shall examine the resident and complete a medical examination form provided by the agency within 30 days following the admission to the facility to enable the facility owner or administrator to determine the appropriateness of the admission. The medical examination form shall become a permanent part of the record of the resident at the facility and shall be made available to the agency during inspection by the agency or upon request.

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(6) Any resident accepted in a facility and placed by the department or the Department of Children and Families ~~Family Services~~ shall have been examined by medical personnel within 30 days before placement in the facility. The examination shall include an assessment of the appropriateness of placement in a facility. The findings of this examination shall be recorded on the examination form provided by the agency. The completed form shall accompany the resident and shall be submitted to the facility owner or administrator. Additionally, in the case of a mental health resident, the Department of Children and Families ~~Family Services~~ must provide documentation that the individual has been assessed by a psychiatrist, clinical psychologist, clinical social worker, or psychiatric-mental health advanced practice registered ~~psychiatric~~ nurse, or an individual who is supervised by one of these professionals, and determined to be appropriate to reside in an assisted living facility. The documentation must be in the facility within 30 days after the mental health resident has been admitted to the facility. An evaluation completed upon discharge from a state mental hospital meets the requirements of this subsection related to appropriateness for placement as a mental health resident providing it was completed within 90 days before ~~prior to~~ admission to the facility. The applicable department shall provide to the facility administrator any information about the resident that would help the administrator meet his or her responsibilities under subsection (1). Further, department personnel shall explain to the facility operator any special needs of the resident and advise the operator whom to call should problems arise. The applicable department shall advise

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and assist the facility administrator where the special needs of residents who are recipients of optional state supplementation require such assistance.

Section 59. Paragraph (a) of subsection (2) and paragraph (a) of subsection (7) of section 429.918, Florida Statutes, are amended to read:

429.918 Licensure designation as a specialized Alzheimer's services adult day care center.—

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

(a) "ADRD participant" means a participant who has a documented diagnosis of Alzheimer's disease or a dementia-related disorder (ADRD) from a licensed physician, licensed physician assistant, or a licensed advanced practice registered nurse ~~practitioner~~.

(7)(a) An ADRD participant admitted to an adult day care center having a license designated under this section, or the caregiver when applicable, must:

1. Require ongoing supervision to maintain the highest level of medical or custodial functioning and have a demonstrated need for a responsible party to oversee his or her care.

2. Not actively demonstrate aggressive behavior that places himself, herself, or others at risk of harm.

3. Provide the following medical documentation signed by a licensed physician, licensed physician assistant, or ~~a~~ licensed advanced practice registered nurse ~~practitioner~~:

a. Any physical, health, or emotional conditions that require medical care.

b. A listing of the ADRD participant's current prescribed

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and over-the-counter medications and dosages, diet restrictions, mobility restrictions, and other physical limitations.

4. Provide documentation signed by a health care provider licensed in this state which indicates that the ADRD participant is free of the communicable form of tuberculosis and free of signs and symptoms of other communicable diseases.

Section 60. Paragraph (e) of subsection (5) of section 440.102, Florida Statutes, is amended to read:

440.102 Drug-free workplace program requirements.—The following provisions apply to a drug-free workplace program implemented pursuant to law or to rules adopted by the Agency for Health Care Administration:

(5) PROCEDURES AND EMPLOYEE PROTECTION.—All specimen collection and testing for drugs under this section shall be performed in accordance with the following procedures:

(e) A specimen for a drug test may be taken or collected by any of the following persons:

1. A physician, a physician assistant, a registered professional nurse, a licensed practical nurse, or an advanced practice registered ~~a~~ nurse ~~practitioner~~ or a certified paramedic who is present at the scene of an accident for the purpose of rendering emergency medical service or treatment.

2. A qualified person employed by a licensed or certified laboratory as described in subsection (9).

Section 61. Section 456.0391, Florida Statutes, is amended to read:

456.0391 Advanced practice registered nurses ~~nurse practitioners~~; information required for certification.—

(1)(a) Each person who applies for initial certification

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under s. 464.012 must, at the time of application, and each person certified under s. 464.012 who applies for certification renewal must, in conjunction with the renewal of such certification and under procedures adopted by the Department of Health, and in addition to any other information that may be required from the applicant, furnish the following information to the Department of Health:

1. The name of each school or training program that the applicant has attended, with the months and years of attendance and the month and year of graduation, and a description of all graduate professional education completed by the applicant, excluding any coursework taken to satisfy continuing education requirements.

2. The name of each location at which the applicant practices.

3. The address at which the applicant will primarily conduct his or her practice.

4. Any certification or designation that the applicant has received from a specialty or certification board that is recognized or approved by the regulatory board or department to which the applicant is applying.

5. The year that the applicant received initial certification and began practicing the profession in any jurisdiction and the year that the applicant received initial certification in this state.

6. Any appointment which the applicant currently holds to the faculty of a school related to the profession and an indication as to whether the applicant has had the responsibility for graduate education within the most recent 10

years.

7. A description of any criminal offense of which the applicant has been found guilty, regardless of whether adjudication of guilt was withheld, or to which the applicant has pled guilty or nolo contendere. A criminal offense committed in another jurisdiction which would have been a felony or misdemeanor if committed in this state must be reported. If the applicant indicates that a criminal offense is under appeal and submits a copy of the notice for appeal of that criminal offense, the department must state that the criminal offense is under appeal if the criminal offense is reported in the applicant's profile. If the applicant indicates to the department that a criminal offense is under appeal, 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.

8. A description of any final disciplinary action taken within the previous 10 years against the applicant by a licensing or regulatory body in any jurisdiction, by a specialty board that is recognized by the board or department, or by a licensed hospital, health maintenance organization, prepaid health clinic, ambulatory surgical center, or nursing home. Disciplinary action includes resignation from or nonrenewal of staff membership or the restriction of privileges at a licensed hospital, health maintenance organization, prepaid health clinic, ambulatory surgical center, or nursing home taken in lieu of or in settlement of a pending disciplinary case related to competence or character. If the applicant indicates that the disciplinary action is under appeal and submits a copy of the

document initiating an appeal of the disciplinary action, the department must state that the disciplinary action is under appeal if the disciplinary action is reported in the applicant's profile.

(b) In addition to the information required under paragraph (a), each applicant for initial certification or certification renewal must provide the information required of licensees pursuant to s. 456.049.

(2) The Department of Health shall send a notice to each person certified under s. 464.012 at the certificateholder's last known address of record regarding the requirements for information to be submitted by advanced practice registered nurses ~~nurse practitioners~~ pursuant to this section in conjunction with the renewal of such certificate.

(3) Each person certified under s. 464.012 who has submitted information pursuant to subsection (1) must update that information in writing by notifying the Department of Health within 45 days after the occurrence of an event or the attainment of a status that is required to be reported by subsection (1). Failure to comply with the requirements of this subsection to update and submit information constitutes a ground for disciplinary action under chapter 464 and s. 456.072(1)(k). For failure to comply with the requirements of this subsection to update and submit information, the department or board, as appropriate, may:

(a) Refuse to issue a certificate to any person applying for initial certification who fails to submit and update the required information.

(b) Issue a citation to any certificateholder who fails to

submit and update the required information and may fine the certificateholder up to $50 for each day that the certificateholder is not in compliance with this subsection. The citation must clearly state that the certificateholder may choose, in lieu of accepting the citation, to follow the procedure under s. 456.073. If the certificateholder disputes the matter in the citation, the procedures set forth in s. 456.073 must be followed. However, if the certificateholder 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 constitutes discipline. Service of a citation may be made by personal service or certified mail, restricted delivery, to the subject at the certificateholder's last known address.

(4)(a) An applicant for initial certification under s. 464.012 must submit a set of fingerprints to the Department of Health on a form and under procedures specified by the department, along with payment in an amount equal to the costs incurred by the Department of Health for a national criminal history check of the applicant.

(b) An applicant for renewed certification who has not previously submitted a set of fingerprints to the Department of Health for purposes of certification must submit a set of fingerprints to the department as a condition of the initial renewal of his or her certificate after the effective date of this section. The applicant must submit the fingerprints on a form and under procedures specified by the department, along with payment in an amount equal to the costs incurred by the Department of Health for a national criminal history check. For

subsequent renewals, the applicant for renewed certification must only submit information necessary to conduct a statewide criminal history check, along with payment in an amount equal to the costs incurred by the Department of Health for a statewide criminal history check.

(c)1. The Department of Health shall submit the fingerprints provided by an applicant for initial certification to the Florida Department of Law Enforcement for a statewide criminal history check, and the Florida Department of Law Enforcement shall forward the fingerprints to the Federal Bureau of Investigation for a national criminal history check of the applicant.

2. The department shall submit the fingerprints provided by an applicant for the initial renewal of certification to the Florida Department of Law Enforcement for a statewide criminal history check, and the Florida Department of Law Enforcement shall forward the fingerprints to the Federal Bureau of Investigation for a national criminal history check for the initial renewal of the applicant's certificate after the effective date of this section.

3. For any subsequent renewal of the applicant's certificate, the department shall submit the required information for a statewide criminal history check of the applicant to the Florida Department of Law Enforcement.

(d) Any applicant for initial certification or renewal of certification as an advanced practice registered nurse ~~practitioner~~ who submits to the Department of Health a set of fingerprints and information required for the criminal history check required under this section shall not be required to

provide a subsequent set of fingerprints or other duplicate information required for a criminal history check to the Agency for Health Care Administration, the Department of Juvenile Justice, or the Department of Children and Families ~~Family Services~~ for employment or licensure with such agency or department, if the applicant has undergone a criminal history check as a condition of initial certification or renewal of certification as an advanced practice registered nurse ~~practitioner~~ with the Department of Health, notwithstanding any other provision of law to the contrary. In lieu of such duplicate submission, the Agency for Health Care Administration, the Department of Juvenile Justice, and the Department of Children and Families ~~Family Services~~ shall obtain criminal history information for employment or licensure of persons certified under s. 464.012 by such agency or department from the Department of Health's health care practitioner credentialing system.

(5) Each person who is required to submit information pursuant to this section may submit additional information to the Department of Health. Such information may include, but is not limited to:

(a) Information regarding publications in peer-reviewed professional literature within the previous 10 years.

(b) Information regarding professional or community service activities or awards.

(c) Languages, other than English, used by the applicant to communicate with patients or clients and identification of any translating service that may be available at the place where the applicant primarily conducts his or her practice.

(d) An indication of whether the person participates in the Medicaid program.

Section 62. Subsection (2) of section 456.0392, Florida Statutes, is amended to read:

456.0392 Prescription labeling.—

(2) A prescription for a drug ~~that is not listed as a controlled substance in chapter 893~~ which is written by an advanced practice registered nurse ~~practitioner~~ certified under s. 464.012 is presumed, subject to rebuttal, to be valid and within the parameters of the prescriptive authority delegated by a practitioner licensed under chapter 458, chapter 459, or chapter 466.

Section 63. Paragraph (a) of subsection (1) and subsection (6) of section 456.041, Florida Statutes, are amended 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 practice registered nurse ~~practitioner~~.

(6) The Department of Health shall provide in each practitioner profile for every physician or advanced practice registered nurse ~~practitioner~~ terminated for cause from

participating in the Medicaid program, pursuant to s. 409.913, or sanctioned by the Medicaid program a statement that the practitioner has been terminated from participating in the Florida Medicaid program or sanctioned by the Medicaid program.

Section 64. Subsection (1) of section 456.048, Florida Statutes, is amended to read:

456.048 Financial responsibility requirements for certain health care practitioners.—

(1) As a prerequisite for licensure or license renewal, the Board of Acupuncture, the Board of Chiropractic Medicine, the Board of Podiatric Medicine, and the Board of Dentistry shall, by rule, require that all health care practitioners licensed under the respective board, and the Board of Medicine and the Board of Osteopathic Medicine shall, by rule, require that all anesthesiologist assistants licensed pursuant to s. 458.3475 or s. 459.023, and the Board of Nursing shall, by rule, require that advanced practice registered nurses ~~nurse practitioners~~ certified under s. 464.012, and the department shall, by rule, require that midwives maintain medical malpractice insurance or provide proof of financial responsibility in an amount and in a manner determined by the board or department to be sufficient to cover claims arising out of the rendering of or failure to render professional care and services in this state.

Section 65. Paragraph (c) 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).

(c) A physician, a physician assistant, or an advanced practice registered nurse ~~practitioner~~ must perform a physical examination of a patient on the same day that the physician prescribes a controlled substance to a patient at a pain-management clinic. If the physician prescribes more than a 72-hour dose of controlled substances for the treatment of chronic nonmalignant pain, the physician must document in the patient's record the reason for prescribing that quantity.

Section 66. Paragraph (dd) of subsection (1) of section 458.331, Florida Statutes, is amended to read:

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

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

(dd) Failing to supervise adequately the activities of those physician assistants, paramedics, emergency medical technicians, advanced practice registered nurses ~~nurse practitioners~~, or anesthesiologist assistants acting under the supervision of the physician.

Section 67. Paragraph (c) 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).

(c) An osteopathic physician, a physician assistant, or an advanced practice registered nurse ~~practitioner~~ must perform a

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physical examination of a patient on the same day that the physician prescribes a controlled substance to a patient at a pain-management clinic. If the osteopathic physician prescribes more than a 72-hour dose of controlled substances for the treatment of chronic nonmalignant pain, the osteopathic physician must document in the patient's record the reason for prescribing that quantity.

Section 68. Paragraph (hh) of subsection (1) of section 459.015, Florida Statutes, is amended to read:

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

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

(hh) Failing to supervise adequately the activities of those physician assistants, paramedics, emergency medical technicians, advanced practice registered nurses ~~nurse practitioners~~, anesthesiologist assistants, or other persons acting under the supervision of the osteopathic physician.

Section 69. Subsections (2) and (3) of section 464.003, Florida Statutes, are 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 practice registered nurse ~~practitioner~~. Within the context of advanced or specialized nursing practice, the advanced practice registered nurse ~~practitioner~~ may perform acts of nursing

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diagnosis and nursing treatment of alterations of the health status. The advanced practice registered nurse ~~practitioner~~ may also perform acts of medical diagnosis and treatment, prescription, and operation 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 or s. 459.025.

(3) "Advanced practice registered nurse ~~practitioner~~" means any person licensed in this state to practice professional nursing and certified in advanced or specialized nursing practice, including certified registered nurse anesthetists, certified nurse midwives, and certified nurse practitioners.

Section 70. Subsection (2) of section 464.004, Florida

Statutes, is amended to read:

464.004 Board of Nursing; membership; appointment; terms.—

(2) Seven members of the board must be registered nurses who are residents of this state and who have been engaged in the practice of professional nursing for at least 4 years, including at least one advanced practice registered nurse ~~practitioner~~, one nurse educator member of an approved program, and one nurse executive. These seven board members should be representative of the diverse areas of practice within the nursing profession. In addition, three members of the board must be licensed practical nurses who are residents of this state and who have been actively engaged in the practice of practical nursing for at least 4 years prior to their appointment. The remaining three members must be residents of the state who have never been licensed as nurses and who are in no way connected with the practice of nursing. No person may be appointed as a lay member who is in any way connected with, or has any financial interest in, any health care facility, agency, or insurer. At least one member of the board must be 60 years of age or older.

Section 71. Paragraph (a) of subsection (2) of section 464.016, Florida Statutes, is amended to read:

464.016 Violations and penalties.—

(2) Each of the following acts constitutes a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083:

(a) Using the name or title "Nurse," "Registered Nurse," "Licensed Practical Nurse," "Clinical Nurse Specialist," "Certified Registered Nurse Anesthetist," "Certified Nurse Midwife," "Certified Nurse Practitioner," "Advanced Practice

Registered Nurse ~~Practitioner~~," or any other name or title which implies that a person was licensed or certified as same, unless such person is duly licensed or certified.

Section 72. Paragraph (a) of subsection (4) of section 464.0205, Florida Statutes, is amended to read:

464.0205 Retired volunteer nurse certificate.—

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

(a) Work under the direct supervision of the director of a county health department, a physician working under a limited license issued pursuant to s. 458.317 or s. 459.0075, a physician licensed under chapter 458 or chapter 459, an advanced practice registered nurse ~~practitioner~~ certified under s. 464.012, or a registered nurse licensed under s. 464.008 or s. 464.009.

Section 73. Subsection (2) of section 467.003, Florida Statutes, is amended to read:

467.003 Definitions.—As used in this chapter, unless the context otherwise requires:

(2) "Certified nurse midwife" means a person who is licensed as an advanced practice registered nurse ~~practitioner~~ under part I of chapter 464 and who is certified to practice midwifery by the American College of Nurse Midwives.

Section 74. Subsection (1) of section 480.0475, Florida Statutes, is amended to read:

480.0475 Massage establishments; prohibited practices.—

(1) A person may not operate a massage establishment between the hours of midnight and 5 a.m. This subsection does not apply to a massage establishment:

(a) Located on the premises of a health care facility as defined in s. 408.07; a health care clinic as defined in s. 400.9905(4); a hotel, motel, or bed and breakfast inn, as those terms are defined in s. 509.242; a timeshare property as defined in s. 721.05; a public airport as defined in s. 330.27; or a pari-mutuel facility as defined in s. 550.002;

(b) In which every massage performed between the hours of midnight and 5 a.m. is performed by a massage therapist acting under the prescription of a physician or physician assistant licensed under chapter 458, an osteopathic physician or physician assistant licensed under chapter 459, a chiropractic physician licensed under chapter 460, a podiatric physician licensed under chapter 461, an advanced practice registered nurse ~~practitioner~~ licensed under part I of chapter 464, or a dentist licensed under chapter 466; or

(c) Operating during a special event if the county or municipality in which the establishment operates has approved such operation during the special event.

Section 75. Subsection (7) of section 483.041, Florida Statutes, is amended to read:

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

(7) "Licensed practitioner" means a physician licensed under chapter 458, chapter 459, chapter 460, or chapter 461; a certified optometrist licensed under chapter 463; a dentist licensed under chapter 466; a person licensed under chapter 462; or an advanced practice registered nurse ~~practitioner~~ licensed under part I of chapter 464; or a duly licensed practitioner from another state licensed under similar statutes who orders examinations on materials or specimens for nonresidents of the

State of Florida, but who reside in the same state as the requesting licensed practitioner.

Section 76. Subsection (5) of section 483.801, Florida Statutes, is amended to read:

483.801 Exemptions.—This part applies to all clinical laboratories and clinical laboratory personnel within this state, except:

(5) Advanced practice registered nurses certified ~~nurse practitioners licensed~~ under part I of chapter 464 who perform provider-performed microscopy procedures (PPMP) in an exclusive-use laboratory setting.

Section 77. Paragraph (a) of subsection (11) of section 486.021, Florida Statutes, is amended to read:

486.021 Definitions.—In this chapter, unless the context otherwise requires, the term:

(11) "Practice of physical therapy" means the performance of physical therapy assessments and the treatment of any disability, injury, disease, or other health condition of human beings, or the prevention of such disability, injury, disease, or other condition of health, and rehabilitation as related thereto by the use of the physical, chemical, and other properties of air; electricity; exercise; massage; the performance of acupuncture only upon compliance with the criteria set forth by the Board of Medicine, when no penetration of the skin occurs; the use of radiant energy, including ultraviolet, visible, and infrared rays; ultrasound; water; the use of apparatus and equipment in the application of the foregoing or related thereto; the performance of tests of neuromuscular functions as an aid to the diagnosis or treatment

of any human condition; or the performance of electromyography as an aid to the diagnosis of any human condition only upon compliance with the criteria set forth by the Board of Medicine.

(a) A physical therapist may implement a plan of treatment developed by the physical therapist for a patient or provided for a patient by a practitioner of record or by an advanced practice registered nurse ~~practitioner~~ licensed under s. 464.012. The physical therapist shall refer the patient to or consult with a practitioner of record if the patient's condition is found to be outside the scope of physical therapy. If physical therapy treatment for a patient is required beyond 21 days for a condition not previously assessed by a practitioner of record, the physical therapist shall obtain a practitioner of record who will review and sign the plan. For purposes of this paragraph, a health care practitioner licensed under chapter 458, chapter 459, chapter 460, chapter 461, or chapter 466 and engaged in active practice is eligible to serve as a practitioner of record.

Section 78. Paragraph (d) of subsection (1) of section 490.012, Florida Statutes, is amended to read:

490.012 Violations; penalties; injunction.—

(1)

(d) No person shall hold herself or himself out by any title or description incorporating the word, or a permutation of the word, "psychotherapy" unless such person holds a valid, active license under chapter 458, chapter 459, chapter 490, or chapter 491, or such person is certified as an advanced practice registered nurse ~~practitioner~~, pursuant to s. 464.012, who has been determined by the Board of Nursing as a specialist in

psychiatric mental health.

Section 79. Subsection (1) of section 491.0057, Florida Statutes, is amended to read:

491.0057 Dual licensure as a marriage and family therapist.—The department shall license as a marriage and family therapist any person who demonstrates to the board that he or she:

(1) Holds a valid, active license as a psychologist under chapter 490 or as a clinical social worker or mental health counselor under this chapter, or is certified under s. 464.012 as an advanced practice registered nurse ~~practitioner~~ who has been determined by the Board of Nursing as a specialist in psychiatric mental health.

Section 80. Paragraph (d) of subsection (1) and subsection (2) of section 491.012, Florida Statutes, are amended to read:

491.012 Violations; penalty; injunction.—

(1) It is unlawful and a violation of this chapter for any person to:

(d) Use the terms psychotherapist, sex therapist, or juvenile sexual offender therapist unless such person is licensed pursuant to this chapter or chapter 490, or is certified under s. 464.012 as an advanced practice registered nurse ~~practitioner~~ who has been determined by the Board of Nursing as a specialist in psychiatric mental health and the use of such terms is within the scope of her or his practice based on education, training, and licensure.

(2) It is unlawful and a violation of this chapter for any person to describe her or his services using the following terms or any derivative thereof, unless such person holds a valid,

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active license under this chapter or chapter 490, or is certified under s. 464.012 as an advanced practice registered nurse ~~practitioner~~ who has been determined by the Board of Nursing as a specialist in psychiatric mental health and the use of such terms is within the scope of her or his practice based on education, training, and licensure:

(a) "Psychotherapy."

(b) "Sex therapy."

(c) "Sex counseling."

(d) "Clinical social work."

(e) "Psychiatric social work."

(f) "Marriage and family therapy."

(g) "Marriage and family counseling."

(h) "Marriage counseling."

(i) "Family counseling."

(j) "Mental health counseling."

Section 81. Subsection (2) of section 493.6108, Florida Statutes, is amended to read:

493.6108 Investigation of applicants by Department of Agriculture and Consumer Services.—

(2) In addition to subsection (1), the department shall make an investigation of the general physical fitness of the Class "G" applicant to bear a weapon or firearm. Determination of physical fitness shall be certified by a physician or physician assistant currently licensed pursuant to chapter 458, chapter 459, or any similar law of another state or authorized to act as a licensed physician by a federal agency or department or by an advanced practice registered nurse ~~practitioner~~ currently licensed pursuant to chapter 464. Such certification

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shall be submitted on a form provided by the department.

Section 82. Subsection (1) of section 626.9707, Florida Statutes, is amended to read:

626.9707 Disability insurance; discrimination on basis of sickle-cell trait prohibited.—

(1) An ~~No~~ insurer authorized to transact insurance in this state may not ~~shall~~ refuse to issue and deliver in this state any policy of disability insurance, whether such policy is defined as individual, group, blanket, franchise, industrial, or otherwise, which is currently being issued for delivery in this state and which affords benefits and coverage for any medical treatment or service authorized and permitted to be furnished by a hospital, clinic, health clinic, neighborhood health clinic, health maintenance organization, physician, physician's assistant, advanced practice registered nurse ~~practitioner~~, or medical service facility or personnel solely because the person to be insured has the sickle-cell trait.

Section 83. Paragraph (b) of subsection (1) of section 627.357, Florida Statutes, is amended to read:

627.357 Medical malpractice self-insurance.—

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

(b) "Health care provider" means any:

1. Hospital licensed under chapter 395.

2. Physician licensed, or physician assistant licensed, under chapter 458.

3. Osteopathic physician or physician assistant licensed under chapter 459.

4. Podiatric physician licensed under chapter 461.

5. Health maintenance organization certificated under part

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I of chapter 641.

6. Ambulatory surgical center licensed under chapter 395.

7. Chiropractic physician licensed under chapter 460.

8. Psychologist licensed under chapter 490.

9. Optometrist licensed under chapter 463.

10. Dentist licensed under chapter 466.

11. Pharmacist licensed under chapter 465.

12. Registered nurse, licensed practical nurse, or advanced practice registered nurse ~~practitioner~~ licensed or registered under part I of chapter 464.

13. Other medical facility.

14. Professional association, partnership, corporation, joint venture, or other association established by the individuals set forth in subparagraphs 2., 3., 4., 7., 8., 9., 10., 11., and 12. for professional activity.

Section 84. Subsection (6) of section 627.6471, Florida Statutes, is amended to read:

627.6471 Contracts for reduced rates of payment; limitations; coinsurance and deductibles.—

(6) If psychotherapeutic services are covered by a policy issued by the insurer, the insurer shall provide eligibility criteria for each group of health care providers licensed under chapter 458, chapter 459, chapter 490, or chapter 491, which include psychotherapy within the scope of their practice as provided by law, or for any person who is certified as an advanced practice registered nurse ~~practitioner~~ in psychiatric mental health under s. 464.012. When psychotherapeutic services are covered, eligibility criteria shall be established by the insurer to be included in the insurer's criteria for selection

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of network providers. The insurer may not discriminate against a health care provider by excluding such practitioner from its provider network solely on the basis of the practitioner's license.

Section 85. Subsections (15) and (17) of section 627.6472, Florida Statutes, are amended to read:

627.6472 Exclusive provider organizations.—

(15) If psychotherapeutic services are covered by a policy issued by the insurer, the insurer shall provide eligibility criteria for all groups of health care providers licensed under chapter 458, chapter 459, chapter 490, or chapter 491, which include psychotherapy within the scope of their practice as provided by law, or for any person who is certified as an advanced practice registered nurse ~~practitioner~~ in psychiatric mental health under s. 464.012. When psychotherapeutic services are covered, eligibility criteria shall be established by the insurer to be included in the insurer's criteria for selection of network providers. The insurer may not discriminate against a health care provider by excluding such practitioner from its provider network solely on the basis of the practitioner's license.

(17) An exclusive provider organization shall not discriminate with respect to participation as to any advanced practice registered nurse ~~practitioner~~ licensed and certified pursuant to s. 464.012, who is acting within the scope of such license and certification, solely on the basis of such license or certification. This subsection may ~~shall~~ not be construed to prohibit a plan from including providers only to the extent necessary to meet the needs of the plan's enrollees or from

establishing any measure designed to maintain quality and control costs consistent with the responsibilities of the plan.

Section 86. Paragraph (a) of subsection (1) of section 627.736, Florida Statutes, is amended to read:

627.736 Required personal injury protection benefits; exclusions; priority; claims.—

(1) REQUIRED BENEFITS.—An insurance policy complying with the security requirements of s. 627.733 must provide personal injury protection to the named insured, relatives residing in the same household, persons operating the insured motor vehicle, passengers in the motor vehicle, and other persons struck by the motor vehicle and suffering bodily injury while not an occupant of a self-propelled vehicle, subject to subsection (2) and paragraph (4)(e), to a limit of $10,000 in medical and disability benefits and $5,000 in death benefits resulting from bodily injury, sickness, disease, or death arising out of the ownership, maintenance, or use of a motor vehicle as follows:

(a) *Medical benefits.*—Eighty percent of all reasonable expenses for medically necessary medical, surgical, X-ray, dental, and rehabilitative services, including prosthetic devices and medically necessary ambulance, hospital, and nursing services if the individual receives initial services and care pursuant to subparagraph 1. within 14 days after the motor vehicle accident. The medical benefits provide reimbursement only for:

1. Initial services and care that are lawfully provided, supervised, ordered, or prescribed by a physician licensed under chapter 458 or chapter 459, a dentist licensed under chapter 466, or a chiropractic physician licensed under chapter 460 or

that are provided in a hospital or in a facility that owns, or is wholly owned by, a hospital. Initial services and care may also be provided by a person or entity licensed under part III of chapter 401 which provides emergency transportation and treatment.

2. Upon referral by a provider described in subparagraph 1., followup services and care consistent with the underlying medical diagnosis rendered pursuant to subparagraph 1. which may be provided, supervised, ordered, or prescribed only by a physician licensed under chapter 458 or chapter 459, a chiropractic physician licensed under chapter 460, a dentist licensed under chapter 466, or, to the extent permitted by applicable law and under the supervision of such physician, osteopathic physician, chiropractic physician, or dentist, by a physician assistant licensed under chapter 458 or chapter 459 or an advanced practice registered nurse ~~practitioner~~ licensed under chapter 464. Followup services and care may also be provided by the following persons or entities:

a. A hospital or ambulatory surgical center licensed under chapter 395.

b. An entity wholly owned by one or more physicians licensed under chapter 458 or chapter 459, chiropractic physicians licensed under chapter 460, or dentists licensed under chapter 466 or by such practitioners and the spouse, parent, child, or sibling of such practitioners.

c. An entity that owns or is wholly owned, directly or indirectly, by a hospital or hospitals.

d. A physical therapist licensed under chapter 486, based upon a referral by a provider described in this subparagraph.

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e. A health care clinic licensed under part X of chapter 400 which is accredited by an accrediting organization whose standards incorporate comparable regulations required by this state, or

(I) Has a medical director licensed under chapter 458, chapter 459, or chapter 460;

(II) Has been continuously licensed for more than 3 years or is a publicly traded corporation that issues securities traded on an exchange registered with the United States Securities and Exchange Commission as a national securities exchange; and

(III) Provides at least four of the following medical specialties:

(A) General medicine.

(B) Radiography.

(C) Orthopedic medicine.

(D) Physical medicine.

(E) Physical therapy.

(F) Physical rehabilitation.

(G) Prescribing or dispensing outpatient prescription medication.

(H) Laboratory services.

3. Reimbursement for services and care provided in subparagraph 1. or subparagraph 2. up to $10,000 if a physician licensed under chapter 458 or chapter 459, a dentist licensed under chapter 466, a physician assistant licensed under chapter 458 or chapter 459, or an advanced practice registered nurse ~~practitioner~~ licensed under chapter 464 has determined that the injured person had an emergency medical condition.

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4. Reimbursement for services and care provided in subparagraph 1. or subparagraph 2. is limited to $2,500 if a provider listed in subparagraph 1. or subparagraph 2. determines that the injured person did not have an emergency medical condition.

5. Medical benefits do not include massage as defined in s. 480.033 or acupuncture as defined in s. 457.102, regardless of the person, entity, or licensee providing massage or acupuncture, and a licensed massage therapist or licensed acupuncturist may not be reimbursed for medical benefits under this section.

6. The Financial Services Commission shall adopt by rule the form that must be used by an insurer and a health care provider specified in sub-subparagraph 2.b., sub-subparagraph 2.c., or sub-subparagraph 2.e. to document that the health care provider meets the criteria of this paragraph. Such rule must include a requirement for a sworn statement or affidavit.

Only insurers writing motor vehicle liability insurance in this state may provide the required benefits of this section, and such insurer may not require the purchase of any other motor vehicle coverage other than the purchase of property damage liability coverage as required by s. 627.7275 as a condition for providing such benefits. Insurers may not require that property damage liability insurance in an amount greater than $10,000 be purchased in conjunction with personal injury protection. Such insurers shall make benefits and required property damage liability insurance coverage available through normal marketing channels. An insurer writing motor vehicle liability insurance

in this state who fails to comply with such availability requirement as a general business practice violates part IX of chapter 626, and such violation constitutes an unfair method of competition or an unfair or deceptive act or practice involving the business of insurance. An insurer committing such violation is subject to the penalties provided under that part, as well as those provided elsewhere in the insurance code.

Section 87. Paragraph (e) of subsection (1) of section 633.412, Florida Statutes, is amended to read:

633.412 Firefighters; qualifications for certification.—

(1) A person applying for certification as a firefighter must:

(e) Be in good physical condition as determined by a medical examination given by a physician, surgeon, or physician assistant licensed to practice in the state pursuant to chapter 458; an osteopathic physician, surgeon, or physician assistant licensed to practice in the state pursuant to chapter 459; or an advanced practice registered nurse ~~practitioner~~ licensed to practice in the state pursuant to chapter 464. Such examination may include, but need not be limited to, the National Fire Protection Association Standard 1582. A medical examination evidencing good physical condition shall be submitted to the division, on a form as provided by rule, before an individual is eligible for admission into a course under s. 633.408.

Section 88. Section 641.3923, Florida Statutes, is amended to read:

641.3923 Discrimination against providers prohibited.—A health maintenance organization shall not discriminate with respect to participation as to any advanced practice registered

nurse ~~practitioner~~ licensed and certified pursuant to s. 464.012, who is acting within the scope of such license and certification, solely on the basis of such license or certification. This section shall not be construed to prohibit a plan from including providers only to the extent necessary to meet the needs of the plan's enrollees or from establishing any measure designed to maintain quality and control costs consistent with the responsibilities of the plan.

Section 89. Subsection (8) of section 641.495, Florida Statutes, is amended to read:

641.495 Requirements for issuance and maintenance of certificate.—

(8) Each organization's contracts, certificates, and subscriber handbooks shall contain a provision, if applicable, disclosing that, for certain types of described medical procedures, services may be provided by physician assistants, certified nurse practitioners, or other individuals who are not licensed physicians.

Section 90. Paragraph (a) of subsection (3) of section 744.331, Florida Statutes, is amended to read:

744.331 Procedures to determine incapacity.—

(3) EXAMINING COMMITTEE.—

(a) Within 5 days after a petition for determination of incapacity has been filed, the court shall appoint an examining committee consisting of three members. One member must be a psychiatrist or other physician. The remaining members must be either a psychologist, gerontologist, another psychiatrist, or other physician, a registered nurse, advanced practice registered nurse ~~practitioner~~, licensed social worker, a person

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with an advanced degree in gerontology from an accredited institution of higher education, or other person who by knowledge, skill, experience, training, or education may, in the court's discretion, advise the court in the form of an expert opinion. One of three members of the committee must have knowledge of the type of incapacity alleged in the petition. Unless good cause is shown, the attending or family physician may not be appointed to the committee. If the attending or family physician is available for consultation, the committee must consult with the physician. Members of the examining committee may not be related to or associated with one another, with the petitioner, with counsel for the petitioner or the proposed guardian, or with the person alleged to be totally or partially incapacitated. A member may not be employed by any private or governmental agency that has custody of, or furnishes, services or subsidies, directly or indirectly, to the person or the family of the person alleged to be incapacitated or for whom a guardianship is sought. A petitioner may not serve as a member of the examining committee. Members of the examining committee must be able to communicate, either directly or through an interpreter, in the language that the alleged incapacitated person speaks or to communicate in a medium understandable to the alleged incapacitated person if she or he is able to communicate. The clerk of the court shall send notice of the appointment to each person appointed no later than 3 days after the court's appointment.

Section 91. Subsection (1) of section 744.703, Florida Statutes, is amended to read:

744.703 Office of public guardian; appointment,

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notification.—

(1) The executive director of the Statewide Public Guardianship Office, after consultation with the chief judge and other circuit judges within the judicial circuit and with appropriate advocacy groups and individuals and organizations who are knowledgeable about the needs of incapacitated persons, may establish, within a county in the judicial circuit or within the judicial circuit, one or more offices of public guardian and if so established, shall create a list of persons best qualified to serve as the public guardian, who have been investigated pursuant to s. 744.3135. The public guardian must have knowledge of the legal process and knowledge of social services available to meet the needs of incapacitated persons. The public guardian shall maintain a staff or contract with professionally qualified individuals to carry out the guardianship functions, including an attorney who has experience in probate areas and another person who has a master's degree in social work, or a gerontologist, psychologist, registered nurse, or advanced practice registered nurse ~~practitioner~~. A public guardian that is a nonprofit corporate guardian under s. 744.309(5) must receive tax-exempt status from the United States Internal Revenue Service.

Section 92. Subsection (6) of section 766.102, Florida Statutes, is amended to read:

766.102 Medical negligence; standards of recovery; expert witness.—

(6) A physician licensed under chapter 458 or chapter 459 who qualifies as an expert witness under subsection (5) and who, by reason of active clinical practice or instruction of

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students, has knowledge of the applicable standard of care for nurses, certified nurse practitioners, certified registered nurse anesthetists, certified registered nurse midwives, physician assistants, or other medical support staff may give expert testimony in a medical negligence action with respect to the standard of care of such medical support staff.

Section 93. Subsection (3) of section 766.103, Florida Statutes, is amended to read:

766.103 Florida Medical Consent Law.—

(3) ~~No~~ Recovery is not ~~shall be~~ allowed in any court in this state against any physician licensed under chapter 458, osteopathic physician licensed under chapter 459, chiropractic physician licensed under chapter 460, podiatric physician licensed under chapter 461, dentist licensed under chapter 466, advanced practice registered nurse ~~practitioner~~ certified under s. 464.012, or physician assistant licensed under s. 458.347 or s. 459.022 in an action brought for treating, examining, or operating on a patient without his or her informed consent when:

(a)1. The action of the physician, osteopathic physician, chiropractic physician, podiatric physician, dentist, advanced practice registered nurse ~~practitioner~~, or physician assistant in obtaining the consent of the patient or another person authorized to give consent for the patient was in accordance with an accepted standard of medical practice among members of the medical profession with similar training and experience in the same or similar medical community as that of the person treating, examining, or operating on the patient for whom the consent is obtained; and

2. A reasonable individual, from the information provided

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by the physician, osteopathic physician, chiropractic physician, podiatric physician, dentist, advanced practice registered nurse ~~practitioner~~, or physician assistant, under the circumstances, would have a general understanding of the procedure, the medically acceptable alternative procedures or treatments, and the substantial risks and hazards inherent in the proposed treatment or procedures, which are recognized among other physicians, osteopathic physicians, chiropractic physicians, podiatric physicians, or dentists in the same or similar community who perform similar treatments or procedures; or

(b) The patient would reasonably, under all the surrounding circumstances, have undergone such treatment or procedure had he or she been advised by the physician, osteopathic physician, chiropractic physician, podiatric physician, dentist, advanced practice registered nurse ~~practitioner~~, or physician assistant in accordance with the provisions of paragraph (a).

Section 94. Paragraph (d) of subsection (3) of section 766.1115, Florida Statutes, is amended to read:

766.1115 Health care providers; creation of agency relationship with governmental contractors.—

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

(d) "Health care provider" or "provider" means:

1. A birth center licensed under chapter 383.

2. An ambulatory surgical center licensed under chapter 395.

3. A hospital licensed under chapter 395.

4. A physician or physician assistant licensed under chapter 458.

5. An osteopathic physician or osteopathic physician

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assistant licensed under chapter 459.

6. A chiropractic physician licensed under chapter 460.

7. A podiatric physician licensed under chapter 461.

8. A registered nurse, nurse midwife, licensed practical nurse, or advanced practice registered nurse ~~practitioner~~ licensed or registered under part I of chapter 464 or any facility which employs nurses licensed or registered under part I of chapter 464 to supply all or part of the care delivered under this section.

9. A midwife licensed under chapter 467.

10. A health maintenance organization certificated under part I of chapter 641.

11. A health care professional association and its employees or a corporate medical group and its employees.

12. Any other medical facility the primary purpose of which is to deliver human medical diagnostic services or which delivers nonsurgical human medical treatment, and which includes an office maintained by a provider.

13. A dentist or dental hygienist licensed under chapter 466.

14. A free clinic that delivers only medical diagnostic services or nonsurgical medical treatment free of charge to all low-income recipients.

15. Any other health care professional, practitioner, provider, or facility under contract with a governmental contractor, including a student enrolled in an accredited program that prepares the student for licensure as any one of the professionals listed in subparagraphs 4.-9.

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The term includes any nonprofit corporation qualified as exempt from federal income taxation under s. 501(a) of the Internal Revenue Code, and described in s. 501(c) of the Internal Revenue Code, which delivers health care services provided by licensed professionals listed in this paragraph, any federally funded community health center, and any volunteer corporation or volunteer health care provider that delivers health care services.

Section 95. Subsection (1) of section 766.1116, Florida Statutes, is amended to read:

766.1116 Health care practitioner; waiver of license renewal fees and continuing education requirements.—

(1) As used in this section, the term "health care practitioner" means a physician or physician assistant licensed under chapter 458; an osteopathic physician or physician assistant licensed under chapter 459; a chiropractic physician licensed under chapter 460; a podiatric physician licensed under chapter 461; an advanced practice registered nurse ~~practitioner~~, registered nurse, or licensed practical nurse licensed under part I of chapter 464; a dentist or dental hygienist licensed under chapter 466; or a midwife licensed under chapter 467, who participates as a health care provider under s. 766.1115.

Section 96. Subsection (5) of section 794.08, Florida Statutes, is amended to read:

794.08 Female genital mutilation.—

(5) This section does not apply to procedures performed by or under the direction of a physician licensed under chapter 458, an osteopathic physician licensed under chapter 459, a registered nurse licensed under part I of chapter 464, a

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practical nurse licensed under part I of chapter 464, an advanced practice registered nurse ~~practitioner~~ licensed under part I of chapter 464, a midwife licensed under chapter 467, or a physician assistant licensed under chapter 458 or chapter 459 when necessary to preserve the physical health of a female person. This section also does not apply to any autopsy or limited dissection conducted pursuant to chapter 406.

Section 97. Subsection (6) of section 943.13, Florida Statutes, is amended to read:

943.13 Officers' minimum qualifications for employment or appointment.—On or after October 1, 1984, any person employed or appointed as a full-time, part-time, or auxiliary law enforcement officer or correctional officer; on or after October 1, 1986, any person employed as a full-time, part-time, or auxiliary correctional probation officer; and on or after October 1, 1986, any person employed as a full-time, part-time, or auxiliary correctional officer by a private entity under contract to the Department of Corrections, to a county commission, or to the Department of Management Services shall:

(6) Have passed a physical examination by a licensed physician, physician assistant, or certified advanced practice registered nurse ~~practitioner~~, based on specifications established by the commission. In order to be eligible for the presumption set forth in s. 112.18 while employed with an employing agency, a law enforcement officer, correctional officer, or correctional probation officer must have successfully passed the physical examination required by this subsection upon entering into service as a law enforcement officer, correctional officer, or correctional probation officer

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with the employing agency, which examination must have failed to reveal any evidence of tuberculosis, heart disease, or hypertension. A law enforcement officer, correctional officer, or correctional probation officer may not use a physical examination from a former employing agency for purposes of claiming the presumption set forth in s. 112.18 against the current employing agency.

Section 98. Subsection (2) of section 945.603, Florida Statutes, is amended to read:

945.603 Powers and duties of authority.—The purpose of the authority is to assist in the delivery of health care services for inmates in the Department of Corrections by advising the Secretary of Corrections on the professional conduct of primary, convalescent, dental, and mental health care and the management of costs consistent with quality care, by advising the Governor and the Legislature on the status of the Department of Corrections' health care delivery system, and by assuring that adequate standards of physical and mental health care for inmates are maintained at all Department of Corrections institutions. For this purpose, the authority has the authority to:

(2) Review and make recommendations regarding health care for the delivery of health care services including, but not limited to, acute hospital-based services and facilities, primary and tertiary care services, ancillary and clinical services, dental services, mental health services, intake and screening services, medical transportation services, and the use of advanced practice registered nurse ~~practitioner~~ and physician assistant personnel to act as physician extenders as these

relate to inmates in the Department of Corrections.

Section 99. Paragraph (i) of subsection (3) of section 1002.20, Florida Statutes, is amended to read:

1002.20 K-12 student and parent rights.—Parents of public school students must receive accurate and timely information regarding their child's academic progress and must be informed of ways they can help their child to succeed in school. K-12 students and their parents are afforded numerous statutory rights including, but not limited to, the following:

(3) HEALTH ISSUES.—

(i) *Epinephrine use and supply.*—

1. A student who has experienced or is at risk for life-threatening allergic reactions may carry an epinephrine auto-injector and self-administer epinephrine by auto-injector while in school, participating in school-sponsored activities, or in transit to or from school or school-sponsored activities if the school has been provided with parental and physician authorization. The State Board of Education, in cooperation with the Department of Health, shall adopt rules for such use of epinephrine auto-injectors that shall include provisions to protect the safety of all students from the misuse or abuse of auto-injectors. A school district, county health department, public-private partner, and their employees and volunteers shall be indemnified by the parent of a student authorized to carry an epinephrine auto-injector for any and all liability with respect to the student's use of an epinephrine auto-injector pursuant to this paragraph.

2. A public school may purchase from a wholesale distributor as defined in s. 499.003 and maintain in a locked,

secure location on its premises a supply of epinephrine auto-injectors for use if a student is having an anaphylactic reaction. The participating school district shall adopt a protocol developed by a licensed physician for the administration by school personnel who are trained to recognize an anaphylactic reaction and to administer an epinephrine auto-injection. The supply of epinephrine auto-injectors may be provided to and used by a student authorized to self-administer epinephrine by auto-injector under subparagraph 1. or trained school personnel.

3. The school district and its employees and agents, including the physician who provides the standing protocol for school epinephrine auto-injectors, are not liable for any injury arising from the use of an epinephrine auto-injector administered by trained school personnel who follow the adopted protocol and whose professional opinion is that the student is having an anaphylactic reaction:

a. Unless the trained school personnel's action is willful and wanton;

b. Notwithstanding that the parents or guardians of the student to whom the epinephrine is administered have not been provided notice or have not signed a statement acknowledging that the school district is not liable; and

c. Regardless of whether authorization has been given by the student's parents or guardians or by the student's physician, physician's assistant, or advanced practice registered nurse ~~practitioner~~.

Section 100. Paragraph (b) of subsection (17) of section 1002.42, Florida Statutes, is amended to read:

1002.42 Private schools.—

(17) EPINEPHRINE SUPPLY.—

(b) The private school and its employees and agents, including the physician who provides the standing protocol for school epinephrine auto-injectors, are not liable for any injury arising from the use of an epinephrine auto-injector administered by trained school personnel who follow the adopted protocol and whose professional opinion is that the student is having an anaphylactic reaction:

1. Unless the trained school personnel's action is willful and wanton;

2. Notwithstanding that the parents or guardians of the student to whom the epinephrine is administered have not been provided notice or have not signed a statement acknowledging that the school district is not liable; and

3. Regardless of whether authorization has been given by the student's parents or guardians or by the student's physician, physician's assistant, or advanced practice registered nurse ~~practitioner~~.

Section 101. Subsections (4) and (5) of section 1006.062, Florida Statutes, are amended to read:

1006.062 Administration of medication and provision of medical services by district school board personnel.—

(4) Nonmedical assistive personnel shall be allowed to perform health-related services upon successful completion of child-specific training by a registered nurse or advanced practice registered nurse ~~practitioner~~ licensed under chapter 464, a physician licensed pursuant to chapter 458 or chapter 459, or a physician assistant licensed pursuant to chapter 458

or chapter 459. All procedures shall be monitored periodically by a nurse, advanced practice registered nurse ~~practitioner~~, physician assistant, or physician, including, but not limited to:

(a) Intermittent clean catheterization.

(b) Gastrostomy tube feeding.

(c) Monitoring blood glucose.

(d) Administering emergency injectable medication.

(5) For all other invasive medical services not listed in this subsection, a registered nurse or advanced practice registered nurse ~~practitioner~~ licensed under chapter 464, a physician licensed pursuant to chapter 458 or chapter 459, or a physician assistant licensed pursuant to chapter 458 or chapter 459 shall determine if nonmedical district school board personnel shall be allowed to perform such service.

