



Health Quality Subcommittee

Meeting Packet

**Monday, March 24, 2014
12:30 PM - 2:30 PM
306 HOB**

**Will Weatherford
Speaker**

**Kenneth L. "Ken" Roberson
Chair**

Committee Meeting Notice

HOUSE OF REPRESENTATIVES

Health Quality Subcommittee

Start Date and Time: Monday, March 24, 2014 12:30 pm
End Date and Time: Monday, March 24, 2014 02:30 pm
Location: 306 HOB
Duration: 2.00 hrs

Consideration of the following bill(s):

HB 211 Community Health Workers by Reed
HB 647 Infectious Disease Control by Adkins
HB 687 Florida Drug and Cosmetic Act by Magar
HB 1085 Behavioral Analysts by Rooney
HB 1225 HIV Testing by Saunders

Pursuant to rule 7.12, the deadline for amendments to bills on the agenda by non-appointed members is 6:00 p.m., Friday, March 21, 2014.

By request of the chair, all committee members are asked to have amendments to bills on the agenda submitted to staff by 6:00 p.m., Friday, March 21, 2014.

NOTICE FINALIZED on 03/20/2014 16:00 by Villar.Melissa

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 211 Community Health Workers
SPONSOR(S): Reed
TIED BILLS: IDEN./SIM. BILLS: SB 306

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee		Dunn <i>CD</i>	O'Callaghan <i>mo</i>
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

Community health workers (CHWs) assume a wide range of roles in various settings to assist individuals with health care services, generally by performing patient advocacy, education, and direct care in isolated, underserved, and low socioeconomic neighborhoods. CHWs work as paid or unpaid volunteers within the community in which they live or have strong ties.

The bill defines the activities CHWs perform in communities and requires the Department of Health (DOH) to create the Community Health Worker Task Force (Task Force). The bill provides for and outlines the requirements of the Task Force. The bill requires the Task Force to develop recommendations for inclusion of CHWs in health care or Medicaid reform, inclusion of CHWs in assisting residents with navigation and with provision of information on preventative health care, and inclusion of CHWs into health care delivery teams.

The Task Force will coordinate with The Florida Community Health Worker Coalition, colleges, universities, and other organizations to determine a procedure for standardization of qualifications and skills for CHWs employed by state-supported health care programs.

The bill has an insignificant negative fiscal impact on the DOH that can be absorbed within existing agency resources.

The bill provides a repeal date of December 1, 2015.

The bill shall take effect upon becoming law.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

Community Health Workers (CHWs) serve in local health care systems for pay or as volunteers to help alleviate health care disparities in communities. CHWs deliver health care services with cultural competency, in part through intimate knowledge of the neighborhoods they serve. A report prepared for the U.S. Department of Health and Human Services examined 53 studies between 1980 and 2008 and found evidence that CHWs improve health outcomes.¹ A workgroup under the Centers for Disease Control and Prevention (CDC) reviewed literature on CHWs, and reported the profession is uniquely qualified to strengthen community ties, build partnerships, and foster community action in health care. Research supports that CHWs augment health care utilization, access, and education.²

CHWs are recognized under a variety of names, including lay health educators, peer health promoters, community health outreach workers, and in Spanish, *promotores de salud*.³ In 2010, CHWs received a Standard Occupational Classification.⁴ Texas, Massachusetts, Ohio, and Minnesota have recently officially recognized the job category of CHW.⁵ Due to mounting visibility, more organizations including the Institute of Medicine are calling for CHW integration into health care strategies.⁶

CHWs perform a variety of services that include but are not limited to:

- Culturally competent education regarding prevention and disease management;
- Advocating for individuals and health care needs;
- Social support;
- Translation and interpretation of health care encounters;
- Help with health care literacy and accuracy;
- Providing direct services, such as health care screenings;
- Contributing to coordination of care;
- Strengthening of individual and community capacity;⁷
- Providing coaching, follow ups, referrals; and
- Patient navigation, particularly for chronic conditions.⁸

¹ RTI International-University of North Carolina Evidence-Based Practice Center, *Evidence Report/Technology Assessment Number 181, Outcomes of Community Health Worker Interventions*, June 2009, available at <http://www.ahrq.gov/downloads/pub/evidence/pdf/comhealthwork/comhwork.pdf> (last visited Mar. 20, 2014).