Section 102. Subsection (1) and paragraph (a) of subsection (2) of section 1009.65, Florida Statutes, are amended to read:

1009.65 Medical Education Reimbursement and Loan Repayment Program.—

(1) To encourage qualified medical professionals to practice in underserved locations where there are shortages of such personnel, there is established the Medical Education Reimbursement and Loan Repayment Program. The function of the program is to make payments that offset loans and educational expenses incurred by students for studies leading to a medical or nursing degree, medical or nursing licensure, or advanced practice registered nurse ~~practitioner~~ certification or physician assistant licensure. The following licensed or certified health care professionals are eligible to participate

in this program: medical doctors with primary care specialties, doctors of osteopathic medicine with primary care specialties, physician's assistants, licensed practical nurses and registered nurses, and advanced practice registered nurses ~~nurse practitioners~~ with primary care specialties such as certified nurse midwives. Primary care medical specialties for physicians include obstetrics, gynecology, general and family practice, internal medicine, pediatrics, and other specialties which may be identified by the Department of Health.

(2) From the funds available, the Department of Health shall make payments to selected medical professionals as follows:

(a) Up to $4,000 per year for licensed practical nurses and registered nurses, up to $10,000 per year for advanced practice registered nurses ~~nurse practitioners~~ and physician's assistants, and up to $20,000 per year for physicians. Penalties for noncompliance shall be the same as those in the National Health Services Corps Loan Repayment Program. Educational expenses include costs for tuition, matriculation, registration, books, laboratory and other fees, other educational costs, and reasonable living expenses as determined by the Department of Health.

Section 103. Subsection (2) of section 1009.66, Florida Statutes, is amended to read:

1009.66 Nursing Student Loan Forgiveness Program.—

(2) To be eligible, a candidate must have graduated from an accredited or approved nursing program and have received a Florida license as a licensed practical nurse or a registered nurse or a Florida certificate as an advanced practice

registered nurse ~~practitioner~~.

Section 104. Subsection (3) of section 1009.67, Florida Statutes, is amended to read:

1009.67 Nursing scholarship program.—

(3) A scholarship may be awarded for no more than 2 years, in an amount not to exceed $8,000 per year. However, registered nurses pursuing a graduate degree for a faculty position or to practice as an advanced practice registered nurse ~~practitioner~~ may receive up to $12,000 per year. These amounts shall be adjusted by the amount of increase or decrease in the Consumer Price Index for All Urban Consumers published by the United States Department of Commerce.

Section 105. This act shall take effect July 1, 2014.

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Health Policy

BILL:	SB 1086
INTRODUCER:	Senator Flores and others
SUBJECT:	Optional Medical Payments for Prenatal Care
DATE:	March 21, 2014 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Lloyd	Stovall	HP	**Pre-meeting**
2.			AHS	
3.			AP	

I. Summary:

SB 1086 revises section 409.903, Florida Statutes to increase the eligibility criteria for pregnant women and infants under age 1 from 185 percent of the federal poverty level (FPL) to 200 percent of the FPL. Infants under age 1 are currently covered up to 200 percent of the FPL under an optional Medicaid expansion with Title XXI (Children's Health Insurance Program) funding; however, the bill converts this population to a mandatory coverage group.

II. Present Situation:

Medicaid is a joint federal and state funded program that provides health care for low income Floridians. The program is administered by the Agency for Health Care Administration (AHCA) and financed with federal and state funds. Over 3.3 million Floridians are currently enrolled in Medicaid and the program's estimated expenditures for Fiscal Year 2012-2013 were approximately $21 billion.[1] The statutory authority for the Medicaid program is contained in ch. 409, F.S.

Each state operates its own Medicaid program under a state plan that must be approved by the federal Centers for Medicare and Medicaid Services. The plan outlines current Medicaid eligibility standards, policies, and reimbursement methodologies. Certain services must be included by all states as must certain population groups within designated income limits.

Federal law and regulations require states to cover pregnant women and infants under 1 year of age who have an income level of not more than 185 percent of the FPL.[2] States may seek a higher income level through a state plan amendment or a waiver process. Florida implements the federal law at s. 409.903(5), F.S.

[1] Agency for Health Care Administration, *Florida Medicaid*, http://ahca.myflorida.com/Medicaid/index.shtml (last visited Mar. 20, 2014).
[2] 42 U.S.C. 1396(a) and 42 CFR 435.116 and 435.118.

Once determined eligible for Medicaid, a pregnant woman remains eligible for Medicaid through the end of the calendar month in which the 60th day of the end of the pregnancy falls, regardless of any change in family income.[3] States have the option of providing pregnant women with the full Medicaid coverage or they may elect to limit coverage to certain pregnancy-related services.[4] Florida covers the pregnancy, pregnancy-related services and services for any other illness or medical condition during the eligibility period that may complicate the pregnancy.[5]

Women who apply for Medicaid through a qualified provider, such as hospitals or county health departments, are offered presumptive eligibility until a decision is made on a full Medicaid determination. The presumptive eligibility period begins with the date the eligibility determination is completed and extends for one additional month or until a full Medicaid determination is approved or denied.[6] During the presumptive eligibility period, Medicaid will only reimburse for outpatient prenatal care.[7]

Infants born to a pregnant woman on Medicaid are automatically deemed eligible for Medicaid until the child's first birthday and are eligible for all Medicaid services.[8] Infants under the age of one in families with an income between 185 and 200 percent of the FPL are currently covered as an optional Medicaid expansion group utilizing Title XXI funds.

III. Effect of Proposed Changes:

Section 1 modifies s. 409.903, F.S., to increase the maximum family income threshold for Medicaid eligibility for an infant under the age of 1 and a pregnant woman for the duration of her pregnancy and the federally defined postpartum period.

Increasing the maximum family income for the infant population under age one to 200 percent of the FPL will not expand current eligibility guidelines as this population is currently covered as an optional Medicaid expansion group funded by Title XXI. However, this change does convert the infants to a mandatory coverage group.

The bill also updates references to the Department of Children and Family Services to the Department of Children and Families.

Section 2 provides an effective date of July 1, 2014.

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[3] Centers for Medicare and Medicaid Services, *Pregnant Women,* http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Population/Pregnant-Women/Pregnant-Women.html (last visited Mar. 21, 2014).
[4] *Id.* Pregnancy related services are generally defined as care related to pregnancy, labor, and delivery and any complications that may occur during pregnancy, as well as perinatal care for 60 days postpartum.
[5] Florida Medicaid State Plan, p. 7, http://www.fdhc.state.fl.us/Medicaid/stateplanpdf/section_3.pdf (last visited Mar. 21, 2014).
[6] Department of Children and Families, *Family-Related Medicaid Programs Fact Sheets,* *http://www.dcf.state.fl.us/programs/access/docs/fammedfactsheet.pdf* (last visited Mar. 21, 2014).
[7] Agency for Health Care Administration, *2014 Agency Legislative Bill Analysis - SB 1086,* on file with the Senate Health Policy Committee (Feb. 21, 2014).
[8] Agency for Health Care Administration, *Florida Medicaid Provider General Handbook - Presumptively Eligible Newborns,* p.155, http://portal.flmmis.com/FLPublic/Portals/0/StaticContent/Public/HANDBOOKS/GH_12_12-07-01_Provider_General_Handbook.pdf (last visited Mar. 21, 2014).

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

An increase in the eligibility guidelines for pregnant women and infants under age one may reduce the number of pregnant women that seek prenatal and other medical care from health care providers as self-pay individuals. Expanding eligibility to additional pregnant women may result in an increase in early prenatal services and better birth outcomes.

C. Government Sector Impact:

The AHCA estimates that an additional 3,290 pregnant women for an annual caseload of 21,933 would enroll in Medicaid under the expansion to 200 percent of the FPL for 2014-2015. The fiscal impact for 2014-2015 is estimated at $26,265,937, of which $10,742,768 is the state portion. Caseload in the following year (2015-2016) is based on a 4.4 percent increase over the base year for a state impact of $11,418,553.

The AHCA would also be required to submit a state plan amendment and modify existing administrative rules for the Medicaid program.

The DCF reported no fiscal impact.

VI. Technical Deficiencies:

The bill includes conflicting language beginning on line 62 through line 64 which references a maximum income level of 150 percent of the FPL for a pregnant woman or a child under age 1.

The bill's title incorrectly states it is an act relating to optional medical payments for prenatal care. The bill amends s. 409.903, F.S., relating to mandatory payments for medical care under Medicaid.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 409.903.

IX. Additional Information:

A. Committee Substitute – Statement of Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.

This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.

901480

LEGISLATIVE ACTION

Senate . House

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The Committee on Health Policy (Flores) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause and insert:

Section 1. Section 409.903, Florida Statutes, is amended to read:

409.903 Mandatory payments for eligible persons.—Subject to the availability of moneys and any limitations established by the General Appropriations Act or chapter 216, the agency shall make payments for medical assistance and related services on

behalf of the following Medicaid eligible persons who the department, or the Social Security Administration by contract with the Department of Children and Families ~~Family Services~~, determines to be eligible, subject to the income, assets, and categorical eligibility tests set forth in federal and state law:~~. Payment on behalf of these Medicaid eligible persons is subject to the availability of moneys and any limitations established by the General Appropriations Act or chapter 216.~~

(1) Low-income families with children are eligible for Medicaid provided they meet the following requirements:

(a) The family includes a dependent child who is living with a caretaker relative.

(b) The family's income does not exceed the gross income test limit.

(c) The family's countable income and resources do not exceed the applicable Aid to Families with Dependent Children (AFDC) income and resource standards under the AFDC state plan in effect in July 1996, except as amended in the Medicaid state plan to conform as closely as possible to the requirements of the welfare transition program, to the extent permitted by federal law.

(2) A person who receives payments from, who is determined eligible for, or who was eligible for but lost cash benefits from the federal program known as the Supplemental Security Income program (SSI). This category includes a low-income person age 65 or over and a low-income person under age 65 considered to be permanently and totally disabled.

(3) A child under age 21 living in a low-income, two-parent family, and a child under age 7 living with a nonrelative, if

the income and assets of the family or child, as applicable, do not exceed the resource limits under the Temporary Cash Assistance Program.

(4) A child who is eligible under Title IV-E of the Social Security Act for subsidized board payments, foster care, or adoption subsidies, and a child for whom the state has assumed temporary or permanent responsibility and who does not qualify for Title IV-E assistance but is in foster care, shelter or emergency shelter care, or subsidized adoption. This category includes a young adult who is eligible to receive services under s. 409.1451, until the young adult reaches 21 years of age, without regard to any income, resource, or categorical eligibility test that is otherwise required. This category also includes a person who as a child was eligible under Title IV-E of the Social Security Act for foster care or the state-provided foster care and who is a participant in the Road-to-Independence Program.

(5) A pregnant woman for the duration of her pregnancy and for the postpartum period as defined in federal law and rule, or a child under age 1, ~~if either is living in a family that has an income which is at or below 150 percent of the most current federal poverty level, or, effective January 1, 1992,~~ that has an income which is at or below 200 ~~185~~ percent of the most current federal poverty level. Such a person is not subject to an assets test. Further, a pregnant woman who applies for eligibility for the Medicaid program through a qualified Medicaid provider must be offered the opportunity, subject to federal rules, to be made presumptively eligible for the Medicaid program.

(6) A child born after September 30, 1983, living in a family that has an income which is at or below 100 percent of the current federal poverty level, who has attained the age of 6, but has not attained the age of 19. In determining the eligibility of such a child, an assets test is not required. A child who is eligible for Medicaid under this subsection must be offered the opportunity, subject to federal rules, to be made presumptively eligible. A child who has been deemed presumptively eligible for Medicaid shall not be enrolled in a managed care plan until the child's full eligibility determination for Medicaid has been completed.

(7) A child living in a family that has an income which is at or below 133 percent of the current federal poverty level, who has attained the age of 1, but has not attained the age of 6. In determining the eligibility of such a child, an assets test is not required. A child who is eligible for Medicaid under this subsection must be offered the opportunity, subject to federal rules, to be made presumptively eligible. A child who has been deemed presumptively eligible for Medicaid shall not be enrolled in a managed care plan until the child's full eligibility determination for Medicaid has been completed.

(8) A person who is age 65 or over or is determined by the agency to be disabled, whose income is at or below 100 percent of the most current federal poverty level and whose assets do not exceed limitations established by the agency. However, the agency may only pay for premiums, coinsurance, and deductibles, as required by federal law, unless additional coverage is provided for any or all members of this group by s. 409.904(1).

Section 2. This act shall take effect July 1, 2014.

901480

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99 ================ T I T L E A M E N D M E N T ================
100 And the title is amended as follows:
101 Delete everything before the enacting clause
102 and insert:
103 A bill to be entitled
104 An act relating to mandatory medical payments for
105 pregnancy; amending s. 409.903, F.S.; revising
106 eligibility criteria for a pregnant woman or a child
107 under 1 year of age to qualify for medical assistance
108 and related services payments; providing an effective
109 date.

By Senator Flores

37-01238-14 20141086__

A bill to be entitled

An act relating to optional medical payments for prenatal care; amending s. 409.903, F.S.; revising eligibility criteria for a pregnant woman to qualify for medical assistance payments; providing an effective date.

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

Section 1. Section 409.903, Florida Statutes, is amended to read:

409.903 Mandatory payments for eligible persons.—The agency shall make payments for medical assistance and related services on behalf of the following persons who the department, or the Social Security Administration by contract with the Department of Children and Families ~~Family Services~~, determines to be eligible, subject to the income, assets, and categorical eligibility tests set forth in federal and state law. Payment on behalf of these Medicaid eligible persons is subject to the availability of moneys and any limitations established by the General Appropriations Act or chapter 216.

(1) Low-income families with children are eligible for Medicaid provided they meet the following requirements:

(a) The family includes a dependent child who is living with a caretaker relative.

(b) The family's income does not exceed the gross income test limit.

(c) The family's countable income and resources do not exceed the applicable Aid to Families with Dependent Children

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

37-01238-14 20141086__

(AFDC) income and resource standards under the AFDC state plan in effect in July 1996, except as amended in the Medicaid state plan to conform as closely as possible to the requirements of the welfare transition program, to the extent permitted by federal law.

(2) A person who receives payments from, who is determined eligible for, or who was eligible for but lost cash benefits from the federal program known as the Supplemental Security Income program (SSI). This category includes a low-income person age 65 or over and a low-income person under age 65 considered to be permanently and totally disabled.

(3) A child under age 21 living in a low-income, two-parent family, and a child under age 7 living with a nonrelative, if the income and assets of the family or child, as applicable, do not exceed the resource limits under the Temporary Cash Assistance Program.

(4) A child who is eligible under Title IV-E of the Social Security Act for subsidized board payments, foster care, or adoption subsidies, and a child for whom the state has assumed temporary or permanent responsibility and who does not qualify for Title IV-E assistance but is in foster care, shelter or emergency shelter care, or subsidized adoption. This category includes a young adult who is eligible to receive services under s. 409.1451, until the young adult reaches 21 years of age, without regard to any income, resource, or categorical eligibility test that is otherwise required. This category also includes a person who as a child was eligible under Title IV-E of the Social Security Act for foster care or the state-provided foster care and who is a participant in the Road-to-Independence

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

Program.

(5) A pregnant woman for the duration of her pregnancy and for the postpartum period as defined in federal law and rule, or a child under age 1, if either is living in a family that has an income which is at or below 150 percent of the most current federal poverty level, or~~, effective January 1, 1992,~~ that has an income which is at or below 200 ~~185~~ percent of the most current federal poverty level. Such a person is not subject to an assets test. Further, a pregnant woman who applies for eligibility for the Medicaid program through a qualified Medicaid provider must be offered the opportunity, subject to federal rules, to be made presumptively eligible for the Medicaid program.

(6) A child born after September 30, 1983, living in a family that has an income which is at or below 100 percent of the current federal poverty level, who has attained the age of 6, but has not attained the age of 19. In determining the eligibility of such a child, an assets test is not required. A child who is eligible for Medicaid under this subsection must be offered the opportunity, subject to federal rules, to be made presumptively eligible. A child who has been deemed presumptively eligible for Medicaid shall not be enrolled in a managed care plan until the child's full eligibility determination for Medicaid has been completed.

(7) A child living in a family that has an income which is at or below 133 percent of the current federal poverty level, who has attained the age of 1, but has not attained the age of 6. In determining the eligibility of such a child, an assets test is not required. A child who is eligible for Medicaid under

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

this subsection must be offered the opportunity, subject to federal rules, to be made presumptively eligible. A child who has been deemed presumptively eligible for Medicaid shall not be enrolled in a managed care plan until the child's full eligibility determination for Medicaid has been completed.

(8) A person who is age 65 or over or is determined by the agency to be disabled, whose income is at or below 100 percent of the most current federal poverty level and whose assets do not exceed limitations established by the agency. However, the agency may only pay for premiums, coinsurance, and deductibles, as required by federal law, unless additional coverage is provided for any or all members of this group by s. 409.904(1).

Section 2. This act shall take effect July 1, 2014.

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Health Policy

BILL:	SB 1134
INTRODUCER:	Senator Detert
SUBJECT:	Home Medical Equipment
DATE:	March 19, 2014
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Stovall	HP	**Pre-meeting**
2.			AHS	
3.			AP	

I. Summary:

SB 1134 amends s. 400.925, F.S., to exempt from the definition of "home medical equipment provider" any medical practice that is wholly owned by one or more medical, osteopathic, or chiropractic physicians or owned by a physician and his or her spouse, parent, child, or sibling.

II. Present Situation:

Part VII of ch. 400, F.S., requires that the Agency for Health Care Administration (AHCA) license and regulate any person or entity that holds itself out to the public as providing home medical equipment[1] and services,[2] accepts physician orders for home medical equipment and services, or holds itself out to the public as providing home medical equipment that typically requires home medical services.[3]

Providers operated by the Department of Health (DOH) or the federal government, nursing homes, assisted living facilities, home health agencies, hospices, intermediate care facilities, homes for special services, transitional living facilities, hospitals, ambulatory surgical centers, manufacturers and wholesale distributors who do not sell directly to the consumer, licensed health care practitioners who utilize home medical equipment in the course of their practice but do not sell or rent home medical equipment to their patients, and pharmacies are exempt from the

[1] Defined in s. 400.925, F.S., as any product as defined by the Federal Drug Administration's Drugs, Devices and Cosmetics Act, any products reimbursed under the Medicare Part B Durable Medical Equipment benefits, or any products reimbursed under the Florida Medicaid durable medical equipment program. Home medical equipment includes oxygen and related respiratory equipment; manual, motorized, or customized wheelchairs and related seating and positioning, but does not include prosthetics or orthotics or any splints, braces, or aids custom fabricated by a licensed health care practitioner; motorized scooters; personal transfer systems; and specialty beds, for use by a person with a medical need.

[2] Defined in s. 400.925, F.S., as equipment management and consumer instruction, including selection, delivery, setup, and maintenance of equipment, and other related services for the use of home medical equipment in the consumer's regular or temporary place of residence.

[3] Section 400.93(1) and (2), F.S.

licensure as a home medical equipment providers.[4] Currently there are 980 licensed home medical equipment providers, including those providers that are located out of the state but hold a Florida license.[5]

Any person or entity applying for a license as a home medical equipment provider must provide the AHCA with:

- A report of the medical equipment that will be provided, indicating whether it will be provided directly or by contract;
- A report of the services that will provided, indicating whether the services will be provided directly or by contract;
- A list of the persons and entities with whom they contract;
- Documentation of accreditation, or an application for accreditation, from an organization recognized by the AHCA;
- Proof of liability insurance; and,
- A $300 application fee and a $400 inspection fee, unless exempt from inspection.[6]

As a requirement of licensure, home medical equipment providers must comply with a number of minimum standards including, but not limited to:

- Offering and providing home medical equipment and services, as necessary, to consumers who purchase or rent any equipment that requires such services;
- Providing at least one category of equipment directly from their own inventory;
- Responding to orders for other equipment from either their own inventory or from the inventory of other contracted companies;
- Maintaining trained personnel to coordinate orders and scheduling of equipment and service deliveries;
- Ensuring that their delivery personnel are appropriately trained;
- Ensuring that patients are aware of their service hours and emergency service procedures;
- Answering any questions or complaints a consumer has about an item or the use of an item;
- Maintaining and repairing, either directly or through contract, items rented to consumers;
- Maintaining a safe premises;
- Preparing and maintaining a comprehensive emergency management plan that must be updated annually and provide for continuing home medical equipment services for life-supporting or life-sustaining equipment during an emergency;
- Maintaining a prioritized list of patients who need continued services during an emergency;[7]
- Complying with AHCA rules on minimum qualifications for personnel, including ensuring that all personnel have the necessary training and background screening;[8] and,
- Maintaining a record for each patient that includes the equipment and services the provider has provided and which must contain:
    - Any physician's order or certificate of medical necessity;

[4] Section 400.93(5), F.S.
[5] *See* FloridaHealthFinder.gov list of home medical equipment providers printed on Mar. 19, 2014, on file with Senate Health Policy committee staff
[6] Section 400.931, F.S.
[7] Section 400.934, F.S.
[8] AHCA Rule 59A-25.004, F.A.C. All home medical equipment provider personnel are also subject to a level 2 background screening per s. 400.953, F.S.

- Signed and dated delivery slips;
- Notes reflecting all services, maintenance performed, and equipment exchanges;
- The date on which rental equipment was retrieved; and
- Any other appropriate information.[9]

Licensed home medical equipment providers are subject to periodic inspections including biennial licensure inspections, inspections directed by the Centers for Medicare and Medicaid Services, and licensure complaint investigations. A home medical equipment provider may submit a survey or inspection by an accrediting organization in lieu of a licensure inspection if the provider's accreditation is not provisional and the AHCA receives a report from the accrediting organization. A copy of a valid medical oxygen retail establishment permit issued by the DOH may also be submitted in lieu of a licensure inspection.[10]

III. Effect of Proposed Changes:

The bill amends s. 400.925, F.S., to exempt from the definition of "home medical equipment provider" any medical practice that is wholly owned by one or more medical, osteopathic, or chiropractic physicians or owned by a physician and the spouse, parent, child, or sibling of the physician.

The bill establishes an effective date of July 1, 2014.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

[9] Section 400.94, F.S.
[10] Section 400.933, F.S.

B. Private Sector Impact:

Any exempted medical practices may see an indeterminate positive fiscal impact due to no longer having to pay licensure and inspection fees or meet the licensure requirements of part VII of ch. 400, F.S.

C. Government Sector Impact:

The AHCA may see an indeterminate fiscal impact due to fewer licensed home medical equipment providers.

VI. Technical Deficiencies:

None.

VII. Related Issues:

Section 400.931, F.S., requires that any person or entity that holds itself out to the public as providing home medical equipment and services, accepts physician orders for home medical equipment and services, or holds itself out to the public as providing home medical equipment that typically requires home medical services be licensed as a home medical equipment provider. As such, simply exempting the listed medical practices from the definition of "home medical equipment provider" may not relieve them of the requirement to be licensed if those practices continue to provide home medical equipment and services. If the intent of the bill is to exempt such medical practices from licensure, it may be more clear to do so by adding such medical practices to the list of persons and entities that are exempt from licensure as a home medical equipment provider under s. 400.93(5), F.S.

VIII. Statutes Affected:

This bill substantially amends section 400.925 of the Florida Statutes.

IX. Additional Information:

A. Committee Substitute – Statement of Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.

This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.

141424

LEGISLATIVE ACTION

Senate . House

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The Committee on Health Policy (Grimsley) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause and insert:

Section 1. Paragraph (k) is added to subsection (5) of section 400.93, Florida Statutes, is to read:

400.93 Licensure required; exemptions; unlawful acts; penalties.—

(5) The following are exempt from home medical equipment provider licensure, unless they have a separate company,

141424

corporation, or division that is in the business of providing home medical equipment and services for sale or rent to consumers at their regular or temporary place of residence pursuant to the provisions of this part:

(k) Physicians licensed pursuant to chapter 458, chapter 459, or chapter 460 for the sale or rental of electrostimulation medical equipment and electrostimulation medical equipment supplies to their patients in the course of their practice.

Section 2. This act shall take effect July 1, 2014.

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

And the title is amended as follows:

Delete everything before the enacting clause and insert:

A bill to be entitled

An act relating to home medical equipment; amending section 400.93; exempting allopathic, osteopathic, and chiropractic physicians who sell or rent electrostimulation medical equipment and supplies to their patients in the course of their practice from licensure as home medical equipment providers; providing an effective date.

By Senator Detert

28-00743-14 20141134__

A bill to be entitled

An act relating to home medical equipment; amending s. 400.925, F.S.; redefining the term "home medical equipment provider"; exempting medical practices owned by allopathic, osteopathic, or chiropractic physicians, as well as medical practices owned by physicians and certain family members of such physicians, which sell or rent home medical equipment or services from the requirement that they be licensed as home medical equipment providers; providing an effective date.

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

Section 1. Subsection (7) of section 400.925, Florida Statutes, is amended to read:

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

(7) "Home medical equipment provider" means any person or entity, other than a medical practice that is wholly owned by one or more physicians licensed under chapter 458, chapter 459, or chapter 460, or by a physician and the spouse, parent, child, or sibling of the physician, which ~~that~~ sells or rents or offers to sell or rent to or for a consumer:

(a) Any home medical equipment and services; or

(b) Home medical equipment that requires any home medical equipment services.

Section 2. This act shall take effect July 1, 2014.

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Health Policy

BILL:	SB 1192
INTRODUCER:	Senator Sobel and others
SUBJECT:	Palliative Care
DATE:	March 22, 2014
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Lloyd	Stovall	HP	**Pre-meeting**
2.			AHS	
3.			AP	

I. Summary:

SB 1192 establishes the Florida Palliative Care and Quality of Life Interdisciplinary Advisory Council within the Department of Health (DOH). The bill describes the council's purpose, powers, duties and meeting requirements and authorizes the Governor to appoint nine members from specific backgrounds or organizations.

The bill also creates the Palliative Care Consumer and Professional Information and Education Program within the DOH and directs the DOH to house information and links on its website. The bill directs specific health care practitioners and facilities to provide patients with information about palliative care or to comply with palliative care measures as ordered by the patient's provider.

The DOH has estimated a recurring minimal state fiscal impact.

II. Present Situation:

According to the Center to Advance Palliative Care, palliative care can be defined as specialized medical care for people with serious illnesses that focuses on providing those patients with relief from the symptoms, pain, and stress of that illness with a goal of improving quality of life for both the patient and the patient's family.[1] Examples of serious illnesses helped by palliative care include cancer, cardiac diseases, kidney failure, Alzheimer's disease, HIV/AIDS, and Amyotrophic Lateral Sclerosis (ALS).

[1] Center to Advance Palliative Care, *Defining Palliative Care*, http://www.capc.org/building-a-hospital-based-palliative-care-program/case/definingpc (last visited Mar. 22, 2014).

Palliative care focuses on helping patients get relief from symptoms caused by serious illnesses. Given alone when other treatment is not working or along with curative treatment, palliative care can be given from time of diagnosis until end of life.[2]

Access to palliative care in the United States has more than doubled in the last 5 years.[3] Ten years ago, there were almost no palliative care programs in America's hospitals. State by state calculations show that 62 percent of Florida's hospitals, with 50 or more beds, provide a palliative care team.[4] Public opinion polls show that many Americans are not knowledgeable about palliative care; however, once explained, 92 percent reported they would be highly likely to consider palliative care for themselves or families if they had a serious illness.[5]

Palliative Care in Florida

Under s. 765.102(5) and (6), F.S., the Legislature has recognized the need to establish end-of-life care standards, including pain management and palliative care. Subsection (6) specifically requires the DOH, the Agency for Health Care Administration (AHCA), and the Department of Elder Affairs (DOEA) to jointly develop an end-of-life care campaign. Under current law, the focus, however, is on planning for end-of-life care and includes:[6]

- An opportunity to discuss and plan for end-of-life care;
- Assurance that physical and mental suffering will be carefully attended to;
- Assurance that preferences for withholding and withdrawing life-sustaining interventions will be honored;
- Assurance that the personal goals of the dying person will be addressed;
- Assurance that the dignity of the dying person will be a priority;
- Assurance that health care providers will not abandon the dying person;
- Assurance that the burden to family and others will be addressed;
- Assurance that advance directives for care will be respected regardless of the location of care;
- Assurance that organizational mechanisms are in place to evaluate the availability and quality of end-of-life, palliative, and hospice care services, including the evaluation of administrative and regulatory barriers;
- Assurance that necessary health care services will be provided and that relevant reimbursement policies are available; and,
- Assurance that the goals will be accomplished in a culturally appropriate manner.

In 2013, the DOH's Cancer Program and Cancer Control and Research Advisory Council jointly sponsored a workshop and webinar on palliative care that included speakers from Florida and other national organizations.

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[2] American Cancer Society, *Palliative or Supportive Care*, http://www.cancer.org/treatment/treatmentsandsideeffects/palliativecare/supportive-care (last visited: Mar. 22, 2014).
[3] Center to Advance Palliative Care, *Executive Summary*, *http://www.capc.org/reportcard/summary* (last visited Mar. 22, 2014).
[4] Center to Advance Palliative Care, *State by State Report Card - Florida*, http://www.capc.org/reportcard/home/FL/RC/Florida (last visited: Mar. 22, 2014).
[5] American Cancer Society, *Palliative Care at a Glance*, http://www.acscan.org/content/wp-content/uploads/2012/07/Palliative-Care-at-a-Glance.pdf (last visited Mar. 22, 2014).
[6] s. 765.102(5)(b), F.S.

The AHCA, the DOH, and the DOEA have webpages devoted to end of life resources with links to mostly external resources. In 2005, the DOEA published *Making Choices: A Guide to End of Life Planning* to address strategies for advance care planning.[7] The guide is available on the DOEA's website.

The AHCA is responsible for the licensing and regulation of facilities that provide palliative care including hospitals, long-term care facilities, nursing homes, home health agencies, hospices, intermediate care facilities, prescribed pediatric care centers, and assisted living facilities under chs. 395, 400, and 429, F.S.

The DOH is responsible for the regulation of health care professions regulated under chs. 458, 486, and 464, F.S., which includes allopathic and osteopathic physicians, physician assistants, and levels of the nursing profession.

Statutory Creation of Advisory Bodies, Commissions, or Boards

The statutory creation of any collegial body to serve as an adjunct to an executive agency is subject to certain provisions in s. 20.052, F.S. Such a body may only be created when it is found to be necessary and beneficial to the furtherance of a public purpose, and it must be terminated by the Legislature when it no longer fulfills such a purpose. The Legislature and the public must be kept informed of the numbers, purposes, memberships, activities, and expenses of any collegial or advisory bodies.

Private citizen members of any advisory body (with exceptions for members of commissions or boards of trustees) may only be appointed by the Governor, the head of the executive agency to which the advisory body is adjunct, the executive director of the agency, or a Cabinet officer. Private citizen members of a commission or a board of trustees may only be appointed by the Governor, must be confirmed by the Senate, and are subject to the dual-office-holding prohibition of section 5(a) of Article II of the State Constitution.

Members of agency advisory bodies serve for 4-year staggered terms and are ineligible for any compensation other than travel expenses, unless expressly provided otherwise in the State Constitution. Unless an exemption is specified by law, all meetings are public, and records of minutes and votes must be maintained.

III. Effect of Proposed Changes:

Section 1 creates an undesignated section of law and establishes the Palliative Care and Quality of Life Interdisciplinary Advisory Council (council). Definitions relating to the council and associated patient education program are also provided.

[7] Department of Elder Affairs, *Making Choices: A Guide to End of Life Planning* (2005) http://elderaffairs.state.fl.us/doea/pubs/pubs/EOL.pdf (last visited Mar. 24, 2014).

The advisory council, which is a council as defined under s. 20.03, F.S.,[8] is established within the DOH and consists of nine members appointed by the Governor in consultation with the State Surgeon General. The primary purpose of the council is to consult with and advise the DOH on matters relating to palliative care initiatives in the state.

Council members are to include professionals with expertise in different aspects of palliative care, patient and family caregivers or their advocates, and other members that the State Surgeon General deems appropriate. The Governor, in consultation with the State Surgeon General, is directed to ensure that the council's composition reflects a variety of experiences and representatives from different care settings such as inpatient, outpatient, community and hospice. At least one member must be a representative of the American Cancer Society and at least two members must be board certified hospital and palliative medicine physicians or nurses. Members shall serve for a term of 3 years.

The bill directs the council to adopt organizational procedures, elect a chair, and vice chair whose duties will be established by the council. Staff and assistance for the council will be provided by the DOH. Members will serve without compensation; however, they may be reimbursed for travel expenditures in accordance with s. 112.061, F.S. The council shall set regular meetings but is required to meet at least twice per year.

The bill directs the DOH to establish a palliative care consumer and professional information and education program. The DOH must also publish on its website information and resources about palliative care, including but not limited to, the following:

- Continuing education opportunities for health care practitioners;
- Palliative care delivery in the home and in primary, secondary and tertiary care settings;
- Best practices for palliative care delivery;
- Consumer educational materials; and,
- Referral information, including hospice.

The DOH is authorized to develop other initiatives regarding palliative care and education. In implementing the provisions of this bill, the DOH is directed to consult with the council.

Section 2 creates an undesignated section of law and requires health care practitioners licensed under chs. 458, 459, and 464, F.S., to provide patients with serious illnesses under their care information about palliative care and facilitate access to such services, upon request. Facilities regulated under chs. 395, 400 or 429, F.S., are required to comply with any palliative care measures ordered by the patient's health care practitioner.

Section 3 provides the act shall become effective upon becoming law.

[8] A "council" or "advisory council" under s. 20.03, F.S., means "an advisory body created by specific statutory enactment and appointed to function on a continuing basis for the study of the problems arising in a specified functional or program area of state government and to provide recommendations and policy alternatives."

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Certain health care practitioners and health care facilities are required to provide patients with serious illnesses under their care with information about palliative care and, as appropriate, facilitate access to that care.

C. Government Sector Impact:

The DOH estimates the recurring state fiscal impact for costs associated with administrative support of the council, educational program, website, and council member travel reimbursement.[9]

	1st Year 2014-14	**2nd Year Annualized\Recur**
Salaries		
1- Part Time OPS Health Educator	$13,963	$13,963
OPS Benefits	$202	$202
Expense		
1 - OPS Position	$15,602	$11,829
Council Travel Costs	$9,000	$9,000
2 meetings per year/ 9 members		
Human Resources Services *Calculated with OPS package*	$120	$120
Total Estimated Expenditures:	**$38,887**	**$35,114**

The agency has not submitted a fiscal impact statement.

[9] Department of Health, *2014 Agency Legislative Bill Analysis - SB 1192*, on file with the Senate Health Policy Committee (Feb. 25, 2014).

VI. Technical Deficiencies:

Council does not meet requirements of s. 20.052, F.S., for 4-year staggered terms for council members.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill creates an undesignated section of the Florida Statutes.

IX. Additional Information:

A. Committee Substitute – Statement of Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.

This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.

139958

LEGISLATIVE ACTION

Senate . House

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The Committee on Health Policy (Sobel) recommended the following:

Senate Amendment (with title amendment)

Delete lines 40 - 130

and insert:

supervised by a physician, a physician assistant, or an advanced registered nurse practitioner.

(c) "Palliative care" means patient- and family-centered medical care offered throughout the continuum of an illness which optimizes quality of life by anticipating, preventing, and treating suffering caused by serious illness. Palliative care

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involves addressing physical, emotional, social, and spiritual needs and facilitating patient autonomy, access to information, and choice. The term includes, but is not limited to, discussions of the patient's goals for treatment; discussion of treatment options appropriate to the patient, including, if appropriate, hospice care; and comprehensive pain and symptom management.

(d) "Serious illness" means a medical illness or physical injury or condition that substantially impacts quality of life for more than a short period of time. The term includes, but is not limited to, cancer, renal or liver failure, heart or lung disease, and Alzheimer's disease and related dementias.

(2) PALLIATIVE CARE AND QUALITY OF LIFE INTERDISCIPLINARY ADVISORY COUNCIL.—There is established within the Department of Health a Palliative Care and Quality of Life Interdisciplinary Advisory Council, which is an advisory council as defined in s. 20.03, Florida Statutes.

(a) The primary purpose of the council is to consult with and advise the department on matters relating to the establishment, maintenance, operation, and outcome evaluation of palliative care initiatives in this state.

(b) The council shall consist of nine members appointed by the Governor in consultation with the State Surgeon General and include professionals who have expertise in various aspects of palliative care, including, but not limited to, interdisciplinary palliative care, medical, nursing, social work, pharmacy, and spiritual expertise; patient and family caregivers or their advocates; and such other members as the State Surgeon General deems appropriate. The Governor in

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consultation with the State Surgeon General shall ensure that representation on the council reflects a broad perspective of palliative care and includes experience in palliative care in a variety of inpatient, outpatient, and community settings, such as acute care, long-term care, and hospice, and with a variety of populations, including pediatric, youth, and adult. One council member shall be a designee of the American Cancer Society. At least two council members shall be board-certified hospice and palliative medicine physicians, physician assistants, or nurses. Members shall serve for a term of 3 years.

(c) The council shall adopt internal organizational procedures as necessary for its efficient organization which must, at a minimum, require the council to elect a chair and vice chair whose duties shall be established by the council.

(d) The department shall provide such staff, information, and other assistance as is reasonably necessary to assist the council in carrying out its responsibilities.

(e) Members of the council shall serve without compensation, but may receive reimbursement as provided in s. 112.061, Florida Statutes, for travel and other necessary expenses incurred in the performance of their official duties.

(f) The department shall fix a time and place for regular meetings of the council, which shall meet at least twice a year.

(3) PALLIATIVE CARE CONSUMER AND PROFESSIONAL INFORMATION AND EDUCATION PROGRAM.—

(a) The department shall establish a palliative care consumer and professional information and education program. The purpose of the program is to maximize the effectiveness of

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palliative care initiatives in this state by making comprehensive and accurate information and education about palliative care available to the public, health care practitioners, and health care facilities.

(b) The department shall publish on its website information and resources, including links to external resources, about palliative care, which shall include, but not be limited to, continuing education opportunities for health care practitioners, information about palliative care delivery in the home and in primary, secondary, and tertiary care settings, best practices for palliative care delivery, and consumer educational materials and referral information for palliative care, including hospice.

(c) The department may develop and implement other initiatives regarding palliative care services and education to further the purposes of this section.

(d) The department shall consult with the Palliative Care and Quality of Life Interdisciplinary Advisory Council in implementing this subsection.

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

And the title is amended as follows:

Delete lines 21 - 27

and insert:

to implement this act; providing an effective date.

333492

LEGISLATIVE ACTION

Senate . House

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The Committee on Health Policy (Bean) recommended the following:

Senate Amendment to Amendment (139958) (with title amendment)

Delete lines 32 - 50
and insert:
(b) The council shall consist of nine members, five appointed by the Governor, two appointed by the President of the Senate, and two appointed by the Speaker of the House of Representatives. The council shall include professionals who have expertise in various aspects of palliative care, including, but not limited to, interdisciplinary palliative care, medical,

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nursing, social work, pharmacy, and spiritual expertise; patient and family caregivers or their advocates. The appointing officials, in consultation with the Surgeon General, shall ensure that representation on the council reflects a broad perspective of palliative care in a variety of inpatient, outpatient, and community settings, such as acute care, long-term care, and hospice, and with a variety of populations, including pediatric, youth, and adult. One council member appointed by the Governor shall be a designee of the American Cancer Society. At least two council members, one each appointed by the President of the Senate and Speaker of the House of Representatives, shall be board-certified hospice and palliative medicine physicians, physician assistants, or nurses. Members shall serve four-year terms, except that, initially to provide for staggered terms, the Governor, the President of the Senate, and the Speaker of the House of Representatives shall each appoint one member to serve a two-year term, and the Governor shall appoint at least one member to serve a three-year term. All other initial appointments and any subsequent appointments shall be for four-year terms.

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

And the title is amended as follows:

Delete line 6

and insert:

the council; providing for staggered terms; requiring the Department of Health to

By Senator Sobel

33-01459-14 20141192__

A bill to be entitled

An act relating to palliative care; defining terms; creating the Palliative Care and Quality of Life Interdisciplinary Advisory Council; specifying the purpose of the council; providing for membership of the council; requiring the Department of Health to provide staff, information, and other assistance as necessary to the council; requiring the department to set regular meeting times for the council; requiring the council to adopt certain internal organization procedures; authorizing reimbursement for certain expenses for council members; requiring the department to establish a palliative care consumer and professional information and education program; requiring the department to publish certain educational information and materials about palliative care on the department website; authorizing the department to develop and implement other services and education initiatives regarding palliative care; requiring the department to consult with the council to implement this act; requiring certain health care practitioners to provide certain patients information about palliative care and information about facilities that offer palliative care; requiring certain health care facilities to comply with palliative care measures ordered by a patient's health care practitioner; providing an effective date.

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

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

33-01459-14 20141192__

Section 1. Palliative Care and Quality of Life Interdisciplinary Advisory Council; palliative care consumer and professional information and education program.—

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

(a) "Appropriate" means consistent with applicable legal, health, and professional standards, the patient's clinical and other circumstances, and the patient's reasonably known wishes and beliefs.

(b) "Medical care" means services provided, requested, or supervised by a physician or advanced registered nurse practitioner.

(c) "Palliative care" means patient- and family-centered medical care offered throughout the continuum of an illness which optimizes quality of life by anticipating, preventing, and treating suffering caused by serious illness. Palliative care involves addressing physical, emotional, social, and spiritual needs and facilitating patient autonomy, access to information, and choice. The term includes, but is not limited to, discussions of the patient's goals for treatment; discussion of treatment options appropriate to the patient, including, if appropriate, hospice care; and comprehensive pain and symptom management.

(d) "Serious illness" means a medical illness or physical injury or condition that substantially impacts quality of life for more than a short period of time. The term includes, but is not limited to, cancer, renal or liver failure, heart or lung disease, and Alzheimer's disease and related dementias.

(2) PALLIATIVE CARE AND QUALITY OF LIFE INTERDISCIPLINARY

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

ADVISORY COUNCIL.—There is established within the Department of Health a Palliative Care and Quality of Life Interdisciplinary Advisory Council, which is an advisory council as defined in s. 20.03, Florida Statutes.

(a) The primary purpose of the council is to consult with and advise the department on matters relating to the establishment, maintenance, operation, and outcome evaluation of palliative care initiatives in this state.

(b) The council shall consist of nine members appointed by the Governor in consultation with the State Surgeon General and include professionals who have expertise in various aspects of palliative care, including, but not limited to, interdisciplinary palliative care, medical, nursing, social work, pharmacy, and spiritual expertise; patient and family caregivers or their advocates; and such other members as the State Surgeon General deems appropriate. The Governor in consultation with the State Surgeon General shall ensure that representation on the council reflects a broad perspective of palliative care and includes experience in palliative care in a variety of inpatient, outpatient, and community settings, such as acute care, long-term care, and hospice, and with a variety of populations, including pediatric, youth, and adult. One council member shall be a designee of the American Cancer Society. At least two council members shall be board-certified hospice and palliative medicine physicians or nurses. Members shall serve for a term of 3 years.

(c) The council shall adopt internal organizational procedures as necessary for its efficient organization which must, at a minimum, require the council to elect a chair and

vice chair whose duties shall be established by the council.

(d) The department shall provide such staff, information, and other assistance as is reasonably necessary to assist the council in carrying out its responsibilities.

(e) Members of the council shall serve without compensation, but may receive reimbursement as provided in s. 112.061, Florida Statutes, for travel and other necessary expenses incurred in the performance of their official duties.

(f) The department shall fix a time and place for regular meetings of the council, which shall meet at least twice a year.

(3) PALLIATIVE CARE CONSUMER AND PROFESSIONAL INFORMATION AND EDUCATION PROGRAM.—

(a) The department shall establish a palliative care consumer and professional information and education program. The purpose of the program is to maximize the effectiveness of palliative care initiatives in this state by making comprehensive and accurate information and education about palliative care available to the public, health care practitioners, and health care facilities.

(b) The department shall publish on its website information and resources, including links to external resources, about palliative care, which shall include, but not be limited to, continuing education opportunities for health care practitioners, information about palliative care delivery in the home and in primary, secondary, and tertiary care settings, best practices for palliative care delivery, and consumer educational materials and referral information for palliative care, including hospice.

(c) The department may develop and implement other

initiatives regarding palliative care services and education to further the purposes of this section.

(d) The department shall consult with the Palliative Care and Quality of Life Interdisciplinary Advisory Council in implementing this subsection.

Section 2. Palliative care for health care practitioners and facilities.—Health care practitioners regulated under chapter 458, chapter 459, or chapter 464, Florida Statutes, shall, as appropriate, provide patients under their care who have serious illnesses with information about palliative care and, upon request, shall facilitate access to palliative care. Facilities regulated under chapter 395, chapter 400, or chapter 429, Florida Statutes, shall comply with the palliative care measures ordered by the patient's health care practitioner.

Section 3. This act shall take effect upon becoming a law.

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Health Policy

BILL:	SB 1066
INTRODUCER:	Senator Grimsley
SUBJECT:	Department of Health
DATE:	March 25, 2014
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Peterson	Stovall	HP	**Pre-meeting**
2.			TR	
3.			AP	

I. Summary:

SB 1066 makes a series of changes to the statutes governing the licensure of health care practitioners and the related operations of the Department of Health (DOH). Specifically, the bill:

- Authorizes fees to be waived for up to one biennial licensing period when the funds of a licensed profession exceed the amount required to administer its licensing program.
- Gives the DOH flexibility in determining the format of the license.
- Authorizes the DOH to access digital images from drivers' licenses for use in licensing and related investigations.
- Revises the method by which the Board of Medicine (BOM) determines continuing education requirements.
- Corrects obsolete provisions related to the responsibility of the DOH for health care practitioner complaint investigation and enforcement.
- Eliminates obsolete or underutilized licensing options related to dental laboratories, nursing home administrators, and massage therapists.
- Eliminates the Council on Certified Nursing Assistants and revises the schedule for in-service hours required for certified nursing assistants.
- Revises the composition of the Board of Nursing Home Administrators.

II. Present Situation:

Regulation of Health Care Professions

The DOH is responsible for licensing and regulating health care practitioners in order to preserve the health, safety, and welfare of the public.[1] General licensing provisions applicable to health

[1] Section 20.43(1)(g), F.S.

care practitioners are contained in ch. 456, F.S., which also sets out in more detail the policy framework for regulation. Specifically, regulation is to occur when:[2]

- Unregulated practice can harm or endanger the health, safety, and welfare of the public, and the potential for harm outweighs the potentially anticompetitive effect of regulation.
- The public is not adequately protected by other means, including other statutes, federal law, or local ordinances.
- Less restrictive means of regulation are not available.

The Division of Medical Quality Assurance (MQA) within the DOH has responsibility for licensing health care practitioners, certain facilities, and businesses; enforcing health care practitioner standards; and providing licensure and disciplinary information to enable health care consumers to make more informed health care decisions.[3]

Practitioners regulated by the MQA include the following professions:

- Emergency Medical Technicians and Paramedics (part III of ch. 401, F.S.)
- Acupuncture (ch. 457, F.S).
- Allopathic Medicine (ch. 458, F.S.)
- Osteopathic Medicine (ch. 459, F.S.
- Chiropractic Medicine (ch. 460, F.S.)
- Podiatric Medicine (ch. 461, F.S.)
- Naturopathy (ch. 462, F.S.)
- Optometry (ch. 463, F.S.)
- Nursing, including Certified Nursing Assistants (ch. 464, F.S.)
- Pharmacy (ch. 465, F.S.)
- Dentistry (ch. 466, F.S.)
- Midwifery (ch. 467, F.S.)
- Speech-Language Pathology and Audiology (part I of ch. 468, F.S.)
- Nursing Home Administration (part II of ch. 468, F.S.)
- Occupational Therapy (part III of ch. 468, F.S.)
- Radiology (part IV of ch. 468, F.S.)
- Respiratory Therapy (part V of ch. 468, F.S.)
- Dietetics and Nutrition (part X of ch. 468, F.S.)
- Athletic Training (part XIII of ch. 468, F.S.)
- Orthotics, Prosthetics, and Pedorthics (part XIV of ch. 468, F.S.)
- Electrolysis (ch. 478, F.S.)
- Massage Therapy (ch. 480, F.S.)
- Clinical Laboratory Personnel (part III of ch. 483, F.S.)
- Medical Physicists (part IV of ch. 483, F.S.)
- Opticianry (part I of ch. 484, F.S.)
- Hearing Aid Specialists (part II of ch. 484, F.S.)
- Physical Therapy Practice (ch. 486, F.S.)

[2] Section 456.003(2), F.S.
[3] Fla. Dept. of Health, *Resource Manual for the Florida Department of Health*, 252 (FY 2012–2013) (on file with the Senate Health Policy Committee).

- Psychology (ch. 490, F.S.)
- Clinical Social Work, Marriage and Family Therapy, and Mental Health Counseling (ch. 491, F.S.)

The following facilities or programs are also regulated or inspected by the MQA:[4]

- Body Piercing Establishments (s. 381.0075, F.S.)
- Brain and Spinal Cord Injury Programs (ss. 381.739 - 381.79, F.S.)
- Counterfeit-proof Prescription Vendors (s. 456.42(2), F.S.)
- Dental Laboratories (ch. 466, F.S.)
- Electrology Facilities (ch. 478, F.S.)
- Electrolysis Training Programs (ch. 478, F.S.)
- EMS Education Programs (ch. 401, F.S.)
- EMS Vehicle Permittees (ch. 401, F.S.)
- Environmental Testing Laboratories (s. 403.0625, F.S.)
- Massage Establishments (ch. 480, F.S.)
- Massage Schools (ch. 480, F.S.)
- Nursing Education Programs (ch. 464, F.S.)
- Office Surgery Sites (ch. 458 and ch. 459, F.S.)
- Optical Establishments (part I of ch. 484, F.S.)
- Pain Management Clinics (ch. 458 and ch. 459, F.S.)
- Pharmacies (ch. 465, F.S.)
- Trauma Centers (part II of ch. 395, F.S.)

As part of its enforcement responsibilities, the DOH investigates complaints against health care practitioners. It must investigate any complaint that is written, signed by the complainant,[5] and legally sufficient,[6] and may initiate an investigation if it believes a violation of law or rule has occurred. Such an investigation may result in an administrative case against the health care practitioner's license.[7] The DOH also has a duty to notify the proper prosecuting authority when there is a criminal violation of any statute related to the practice of a profession regulated by the DOH.[8]

Responsibility for the regulation of health care practitioners once resided with the Department of Business and Professional Regulation. The 1996 Legislature directed the transfer of that function

[4] Other entities regulated by the DOH, although not the MQA, include tanning facilities, X-ray sites, and radioactive materials users, among others.
[5] The DOH may investigate an anonymous complaint or a complaint by a confidential informant if the alleged violation of law or rule is substantial and the DOH has reason to believe, after preliminary inquiry, that the violations alleged in the complaint are true. *See* s. 456.073(1), F.S.
[6] A complaint is legally sufficient if it contains ultimate facts that show a violation of ch. 456, F.S., of any of the practice acts relating to the professions regulated by the DOH, or of any rule adopted by the DOH or one of its regulatory boards has occurred. *See* s. 456.073(1), F.S.
[7] Upon completion of an investigation, the DOH must submit a report to the probable cause panel of the appropriate regulatory board. *See* s. 456.073(2), F.S. If the probable cause panel finds that probable cause exists, it must direct the DOH to file a formal administrative complaint against the licensee. If the DOH declines to prosecute the complaint because it finds that probable cause has been improvidently found by the panel, the regulatory board may still pursue and prosecute an administrative complaint. *See* s. 456.073(4), F.S.
[8] Section 456.066, F.S.

to the Agency for Health Care Administration (AHCA).[9] Then in 1997 the Legislature revised the transfer, moving responsibility for the regulation of health care practitioners instead to the DOH and creating the MQA. Health care practitioner complaint, investigative, and prosecutorial services, however, stayed with the AHCA, and were provided under contract to the MQA.[10] It was not until 2002 that these services were transferred to the MQA.[11]

The 1997 Legislature directed the AHCA to establish a toll-free telephone number for public reporting of complaints relating to medical treatment or services provided by health care professionals.[12] Responsibility for the toll-free consumer complaint hotline was not moved to the MQA when the enforcement services were transferred in 2002. Instead, the established toll-free telephone number remains with the AHCA and is used to take complaints regarding health care facilities regulated by the AHCA. Complaints regarding health care practitioners are forwarded by the AHCA to the MQA.[13]

Likewise, s. 395.3025, F.S., which sets forth when and how hospitals, ambulatory surgical centers, and mobile surgical centers can release patient records was not updated to reflect the transfer. In general, patient records are confidential and cannot be disclosed without consent of the patient or his or her legal guardian.[14] The statute authorizes release of the records without consent, however, to "the agency" for use in the investigation, prosecution, and appeal of disciplinary proceedings.[15] The DOH indicates that a number of hospitals have challenged the DOH's authority to subpoena records based on the current language.[16]

Color Photographic or Digital Imaged Licenses

Drivers' licenses are issued by the Department of Highway Safety and Motor Vehicles (DHSMV) with a full face color photograph or digital image of the licensee.[17] Records of the digital image maintained by the DHSMV are exempt from public records disclosure, but copies may be made for use by the DHSMV or other specified agencies for activities related to their responsibilities, e.g. Department of Business Regulation for reproduction of licenses; Department of State in connection with determining voter eligibility; and Department of Revenue for use in establishing paternity, among others. The law does not authorize release of the records to the DOH.[18]

Currently, some, but not all, initial applicants for licensure as a health care practitioner are required to provide a passport photograph at the time of initial application but are not required to maintain a current photograph on file with the DOH. The DOH stores licensing records electronically and most imaged photographic records become distorted and no longer legible once scanned and converted to a digital image. Photographs assist the DOH in confirming the

[9] Ch. 96-403, s. 11, Laws of Fla.
[10] Ch. 97-261, ss. 1 and 2, Laws of Fla.; ch. 97-273, ss. 1 and 2, Laws of Fla.
[11] Ch. 2002-400, s. 44, Laws of Fla.
[12] Ch. 97-273, s. 24, Laws of Fla.
[13] Fla. Dept. of Health, *Senate Bill 1066 Bill Analysis* (undated) (on file with the Senate Health Policy Committee).
[14] Section 395.3025(4), F.S.
[15] Section 395.3025(4)(e), F.S.
[16] Fla. Dept. of Health, *supra* note 13.
[17] Section 322.142(1), F.S.
[18] Section 322.142(4), F.S.

identity of licensed health care practitioners during its investigation of disciplinary cases and in the service of legal documents. In addition, licenses which are displayed in a practitioner's place of practice do not currently contain a photograph.[19]

Size Requirements for Licenses; Renewal of License

Section 456.013(2), F.S., requires the DOH to issue a wallet-size identification card and a wall card measuring 6.5 inches by 5 inches to health care practitioners licensed in Florida. The DOH produced 494,115 licenses in the 2011-2012 fiscal year at a cost of $72,140.79. The DOH would like the opportunity to explore less costly options.[20]

Health Care Practitioner Continuing Education and Training

Florida law generally requires health care practitioners to complete continuing education or training as a condition of licensure or re-licensure. Some requirements are general obligations to complete a number of hours in subject areas determined by the relevant regulatory board. Examples of these are as follows:

- The Board of Medicine, Board of Chiropractic Medicine, Board of Osteopathic Medicine, and Board of Podiatric Medicine must require licensees to periodically demonstrate professional competency by completing at least 40 hours of continuing education every 2 years. The boards generally establish the criteria and content for continuing education[21] and may authorize up to 25 percent of the hours to be fulfilled by pro bono service to an underserved community.[22] In addition, the boards may approve alternative methods for obtaining credit in risk management, which include: attendance at a board meeting where another practitioner is disciplined; service as a volunteer expert for the DOH; or service on the board's probable cause panel.[23]
- Certified nursing assistants (CNAs) are required by statute to complete 12 hours of in-service training each calendar year.[24] CNA licenses renew biennially on May 31, which conflicts with the statutory requirement of calendar year training. The next scheduled renewal deadline is May 31, 2015.[25]

Other continuing education requirements are expressly created in statute. Examples of these are as follows:

- All health care practitioners regulated by the DOH or a board must complete a course related to prevention of medical errors at initial licensure and biennial renewals thereafter.[26]
- Practitioners licensed or certified under ch. 457, F.S. (Acupuncture), ch. 458, F.S. (Allopathic Medicine), ch. 459, F.S. (Osteopathic Medicine), ch. 460, F.S. (Chiropractic Medicine), ch. 461, F.S., (Podiatric Medicine), ch. 463, F.S. (Optometry), part I of ch. 464,

[19] Fla. Dept. of Health, *supra* note 13
[20] *Id.*
[21] Section 456.013(8), F.S.
[22] Section 456.013(9), F.S.
[23] Section 456.013(6), F.S.
[24] Section 464.203(7), F.S.
[25] Florida Board of Nursing, *Certified Nursing Assistant (CNA)*, http://floridasnursing.gov/renewals/certified-nursing-assistant/ (last visited March 22, 2014).
[26] Section 456.013(7), F.S.

F.S. (Nursing), ch, 465, F.S. (Pharmacy), ch. 466, F.S. (Dentistry and Dental Hygiene), parts II, III, V, and X of ch.468, F.S. (Nursing Home Administration; Occupational Therapy; Respiratory Therapy; and Dietetics and Nutrition), are required to complete a course on HIV/AIDS one time, no later than first renewal.[27]

Licensure Fees

The law requires the costs of regulating health care practitioners to be borne solely by licensed practitioners and licensure applicants. The boards, in consultation with the DOH, are responsible for establishing fees that are:[28]

- Based on revenue projections prepared using generally accepted accounting procedures;
- Adequate to cover all expenses relating to that board identified in the DOH's long-range policy plan;
- Reasonable, fair, and not serve as a barrier to licensure;
- Based on potential earnings from working under the scope of the license;
- Similar to fees imposed on similar licensure types; and,
- Not more than 10 percent greater than the actual cost to regulate that profession for the previous biennium.

Licensure fees are subject to challenge pursuant to ch. 120, F.S.

Since the 2008 Session, a total of $82 million has been authorized for transfer from the MQA Trust Fund to the Budget Stabilization Fund and General Revenue Fund in the General Appropriations Act. Despite the transfers, the MQA Trust Fund continues to maintain an average cash balance of $24 million. Since the 2008-2009 fiscal year, the cost of regulating health care practitioners has averaged $63,198,327 annually, and the MQA has collected an average of $72,035,217 in revenue annually. The MQA's revenue projections for the 2012-2013 fiscal year and the next five years indicate an average of $74,672,466 in revenue annually. The MQA projects that operating expenses will remain stable and may even decrease as a result of implementation of a number of process efficiencies.[29]

Council of Certified Nursing Assistants

The Council on Certified Nursing Assistants is created under the Board of Nursing to make recommendations to the DOH regarding policies and procedures for certification of CNAs and to develop rules regulating the education, training, and certification process. The Board of Nursing has discretion to adopt the rules recommended by the council.[30]

Dental Laboratories

Dental laboratories must be registered and reregistered biennially with the DOH.[31] Renewal notices are sent to the last known address of each dental laboratory 120 days prior to the

[27] Section 456.033, F.S.
[28] Section 456.025(1), F.S.
[29] Fla. Dept. of Health, *supra* note 13.
[30] Section 464.2085, F.S.
[31] Section 466.032(1), F.S.

expiration date of the license, which is February 28 of even-numbered years.[32] If a dental laboratory operator fails to reregister timely, the DOH must notify the operator by registered mail, within one month after the renewal date, return receipt requested.[33] Dental laboratory operators then have three additional months to renew the establishment license with no late fee. If a dental laboratory fails to renew within that 3-month window, the operator must pay a delinquency fee of $40, in addition to the current renewal fee, to renew.[34] As of March 30, 2013, 1,086 dental laboratories were licensed in Florida.[35]

During this past licensure renewal period, the DOH mailed 281 return-receipt notices to delinquent dental laboratories. Eighty-six were returned as undeliverable. The requirement to send registered letters to delinquent dental laboratories costs over $2,000 every 2 years. Staff spends approximately 35 hours preparing and mailing the registered letters. This process is not required for any other regulated health care professions.[36]

Nursing Home Administrators

Nursing home administrators are regulated by the Board of Nursing Home Administrators, within the DOH, under part II, ch. 468, F.S. The board consists of seven members appointed by the Governor and confirmed by the Senate to a 4-year term. Three members must be licensed nursing home administrators; two members must be health care practitioners; and the remaining two members must be laypersons. At least one member of the board must be older than 60 years of age.[37]

The DOH may issue a provisional license to fill a position of a nursing home administrator that unexpectedly becomes vacant due to illness, sudden death of the administrator, or abandonment of the position. The provisional license is valid for 6 months.[38] The last provisional license was issued by the Board of Nursing Home Administrators in December 2007. The board repealed the rule implementing the provision license in 2010 because provisional licenses were no longer necessary for the regulation of the profession.[39]

Massage Therapists and Massage Establishments

Massage therapists and massage establishments in Florida are regulated by the Board of Massage Therapy, within the DOH, under the Massage Practice Act, ch. 480, F.S. A person must be licensed as a massage therapist to practice massage for compensation, unless otherwise specifically exempted under the Massage Practice Act.[40] In order to be licensed as a massage therapist, an applicant must: [41]

[32] Fla. Board of Dentistry, *Dental Laboratory*, http://floridasdentistry.gov/renewals/dental-laboratory/ (last visited Mar. 22, 2014).
[33] Section 466.032(2), F.S.
[34] Section 466.032(3), F.S.
[35] Fla. Dept. of Health, *supra* note 13.
[36] *Id.*
[37] Section 468.1665, F.S.
[38] Section 468.1735, F.S.
[39] Fla. Dept. of Health, *supra* note 13
[40] Section 480.047(1)(a), F.S.; s. 480.034, F.S.
[41] Section 480.041 and 480.042, F.S.

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

For the 10-year period ending June 21, 2013, the Board of Massage Therapy has received 300 applications for apprenticeship. Of those 300, only eight have obtained full licensure as a massage therapist.[42]

III. Effect of Proposed Changes:

Section 1 amends s. 322.142, F.S., to authorize the DHSMV to enter into an interagency agreement with the DOH authorizing it to access digital images retained from drivers' licenses to verify the identity of a health care practitioner who is under investigation pursuant to ch. 456, F.S., and for use in reproducing licenses.

Section 2 amends s. 395.3025, F.S., to authorize hospitals, ambulatory surgical centers, and mobile surgical facilities to release patient records without patient consent to the DOH for use in health care practitioner investigation and disciplinary proceedings. This corrects an error created when the enforcement responsibilities were transferred from the AHCA to the DOH in 2002. The bill also deletes obsolete language regarding public access to the records, which is already in s. 456.057, F.S.

Section 3 amends s. 456.013, F.S., to eliminate the size requirements for licenses issued by the DOH.

This section and sections 5 and 7 of the bill revise the continuing education requirements for allopathic physicians. The requirements for physicians to complete two of the courses that are required by statute—HIV/AIDS and medical errors—are deleted. New authority is created in ch. 458, F.S., for the BOM to determine continuing education requirements and means for satisfying the requirements. Section 3 deletes the medical errors requirement. Sections 5 and 7 contain the other provisions.

Section 4 amends s. 456.025, F.S., to delete authority for the boards, or the DOH when there is no board, to charge a fee up to $25 for issuing wall certificates. This section also authorizes the boards, or the DOH when there is no board to adopt rules to waive fees (initial application, initial licensure, unlicensed activity, or renewal) for any profession the DOH determines, based on its long-range estimate, will have more revenue than necessary to fund its operations. A fee waiver may not exceed 2 years.

Section 5 amends s. 456.033, F.S., to eliminate the requirement for allopathic physicians to complete a one-time course on HIV/AIDS.

[42] Fla. Dept. of Health, *supra* note 13.

Section 6 amends s. 456.068, F.S., to require the DOH to establish a toll-free telephone number for public reporting of complaints related to health care professionals. This corrects an error created when the enforcement responsibilities were transferred from the AHCA to the DOH in 2002.

Section 7 amends s. 458.319, F.S., to create new authority for the BOM to determine continuing education requirements for allopathic physicians. Physicians will continue to complete 40 hours biennially. The BOM is authorized to determine and mandate specific continuing education and to approve alternative methods for obtaining credits, including: attending board meetings; serving as a volunteer expert witness; or as a member of a probable cause panel. These options exist today, but only as a means to obtain risk management credit. In addition, the BOM is authorized to allow up to 25 percent of the required hours through pro bono service to indigent, underserved populations, or patients in areas of critical need. This option exists in current law. Finally, the BOM is authorized to award credit for research in critical need areas, or training for advanced professional certification. The BOM is given rulemaking authority to define underserved and critical need area.

Section 8 amends s. 464.203, F.S., to change the annual in-service training requirement for CNAs to a biennial requirement of 24 hours, thereby conforming, without reducing, the requirement to the renewal schedule. The authority for the Council on Certified Nursing Assistants to recommend rules for implementation of the section is deleted.

Section 9 repeals s. 464.2085, F.S., thereby eliminating the Council on Certified Nursing Assistants.

Section 10 amends s. 466.032, F.S., to delete the requirement for the DOH to send laboratory operators a registered letter when the operator misses the deadline for renewing the laboratory's registration.

Section 11 amends s. 467.009, F.S., to reflect the name change of the midwifery education accrediting organization, from Commission on Recognition of Postsecondary Accreditation to Council for Higher Education Accreditation.

Section 12 amends s. 468.1665, F.S., to revise the composition of the Board of Nursing Home Administrators. The number of administrator representatives is increased by one, to four, and the number of lay members is decreased by one, to one.

Section 13 amends s. 468.1695, F.S., to allow a candidate who has a master's degree, not just a bachelor's degree, in the specified subject areas to take the nursing home administrator examination.

Section 14 repeals s. 468.1735, F.S., thereby eliminating the provisional nursing home administrator license.

Section 15 and 16 amend ss. 468.805 and 468.505, F.S., to reflect the name change of the accrediting body for registered dietitians, from Commission on Dietetic Registration, the

accrediting body of the American Dietetic Association, to the accrediting body of the Academy of Nutrition and Dietetics.

Sections 17, 18, and 20 amend ss. 480.033, 480.041, and 480.044, F.S., to eliminate the apprenticeship program as a pathway to licensure as a massage therapist and repeal related provisions of law.

Section 19 amends s. 480.042, F.S., to delete obsolete language. The DOH no longer administers the massage therapy license.

Section 21 amends s. 823.05, F.S., to conform a cross-reference.

Section 22 provides an effective date of July 1, 2014.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Health care practitioners will experience a positive fiscal impact if a fee waiver is implemented as authorized by the bill.

C. Government Sector Impact:

Licensure Fee Waiver
The DOH will experience a decrease in revenues if a fee waiver as a result of excess trust fund balance is implemented as authorized by the bill.

Color Photographic or Digital Imaged Licenses
The MQA may experience a non-recurring increase in workload associated with the initial set up for the DOH to access the DHSMV photographic records of licensed health care practitioners, but current resources are adequate to absorb.

Size Requirements for Licenses
The fiscal impact is indeterminate at this time, but the DOH anticipates the change will result in a cost savings.

HIV and AIDS Instruction
The DOH will incur non-recurring costs for rulemaking, which current budget authority is adequate to absorb.

Toll-free Consumer Complaint Line
The DOH will incur a cost of $0.043 cents per minute for the toll-free line, which current budget authority is adequate to absorb. The DOH will incur a recurring increase in workload to staff the line. The DOH estimates an increase in the number of phone calls and complaints it will receive, or 7,510 calls will come through the hotline. The DOH is requesting 1 FTE for a Regulatory Specialist I, no travel.

Elimination Council of Certified Nursing Assistants
The DOH will experience a cost savings of approximately $40,000 per fiscal year related to the administration of the council.

Dental Laboratory
The DOH will experience a cost savings of over $2,000 biennially for postage and staff time required to send delinquency notices by registered mail.[43]

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 322.142, 395.3025, 456.013, 456.025, 456.033, 456.068, 458.319, 464.203, 466.032, 467.009, 468.1665, 468.1695, 468.503, 468.505, 480.033, 480.041, 480.042, 480.044, and 823.05, F.S.

The bill repeals the following sections of the Florida Statutes: 464.2085 and 468.1735.

[43] Fla. Dept. of Health, *supra* note 13.

IX. Additional Information:

A. Committee Substitute – Statement of Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.

This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.

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LEGISLATIVE ACTION

Senate . House

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The Committee on Health Policy (Grimsley) recommended the following:

Senate Amendment (with title amendment)

Delete lines 157 - 373

and insert:

Section 3. Subsection (2) of section 456.013, Florida Statutes, is amended to read:

456.013 Department; general licensing provisions.—

(2) Before the issuance of a ~~any~~ license, the department shall charge an initial license fee as determined by the applicable board or, if there is no board, by rule of the

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department. Upon receipt of the appropriate license fee, the department shall issue a license to a ~~any~~ person certified by the appropriate board, or its designee, as having met the licensure requirements imposed by law or rule. ~~The license shall consist of a wallet-size identification card and a wall card measuring 6 1/2 inches by 5 inches.~~ The licensee shall surrender the license to the department ~~the wallet-size identification card and the wall card~~ if the ~~licensee's~~ license was ~~is~~ issued in error or is revoked.

Section 4. Present subsections (5) through (11) of section 456.025, Florida Statutes, are redesignated as subsections (4) through (10), respectively, and present subsections (4) and (6) are amended to read:

456.025 Fees; receipts; disposition.—

~~(4) Each board, or the department if there is no board, may charge a fee not to exceed $25, as determined by rule, for the issuance of a wall certificate pursuant to s. 456.013(2) requested by a licensee who was licensed prior to July 1, 1998, or for the issuance of a duplicate wall certificate requested by any licensee.~~

(5)~~(6)~~ If the cash balance of the trust fund at the end of any fiscal year exceeds the total appropriation provided for the regulation of the health care professions in the prior fiscal year, the boards, in consultation with the department, may lower the license renewal fees. When the department determines, based on long-range estimates of revenue, that a profession's trust fund balance exceeds the amount required to cover necessary functions, each board, or the department when there is no board, may adopt rules to implement the waiver of initial application

fees, initial licensure fees, unlicensed activity fees, or renewal fees for that profession. The waiver of renewal fees may not exceed 2 years.

Section 5. Subsections (2) through (4) of section 458.319, Florida Statutes, are redesignated as subsections (3) through (5), respectively, and a new subsection (2) is added to that section, to read:

458.319 Renewal of license.—

(2) Each licensee shall demonstrate his or her professional competency by completing at least 40 hours of continuing medical education every 2 years. The board, by rule, may:

(a) Provide that continuing medical education approved by the American Medical Association satisfies some or all of the continuing medical education requirements.

(b) Mandate specific continuing medical education requirements.

(c) Approve alternative methods for obtaining continuing medical education credits, including, but not limited to:

1. Attendance at a board meeting at which another licensee is disciplined;

2. Service as a volunteer expert witness for the department in a disciplinary proceeding; or

3. Service as a member of a probable cause panel following expiration of a board member’s term.

(d) Provide that up to 25 percent of the required continuing medical education hours may be fulfilled through pro bono services to the indigent, underserved populations, or patients in critical need areas in the state where the licensee practices.

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1. The board shall require that any pro bono service be approved in advance to receive credit for continuing medical education under this paragraph.

2. The standard for determining indigency is that recognized by the federal poverty guidelines and must be less than 150 percent of the federal poverty level.

(e) Provide that a portion of the continuing medical education hours may be fulfilled by performing research in critical need areas or by training for advanced professional certification.

(f) Adopt rules to define underserved and critical need areas.

Section 6. Subsection (3) of section 458.3485, Florida Statutes, is amended to read:

458.3485 Medical assistant.—

~~(3) CERTIFICATION.—Medical assistants may be certified by the American Association of Medical Assistants or as a Registered Medical Assistant by the American Medical Technologists.~~

Section 7. Subsection (7) of section 464.203, Florida Statutes, is amended to read:

464.203 Certified nursing assistants; certification requirement.—

(7) A certified nursing assistant shall complete 24 ~~12~~ hours of inservice training during each biennium ~~calendar year~~. The certified nursing assistant shall maintain ~~be responsible for maintaining~~ documentation demonstrating compliance with these provisions. ~~The Council on Certified Nursing Assistants, in accordance with s. 464.2085(2)(b), shall propose rules to~~

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~~implement this subsection.~~

Section 8. Section 464.2085, Florida Statutes, is repealed.

Section 9. Subsection (2) of section 466.032, Florida Statutes, is amended to read:

466.032 Registration.—

~~(2) Upon the failure of any dental laboratory operator to comply with subsection (1), the department shall notify her or him by registered mail, within 1 month after the registration renewal date, return receipt requested, at her or his last known address, of such failure and inform her or him of the provisions of subsections (3) and (4).~~

Section 10. Subsection (8) of section 467.009, Florida Statutes, is amended to read:

467.009 Midwifery programs; education and training requirements.—

(8) Nonpublic educational institutions that conduct approved midwifery programs shall be accredited by a member of the Council for Higher Education ~~Commission on Recognition of Postsecondary~~ Accreditation and shall be licensed by the Commission for Independent Education.

Section 11. Subsection (2) of section 468.1665, Florida Statutes, is amended to read:

468.1665 Board of Nursing Home Administrators; membership; appointment; terms.—

(2) Four ~~Three~~ members of the board must be licensed nursing home administrators. One member ~~Two members~~ of the board must be a health care practitioner ~~practitioners~~. The remaining two members of the board must be laypersons who are not, and have never been, nursing home administrators or members of any

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health care profession or occupation. At

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

And the title is amended as follows:

Delete lines 16 - 45

and insert:

amending s. 456.025, F.S.; deleting a fee provision for the issuance of wall certificates for various health profession licenses; authorizing the boards or the department to adopt rules waiving certain fees for a specified period in certain circumstances; amending s. 458.319, F.S.; providing continuing medical education requirements for Board of Medicine licensees; authorizing the board to adopt rules; amending s. 458.3485, F.S.; deleting language relating to the certification and registration of medical assistants; amending s. 464.203, F.S.; revising certified nursing assistant inservice training requirements; repealing s. 464.2085, F.S., relating to the creation, membership, and duties of the Council on Certified Nursing Assistants; amending s. 466.032, F.S.; deleting a requirement that the department provide certain notice to a dental laboratory operator who fails to renew her or his registration; amending s. 467.009, F.S.; updating the name of the organization that accredits certain midwifery programs; amending s. 468.1665, F.S.; increasing the number of members of the Board of Nursing Home Administrators who must be licensed nursing home

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administrators and decreasing the number of members who must be health care practitioners; amending

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LEGISLATIVE ACTION

Senate . House

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The Committee on Health Policy (Brandes) recommended the following:

Senate Amendment (with title amendment)

Between lines 471 and 472
insert:

Section 21. Subsection (3) of section 486.031, Florida Statutes, is amended to read:

486.031 Physical therapist; licensing requirements.—To be eligible for licensing as a physical therapist, an applicant must:

(3)(a) Have been graduated from a school of physical

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therapy which has been approved for the educational preparation of physical therapists by the appropriate accrediting agency recognized by the Commission on Recognition of Postsecondary Accreditation or the United States Department of Education at the time of her or his graduation and have passed, to the satisfaction of the board, the American Registry Examination before ~~prior to~~ 1971 or a national examination approved by the board to determine her or his fitness for practice as a physical therapist as hereinafter provided;

(b) Have received a diploma from a program in physical therapy in a foreign country and have educational credentials deemed equivalent to those required for the educational preparation of physical therapists in this country, as recognized by the board or by an appropriate agency ~~as~~ identified by the board, and have passed to the satisfaction of the board an examination to determine her or his fitness for practice as a physical therapist ~~as hereinafter provided~~; or

(c) Be entitled to licensure without examination as provided in s. 486.081.

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

And the title is amended as follows:

Delete line 63

and insert:

apprentices; amending s. 486.031, F.S.; revising provisions relating to the recognition of physical therapy programs and educational credentials from foreign countries to meet requirements for licensing as a physical therapist; amending s. 823.05, F.S.;

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conforming a

By Senator Grimsley

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A bill to be entitled

An act relating to the Department of Health; amending s. 322.142, F.S.; authorizing the Department of Highway Safety and Motor Vehicles to provide reproductions of specified records to the Department of Health under certain circumstances; amending s. 395.3025, F.S.; clarifying duties of the Department of Health to maintain the confidentiality of patient records that it obtains under subpoena pursuant to an investigation; authorizing licensees under investigation to inspect or receive copies of patient records connected with the investigation, subject to certain conditions; amending s. 456.013, F.S.; deleting requirements for the physical size of licenses issued for various health professions; exempting Board of Medicine licensees from certain continuing education requirements applicable to other health professions; amending s. 456.025, F.S.; deleting a fee provision for the issuance of wall certificates for various health profession licenses; authorizing the boards or the department to adopt rules waiving certain fees for a specified period in certain circumstances; amending s. 456.033, F.S.; exempting Board of Medicine licensees from certain continuing education requirements relating to instruction on HIV and AIDS; amending s. 456.068, F.S.; requiring the department to establish a toll-free telephone number for public reporting of certain complaints; amending s. 458.319, F.S.; providing

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

21-00806A-14 20141066__

continuing medical education requirements for Board of Medicine licensees; authorizing the board to adopt rules; amending s. 464.203, F.S.; revising certified nursing assistant inservice training requirements; repealing s. 464.2085, F.S., relating to the creation, membership, and duties of the Council on Certified Nursing Assistants; amending s. 466.032, F.S.; deleting a requirement that the department provide certain notice to a dental laboratory operator who fails to renew her or his registration; amending s. 467.009, F.S.; revising the organization that must accredit certain midwifery programs; amending s. 468.1665, F.S.; increasing the number of members of the Board of Nursing Home Administrators who must be licensed nursing home administrators and decreasing the number of members who must be laypersons; amending s. 468.1695, F.S.; revising the qualifications of applicants who may sit for the licensed nursing home administrator examination to include an applicant with a master's degree in certain subjects; repealing s. 468.1735, F.S., relating to provisional licenses for nursing home administrators; amending ss. 468.503 and 468.505, F.S.; revising the organization with whom an individual must be registered to be a registered dietitian; revising a definition; amending ss. 480.033 and 480.041, F.S.; deleting provisions relating to massage therapy apprentices and apprenticeship programs; deleting a definition and revising licensure requirements for massage therapists, to conform;

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

amending s. 480.042, F.S.; revising requirements for conducting massage therapist licensing examinations and maintaining examination records; amending s. 480.044, F.S.; deleting a fee for massage therapy apprentices; amending s. 823.05, F.S.; conforming a cross-reference; providing an effective date.

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

Section 1. Subsection (4) of section 322.142, Florida Statutes, is amended to read:

322.142 Color photographic or digital imaged licenses.—

(4) The department may maintain a film negative or print file. The department shall maintain a record of the digital image and signature of the licensees, together with other data required by the department for identification and retrieval. Reproductions from the file or digital record are exempt from the provisions of s. 119.07(1) and shall be made and issued only:

(a) For departmental administrative purposes;

(b) For the issuance of duplicate licenses;

(c) In response to law enforcement agency requests;

(d) To the Department of Business and Professional Regulation pursuant to an interagency agreement for the purpose of accessing digital images for reproduction of licenses issued by the Department of Business and Professional Regulation;

(e) To the Department of State pursuant to an interagency agreement to facilitate determinations of eligibility of voter registration applicants and registered voters in accordance with

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ss. 98.045 and 98.075;

(f) To the Department of Revenue pursuant to an interagency agreement for use in establishing paternity and establishing, modifying, or enforcing support obligations in Title IV-D cases;

(g) To the Department of Children and Families pursuant to an interagency agreement to conduct protective investigations under part III of chapter 39 and chapter 415;

(h) To the Department of Children and Families pursuant to an interagency agreement specifying the number of employees in each of that department's regions to be granted access to the records for use as verification of identity to expedite the determination of eligibility for public assistance and for use in public assistance fraud investigations;

(i) To the Department of Financial Services pursuant to an interagency agreement to facilitate the location of owners of unclaimed property, the validation of unclaimed property claims, and the identification of fraudulent or false claims;

(j) To district medical examiners pursuant to an interagency agreement for the purpose of identifying a deceased individual, determining cause of death, and notifying next of kin of any investigations, including autopsies and other laboratory examinations, authorized in s. 406.11; ~~or~~

(k) To the following persons for the purpose of identifying a person as part of the official work of a court:

1. A justice or judge of this state;

2. An employee of the state courts system who works in a position that is designated in writing for access by the Chief Justice of the Supreme Court or a chief judge of a district or circuit court, or by his or her designee; or

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3. A government employee who performs functions on behalf of the state courts system in a position that is designated in writing for access by the Chief Justice or a chief judge, or by his or her designee; or

(l) To the Department of Health, pursuant to an interagency agreement to access digital images to verify the identity of an individual during an investigation under chapter 456, and for the reproduction of licenses issued by the Department of Health.

Section 2. Paragraph (e) of subsection (4) of section 395.3025, Florida Statutes, is amended to read:

395.3025 Patient and personnel records; copies; examination.—

(4) Patient records are confidential and may ~~must~~ not be disclosed without the consent of the patient or his or her legal representative, but appropriate disclosure may be made without such consent to:

(e) The department ~~agency~~ upon subpoena issued pursuant to s. 456.071.~~, but~~ The records obtained ~~thereby~~ must be used solely for the purpose of the department ~~agency~~ and the appropriate professional board in its investigation, prosecution, and appeal of disciplinary proceedings. If the department ~~agency~~ requests copies of the records, the facility shall charge a fee pursuant to this section ~~no more than its actual copying costs, including reasonable staff time~~. The department and the appropriate professional board must maintain the confidentiality of patient records obtained under this paragraph pursuant to s. 456.057. A licensee who is the subject of a department investigation may inspect or receive a copy of a patient record connected with the investigation if the licensee

agrees in writing to maintain the confidentiality of the patient record pursuant to s. 456.057 ~~must be sealed and must not be available to the public pursuant to s. 119.07(1) or any other statute providing access to records, nor may they be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the agency or the appropriate regulatory board. However, the agency must make available, upon written request by a practitioner against whom probable cause has been found, any such records that form the basis of the determination of probable cause.~~

Section 3. Subsections (2), (6), and (7) of section 456.013, Florida Statutes, are amended to read:

456.013 Department; general licensing provisions.—

(2) Before the issuance of a ~~any~~ license, the department shall charge an initial license fee as determined by the applicable board or, if there is no board, by rule of the department. Upon receipt of the appropriate license fee, the department shall issue a license to a ~~any~~ person certified by the appropriate board, or its designee, as having met the licensure requirements imposed by law or rule. ~~The license shall consist of a wallet-size identification card and a wall card measuring 6 1/2 inches by 5 inches.~~ The licensee shall surrender the license to the department ~~the wallet-size identification card and the wall card~~ if the ~~licensee's~~ license was ~~is~~ issued in error or is revoked.

(6) As a condition of renewal of a license, ~~the Board of Medicine,~~ the Board of Osteopathic Medicine, the Board of Chiropractic Medicine, and the Board of Podiatric Medicine shall

~~each~~ require their respective licensees ~~which they respectively regulate~~ to periodically demonstrate their professional competency by completing at least 40 hours of continuing education every 2 years. The boards may require by rule that up to 1 hour of the required 40 or more hours be in the area of risk management or cost containment. This provision does ~~shall~~ not ~~be construed to~~ limit the number of hours that a licensee may obtain in risk management or cost containment to be credited toward satisfying the 40 or more required hours. This provision does ~~shall~~ not ~~be construed to~~ require the boards to impose any requirement on licensees except for the completion of at least 40 hours of continuing education every 2 years. Each of the ~~such~~ boards shall determine whether any specific continuing education requirements not otherwise mandated by law will ~~shall~~ be mandated and shall approve criteria for, and the content of, ~~any~~ continuing education mandated by such board. Notwithstanding any other provision of law, the board, or the department when there is no board, may approve by rule alternative methods of obtaining continuing education credits in risk management. The alternative methods may include attending a board meeting at which another licensee is disciplined, serving as a volunteer expert witness for the department in a disciplinary case, or serving as a member of a probable cause panel following the expiration of a board member's term. Other boards within the Division of Medical Quality Assurance, or the department if there is no board, may adopt rules granting continuing education hours in risk management for attending a board meeting at which another licensee is disciplined, for serving as a volunteer expert witness for the department in a disciplinary case, or for

serving as a member of a probable cause panel following the expiration of a board member's term.

(7) The boards, except the Board of Medicine, or the department when there is no board, shall require the completion of a 2-hour course relating to prevention of medical errors as part of the licensure and renewal process. The 2-hour course shall count towards the total number of continuing education hours required for the profession. The course shall be approved by the board or department, as appropriate, and shall include a study of root-cause analysis, error reduction and prevention, and patient safety. In addition, the course approved by ~~the Board of Medicine and~~ the Board of Osteopathic Medicine shall include information relating to the five most misdiagnosed conditions during the previous biennium, as determined by the board. If the course is being offered by a facility licensed pursuant to chapter 395 for its employees, the board may approve up to 1 hour of the 2-hour course to be specifically related to error reduction and prevention methods used in that facility.

Section 4. Present subsections (5) through (11) of section 456.025, Florida Statutes, are redesignated as subsections (4) through (10), respectively, and present subsections (4) and (6) are amended to read:

456.025 Fees; receipts; disposition.—

~~(4) Each board, or the department if there is no board, may charge a fee not to exceed $25, as determined by rule, for the issuance of a wall certificate pursuant to s. 456.013(2) requested by a licensee who was licensed prior to July 1, 1998, or for the issuance of a duplicate wall certificate requested by any licensee.~~

(5) ~~(6)~~ If the cash balance of the trust fund at the end of any fiscal year exceeds the total appropriation provided for the regulation of the health care professions in the prior fiscal year, the boards, in consultation with the department, may lower the license renewal fees. When the department determines, based on long-range estimates of revenue, that a profession's trust fund balance exceeds the amount required to cover necessary functions, each board, or the department when there is no board, may adopt rules to implement the waiver of initial application fees, initial licensure fees, unlicensed activity fees, or renewal fees for that profession. The waiver of renewal fees may not exceed 2 years.

Section 5. Section 456.033, Florida Statutes, is amended to read:

456.033 Requirement for instruction for certain licensees on HIV and AIDS.—The following requirements apply to each person licensed or certified under chapter 457; ~~chapter 458;~~ chapter 459; chapter 460; chapter 461; chapter 463; part I of chapter 464; chapter 465; chapter 466; part II, part III, part V, or part X of chapter 468; or chapter 486:

(1) Each person shall be required by the appropriate board to complete no later than upon first renewal a continuing educational course, approved by the board, on human immunodeficiency virus and acquired immune deficiency syndrome as part of biennial relicensure or recertification. The course shall consist of education on the modes of transmission, infection control procedures, clinical management, and prevention of human immunodeficiency virus and acquired immune deficiency syndrome. Such course shall include information on

current Florida law on acquired immune deficiency syndrome and its impact on testing, confidentiality of test results, treatment of patients, and any protocols and procedures applicable to human immunodeficiency virus counseling and testing, reporting, the offering of HIV testing to pregnant women, and partner notification issues pursuant to ss. 381.004 and 384.25.

(2) Each person shall submit confirmation of having completed the course required under subsection (1), on a form as provided by the board, when submitting fees for first renewal.

(3) The board shall have the authority to approve additional equivalent courses that may be used to satisfy the requirements in subsection (1). Each licensing board that requires a licensee to complete an educational course pursuant to this section may count the hours required for completion of the course included in the total continuing educational requirements as required by law.

(4) Any person holding two or more licenses subject to the provisions of this section shall be permitted to show proof of having taken one board-approved course on human immunodeficiency virus and acquired immune deficiency syndrome, for purposes of relicensure or recertification for additional licenses.

(5) Failure to comply with the above requirements shall constitute grounds for disciplinary action under each respective licensing chapter and s. 456.072(1)(e). In addition to discipline by the board, the licensee shall be required to complete the course.

Section 6. Section 456.068, Florida Statutes, is amended to read:

456.068 Toll-free telephone number for reporting of complaints.—The Department of Health ~~Agency for Health Care Administration~~ shall establish a toll-free telephone number for public reporting of complaints relating to medical treatment or services provided by health care professionals.

Section 7. Subsections (2) through (4) of section 458.319, Florida Statutes, are redesignated as subsections (3) through (5), respectively, and a new subsection (2) is added to that section, to read:

458.319 Renewal of license.—

(2) Each licensee shall demonstrate his or her professional competency by completing at least 40 hours of continuing medical education every 2 years. The board, by rule, may:

(a) Provide that continuing medical education approved by the American Medical Association satisfies some or all of the continuing medical education requirements.

(b) Mandate specific continuing medical education requirements.

(c) Approve alternative methods for obtaining continuing medical education credits, including, but not limited to:

1. Attendance at a board meeting at which another licensee is disciplined;

2. Service as a volunteer expert witness for the department in a disciplinary proceeding; or

3. Service as a member of a probable cause panel following expiration of a board member's term.

(d) Provide that up to 25 percent of the required continuing medical education hours may be fulfilled through pro bono services to the indigent, underserved populations, or

patients in critical need areas in the state where the licensee practices.

1. The board shall require that any pro bono service be approved in advance to receive credit for continuing medical education under this paragraph.

2. The standard for determining indigency shall be that recognized by the federal poverty guidelines and shall be less than 150 percent of the federal poverty level.

(e) Provide that a portion of the continuing medical education hours may be fulfilled by performing research in critical need areas or by training for advanced professional certification.

(f) Adopt rules to define underserved and critical need areas.

Section 8. Subsection (7) of section 464.203, Florida Statutes, is amended to read:

464.203 Certified nursing assistants; certification requirement.—

(7) A certified nursing assistant shall complete 24 ~~12~~ hours of inservice training during each biennium ~~calendar year~~. The certified nursing assistant is ~~shall be~~ responsible for maintaining documentation demonstrating compliance with these provisions. ~~The Council on Certified Nursing Assistants, in accordance with s. 464.2085(2)(b), shall propose rules to implement this subsection.~~

Section 9. Section 464.2085, Florida Statutes, is repealed.

Section 10. Subsection (2) of section 466.032, Florida Statutes, is amended to read:

466.032 Registration.—

~~(2) Upon the failure of any dental laboratory operator to comply with subsection (1), the department shall notify her or him by registered mail, within 1 month after the registration renewal date, return receipt requested, at her or his last known address, of such failure and inform her or him of the provisions of subsections (3) and (4).~~

Section 11. Subsection (8) of section 467.009, Florida Statutes, is amended to read:

467.009 Midwifery programs; education and training requirements.—

(8) Nonpublic educational institutions that conduct approved midwifery programs shall be accredited by a member of the Council for Higher Education Accreditation ~~Commission on Recognition of Postsecondary Accreditation~~ and shall be licensed by the Commission for Independent Education.

Section 12. Subsection (2) of section 468.1665, Florida Statutes, is amended to read:

468.1665 Board of Nursing Home Administrators; membership; appointment; terms.—

(2) Four ~~Three~~ members of the board must be licensed nursing home administrators. Two members of the board must be health care practitioners. The remaining member ~~two members~~ of the board must be a layperson ~~laypersons~~ who is ~~are~~ not, and has ~~have~~ never been, a nursing home administrator ~~administrators~~ or member ~~members~~ of any health care profession or occupation. At least one member of the board must be 60 years of age or older.

Section 13. Subsection (2) of section 468.1695, Florida Statutes, is amended to read:

468.1695 Licensure by examination.—

(2) The department shall examine each applicant who the board certifies has completed the application form and remitted an examination fee set by the board not to exceed $250 and who:

(a)1. Holds a baccalaureate or master's degree from an accredited college or university and majored in health care administration, health services administration, or an equivalent major, or has credit for at least 60 semester hours in subjects, as prescribed by rule of the board, which prepare the applicant for total management of a nursing home; and

2. Has fulfilled the requirements of a college-affiliated or university-affiliated internship in nursing home administration or of a 1,000-hour nursing home administrator-in-training program prescribed by the board; or

(b)1. Holds a baccalaureate degree from an accredited college or university; and

2.a. Has fulfilled the requirements of a 2,000-hour nursing home administrator-in-training program prescribed by the board; or

b. Has 1 year of management experience allowing for the application of executive duties and skills, including the staffing, budgeting, and directing of resident care, dietary, and bookkeeping departments within a skilled nursing facility, hospital, hospice, assisted living facility with a minimum of 60 licensed beds, or geriatric residential treatment program and, if such experience is not in a skilled nursing facility, has fulfilled the requirements of a 1,000-hour nursing home administrator-in-training program prescribed by the board.

Section 14. Section 468.1735, Florida Statutes, is repealed.

Section 15. Subsection (11) of section 468.503, Florida Statutes, is amended to read:

468.503 Definitions.—As used in this part:

(11) "Registered dietitian" means an individual registered with the accrediting body of the Academy of Nutrition and Dietetics ~~Commission on Dietetic Registration, the accrediting body of the American Dietetic Association~~.

Section 16. Subsection (4) of section 468.505, Florida Statutes, is amended to read:

468.505 Exemptions; exceptions.—

(4) Notwithstanding any other provision of this part, an individual registered by the accrediting body of the Academy of Nutrition and Dietetics ~~Commission on Dietetic Registration of the American Dietetic Association~~ has the right to use the title "Registered Dietitian" and the designation "R.D."

Section 17. Subsection (5) of section 480.033, Florida Statutes, is amended to read:

480.033 Definitions.—As used in this act:

~~(5) "Apprentice" means a person approved by the board to study massage under the instruction of a licensed massage therapist.~~

Section 18. Subsections (1) and (4) of section 480.041, Florida Statutes, are amended to read:

480.041 Massage therapists; qualifications; licensure; endorsement.—

(1) A ~~Any~~ person is qualified for licensure as a massage therapist under this act who:

(a) Is at least 18 years of age or has received a high school diploma or graduate equivalency diploma;

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(b) Has completed a course of study at a board-approved massage school ~~or has completed an apprenticeship program that meets standards adopted by the board~~; and

(c) Has received a passing grade on an examination administered by the department.

(4) The board shall adopt rules:

(a) ~~Establishing a minimum training program for apprentices.~~

~~(b)~~ Providing for educational standards, examination, and certification for the practice of colonic irrigation, as defined in s. 480.033~~(6)~~, by massage therapists.

(b) ~~(c)~~ Specifying licensing procedures for practitioners desiring to be licensed in this state who hold an active license and have practiced in any other state, territory, or jurisdiction of the United States or any foreign national jurisdiction which has licensing standards substantially similar to, equivalent to, or more stringent than the standards of this state.

Section 19. Subsection (5) of section 480.042, Florida Statutes, is amended to read:

480.042 Examinations.—

(5) ~~All licensing examinations shall be conducted in such manner that the applicant shall be known to the department by number until her or his examination is completed and the proper grade determined.~~ An accurate record of each examination shall be maintained, ~~made,~~ and that record, together with all examination papers, ~~shall be filed with the State Surgeon General and~~ shall be kept by the testing entities for reference and inspection for a period of not less than 2 years immediately

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following the examination.

Section 20. Paragraph (h) of subsection (1) of section 480.044, Florida Statutes, is amended to read:

480.044 Fees; disposition.—

(1) The board shall set fees according to the following schedule:

~~(h) Fee for apprentice: not to exceed $100.~~

Section 21. Subsection (3) of section 823.05, Florida Statutes, is amended to read:

823.05 Places and groups engaged in criminal gang-related activity declared a nuisance; massage establishments engaged in prohibited activity; may be abated and enjoined.—

(3) A massage establishment as defined in s. 480.033~~(7)~~ that operates in violation of s. 480.0475 or s. 480.0535(2) is declared a nuisance and may be abated or enjoined as provided in ss. 60.05 and 60.06.