² National Center for Chronic Disease Prevention and Health Promotion, Division of Diabetes Translation, *Community Health Workers/Promotores de Salud: Critical Connections in Communities*, May 20, 2011, available at <http://www.cdc.gov/diabetes/projects/comm.htm> (last visited Mar. 20, 2014).

³ *Id.*

⁴ Bureau of Labor Statistics, *Standard Occupational Classification 21-1094 Community Health Workers*, March 11, 2010, available at <http://www.bls.gov/soc/2010/soc211094.htm> (last visited Mar. 20, 2014).

⁵ Hector Balcazar et al., *Community Health Workers Can be a Public Health Force for Change in The United States: Three Actions for a New Paradigm*, 101 AM. J. PUB. HEALTH 2199, 2199 (2011), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3222447/#R19> (last visited Mar. 20, 2014).

⁶ *Id.*

⁷ American Public Health Association, *Policy Database, Support for Community Health Workers to Increase Access and Reduce Health Inequities*, 2009, available at <http://www.apha.org/advocacy/policy/policysearch/default.htm?id=1393> (last visited Mar. 20, 2014).

⁸ See Hector Balcazar et al., *Community Health Workers Can be a Public Health Force for Change in The United States: Three Actions for a New Paradigm*, *supra* note 5.

In 2007, it was reported that Florida has 2,640 paid and 1,556 volunteer CHWs for a total of 4,205 CHWs, the fourth highest number in the country.⁹ In October 2010, the Department of Health (DOH) received the Policy, Environmental and System Change grant from the CDC to assist cancer coalitions.¹⁰ The Florida Cancer Control and Research Advisory Council (CCRAB)¹¹ called for utilization of CHWs as a priority strategy to facilitate treatment and access to services for minorities.¹² The CDC funds and CCRAB permitted the DOH to develop the Florida Community Health Worker Taskforce initiative in 2010 that evolved into the Florida Community Health Worker Coalition.¹³ The group promotes the profession of CHWs. The coalition is composed of five committees: Policy, Curriculum, Networking/Sustainability, Research, and Practice.¹⁴

Effect of Proposed Changes

The bill states that a “community health worker” (CHW) is a front line health care worker who is a trusted member of a community or has close insight into that community, and functions to enhance quality of health care by fostering a bridge between individuals and services in a culturally competent manner. The bill states that a CHW works in a “medically underserved community,” which is defined as a geographic area with a shortage of health care professionals that has a population with income below 185 percent of the federal poverty level and who lack health insurance and the ability to pay for it.

The bill delineates activities CHWs perform in communities to assist local residents with clinical services, education, outreach, advocacy, and data collection in a culturally competent manner. CHWs provide residents information on local resources, give social support, educate and deliver information on wellness and disease prevention, and help administer first aid and blood pressure screenings. CHWs advocate for oral health, mental health, and nutritional needs. CHWs facilitate communication with health care providers by fostering communication skills in residents, and ensuring appropriate coordination of care.

The bill directs the DOH to establish the Community Health Worker Task Force (Task Force) within a Florida College System institution or state university and at the request of an elected chair, use available resources to provide administrative support and services. The Task Force is comprised of:

- A member of the Senate appointed by the President of the Senate;
- A member of the House of Representatives appointed by the Speaker of the House of Representatives;
- A state official appointed by the Governor;
- Six culturally and regionally diverse CHWs appointed by the Surgeon General; and
- Three representatives of the Florida Community Health Worker Coalition appointed by the chair of the Florida Community Health Worker Coalition.

The bill states that the 12 Task Force members must elect a vice chair and chair, serve without compensation, meet at least quarterly, consist of a quorum of seven, and have a concurring vote by the majority of members to take action. The bill also provides that meetings may be held in person, by teleconference, or by other electronic means.

⁹ U.S. Department of Health and Human Services, Health Resources Services Administration, Bureau of Health Professionals, *Community Health Worker National Workforce Study*, March 2007, available at <http://bhpr.hrsa.gov/healthworkforce/reports/chwstudy2007.pdf> (last visited Mar. 20, 2014).

¹⁰ Department of Health Bill Analysis of HB 241, January 22, 2013, on file with committee staff.