Section 22. This act shall take effect July 1, 2014.

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The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Health Policy

BILL:	SB 1254
INTRODUCER:	Senator Grimsley
SUBJECT:	Health Care Services Rulemaking
DATE:	March 20, 2014 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Stovall	HP	**Pre-meeting**
2.			RC	

I. Summary:

SB 1254 amends various sections of the Florida Statutes to delete unused, obsolete, and redundant rulemaking authority granted to the Agency for Health Care Administration (AHCA) and the Department of Elder Affairs (DOEA) and make other technical and conforming changes.

II. Present Situation:

The AHCA has a number of regulatory responsibilities, among these being the licensure of health care facilities including abortion clinics, nursing homes and clinical laboratories.

In recent years, many of the facilities licensed by the AHCA have come under increasing regulatory control of federal law relating to Medicaid and Medicare, and state laws providing greater specificity than previously provided. At the same time, frequent changes to many of these overlapping legal environments have made it difficult for the AHCA to maintain rules consistent with current law. Some of this difficulty has related to unnecessary rulemaking mandates, particularly relating to statutes that provide sufficient specificity to enforce without resort to rulemaking.

Rulemaking is required by the Administrative Procedures Act (APA) whenever an agency has express authority to make rules, and must resort to rulemaking in order to implement, interpret or prescribe law, policy or requirements including mandatory forms.[1] Rulemaking is not discretionary under the APA.[2]

In 2009 and again in 2013, the Joint Administrative Procedures Committee held hearings focusing on 2007 legislation that, on its face, requires the AHCA to make rules that have yet to

[1] Section 120.52(16), F.S., defines "rule" to mean "each agency statement of general applicability that implements, interprets, or prescribes law or policy or describes the procedure or practice requirements of an agency and includes any form which imposes any requirement or solicits any information not specifically required by statute…"
[2] Section 120.54(1)(a), F.S.

be finally adopted. In some cases, that legislation and similar legislation contemplated rulemaking that was either unnecessary under the APA or already promulgated under previously enacted law.

III. Effect of Proposed Changes:

Section 1 amends s. 390.012, F.S., relating to the disposal of fetal remains, to repeal the requirement that the AHCA adopt rules to require that abortion clinics be in compliance with s. 390.0111, F.S., relating to termination of pregnancies. This rule requirement is not necessary since abortion clinics must already comply with that section of law.

Sections 2 - 4 amend ss. 400.021, 400.0712, and 400.23, F.S., relating to the regulation of nursing homes, to repeal specific mandatory rule requirements and replace them with general authority allowing the AHCA to adopt rules to implement part II of ch. 400, F.S.

Sections 5 - 8 amends ss. 400.487, 400.497, 400.506, and 400.509, F.S., relating to home health agencies, to repeal specific mandatory rule requirements and replace them with general authority allowing the AHCA to adopt rules to implement part III of ch. 400, F.S.

Sections 9, 18, and 19 amend ss. 400.6095, 429.255, and 429.73, F.S., respectively, to repeal the requirement to adopt rules to implement do not resuscitate orders in hospice and assisted living facilities pursuant to s. 401.45, F.S. These grants of rulemaking authority are unnecessary since the statute is self-executing;

Sections 10-11 amend s. 400.914, F.S., and create s. 400.9141, F.S., respectively, to substitute mandatory rulemaking with discretionary rulemaking authority as needed to administer part VI of ch. 400, F.S., relating to prescribed pediatric extended care centers. Section 400.9141, F.S., is also created with language moved from s. 400.914, F.S., to make the conditions self-executing.

Sections 12-13 amend ss. 400.934 and 400.935, F.S., relating to home medical equipment providers, to repeal specific mandatory rule requirements and replace them with general authority allowing the AHCA to adopt rules to administer part VII of ch. 400, F.S.

Sections 14-15 amend ss. 400.962 and 400.967, F.S., relating to intermediate care facilities for developmentally disabled persons, to repeal specific mandatory rule requirements and replace them with general authority allowing the AHCA to adopt rules to administer part VIII of ch. 400, F.S.

Section 16 amends s. 400.980, F.S., relating to health care service pools, to repeal a mandate that the AHCA adopt rules for the registration of health care services pools.

Section 17 amends s. 409.912, F.S., relating to the cost-effective purchasing of health care in the Medicaid program, to repeal the requirement for the AHCA to adopt rules to administer subsection 409.912(43), F.S., related to provider lock in programs. The subsection expires on October 1, 2014.

Section 20 amends s. 440.255, F.S., to repeal the requirement that the AHCA adopt rules in order to adopt general guidelines for modeling drug-free workplace laboratories.

Section 21 amends s. 483.245, F.S., to repeal the requirement that the AHCA adopt rules to assess administrative penalties for clinical laboratories that pay or receive kickbacks.

Sections 22 and 23 amend ss. 765.541 and 765.544, F.S., relating to organ and tissue procurement agencies, to repeal specific mandatory rule requirements and replace them with general authority allowing the AHCA to adopt rules to administer ss. 765.541 - 765.546, F.S.

The bill also makes technical, clarifying, and conforming changes as necessary throughout the sections of law amended by the bill.

Section 24 establishes an effective date of July 1, 2014.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 390.012, 400.021, 400.0712, 400.23, 400.487, 400.497, 400.506, 400.509, 400.6095, 400.914, 400.934, 400.935, 400.962, 400.967, 400.980, 409.912, 429.255, 429.73, 440.102, 483.245, 765.541, and 765.544.

This bill creates section 400.9141 of the Florida Statutes.

IX. Additional Information:

A. Committee Substitute – Statement of Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.

This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.

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LEGISLATIVE ACTION

Senate . House

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The Committee on Health Policy (Grimsley) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause and insert:

Section 1. Paragraph (d) of subsection (3) of section 390.012, Florida Statutes, is amended to read:

390.012 Powers of agency; rules; disposal of fetal remains.—

(3) For clinics that perform or claim to perform abortions after the first trimester of pregnancy, the agency shall adopt

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rules pursuant to ss. 120.536(1) and 120.54 to implement the provisions of this chapter, including the following:

(d) Rules relating to the medical screening and evaluation of each abortion clinic patient. At a minimum, these rules must ~~shall~~ require:

1. A medical history including reported allergies to medications, antiseptic solutions, or latex; past surgeries; and an obstetric and gynecological history.

2. A physical examination, including a bimanual examination estimating uterine size and palpation of the adnexa.

3. The appropriate laboratory tests, including:

a. Urine or blood tests for pregnancy performed before the abortion procedure.

b. A test for anemia.

c. Rh typing, unless reliable written documentation of blood type is available.

d. Other tests as indicated from the physical examination.

4. An ultrasound evaluation for all patients. The rules must ~~shall~~ require that if a person who is not a physician performs an ultrasound examination, that person shall have documented evidence that he or she has completed a course in the operation of ultrasound equipment as prescribed in rule. ~~The rules shall require clinics to be in compliance with s. 390.0111.~~

5. That the physician is responsible for estimating the gestational age of the fetus based on the ultrasound examination and obstetric standards in keeping with established standards of care regarding the estimation of fetal age as defined in rule and shall write the estimate in the patient's medical history.

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The physician shall keep original prints of each ultrasound examination of a patient in the patient's medical history file.

Section 2. Subsection (11) of section 400.021, Florida Statutes, is amended to read:

400.021 Definitions.—When used in this part, unless the context otherwise requires, the term:

(11) "Nursing home bed" means an accommodation that ~~which~~ is ready for immediate occupancy, or is capable of being made ready for occupancy within 48 hours, excluding the provision of staffing, ~~;~~ and that ~~which~~ conforms to minimum space requirements, including the availability of appropriate equipment and furnishings within the 48 hours, as specified by ~~rule of~~ the agency, for the provision of services specified in this part to a single resident.

Section 3. Subsection (3) of section 400.0712, Florida Statutes, is amended to read:

400.0712 Application for inactive license.—

~~(3) The agency shall adopt rules pursuant to ss. 120.536(1) and 120.54 necessary to implement this section.~~

Section 4. Section 400.23, Florida Statutes, is amended to read:

400.23 Rules; evaluation and deficiencies; licensure status.—

(1) It is the intent of the Legislature that rules published and enforced pursuant to this part and part II of chapter 408 ~~shall~~ include criteria by which a reasonable and consistent quality of resident care may be ensured, ~~and~~ the results of such resident care can be demonstrated, and ~~by which~~ safe and sanitary nursing homes can be provided. It is further

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intended that reasonable efforts be made to accommodate the needs and preferences of residents to enhance the quality of life in a nursing home. In addition, efforts shall be made to minimize the amount of paperwork associated with the reporting and documentation requirements of these rules.

(2) Pursuant to the intention of the Legislature, the agency, in consultation with the Department of Health and the Department of Elderly Affairs, may ~~shall~~ adopt ~~and enforce~~ rules to administer ~~implement~~ this part and part II of chapter 408. The rules must specify, but are not limited to, ~~which shall include~~ reasonable and fair criteria relating ~~in relation~~ to:

(a) The location of the facility and housing conditions that will ensure the health, safety, and comfort of residents, including an adequate call system. In adopting ~~making~~ such rules, the agency shall be guided by criteria recommended by nationally recognized reputable professional groups and associations that have ~~with~~ knowledge of such subject matters. The agency shall update or revise the ~~such~~ criteria as the need arises. The agency may require alterations to a building if it determines that an existing condition constitutes a distinct hazard to life, health, or safety. In performing ~~any~~ inspections of facilities authorized by this part or part II of chapter 408, the agency may enforce the special-occupancy provisions of the Florida Building Code and the Florida Fire Prevention Code which apply to nursing homes. A resident ~~Residents~~ or his or her representative must ~~their representatives shall~~ be able to request a change in the placement of the bed in his or her ~~their~~ room if, ~~provided that~~ at admission, the resident is ~~they are~~ presented with a room that meets requirements of the Florida

Building Code. The location of a bed may be changed if the requested placement does not infringe on the resident's roommate or interfere with the resident's care or safety as determined by the care planning team in accordance with facility policies and procedures. In addition, the bed placement may not be used as a restraint. Each facility shall maintain a log of resident rooms with beds that are not in strict compliance with the Florida Building Code in order for such log to be used by surveyors and nurse monitors during inspections and visits. A resident or a resident's ~~resident~~ representative who requests that a bed be moved must ~~shall~~ sign a statement indicating that he or she understands that the room will not be in compliance with the Florida Building Code, but that he or she ~~they~~ would prefer to exercise the ~~their~~ right to self-determination. The statement must be retained as part of the resident's care plan. A ~~Any~~ facility that offers this option must submit a letter signed by the nursing home administrator of record to the agency notifying it of this practice along with a copy of the policies and procedures of the facility. The agency is directed to provide assistance to the Florida Building Commission in updating the construction standards of the code relating ~~relative~~ to nursing homes.

(b) The number and qualifications of all personnel, including management, medical, nursing, and other professional personnel, and nursing assistants, orderlies, and support personnel, having responsibility for any part of the care given residents.

(c) All sanitary conditions within the facility and its surroundings, including water supply, sewage disposal, food

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handling, and general hygiene which will ensure the health and comfort of residents.

(d) The equipment essential to the health and welfare of the residents.

(e) A uniform accounting system.

(f) The care, treatment, and maintenance of residents and measurement of the quality and adequacy thereof, based on rules developed under this chapter and the Omnibus Budget Reconciliation Act of 1987, ~~(~~Pub. L. No. 100-203~~) (December 22, 1987)~~, Title IV (Medicare, Medicaid, and Other Health-Related Programs), Subtitle C (Nursing Home Reform), as amended.

(g) The preparation and annual update of a comprehensive emergency management plan. The agency shall establish ~~adopt rules establishing~~ minimum criteria for the plan after consultation with the Division of Emergency Management. At a minimum, the ~~rules must provide for~~ plan components must provide ~~that address~~ emergency evacuation transportation; adequate sheltering arrangements; postdisaster activities, including emergency power, food, and water; postdisaster transportation; supplies; staffing; emergency equipment; individual identification of residents and transfer of records; and responding to family inquiries. The comprehensive emergency management plan is subject to review and approval by the local emergency management agency. During the ~~its~~ review, the local emergency management agency shall ensure that the following agencies, at a minimum, are given the opportunity to review the plan: the Department of Elderly Affairs, the Department of Health, the Agency for Health Care Administration, and the Division of Emergency Management. ~~Also,~~ Appropriate volunteer

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organizations must also be given the opportunity to review the plan. The local emergency management agency shall complete its review within 60 days and ~~either~~ approve the plan or advise the facility of necessary revisions.

(h) The availability, distribution, and posting of reports and records pursuant to s. 400.191 and the Gold Seal Program pursuant to s. 400.235.

(3)(a)~~1.~~ The agency shall enforce ~~adopt rules providing~~ minimum staffing requirements for nursing home facilities.

1. These requirements must include, for each facility:

a. A combined minimum weekly average of certified nursing assistant and licensed nursing staffing ~~combined~~ of 3.6 hours of direct care per resident per day. As used in this sub-subparagraph, a week is defined as Sunday through Saturday.

b. A minimum certified nursing assistant staffing of 2.5 hours of direct care per resident per day. A facility may not staff below one certified nursing assistant per 20 residents.

c. A minimum licensed nursing staffing of 1.0 hour of direct care per resident per day. A facility may not staff below one licensed nurse per 40 residents.

2. Nursing assistants employed under s. 400.211(2) may be included in computing the staffing ratio for certified nursing assistants if their job responsibilities include only nursing-assistant-related duties.

3. Each nursing home facility must document compliance with staffing standards ~~as~~ required under this paragraph and post daily the names of staff on duty for the benefit of facility residents and the public.

4. The agency shall recognize the use of licensed nurses

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for compliance with the minimum staffing requirements for certified nursing assistants if the nursing home facility otherwise meets the minimum staffing requirements for licensed nurses and the licensed nurses are performing the duties of ~~a~~ certified nursing assistants ~~assistant~~. Unless otherwise approved by the agency, licensed nurses counted toward the minimum staffing requirements for certified nursing assistants must exclusively perform the duties of ~~a~~ certified nursing assistants ~~assistant~~ for the entire shift and not also be counted toward the minimum staffing requirements for licensed nurses. If the agency approved a facility's request to use a licensed nurse to perform both licensed nursing and certified nursing assistant duties, the facility must allocate the amount of staff time specifically spent on certified nursing assistant duties for the purpose of documenting compliance with minimum staffing requirements for certified and licensed nursing staff. The hours of a licensed nurse with dual job responsibilities may not be counted twice.

(b) Nonnursing staff providing eating assistance to residents does ~~shall~~ not count toward compliance with minimum staffing standards.

(c) Licensed practical nurses licensed under chapter 464 who are providing nursing services in nursing home facilities under this part may supervise the activities of other licensed practical nurses, certified nursing assistants, and other unlicensed personnel providing services in such facilities in accordance with rules adopted by the Board of Nursing.

(4) ~~Rules developed pursuant to~~ This section does ~~shall~~ not restrict the use of shared staffing and shared programming in

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facilities that ~~which~~ are part of retirement communities that provide multiple levels of care and otherwise meet the requirement of law or rule.

(5) ~~The agency, in collaboration with the Division of Children's Medical Services of the Department of Health, must adopt rules for:~~

(a) Minimum standards of care for persons under 21 years of age who reside in nursing home facilities may be established by the agency, in collaboration with the Division of Children's Medical Services of the Department of Health. A facility may be exempted from these standards and the provisions of paragraph (b) for specified ~~specific~~ persons between 18 and 21 years of age~~,~~ if the person's physician agrees that minimum standards of care based on age are not necessary.

(b) The following ~~Minimum~~ staffing requirements for persons under 21 years of age who reside in nursing home facilities~~,~~ ~~which~~ apply in lieu of the requirements contained in subsection (3):~~.~~

1. For persons under 21 years of age who require skilled care:

a. A minimum combined average of 3.9 hours of direct care per resident per day must be provided by licensed nurses, respiratory therapists, respiratory care practitioners, and certified nursing assistants.

b. A minimum licensed nursing staffing of 1.0 hour of direct care per resident per day ~~must be provided~~.

c. Up to ~~No more than~~ 1.5 hours of certified nursing assistant care per resident per day may be counted in determining the minimum direct care hours required.

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d. One registered nurse must be on duty on the site 24 hours per day on the unit where children reside.

2. For persons under 21 years of age who are medically fragile:

a. A minimum combined average of 5.0 hours of direct care per resident per day must be provided by licensed nurses, respiratory therapists, respiratory care practitioners, and certified nursing assistants.

b. A minimum licensed nursing staffing of 1.7 hours of direct care per resident per day must be provided.

c. Up to ~~No more than~~ 1.5 hours of certified nursing assistant care per resident per day may be counted in determining the minimum direct care hours required.

d. One registered nurse must be on duty on the site 24 hours per day on a ~~the~~ unit where children reside.

(6) Before ~~Prior to~~ conducting a survey of the facility, the survey team shall obtain a copy of the local long-term care ombudsman council report on the facility. Problems noted in the report shall be incorporated into and followed up through the agency's inspection process. This procedure does not preclude the local long-term care ombudsman council from requesting the agency to conduct a followup visit to the facility.

(7) The agency shall, at least every 15 months, evaluate all nursing home facilities and determine ~~make a determination as to~~ the degree of compliance by each licensee with the established rules adopted under this part as a basis for assigning a licensure status to a ~~that~~ facility. The agency shall base its evaluation on the most recent inspection report, taking into consideration findings from other official reports,

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surveys, interviews, investigations, and inspections. In addition to license categories authorized under part II of chapter 408, the agency shall assign a ~~licensure status of~~ standard or conditional licensure status to each nursing home.

(a) A standard licensure status means that a facility has no class I or class II deficiencies and has corrected all class III deficiencies within the time established by the agency.

(b) A conditional licensure status means that a facility, due to the presence of one or more class I or class II deficiencies, or class III deficiencies not corrected within the time established by the agency, is not in substantial compliance at the time of the survey with criteria established under this part or with rules adopted by the agency. If the facility has no class I, class II, or class III deficiencies at the time of the followup survey, a standard licensure status may be assigned.

(c) In evaluating the overall quality of care and services and determining whether the facility will receive a conditional or standard license, the agency shall consider the needs and limitations of residents in the facility and the results of interviews and surveys of a representative sampling of residents, families of residents, ombudsman council members in the planning and service area in which the facility is located, guardians of residents, and staff of the nursing home facility.

(d) The current licensure status of each facility must be indicated in bold print on the face of the license. A list of the deficiencies of the facility shall be posted in a prominent place that is in clear and unobstructed public view at or near the place where residents are being admitted to that facility. Licensees receiving a conditional licensure status for a

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facility shall prepare, within 10 working days after receiving notice of deficiencies, a plan for correction of all deficiencies and ~~shall~~ submit the plan to the agency for approval.

(e) The agency shall ~~adopt rules that~~:

1. Establish uniform procedures for the evaluation of facilities.

2. Provide criteria in the areas referenced in paragraph (c).

3. Address other areas necessary for carrying out the intent of this section.

(8) The agency shall ensure ~~adopt rules pursuant to this part and part II of chapter 408 to provide~~ that, if ~~when~~ the criteria established under subsection (2) are not met, such deficiencies shall be classified according to the nature and the scope of the deficiency. The scope shall be cited as isolated, patterned, or widespread. An isolated deficiency is a deficiency affecting one or a very limited number of residents, or involving one or a very limited number of staff, or a situation that occurred only occasionally or in a very limited number of locations. A patterned deficiency is a deficiency in which ~~where~~ more than a very limited number of residents are affected, or more than a very limited number of staff are involved, or the situation has occurred in several locations, or the same resident or residents have been affected by repeated occurrences of the same deficient practice but the effect of the deficient practice is not found to be pervasive throughout the facility. A widespread deficiency is a deficiency in which the problems causing the deficiency are pervasive in the facility or

represent systemic failure that has affected or has the potential to affect a large portion of the facility's residents. The agency shall indicate the classification on the face of the notice of deficiencies as follows:

(a) A class I deficiency is a deficiency that the agency determines presents a situation in which immediate corrective action is necessary because the facility's noncompliance has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident receiving care in a facility. The condition or practice constituting a class I violation must ~~shall~~ be abated or eliminated immediately, unless a fixed period of time, as determined by the agency, is required for correction. A class I deficiency is subject to a civil penalty of $10,000 for an isolated deficiency, $12,500 for a patterned deficiency, and $15,000 for a widespread deficiency. The fine amount is ~~shall be~~ doubled for each deficiency if the facility was previously cited for one or more class I or class II deficiencies during the last licensure inspection or during an ~~any~~ inspection or complaint investigation since the last licensure inspection. A fine must be levied notwithstanding the correction of the deficiency.

(b) A class II deficiency is a deficiency that the agency determines has compromised a ~~the~~ resident's ability to maintain or reach his or her highest practicable physical, mental, and psychosocial well-being, as defined by an accurate and comprehensive resident assessment, plan of care, and provision of services. A class II deficiency is subject to a civil penalty of $2,500 for an isolated deficiency, $5,000 for a patterned deficiency, and $7,500 for a widespread deficiency. The fine

amount is ~~shall be~~ doubled for each deficiency if the facility was previously cited for one or more class I or class II deficiencies during the last licensure inspection or an ~~any~~ inspection or complaint investigation since the last licensure inspection. A fine shall be levied notwithstanding the correction of the deficiency.

(c) A class III deficiency is a deficiency that the agency determines will result in no more than minimal physical, mental, or psychosocial discomfort to a ~~the~~ resident or has the potential to compromise a ~~the~~ resident's ability to maintain or reach his or her highest practical physical, mental, or psychosocial well-being, as defined by an accurate and comprehensive resident assessment, plan of care, and provision of services. A class III deficiency is subject to a civil penalty of $1,000 for an isolated deficiency, $2,000 for a patterned deficiency, and $3,000 for a widespread deficiency. The fine amount is ~~shall be~~ doubled for each deficiency if the facility was previously cited for one or more class I or class II deficiencies during the last licensure inspection or an ~~any~~ inspection or complaint investigation since the last licensure inspection. A citation for a class III deficiency must specify the time within which the deficiency is required to be corrected. If a class III deficiency is corrected within the time specified, a civil penalty may not be imposed.

(d) A class IV deficiency is a deficiency that the agency determines has the potential for causing no more than a minor negative impact on a ~~the~~ resident. If the class IV deficiency is isolated, no plan of correction is required.

(9) Civil penalties paid by a ~~any~~ licensee under subsection

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(8) shall be deposited in the Health Care Trust Fund and expended as provided in s. 400.063.

(10) Agency records, reports, ranking systems, Internet information, and publications must be promptly updated to reflect the most current agency actions.

Section 5. Subsection (7) of section 400.487, Florida Statutes, is amended to read:

400.487 Home health service agreements; physician's, physician assistant's, and advanced registered nurse practitioner's treatment orders; patient assessment; establishment and review of plan of care; provision of services; orders not to resuscitate.—

(7) Home health agency personnel may withhold or withdraw cardiopulmonary resuscitation if presented with an order not to resuscitate executed pursuant to s. 401.45. ~~The agency shall adopt rules providing for the implementation of such orders.~~ Home health personnel and agencies are ~~shall~~ not ~~be~~ subject to criminal prosecution or civil liability and are not~~, nor be~~ considered to have engaged in negligent or unprofessional conduct~~,~~ for withholding or withdrawing cardiopulmonary resuscitation pursuant to such ~~an~~ order ~~and rules adopted by the agency~~.

Section 6. Section 400.497, Florida Statutes, is amended to read:

400.497 Rules establishing minimum standards.—The agency may ~~shall~~ adopt~~, publish, and enforce~~ rules to administer ~~implement~~ part II of chapter 408 and this part, including the provider's duties and responsibilities under~~, as applicable,~~ ss. 400.506 and 400.509. Rules shall specify, but are not limited

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to, ~~which must provide~~ reasonable and fair minimum standards relating to:

(1) The home health aide competency test and home health aide training. The agency shall create the home health aide competency test and establish the curriculum and instructor qualifications for home health aide training. Licensed home health agencies may provide this training and shall furnish documentation of such training to other licensed home health agencies upon request. Successful passage of the competency test by home health aides may be substituted for the training required under this section and agency ~~any~~ rule ~~adopted pursuant thereto~~.

(2) Shared staffing. ~~The agency shall allow~~ Shared staffing is allowed if the home health agency is part of a retirement community that provides multiple levels of care, is located on one campus, is licensed under this chapter or chapter 429, and otherwise meets the requirements of law and rule.

(3) The criteria for the frequency of onsite licensure surveys.

(4) Licensure application and renewal.

(5) Oversight by the director of nursing, including~~. The agency shall develop rules related to~~:

(a) Standards that address oversight responsibilities by the director of nursing for ~~of~~ skilled nursing and personal care services provided by the home health agency's staff;

(b) Requirements for a director of nursing to provide to the agency, upon request, a certified daily report of the home health services provided by a specified direct employee or contracted staff member on behalf of the home health agency. The

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agency may request a certified daily report for up to ~~only for a period not to exceed~~ 2 years before ~~prior to~~ the date of the request; and

(c) A quality assurance program for home health services provided by the home health agency.

(6) Conditions for using a recent unannounced licensure inspection for the inspection required under ~~in~~ s. 408.806 related to a licensure application associated with a change in ownership of a licensed home health agency.

(7) The requirements for onsite and electronic accessibility of supervisory personnel of home health agencies.

(8) Information to be included in patients' records.

(9) Geographic service areas.

(10) Preparation of a comprehensive emergency management plan pursuant to s. 400.492.

~~(a) The Agency for Health Care Administration shall adopt rules establishing minimum criteria for the plan and plan updates, with the concurrence of the Department of Health and in consultation with the Division of Emergency Management.~~

(a) ~~(b)~~ An emergency plan ~~The rules~~ must ~~address the requirements in s. 400.492. In addition, the rules shall~~ provide for the maintenance of patient-specific medication lists that can accompany patients who are transported from their homes.

(b) ~~(c)~~ The plan is subject to review and approval by the county health department. During its review, the county health department shall contact state and local health and medical stakeholders when necessary. The county health department shall complete its review to ensure that the plan is in accordance with the requirements of law ~~criteria in the Agency for Health~~

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~~Care Administration rules~~ within 90 days after receipt of the plan and shall approve the plan or advise the home health agency of necessary revisions. If the home health agency fails to submit a plan or fails to submit the requested information or revisions to the county health department within 30 days after written notification from the county health department, the county health department shall notify the Agency for Health Care Administration. The agency shall notify the home health agency that its failure constitutes a deficiency, subject to a fine of $5,000 per occurrence. If the plan is not submitted, information is not provided, or revisions are not made as requested, the agency may impose the fine.

(c) ~~(d)~~ For a ~~any~~ home health agency that operates in more than one county, the Department of Health shall review the plan, after consulting with state and local health and medical stakeholders when necessary. The department shall complete its review within 90 days after receipt of the plan and shall approve the plan or advise the home health agency of necessary revisions. The department shall make every effort to avoid imposing differing requirements on a home health agency that operates in more than one county as a result of differing or conflicting comprehensive plan requirements of the counties in which the home health agency operates.

(d) ~~(c)~~ The requirements in this subsection do not apply to:

1. A facility that is certified under chapter 651 and has a licensed home health agency used exclusively by residents of the facility; or

2. A retirement community that consists of both residential units for independent living and ~~either~~ a licensed nursing home

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or an assisted living facility~~,~~ and has a licensed home health agency used exclusively by ~~the~~ residents of the retirement community, if~~, provided~~ the comprehensive emergency management plan for the facility or retirement community provides for continuous care of all residents with special needs during an emergency.

Section 7. Paragraph (f) of subsection (12) and subsection (17) of section 400.506, Florida Statutes, are amended to read:

400.506 Licensure of nurse registries; requirements; penalties.—

(12) Each nurse registry shall prepare and maintain a comprehensive emergency management plan that is consistent with the criteria in this subsection and with the local special needs plan. The plan shall be updated annually. The plan shall include the means by which the nurse registry will continue to provide the same type and quantity of services to its patients who evacuate to special needs shelters which were being provided to those patients prior to evacuation. The plan shall specify how the nurse registry shall facilitate the provision of continuous care by persons referred for contract to persons who are registered pursuant to s. 252.355 during an emergency that interrupts the provision of care or services in private residences. Nurse registries may establish links to local emergency operations centers to determine a mechanism by which to approach specific areas within a disaster area in order for a provider to reach its clients. Nurse registries shall demonstrate a good faith effort to comply with the requirements of this subsection by documenting attempts of staff to follow procedures outlined in the nurse registry’s comprehensive

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emergency management plan which support a finding that the provision of continuing care has been attempted for patients identified as needing care by the nurse registry and registered under s. 252.355 in the event of an emergency under this subsection.

~~(f) The Agency for Health Care Administration shall adopt rules establishing minimum criteria for the comprehensive emergency management plan and plan updates required by this subsection, with the concurrence of the Department of Health and in consultation with the Division of Emergency Management.~~

~~(17) The Agency for Health Care Administration shall adopt rules to implement this section and part II of chapter 408.~~

Section 8. Subsection (7) of section 400.509, Florida Statutes, is amended to read:

400.509 Registration of particular service providers exempt from licensure; certificate of registration; regulation of registrants.—

~~(7) The Agency for Health Care Administration shall adopt rules to administer this section and part II of chapter 408.~~

Section 9. Subsection (8) of section 400.6095, Florida Statutes, is amended to read:

400.6095 Patient admission; assessment; plan of care; discharge; death.—

(8) The hospice care team may withhold or withdraw cardiopulmonary resuscitation if presented with an order not to resuscitate executed pursuant to s. 401.45. ~~The department shall adopt rules providing for the implementation of such orders.~~ Hospice staff <u>are</u> ~~shall~~ not ~~be~~ subject to criminal prosecution or civil liability, nor ~~be~~ considered to have engaged in

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negligent or unprofessional conduct, for withholding or withdrawing cardiopulmonary resuscitation pursuant to such an order and applicable rules. The absence of an order to resuscitate executed pursuant to s. 401.45 does not preclude a physician from withholding or withdrawing cardiopulmonary resuscitation as otherwise permitted by law.

Section 10. Section 400.914, Florida Statutes, is amended to read:

400.914 Rulemaking; ~~Rules establishing~~ standards.—

(1) Pursuant to the intention of the Legislature to provide safe and sanitary facilities and healthful programs, the agency in conjunction with the Division of Children's Medical Services of the Department of Health may ~~shall~~ adopt ~~and publish~~ rules to administer ~~implement the provisions of~~ this part and part II of chapter 408~~, which shall include reasonable and fair standards~~. Any conflict between these rules ~~standards~~ and those established ~~that may be set forth~~ in local, county, or city ordinances shall be resolved in favor of those having statewide effect.

(2) The rules must specify, but are not limited to, reasonable and fair standards relating ~~Such standards shall relate~~ to:

(a) The assurance that PPEC services are family centered and provide individualized medical, developmental, and family training services.

(b) The maintenance of PPEC centers, not in conflict with ~~the provisions of~~ chapter 553 and based upon the size of the structure and number of children, relating to plumbing, heating, lighting, ventilation, and other building conditions, including adequate space, which will ensure the health, safety, comfort,

and protection from fire of the children served.

(c) The application of the appropriate provisions of the most recent edition of the "Life Safety Code" (NFPA-101) ~~shall be applied~~.

(d) The number and qualifications of all personnel who have responsibility for the care of the children served.

(e) All sanitary conditions within the PPEC center and its surroundings, including water supply, sewage disposal, food handling, and general hygiene, and maintenance thereof, which will ensure the health and comfort of children served.

(f) Programs and basic services promoting and maintaining the health and development of the children served and meeting the training needs of the children's legal guardians.

(g) Supportive, contracted, other operational, and transportation services.

(h) Maintenance of appropriate medical records, data, and information relative to the children and programs. Such records shall be maintained in the facility for inspection by the agency.

~~(2) The agency shall adopt rules to ensure that:~~

~~(a) No child attends a PPEC center for more than 12 hours within a 24-hour period.~~

~~(b) No PPEC center provides services other than those provided to medically or technologically dependent children.~~

Section 11. Section 400.9141, Florida Statutes, is created to read:

400.9141 Limitations.—

(1) A child may not attend a PPEC center for more than 12 hours within a 24-hour period.

(2) A PPEC center may provide services only to medically or technologically dependent children.

Section 12. Paragraph (a) of subsection (20) of section 400.934, Florida Statutes, is amended to read:

400.934 Minimum standards.—As a requirement of licensure, home medical equipment providers shall:

(20)(a) Prepare and maintain a comprehensive emergency management plan that meets minimum criteria established by agency rule, including criteria for the maintenance of patient equipment and supply lists that accompany patients who are transported from their homes. Such rules shall be formulated in consultation with the Department of Health and the Division of Emergency Management ~~under s. 400.935~~. The plan shall be updated annually and shall provide for continuing home medical equipment services for life-supporting or life-sustaining equipment, as defined in s. 400.925, during an emergency that interrupts home medical equipment services in a patient's home. The plan must ~~shall~~ include:

1. The means by which the home medical equipment provider will continue to provide equipment to perform the same type and quantity of services to its patients who evacuate to special needs shelters which were being provided to those patients before ~~prior to~~ evacuation.

2. The means by which the home medical equipment provider establishes and maintains an effective response to emergencies and disasters, including plans for:

a. Notification of staff when emergency response measures are initiated.

b. Communication between staff members, county health

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departments, and local emergency management agencies, which includes provisions for a backup communications system.

c. Identification of resources necessary to continue essential care or services or referrals to other organizations subject to written agreement.

d. Contacting and prioritizing patients in need of continued medical equipment services and supplies.

Section 13. Section 400.935, Florida Statutes, is amended to read:

400.935 Rule authority ~~Rules establishing minimum standards~~.—The agency shall adopt~~, publish, and enforce~~ rules as necessary to implement this part and part II of chapter 408. The rules shall specify, but not be limited to, ~~which must provide~~ reasonable and fair minimum standards relating to:

(1) The qualifications and minimum training requirements of all home medical equipment provider personnel.

~~(2) Financial ability to operate.~~

(2)~~(3)~~ The administration of the home medical equipment provider.

~~(4) Procedures for maintaining patient records.~~

(3)~~(5)~~ Ensuring that the home medical equipment and services provided by a home medical equipment provider are in accordance with the plan of treatment established for each patient, when provided as a part of a plan of treatment.

(4)~~(6)~~ Contractual arrangements for the provision of home medical equipment and services by providers not employed by the home medical equipment provider providing for the consumer's needs.

(5)~~(7)~~ Physical location and zoning requirements.

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(6) ~~(8)~~ Home medical equipment requiring home medical equipment services.

~~(9) Preparation of the comprehensive emergency management plan under s. 400.934 and the establishment of minimum criteria for the plan, including the maintenance of patient equipment and supply lists that can accompany patients who are transported from their homes. Such rules shall be formulated in consultation with the Department of Health and the Division of Emergency Management.~~

Section 14. Subsection (5) of section 400.962, Florida Statutes, is amended to read:

400.962 License required; license application.—

(5) The applicant must agree to provide or arrange for active treatment services by an interdisciplinary team in order to maximize individual independence or prevent regression or loss of functional status. ~~Standards for active treatment shall be adopted by the Agency for Health Care Administration by rule pursuant to ss. 120.536(1) and 120.54.~~ Active treatment services shall be provided in accordance with the individual support plan and shall be reimbursed as part of the per diem rate as paid under the Medicaid program.

Section 15. Subsections (2) and (3) of section 400.967, Florida Statutes, are amended to read:

400.967 Rules and classification of deficiencies.—

(2) ~~Pursuant to the intention of the Legislature,~~ The agency, in consultation with the Agency for Persons with Disabilities and the Department of Elderly Affairs, may ~~shall~~ adopt and enforce rules as necessary to administer this part and part II of chapter 408, which ~~shall~~ include ~~reasonable and fair~~

criteria governing:

(a) The location and construction of the facility; including fire and life safety, plumbing, heating, cooling, lighting, ventilation, and other housing conditions that ensure the health, safety, and comfort of residents. The agency shall establish standards for facilities and equipment to increase the extent to which new facilities, and a new wing or floor added to an existing facility after July 1, 2000, are structurally capable of serving as shelters only for residents, staff, and families of residents and staff, and equipped to be self-supporting during and immediately following disasters. The agency shall update or revise the criteria as the need arises. ~~All~~ Facilities must comply with the ~~those~~ lifesafety code requirements and building code standards applicable when ~~at the time of approval of~~ their construction plans are approved. The agency may require alterations to a building if it determines that an existing condition constitutes a ~~distinct~~ hazard to life, health, or safety. The agency may state the ~~shall adopt fair and reasonable rules setting forth~~ conditions under which existing facilities undergoing additions, alterations, conversions, renovations, or repairs are required to comply with the most recent updated or revised standards.

(b) The number and qualifications of all personnel, including management, medical, nursing, and other personnel, having responsibility for any part of the care given to residents.

(c) ~~All~~ Sanitary conditions within the facility and its surroundings, including water supply, sewage disposal, food handling, and general hygiene, which ~~will~~ ensure the health and

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comfort of residents.

(d) ~~The~~ Equipment essential to the health and welfare of the residents.

(e) A uniform accounting system.

(f) The care, treatment, and maintenance of residents and the assessment ~~measurement~~ of the quality and adequacy thereof.

(g) The preparation and annual update of a comprehensive emergency management plan. After consultation with the Division of Emergency Management, the agency may establish ~~shall adopt rules establishing~~ minimum criteria for ~~the plan after consultation with the Division of Emergency Management. At a minimum, the rules must provide for~~ plan components that address emergency evacuation transportation; adequate sheltering arrangements; postdisaster activities, including emergency power, food, and water; postdisaster transportation; supplies; staffing; emergency equipment; individual identification of residents and transfer of records; and responding to family inquiries. The comprehensive emergency management plan is subject to review and approval by the local emergency management agency. During the ~~its~~ review, the local emergency management agency shall ensure that the following agencies, at a minimum, are given the opportunity to review the plan: the Department of Elderly Affairs, the Agency for Persons with Disabilities, the Agency for Health Care Administration, and the Division of Emergency Management. ~~Also,~~ Appropriate volunteer organizations must also be given the opportunity to review the plan. The local emergency management agency shall complete its review within 60 days and ~~either~~ approve the plan or advise the facility of necessary revisions.

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(h) The use of restraint and seclusion. Such criteria ~~rules~~ must be consistent with recognized best practices; prohibit inherently dangerous restraint or seclusion procedures; establish limitations on the use and duration of restraint and seclusion; establish measures to ensure the safety of clients and staff during an incident of restraint or seclusion; establish procedures for staff to follow before, during, and after incidents of restraint or seclusion, including individualized plans for the use of restraints or seclusion in emergency situations; establish professional qualifications of and training for staff who may order or be engaged in the use of restraint or seclusion; establish requirements for facility data collection and reporting relating to the use of restraint and seclusion; and establish procedures relating to the documentation of the use of restraint or seclusion in the client's facility or program record.

(3) If ~~The agency shall adopt rules to provide that, when~~ the criteria established under this part and part II of chapter 408 are not met, such deficiencies shall be classified according to the nature of the deficiency. The agency shall indicate the classification on the face of the notice of deficiencies as follows:

(a) Class I deficiencies are those which the agency determines present an imminent danger to ~~the~~ residents or guests of the facility or a substantial probability that death or serious physical harm will ~~would~~ result therefrom. The condition or practice constituting a class I violation must be abated or eliminated immediately, unless the agency determines that a fixed period of time~~, as determined by the agency,~~ is required

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for correction. A class I deficiency is subject to a civil penalty in an amount of at least ~~not less than~~ $5,000 but not more than ~~and not exceeding~~ $10,000 for each deficiency. A fine may be levied notwithstanding the correction of the deficiency.

(b) Class II deficiencies are those which the agency determines have a direct or immediate relationship to the health, safety, or security of ~~the~~ facility residents but do not meet the criteria established for~~, other than~~ class I deficiencies. A class II deficiency is subject to a civil penalty in an amount of at least ~~not less than~~ $1,000 and not more than ~~not exceeding~~ $5,000 for each deficiency. A citation for a class II deficiency must ~~shall~~ specify the time within which the deficiency must be corrected. If a class II deficiency is corrected within the time specified, a ~~no~~ civil penalty may not ~~shall~~ be imposed, unless it is a repeated offense.

(c) Class III deficiencies are those which the agency determines to have an indirect or potential relationship to the health, safety, or security of ~~the~~ facility residents but do not meet the criteria for~~, other than~~ class I or class II deficiencies. A class III deficiency is subject to a civil penalty of at least ~~not less than~~ $500 and not more than ~~exceeding~~ $1,000 for each deficiency. A citation for a class III deficiency must ~~shall~~ specify the time within which the deficiency must be corrected. If a class III deficiency is corrected within the time specified, a ~~no~~ civil penalty may not ~~shall~~ be imposed, unless it is a repeated offense.

Section 16. Subsection (2) of section 400.980, Florida Statutes, is amended to read:

400.980 Health care services pools.—

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(2) The requirements of part II of chapter 408 apply to the provision of services that require licensure or registration pursuant to this part and part II of chapter 408 and to entities registered by or applying for such registration from the agency pursuant to this part. Registration or a license issued by the agency is required for the operation of a health care services pool in this state. In accordance with s. 408.805, an applicant or licensee shall pay a fee for each license application submitted using this part, part II of chapter 408, and applicable rules. The agency shall ~~adopt rules and~~ provide forms required for such registration and shall impose a registration fee in an amount sufficient to cover the cost of administering this part and part II of chapter 408. In addition to the requirements in part II of chapter 408, the registrant must provide the agency with any change of information contained on the original registration application within 14 days before ~~prior to~~ the change.

Section 17. Subsection (43) of section 409.912, Florida Statutes, is amended to read:

409.912 Cost-effective purchasing of health care.—The agency shall purchase goods and services for Medicaid recipients in the most cost-effective manner consistent with the delivery of quality medical care. To ensure that medical services are effectively utilized, the agency may, in any case, require a confirmation or second physician’s opinion of the correct diagnosis for purposes of authorizing future services under the Medicaid program. This section does not restrict access to emergency services or poststabilization care services as defined in 42 C.F.R. part 438.114. Such confirmation or second opinion

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shall be rendered in a manner approved by the agency. The agency shall maximize the use of prepaid per capita and prepaid aggregate fixed-sum basis services when appropriate and other alternative service delivery and reimbursement methodologies, including competitive bidding pursuant to s. 287.057, designed to facilitate the cost-effective purchase of a case-managed continuum of care. The agency shall also require providers to minimize the exposure of recipients to the need for acute inpatient, custodial, and other institutional care and the inappropriate or unnecessary use of high-cost services. The agency shall contract with a vendor to monitor and evaluate the clinical practice patterns of providers in order to identify trends that are outside the normal practice patterns of a provider’s professional peers or the national guidelines of a provider’s professional association. The vendor must be able to provide information and counseling to a provider whose practice patterns are outside the norms, in consultation with the agency, to improve patient care and reduce inappropriate utilization. The agency may mandate prior authorization, drug therapy management, or disease management participation for certain populations of Medicaid beneficiaries, certain drug classes, or particular drugs to prevent fraud, abuse, overuse, and possible dangerous drug interactions. The Pharmaceutical and Therapeutics Committee shall make recommendations to the agency on drugs for which prior authorization is required. The agency shall inform the Pharmaceutical and Therapeutics Committee of its decisions regarding drugs subject to prior authorization. The agency is authorized to limit the entities it contracts with or enrolls as Medicaid providers by developing a provider network through

provider credentialing. The agency may competitively bid single-source-provider contracts if procurement of goods or services results in demonstrated cost savings to the state without limiting access to care. The agency may limit its network based on the assessment of beneficiary access to care, provider availability, provider quality standards, time and distance standards for access to care, the cultural competence of the provider network, demographic characteristics of Medicaid beneficiaries, practice and provider-to-beneficiary standards, appointment wait times, beneficiary use of services, provider turnover, provider profiling, provider licensure history, previous program integrity investigations and findings, peer review, provider Medicaid policy and billing compliance records, clinical and medical record audits, and other factors. Providers are not entitled to enrollment in the Medicaid provider network. The agency shall determine instances in which allowing Medicaid beneficiaries to purchase durable medical equipment and other goods is less expensive to the Medicaid program than long-term rental of the equipment or goods. The agency may establish rules to facilitate purchases in lieu of long-term rentals in order to protect against fraud and abuse in the Medicaid program as defined in s. 409.913. The agency may seek federal waivers necessary to administer these policies.

(43) Subject to the availability of funds, the agency shall mandate a recipient’s participation in a provider lock-in program, when appropriate, if a recipient is found by the agency to have used Medicaid goods or services at a frequency or amount not medically necessary, limiting the receipt of goods or services to medically necessary providers after the 21-day

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appeal process has ended, for at least ~~a period of not less than~~ 1 year. The lock-in programs must ~~shall~~ include, but are not limited to, pharmacies, medical doctors, and infusion clinics. The limitation does not apply to emergency services and care provided to the recipient in a hospital emergency department. The agency shall seek any federal waivers necessary to implement this subsection. ~~The agency shall adopt any rules necessary to comply with or administer this subsection.~~ This subsection expires October 1, 2014.

Section 18. Subsection (13) of section 409.962, Florida Statutes, is amended to read:

409.962 Definitions.—As used in this part, except as otherwise specifically provided, the term:

(13) "Provider service network" means an entity qualified pursuant to s. 409.912(4)(d) of which a controlling interest is owned by a health care provider, or group of ~~affiliated~~ providers affiliated for the purpose of providing health care, or a public agency or entity that delivers health services. Health care providers include Florida-licensed health care practitioners ~~professionals~~ or licensed health care facilities, federally qualified health care centers, and home health care agencies.

Section 19. Paragraph (e) of subsection (2) of section 409.972, Florida Statutes, is amended to read:

409.972 Mandatory and voluntary enrollment.—

(2) The following Medicaid-eligible persons are exempt from mandatory managed care enrollment required by s. 409.965, and may voluntarily choose to participate in the managed medical assistance program:

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(e) Medicaid recipients enrolled in the home and community based services waiver pursuant to chapter 393, ~~and~~ Medicaid recipients waiting for waiver services, and Medicaid recipients under the age of 21 who are not receiving waiver services but are authorized by the Agency for Persons with Disabilities or the Department of Children and Families to reside in a group home facility licensed pursuant to chapter 393.

Section 20. Subsection (1) of section 409.974, Florida Statutes, is amended to read:

409.974 Eligible plans.—

(1) ELIGIBLE PLAN SELECTION.—The agency shall select and contract with eligible plans through the procurement process described in s. 409.966. The agency shall notice invitations to negotiate by ~~no later than~~ January 1, 2013.

(a) The agency shall procure and contract with two plans for Region 1. At least one plan shall be a provider service network if any provider service networks submit a responsive bid.

(b) The agency shall procure and contract with two plans for Region 2. At least one plan shall be a provider service network if any provider service networks submit a responsive bid.

(c) The agency shall procure and contract with at least three plans and up to five plans for Region 3. At least one plan must be a provider service network if any provider service networks submit a responsive bid.

(d) The agency shall procure and contract with at least three plans and up to five plans for Region 4. At least one plan must be a provider service network if any provider service

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networks submit a responsive bid.

(e) The agency shall procure and contract with at least two plans and up to four plans for Region 5. At least one plan must be a provider service network if any provider service networks submit a responsive bid.

(f) The agency shall procure and contract with at least four plans and up to seven plans for Region 6. At least one plan must be a provider service network if any provider service networks submit a responsive bid.

(g) The agency shall procure and contract with at least three plans and up to six plans for Region 7. At least one plan must be a provider service network if any provider service networks submit a responsive bid.

(h) The agency shall procure and contract with at least two plans and up to four plans for Region 8. At least one plan must be a provider service network if any provider service networks submit a responsive bid.

(i) The agency shall procure and contract with at least two plans and up to four plans for Region 9. At least one plan must be a provider service network if any provider service networks submit a responsive bid.

(j) The agency shall procure and contract with at least two plans and up to four plans for Region 10. At least one plan must be a provider service network if any provider service networks submit a responsive bid.

(k) The agency shall procure and contract with at least five plans and up to 10 plans for Region 11. At least one plan must be a provider service network if any provider service networks submit a responsive bid.

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If no provider service network submits a responsive bid, the agency shall procure up to ~~no more than~~ one less than the maximum number of eligible plans permitted in that region and,~~.~~ within the next 12 months after the initial invitation to negotiate, shall issue an invitation to negotiate in order ~~the agency shall attempt~~ to procure and contract with a provider service network. In a region in which the agency has contracted with only one provider service network and changes in the ownership or business structure of the network result in the network no longer meeting the definition of a provider service network under s. 409.962, the agency must, within the next 12 months, terminate the contract, provide ~~shall~~ notice of another invitation to negotiate, and procure and contract ~~only~~ with a provider service network in that region ~~networks in those regions where no provider service network has been selected~~.

Section 21. Subsection (4) of section 429.255, Florida Statutes, is amended to read:

429.255 Use of personnel; emergency care.—

(4) Facility staff may withhold or withdraw cardiopulmonary resuscitation or the use of an automated external defibrillator if presented with an order not to resuscitate executed pursuant to s. 401.45. ~~The department shall adopt rules providing for the implementation of such orders.~~ Facility staff and facilities are ~~shall~~ not ~~be~~ subject to criminal prosecution or civil liability, nor ~~be~~ considered to have engaged in negligent or unprofessional conduct, for withholding or withdrawing cardiopulmonary resuscitation or use of an automated external defibrillator pursuant to such an order ~~and rules adopted by the department~~.

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The absence of an order to resuscitate executed pursuant to s. 401.45 does not preclude a physician from withholding or withdrawing cardiopulmonary resuscitation or use of an automated external defibrillator as otherwise permitted by law.

Section 22. Subsection (3) of section 429.73, Florida Statutes, is amended to read:

429.73 Rules and standards relating to adult family-care homes.—

(3) ~~The department shall adopt rules providing for the implementation of orders not to resuscitate.~~ The provider may withhold or withdraw cardiopulmonary resuscitation if presented with an order not to resuscitate executed pursuant to s. 401.45. The provider is ~~shall~~ not ~~be~~ subject to criminal prosecution or civil liability, nor ~~be~~ considered to have engaged in negligent or unprofessional conduct, for withholding or withdrawing cardiopulmonary resuscitation pursuant to such an order ~~and applicable rules~~.

Section 23. Subsection (10) of section 440.102, Florida Statutes, is amended to read:

440.102 Drug-free workplace program requirements.—The following provisions apply to a drug-free workplace program implemented pursuant to law or to rules adopted by the Agency for Health Care Administration:

(10) RULES.—~~The Agency for Health Care Administration shall adopt rules~~ Pursuant to s. 112.0455, part II of chapter 408, and using criteria established by the United States Department of Health and Human Services, the agency shall adopt rules ~~as general guidelines~~ for ~~modeling~~ drug-free workplace laboratories, including ~~concerning~~, but not limited to:

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(a) Standards for licensing drug-testing laboratories and suspension and revocation of such licenses.

(b) Urine, hair, blood, and other body specimens and minimum specimen amounts that are appropriate for drug testing.

(c) Methods of analysis and procedures to ensure reliable drug-testing results, including standards for initial tests and confirmation tests.

(d) Minimum cutoff detection levels for each drug or metabolites of such drug for the purposes of determining a positive test result.

(e) Chain-of-custody procedures to ensure proper identification, labeling, and handling of specimens tested.

(f) Retention, storage, and transportation procedures to ensure reliable results on confirmation tests and retests.

Section 24. Subsection (2) of section 483.245, Florida Statutes, is amended to read:

483.245 Rebates prohibited; penalties.—

(2) The agency may establish and ~~shall adopt rules that~~ assess administrative penalties for acts prohibited by subsection (1). If ~~In the case of~~ an entity is licensed by the agency, such penalties may include any disciplinary action available to the agency under the appropriate licensing laws. If ~~In the case of~~ an entity is not licensed by the agency, such penalties may include:

(a) A fine not to exceed $1,000;

(b) If applicable, a recommendation by the agency to the appropriate licensing board that disciplinary action be taken.

Section 25. Subsection (2) of section 765.541, Florida Statutes, is amended to read:

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765.541 Licensure ~~Certification~~ of procurement organizations; agency responsibilities.—The agency shall:

(1) Establish a program for the licensure ~~certification~~ of organizations, corporations, or other entities engaged in the procurement of organs, tissues, and eyes within the state for transplantation.

(2) Adopt rules as necessary to implement ~~that set forth appropriate standards and guidelines for the program in accordance with~~ ss. 765.541-765.546 and part II of chapter 408.

(a) ~~These~~ Standards and guidelines for the program adopted by the agency must be substantially based on the ~~existing~~ laws of the Federal Government and this state, and the ~~existing~~ standards and guidelines of the Organ Procurement and Transplantation Network (OPTN), the Association of Organ Procurement Organizations (AOPO)~~United Network for Organ Sharing (UNOS), the American Association of Tissue Banks (AATB), the South-Eastern Organ Procurement Foundation (SEOPF), the North American Transplant Coordinators Organization (NATCO)~~, and the Eye Bank Association of America (EBAA). ~~In addition, the agency shall, before adopting these standards and guidelines, seek input from all procurement organizations based in this state.~~

Section 26. Subsection (2) of section 765.544, Florida Statutes, is amended to read:

765.544 Fees; organ and tissue donor education and procurement.—

~~(2) The agency shall specify by rule the administrative penalties for the purpose of ensuring adherence to the standards of quality and practice required by this chapter, part II of chapter 408, and applicable rules of the agency for continued~~

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~~certification.~~

Section 27. This act shall take effect July 1, 2014.

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

And the title is amended as follows:

Delete everything before the enacting clause and insert:

A bill to be entitled

An act relating to health care services; amending ss. 390.012, 400.021, 400.0712, 400.23, 400.487, 400.497, 400.506, 400.509, 400.6095, 400.914, 400.935, 400.962, 400.967, 400.980, 409.912, 429.255, 429.73, 440.102, 483.245, 765.541, and 765.544, F.S.; removing certain rulemaking authority relating to the disposal of fetal remains by abortion clinics, nursing home equipment and furnishings, license applications for nursing home facilities, evaluation of nursing home facilities, home health agencies and cardiopulmonary resuscitation, home health agency standards, nurse registry emergency management plans, registration of certain service providers, hospice and cardiopulmonary resuscitation, standards for prescribed pediatric extended care facilities, minimum standards relating to home medical equipment providers, standards for intermediate care facilities for the developmentally disabled, rules and the classification of deficiencies for intermediate care facilities for the developmentally disabled, the registration of health care service pools, participation in a Medicaid

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provider lock-in program, assisted living facilities and cardiopulmonary resuscitation, adult family-care homes and cardiopulmonary resuscitation, guidelines for drug-free workplace laboratories, penalties for rebates, standards for organ procurement organizations; administrative penalties for violations of the organ and tissue donor education and procurement program; creating s. 400.9141; limiting services at PPEC centers; amending s. 400.934, relating to home medical equipment providers; requiring that the emergency management plan include criteria relating to the maintenance of patient equipment and supply lists; amending s. 409.962, F.S.; redefining the term "provider service network"; amending s. 409.972; exempting certain people from the requirement to enroll in Medicaid managed care; amending s. 409.974, F.S.; providing for contracting with eligible plans; revising provisions relating to negotiation with a provider service network; providing requirements for termination of a contract with a provider service network; providing an effective date.

By Senator Grimsley

21-00602A-14 20141254__

A bill to be entitled

An act relating to health care services rulemaking; amending ss. 390.012, 400.021, 400.0712, 400.23, 400.487, 400.497, 400.506, 400.509, 400.6095, 400.914, 400.935, 400.962, 400.967, 400.980, 409.912, 429.255, 429.73, 440.102, 483.245, 765.541, and 765.544, F.S.; removing certain rulemaking authority relating to the disposal of fetal remains by abortion clinics, nursing home equipment and furnishings, license applications for nursing home facilities, evaluation of nursing home facilities, home health agencies and cardiopulmonary resuscitation, home health agency standards, nurse registry emergency management plans, registration of certain service providers, hospice and cardiopulmonary resuscitation, standards for prescribed pediatric extended care facilities, minimum standards relating to home medical equipment providers, standards for intermediate care facilities for the developmentally disabled, rules and the classification of deficiencies for intermediate care facilities for the developmentally disabled, the registration of health care service pools, participation in a Medicaid provider lock-in program, assisted living facilities and cardiopulmonary resuscitation, adult family-care homes and cardiopulmonary resuscitation, guidelines for drug-free workplace laboratories, penalties for rebates, standards for organ procurement organizations; administrative penalties for violations of the organ

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21-00602A-14 20141254__

and tissue donor education and procurement program; creating s. 400.9141; limiting services at PPEC centers; amending s. 400.934, relating to home medical equipment providers; requiring that the emergency management plan include criteria relating to the maintenance of patient equipment and supply lists; providing an effective date.

WHEREAS, rulemaking is not a matter of agency discretion; rulemaking authority is delegated by the Legislature for agencies to adopt statements of general applicability that interpret or implement law; the valid adoption of a rule requires both a grant of express rulemaking authority and a specific law to be implemented or interpreted, and

WHEREAS, the repeal or deletion of a redundant or unnecessary provision authorizing agency rulemaking does not repeal rulemaking authority otherwise provided that clearly applies to the same subject, and

WHEREAS, statutory provisions mandating rules, when the substantive law otherwise would be implemented without the need for administrative rules or by rulemaking under a broader grant of authority, may be repealed without altering the substantive law or rulemaking authority on which existing rules rely, NOW, THEREFORE,

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

Section 1. Paragraph (d) of subsection (3) of section 390.012, Florida Statutes, is amended to read:

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390.012 Powers of agency; rules; disposal of fetal remains.—

(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:

(d) Rules relating to the medical screening and evaluation of each abortion clinic patient. At a minimum, these rules must ~~shall~~ require:

1. A medical history including reported allergies to medications, antiseptic solutions, or latex; past surgeries; and an obstetric and gynecological history.

2. A physical examination, including a bimanual examination estimating uterine size and palpation of the adnexa.

3. The appropriate laboratory tests, including:

a. Urine or blood tests for pregnancy performed before the abortion procedure.

b. A test for anemia.

c. Rh typing, unless reliable written documentation of blood type is available.

d. Other tests as indicated from the physical examination.

4. An ultrasound evaluation for all patients. The rules must ~~shall~~ require that if a person who is not a physician performs an ultrasound examination, that person shall have documented evidence that he or she has completed a course in the operation of ultrasound equipment as prescribed in rule. ~~The rules shall require clinics to be in compliance with s. 390.0111.~~

5. That the physician is responsible for estimating the

gestational age of the fetus based on the ultrasound examination and obstetric standards in keeping with established standards of care regarding the estimation of fetal age as defined in rule and shall write the estimate in the patient's medical history. The physician shall keep original prints of each ultrasound examination of a patient in the patient's medical history file.

Section 2. Subsection (11) of section 400.021, Florida Statutes, is amended to read:

400.021 Definitions.—When used in this part, unless the context otherwise requires, the term:

(11) "Nursing home bed" means an accommodation that ~~which~~ is ready for immediate occupancy, or is capable of being made ready for occupancy within 48 hours, excluding the provision of staffing, ~~,~~ and that ~~which~~ conforms to minimum space requirements, including the availability of appropriate equipment and furnishings within the 48 hours, as specified by ~~rule of~~ the agency, for the provision of services specified in this part to a single resident.

Section 3. Subsection (3) of section 400.0712, Florida Statutes, is amended to read:

400.0712 Application for inactive license.—

~~(3) The agency shall adopt rules pursuant to ss. 120.536(1) and 120.54 necessary to implement this section.~~

Section 4. Section 400.23, Florida Statutes, is amended to read:

400.23 Rules; evaluation and deficiencies; licensure status.—

(1) It is the intent of the Legislature that rules published and enforced pursuant to this part and part II of

chapter 408 ~~shall~~ include criteria by which a reasonable and consistent quality of resident care may be ensured, ~~and~~ the results of such resident care can be demonstrated, and ~~by which~~ safe and sanitary nursing homes can be provided. It is further intended that reasonable efforts be made to accommodate the needs and preferences of residents to enhance the quality of life in a nursing home. In addition, efforts shall be made to minimize the amount of paperwork associated with the reporting and documentation requirements of these rules.

(2) Pursuant to the intention of the Legislature, the agency, in consultation with the Department of Health and the Department of Elderly Affairs, may ~~shall~~ adopt ~~and enforce~~ rules to administer ~~implement~~ this part and part II of chapter 408. The rules must specify, but are not limited to, ~~which shall include~~ reasonable and fair criteria relating ~~in relation~~ to:

(a) The location of the facility and housing conditions that will ensure the health, safety, and comfort of residents, including an adequate call system. In adopting ~~making~~ such rules, the agency shall be guided by criteria recommended by nationally recognized reputable professional groups and associations that have ~~with~~ knowledge of such subject matters. The agency shall update or revise the ~~such~~ criteria as the need arises. The agency may require alterations to a building if it determines that an existing condition constitutes a distinct hazard to life, health, or safety. In performing ~~any~~ inspections of facilities authorized by this part or part II of chapter 408, the agency may enforce the special-occupancy provisions of the Florida Building Code and the Florida Fire Prevention Code which apply to nursing homes. A resident ~~Residents~~ or his or her

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representative must ~~their representatives shall~~ be able to request a change in the placement of the bed in his or her ~~their~~ room if, ~~provided that~~ at admission, the resident is ~~they are~~ presented with a room that meets requirements of the Florida Building Code. The location of a bed may be changed if the requested placement does not infringe on the resident's roommate or interfere with the resident's care or safety as determined by the care planning team in accordance with facility policies and procedures. In addition, the bed placement may not be used as a restraint. Each facility shall maintain a log of resident rooms with beds that are not in strict compliance with the Florida Building Code in order for such log to be used by surveyors and nurse monitors during inspections and visits. A resident or a resident's ~~resident~~ representative who requests that a bed be moved must ~~shall~~ sign a statement indicating that he or she understands that the room will not be in compliance with the Florida Building Code, but that he or she ~~they~~ would prefer to exercise the ~~their~~ right to self-determination. The statement must be retained as part of the resident's care plan. A ~~Any~~ facility that offers this option must submit a letter signed by the nursing home administrator of record to the agency notifying it of this practice along with a copy of the policies and procedures of the facility. The agency is directed to provide assistance to the Florida Building Commission in updating the construction standards of the code relating ~~relative~~ to nursing homes.

(b) The number and qualifications of all personnel, including management, medical, nursing, and other professional personnel, and nursing assistants, orderlies, and support

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personnel, having responsibility for any part of the care given residents.

(c) All sanitary conditions within the facility and its surroundings, including water supply, sewage disposal, food handling, and general hygiene which will ensure the health and comfort of residents.

(d) The equipment essential to the health and welfare of the residents.

(e) A uniform accounting system.

(f) The care, treatment, and maintenance of residents and measurement of the quality and adequacy thereof, based on rules developed under this chapter and the Omnibus Budget Reconciliation Act of 1987, ~~(~~Pub. L. No. 100-203~~) (December 22, 1987)~~, Title IV (Medicare, Medicaid, and Other Health-Related Programs), Subtitle C (Nursing Home Reform), as amended.

(g) The preparation and annual update of a comprehensive emergency management plan. The agency shall establish ~~adopt rules establishing~~ minimum criteria for the plan after consultation with the Division of Emergency Management. At a minimum, the ~~rules must provide for~~ plan components must provide ~~that address~~ emergency evacuation transportation; adequate sheltering arrangements; postdisaster activities, including emergency power, food, and water; postdisaster transportation; supplies; staffing; emergency equipment; individual identification of residents and transfer of records; and responding to family inquiries. The comprehensive emergency management plan is subject to review and approval by the local emergency management agency. During the ~~its~~ review, the local emergency management agency shall ensure that the following

agencies, at a minimum, are given the opportunity to review the plan: the Department of Elderly Affairs, the Department of Health, the Agency for Health Care Administration, and the Division of Emergency Management. ~~Also,~~ Appropriate volunteer organizations must also be given the opportunity to review the plan. The local emergency management agency shall complete its review within 60 days and ~~either~~ approve the plan or advise the facility of necessary revisions.

(h) The availability, distribution, and posting of reports and records pursuant to s. 400.191 and the Gold Seal Program pursuant to s. 400.235.

(3)(a)~~1.~~ The agency shall enforce ~~adopt rules providing~~ minimum staffing requirements for nursing home facilities.

1. These requirements must include, for each facility:

a. A combined minimum weekly average of certified nursing assistant and licensed nursing staffing ~~combined~~ of 3.6 hours of direct care per resident per day. As used in this sub-subparagraph, a week is defined as Sunday through Saturday.

b. A minimum certified nursing assistant staffing of 2.5 hours of direct care per resident per day. A facility may not staff below one certified nursing assistant per 20 residents.

c. A minimum licensed nursing staffing of 1.0 hour of direct care per resident per day. A facility may not staff below one licensed nurse per 40 residents.

2. Nursing assistants employed under s. 400.211(2) may be included in computing the staffing ratio for certified nursing assistants if their job responsibilities include only nursing-assistant-related duties.

3. Each nursing home facility must document compliance with

staffing standards ~~as~~ required under this paragraph and post daily the names of staff on duty for the benefit of facility residents and the public.

4. The agency shall recognize the use of licensed nurses for compliance with the minimum staffing requirements for certified nursing assistants if the nursing home facility otherwise meets the minimum staffing requirements for licensed nurses and the licensed nurses are performing the duties of ~~a~~ certified nursing assistants ~~assistant~~. Unless otherwise approved by the agency, licensed nurses counted toward the minimum staffing requirements for certified nursing assistants must exclusively perform the duties of ~~a~~ certified nursing assistants ~~assistant~~ for the entire shift and not also be counted toward the minimum staffing requirements for licensed nurses. If the agency approved a facility's request to use a licensed nurse to perform both licensed nursing and certified nursing assistant duties, the facility must allocate the amount of staff time specifically spent on certified nursing assistant duties for the purpose of documenting compliance with minimum staffing requirements for certified and licensed nursing staff. The hours of a licensed nurse with dual job responsibilities may not be counted twice.

(b) Nonnursing staff providing eating assistance to residents does ~~shall~~ not count toward compliance with minimum staffing standards.

(c) Licensed practical nurses licensed under chapter 464 who are providing nursing services in nursing home facilities under this part may supervise the activities of other licensed practical nurses, certified nursing assistants, and other

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unlicensed personnel providing services in such facilities in accordance with rules adopted by the Board of Nursing.

(4) ~~Rules developed pursuant to~~ This section does ~~shall~~ not restrict the use of shared staffing and shared programming in facilities that ~~which~~ are part of retirement communities that provide multiple levels of care and otherwise meet the requirement of law or rule.

(5) ~~The agency, in collaboration with the Division of Children's Medical Services of the Department of Health, must adopt rules for:~~

(a) Minimum standards of care for persons under 21 years of age who reside in nursing home facilities may be established by the agency, in collaboration with the Division of Children's Medical Services of the Department of Health. A facility may be exempted from these standards and the provisions of paragraph (b) for specified ~~specific~~ persons between 18 and 21 years of age~~,~~ if the person's physician agrees that minimum standards of care based on age are not necessary.

(b) The following ~~Minimum~~ staffing requirements for persons under 21 years of age who reside in nursing home facilities~~,~~ ~~which~~ apply in lieu of the requirements contained in subsection (3):~~.~~

1. For persons under 21 years of age who require skilled care:

a. A minimum combined average of 3.9 hours of direct care per resident per day must be provided by licensed nurses, respiratory therapists, respiratory care practitioners, and certified nursing assistants.

b. A minimum licensed nursing staffing of 1.0 hour of

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direct care per resident per day ~~must be provided~~.

c. Up to ~~No more than~~ 1.5 hours of certified nursing assistant care per resident per day may be counted in determining the minimum direct care hours required.

d. One registered nurse must be on duty on the site 24 hours per day on the unit where children reside.

2. For persons under 21 years of age who are medically fragile:

a. A minimum combined average of 5.0 hours of direct care per resident per day must be provided by licensed nurses, respiratory therapists, respiratory care practitioners, and certified nursing assistants.

b. A minimum licensed nursing staffing of 1.7 hours of direct care per resident per day must be provided.

c. Up to ~~No more than~~ 1.5 hours of certified nursing assistant care per resident per day may be counted in determining the minimum direct care hours required.

d. One registered nurse must be on duty on the site 24 hours per day on a ~~the~~ unit where children reside.

(6) Before ~~Prior to~~ conducting a survey of the facility, the survey team shall obtain a copy of the local long-term care ombudsman council report on the facility. Problems noted in the report shall be incorporated into and followed up through the agency's inspection process. This procedure does not preclude the local long-term care ombudsman council from requesting the agency to conduct a followup visit to the facility.

(7) The agency shall, at least every 15 months, evaluate all nursing home facilities and determine ~~make a determination as to~~ the degree of compliance by each licensee with the

established rules adopted under this part as a basis for assigning a licensure status to a ~~that~~ facility. The agency shall base its evaluation on the most recent inspection report, taking into consideration findings from other official reports, surveys, interviews, investigations, and inspections. In addition to license categories authorized under part II of chapter 408, the agency shall assign a ~~licensure status of~~ standard or conditional licensure status to each nursing home.

(a) A standard licensure status means that a facility has no class I or class II deficiencies and has corrected all class III deficiencies within the time established by the agency.

(b) A conditional licensure status means that a facility, due to the presence of one or more class I or class II deficiencies, or class III deficiencies not corrected within the time established by the agency, is not in substantial compliance at the time of the survey with criteria established under this part or with rules adopted by the agency. If the facility has no class I, class II, or class III deficiencies at the time of the followup survey, a standard licensure status may be assigned.

(c) In evaluating the overall quality of care and services and determining whether the facility will receive a conditional or standard license, the agency shall consider the needs and limitations of residents in the facility and the results of interviews and surveys of a representative sampling of residents, families of residents, ombudsman council members in the planning and service area in which the facility is located, guardians of residents, and staff of the nursing home facility.

(d) The current licensure status of each facility must be indicated in bold print on the face of the license. A list of

the deficiencies of the facility shall be posted in a prominent place that is in clear and unobstructed public view at or near the place where residents are being admitted to that facility. Licensees receiving a conditional licensure status for a facility shall prepare, within 10 working days after receiving notice of deficiencies, a plan for correction of all deficiencies and ~~shall~~ submit the plan to the agency for approval.

(e) The agency shall ~~adopt rules that~~:

1. Establish uniform procedures for the evaluation of facilities.

2. Provide criteria in the areas referenced in paragraph (c).

3. Address other areas necessary for carrying out the intent of this section.

(8) The agency shall ensure ~~adopt rules pursuant to this part and part II of chapter 408 to provide~~ that, if ~~when~~ the criteria established under subsection (2) are not met, such deficiencies shall be classified according to the nature and the scope of the deficiency. The scope shall be cited as isolated, patterned, or widespread. An isolated deficiency is a deficiency affecting one or a very limited number of residents, or involving one or a very limited number of staff, or a situation that occurred only occasionally or in a very limited number of locations. A patterned deficiency is a deficiency in which ~~where~~ more than a very limited number of residents are affected, or more than a very limited number of staff are involved, or the situation has occurred in several locations, or the same resident or residents have been affected by repeated occurrences

of the same deficient practice but the effect of the deficient practice is not found to be pervasive throughout the facility. A widespread deficiency is a deficiency in which the problems causing the deficiency are pervasive in the facility or represent systemic failure that has affected or has the potential to affect a large portion of the facility's residents. The agency shall indicate the classification on the face of the notice of deficiencies as follows:

(a) A class I deficiency is a deficiency that the agency determines presents a situation in which immediate corrective action is necessary because the facility's noncompliance has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident receiving care in a facility. The condition or practice constituting a class I violation must ~~shall~~ be abated or eliminated immediately, unless a fixed period of time, as determined by the agency, is required for correction. A class I deficiency is subject to a civil penalty of $10,000 for an isolated deficiency, $12,500 for a patterned deficiency, and $15,000 for a widespread deficiency. The fine amount is ~~shall be~~ doubled for each deficiency if the facility was previously cited for one or more class I or class II deficiencies during the last licensure inspection or during an ~~any~~ inspection or complaint investigation since the last licensure inspection. A fine must be levied notwithstanding the correction of the deficiency.

(b) A class II deficiency is a deficiency that the agency determines has compromised a ~~the~~ resident's ability to maintain or reach his or her highest practicable physical, mental, and psychosocial well-being, as defined by an accurate and

comprehensive resident assessment, plan of care, and provision of services. A class II deficiency is subject to a civil penalty of $2,500 for an isolated deficiency, $5,000 for a patterned deficiency, and $7,500 for a widespread deficiency. The fine amount is ~~shall be~~ doubled for each deficiency if the facility was previously cited for one or more class I or class II deficiencies during the last licensure inspection or an ~~any~~ inspection or complaint investigation since the last licensure inspection. A fine shall be levied notwithstanding the correction of the deficiency.

(c) A class III deficiency is a deficiency that the agency determines will result in no more than minimal physical, mental, or psychosocial discomfort to a ~~the~~ resident or has the potential to compromise a ~~the~~ resident's ability to maintain or reach his or her highest practical physical, mental, or psychosocial well-being, as defined by an accurate and comprehensive resident assessment, plan of care, and provision of services. A class III deficiency is subject to a civil penalty of $1,000 for an isolated deficiency, $2,000 for a patterned deficiency, and $3,000 for a widespread deficiency. The fine amount is ~~shall be~~ doubled for each deficiency if the facility was previously cited for one or more class I or class II deficiencies during the last licensure inspection or an ~~any~~ inspection or complaint investigation since the last licensure inspection. A citation for a class III deficiency must specify the time within which the deficiency is required to be corrected. If a class III deficiency is corrected within the time specified, a civil penalty may not be imposed.

(d) A class IV deficiency is a deficiency that the agency

determines has the potential for causing no more than a minor negative impact on a ~~the~~ resident. If the class IV deficiency is isolated, no plan of correction is required.

(9) Civil penalties paid by a ~~any~~ licensee under subsection (8) shall be deposited in the Health Care Trust Fund and expended as provided in s. 400.063.

(10) Agency records, reports, ranking systems, Internet information, and publications must be promptly updated to reflect the most current agency actions.

Section 5. Subsection (7) of section 400.487, Florida Statutes, is amended to read:

400.487 Home health service agreements; physician's, physician assistant's, and advanced registered nurse practitioner's treatment orders; patient assessment; establishment and review of plan of care; provision of services; orders not to resuscitate.—

(7) Home health agency personnel may withhold or withdraw cardiopulmonary resuscitation if presented with an order not to resuscitate executed pursuant to s. 401.45. ~~The agency shall adopt rules providing for the implementation of such orders.~~ Home health personnel and agencies are ~~shall~~ not ~~be~~ subject to criminal prosecution or civil liability and are not~~, nor be~~ considered to have engaged in negligent or unprofessional conduct~~,~~ for withholding or withdrawing cardiopulmonary resuscitation pursuant to such ~~an~~ order ~~and rules adopted by the agency~~.

Section 6. Section 400.497, Florida Statutes, is amended to read:

400.497 Rules establishing minimum standards.—The agency

may ~~shall~~ adopt~~, publish, and enforce~~ rules to administer ~~implement~~ part II of chapter 408 and this part, including the agency's duties and responsibilities under~~, as applicable,~~ ss. 400.506 and 400.509. Rules shall specify, but are not limited to, ~~which must provide~~ reasonable and fair minimum standards relating to:

(1) The home health aide competency test and home health aide training. The agency shall create the home health aide competency test and establish the curriculum and instructor qualifications for home health aide training. Licensed home health agencies may provide this training and shall furnish documentation of such training to other licensed home health agencies upon request. Successful passage of the competency test by home health aides may be substituted for the training required under this section and agency ~~any~~ rule ~~adopted pursuant thereto~~.

(2) Shared staffing. ~~The agency shall allow~~ Shared staffing is allowed if the home health agency is part of a retirement community that provides multiple levels of care, is located on one campus, is licensed under this chapter or chapter 429, and otherwise meets the requirements of law and rule.

(3) The criteria for the frequency of onsite licensure surveys.

(4) Licensure application and renewal.

(5) Oversight by the director of nursing, including~~. The agency shall develop rules related to~~:

(a) Standards that address oversight responsibilities by the director of nursing for ~~of~~ skilled nursing and personal care services provided by the home health agency's staff;

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(b) Requirements for a director of nursing to provide to the agency, upon request, a certified daily report of the home health services provided by a specified direct employee or contracted staff member on behalf of the home health agency. The agency may request a certified daily report for up to ~~only for a period not to exceed~~ 2 years before ~~prior to~~ the date of the request; and

(c) A quality assurance program for home health services provided by the home health agency.

(6) Conditions for using a recent unannounced licensure inspection for the inspection required under ~~in~~ s. 408.806 related to a licensure application associated with a change in ownership of a licensed home health agency.

(7) The requirements for onsite and electronic accessibility of supervisory personnel of home health agencies.

(8) Information to be included in patients' records.

(9) Geographic service areas.

(10) Preparation of a comprehensive emergency management plan pursuant to s. 400.492.

~~(a) The Agency for Health Care Administration shall adopt rules establishing minimum criteria for the plan and plan updates, with the concurrence of the Department of Health and in consultation with the Division of Emergency Management.~~

(a)~~(b)~~ An emergency plan ~~The rules~~ must ~~address the requirements in s. 400.492. In addition, the rules shall~~ provide for the maintenance of patient-specific medication lists that can accompany patients who are transported from their homes.

(b)~~(c)~~ The plan is subject to review and approval by the county health department. During its review, the county health

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department shall contact state and local health and medical stakeholders when necessary. The county health department shall complete its review to ensure that the plan is in accordance with the requirements of law ~~criteria in the Agency for Health Care Administration rules~~ within 90 days after receipt of the plan and shall approve the plan or advise the home health agency of necessary revisions. If the home health agency fails to submit a plan or fails to submit the requested information or revisions to the county health department within 30 days after written notification from the county health department, the county health department shall notify the Agency for Health Care Administration. The agency shall notify the home health agency that its failure constitutes a deficiency, subject to a fine of $5,000 per occurrence. If the plan is not submitted, information is not provided, or revisions are not made as requested, the agency may impose the fine.

(c) ~~(d)~~ For a ~~any~~ home health agency that operates in more than one county, the Department of Health shall review the plan, after consulting with state and local health and medical stakeholders when necessary. The department shall complete its review within 90 days after receipt of the plan and shall approve the plan or advise the home health agency of necessary revisions. The department shall make every effort to avoid imposing differing requirements on a home health agency that operates in more than one county as a result of differing or conflicting comprehensive plan requirements of the counties in which the home health agency operates.

(d) ~~(c)~~ The requirements in this subsection do not apply to:

1. A facility that is certified under chapter 651 and has a

licensed home health agency used exclusively by residents of the facility; or

2. A retirement community that consists of both residential units for independent living and ~~either~~ a licensed nursing home or an assisted living facility~~,~~ and has a licensed home health agency used exclusively by ~~the~~ residents of the retirement community, if~~, provided~~ the comprehensive emergency management plan for the facility or retirement community provides for continuous care of all residents with special needs during an emergency.

Section 7. Paragraph (f) of subsection (12) and subsection (17) of section 400.506, Florida Statutes, are amended to read:

400.506 Licensure of nurse registries; requirements; penalties.—

(12) Each nurse registry shall prepare and maintain a comprehensive emergency management plan that is consistent with the criteria in this subsection and with the local special needs plan. The plan shall be updated annually. The plan shall include the means by which the nurse registry will continue to provide the same type and quantity of services to its patients who evacuate to special needs shelters which were being provided to those patients prior to evacuation. The plan shall specify how the nurse registry shall facilitate the provision of continuous care by persons referred for contract to persons who are registered pursuant to s. 252.355 during an emergency that interrupts the provision of care or services in private residences. Nurse registries may establish links to local emergency operations centers to determine a mechanism by which to approach specific areas within a disaster area in order for a

provider to reach its clients. Nurse registries shall demonstrate a good faith effort to comply with the requirements of this subsection by documenting attempts of staff to follow procedures outlined in the nurse registry's comprehensive emergency management plan which support a finding that the provision of continuing care has been attempted for patients identified as needing care by the nurse registry and registered under s. 252.355 in the event of an emergency under this subsection.

~~(f) The Agency for Health Care Administration shall adopt rules establishing minimum criteria for the comprehensive emergency management plan and plan updates required by this subsection, with the concurrence of the Department of Health and in consultation with the Division of Emergency Management.~~

~~(17) The Agency for Health Care Administration shall adopt rules to implement this section and part II of chapter 408.~~

Section 8. Subsection (7) of section 400.509, Florida Statutes, is amended to read:

400.509 Registration of particular service providers exempt from licensure; certificate of registration; regulation of registrants.—

~~(7) The Agency for Health Care Administration shall adopt rules to administer this section and part II of chapter 408.~~

Section 9. Subsection (8) of section 400.6095, Florida Statutes, is amended to read:

400.6095 Patient admission; assessment; plan of care; discharge; death.—

(8) The hospice care team may withhold or withdraw cardiopulmonary resuscitation if presented with an order not to

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resuscitate executed pursuant to s. 401.45. ~~The department shall adopt rules providing for the implementation of such orders.~~ Hospice staff are ~~shall~~ not ~~be~~ subject to criminal prosecution or civil liability, nor ~~be~~ considered to have engaged in negligent or unprofessional conduct, for withholding or withdrawing cardiopulmonary resuscitation pursuant to such an order and applicable rules. The absence of an order to resuscitate executed pursuant to s. 401.45 does not preclude a physician from withholding or withdrawing cardiopulmonary resuscitation as otherwise permitted by law.

Section 10. Section 400.914, Florida Statutes, is amended to read:

400.914 Rulemaking; ~~Rules establishing~~ standards.—

(1) Pursuant to the intention of the Legislature to provide safe and sanitary facilities and healthful programs, the agency in conjunction with the Division of Children's Medical Services of the Department of Health may ~~shall~~ adopt ~~and publish~~ rules to administer ~~implement the provisions of~~ this part and part II of chapter 408~~, which shall include reasonable and fair standards~~. Any conflict between these rules ~~standards~~ and those established ~~that may be set forth~~ in local, county, or city ordinances shall be resolved in favor of those having statewide effect.

(2) The rules must specify, but are not limited to, reasonable and fair standards relating ~~Such standards shall relate~~ to:

(a) The assurance that PPEC services are family centered and provide individualized medical, developmental, and family training services.

(b) The maintenance of PPEC centers, not in conflict with

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~~the provisions of~~ chapter 553 and based upon the size of the structure and number of children, relating to plumbing, heating, lighting, ventilation, and other building conditions, including adequate space, which will ensure the health, safety, comfort, and protection from fire of the children served.

(c) The application of the appropriate provisions of the most recent edition of the "Life Safety Code" (NFPA-101) ~~shall be applied~~.

(d) The number and qualifications of all personnel who have responsibility for the care of the children served.

(e) All sanitary conditions within the PPEC center and its surroundings, including water supply, sewage disposal, food handling, and general hygiene, and maintenance thereof, which will ensure the health and comfort of children served.

(f) Programs and basic services promoting and maintaining the health and development of the children served and meeting the training needs of the children's legal guardians.

(g) Supportive, contracted, other operational, and transportation services.

(h) Maintenance of appropriate medical records, data, and information relative to the children and programs. Such records shall be maintained in the facility for inspection by the agency.

~~(2) The agency shall adopt rules to ensure that:~~

~~(a) No child attends a PPEC center for more than 12 hours within a 24-hour period.~~

~~(b) No PPEC center provides services other than those provided to medically or technologically dependent children.~~

Section 11. Section 400.9141, Florida Statutes, is created

to read:

400.9141 Limitations.—

(1) A child may not attend a PPEC center for more than 12 hours within a 24-hour period.

(2) A PPEC center may provide services only to medically or technologically dependent children.

Section 12. Paragraph (a) of subsection (20) of section 400.934, Florida Statutes, is amended to read:

400.934 Minimum standards.—As a requirement of licensure, home medical equipment providers shall:

(20)(a) Prepare and maintain a comprehensive emergency management plan that meets minimum criteria established by agency rule, including criteria for the maintenance of patient equipment and supply lists that accompany patients who are transported from their homes. Such rules shall be formulated in consultation with the Department of Health and the Division of Emergency Management ~~under s. 400.935~~. The plan shall be updated annually and shall provide for continuing home medical equipment services for life-supporting or life-sustaining equipment, as defined in s. 400.925, during an emergency that interrupts home medical equipment services in a patient's home. The plan must ~~shall~~ include:

1. The means by which the home medical equipment provider will continue to provide equipment to perform the same type and quantity of services to its patients who evacuate to special needs shelters which were being provided to those patients before ~~prior to~~ evacuation.

2. The means by which the home medical equipment provider establishes and maintains an effective response to emergencies

and disasters, including plans for:

a. Notification of staff when emergency response measures are initiated.

b. Communication between staff members, county health departments, and local emergency management agencies, which includes provisions for a backup communications system.

c. Identification of resources necessary to continue essential care or services or referrals to other organizations subject to written agreement.

d. Contacting and prioritizing patients in need of continued medical equipment services and supplies.

Section 13. Section 400.935, Florida Statutes, is amended to read:

400.935 Rule authority ~~Rules establishing minimum standards~~.—The agency shall adopt~~, publish, and enforce~~ rules as necessary to administer ~~implement~~ this part and part II of chapter 408~~, which must provide reasonable and fair minimum standards relating to:~~

~~(1) The qualifications and minimum training requirements of all home medical equipment provider personnel~~.

~~(2) Financial ability to operate.~~

~~(3) The administration of the home medical equipment provider.~~

~~(4) Procedures for maintaining patient records.~~

~~(5) Ensuring that the home medical equipment and services provided by a home medical equipment provider are in accordance with the plan of treatment established for each patient, when provided as a part of a plan of treatment.~~

~~(6) Contractual arrangements for the provision of home~~

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~~medical equipment and services by providers not employed by the home medical equipment provider providing for the consumer's needs.~~

~~(7) Physical location and zoning requirements.~~

~~(8) Home medical equipment requiring home medical equipment services.~~

~~(9) Preparation of the comprehensive emergency management plan under s. 400.934 and the establishment of minimum criteria for the plan, including the maintenance of patient equipment and supply lists that can accompany patients who are transported from their homes. Such rules shall be formulated in consultation with the Department of Health and the Division of Emergency Management.~~

Section 14. Subsection (5) of section 400.962, Florida Statutes, is amended to read:

400.962 License required; license application.—

(5) The applicant must agree to provide or arrange for active treatment services by an interdisciplinary team in order to maximize individual independence or prevent regression or loss of functional status. ~~Standards for active treatment shall be adopted by the Agency for Health Care Administration by rule pursuant to ss. 120.536(1) and 120.54.~~ Active treatment services shall be provided in accordance with the individual support plan and shall be reimbursed as part of the per diem rate as paid under the Medicaid program.

Section 15. Subsections (2) and (3) of section 400.967, Florida Statutes, are amended to read:

400.967 Rules and classification of deficiencies.—

(2) ~~Pursuant to the intention of the Legislature,~~ The

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agency, in consultation with the Agency for Persons with Disabilities and the Department of Elderly Affairs, may ~~shall~~ adopt and enforce rules as necessary to administer this part and part II of chapter 408, which ~~shall~~ include ~~reasonable and fair~~ criteria governing:

(a) The location and construction of the facility; including fire and life safety, plumbing, heating, cooling, lighting, ventilation, and other housing conditions that ensure the health, safety, and comfort of residents. The agency shall establish standards for facilities and equipment to increase the extent to which new facilities, and a new wing or floor added to an existing facility after July 1, 2000, are structurally capable of serving as shelters only for residents, staff, and families of residents and staff, and equipped to be self-supporting during and immediately following disasters. The agency shall update or revise the criteria as the need arises. ~~All~~ Facilities must comply with the ~~those~~ lifesafety code requirements and building code standards applicable when ~~at the time of approval of~~ their construction plans are approved. The agency may require alterations to a building if it determines that an existing condition constitutes a ~~distinct~~ hazard to life, health, or safety. The agency may state the ~~shall adopt fair and reasonable rules setting forth~~ conditions under which existing facilities undergoing additions, alterations, conversions, renovations, or repairs are required to comply with the most recent updated or revised standards.

(b) The number and qualifications of all personnel, including management, medical, nursing, and other personnel, having responsibility for any part of the care given to

residents.

(c) ~~All~~ Sanitary conditions within the facility and its surroundings, including water supply, sewage disposal, food handling, and general hygiene, which ~~will~~ ensure the health and comfort of residents.

(d) ~~The~~ Equipment essential to the health and welfare of the residents.

(e) A uniform accounting system.

(f) The care, treatment, and maintenance of residents and the assessment ~~measurement~~ of the quality and adequacy thereof.

(g) The preparation and annual update of a comprehensive emergency management plan. After consultation with the Division of Emergency Management, the agency may establish ~~shall adopt rules establishing~~ minimum criteria for ~~the plan after consultation with the Division of Emergency Management. At a minimum, the rules must provide for~~ plan components that address emergency evacuation transportation; adequate sheltering arrangements; postdisaster activities, including emergency power, food, and water; postdisaster transportation; supplies; staffing; emergency equipment; individual identification of residents and transfer of records; and responding to family inquiries. The comprehensive emergency management plan is subject to review and approval by the local emergency management agency. During the ~~its~~ review, the local emergency management agency shall ensure that the following agencies, at a minimum, are given the opportunity to review the plan: the Department of Elderly Affairs, the Agency for Persons with Disabilities, the Agency for Health Care Administration, and the Division of Emergency Management. ~~Also,~~ Appropriate volunteer organizations

must also be given the opportunity to review the plan. The local emergency management agency shall complete its review within 60 days and ~~either~~ approve the plan or advise the facility of necessary revisions.

(h) The use of restraint and seclusion. Such criteria ~~rules~~ must be consistent with recognized best practices; prohibit inherently dangerous restraint or seclusion procedures; establish limitations on the use and duration of restraint and seclusion; establish measures to ensure the safety of clients and staff during an incident of restraint or seclusion; establish procedures for staff to follow before, during, and after incidents of restraint or seclusion, including individualized plans for the use of restraints or seclusion in emergency situations; establish professional qualifications of and training for staff who may order or be engaged in the use of restraint or seclusion; establish requirements for facility data collection and reporting relating to the use of restraint and seclusion; and establish procedures relating to the documentation of the use of restraint or seclusion in the client's facility or program record.

(3) If ~~The agency shall adopt rules to provide that, when~~ the criteria established under this part and part II of chapter 408 are not met, such deficiencies shall be classified according to the nature of the deficiency. The agency shall indicate the classification on the face of the notice of deficiencies as follows:

(a) Class I deficiencies are those which the agency determines present an imminent danger to ~~the~~ residents or guests of the facility or a substantial probability that death or

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serious physical harm will ~~would~~ result therefrom. The condition or practice constituting a class I violation must be abated or eliminated immediately, unless the agency determines that a fixed period of time~~, as determined by the agency,~~ is required for correction. A class I deficiency is subject to a civil penalty in an amount of at least ~~not less than~~ $5,000 but not more than ~~and not exceeding~~ $10,000 for each deficiency. A fine may be levied notwithstanding the correction of the deficiency.

(b) Class II deficiencies are those which the agency determines have a direct or immediate relationship to the health, safety, or security of ~~the~~ facility residents but do not meet the criteria established for~~, other than~~ class I deficiencies. A class II deficiency is subject to a civil penalty in an amount of at least ~~not less than~~ $1,000 and not more than ~~not exceeding~~ $5,000 for each deficiency. A citation for a class II deficiency must ~~shall~~ specify the time within which the deficiency must be corrected. If a class II deficiency is corrected within the time specified, a ~~no~~ civil penalty may not ~~shall~~ be imposed, unless it is a repeated offense.

(c) Class III deficiencies are those which the agency determines to have an indirect or potential relationship to the health, safety, or security of ~~the~~ facility residents but do not meet the criteria for~~, other than~~ class I or class II deficiencies. A class III deficiency is subject to a civil penalty of at least ~~not less than~~ $500 and not more than ~~exceeding~~ $1,000 for each deficiency. A citation for a class III deficiency must ~~shall~~ specify the time within which the deficiency must be corrected. If a class III deficiency is corrected within the time specified, a ~~no~~ civil penalty may not

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~~shall~~ be imposed, unless it is a repeated offense.

Section 16. Subsection (2) of section 400.980, Florida Statutes, is amended to read:

400.980 Health care services pools.—

(2) The requirements of part II of chapter 408 apply to the provision of services that require licensure or registration pursuant to this part and part II of chapter 408 and to entities registered by or applying for such registration from the agency pursuant to this part. Registration or a license issued by the agency is required for the operation of a health care services pool in this state. In accordance with s. 408.805, an applicant or licensee shall pay a fee for each license application submitted using this part, part II of chapter 408, and applicable rules. The agency shall ~~adopt rules and~~ provide forms required for such registration and shall impose a registration fee in an amount sufficient to cover the cost of administering this part and part II of chapter 408. In addition to the requirements in part II of chapter 408, the registrant must provide the agency with any change of information contained on the original registration application within 14 days before ~~prior to~~ the change.

Section 17. Subsection (43) of section 409.912, Florida Statutes, is amended to read:

409.912 Cost-effective purchasing of health care.—The agency shall purchase goods and services for Medicaid recipients in the most cost-effective manner consistent with the delivery of quality medical care. To ensure that medical services are effectively utilized, the agency may, in any case, require a confirmation or second physician's opinion of the correct

diagnosis for purposes of authorizing future services under the Medicaid program. This section does not restrict access to emergency services or poststabilization care services as defined in 42 C.F.R. part 438.114. Such confirmation or second opinion shall be rendered in a manner approved by the agency. The agency shall maximize the use of prepaid per capita and prepaid aggregate fixed-sum basis services when appropriate and other alternative service delivery and reimbursement methodologies, including competitive bidding pursuant to s. 287.057, designed to facilitate the cost-effective purchase of a case-managed continuum of care. The agency shall also require providers to minimize the exposure of recipients to the need for acute inpatient, custodial, and other institutional care and the inappropriate or unnecessary use of high-cost services. The agency shall contract with a vendor to monitor and evaluate the clinical practice patterns of providers in order to identify trends that are outside the normal practice patterns of a provider's professional peers or the national guidelines of a provider's professional association. The vendor must be able to provide information and counseling to a provider whose practice patterns are outside the norms, in consultation with the agency, to improve patient care and reduce inappropriate utilization. The agency may mandate prior authorization, drug therapy management, or disease management participation for certain populations of Medicaid beneficiaries, certain drug classes, or particular drugs to prevent fraud, abuse, overuse, and possible dangerous drug interactions. The Pharmaceutical and Therapeutics Committee shall make recommendations to the agency on drugs for which prior authorization is required. The agency shall inform

the Pharmaceutical and Therapeutics Committee of its decisions regarding drugs subject to prior authorization. The agency is authorized to limit the entities it contracts with or enrolls as Medicaid providers by developing a provider network through provider credentialing. The agency may competitively bid single-source-provider contracts if procurement of goods or services results in demonstrated cost savings to the state without limiting access to care. The agency may limit its network based on the assessment of beneficiary access to care, provider availability, provider quality standards, time and distance standards for access to care, the cultural competence of the provider network, demographic characteristics of Medicaid beneficiaries, practice and provider-to-beneficiary standards, appointment wait times, beneficiary use of services, provider turnover, provider profiling, provider licensure history, previous program integrity investigations and findings, peer review, provider Medicaid policy and billing compliance records, clinical and medical record audits, and other factors. Providers are not entitled to enrollment in the Medicaid provider network. The agency shall determine instances in which allowing Medicaid beneficiaries to purchase durable medical equipment and other goods is less expensive to the Medicaid program than long-term rental of the equipment or goods. The agency may establish rules to facilitate purchases in lieu of long-term rentals in order to protect against fraud and abuse in the Medicaid program as defined in s. 409.913. The agency may seek federal waivers necessary to administer these policies.