¹¹ Section 1004.435, F.S.

¹² Florida Cancer Control and Research Advisory Council, Florida Cancer Plan Council: 2012-2013, available at <http://ccrab.org/Libraries/Document Library/2012-2013 Florida Cancer Plan Priority Strategies.sflb.aslx> (last visited Mar. 20, 2014).

¹³ University of Florida, College of Pharmacy, *Coalition: Development of the Coalition*, available at <http://floridachwn.pharmacy.ufl.edu/coalition-2/> (last visited Mar. 20, 2014).

¹⁴ *Id.*

The Task Force will collaborate with organizations such as the Florida Community Health Worker Coalition and Florida College System institutions and state universities to create a process for standardization of qualifications and skills of CHWs who work in state-supported health care programs.

The Task Force will submit a report with findings, conclusions, and recommendations to the Governor, President of the Senate, and Speaker of the House of Representatives by June 30, 2015. Recommendations will include involving CHWs in the effort to increase enrollment into Medicaid Managed Care or other statewide health care programs, deliver information on preventative health care, aid in health care navigation, and participate in health care delivery teams of community health centers and other "safety net" providers. The bill also requires the Task Force to determine mechanisms for integrating CHWs into the health care system.

The bill provides a repeal date of December 1, 2015.

B. SECTION DIRECTORY:

Section 1. Creates an unnumbered section of law entitled Community Health Worker Task Force.
Section 2. Provides the act shall take effect upon becoming a law.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

The bill has an insignificant negative fiscal impact on the DOH associated with establishing, and providing administrative support and services to the Task Force. These expenditures can be absorbed within existing agency resources.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The DOH has appropriate rule-making authority to implement this provision.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to community health workers; providing definitions; specifying the duties and activities of community health workers; creating the Community Health Worker Task Force within a Florida College System institution or state university; requiring the Department of Health to provide administrative support and services; providing membership and duties of the task force; requiring the members of the task force to elect a chair and vice chair; providing that task force members serve without compensation and are not entitled to reimbursement for per diem or travel expenses; requiring that the task force meet at least quarterly; authorizing the task force members to meet in person or by teleconference or other electronic means; specifying the number of members required for a quorum; requiring the task force to submit a report to the Governor and the Legislature by a specified date; providing for future repeal of the task force; providing an effective date.

WHEREAS, Florida continues to experience critical shortages of providers in primary health care, oral health care, and behavioral health care, particularly in rural and inner-city areas, and

WHEREAS, there is substantial evidence that comprehensive

27 | coordination of care for individuals who have chronic diseases
 28 | and the provision of information regarding preventive care can
 29 | improve individual health, create a healthier population, reduce
 30 | the costs of health care, and increase appropriate access to
 31 | health care, and

32 | WHEREAS, community health workers have demonstrated success
 33 | in increasing access to health care in underserved communities,
 34 | providing culturally appropriate education regarding disease
 35 | prevention and management, providing translating and
 36 | interpreting services for non-English speakers, improving health
 37 | outcomes through the coordination of care, increasing individual
 38 | health care literacy and advocacy, and organizing to improve the
 39 | health care of medically underserved communities while reducing
 40 | costs in the state's health care system, and

41 | WHEREAS, the Legislature recognizes that community health
 42 | workers are important members of the health care delivery system
 43 | in this state, and the Florida Community Health Worker Coalition
 44 | has begun to explore options that would allow community health
 45 | workers to earn a living wage and be part of an integrated
 46 | health delivery team, NOW, THEREFORE,

47 |
 48 | Be It Enacted by the Legislature of the State of Florida:

49 |
 50 | Section 1. Community Health Worker Task Force.—

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

52 | (a) "Community health worker" means a front-line health

53 care worker who is a trusted member or has an unusually close
54 understanding of the community that he or she serves and who:

55 1. Serves as a liaison, link, or intermediary between the
56 health care services or social services and the community in
57 order to facilitate access to health care services and improve
58 the quality of health care services and the cultural competency
59 of health care providers.

60 2. Performs the following activities in a community
61 setting:

62 a. Provides information regarding available resources.

63 b. Provides social support.

64 c. Advocates for individuals and their health care needs.

65 d. Provides services, such as first aid and blood pressure
66 screening.