(43) Subject to the availability of funds, the agency shall mandate a recipient's participation in a provider lock-in

program, when appropriate, if a recipient is found by the agency to have used Medicaid goods or services at a frequency or amount not medically necessary, limiting the receipt of goods or services to medically necessary providers after the 21-day appeal process has ended, for at least ~~a period of not less than~~ 1 year. The lock-in programs must ~~shall~~ include, but are not limited to, pharmacies, medical doctors, and infusion clinics. The limitation does not apply to emergency services and care provided to the recipient in a hospital emergency department. The agency shall seek any federal waivers necessary to implement this subsection. ~~The agency shall adopt any rules necessary to comply with or administer this subsection.~~ This subsection expires October 1, 2014.

Section 18. Subsection (4) of section 429.255, Florida Statutes, is amended to read:

429.255 Use of personnel; emergency care.—

(4) Facility staff may withhold or withdraw cardiopulmonary resuscitation or the use of an automated external defibrillator if presented with an order not to resuscitate executed pursuant to s. 401.45. ~~The department shall adopt rules providing for the implementation of such orders.~~ Facility staff and facilities are ~~shall~~ not ~~be~~ subject to criminal prosecution or civil liability, nor ~~be~~ considered to have engaged in negligent or unprofessional conduct, for withholding or withdrawing cardiopulmonary resuscitation or use of an automated external defibrillator pursuant to such an order ~~and rules adopted by the department~~. The absence of an order to resuscitate executed pursuant to s. 401.45 does not preclude a physician from withholding or withdrawing cardiopulmonary resuscitation or use of an automated

external defibrillator as otherwise permitted by law.

Section 19. Subsection (3) of section 429.73, Florida Statutes, is amended to read:

429.73 Rules and standards relating to adult family-care homes.—

(3) ~~The department shall adopt rules providing for the implementation of orders not to resuscitate.~~ The provider may withhold or withdraw cardiopulmonary resuscitation if presented with an order not to resuscitate executed pursuant to s. 401.45. The provider is ~~shall~~ not ~~be~~ subject to criminal prosecution or civil liability, nor ~~be~~ considered to have engaged in negligent or unprofessional conduct, for withholding or withdrawing cardiopulmonary resuscitation pursuant to such an order ~~and applicable rules~~.

Section 20. Subsection (10) of section 440.102, Florida Statutes, is amended to read:

440.102 Drug-free workplace program requirements.—The following provisions apply to a drug-free workplace program implemented pursuant to law or to rules adopted by the Agency for Health Care Administration:

(10) RULES.—~~The Agency for Health Care Administration shall adopt rules~~ Pursuant to s. 112.0455, part II of chapter 408, and criteria established by the United States Department of Health and Human Services, the agency shall adopt ~~as~~ general guidelines for modeling drug-free workplace laboratories, including ~~concerning~~, but not limited to:

(a) Standards for licensing drug-testing laboratories and suspension and revocation of such licenses.

(b) Urine, hair, blood, and other body specimens and

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

minimum specimen amounts that are appropriate for drug testing.

(c) Methods of analysis and procedures to ensure reliable drug-testing results, including standards for initial tests and confirmation tests.

(d) Minimum cutoff detection levels for each drug or metabolites of such drug for the purposes of determining a positive test result.

(e) Chain-of-custody procedures to ensure proper identification, labeling, and handling of specimens tested.

(f) Retention, storage, and transportation procedures to ensure reliable results on confirmation tests and retests.

Section 21. Subsection (2) of section 483.245, Florida Statutes, is amended to read:

483.245 Rebates prohibited; penalties.—

(2) The agency may establish and ~~shall adopt rules that~~ assess administrative penalties for acts prohibited by subsection (1). If ~~In the case of~~ an entity is licensed by the agency, such penalties may include any disciplinary action available to the agency under the appropriate licensing laws. If ~~In the case of~~ an entity is not licensed by the agency, such penalties may include:

(a) A fine not to exceed $1,000;

(b) If applicable, a recommendation by the agency to the appropriate licensing board that disciplinary action be taken.

Section 22. Subsection (2) of section 765.541, Florida Statutes, is amended to read:

765.541 Certification of procurement organizations; agency responsibilities.—The agency shall:

(2) Adopt rules as necessary to administer ~~that set forth~~

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

~~appropriate standards and guidelines for the program in accordance with~~ ss. 765.541-765.546 and part II of chapter 408.

(a) ~~These~~ Standards and guidelines for the program adopted by the agency must be substantially based on the ~~existing~~ laws of the Federal Government and this state, and the ~~existing~~ standards and guidelines of the United Network for Organ Sharing (UNOS), the American Association of Tissue Banks (AATB), the South-Eastern Organ Procurement Foundation (SEOPF), the North American Transplant Coordinators Organization (NATCO), and the Eye Bank Association of America (EBAA) which were in effect as of January 1, 2014.

(b) ~~In addition, the agency shall,~~ Before adopting ~~these~~ standards and guidelines for the program, the agency shall seek input from all procurement organizations based in this state.

Section 23. Subsection (2) of section 765.544, Florida Statutes, is amended to read:

765.544 Fees; organ and tissue donor education and procurement.—

~~(2) The agency shall specify by rule the administrative penalties for the purpose of ensuring adherence to the standards of quality and practice required by this chapter, part II of chapter 408, and applicable rules of the agency for continued certification.~~

Section 24. This act shall take effect July 1, 2014.

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Health Policy

BILL:	CS/SB 836
INTRODUCER:	Regulated Industries Committee and Senator Bean
SUBJECT:	Medical Gas
DATE:	March 21, 2014
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Niles	Imhof	RI	**Fav/CS**
2.	Looke	Stovall	HP	**Pre-meeting**

Please see Section IX. for Additional Information:

PLEASE MAKE SELECTION

I. Summary:

CS/SB 836 removes the regulation of medical gas from Part I of the "Florida Drug and Cosmetic Act" and creates a new Part III of ch. 499, F.S., consisting of ss. 499.81 - 499.95, F.S., entitled "Medical gas."

The bill provides permit application procedures and permit requirements for medical gas wholesale distributors, medical gas manufacturers, and medical oxygen retail establishments. The bill grants the Department of Business and Professional Regulation (department) the authority to adopt rules related to the form and content of a permit application. The department is also granted authority to deny applications and revoke or refuse to renew permits.

The bill requires specific storage and security procedures related to medical gas. The bill requires wholesale distributors of medical gas to examine medical gas containers, act in due diligence, establish and maintain records regarding receipt and distribution of medical gas, and to establish specific policies and procedures to deal with normal business activity as well as emergency and theft situations. The bill also lays out prohibited and criminal acts in relation to medical gas and enforcement regarding these acts and this part.

II. Present Situation:

Currently, ch. 499, F.S., consists of two parts that cover drug, cosmetic, and household products and ether. Medical gas is covered in the first part under drug, cosmetic and household products of the "Florida Drug and Cosmetic Act" found in ss. 499.001 - 499.079, F.S.

Definitions

Section 499.003(11), F.S., defines "compressed medical gas" as any liquefied or vaporized gas that is a prescription drug, whether it is alone or in combination with other gases.

Section 499.003(46), F.S., defines "prescription medical oxygen" as oxygen USP[1] which is a drug that can only be sold by the order or prescription of a practitioner authorized by law to prescribe. The label of prescription medical oxygen must comply with current labeling requirements for oxygen under the Federal Food, Drug, and Cosmetic Act.

Section 499.003(55), F.S., defines a "wholesale distributor" as any person 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 409.9201(1), F.S., describes medical fraud with s. 409.9201(1)(a), F.S., defining "prescription drug" as any drug, including, but not limited to, finished dosage forms or active ingredients that are subject to, defined by, or described in the Federal Food, Drug, and Cosmetic Act or by s. 465.003(8), s. 499.003(46) or (53) or s. 499.007(13), F.S.

Permits

Section 499.01, F.S., lists the entities that require permits under the Florida Drug and Cosmetics Act and describes them in detail. These permitted entities include medical oxygen retail establishments, compressed medical gas wholesale distributors, and compressed medical gas manufacturers, among others.

A compressed medical gas wholesale distributor is limited to the wholesale distribution of compressed medical gases to other than the consumer or patient.[2] A compressed medical gas manufacturer permit is required for any person that engages in the manufacture of compressed medical gases or repackages compressed medical gases from one container to another.[3] A medical gas retail establishment permit is required for any person who sells medical oxygen to patients only.[4] Permit holders are overseen by the department under the Division of Drugs, Devices and Cosmetics.

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[1] The United States Pharmacopoeia (USP) is a list of drugs licensed for use in the U.S. with standards necessary to determine purity suitable for persons.
[2]Florida Department of Business and Professional Regulation, Compressed Medical Gas Wholesale Distributor, *available at* www.myfloridalicense.com/dbpr/ddc/CompressedMedicalGasesWholesaleDistributor.html (Last visited March 21, 2014).
[3] Florida Department of Business and Professional Regulation, Compressed Medical Gas Manufacturer, available at www.myfloridalicense.com/dbpr/ddc/CompressedMedicalGasesManufacturer.html (Last visited March 21, 2014).
[4] Florida Department of Business and Professional Regulation, Medical Oxygen Retail Establishment, available at http://www.myfloridalicense.com/dbpr/ddc/MedicalOxygenRetail.html (Last visited March 21, 2014).

Drug Wholesale Distributor Advisory Council

Section 499.01211, F.S., creates the Drug Wholesale Distributor Advisory Council (council). The council meets each calendar quarter to review Part I of ch. 499, F.S., and the rules adopted to administer that part, to annually provide input to the department, and to make recommendations to minimize the impact of regulation of the wholesale distribution industry while ensuring protection of the public health. The council consists of eleven members including the Secretary of Business and Professional Regulation, or his or her designee, and the Secretary of Health Care Administration, or her or his designee. The remaining nine members are appointed by the Secretary of Business and Professional Regulation to a term of four years each, as follows:

- Three different persons each of whom is employed by a different prescription drug wholesale distributor licensed under this part which operates nationally and is a primary wholesale distributor, as defined in s. 499.003(47), F.S.;
- One person employed by a prescription drug wholesale distributor licensed under this part which is a secondary wholesale distributor, as defined in s. 499.003(52), F.S.;
- One person employed by a retail pharmacy chain located in this state;
- One person who is a member of the Board of Pharmacy and is a pharmacist licensed under ch. 465, F.S.;
- One person who is a physician licensed under ch. 458, F.S., or ch. 459, F.S.;
- One person who is an employee of a hospital licensed under ch.395, F.S., and is a pharmacist licensed under ch.465, F.S.; and
- One person who is an employee of a pharmaceutical manufacturer.

Compressed Gas Association

The Compressed Gas Association (association) has been dedicated to the development and promotion of safety standards and safe practices in the industrial gas industry since 1913.[5] Their mission is to promote safe, secure, and environmentally responsible manufacture, transportation, storage, transfilling, and disposal of industrial and medical gases and their containers.[6] Their activities include the manufacture, transportation, storage, transfilling, and disposal of compressed gas and the containers and valves which hold the compressed gases. Their scope includes related apparatus if such apparatus is necessary for the safe dispensing or delivery of the gases in a commercial, industrial, research, or medical application along with providing safety information or warnings about the chemical or physical properties of gases and their containers.[7] The association defines industrial and medical gases as liquefied, nonliquefied, dissolved, or cryogenic gases.[8]

III. Effect of Proposed Changes:

The bill creates Part III of ch. 499, F.S., entitled "Medical Gas," ss. 499.81-499.95, F.S.

[5] Compressed Gas Association, About Us, *available at* http://www.cganet.com/about.php (Last visited March 4, 2014).
[6] Compressed Gas Association, CGA Mission, *available at* http://www.cganet.com/mission.php (last visited March 4, 2014).
[7] *Id.*
[8] *Id*.

Definitions

The bill deletes s. 499.003(11), F.S., defining "compressed medical gas," and s. 499.003(46), F.S., defining "prescription medical oxygen." The bill adds a new definition to s. 499.003(32), F.S., for "Medical gas" which is defined "in accordance with the federal act and means a liquefied or vaporized gas that is a prescription drug, regardless of whether it is alone or combined with other gases." The bill creates a new definitions section for Part III of ch. 499, F.S., that contains numerous definitions related to medical gas.[9] The bill deletes cross-references to the old sections and adds the new section throughout the bill where necessary.

Permits

The bill deletes medical oxygen retail establishment, compressed medical gas wholesale distributor, and compressed medical gas manufacturer as entities requiring permits under s. 499.01(1), F.S. The bill creates s. 499.82, F.S., providing for permits associated with medical gas. A person or establishment intending to distribute medical gas within or into this state must obtain the applicable permit before operating. The following are authorized to receive medical gas:

- Permitted medical gas manufacturers or permitted wholesale distributors;
- Licensed pharmacies or health care entities;
- People authorized to receive emergency use oxygen without a prescription;
- Locations with automated external defibrillation machines where emergency use oxygen is intended to be used with such machines; or
- Companies that need medical gas in the installation and refurbishment of piping and equipment used to contain or administer medical gas.

The bill establishes requirements for wholesale distributors. Wholesale distributors may not operate from a residence, except delivery by home respiratory care technicians. Each location must be permitted. Out-of-state wholesale distributors must be legally authorized as a wholesale distributor in their state of residence or incorporation to provide services in Florida.

The bill establishes three types of permits, a medical gas wholesale distributor permit, a medical gas manufacturer permit, and a medical oxygen retail establishment permit.

A *medical gas wholesale distributor permit* is required for wholesale distribution within or into Florida. The permit:

- Does not authorize distribution to a consumer or patient;
- Requires medical gas be in the same container as obtained with no further manufacturing operations performed; and
- Prohibits distributor to possess or engage in the wholesale distribution of other prescription drugs.

[9] Section 499.81, F.S., defines the terms "adulterated", "department", "distribute" or "distribution", "emergency use oxygen", "FDA", "federal act", "health care entity", "immediate container", "intracompany transaction", "label", "manufacturer", "medical gas", "medical gas-related equipment", "misbranded", "prescription medical oxygen, "USP-NF" or "USP", "wholesale distribution", and "wholesale distributor". Some of the definitions duplicate those in s. 499.003, F.S.

A *medical gas manufacturer permit* is required for a person manufacturing[10] medical gas and distributing such medical gas within or into this state. A medical gas manufacturer:

- May not manufacture or possess another prescription drug without obtaining the appropriate permit;
- May engage in the wholesale distribution of medical gas manufactured at permitted establishment if complying with this part and applicable rules; and
- Must comply with all appropriate good manufacturing practices.

A *medical oxygen retail establishment permit* is required for a person, except a pharmacy under chapter 465, F.S., who sells prescription medical oxygen directly to patients. Sales must be based upon an order or prescription. A medical oxygen retail establishment:

- May not possess, purchase, sell, or trade a prescription drug other than medical oxygen without obtaining other appropriate permits;
- May not receive back into its inventory any prescription medical oxygen sold pursuant to a licensed practitioner's order;
- May refill a prescription medical oxygen container for a patient based on an authorized order or prescription, and shall comply with all appropriate good manufacturing practices if doing so; and
- Must comply with storage and handling requirements under s. 499.84, F.S.

The bill creates s. 499.821, F.S., granting the department the authority to adopt rules relating to permit applications and describing the application requirements for permits listed in s. 499.82, F.S. The fee for permits are removed from s. 499.041, F.S., and added to s. 499.821(4), F.S. Section 499.822, F.S., provides for permits to expire after two years, provides renewal procedures, and authorizes the department to adopt rules and a reasonable fee for renewal. Section 499.821, F.S., sets annual fees of between $200 and $300 for medical gas wholesale distributors and medical oxygen retail establishments and annual fees of between $400 and $500 for medical gas manufacturers.

The bill creates s. 499.823, F.S., granting the department the authority to deny a permit or renewal application based on relevant factors including the applicant's past experience, previous noncompliance, criminal background, and other qualifications that the department considers relevant to and consistent with public health and safety.

The bill creates s. 499.824, F.S., restricting permit use to the person or entity granted but allowing specific changes to be made by the approval of the department. A change of location may be made with 30 days prior notification and payment of a change-of-location fee not to exceed $100. Change of ownership requires a new permit application 30 days prior to the transfer of the majority of the ownership, controlling interest, or legal liability. If the new-owner-applicant is already a permit holder, the application is not required until the date of the transfer, sale, assignment or lease and this applicant may distribute under the permit number of the previous owner from the date of transfer until the date of application approval. A change of name does not require a new permit, but does require the permit holder to notify the department 30

[10]Manufacturing can be done by physical air separation, chemical action, purification, or filling containers using a liquid-to-liquid, liquid-to-gas, or gas-to-gas process.

days prior to the change. Closure of the business requires a permit holder to notify the department and indicate how the inventory will be dispersed.

Any change in information, other than relating to location, ownership, name, or closure, must be submitted to the department within 30 days of such change. A permit holder in good standing may apply to change the type of permit held and will be required to pay the difference in fees. The department may revoke a permit for noncompliance with these requirements.

Medical Gas Storage and Security Measures

The bill creates s. 499.84, F.S., setting out the minimum requirements for storage and handling of medical gas and mandating that medical gas be stored in accordance to manufacturers' recommendations, or in their absence, according to applicable industry standards. Medical gas must be packaged in accordance with official compendium standards such as the United States Pharmacopeia and The National Formulary (USP-NF).[11]

The bill creates s. 499.85, F.S., requiring security measures for wholesale distribution facilities and vehicles used for delivering oxygen-related equipment. Under this section, the department is granted the authority to adopt rules governing wholesale distribution of prescription medical oxygen for emergency use by persons authorized to receive emergency use oxygen so long as the rules are consistent with federal rules, unless state law specifically directs otherwise.

Wholesale Distributor Requirements

The bill creates s. 499.86, F.S., that requires examination of medical gas containers by wholesale distributors and review of records documenting the acquisition of the medical gas. The bill also creates s. 499.87, F.S., that provides procedures to handle defective gas or containers, and requires damaged, misbranded or adulterated medical gas to be quarantined until returned to the manufacturer or wholesale distributor, or until it is destroyed. If medical gas is adulterated or misbranded, or suspected as such, notice shall be provided to the manufacturer or wholesale distributor from which the medical gas was acquired and to the appropriate boards and federal regulatory bodies.

The bill creates s. 499.88, F.S., to require wholesale distributors to act with due diligence, obtaining appropriate documentation of registration from the wholesale distributor or manufacturer before an initial acquisition of medical gas from that distributor or manufacturer, except from a manufacturer that is registered with the FDA and proof of the registration is provided along with proof of inspection within the last three years or proof of compliance with industry standards or guidelines as identified by the department.

The bill creates s. 499.89, F.S., that requires wholesale distributors to establish and maintain a record of transactions regarding the receipt and distribution, or other disposition, of medical gases, and the information to be included. These records constitute an audit trail and must contain information sufficient to perform a recall of medical gas in compliance with 21 C.F.R.

[11] The USP–NF is a book of public pharmacopeial standards. See U.S. Pharmacopial Convention, USP-NF, *available at* http://www.usp.org/usp-nf (Last visited March 21, 2014).

s. 211.196 and 21 C.F.R. s. 820.160(b). A pedigree paper is not required for the wholesale distribution of medical gas.

The bill creates s. 499.90, F.S., that requires wholesale distributors to establish, maintain, and adhere to written policies and procedures for the receipt, security, storage, transport, shipping, and wholesale distribution of medical gas and for maintaining inventory and correcting all errors in inventory associated with nitrous oxide. Procedures are required for handling recalls and withdrawals, preparing for and avoiding crisis, and reporting criminal activity involving nitrous oxide.

Prohibited and Criminal Acts

The bill creates s. 499.91, F.S., that prohibits a person from performing or aiding the performance of the following:

- Manufacture, sale, or delivery, or the holding or offering for sale, of medical gas that is adulterated, misbranded, or has otherwise been rendered unfit for distribution;
- Adulterating or misbranding of medical gas;
- The receipt of adulterated or fraudulently obtained medical gas;
- Altering, mutilating, destroying, obliterating, or removing the whole or any part of the product labeling of medical gas or the willful commission of any other act of misbranding;
- Purchasing or receiving medical gas from a person who is not authorized by permit to distribute wholesale medical gas or who is exempted from permitting requirements to distribute wholesale medical gas to such purchaser or recipient;
- Knowing and willful sale or transfer of medical gas to a recipient who is not legally authorized to receive medical gas, except for limited distributions as necessary to protect the health, safety, or welfare of a patient in his or her home;
- Failing to maintain or provide records required under this part;
- Providing the department or any of its representatives or any state or federal official with false or fraudulent records or making false or fraudulent statements regarding this part and its implementing regulations;
- Wholesale distribution of medical gas that was purchased by a health care entity without an authorized recipient, donated or supplied at a reduced price to a charitable organization, or stolen or obtained by fraud or deceit;
- Operating without a valid permit;
- Obtaining of medical gas by fraud, deceit, or misrepresentation or engaging in misrepresentation or fraud in the distribution of medical gas;
- Except for oxygen USP in emergency situations, the distribution of medical gas to a patient without an order or prescription from a licensed practitioner authorized by law to prescribe;
- Distributing medical gas that was previously dispensed by a pharmacy or a licensed practitioner authorized by law to prescribe;
- Distributing medical gas or medical gas-related equipment to a patient, unless the patient has been provided with the appropriate information and counseling on the use, storage, and disposal of medical gas;
- Failing to report an act prohibited under this part and its implementing regulations; and,
- Failing to exercise due diligence as provided in s. 499.88, F.S.

The bill creates s. 499.92, F.S., that provides that a person commits a felony in the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, F.S., if he or she:

- With intent to defraud or deceive adulterates or misbrands medical gas;
- Engages in the wholesale distribution of, and knowingly purchases or receives, medical gas from a person not legally authorized to distribute medical gas;
- Engages in the wholesale distribution of, and knowingly sells, barters, brokers, or transfers, medical gas to a person not legally authorized to purchase medical gas in the jurisdiction in which the person receives the medical gas. However a violation is not committed by a distributor that provides oxygen to a permitted medical oxygen retail establishment if the distributor is out of compliance with only the change of location notice requirement.
- Knowingly, falsely creates a label for medical gas or knowingly, falsely represents a factual matter contained in a label for medical gas.

A court with authority over a person that convicts a person who violates this section shall order that person to forfeit to the state real or personal property used or intended to be used to commit such a violation and that is constituting, derived from, or traceable to the gross proceeds gained as a result of the violation. Moneys or proceeds from the sale of assets ordered to be forfeited shall be equitably divided between the department and agencies involved in the investigation and prosecution that led to the conviction. Other property ordered to be forfeited after conviction of a defendant may, at the discretion of the investigating agencies, be placed into official use by the department or the agencies involved in the investigation and prosecution.

Drug Wholesale Distributor Advisory Council

The bill adds an additional position on the council, now twelve members, appointed by the *Compressed Gas Association* who is an employee of a permitted medical gas wholesale distributor or manufacturer.

Inspections

The bill creates s. 499.93, F.S., that allows the department to require a facility engaged in the manufacturing, retail sale, or wholesale distribution of medical gas to undergo an inspection, and the department may recognize other state inspections if that state's laws are determined to be substantially equivalent with this state's laws. A manufacturing facility registered with the FDA and verified as such and providing proof of an inspection within the past three years is exempt from inspection.

The bill requires a wholesale distributor to have readily available its state permits and its most recent inspection report administered by the department.

The bill allows the department to authorize a third party to inspect wholesale distributors who distribute within or into this state.

The bill requires the department to ensure that information identified as a trade secret, as defined in s. 812.081, F.S., is maintained and remains confidential as required under s. 499.015, F.S., while it is retained by the department.

Enforcement

The bill allows the department to collect evidence and testimony for the purposes of initiating an investigation or proceeding under this part. A state, county, or municipal attorney shall timely institute proceedings and prosecute violations reported to them by the department or designated agent in a manner required by law.

The bill provides that the provisions of part III are cumulative and do not repeal or affect the power, duty, or authority of the department, but establishes that part III controls where it conflicts with other law.

Sections 22-38 of the bill conform those sections to changes made in the bill

Section 31 establishes an effective date of October 1, 2014.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

This bill may have an indeterminate fiscal impact on private sector entities who are affected by the regulations implemented by the bill.

C. Government Sector Impact:

Expenses associated with the additional Drug Wholesale Distributor Advisory Council member are indeterminate but are expected to be minimal and can be funded with existing resources.[12] The members of the council are not paid employees; they serve without compensation.[13] The Drugs, Devices and Cosmetics Division under the

[12] *2014 Legislative Bill Analysis for SB 836*, Department of Business and Professional Regulation (Mar. 21, 2014).
[13] *Id.*

department is responsible for expenses associated with the logistics of the council meetings.[14]

The bill provides that fees collected under part III are to be used to administer "this part," which seems to limit the fees and monies collected to use for administering only part III. This may require separate accounting and recordkeeping to be set up by the department's fiscal unit. It is unclear at this time what the estimated fees and costs associated with medical gas regulation would be, and this is a change from the way the division currently operates.[15]

VI. Technical Deficiencies:

The bill allows the Compressed Gas Association to appoint a person to the Drug Wholesale Distributor Advisory Council. Currently, the Secretary makes the appointments of these members, with the exception of the Agency for Health Care Administration's representative.[16]

VII. Related Issues:

The bill sets forth a list of entities authorized to receive medical gas, but does not clearly indicate if these entities must reside in Florida. The presumption is that they must reside in Florida, but the wording could be interpreted as otherwise.[17]

The definition of "adulteration" in the bill does not include transfer or possession by an unauthorized source.[18] Generally under the current law, if an unauthorized person holds, transfers, purchases, or sells a prescription drug, that drug becomes adulterated.[19] Currently, if medical oxygen is delivered to a patient who does not have a current, valid prescription for medical oxygen, then the medical oxygen could be deemed adulterated and thus unfit for consumption.[20] The bill may reduce the incentive of providers to verify current prescriptions before making deliveries.[21]

The bill provides that "people authorized to receive emergency use oxygen without a prescription" are legally authorized to receive medical gas. One interpretation of that passage might allow anyone authorized to receive emergency use oxygen without a prescription to receive any medical gas.[22]

The bill removes any requirement to show the transaction history in one document. This may make it more difficult to review an audit trail, especially in cases of product recalls.[23]

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[14] *Id.*
[15] *Id.*
[16] *Id.*, also *see* s. 20.052(5)(a), F.S., requiring private citizen members of an advisory board that is adjunct to an agency be appointed by the governor, the head of the department, the executive director of the department, or a cabinet officer.
[17] *Id.*
[18] *Id.*
[19] *Id.*
[20] *Id.*
[21] *Id.*
[22] *2014 Legislative Bill Analysis for SB 836*, Department of Business and Professional Regulation (Mar. 21, 2014).
[23] *Id.*

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 499.001, 499.003, 409.9201, 460.403, 465.0265, 499.01, 499.0121, 499.01211, 499.01212, 499.015, 499.024, 499.041, 499.05, 499.051, 499.066, 499.0661, and 499.067.

This bill creates the following sections of the Florida Statutes: 499.81, 499.95, 499.82, 499.821, 499.822, 499.823, 499.824, 499.83, 499.84, 499.85, 499.86, 499.87, 499.88, 499.89, 499.90, 499.91, 499.92, 499.93, and 499.94.

IX. Additional Information:

A. Committee Substitute – Statement of Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Regulated Industries Committee on March 6, 2014:
The CS adds that a permit holder under this section must notify the department 30 days prior to change in location, ownership, or name. The CS also adds a requirement that such permit holder notify the department within 30 days of change in information required under this part but not falling within one of those categories or closure.

The CS adds an exception under criminal acts, excluding as a violation a distributor providing oxygen to a permitted medical oxygen retail establishment if the distributor is out of compliance with only the change of location notice requirement.

The CS adds a facility that engages in the retail sale of medical gas to the list of facilities that the department may require to undergo an inspection.

The CS removes the trade secret provisions created s. 499.93(5), F.S. The bill creates section 499.931, F.S., which requires the department to maintain trade secrets as provided in s. 499.051, F.S.[24]

B. Amendments:

None.

This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.

[24] Section 499.051, F.S., provides that trade secrets must be confidential and exempt from disclosure under ch. 119, F.S., and s. 24(a), Art. I, Florida Constitution. The department is allowed to use this information for regulatory and enforcement proceedings and to provide the information to law enforcement and regulatory agencies.

By the Committee on Regulated Industries; and Senator Bean

580-02206-14 2014836c1

A bill to be entitled

An act relating to medical gas; creating part III of ch. 499, F.S., entitled "Medical Gas"; creating s. 499.81, F.S.; defining terms; creating s. 499.82, F.S.; requiring a person or establishment located inside or outside the state which intends to distribute medical gas within or into this state to obtain an applicable permit before operating; listing the people or entities that are legally authorized to receive medical gas; establishing categories of permits and setting requirements for each; creating s. 499.821, F.S.; requiring the Department of Business and Professional Regulation to establish the form and content of an application; stating that an applicant who is denied a permit has a right of review pursuant to ch. 120, F.S.; authorizing the department to set fees within certain parameters; creating s. 499.822, F.S.; requiring a permit to expire 2 years after the last day of the month in which the permit was issued; providing requirements for the renewal of a permit; requiring the department to adopt rules for the renewal of permits; creating s. 499.823, F.S.; authorizing the department to consider certain factors in determining the eligibility of an applicant; creating s. 499.824, F.S.; authorizing the department to approve certain permitholder changes; authorizing the department to revoke the permit of a person that fails to comply with this section; creating s. 499.83, F.S.; requiring an applicant for or a holder of a

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permit as a wholesale distributor of medical gas or as a medical oxygen retailer to designate a registered agent; creating s. 499.84, F.S.; setting the minimum requirements for the storage and handling of medical gas; creating s. 499.85, F.S.; requiring a wholesale distributor of medical gas to implement measures to secure the location from unauthorized entry; setting facility requirements for security purposes; authorizing a vehicle used for on-call delivery of oxygen USP and oxygen-related equipment to be parked at a place of residence; requiring the department to adopt rules governing the wholesale distribution of prescription medical oxygen; creating s. 499.86, F.S.; requiring a wholesale distributor of medical gases to visually examine an immediate container upon receipt for identity and to determine if the medical gas container has been damaged or is otherwise unfit for distribution; requiring a medical gas container that is damaged or otherwise unfit for distribution to be quarantined; requiring outgoing shipments to be inspected; requiring wholesale distributors to review certain records; creating s. 499.87, F.S.; authorizing the return of medical gas that has left the control of the wholesale distributor; requiring that medical gas that is damaged, misbranded, or adulterated be quarantined from other medical gases until it is destroyed or returned to the manufacturer or wholesale distributor from which it was acquired; creating s. 499.88, F.S.; requiring a wholesale distributor to

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obtain certain information before the initial acquisition of the medical gas; providing certain exemptions; creating s. 499.89, F.S.; requiring a wholesale distributor to establish and maintain transactional records; providing a retention period for certain records and requiring that the records be available for inspection during that period; creating s. 499.90, F.S.; requiring a wholesale distributor to establish, maintain, and adhere to certain written policies and procedures; creating s. 499.91, F.S.; prohibiting certain acts; creating s. 499.92, F.S.; establishing criminal penalties; authorizing property or assets subject to forfeiture to be seized pursuant to a warrant; creating s. 499.93, F.S.; authorizing the department to require a facility that engages in wholesale distribution to undergo an inspection; authorizing the department to authorize a third party to inspect wholesale distributors; creating s. 499.931, F.S.; providing that trade secret information required to submitted pursuant to this part must be maintained by the department; creating s. 499.94, F.S.; requiring fees collected pursuant to this part to be deposited into the Professional Regulation Trust Fund; creating s. 499.95, F.S.; authorizing the department for the purpose of initiating an investigation or proceeding under this part to administer oaths, take depositions, issue and serve subpoenas, and compel attendance of witnesses and the production of books, papers, documents or other

evidence; requiring an attorney to whom the department reports a violation of this part to timely institute proceedings in the court of competent jurisdiction; exempting minor violations from reporting requirements at the department's discretion; providing that this part is cumulative and does not repeal or affect the power, duty, or authority of the department; amending ss. 409.9201, 460.403, and 465.0265; conforming provisions to changes made by the act; amending s. 499.001, F.S.; conforming a provision to changes made by the act; amending s. 499.003, F.S.; conforming terminology, deleting a definition, and defining the term "medical gas"; amending ss. 499.01 and 499.0121, F.S.; conforming provisions to changes made by the act; amending s. 499.01211, F.S.; changing the membership of the Drug Wholesale Distributor Advisory Council; requiring the Compressed Gas Association to appoint one person to the council; amending ss. 499.01212, 499.015, 499.024, 499.041, 499.05, 499.051, 499.066, 499.0661, and 499.067, 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. Part III of chapter 499, Florida Statutes, consisting of ss. 499.81-499.95, Florida Statutes, is created and is entitled "Medical Gas."

Section 2. Section 499.81, Florida Statutes, is created to

read:

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

(1) "Adulterated" with respect to medical gas means medical gas that:

(a) Consists, in whole or in part, of impurities or deleterious substances that exceed normal specifications;

(b) Has been produced, prepared, packed, or held under conditions whereby the gas may have been contaminated, causing it to be rendered injurious to health; or was manufactured, processed, packed, or held using methods, facilities, or controls that do not conform to or are not operated or administered in conformity with current good manufacturing practices;

(c) Has a container interior that is composed, in whole or in part, of a poisonous or deleterious substance that may render the container contents injurious to health; or

(d) Has a strength that differs from, or that is of a quality or purity that fails to meet, the standards established in the USP-NF, if the gas is purported to be, or is represented as, medical gas as recognized in the USP-NF. Such a determination as to strength, quality, or purity must be made in accordance with the tests or methods of assay set forth in the USP-NF or a validated equivalent, or, in the absence or inadequacy of these tests or methods of assay, those prescribed under the authority of the federal act shall be used. However, a gas that is purported to be, or is represented as, medical gas as recognized in the USP-NF but that differs in strength, quality, or purity from the standards established in the USP-NF may not be deemed adulterated for purposes of this paragraph if

the difference is plainly stated on its label.

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

(3) "Distribute" or "distribution" means to sell or offer to sell, deliver or offer to deliver, broker, give away, or transfer medical gas, by passage of title or by physical movement. The term does not include:

(a) Dispensing or administering medical gas;

(b) Delivering or offering to deliver medical gas by a common carrier in its usual course of business; or

(c) A sales activity that takes place in an establishment that is owned or controlled by a person or business entity authorized to distribute medical gas within or into this state or staffed by persons employed by such person, if the location where the sales activity takes place does not physically store or transport medical gas.

(4) "Emergency use oxygen" means oxygen USP that is administered without a prescription for an emergency situation concerning oxygen deficiency or resuscitation and that is in a container labeled in accordance with FDA standards.

(5) "FDA" means the federal Food and Drug Administration.

(6) "Federal act" means the federal Food, Drug, and Cosmetic Act, 21 U.S.C. ss. 301 et seq.

(7) "Health care entity" means a person, including an organization business entity, which provides diagnostic, medical, surgical, or dental treatment or rehabilitative care. The term includes a home respiratory care provider or a person or entity authorized to administer emergency use oxygen, but does not include a retail pharmacy or wholesale distributor.

(8) "Immediate container" means a compressed gas cylinder or liquid container that contains medical gas. The term does not include a large-bulk liquid or high pressure container, such as a storage tank, vehicle-mounted vessel, trailer, or railcar.

(9) "Intracompany transaction" means a transaction between divisions, subsidiaries, parents, or affiliated or related companies under the common ownership and control of a single corporate entity.

(10) "Label" means a display of a written, printed, or graphic matter upon an immediate container. The term does not include the letters, numbers, or symbols stamped onto a container as required by the United States Department of Transportation.

(11) "Manufacturer" means a person or entity that manufactures medical gas in bulk or that transfers the gas or liquefied gas product from one container to another.

(12) "Medical gas" is defined in accordance with the federal act and means a liquefied or vaporized gas that is a prescription drug, regardless of whether it is alone or combined with other gases.

(13) "Medical gas-related equipment" means a device used as an accessory or component part to contain or control flow, delivery, or pressure during the administration of medical gas, such as liquid-oxygen base and portable units, pressure regulators, flow meters, and oxygen concentrators.

(14) "Misbranded" means medical gas that has a label that is false or misleading or a label that does not:

(a) Display the name and address of the manufacturer, packer, or distributor;

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(b) Provide an accurate statement of the quantity of active ingredients or show an accurate monograph for the medical gas; or

(c) In the case of mixtures of designated medical gases, identify the component percentages of each designated medical gas used to make the mixture.

(15) "Prescription medical oxygen" means oxygen USP, a drug that may be sold only by the order or prescription of a licensed practitioner authorized by law to prescribe.

(16) "USP-NF" or "USP" means the standards published in the official book, "The United States Pharmacopeia and the National Formulary."

(17) "Wholesale distribution" means the distribution of medical gas by a wholesale distributor of medical gas to a person other than a consumer or patient. The term does not include:

(a) The sale, purchase, or trade of a medical gas, an offer to sell, purchase, or trade a prescription drug or device, or the dispensing of medical gas pursuant to a prescription;

(b) The sale, purchase, or trade of a medical gas or an offer to sell, purchase, or trade medical gas for an emergency medical reason that includes, but is not limited to:

1. A transfer of a medical gas between wholesale distributors or between a wholesale distributor and a retail pharmacy or health care entity to alleviate a temporary shortage of medical gas resulting from a delay in or an interruption of a regular distribution schedule;

2. Sales to a licensed emergency medical service provider, such as an ambulance company, a firefighting organization, or a

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licensed practitioner authorized to prescribe medical gases;

3. Provision of minimal emergency supplies of medical gas to a nursing home for use in an emergency or during the hours of the day when necessary medical gas cannot be obtained; or

4. Transfers of medical gases to alleviate a temporary shortage between retail pharmacies;

(c) An intracompany transaction;

(d) The sale, purchase, or trade of medical gas or an offer to sell, purchase, or trade medical gas among hospitals, pharmacies, or other health care entities that are under common control;

(e) The sale, purchase, or trade of medical gas, or the offer to sell, purchase, or trade medical gas by a charitable organization that has been granted an exemption under s. 501(c)(3) of the Internal Revenue Code to a nonprofit affiliate of the organization, to the extent otherwise permitted by law;

(f) The purchase or other acquisition of medical gas by a hospital or other similar health care entity that is a member of a group purchasing organization, for the hospital's or the health care entity's own use, from the group purchasing organization or from another hospital or similar health care entity that is a member of such organization;

(g) The return of residual medical gas that may be reprocessed in accordance with the manufacturer's procedures or the return of recalled, expired, damaged, or otherwise nonsalable medical gas, when returned by a hospital, health care entity, pharmacy, or charitable institution to a wholesale distributor;

(h) An activity that is exempt from the definition of the

term "wholesale distribution" as provided in s. 499.003; or

(i) A transaction that is excluded from the definition of the term "wholesale distribution" under the federal act or regulations implemented under the federal act related to medical gas.

(18) "Wholesale distributor" means a person or entity engaged in the wholesale distribution of medical gas within or into this state, including, but not limited to, a manufacturer, an own-label distributor, a private-label distributor, a warehouse, including a manufacturers' and distributors' warehouse, and a wholesale medical gas warehouse.

Section 3. Section 499.82, Florida Statutes, is created to read:

499.82 Permits.—

(1) A person or establishment, located inside or outside the state, which intends to distribute medical gas within or into this state must obtain the applicable permit before operating.

(2) All of the following are legally authorized to receive medical gas: permitted medical gas manufacturers or permitted wholesale distributors, licensed pharmacies or health care entities, people authorized to receive emergency use oxygen without a prescription, locations with automated external defibrillation machines where emergency use oxygen is intended to be used with such machines, or companies that need medical gas in the installation and refurbishment of piping and equipment used to contain or administer medical gas.

(3) An applicant who is a natural person must be at least 18 years of age or an applicant must be managed, controlled, or

overseen, directly or indirectly, by a natural person who is at least 18 years of age.

(4) An out-of-state wholesale distributor that provides services in this state must be legally authorized as a wholesale distributor in the state in which it resides or is incorporated.

(5) A wholesale distributor may not operate from a place of residence, and a place of residence may not be granted a permit or operate under this part, except for the on-call delivery of home care oxygen by a home respiratory care technician.

(6) If wholesale distribution is conducted at more than one location within this state or more than one location distributing into this state, each location must be permitted by the department.

(7) The following permits are established:

(a) Medical gas wholesale distributor permit.—A medical gas wholesale distributor permit is required for wholesale distribution within or into this state.

1. Such permit does not authorize distribution to a consumer or patient.

2. The medical gas must be in the container that was obtained by that wholesale distributor without further manufacturing operations being performed.

3. A wholesale distributor may not possess or engage in the wholesale distribution of any prescription drug other than medical gas.

(b) Medical gas manufacturer permit.—A medical gas manufacturer permit is required for a person who engages in the manufacture of medical gas by physical air separation, chemical action, purification, or filling containers using a liquid-to-

liquid, liquid-to-gas, or gas-to-gas process and distributes such medical gas within or into this state. A medical gas manufacturer:

1. May not manufacture or possess a prescription drug other than medical gas unless the appropriate permit is obtained.

2. May engage in the wholesale distribution of medical gas that is manufactured at the permitted establishment without obtaining a medical gas wholesale distributor permit, but shall comply with this part and applicable rules.

3. Shall comply with all appropriate state and federal good manufacturing practices.

(c) Medical oxygen retail establishment permit.—A medical oxygen retail establishment permit is required for a person who sells prescription medical oxygen directly to patients. Such sales must be based upon an order or prescription from a licensed practitioner authorized by law to prescribe. A pharmacy licensed under chapter 465 is exempt from this paragraph. A medical oxygen retail establishment:

1. May not possess, purchase, sell, or trade a prescription drug other than medical oxygen unless other appropriate permits are obtained.

2. May refill a prescription medical oxygen container for a patient based on an order or prescription from a licensed practitioner authorized by law to prescribe. A medical oxygen retail establishment that refills prescription medical oxygen shall comply with all appropriate state and federal good manufacturing practices.

3. Shall comply with the storage and handling requirements under s. 499.84.

4. May not receive back into its inventory any prescription medical oxygen that it sold pursuant to a licensed practitioner's order.

Section 4. Section 499.821, Florida Statutes, is created to read:

499.821 Permit application.—

(1) The department shall establish by rule the form and content of an application to obtain a permit listed under s. 499.82.

(a) An application for a permit must be filed with the department and must include the following information:

1. The trade or business names, including fictitious names, currently and formerly used by the applicant, which may not be identical to a name used by an unrelated wholesale distributor authorized in this state to purchase medical gas.

2. The name or names of the owner and operator of the permittee, if not the same person or entity. The application must also include the following if the applicant is:

a. An individual: the applicant's business address and date of birth.

b. A sole proprietorship: the business address of the sole proprietor and the name and federal employer identification number of the business entity.

c. A partnership: the business address and date of birth of each partner and the name and federal employer identification number of the partnership.

d. A limited liability company: the business address and title of each company officer, the name and federal employer identification number of the limited liability company, and the

state of incorporation.

e. A corporation: the business address and title of each corporate officer and director; the name, state of incorporation, and federal employer identification number of the corporation; and the name and business address of any parent company.

3. A list of disciplinary actions pertinent to wholesale distributors of prescription drugs or controlled substances by a state or federal agency against the applicant seeking to distribute into this state and against a principal, owner, director, or officer.

4. An address and description of each facility or warehouse, including a description of the security system for any location used for medical gas storage or wholesale distribution.

(b) The applicant shall attest in writing that the information contained in the application is complete and accurate, that the applicant has not been convicted of or disciplined for a criminal or prohibited act, and that the application contains complete disclosure of any past criminal convictions or violations of state or federal law relating to medical gases.

(2) An applicant that is denied a permit has the right to review of the department's decision pursuant to chapter 120.

(3) An applicant must submit a reasonable fee, to be determined by the department, in order to obtain a permit. The fee for a medical gas wholesale distributor permit may not be less than $200 or more than $300 annually. The fee for a medical gas manufacturer permit may not be less than $400 or more than

$500 annually. The fee for a medical oxygen retail establishment permit may not be less than $200 or more than $300 annually.

Section 5. Section 499.822, Florida Statutes, is created to read:

499.822 Expiration and renewal of a permit.—

(1) A permit issued under this part automatically expires 2 years after the last day of the month in which the permit was originally issued unless the permit is suspended or revoked before the automatic expiration date.

(2) A permit issued under this part may be renewed by submitting an application for renewal on a form furnished by the department and paying the appropriate fee. The application for renewal must contain a statement by the applicant attesting that the information is true and correct. If a renewal application and renewal 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, within 60 days after the expiration date.

(3) Failure to renew a permit in accordance with this section precludes future renewal. If a permit has expired and cannot be renewed, the person or 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 before engaging in an activity that requires a permit under this part.

(4) The department shall adopt rules to administer this section, including setting a reasonable fee for a renewal application.

Section 6. Section 499.823, Florida Statutes, is created to

read:

499.823 Minimum qualifications.—The department may deny an application for a permit or refuse to renew a permit based upon:

(1) Whether the applicant has violated, or has been disciplined by a regulatory agency in any state for violating, a federal, state, or local law relating to wholesale distribution;

(2) The applicant's criminal convictions;

(3) The applicant's past experience in manufacturing or distributing medical gas;

(4) Any false or fraudulent material contained in an application;

(5) Suspension, sanction, or revocation of a permit currently or previously held by the applicant for violations of a state or federal law relating to medical gas;

(6) Compliance with previously granted permit requirements;

(7) Compliance with the requirements to maintain or make available to the department or permitting authority or to a federal, state, or local law enforcement official records required to be maintained by a wholesale distributor; and

(8) Any other factors or qualifications that the department considers relevant to and consistent with public health and safety.

Section 7. Section 499.824, Florida Statutes, is created to read:

499.824 Permitholder changes.—

(1) A permit issued by the department is valid only for the person or entity to which it is issued and is not subject to sale, assignment, or other transfer, voluntarily or involuntarily, and is not valid for an establishment other than

the establishment for which it was originally issued, except as provided in this part. The department may approve the following changes, and a person or entity may continue to operate in the following manner:

(a) *Change of location.*—A person or entity permitted under this part must notify the department 30 days before changing location. The department shall set a change-of-location fee not to exceed $100.

(b) *Change in ownership.*—If a majority of the ownership or controlling interest of a permitted establishment is transferred or assigned or if a lessee agrees to undertake or provide services such that legal liability for operation of the establishment will rest with the lessee, an application for a new permit is required. The application for the new permit must be submitted 30 days before the change of ownership. However, if an applicant is a permitholder or is wholly owned by or wholly owns a permitholder under this part, the application for the new permit must be made by the date of the sale, transfer, assignment, or lease. Between the date of the change of ownership and the date of the application approval or denial by the department, an applicant may distribute under the permit number of the previous owner.

(c) *Change of name.*—A permitholder may change its name without submitting a new permit application. However, the permitholder must notify the department 30 days before changing its name. The permitholder may continue to operate the establishment while the notification is being processed.