67 3. Builds individual and community capacity to prevent
68 disease and promote health by increasing knowledge regarding
69 wellness, disease prevention, and self-sufficiency among the
70 members of the community through a range of activities, such as
71 community outreach, education, and advocacy.

72 4. Collects data to help identify the health care needs in
73 a medically underserved community by:

74 a. Enhancing the communication skills of members of the
75 community in order to assist them in effectively communicating
76 with health care providers.

77 b. Providing culturally and linguistically appropriate
78 health or nutrition education.

79 c. Advocating for better individual and community health,
 80 including oral health, mental health, and nutritional needs.

81 d. Providing referral services, followup services, and
 82 coordination of care.

83 (b) "Department" means the Department of Health.

84 (c) "Medically underserved community" means a community in
 85 a geographic area that has a shortage of health care
 86 professionals and has a population that includes persons who do
 87 not have public or private health insurance, are unable to pay
 88 for health care, and have incomes at or below 185 percent of the
 89 federal poverty level.

90 (d) "Task force" means the Community Health Worker Task
 91 Force established by the department under this section.

92 (2) (a) The department shall establish the Community Health
 93 Worker Task Force within a Florida College System institution or
 94 state university. The department shall provide administrative
 95 support and services to the task force to the extent requested
 96 by the chair of the task force and within available resources of
 97 the department.

98 (b) The task force shall consist of the following 12
 99 members:

100 1. One member of the Senate appointed by the President of
 101 the Senate.

102 2. One member of the House of Representatives appointed by
 103 the Speaker of the House of Representatives.

104 3. One state official appointed by the Governor.

105 4. Six culturally and regionally diverse community health
 106 workers appointed by the State Surgeon General.

107 5. Three representatives of the Florida Community Health
 108 Worker Coalition appointed by the chair of the Florida Community
 109 Health Worker Coalition.

110 (c) The task force shall develop recommendations for:

111 1. Including community health workers in the development
 112 of proposals for health care or Medicaid reform in this state as
 113 part of the outreach efforts for enrolling residents of this
 114 state in Medicaid managed care programs or other health care
 115 delivery services.

116 2. Including community health workers in providing
 117 assistance to residents in navigating the health care system and
 118 providing information and guidance regarding preventive health
 119 care.

120 3. Providing support to community health centers and other
 121 "safety net" providers through the integration of community
 122 health workers as part of health care delivery teams.

123 (d) The task force shall also collaborate with the Florida
 124 Community Health Worker Coalition, colleges and universities in
 125 the state, and other organizations and institutions to recommend
 126 a process that leads to the standardization of qualifications
 127 and skills of community health workers who are employed in
 128 state-supported health care programs.

129 (e) The members of the task force shall elect a chair and
 130 vice chair.

131 (f) Members of the task force shall serve without
 132 compensation and are not entitled to reimbursement for per diem
 133 and travel expenses.

134 (g) The task force shall meet at least quarterly and may
 135 meet at other times upon the call of the chair or as determined
 136 by a majority of members. Meetings of the task force may be held
 137 in person or by teleconference or other electronic means.

138 (h) A quorum shall consist of seven members, and the
 139 concurring vote of a majority of the members present is required
 140 for final action.

141 (i) The task force shall submit a report by June 30, 2015,
 142 to the Governor, the President of the Senate, and the Speaker of
 143 the House of Representatives which states the findings,
 144 conclusions, and recommendations of the task force.

145 (3) This section is repealed December 1, 2015.

146 Section 2. This act shall take effect upon becoming a law.

COMMITTEE/SUBCOMMITTEE AMENDMENT

Bill No. HB 211 (2014)

Amendment No.

COMMITTEE/SUBCOMMITTEE ACTION

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

1 Committee/Subcommittee hearing bill: Health Quality
2 Subcommittee
3 Representative Watson, C. offered the following:

4
5 **Amendment**

6 Remove lines 105-109 and insert:

7 4. Nine culturally and regionally diverse community health
8 workers appointed by the Surgeon General, three of whom are
9 recommended by the chair of the Florida Community Health Worker
10 Coalition.