(d) *Closure.*—If an establishment permitted under this part closes, the owner must notify the department, in writing, before

the effective date of the closure and must:

1. Return the permit to the department; and

2. If the permittee is authorized to distribute medical gas, indicate the disposition of such medical gas, including the name, address, and inventory, and provide the name and address of a person to contact regarding access to the records that are required to be maintained under this part. Transfer of ownership of medical gas may be made only to persons authorized to receive medical gas pursuant to this part.

(e) *Change in information.*—Any change in information required under this part, other than a change of information as set forth in paragraphs (a)-(d), must be submitted to the department within 30 days after such change.

(2) Notwithstanding paragraph (1)(a), a permitholder in good standing may change the type of permit issued by completing a new application for the requested permit, paying the amount of the difference in the permit fees, and meeting the applicable permitting requirements for the new permit type. 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. The new permit expires on the expiration date of the original permit being changed.

(3) The department may revoke a permit for failure to comply with this section.

Section 8. Section 499.83 Florida Statutes, is created to read:

499.83 Registered agent.—An applicant for or a holder of a permit as a medical gas wholesale distributor or as a medical oxygen retail establishment shall designate a registered agent in this state for purposes of service of process. If an

applicant or a permitted wholesale distributor or medical oxygen retailer fails to designate a registered agent, the Secretary of State shall be deemed the true and lawful attorney of the applicant or the permitted wholesale distributor or medical oxygen retailer, and, in such case, the legal processes in any action or proceeding against an applicant or permitted wholesale distributor or medical oxygen retailer which grows out of or arising from wholesale distribution or retail may be served upon the Secretary of State. A copy of the service of process shall be mailed to the applicant or the permitted wholesale distributor or medical oxygen retailer by the department by certified mail, return receipt requested, postage prepaid, at the address of the applicant or the distributor or retailer as designated on the application for a permit in this state.

Section 9. Section 499.84, Florida Statutes, is created to read:

499.84 Minimum requirements for the storage and handling of medical gas.—

(1) A facility that receives, stores, warehouses, handles, holds, offers, markets, displays, or transports medical gas must avoid any negative effect on the identity, strength, quality, or purity of medical gas by:

(a) Being constructed in a way that ensures that medical gas is maintained in accordance with its product labeling recommendations or in compliance with official compendium standards, such as the USP-NF;

(b) Being of a suitable size and construction that facilitates cleaning, maintenance, and proper wholesale distribution;

(c) Having an adequate storage area with appropriate lighting, ventilation, space, equipment, and security conditions;

(d) Having a quarantine area for the storage of medical gas that is suspected of being misbranded, adulterated, or otherwise unfit for distribution;

(e) Being maintained in an orderly condition;

(f) Being in a commercial location, except if a personal dwelling location is used for the on-call delivery of oxygen USP for home care use and the person providing on-call delivery is employed by or acting under a written contract with a permittee;

(g) Providing for the secure storage of patient information, if applicable, by restricting access and implementing policies and procedures that protect the integrity and confidentiality of patient information; and

(h) Providing and maintaining appropriate inventory controls in order to detect and document any theft of nitrous oxide.

(2) Medical gas must be stored under appropriate conditions in accordance with the manufacturers' recommendations on product labeling and department rules or, in the absence of rules, in accordance with applicable industry standards. Medical gas must be packaged in accordance with official compendium standards, such as the USP-NF.

Section 10. Section 499.85, Florida Statutes, is created to read:

499.85 Security.—

(1) A facility that engages in wholesale distribution shall implement measures to secure its facility from unauthorized

entry. Such measures must include the following:

(a) Access from outside the premises must be well-controlled and kept to a minimum.

(b) The outside perimeter of the premises must be well-lighted.

(c) Areas in which medical gas is held must be restricted by a fence or other system that detects or deters entry after hours and limits access only to authorized personnel.

(2) A facility that engages in wholesale distribution must have:

(a) A security system that provides protection against theft and, if appropriate, theft that is enabled or obscured by tampering with computers or electronic records.

(b) A security system that protects the integrity and confidentiality of data and documents.

(3) If a wholesale distributor uses electronic distribution records, he or she must employ, train, and document the training of personnel for the proper use of the applicable technology and equipment.

(4) A vehicle used for on-call delivery of oxygen USP and oxygen-related equipment for home care use by a home care provider may be parked at a place of residence. Such vehicle while unattended must be locked and equipped with an audible alarm.

(5) The department shall adopt rules that govern the wholesale distribution of prescription medical oxygen for emergency use by persons authorized to receive emergency use oxygen. Unless the laws of this state specifically direct otherwise, such rules must be consistent with federal rules and

regulations, including the labeling requirements of oxygen under the federal act.

Section 11. Section 499.86, Florida Statutes, is created to read:

499.86 Examination of materials.—

(1) A wholesale distributor must visually examine an immediate container upon receipt from the manufacturer in order to identify the medical gas and to determine if the container has been damaged or is otherwise unfit for wholesale distribution. Such examination must occur in a manner that would reveal damage to the container which could suggest possible adulteration or misbranding.

(2) A medical gas container that is damaged or otherwise unfit pursuant to subsection (1) must be quarantined from the rest of the stock of medical gas until it is determined that the medical gas in question was not misbranded or adulterated.

(3) An outgoing shipment must be inspected for identity and to ensure that medical gas containers that have been damaged in storage or held under improper conditions are not delivered.

(4) A wholesale distributor must review records documenting the acquisition of medical gas upon receipt for accuracy and completeness.

Section 12. Section 499.87, Florida Statutes, is created to read:

499.87 Returned, damaged, and outdated medical gas.—

(1) Medical gas that has left the control of a wholesale distributor may be returned to the manufacturer or wholesale distributor from which it was acquired.

(2) Unless medical gas is reprocessed by a manufacturer

employing proper and adequate controls to ensure the identity, strength, quality, and purity of the reprocessed medical gas, the gas may not be resold as a medical gas even if its integrity was maintained.

(3) Medical gas that has been subjected to improper conditions, such as a fire, accident, or natural disaster, may not be salvaged or reprocessed.

(4) Medical gas, including its container, which is damaged, misbranded, or adulterated must be quarantined from other medical gases until it is destroyed or returned to the manufacturer or wholesale distributor from which it was acquired. External contamination to a medical gas container or closure system which does not impact the integrity of the medical gas is not considered damage or adulteration for purposes of this subsection. If medical gas is adulterated or misbranded or suspected of being adulterated or misbranded, notice shall be provided to the manufacturer or wholesale distributor from which the medical gas was acquired and to the appropriate boards and federal regulatory bodies.

(5) A medical gas container that has been opened or used but is not adulterated or misbranded is considered empty and must be quarantined from nonempty medical gas containers and returned to the manufacturer or wholesale distributor from which it was acquired for destruction or reprocessing.

(6) Medical gas, its container, or its associated documentation or labeling that is suspected of being used in criminal activity must be retained until its disposition is authorized by the department or an applicable law enforcement agency.

Section 13. Section 499.88, Florida Statutes, is created to read:

499.88 Due diligence.—

(1) A wholesale distributor shall obtain, before the initial acquisition of medical gas, the following information from the supplying wholesale distributor or manufacturer:

(a) If a manufacturer is distributing to a wholesale distributor, evidence that the manufacturer is registered and the medical gas is listed with the FDA;

(b) If a wholesale distributor is distributing to a wholesale distributor, evidence that the wholesale distributor supplying the medical gas is permitted to distribute medical gas within or into the state;

(c) The name of the contact person for the supplying manufacturer or wholesale distributor; and

(d) Certification that the manufacturer's or wholesale distributor's policies and procedures comply with this part.

(2) A wholesale distributor is exempt from obtaining the information from a manufacturer as required under subsection (1) if the manufacturer is registered with the FDA in accordance with s. 510 of the federal act and provides:

(a) Proof of such registration; and

(b) Proof of inspection within the past 3 years by the FDA or other regulatory body or proof of conformance with industry standards or guidelines as identified by the department.

(3) A manufacturer or wholesale distributor that distributes to or acquires medical gas from another wholesale distributor shall provide to or obtain from the distributing or acquiring manufacturer or distributor the information required

by s. 499.89(1), as applicable.

Section 14. Section 499.89, Florida Statutes, is created to read:

499.89 Recordkeeping.—

(1) A wholesale distributor shall establish and maintain a record of transactions regarding the receipt and the distribution, or other disposition, of medical gases. Such records constitute an audit trail and must contain information sufficient to perform a recall of medical gas in compliance with 21 C.F.R. s. 211.196 and 21 C.F.R. s. 820.160(b). Such records must include all the following information, which need not appear in the same document:

(a) The dates of receipt and wholesale distribution, or other disposition, of the medical gas.

(b) The name, address, permit number, and permit expiration date for the entity purchasing the medical gas from the wholesale distributor.

(c) The name, address, permit number, and permit expiration date for the entity receiving the medical gas from the wholesale distributor, if different from the information required under paragraph (b).

(d) Information sufficient to perform a recall of all medical gas received or distributed.

(2) From the time of their creation, such records shall be kept for 3 years for high pressure medical gas and for 1 year for cryogenic or refrigerated liquid medical gas.

(3) During the retention period, such records shall be made available for inspection and photocopying by an authorized official of a state, federal, or local governmental agency. If

such records are kept at the inspection site or could be immediately retrieved by electronic means, they shall be made readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within 2 business days of a request.

(4) A pedigree paper is not required for the wholesale distribution of medical gas.

Section 15. Section 499.90, Florida Statutes, is created to read:

499.90 Policies and procedures.—A wholesale distributor shall establish, maintain, and adhere to written policies and procedures for the receipt, security, storage, transport, shipping, and wholesale distribution of medical gas and shall establish, maintain, and adhere to procedures for maintaining inventories; for identifying, recording, and reporting losses or thefts; and for correcting all errors and inaccuracies in inventories associated with nitrous oxide. A wholesale distributor shall include in its written policies and procedures the following:

(1) A procedure for handling recalls and withdrawals of medical gas. Such procedure must deal with recalls and withdrawals due to:

(a) Action initiated at the request of the FDA or any federal, state, or local law enforcement or other government agency, including the department; or

(b) Voluntary action by the manufacturer of medical gas to remove defective or potentially defective medical gases from the market.

(2) A procedure preparing for, protecting against, and handling a crisis that affects the security or operation of a facility in the event of a strike, fire, flood, or other natural disaster or other situations of local, state, or national emergency.

(3) A procedure for reporting criminal or suspected criminal activity involving the inventory of nitrous oxide to the department and to applicable law enforcement agencies within 3 business days after becoming aware of the criminal or suspected criminal activity.

Section 16. Section 499.91, Florida Statutes, is created to read:

499.91 Prohibited acts.—A person may not perform or cause the performance of, or aid and abet in, any of the following acts in this state:

(1) The manufacture, sale, or delivery, or the holding or offering for sale, of medical gas that is adulterated, misbranded, or has otherwise been rendered unfit for distribution.

(2) The adulteration or misbranding of medical gas.

(3) The receipt of medical gas that is adulterated, misbranded, stolen, or obtained by fraud or deceit or the delivery or proffered delivery of such medical gas for pay or otherwise.

(4) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the product labeling of medical gas or the willful commission of any other act with respect to medical gas that results in it being misbranded.

(5) The purchase or receipt of medical gas from a person

who is not authorized by permit to distribute wholesale medical gas or who is exempted from permitting requirements to distribute wholesale medical gas to such purchaser or recipient.

(6) The knowing and willful sale or transfer of medical gas to a recipient who is not legally authorized to receive medical gas, except that a violation does not exist as to a distributor that provides oxygen to a permitted medical oxygen retail establishment if the distributor is out of compliance with only the change of location notice requirement under s. 499.824.

(7) The failure to maintain or provide records required under this part and its implementing regulations.

(8) Providing the department or any of its representatives or any state or federal official with false or fraudulent records or making false or fraudulent statements regarding this part and its implementing regulations.

(9) The wholesale distribution of medical gas that was:

(a) Purchased by a public or private hospital or other health care entity, except for the physical distribution of such medical gas to an authorized recipient at the direction of a hospital or other health care entity;

(b) Donated or supplied at a reduced price to a charitable organization; or

(c) Stolen or obtained by fraud or deceit.

(10) The failure to obtain a permit or operating without a valid permit when a permit is required.

(11) The obtaining of or attempt to obtain medical gas by fraud, deceit, or misrepresentation or engaging in misrepresentation or fraud in the distribution of medical gas.

(12) Except for oxygen USP in emergency situations, the

distribution of medical gas to a patient without an order or prescription from a licensed practitioner authorized by law to prescribe.

(13) The distribution of medical gas that was previously dispensed by a pharmacy or a licensed practitioner authorized by law to prescribe.

(14) The distribution of medical gas or medical gas-related equipment to a patient, unless the patient has been provided with the appropriate information and counseling on the use, storage, and disposal of medical gas.

(15) The failure to report an act prohibited under this part and its implementing regulations.

(16) The failure to exercise due diligence as provided in s. 499.88.

Section 17. Section 499.92, Florida Statutes, is created to read:

499.92 Criminal acts.—

(1) A person commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, if he or she:

(a) With intent to defraud or deceive adulterates or misbrands medical gas.

(b) Engages in the wholesale distribution of, and knowingly purchases or receives, medical gas from a person not legally authorized to distribute medical gas.

(c) Engages in the wholesale distribution of, and knowingly sells, barters, brokers, or transfers, medical gas to a person not legally authorized to purchase medical gas in the jurisdiction in which the person receives the medical gas,

except that a violation does not exist as to a distributor that provides oxygen to a permitted medical oxygen retail establishment if the distributor is out of compliance with only the change of location notice requirement under s. 499.824.

(d) Knowingly, falsely creates a label for medical gas or knowingly, falsely represents a factual matter contained in a label for medical gas.

(2) A court that has authority over a person who violates this section and that convicts such person shall order him or her to forfeit to the state real or personal property or assets:

(a) Used or intended to be used to commit, facilitate, or promote the commission of such violation; and

(b) Constituting, derived from, or traceable to the gross proceeds that the defendant obtained as a result of the violation.

(3) Property or assets subject to forfeiture under subsection (2) may be seized pursuant to a warrant obtained in the same manner as a search warrant or as otherwise authorized by law and held until the case against the defendant is adjudicated. Moneys ordered to be forfeited or proceeds from the sale of assets ordered to be forfeited shall be equitably divided between the department and agencies involved in the investigation and prosecution that led to the conviction. Other property ordered to be forfeited after conviction of a defendant may, at the discretion of the investigating agencies, be placed into official use by the department or the agencies involved in the investigation and prosecution.

Section 18. Section 499.93, Florida Statutes, is created to read:

499.93 Inspections.—

(1) The department may require a facility that engages in the manufacture, retail sale, or wholesale distribution of medical gas to undergo an inspection in accordance with a schedule to be determined by the department.

(2) The department may recognize other state inspections of a manufacturer or wholesale distributor in another state if such state's laws are deemed to be substantially equivalent to the laws of this state.

(3) A manufacturing facility is exempt from inspection by the department if the facility:

(a) Is currently registered with the FDA in accordance with s. 510 of the federal act and can provide proof of such registration, such as a copy of the online verification page; and

(b) Can provide proof of inspection within the past 3 years by the FDA or, if the facility is located in another state, by another governmental entity charged with regulation of good manufacturing practices related to medical gas.

(4) A wholesale distributor must exhibit or have readily available its state permits and its most recent inspection report administered by the department. The department may authorize a third party to inspect wholesale distributors who distribute within or into this state.

Section 19. Section 499.931, Florida Statutes, is created to read:

499.931 Trade secret information.—Information required to be submitted under this part which is a trade secret as defined in s. 812.081(1)(c) and designated as a trade secret by an

applicant or permit holder must be maintained as required under s. 499.051.

Section 20. Section 499.94, Florida Statutes, is created to read:

499.94 Fees.—A fee collected for a permit under this part shall be deposited into the Professional Regulation Trust Fund. Moneys collected under this part shall be used for administering this part. The department shall maintain a separate account in the trust fund for the Drugs, Devices, and Cosmetics program.

Section 21. Section 499.95, Florida Statues, is created to read:

499.95 Enforcement and construction of this part.—

(1) For the purpose of initiating an investigation or proceeding under this part, the department may administer oaths, take depositions, issue and serve subpoenas, and compel the attendance of witnesses and the production of books, papers, documents, or other evidence. Challenges to, and enforcement of, a subpoena and an order shall be conducted in accordance with s. 120.569.

(2) A state, county, or municipal attorney to whom the department or its designated agent reports a violation of this part shall timely institute proceedings in the court of competent jurisdiction and shall prosecute in the manner required by law.

(3) The department is not required to report minor violations to a state, county, or municipal attorney if the department determines that the public interest is best served by issuance of a written notice or warning to the violator.

(4) This part is cumulative and does not repeal or affect

the power, duty, or authority of the department. However, relating to the regulation of medical gas, if this part conflicts with other law, this part controls.

Section 22. Section 499.001, Florida Statutes, is amended to read:

499.001 Florida Drug and Cosmetic Act; short title.—Sections 499.001-499.95 ~~499.001-499.081~~ may be cited as the "Florida Drug and Cosmetic Act."

Section 23. Present subsections (11) through (32) and (46) through (55) of section 499.003, Florida Statutes, are amended, and a new subsection (32) is added to that section, to read:

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

~~(11) "Compressed medical gas" means any liquefied or vaporized gas that is a prescription drug, whether it is alone or in combination with other gases.~~

(11)~~(12)~~ "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 pedigree paper does not exist~~,~~ or for which the pedigree paper in existence has been forged, counterfeited, falsely created, or contains any altered, false, or misrepresented matter.

(12)~~(13)~~ "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)~~(14)~~ "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)~~(15)~~ "Department" means the Department of Business and Professional Regulation.

(15)~~(16)~~ "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)~~(17)~~ "Distribute" or "distribution" means 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)~~(18)~~ "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.

(18)~~(19)~~ "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.

(19)~~(20)~~ "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.

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

(21)~~(22)~~ "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.

(22)~~(23)~~ "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)(g)1.c.

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

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

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

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

(27)~~(28)~~ "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.

(28)~~(29)~~ "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.

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

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

(a) A person who prepares, derives, manufactures, or produces a drug, device, or cosmetic;

(b) 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) 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;

(d) 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.

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

(32) "Medical gas" is defined in accordance with the federal act and means a liquefied or vaporized gas that is a prescription drug, regardless of whether it is alone or combined with other gases.

(46) ~~"Prescription medical oxygen" means oxygen USP which is a drug that can only be sold on the order or prescription of a practitioner authorized by law to prescribe. The label of prescription medical oxygen must comply with current labeling requirements for oxygen under the Federal Food, Drug, and Cosmetic Act.~~

~~(47)~~ "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.

(47) ~~(48)~~ "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.

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

(49) ~~(50)~~ "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.

(50) ~~(51)~~ "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) ~~(52)~~ "Secondary wholesale distributor" means a wholesale distributor that is not a primary wholesale distributor.

(52) ~~(53)~~ "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."

(53) ~~(54)~~ "Wholesale distribution" means distribution of prescription drugs to persons other than a 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)(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 sale, purchase, or trade of a prescription drug or an offer to 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 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 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 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 described ~~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 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 sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug for emergency medical reasons. 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.

3. The 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.

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.

6. The 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.

7. The 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 transfers prescription drugs pursuant to this subparagraph must reconcile all drugs transferred and returned and resolve any discrepancies in a timely manner.

(c) The distribution of prescription drug samples by manufacturers' representatives or distributors' representatives conducted in accordance with s. 499.028.

(d) The 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.

(e) The lawful dispensing of a prescription drug in accordance with chapter 465.

(f) The sale, purchase, or trade of a prescription drug between pharmacies as a result of a sale, transfer, merger, or

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

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.

(54)~~(55)~~ "Wholesale distributor" means any person 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 24. 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 ~~by~~, or described in ~~by~~ s. 503(b) of the Federal Food, Drug, and Cosmetic Act or in ~~by~~ s. 465.003(8), s. 499.003(52), ~~s. 499.003(46) or (53) or~~ s. 499.007(13), or s. 499.81(15).

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 25. Paragraph (c) of subsection (9) of section

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

460.403, Florida Statutes, is amended to read:

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

(9)

(c)1. Chiropractic physicians may adjust, manipulate, or treat the human body by manual, mechanical, electrical, or natural methods; by the use of physical means or physiotherapy, including light, heat, water, or exercise; by the use of acupuncture; or by the administration of foods, food concentrates, food extracts, and items for which a prescription is not required and may apply first aid and hygiene, but chiropractic physicians are expressly prohibited from prescribing or administering to any person any legend drug except as authorized under subparagraph 2., from performing any surgery except as stated herein, or from practicing obstetrics.

2. Notwithstanding the prohibition against prescribing and administering legend drugs under subparagraph 1. or s. 499.82(7)(c) ~~s. 499.01(2)(m)~~, pursuant to board rule chiropractic physicians may order, store, and administer, for emergency purposes only at the chiropractic physician's office or place of business, prescription medical oxygen and may also order, store, and administer the following topical anesthetics in aerosol form:

a. Any solution consisting of 25 percent ethylchloride and 75 percent dichlorodifluoromethane.

b. Any solution consisting of 15 percent dichlorodifluoromethane and 85 percent trichloromonofluoromethane.

However, this paragraph does not authorize a chiropractic

physician to prescribe medical oxygen as defined in chapter 499.

Section 26. Subsection (3) of section 465.0265, Florida Statutes, is amended to read:

465.0265 Centralized prescription filling.—

(3) The filling, delivery, and return of a prescription by one pharmacy for another pursuant to this section may ~~shall~~ not be construed as the filling of a transferred prescription as described ~~set forth~~ in s. 465.026 or as a wholesale distribution as defined ~~set forth~~ in s. 499.003 ~~s. 499.003(54)~~.

Section 27. Subsection (1), paragraphs (a), (c), (g), (m), (n), and (o) of subsection (2), and subsection (5) of section 499.01, Florida Statutes, are 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 prescription drug wholesale distributor;

(e) An out-of-state prescription drug wholesale distributor;

(f) A retail pharmacy drug wholesale distributor;

(g) A restricted prescription drug distributor;

(h) A complimentary drug distributor;

(i) A freight forwarder;

(j) A veterinary prescription drug retail establishment;

(k) A veterinary prescription drug wholesale distributor;

(l) A limited prescription drug veterinary wholesale distributor;

~~(m) A medical oxygen retail establishment;~~

~~(n) A compressed medical gas wholesale distributor;~~

~~(o) A compressed medical gas manufacturer;~~

(m) ~~(p)~~ An over-the-counter drug manufacturer;

(n) ~~(q)~~ A device manufacturer;

(o) ~~(r)~~ A cosmetic manufacturer;

(p) ~~(s)~~ A third party logistics provider; or

(q) ~~(t)~~ 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 manufactured at that establishment and must comply with all 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.

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(53)(d) ~~s. 499.003(54)(d)~~ is not required to be permitted as a prescription drug manufacturer under this paragraph or to register products under s. 499.015.

(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 wholesale distributor under this part, except s. 499.01212.

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. This subparagraph does not apply to a manufacturer as defined in s. 499.003(30)(e) ~~s. 499.003(31)(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 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.

(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(53)(a) ~~s. 499.003(54)(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(53)(d) ~~s. 499.003(54)(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

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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 described ~~set forth~~ in s. 499.01212 if

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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.

~~(m) *Medical oxygen retail establishment permit.* A medical oxygen retail establishment permit is required for any person that sells medical oxygen to patients only. The sale must be based on an order from a practitioner authorized by law to prescribe. The term does not include a pharmacy licensed under chapter 465.~~

~~1. A medical oxygen retail establishment may not possess, purchase, sell, or trade any prescription drug other than medical oxygen.~~

~~2. A medical oxygen retail establishment may refill medical oxygen for an individual patient based on an order from a practitioner authorized by law to prescribe. A medical oxygen retail establishment that refills medical oxygen must comply with all appropriate state and federal good manufacturing practices.~~

~~3. A medical oxygen retail establishment must comply with all of the wholesale distribution requirements of s. 499.0121.~~

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~~4. Prescription medical oxygen sold by a medical oxygen retail establishment pursuant to a practitioner's order may not be returned into the retail establishment's inventory.~~

~~(n) *Compressed medical gas wholesale distributor permit.* A compressed medical gas wholesale distributor is a wholesale distributor that is limited to the wholesale distribution of compressed medical gases to other than the consumer or patient. The compressed medical gas must be in the original sealed container that was purchased by that wholesale distributor. A compressed medical gas wholesale distributor may not possess or engage in the wholesale distribution of any prescription drug other than compressed medical gases. The department shall adopt rules that govern the wholesale distribution of prescription medical oxygen for emergency use. With respect to the emergency use of prescription medical oxygen, those rules may not be inconsistent with rules and regulations of federal agencies unless the Legislature specifically directs otherwise.~~

~~(o) *Compressed medical gas manufacturer permit.* A compressed medical gas manufacturer permit is required for any person that engages in the manufacture of compressed medical gases or repackages compressed medical gases from one container to another.~~

~~1. A compressed medical gas manufacturer may not manufacture or possess any prescription drug other than compressed medical gases.~~

~~2. A compressed medical gas manufacturer may engage in wholesale distribution of compressed medical gases manufactured at that establishment and must comply with all the provisions of this part and the rules adopted under this part that apply to a~~

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~~wholesale distributor.~~

~~3. A compressed medical gas manufacturer must comply with all appropriate state and federal good manufacturing practices.~~

(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(53)(a)3. ~~s. 499.003(54)(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.

Section 28. Paragraph (b) of subsection (2) of section 499.0121, Florida Statutes, is 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.

(2) SECURITY.—

(b) An establishment that is used for wholesale drug distribution must be equipped with:

1. An alarm system to detect entry after hours; however, the department may exempt by rule establishments that only hold a permit as prescription drug wholesale distributor-brokers ~~and establishments that only handle medical oxygen~~; and

2. A security system that will provide suitable protection against theft and diversion. When appropriate, the security system must provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

Section 29. Section 499.01211, Florida Statutes, is amended to read:

499.01211 Drug Wholesale Distributor Advisory Council.—

(1) There is created the Drug Wholesale Distributor

Advisory Council within the department. The council shall meet at least once each calendar quarter. Staff for the council shall be provided by the department. The council shall consist of 12 ~~11~~ members who shall serve without compensation. The council shall elect a chairperson and a vice chairperson annually.

(2) The Secretary of Business and Professional Regulation or his or her designee and the Secretary of Health Care Administration or her or his designee shall be members of the council. The Secretary of Business and Professional Regulation shall appoint nine additional members to the council who shall be appointed to a term of 4 years each, as follows:

(a) Three different persons each of whom is employed by a different prescription drug wholesale distributor licensed under this part which operates nationally and is a primary wholesale distributor, as defined in s. 499.003 ~~s. 499.003(47)~~.

(b) One person employed by a prescription drug wholesale distributor licensed under this part which is a secondary wholesale distributor, as defined in s. 499.003 ~~s. 499.003(52)~~.

(c) One person employed by a retail pharmacy chain located in this state.

(d) One person who is a member of the Board of Pharmacy and is a pharmacist licensed under chapter 465.

(e) One person who is a physician licensed pursuant to chapter 458 or chapter 459.

(f) One person who is an employee of a hospital licensed pursuant to chapter 395 and is a pharmacist licensed pursuant to chapter 465.

(g) One person who is an employee of a pharmaceutical manufacturer.

(3) The Compressed Gas Association shall appoint one person to the council who is an employee of a permitted medical gas wholesale distributor or manufacturer.

(4) ~~(3)~~ The council shall review this part and the rules adopted to administer this part annually, provide input to the department regarding all proposed rules to administer this part, make recommendations to the department to improve the protection of the prescription drugs and public health, make recommendations to improve coordination with other states' regulatory agencies and the federal government concerning the wholesale distribution of drugs, and make recommendations to minimize the impact of regulation of the wholesale distribution industry while ensuring protection of the public health.

Section 30. Paragraph (b) of subsection (2) of section 499.01212, Florida Statutes, is amended to read:

499.01212 Pedigree paper.—

(2) FORMAT.—A pedigree paper must contain the following information:

(b) For all other wholesale distributions of prescription drugs:

1. The quantity, dosage form, and strength of the prescription drugs.

2. The lot numbers of the prescription drugs.

3. The name and address of each owner of the prescription drug and his or her signature.

4. Shipping information, including the name and address of each person certifying delivery or receipt of the prescription drug.

5. An invoice number, a shipping document number, or

another number uniquely identifying the transaction.

6. A certification that the recipient wholesale distributor has authenticated the pedigree papers.

7. The unique serialization of the prescription drug, if the manufacturer or repackager has uniquely serialized the individual prescription drug unit.

8. 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.

When an affiliated group member obtains title to a prescription drug before distributing the prescription drug as the manufacturer as defined in s. 499.003(30)(e) ~~under s. 499.003(31)(c)~~, information regarding the distribution between those affiliated group members may be omitted from a pedigree paper required under this paragraph for subsequent distributions of that prescription drug.

Section 31. Paragraph (a) of subsection (1) and subsection (3) 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 ~~s. 499.003(31)~~, any person who manufactures, packages, repackages, labels, or relabels a drug, device, or cosmetic in this state must register such drug, 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, device, or cosmetic at the time

of registration.

(3) Except for those persons exempted from the definition of manufacturer in s. 499.003 ~~s. 499.003(31)~~, 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, 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.

Section 32. Subsection (3) of section 499.024, Florida Statutes, is amended to read:

499.024 Drug product classification.—The department shall adopt rules to classify drug products intended for use by humans which the United States Food and Drug Administration has not classified in the federal act or the Code of Federal Regulations.

(3) Any product that falls under the definition of drug in s. 499.003 ~~s. 499.003(19)~~ may be classified under the authority of this section. This section does not subject portable emergency oxygen inhalators to classification; however, this section does not exempt any person from ss. 499.01 and 499.015.

Section 33. Paragraph (e) of subsection (1), paragraph (b) of subsection (2), and paragraph (b) of subsection (3) of section 499.041, Florida Statutes, are amended to read:

499.041 Schedule of fees for drug, device, and cosmetic applications and permits, product registrations, and free-sale certificates.—

(1) The department shall assess applicants requiring a manufacturing permit an annual fee within the ranges established in this section for the specific type of manufacturer.

~~(c) The fee for a compressed medical gas manufacturer permit may not be less than $400 or more than $500 annually.~~

(2) The department shall assess an applicant that is required to have a wholesaling permit an annual fee within the ranges established in this section for the specific type of wholesaling.

~~(b) The fee for a compressed medical gas wholesale distributor permit may not be less than $200 or more than $300 annually.~~

(3) The department shall assess an applicant that is required to have a retail establishment permit an annual fee within the ranges established in this section for the specific type of retail establishment.

~~(b) The fee for a medical oxygen retail establishment permit may not be less than $200 or more than $300 annually.~~

Section 34. Paragraphs (i) and (m) 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 ~~part~~ with respect to:

(i) Additional conditions that qualify as an emergency medical reason under s. 499.003(53)(b)2. ~~s. 499.003(54)(b)2~~.

(m) The recordkeeping, storage, and handling with respect to each of the distributions of prescription drugs specified in s. 499.003(53)(a)-(d) ~~s. 499.003(54)(a)-(d)~~.

Section 35. Subsections (1) through (4) of section 499.051, Florida Statutes, are amended to read:

499.051 Inspections and investigations.—

(1) The agents of the department and of the Department of

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Law Enforcement, after they present proper identification, may inspect, monitor, and investigate any establishment permitted pursuant to this chapter ~~part~~ during business hours for the purpose of enforcing this chapter ~~part~~, chapters 465, 501, and 893, and the rules of the department that protect the public health, safety, and welfare.

(2) In addition to the authority set forth in subsection (1), the department and any duly designated officer or employee of the department may enter and inspect any other establishment for the purpose of determining compliance with this part and rules adopted under this chapter ~~part~~ regarding any drug, device, or cosmetic product.

(3) Any application for a permit or product registration or for renewal of such permit or registration made pursuant to this chapter ~~part~~ and rules adopted under this chapter ~~part~~ constitutes permission for any entry or inspection of the premises in order to verify compliance with this chapter ~~part~~ and rules; to discover, investigate, and determine the existence of compliance; or to elicit, receive, respond to, and resolve complaints and violations.

(4) Any application for a permit made pursuant to s. 499.012 or s. 499.821 and rules adopted under those sections ~~that section~~ constitutes permission for agents of the department and the Department of Law Enforcement, after presenting proper identification, to inspect, review, and copy any financial document or record related to the manufacture, repackaging, or distribution of a drug as is necessary to verify compliance with this chapter ~~part~~ and the rules adopted by the department to administer this chapter ~~part~~, in order to discover, investigate,

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and determine the existence of compliance, or to elicit, receive, respond to, and resolve complaints and violations.

Section 36. Section 499.066, Florida Statutes, is amended to read:

499.066 Penalties; remedies.—In addition to other penalties and other enforcement provisions:

(1) The department may institute such suits or other legal proceedings as are required to enforce any provision of this chapter ~~part~~. If it appears that a person has violated any provision of this chapter ~~part~~ for which criminal prosecution is provided, the department may provide the appropriate state attorney or other prosecuting agency having jurisdiction with respect to such prosecution with the relevant information in the department's possession.

(2) If any person engaged in any activity covered by this chapter ~~part~~ violates any provision of this chapter ~~part~~, any rule adopted under this chapter ~~part~~, or a cease and desist order as provided by this chapter ~~part~~, the department may obtain an injunction in the circuit court of the county in which the violation occurred or in which the person resides or has its principal place of business, and may apply in that court for such temporary and permanent orders as the department considers necessary to restrain the person from engaging in any such activities until the person complies with this chapter ~~part~~, the rules adopted under this chapter ~~part~~, and the orders of the department authorized by this chapter ~~part~~ or to mandate compliance with this chapter ~~part~~, the rules adopted under this chapter ~~part~~, and any order or permit issued by the department under this chapter ~~part~~.

(3) The department may impose an administrative fine, not to exceed $5,000 per violation per day, for the violation of any provision of this chapter ~~part~~ or rules adopted under this chapter ~~part~~. Each day a violation continues constitutes a separate violation, and each separate violation is subject to a separate fine. All amounts collected pursuant to this section shall be deposited into the Professional Regulation Trust Fund and are appropriated for the use of the department in administering this chapter ~~part~~. In determining the amount of the fine to be levied for a violation, the department shall consider:

(a) The severity of the violation;

(b) Any actions taken by the person to correct the violation or to remedy complaints; and

(c) Any previous violations.

(4) The department shall deposit any rewards, fines, or collections that are due the department and which derive from joint enforcement activities with other state and federal agencies which relate to this chapter ~~part~~, chapter 893, or the federal act, into the Professional Regulation Trust Fund. The proceeds of those rewards, fines, and collections are appropriated for the use of the department in administering this chapter ~~part~~.

(5) The department may issue an emergency order immediately suspending or revoking a permit if it determines that any condition in the establishment presents a danger to the public health, safety, and welfare.

(6) The department may issue an emergency order to immediately remove from commerce and public access any drug,

device, or cosmetic, if the department determines that the drug, device, or cosmetic presents a clear and present danger to the public health, safety, and welfare.

(7) Resignation or termination of an affiliated party does not affect the department's jurisdiction or discretion to proceed with action to suspend or revoke a permit or to impose other penalties or enforcement actions authorized by law.

Section 37. Paragraph (a) of subsection (1) and paragraph (a) of subsection (2) of section 499.0661, Florida Statutes, are amended to read:

499.0661 Cease and desist orders; removal of certain persons.—

(1) CEASE AND DESIST ORDERS.—

(a) In addition to any authority otherwise provided in this chapter, the department may issue and serve a complaint stating charges upon any permittee or upon any affiliated party, whenever the department has reasonable cause to believe that the person or individual named therein is engaging in or has engaged in conduct that is:

1. An act that demonstrates a lack of fitness or trustworthiness to engage in the business authorized under the permit issued pursuant to this chapter ~~part~~, is hazardous to the public health, or constitutes business operations that are a detriment to the public health;

2. A violation of any provision of this chapter ~~part~~;

3. A violation of any rule of the department;

4. A violation of any order of the department; or

5. A breach of any written agreement with the department.

(2) REMOVAL OF AFFILIATED PARTIES BY THE DEPARTMENT.—

(a) The department may issue and serve a complaint stating charges upon any affiliated party and upon the permittee involved whenever the department has reason to believe that an affiliated party is engaging in or has engaged in conduct that constitutes:

1. An act that demonstrates a lack of fitness or trustworthiness to engage in the business authorized under the permit issued pursuant to this chapter ~~part~~, is hazardous to the public health, or constitutes business operations that are a detriment to the public health;

2. A willful violation of this chapter ~~part~~; however, if the violation constitutes a misdemeanor, a complaint may not be served as provided in this section until the affiliated party is notified in writing of the matter of the violation and has been afforded a reasonable period of time, as set forth in the notice, to correct the violation and has failed to do so;

3. A violation of any other law involving fraud or moral turpitude which constitutes a felony;

4. A willful violation of any rule of the department;

5. A willful violation of any order of the department; or

6. A material misrepresentation of fact, made knowingly and willfully or made with reckless disregard for the truth of the matter.

Section 38. Section 499.067, Florida Statutes, is amended to read:

499.067 Denial, suspension, or revocation of permit, certification, or registration.—

(1)(a) The department may deny, suspend, or revoke a permit if it finds that there has been a substantial failure to comply

with this chapter ~~part~~ or chapter 465, chapter 501, or chapter 893, the rules adopted under this chapter ~~part~~ or those chapters, any final order of the department, or applicable federal laws or regulations or other state laws or rules governing drugs, devices, or cosmetics.

(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(16) demonstrates any of the conditions enumerated in s. 499.012.

5. The applicant, permittee, or person certified under s. 499.012(16) has committed any violation of ss. 499.005-499.0054.

(2) The department may deny, suspend, or revoke any registration required by the provisions of this chapter ~~part~~ for the violation of any provision of this chapter ~~part~~ or of any rules adopted under this chapter ~~part~~.

(3) The department may revoke or suspend a permit:

(a) If the permit was obtained by misrepresentation or fraud or through a mistake of the department;

(b) If the permit was procured, or attempted to be

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procured, for any other person by making or causing to be made any false representation; or

(c) If the permittee has violated any provision of this chapter ~~part~~ or rules adopted under this chapter ~~part~~.

(4) If any permit issued under this chapter ~~part~~ is revoked or suspended, the owner, manager, operator, or proprietor of the establishment shall cease to operate as the permit authorized, from the effective date of the suspension or revocation until the person is again registered with the department and possesses the required permit. If a permit is revoked or suspended, the owner, manager, or proprietor shall remove all signs and symbols that identify the operation as premises permitted as a drug wholesaling establishment; drug, device, or cosmetic manufacturing establishment; or retail establishment. The department shall determine the length of time for which the permit is to be suspended. If a permit is revoked, the person that owns or operates the establishment may not apply for any permit under this chapter ~~part~~ for a period of 1 year after the date of the revocation. A revocation of a permit may be permanent if the department considers that to be in the best interest of the public health.

(5) The department may deny, suspend, or revoke a permit issued under this chapter ~~part~~ which authorizes the permittee to purchase prescription drugs if any owner, officer, employee, or other person who participates in administering or operating the establishment has been found guilty of any violation of this chapter ~~part~~ or chapter 465, chapter 501, or chapter 893, any rules adopted under this chapter ~~part~~ or those chapters, or any federal or state drug law, regardless of whether the person has

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been pardoned, had her or his civil rights restored, or had adjudication withheld.

(6) The department shall deny, suspend, or revoke the permit of any person or establishment if the assignment, sale, transfer, or lease of an establishment permitted under this chapter ~~part~~ will avoid an administrative penalty, civil action, or criminal prosecution.

(7) Notwithstanding s. 120.60(5), if a permittee fails to comply with s. 499.012(6) or s. 499.83, as applicable, the department may revoke the permit of the permittee and shall provide notice of the intended agency action by posting a notice at the department's headquarters and by mailing a copy of the notice of intended agency action by certified mail to the most recent mailing address on record with the department and, if the permittee is not a natural person, to the permittee's registered agent on file with the Department of State.

(8) The department may deny, suspend, or revoke a permit under this part if it finds the permittee has not complied with the credentialing requirements of s. 499.0121(15).

(9) The department may deny, suspend, or revoke a permit under this part if it finds the permittee has not complied with the reporting requirements of, or knowingly made a false statement in a report required by, s. 499.0121(14).

Section 39. This act shall take effect October 1, 2014.

HID Global
15370 Barranca Pkwy
Irvine, CA 92618-2215 USA

March 21, 2014

Senator Aaron Bean
Chairman, Senate Committee on Health Policy
Florida State Senate
302 Senate Office Building
404 South Monroe Street
Tallahassee, FL 32399-1100

Dear Senator Bean:

On behalf of HID Global, a worldwide leader in secure identity solutions, I am writing to you in support of SB 836, which includes a provision that requires a secured location for a wholesale medical gas distribution operation.

As security becomes a significant concern that translates across most all facets of day-to-day life, policymakers are increasingly focused on security solutions that are efficient, effective and most importantly, will provide assurance that citizens are safe as they go about their daily affairs both in their workplace and at home. The passage of SB 836 would ensure that employees of a medical gas wholesale distribution center are working in a secured facility as they serve their customers. Additionally, it would also provide peace-of-mind to customers that the product they purchase is handled in a safe and secure manner.

Thank you for your service and your time. I am available anytime if you'd like to discuss this in greater detail, and HID Global would be happy to serve as a resource, if needed.

Best,

Wendy Reilly
Manager, Government Relations, HID Global

CC: Kathleen Carroll, Director, Government Relations, HID Global

By e-mail

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The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Health Policy

BILL:	SB 282
INTRODUCER:	Senators Garcia and Flores
SUBJECT:	Florida Kidcare Program
DATE:	March 20, 2014 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Lloyd	Stovall	HP	**Pre-meeting**
2.			AHS	
3.			AP	

I. Summary:

SB 282 extends Medicaid and Children's Health Insurance Program (CHIP) eligibility to a "lawfully residing child" who meets other eligibility qualifications of the Medicaid or CHIP program, as applicable. The federal programs permit states to cover this population group, those in a 5-year waiting period, if the state elects to do so.

The bill defines "lawfully residing child" which conforms to the federal program eligibility requirements and deletes references to "qualified alien." The bill specifies that the definition of lawfully residing child does not extend Kidcare program eligibility to undocumented immigrants.

The bill has a substantial fiscal impact for Fiscal Year 2014-2015 for recurring and non-recurring state costs of $27,611,139.

II. Present Situation:

The Medicaid Program

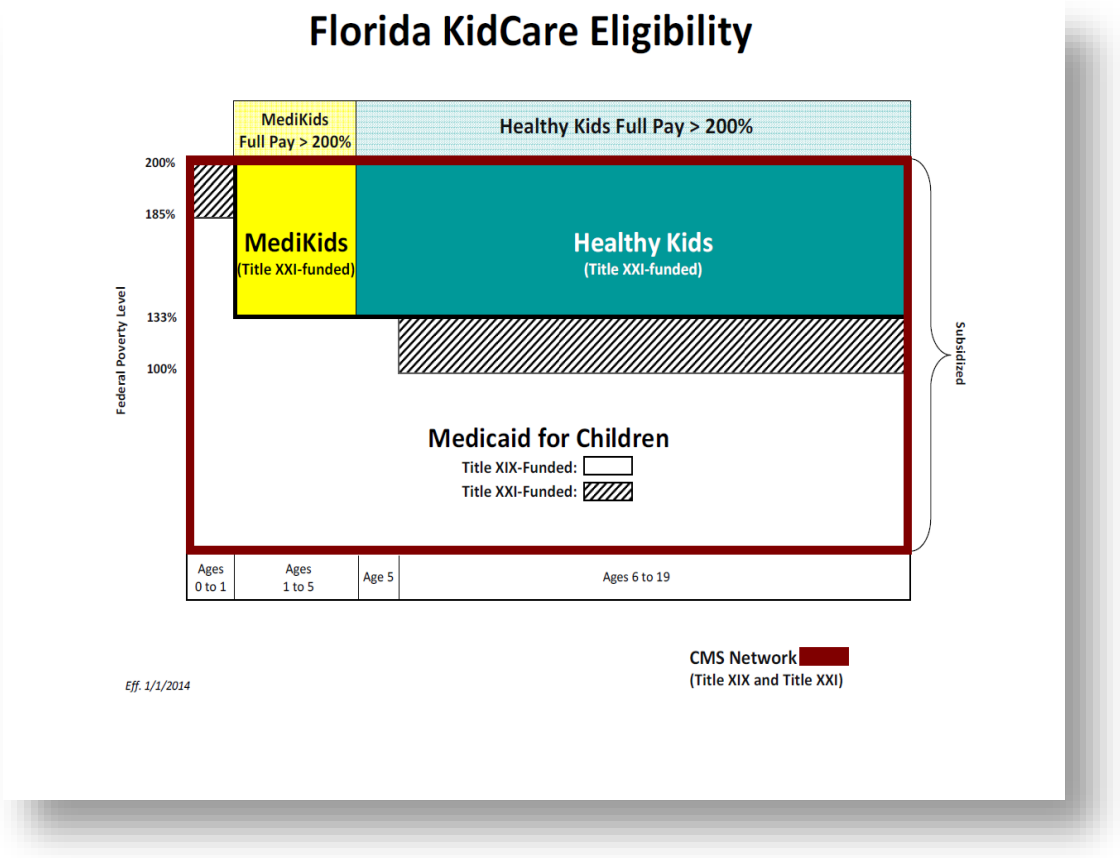
The Florida Medicaid Program is a partnership between the federal and state governments where the federal and state governments share the costs of the program. Each state operates its own Medicaid program under a state plan that must be approved by the federal Centers for Medicare and Medicaid Services. The plan outlines current Medicaid eligibility standards, policies, and reimbursement methodologies.

Eligibility for the Medicaid program is based on a number of factors, including age, household or individual income, and assets. State Medicaid eligibility payment guidelines are provided in statute under s. 409.903, F.S., (Mandatory Payments for Eligible Persons) and s. 409.904, F.S., (Optional Payments for Eligible Persons). Minimum coverage thresholds are established in federal law for certain population groups, such as children.

Florida Kidcare Program

The Florida Kidcare Program (the program) was created in 1998 by the Florida Legislature in response to the federal enactment of the Children's Health Insurance Program (CHIP) in 1997.[1] Initially authorized for 10 years and then re-authorized[2] through 2019 with federal funding through 2015, the CHIP provides subsidized health insurance coverage to uninsured children who do not qualify for Medicaid but who have family incomes under 200 percent of the federal poverty level (FPL) and meet other eligibility criteria. The state statutory authority for the program is found under part II of ch. 409, ss. 409.810 through 409.821, F.S.

The program includes four operating components: Medicaid for children, Medikids, the Children's Medical Services Network, and the Florida Healthy Kids Corporation (FHKC). The following chart illustrates the different program components and funding sources:[3]



[1] Social Security Administration, *Title XXI - State Children's Health Insurance Program*, http://www.ssa.gov/OP_Home/ssact/title21/2100.htm (last visited Mar. 20, 2014).
[2] Children's Health Insurance Re-Authorization Act of 2009, Pub. Law 2009-3, http://www.gpo.gov/fdsys/pkg/PLAW-111publ3/pdf/PLAW-111publ3.pdf (last visited Mar. 20, 2014).
[3] Department of Health - Florida Kidcare, *Florida Kidcare Eligibility Chart*, http://www.floridahealth.gov/AlternateSites/KidCare/images/data/2014KidCareFlag.pdf (last visited Mar. 20, 2014).

Coverage for the non-Medicaid program components are funded through Title XXI of the federal Social Security Act. Title XIX of the Social Security Act (Medicaid), state funds and family contributions also provide funding for the different components. Family contributions under the Title XXI component are based on family size, household incomes, and other eligibility factors. Families above the income limits for premium assistance or who are not otherwise eligible for premium assistance are offered the opportunity to participate in the program at a non-subsidized rate (full pay). Currently, the income limit for premium assistance is 200 percent of the FPL.

Several state agencies and the FHKC share responsibilities for the program. The Agency for Health Care Administration (AHCA), the Department of Children and Families (DCF), the Department of Health (DOH), and the FHKC have specific duties under Kidcare as detailed in part II of ch. 409, F.S. The DCF determines eligibility for Medicaid. The FHKC receives all Kidcare applications and screens for Medicaid eligibility and determines eligibility for all Title XXI programs, referring applications to the DCF, as appropriate, for a complete Medicaid determination.

To enroll in Kidcare, families use a form that is both a Medicaid and a CHIP application. Families may apply using the paper application or an online application. Both formats are available in English, Spanish, and Creole. Income eligibility is determined through electronic data matches with available databases or, in cases where income cannot be verified electronically, through submission of current pay stubs, tax returns, or W-2 forms.

The 2013-2014 General Appropriations Act appropriated $474,825,007 for the Title XXI (CHIP) components.[4] As of February 1, 2014, a total of 2,121,428 children enrolled in Kidcare.[5]

PROGRAM	ENROLLMENT
Medicaid - Title XIX funded	1,809,869
Medicaid - Title XXI funded	279,396
Healthy Kids - Total	231,345
Children's Medical Services Network	21,145
Medikids	31,454
Total Florida Kidcare Enrollment:	**2,121,428**

Under s. 409.814, F.S., the program's eligibility guidelines are described in conformity with current Title XIX and Title XXI terminology and requirements for each funding component. A child who is an alien, but does not meet the definition of a qualified alien in the United States, is specifically excluded from eligibility from Title XXI premium assistance.

Eligibility of Alien Children for Medicaid and the CHIP

The Immigration and Nationality Act (INA) was created in 1952 to consolidate a variety of statutes governing immigration law. The INA has been amended numerous times since 1952.

[4] 2013-2014 General Appropriation Act, Ch 2013-40, ss. 174-179, Laws of Fla.
[5] Agency for Health Care Administration, *Florida Kidcare Enrollment Report - February 2014*, on file with the Senate Health Policy Committee.

The INA defines the term "alien" as "any person not a citizen or national of the United States."[6] Nationals of the United States are citizens of the United States, or persons who, though not a citizen of the United States, owe permanent allegiance to the United States.[7]

Generally, under the INA, an alien is not eligible for any state or local public benefit, including health benefits, unless the alien is:[8]

- A qualified alien;[9]
- A nonimmigrant alien;[10] or,
- An alien who is paroled into the United States under the INA.[11]

There are limited exceptions to the ineligibility for public benefits for treatment of emergency medical conditions, emergency disaster relief, immunizations, and services such as soup kitchens, crisis counseling and intervention, and short term shelter.[12]

The INA gives states the authority to provide that an alien who is not lawfully present in the United States is eligible for any state or local public benefit for which the alien would otherwise be eligible, but only through the enactment of a state law which affirmatively provides for such eligibility.[13]

The enactment of the Personal Responsibility and Work Opportunity Reconciliation Act (PRWORA) of 1996 (Public Law 104-193), placed limitations on federal funding for health care of immigrant families. The law imposed a 5-year waiting period on certain groups of qualified aliens, including most children and pregnant women who were otherwise eligible for Medicaid.[14] Medicaid coverage for individuals subject to the 5-year waiting period and for those who do not meet the definition of qualified alien was limited to treatment of an emergency medical condition. The 5-year waiting period also applies to children and pregnant women under the CHIP. The PRWORA did not affect eligibility of undocumented aliens and these individuals remain ineligible for services, except for emergency services under Medicaid.

The Children's Health Insurance Program Reauthorization Act (CHIPRA) of 2009 (Public Law 111-3), permits states to cover certain children and pregnant women who are "lawfully residing in the United States" in both Medicaid and CHIP, notwithstanding certain provisions under PRWORA. States may elect to cover these groups under Medicaid only or under both Medicaid and CHIP. The law does not permit states to cover these new groups only in CHIP, without also extending the option to Medicaid children.[15]

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[6] *See* 8 U.S.C. s. 1101(a)(3).
[7] *See* 8 U.S.C. s. 1101(a)(21) and (22).
[8] *See* 8 U.S.C. s. 1621(a).
[9] *See* 8 U.S.C. s.1641(b) and (c). There are nine classes of qualified aliens.
[10] *See* 8 U.S.C. s. 1101(a)(15). There are 22 classes of nonimmigrant aliens identified in this section.
[11] *See* 8. U.S.C. s. 1182(d)(5).
[12] *See* 8 U.S.C. s. 1621(b).
[13] *See* 8 U.S.C. s. 1621(d).
[14] Section 403 of Pub. L No. 104-193, H.R. 3734,104th Congress (Aug. 22, 1996).
[15] *See* 42 U.S.C. s. 1397gg(e).

Prior to the enactment of the CHIPRA provisions, the term "lawfully residing" had not been used to define eligibility for either Medicaid or CHIP; however, the term has been used by the United States Department of Agriculture (USDA) and the Social Security Administration (SSA). The federal Centers for Medicare and Medicaid Services utilized existing regulations from these agencies to define a lawful presence for Medicaid and CHIP through a July 1, 2010 "Dear State Health Official" letter.[16] The letter states that children and pregnant women who fall into one of the following categories will be considered "lawfully present." These individuals are eligible for Medicaid and CHIP, if the state elects the option under CHIPRA, and the child or pregnant woman meets the state residency requirements and other Medicaid or CHIP eligibility requirements.

- A qualified alien as defined in section 431 of PRWORA;
- An alien in non-immigrant status who has not violated the terms of the status under which he or she was admitted or to which he or she has changed after admission;
- An alien who has been paroled into the United States pursuant to section 212(d)(5) of the INA for less than 1 year, except for an alien paroled for prosecution, for deferred inspection or pending removal proceedings;
- An alien who belongs to one of the following classes:
  - Temporary resident status pursuant to section 210 or 245A of the INA (8 U.S.C. s. 1160 or 1255a, respectively);
  - Temporary Protected Status (TPS) pursuant to section 244 of the INA (8 U.S.C. s. 1254a), and pending applicants for TPS who have been granted employment authorization under 8 C.F.R. s. 274a.12(c)(9), (10), (16), (18), (20), (22), or (24);
  - Family Unity beneficiaries pursuant to section 301 of Public Law 101-649, as amended;
  - Deferred Enforced Departure (DED) pursuant to a decision made by the President;
  - Deferred action status; or,
  - Visa petition has been approved and has a pending application for adjustment of status.
- A pending applicant for asylum under section 208(a) of the INA (8 U.S.C. s. 1158) or for withholding of removal under section 241(b)(3) of the INA (8 U.S.C. s. 1231) or under the Convention Against Torture, who has been guaranteed employment authorization, and such an applicant under the age of 14 who has had an application pending for at least 180 days;
- An alien who has been granted withholding of removal under the Convention Against Torture;
- A child who has a pending application for Special Immigrant Juvenile status as described in section 101(a)(27)(J) of the INA (8 U.S.C. s. 1101 (a)(27)(J));
- An alien who is lawfully present in the Commonwealth of the Northern Mariana Islands under 48 U.S.C. s. 1806(e); or,
- An alien who is lawfully present in American Samoa under the immigration laws of American Samoa.

[16] Centers for Medicare and Medicaid Services, *Medicaid and CHIP Coverage of "Lawfully Residing" Children and Pregnant Women*, State Health Official Letter, CHIPRA#17 (July 1, 2010), http://downloads.cms.gov/cmsgov/archived-downloads/SMDL/downloads/SHO10006.pdf (last visited Mar. 20, 2014).

As of January 31, 2014, 21 states cover lawfully residing children in both Medicaid and CHIP and 27 states, including Washington, D.C., cover these children in Medicaid only.[17]

III. Effect of Proposed Changes:

Section 1 amends s. 409.811, F.S., to define a "lawfully residing child" as a child who:

- Is present in the United States as defined under 8 C.F.R. s. 103.12(a);
- Meets Medicaid or federal Children's Health Insurance Program (CHIP) residency requirements, and,
- May be eligible for federal premium assistance under s. 214 of CHIPRA and related federal regulations.

The definition for a "qualified alien" is deleted from s. 409.811, F.S.

Section 2 amends s. 409.814, F.S., to replace references to "qualified alien" with "lawfully residing child" when referring to children who are not eligible for Title XXI funded premium assistance. The bill also clarifies that Kidcare program eligibility is not being extended to an undocumented immigrant.

Section 3 amends s. 409.904, F.S., relating to optional Medicaid payments, to designate that a child younger than 19 years of age that is a lawfully residing child as defined in s. 409.811, F.S., is eligible for Medicaid under s. 409.903, F.S.

Section 4 amends s. 624.91, F.S., the Florida Healthy Kids Corporation Act, to conform to changes made under the act and update references to modified or deleted terms.

Section 5 provides an effective date of July 1, 2014.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

[17] Centers for Medicare and Medicaid Services, *Medicaid and CHIP Coverage of Lawfully Residing Children and Pregnant Women*, http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Outreach-and-Enrollment/Lawfully-Residing.html (last visited Mar. 20, 2014).

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Expanding eligibility to additional children who may currently be uninsured may have a positive impact on health care providers that currently provide health care services to this population. Uncompensated care costs by these providers may be reduced with increased insured rates.

C. Government Sector Impact:

Since more children would apply for Medicaid and CHIP, the additional enrollment would have an administrative and enrollment impact on the agency, the DOH, and the Florida Healthy Kids Corporation. The combined enrollment impact for the 2014-2015 fiscal year is provided below:

Agency for Health Care Administration

Title XXI - Children's Health Insurance Program Impact	
Total Additional Costs:	$5,580,328
Less: Federal Funds under Title XXI (28.63% Federal Match)	$3,741,169
Less: Grants & Donations Trust Fund (Family Premium Contributions)	$338,392
State Funds Required - General Revenue (71.37 % State Match)	$1,500,766
Assumes 2,652 additional children would be covered per month for the first 12 months and on a recurring basis.	
Title XIX - Medicaid	
Total Additional Costs:	$63,632,779
Less: Federal Funds under Title XIX: (59.10% Federal Match)	$37,606,972
Less: Grants & Donations Trust Fund:	$0
State Funds Required: General Revenue: (40.90% State Match)	$26,025,807
Assumes 22,903 additional children would be covered in Medicaid per month for the first month and on a recurring basis.	
TOTAL ENROLLMENT COST IMPACT RECURRING STATE REVENUE NEEDED - AHCA:	**$27,526,573**

Department of Children and Families

In addition to enrollment costs, the DCF estimates recurring administrative costs for workload increases related to additional enrollment and non-recurring costs for programming changes to the eligibility system for the 2014-2015 fiscal year for a total of all funds of $169,132, approximately 50 percent of which would be funded through a Medicaid administration grant.

Salaries and Benefits - 3 FTEs:	$107,530
$27,941 Minimum Salary @ 3 FTE (8.3% lapse)	
$10,785 Benefits @ 3 FTE	
Expenses:	
Recurring Costs per FTE @ $6,261	$18,783
Non-Recurring Programming Costs, Equipment	$42,819
TOTAL:	$169,132
State Funds Required for 2014-2015: (50% Federal/State Match)	**$84,566**

The Florida Healthy Kids Corporation reports no additional impact. Enrollment in the Children's Medical Services Network component is incorporated in the Title XXI and Title XIX projections.

The combined total state funds required for the 2014-2015 fiscal year for recurring and non-recurring state costs is estimated at $27,611,139.

VI. Technical Deficiencies:

The AHCA does not believe the proposed language for s. 409.904, F.S., extends eligibility for optional Medicaid services to immigrant children lawfully residing in the United States without requiring them to wait. The AHCA suggests the provision be re-written to clarify that these lawfully-residing children are eligible for Medicaid goods and services.[18]

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 409.811, 409.814, 409.904, and 624.91.

[18] Agency for Health Care Administration, *2014 Agency Legislative Bill Analysis - HB 7 (January 21, 2014)*, on file with Senate Health Policy. Confirmed via telephone conversation with Gail Hansen, Agency staff that SB 282 contains similar conflict on Mar. 20, 2014.

IX. Additional Information:

A. Committee Substitute – Statement of Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.

This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.

By Senator Garcia

38-00239A-14 2014282__

A bill to be entitled

An act relating to the Florida Kidcare program; amending s. 409.811, F.S.; defining the term "lawfully residing child" and deleting the definition for "qualified alien"; amending s. 409.814, F.S.; revising eligibility for the program to conform to changes made in the definitions; clarifying that undocumented immigrants are excluded from eligibility; amending s. 409.904, F.S.; providing eligibility for optional payments for medical assistance and related services for certain lawfully residing children; clarifying that undocumented immigrants are excluded from eligibility for optional Medicaid payments or related services; amending s. 624.91, 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. Present subsections (17) through (22) of section 409.811, Florida Statutes, are renumbered as subsections (18) through (23), respectively, a new subsection (17) is added to that section, and present subsection (23) of that section is amended, to read:

409.811 Definitions relating to Florida Kidcare Act.—As used in ss. 409.810-409.821, the term:

(17) "Lawfully residing child" means a child who is lawfully present in the United States as defined in 8 C.F.R. s. 103.12(a), meets Medicaid or federal Children's Health Insurance Program (CHIP) residency requirements, and may be eligible for medical assistance with federal financial participation as provided under s. 214 of the Children's Health Insurance Program Reauthorization Act of 2009, Pub. L. No. 111-3, and related federal regulations.

~~(23) "Qualified alien" means an alien as defined in s. 431 of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996, as amended, Pub. L. No. 104-193.~~

Section 2. Paragraph (c) of subsection (4) of section 409.814, Florida Statutes, is amended to read:

409.814 Eligibility.—A child who has not reached 19 years of age whose family income is equal to or below 200 percent of the federal poverty level is eligible for the Florida Kidcare program as provided in this section. If an enrolled individual is determined to be ineligible for coverage, he or she must be immediately disenrolled from the respective Florida Kidcare program component.

(4) The following children are not eligible to receive Title XXI-funded premium assistance for health benefits coverage under the Florida Kidcare program, except under Medicaid if the child would have been eligible for Medicaid under s. 409.903 or s. 409.904 as of June 1, 1997:

(c) A child who is an alien~~,~~ but who does not meet the definition of a lawfully residing child ~~qualified alien, in the United States~~. This paragraph does not extend Kidcare program eligibility to an undocumented immigrant.

Section 3. Present subsections (8) and (9) of section 409.904, Florida Statutes, are renumbered as subsections (9) and (10), respectively, and a new subsection (8) is added to that

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

section, to read:

409.904 Optional payments for eligible persons.—The agency may make payments for medical assistance and related services on behalf of the following persons who are determined to be eligible subject to the income, assets, and categorical eligibility tests set forth in federal and state law. Payment on behalf of these Medicaid eligible persons is subject to the availability of moneys and any limitations established by the General Appropriations Act or chapter 216.

(8) A child younger than 19 years of age who, notwithstanding s. 414.095(3), would be eligible for Medicaid under s. 409.903, except that the child is a lawfully residing child as defined in s. 409.811. This subsection does not extend eligibility for optional Medicaid payments or related services to an undocumented immigrant.

Section 4. Paragraph (b) of subsection (3) of section 624.91, Florida Statutes, is amended to read:

624.91 The Florida Healthy Kids Corporation Act.—

(3) ELIGIBILITY FOR STATE-FUNDED ASSISTANCE.—Only the following individuals are eligible for state-funded assistance in paying Florida Healthy Kids premiums:

(b) Notwithstanding s. 409.814, a legal alien ~~aliens~~ who is ~~are~~ enrolled in the Florida Healthy Kids program as of January 31, 2004, who does ~~do~~ not qualify for Title XXI federal funds because he or she is ~~they are~~ not a lawfully residing child ~~qualified aliens~~ as defined in s. 409.811.

Section 5. This act shall take effect July 1, 2014.

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Health Policy

BILL:	SB 572
INTRODUCER:	Senator Sobel
SUBJECT:	Use of a Tanning Facility by a Minor
DATE:	March 19, 2014
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Peterson	Stovall	HP	**Pre-meeting**
2.			CJ	
3.			RC	

I. Summary:

This bill prohibits minors from using tanning devices, such as tanning beds, at a tanning facility unless the use is prescribed by a physician to treat a medical condition and the minor's parent or legal guardian gives written consent. The consent requirement includes a statement signed by the minor's parent or guardian that is witnessed by the tanning facility operator or proprietor authorizing a specified number of sessions as prescribed by the minor's health care provider. The specified number of tanning sessions may not exceed the number prescribed, the rules of the Department of Health (DOH), or the manufacturer's exposure schedule.

II. Present Situation:

Ultraviolet Radiation Exposure Risks

Skin cancer is the most common form of cancer. Basal cell and squamous cell carcinomas, two types of skin cancer, are successfully cured at high rates. However, melanoma, the third most common skin cancer, poses a greater threat, especially among minors. Approximately 65 to 90 percent of melanomas are caused by exposure to UV light. Persons with a history of one or more blistering sunburns during childhood or adolescence are two times more likely to develop melanoma than those who did not have such exposures. More than one half of a person's lifetime UV light exposure occurs during childhood and adolescence.[1] The American Cancer Society has estimated that there were 4,330 new cases of melanoma of the skin for the state of Florida in 2013.[2]

[1] Centers for Disease Control and Prevention, *Guidelines for School Programs to Prevent Skin Cancer* (Apr. 26, 2002), *available at* http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5104a1.htm (last visited on Mar. 19, 2014).
[2] American Cancer Society, Surveillance and Health Policy Research, *Cancer Facts & Figures 2013*, 5, *available at* http://www.cancer.org/acs/groups/content/@epidemiologysurveilance/documents/document/acspc-036845.pdf (last visited Mar. 19, 2014).

According to the Centers for Disease Control and Prevention (CDC), the best way to prevent skin cancer is to protect oneself from the sun by seeking shade, covering up skin exposed to the sun, wearing a wide brim hat, wearing sunglasses, and wearing sunscreen. The CDC recommends avoiding tanning beds and sunlamps because they emit UV rays that are as dangerous as those from the sun.[3]

According to the 2011 Youth Risk Behavior Surveillance System,[4] the following proportions of youth report indoor tanning:[5]

- 13 percent of all high school students.
- 21 percent of high school girls.
- 32 percent of girls in grade 12.
- 29 percent of white high school girls.

Federal Regulation of Sunlamp Products

Since 1979, the U.S. Food and Drug Administration (FDA) has regulated the manufacture of sunlamp products and ultraviolet lamps. The regulation, codified in 21 C.F.R. s. 1040.20, specifies several sunlamp product requirements including: protective eyewear, a UV radiation warning label, detailed user instructions, a timer system, a recommended exposure schedule, and the maximum recommended exposure time. The FDA also regulates the use of dihydroxyacetone (DHA), a color additive that darkens the skin by reacting with amino acids in the skin's surface, which is commonly the active ingredient in most sunless tanning sprays or bronzers.[6]

State Regulation of Tanning Facilities

As of February 2014, at least 33 states and the District of Columbia regulate minors' use of tanning devices.[7] The policies that states have adopted vary, but generally include one or more of these limitations: age restrictions, parental accompaniment requirements, and parental written permission. Currently California, Illinois, Nevada, Texas and Vermont ban the use of tanning beds for all minors under 18.[8]

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[3] Centers for Disease Control and Prevention, *What Can I Do to Reduce My Risk?*, http://www.cdc.gov/cancer/skin/basic_info/prevention.htm (last visited Mar. 19, 2014).

[4] The Youth Risk Behavior Surveillance System within the Centers for Disease Control monitors six types of health-risk behaviors that contribute to the leading causes of death and disability among youth and adults, including: behaviors that contribute to unintentional injuries and violence; sexual behaviors that contribute to unintended pregnancy and sexually transmitted diseases, including HIV infection; alcohol and other drug use; tobacco use; unhealthy dietary behaviors; and inadequate physical activity.

[5] Centers for Disease Control, *Skin Cancer*, http://www.cdc.gov/cancer/skin/basic_info/indoor_tanning.htm (last visited Mar. 19, 2014).

[6] 21 C.F.R. s. 73.1150.

[7] National Conference of State Legislatures, *Indoor Tanning Restrictions for Minors, A State-by-State Comparison*, http://www.ncsl.org/research/health/indoor-tanning-restrictions.aspx (last visited Mar. 19, 2014).

[8] *Id.*

Regulation of Tanning Facilities in Florida

The DOH, through the county health departments, currently licenses and inspects more than 1,600 tanning facilities with over 7,100 tanning devices.[9] Tanning facilities[10] subject to state regulation are facilities that operate tanning devices[11], which emit electromagnetic radiation of wavelengths between 200 and 400 nanometers.[12] The DOH does not regulate products or devices that create the appearance of a tan, such as airbrush tanning or spray-on tanning.[13] To operate a tanning facility a person must obtain a license, subject to annual renewal, and meet minimum requirements including: training, sanitation standards, safety provisions, and record requirements.[14]

Tanning facilities are required to provide each customer a written warning that states:[15]

- Not wearing the provided eye protection can cause damage to the eyes;
- Overexposure causes burns;
- Repeated exposure can cause premature aging of the skin or skin cancer;
- Abnormal skin sensitivity or burning may be caused by certain foods, cosmetics, or medications, including, without limitation, tranquilizers, diuretics, antibiotics, high blood pressure medicines, or birth control pills;
- Any person who takes prescription or over-the-counter medication should consult a physician before using a tanning device; and,
- The tanning facility's liability insurance information or a statement that the facility does not carry liability insurance for injuries caused by tanning devices.

Tanning facilities are also required to post a sign near each tanning device which states, in all caps, "Danger, Ultraviolet Radiation," with a list of detailed instructions.[16] Each time a customer uses a tanning device or executes or renews a contract, facilities must require the customer to sign a written statement acknowledging that he or she has read and understands the warnings and agrees to use protective eyewear.[17]

Tanning facilities must limit each customer to the maximum exposure time recommended by the manufacturer of the tanning device.[18] The DOH requires tanning facilities to limit customers to one tanning session within a 24-hour period.[19]

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[9] Florida Department of Health, *Health Issues*, http://www.floridahealth.gov/healthy-environments/tanning-facilities/index.html (last visited March 20, 2014).
[10] "Tanning facility" is defined as a place of business which provides access to a tanning device by customers. (s. 381.89(1)(a), F.S.)
[11] This includes a sunlamp, tanning booth, or tanning bed or any accompanying equipment." (*See* s. 381.89(1)(c), F.S.)
[12] Tanning facilities that use only phototherapy devices that emit ultraviolet radiation which are used by or under the direct supervision of a physician are exempt from regulation under s. 381.89, F.S. *See* s. 381.89(2), F.S.
[13] Air-brush and spray-on tanning devices contain DHA, which is subject to FDA regulation. (*Supra* note 6.)
[14] Section 381.89, F.S., and Rule 64E-17, F.A.C.
[15] Section 381.89(4)(a), F.S.
[16] Section 381.89(4)(b), F.S.
[17] Section 381.89(6)(g), F.S.
[18] Section 381.89(6)(e), F.S.
[19] Rule 64E-17.002(2)(m), F.A.C.

Minors 14 years of age or older may use a tanning device if the tanning facility has a statement on file signed by the minor's parent or legal guardian stating that the parent or legal guardian has read and understands the warnings provided by the tanning facility, consents to the minor's use of a tanning device, and agrees that the minor will use the provided protective eyewear. Minors under the age of 14 must be accompanied by a parent or legal guardian during each visit to a tanning facility.[20]

III. Effect of Proposed Changes:

This bill further restricts the use of tanning facilities by minors. Specifically, the bill prohibits a tanning facility from allowing a minor to use a tanning device unless the use is prescribed by a physician to treat a medical condition and the minor's parent or legal guardian gives written consent. The required consent must include a statement signed by the minor's parent or guardian that is witnessed by the tanning facility operator or proprietor authorizing a specified number of sessions as prescribed by the minor's health care provider. The specified number of tanning sessions may not exceed the number prescribed, the rules of the DOH, or the manufacturer's exposure schedule.

The bill has an effective date of October 1, 2014.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Tanning facilities may incur a small cost because of the cost to revise their consent forms to comply with the requirement for the forms to be witnessed and to authorize a specified number of visits.

[20] Section 381.89(7) and (8), F.S.

Tanning facilities are likely to lose a portion of their business because the bill conditions minor's use on a written prescription for a related medical condition.

C. Government Sector Impact:

The DOH anticipates an additional, but indeterminate, expense resulting from facility inspections to determine compliance with the new requirements or to investigate any related complaints.

VI. Technical Deficiencies:

The term "health care provider" is not defined by the bill. The Legislature may wish to define or narrow the scope of the term if its intent is to capture only dermatologists or those health care practitioners who are most likely to prescribe UV light treatment for medical conditions.

Line 60 refers to a health care provider "authorizing" tanning sessions. That would should be changed to "prescribed," consistent with the terminology used on line 48.

Current law requires a tanning facility to limit a customer to the maximum exposure time recommended by the device manufacturer, so including this same prohibition on lines 63–64 is redundant.[21] As an alternative, the Legislature may wish to require that the tanning facility may not exceed the exposure time or scheduled frequency of visits[22] when indicated on the prescription or practitioner's order, if lower than what is currently allowed by statute and rule.

VII. Related Issues:

The DOH has expressed concern regarding the intent of lines 61 – 64 and whether the DOH is expected to adopt new rules to implement the bill's provisions, or whether the reference to department rules is to the existing rule that prohibits more than one tanning session in a 24-hour period.

VIII. Statutes Affected:

This bill substantially amends section 381.89 of the Florida Statutes.

IX. Additional Information:

A. Committee Substitute – Statement of Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.

[21] *Supra* note 18.
[22] *Supra* note 19.

This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.

974516

LEGISLATIVE ACTION

Senate . House

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The Committee on Health Policy (Sobel) recommended the following:

Senate Amendment (with title amendment)

Delete lines 60 - 64

and insert:

the minor as prescribed by the minor's health care provider.

(b) The tanning sessions provided by a tanning facility may not exceed the number, frequency, or exposure time prescribed by the health care provider if the number, frequency, or exposure time in the prescription is less than otherwise allowed by this section or rule of the department.

974516

11
12 ========== T I T L E A M E N D M E N T ==========
13 And the title is amended as follows:
14 Delete lines 13 - 16
15 and insert:
16 prohibiting a tanning facility from providing tanning
17 sessions that exceed the number, frequency, or
18 exposure time prescribed by the health care provider
19 or allowed under department's rule; requiring a

By Senator Sobel

33-00527A-14 2014572__

A bill to be entitled

An act relating to the use of a tanning facility by a minor; providing a short title; amending s. 381.89, F.S.; revising the age of a minor prohibited from using a tanning device at a tanning facility; prohibiting a minor of any age from using a tanning device; providing an exception if a health care provider prescribes tanning sessions for a minor to treat a medical condition and the tanning facility has on file a statement signed by the minor's parent or guardian; requiring the statement to be witnessed by the operator or proprietor of the tanning facility; prohibiting a tanning facility from providing a number of tanning sessions that exceeds the health care provider's authorization, the department's rules, or the manufacturer's exposure schedule; requiring a parent or guardian to accompany a minor who is younger than 14 years of age during the prescribed tanning sessions; providing an effective date.

WHEREAS, frequent exposure to ultraviolet radiation through the use of tanning devices increases the risk of developing skin cancer, including melanoma, the deadliest form of skin cancer, and

WHEREAS, the American Academy of Dermatology estimates that nearly 2.3 million minors use tanning devices annually, and

WHEREAS, the United States Food and Drug Administration warns that a minor's overexposure to ultraviolet radiation during childhood greatly increases the chances of developing

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

33-00527A-14 2014572__

skin cancer later in life, and

WHEREAS, the Legislature finds that it is in the public interest to protect children from the harmful effects of ultraviolet radiation through the use of tanning devices by restricting a minor's access to such devices unless authorized by a health care provider, NOW, THEREFORE,

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

Section 1. This act may be cited as the "Preventing Youth Cancer Act."

Section 2. Present subsections (9) through (13) of section 381.89, Florida Statutes, are redesignated as subsections (8) through (12), respectively, and present subsections (7), (8), and (10) of that section are amended, to read:

381.89 Regulation of tanning facilities.—

(7)(a) A tanning facility may not allow a minor ~~between the ages of 14 and 18~~ to use a tanning device unless:

1. The use of the tanning device is prescribed by a health care provider to treat a medical condition; and

2. The tanning facility ~~it~~ has on file a statement signed by the minor's parent or legal guardian and witnessed by the operator or proprietor of the tanning facility stating that the parent or legal guardian:

a. Has read and understands the warnings given by the tanning facility;~~,~~

b. Consents to the minor's use of a tanning device;~~, and~~

c. Agrees that the minor will use the provided protective eyewear; and~~.~~

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

d. Authorizes a specified number of tanning sessions for the minor as authorized by the minor's health care provider.

(b) The number of tanning sessions provided by a tanning facility may not exceed the number of sessions prescribed by the health care provider, the rules of the department, or the manufacturer's exposure schedule.

(c) The parent or legal guardian must accompany a minor who is younger than 14 years of age during the prescribed tanning sessions.

~~(8) A minor under the age of 14 must be accompanied by a parent or legal guardian when using a tanning device.~~

(9)~~(10) PENALTIES.~~

(a) Each of the following acts constitutes a felony of the third degree, punishable as provided in s. 775.082 or s. 775.083:

1. Owning or operating, or soliciting business as, a tanning facility in this state without first procuring a license from the department, unless specifically exempted by this section.

2. Obtaining or attempting to obtain a license by means of fraud, misrepresentation, or concealment.

(b) Each of the following acts constitutes a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083:

1. Failing to maintain the records required by this section or knowingly making false entries in such records.

2. Failing to comply with subsection (7) ~~or subsection (8)~~.

(c) The court may, in addition to other punishment provided for, suspend or revoke the license of any licensee under this

section who has been found guilty of any violation listed in paragraph (a) or paragraph (b).

(d) In the event the department or any state attorney shall have probable cause to believe that a tanning facility or other person has violated any provision of paragraph (a), an action may be brought by the department or any state attorney to enjoin such tanning facility or ~~any~~ person from continuing such violation, or engaging therein or doing any acts in furtherance thereof, and for such other relief as to the court seems appropriate.

Section 3. This act shall take effect October 1, 2014.

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Health Policy

BILL:	SB 584
INTRODUCER:	Senator Lee
SUBJECT:	Medical Examiners
DATE:	March 5, 2014
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Stovall	HP	**Pre-meeting**
2.			CA	

I. Summary:

SB 584 amends section 406.06 of the Florida Statutes to prevent a medical examiner or a county from charging a user fee for an examination, investigation, or autopsy performed pursuant to s. 406.11, F.S. The bill also amends s. 382.011, F.S.[1] to correctly cite only to ss. 406.11(1), F.S., rather than the entire section and to conform the language between the two sections of law that the death *involves* any of the enumerated circumstances rather than it is *due to* one of the enumerated circumstances.

II. Present Situation:

Medical Examiners Act

Part I of ch. 406 is titled the "Medical Examiners Act"[2] (act) and lays out minimum and uniform requirements for statewide medical examiner services. Among other things, the act establishes the Medical Examiners Commission[3] (commission) with duties including initiating cooperative policies with any agencies of the state; investigating, suspending, and removing medical examiners for violations of the act; overseeing the distribution of state funds for the medical examiner districts; and making any necessary agreements and contracts in order to effect the provisions of the act, subject to the approval of the executive director of the Florida Department of Law Enforcement (FDLE).[4] The act also requires the commission to establish medical

[1] This section requires the district medical examiner to determine the cause of death or fetal death for decedents whose death was due to any of the circumstances listed in s. 406.11, F.S., and who had not seen their primary or attending physician for over a year or for which there is a reason to believe that the death may have been due to an unlawful act or neglect.
[2] s. 406.01, F.S.
[3] The Medical Examiners Commission consists of seven members appointed by the Governor, one member appointed by the State Attorney General, and one member appointed by the State Surgeon General.
[4] s. 406.02, F.S.

examiner districts each of which is served by a medical examiner who is appointed by the Governor.[5] Currently, there are 24 medical examiner districts.[6]

Section 406.11(1), F.S., requires district medical examiners to determine the cause of death of a decedent who died or was found dead in their district:

- If the person died:
  - Of criminal violence;
  - By accident;
  - By suicide;
  - Suddenly, when in apparent good health;
  - Unattended by a practicing physician or other recognized practitioner;
  - In any prison or penal institution;
  - In police custody;
  - In any suspicious or unusual circumstance;
  - By criminal abortion;
  - By poison;
  - By disease constituting a threat to public health; or
  - By disease, injury, or toxic agent resulting from employment.
- If the dead body was brought into the state without proper medical certification; or,
- If the dead body is to be cremated, dissected, or buried at sea.[7,8]

Subsections (1) and (2)(a) of s. 406.11, F.S., require and grant authority to the medical examiner to make or have performed any examinations, investigations, and autopsies they deem necessary or that are requested by the state attorney for the purpose of determining the cause of death. Subsection (2) also restricts the medical examiners from retaining or furnishing any body part for any purpose other than those authorized in statute[9] without notifying the next of kin and grant rulemaking authority to the Commission to adopt rules for such notifications. Subsection (3) grants the Commission rulemaking authority to incorporate practice parameters for medical examiners.

Medical Examiner Fees

Section 406.06(3), F.S., entitles district and associate medical examiners to "compensation and such reasonable salary and fees as are established by the board of county commissioners in the respective districts." Presently, as required in s. 406.08, F.S., district medical examiners submit

[5] ss. 406.05 and 406.06, F.S.
[6] A map of the medical examiner districts can be found at http://myfloridamedicalexaminer.com/, last visited on Mar. 6, 2014.
[7] The medical examiner must approve the cremation of a dead body through a consent process that differs from one district to another. Some medical examiner districts require written consent while others may allow telephone approval. Approval will not be written in the death record margin or in such a way as to deface the record. See Vital Records Registration Handbook, 2012 revision, found at http://www.floridahealth.gov/certificates-and-registries/certificates/EDRS/_documents/HB2012Final.pdf, last visited on Mar. 6, 2014, page 73.
[8] In 2012, 44,895 dead bodies were buried, 106,827 were cremated, 1,001 were donated, and 8 were buried at sea. See Florida Death Count Query System, found at http://www.floridacharts.com/FLQUERY/Death/DeathCount.aspx, last visited on Mar. 6, 2014.
[9] In ch. 406, F.S., relating to medical examiners and the disposition of human remains; Part V of ch. 765, F.S., relating to the granting of anatomical gifts; and ch. 873, F.S., relating to the sale of anatomical matter.

an annual budget to the board of county commissioners which includes fees, salaries, and expenses for their office. Medical examiner office budgets that are established through contract with county governments[10] are often based on a fee-for-service schedule.[11] Each specific fee is approved by the board of county commissioners in each county within the district, and the fee may vary from county to county. In some districts, fees for a specific type of service are paid directly to the medical examiner's office, while in other districts, such fees go directly to the county's general revenue fund.[12] The fees charged by district medical examiner's offices for the services provided pursuant to s. 406.11, F.S., vary from district to district and, occasionally, from county to county. For example, according to the Medical Examiners Commission, for cremation services ten counties charge no fee[13] while the other 57 counties' fees vary with Miami-Dade county charging the highest fee at $63 and the average fee being approximately $31.30. The total amount of revenue generated by cremation service fees in 2012 was approximately $3.93 million.[14]

III. Effect of Proposed Changes:

Section 1 of the bill amends s. 382.011, F.S., to correctly cite to s. 406.11(1), F.S., rather than the whole section. Only subsection (1) of section 406.11, F.S., relates to causes of death. In addition, the conditions when a funeral director or other person must refer the case to the district medical examiner are changed from when the death was "due to" the causes in s. 406.11, F.S., which is conclusive, to when the death "involves" any such circumstances.

Section 2 of the bill amends s. 406.06, F.S., to restrict counties and medical examiners from charging user fees for examinations, investigations, and autopsies performed pursuant to s. 406.11, F.S.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

Article VII, subsection 18(a) of the Florida Constitution, provides that a county or municipality may not be bound by any general law requiring the county or municipality to spend funds or to take an action requiring the expenditure of funds, unless the Legislature has determined that such law fulfills an important state interest and unless:

- Funds have been appropriated that have been estimated at the time of enactment to be sufficient to fund such expenditure;
- The Legislature authorizes or has authorized a county or municipality to enact a funding source not available for such county or municipality on February 1, 1989, that can be used to generate the amount of funds estimated to be sufficient to fund such expenditure by a simple majority vote of the governing body of such county or municipality;

[10] Medical examiner services are provided by private contract in districts 1, 2, 5, 6, 8, 10, 12, 14, 16, 21, and 22. See FDLE bill analysis for SB 584, on file with Health Policy Committee Staff.
[11] Id.
[12] Supra n. 10
[13] Hardee, Highlands, Bay, Calhoun, Gulf, Holmes, Jackson, Washington, Collier, and Charlotte counties.
[14] Supra n. 10

- The law requiring such expenditure is approved by two-thirds of the membership in each house of the Legislature;
- The expenditure is required to comply with a law that applies to all persons similarly situated, including the state and local governments; or
- The law is either required to comply with a federal requirement or required for eligibility for a federal entitlement, which federal requirement specifically contemplates actions by counties or municipalities for compliance.

Subsection 18(d) provides an exemption from this prohibition. Laws determined to have an "insignificant fiscal impact," which means an amount not greater than the average statewide population for the applicable fiscal year times 10 cents (which is $1.93 million for 2012-2013 fiscal year), are exempt.

SB 584 may prevent counties and district medical examiners from charging fees which generated at least $3.93 million in revenue in 2012. As such, the law may be unenforceable unless passed by a two-thirds majority in each house of the Legislature.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Cost savings may be generated for individuals in the private sector who would have been charged a fee for one of the specified medical examiner services, however, these individual cost savings may result in increased costs to the private sector as a whole if affected counties choose to increase local taxes to recoup the lost fee revenue.

C. Government Sector Impact:

Local governments may incur a loss in revenue if they currently charge fees to cover costs of operations which would be prohibited by the changes in the bill.

VI. Technical Deficiencies:

None.

VII. Related Issues:

There is no distinction drawn in the bill between the types of fees allowed to be charged by a medical examiner and the "user fees" that are prohibited by the bill. Since the term "user fee" is not defined, this may cause some confusion as to exactly which fees may and may not be charged.[15]

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 382.011 and 406.06.

IX. Additional Information:

A. Committee Substitute – Statement of Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.

This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.

[15] Supra n. 10 at page 3

802414

LEGISLATIVE ACTION

Senate	.	House
Comm: WD	.	
03/11/2014	.	
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	.	
	.	

The Committee on Health Policy (Sobel) recommended the following:

Senate Amendment (with title amendment)

Delete lines 34 - 37
and insert:
county commissioners in the respective districts; however, a medical examiner or a county, other than a home rule charter county that has a population of at least 1.3 million, may not charge a user fee for an examination, investigation, or autopsy performed pursuant to s. 406.11.

802414

========== T I T L E A M E N D M E N T ==========
And the title is amended as follows:
Delete line 9
and insert:
of death; providing an exception; providing an effective date.

122668

LEGISLATIVE ACTION

Senate . House

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The Committee on Health Policy (Sobel) recommended the following:

Senate Amendment (with title amendment)

Delete lines 34 - 37

and insert:

county commissioners in the respective districts; however, a medical examiner or a county, other than a home rule charter county or a consolidated local government that has a population of at least 850,000, may not charge a user fee for an examination, investigation, or autopsy performed pursuant to s. 406.11.

122668

11
12 ========== T I T L E A M E N D M E N T ==========
13 And the title is amended as follows:
14 Delete line 7
15 and insert:
16 certain medical examiners from charging user fees for

868470

LEGISLATIVE ACTION

Senate . House

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The Committee on Health Policy (Brandes) recommended the following:

Senate Substitute for Amendment (122668) (with title amendment)

Delete lines 34 - 37
and insert:
county commissioners in the respective districts except that a medical examiner or a county may not charge more than $50 for determining the cause of death when a body is to be cremated, buried at sea, or dissected.

868470

========== T I T L E A M E N D M E N T ==========
And the title is amended as follows:
Delete lines 7 - 9
and insert:
medical examiners or counties from charging more than $50 for determining the cause of death when a body is to be cremated, buried at sea, or dissected; providing an effective date.

By Senator Lee

24-00733-14 2014584__

A bill to be entitled

An act relating to medical examiners; amending s. 382.011, F.S.; clarifying the circumstances under which a case must be referred to the district medical examiner for an investigation and determination of cause of death; amending s. 406.06, F.S.; prohibiting medical examiners from charging user fees for specified services involving a determination of cause of death; providing an effective date.

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

Section 1. Subsection (1) of section 382.011, Florida Statutes, is amended to read:

382.011 Medical examiner determination of cause of death.—

(1) In the case of a ~~any~~ death or fetal death involving any of the circumstances ~~due to causes or conditions~~ listed in s. 406.11(1) ~~406.11~~, which ~~any death that~~ occurred more than 12 months after the decedent was last treated by a primary or attending physician identified ~~as defined~~ in s. 382.008(3), or ~~any death~~ for which there is reason to believe that the death may have been due to an unlawful act or neglect, the funeral director or other person to whose attention the death may come shall refer the case to the district medical examiner of the county in which the death occurred or the body was found for investigation and determination of the cause of death.

Section 2. Subsection (3) of section 406.06, Florida Statutes, is amended to read:

406.06 District medical examiners; associates; suspension of medical examiners.—

(3) District medical examiners and associate medical examiners are ~~shall be~~ entitled to compensation and such reasonable salary and fees as are established by the board of county commissioners in the respective districts; however, a medical examiner or a county may not charge a user fee for an examination, investigation, or autopsy performed pursuant to s. 406.11.

Section 3. This act shall take effect July 1, 2014.

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Health Policy

BILL:	SB 1412
INTRODUCER:	Senator Joyner
SUBJECT:	Closing the Gap Grant Program
DATE:	March 25, 2014
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Peterson	Stovall	HP	**Pre-meeting**
2.			AHS	
3.			AP	

I. Summary:

SB 1412 expands the potential focus of Closing the Gap projects to include sickle cell disease. Projects receive Closing the Gap grants for activities that reduce racial and ethnic health disparities.

II. Present Situation:

Closing the Gap Grant Program

In 2000, the Legislature created the Reducing the Racial and Ethnic Health Disparities: "Closing the Gap" grant program, to stimulate the development of community and neighborhood-based projects to improve health outcomes of racial and ethnic populations.[1] The program is administered by the Department of Health (DOH). Grants are awarded for 1 year, but may be renewed annually, subject to available funds, if the funded project has achieved its quality standards, objectives, and outcomes.[2] Grants require a local match of one dollar for every three dollars awarded, although a portion[3] of the match may be in kind, in the form of free services or human resources.[4]

Applications must address each of the following required items:[5]

- The purpose and objectives of the project and which of the following required racial or ethnic disparities it addresses:
  - Decreasing racial and ethnic disparities in maternal and infant mortality rates or oral health care;

[1] Section 381.7352, F.S.
[2] Section 381.7355(4), F.S.
[3] Up to 50% in counties over 50,000 in population and 100% in counties of 50,000 or less. (s. 381.7355(2)(a), F.S.)
[4] Section 381.7356(2), F.S.
[5] Section 381.7355(2), F.S.

  - Decreasing racial and ethnic disparities in morbidity and mortality rates relating to cancer, HIV/AIDS, cardiovascular disease, or diabetes; or
  - Increasing adult and child immunization rates in certain racial and ethnic populations.
- Identification and relevance of the target population.
- Methods for obtaining baseline health status data and assessment of community health needs.
- Mechanisms for mobilizing community resources and gaining local commitment.
- Development and implementation of health promotion and disease prevention interventions.
- Mechanisms and strategies for evaluating the project's objectives, procedures, and outcomes.
- A proposed work plan, including a timeline for implementing the project.
- Likelihood that project activities will occur and continue in the absence of funding.

In the 2013-2014 fiscal year, the program received $3.1 million in state funding and awarded 15 grants averaging between $150,000 and $200,000.[6]

Sickle Cell Disease

Sickle Cell Disease (SCD) is a group of inherited red blood cell disorders. Healthy red blood cells are round. In someone who has SCD, the red blood cells become hard, sticky, and C (or sickle)-shaped. The sickle cells die early, which causes a constant shortage of red blood cells, and the cells clog blood flow in small blood vessels, which can cause pain and other serious problems such as infection, acute chest syndrome, and stroke.[7]

Sickle Cell Disease is diagnosed with a blood test, most often at birth during routine newborn screening tests.[8] It is a genetic disorder, inherited when a child inherits the gene from both parents. The only cure is bone marrow or stem cell transplant.

The exact number of persons with SCD is not known. The Centers for Disease Control and Prevention estimates that:[9]
- SCD affects 90,000 to 100,000 Americans.
- SCD occurs among about 1 out of every 500 Black or African-American births.
- SCD occurs among about 1 out of every 36,000 Hispanic-American births.

In 2005, medical expenditures for children with SCD averaged $11,702 for children with Medicaid coverage and $14,772 for children with employer-sponsored insurance. About 40 percent of both groups had at least one hospital stay.[10]

[6] Conversation with Mike Mason, Director, Office of Minority Health, Florida Dept. of Health (Mar. 21, 2014).
[7] Centers for Disease Control and Prevention, *Facts About Sickle Cell Disease*, http://www.cdc.gov/ncbddd/sicklecell/facts.html (last visited Mar. 22, 2014).
[8] Florida's newborn screening program includes sickle cell among the genetic disorders that are tested in newborns.
[9] Centers for Disease Control and Prevention, *Sickle Cell Disease, Data and Statistics*, http://www.cdc.gov/ncbddd/sicklecell/data.html (last visited Mar. 22, 2014).
[10] *Id.*

III. Effect of Proposed Changes:

SB 1412 adds decreasing racial and ethnic disparities in morbidity and mortality rates relating to sickle cell disease to the priority areas that a project receiving a Closing the Gap grant may address.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

SB 1412 expands the types of community-based projects that may receive state funding. Actual amounts will result from the award of available funds and are unknown at this time.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends section 381.7355 of the Florida Statutes.

IX. Additional Information:

A. Committee Substitute – Statement of Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.

This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.

By Senator Joyner

19-01229-14 20141412__

A bill to be entitled

An act relating to the Closing the Gap grant program; amending s. 381.7355, F.S.; adding a requirement for project proposals under the grant program to address racial and ethnic disparities in morbidity and mortality rates relating to sickle cell disease; providing an effective date.

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

Section 1. Paragraph (a) of subsection (2) of section 381.7355, Florida Statutes, is amended to read:

381.7355 Project requirements; review criteria.—

(2) A proposal must include each of the following elements:

(a) The purpose and objectives of the proposal, including identification of the particular racial or ethnic disparity the project will address. The proposal must address one or more of the following priority areas:

1. Decreasing racial and ethnic disparities in maternal and infant mortality rates.

2. Decreasing racial and ethnic disparities in morbidity and mortality rates relating to cancer.

3. Decreasing racial and ethnic disparities in morbidity and mortality rates relating to HIV/AIDS.

4. Decreasing racial and ethnic disparities in morbidity and mortality rates relating to cardiovascular disease.

5. Decreasing racial and ethnic disparities in morbidity and mortality rates relating to diabetes.

6. Increasing adult and child immunization rates in certain

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

19-01229-14 20141412__

racial and ethnic populations.

7. Decreasing racial and ethnic disparities in oral health care.

8. Decreasing racial and ethnic disparities in morbidity and mortality rates relating to sickle cell disease.

Section 2. This act shall take effect July 1, 2014.

CODING: Words ~~stricken~~ are deletions; words underlined are additions.