11

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 647 Infectious Disease Control

SPONSOR(S): Adkins

TIED BILLS: IDEN./SIM. BILLS:

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee		Guzzo <i>TG</i>	O'Callaghan <i>MO</i>
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

The powers and duties of the Department of Health (DOH) are enumerated in s. 381.0011, F.S. Current law requires DOH to administer and enforce laws and rules relating to "communicable" diseases. The bill amends s. 381.0011, F.S., to replace the word "communicable" with "infectious".

The bill also requires DOH to develop an internet website to collect information related to treatment-resistant bacterial infections to be disseminated to the public. Physicians, osteopathic physicians, physician assistants, nurses, and advanced registered nurse practitioners licensed in Florida must report confirmed treatment-resistant bacterial infections and their location using the website. Certain information is exempt from public access on the website, including the identity of the health care practitioner reporting and protected patient health information.

Finally, the bill requires DOH to create:

- A research panel tasked with making recommendations to state agencies on needed research programs and developing protocols for control of treatment-resistant bacterial infections;
- An interagency task force to identify emergency response protocols for the 29 types of healthcare facilities licensed by the Agency for Health Care Administration; and
- A volunteer response team to investigate, and report outbreaks of treatment-resistant bacterial infections to DOH and the Centers for Disease Control and Prevention.

The bill is expected to have a negative fiscal impact on DOH.

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

Surveillance and Prevention

The Department of Health (DOH) is required to conduct monitoring or surveillance for organisms of public health significance.¹ The organisms of public health significance currently under surveillance are based on the diseases recommended to be nationally notifiable by the Council of State and Territorial Epidemiologists (CSTE) and the Centers for Disease Control and Prevention (CDC).² In order to ensure effective disease control and prevention, disease surveillance by DOH is conducted for organisms regardless of their treatment susceptibility due to the fact that both susceptible and resistant organisms have equal ability to cause severe infection, disability, and be contagious to others. Further, DOH conducts surveillance for both susceptible and resistant organisms to track changes in resistance patterns over time.³

Hospitals, laboratories, and physicians are required to report information to DOH, which DOH uses to produce weekly tables and annual summaries of antimicrobial resistance of the organisms under surveillance. The data is available to the public on a DOH website.⁴ Physicians utilize the established protocols of reporting diseases and conditions of public health significance. All outbreaks are required to be reported via telephone (with a subsequent written report within 72 hours), facsimile, electronic data transfer, or other confidential means of communication to the county health department having jurisdiction for the area in which the office of the reporting practitioner, hospital, laboratory or patient's residence is located. DOH uses established protocols developed by the CDC and the CSTE for reporting cases, outbreaks and other infections to the CDC.⁵

DOH is currently proposing to add requirements for disease reporting to Rule 64D-3.029, F.A.C., for electronic reporting of laboratory results for certain antibiotic resistant organisms. If approved, the revised rule will take effect by the end of 2014.⁶

Currently, health care facilities participating in the Medicare and Medicaid performance programs report specific infections to the CDC via the National Healthcare Safety Network. The reporting requirements include infections due to antibiotic resistant bacteria such as *Staphylococcus aureus* and *Clostridium difficile*, as well as certain procedure and device associated infections. The public can compare hospital performance to national benchmarks for healthcare-associated infections for participating hospitals by accessing the federal website.⁷

Currently, DOH has a Healthcare-associated Infection Prevention Program funded through a federal grant from CDC that is guided by a multi-disciplinary advisory board comprised of key stakeholders, including, but not limited to: the Florida Hospital Association, the Florida Health Care Association, the Florida Association for Directors of Nursing Administration in Long-term Care, the Florida Medical Quality Assurance, Inc., Florida's Infectious Disease Society, and the Agency for Health Care Administration. This program works with health care facilities across the continuum to improve

¹ Section 381.0031(8), F.S.

² Rule 64D-3.029, F.A.C.

³ Florida Department of Health, 2014 Agency Legislative Bill Analysis, January 23, 2014 (on file with subcommittee staff).

⁴ See the Department of Health's Disease Reporting and Surveillance website at <http://www.floridahealth.gov/diseases-and-conditions/disease-reporting-and-management/disease-reporting-and-surveillance/index.html> (last visited on March 21, 2014).

⁵ *Supra* fn. 3.

⁶ *Id.*

⁷ *Id.*

infection control policies and practices and to support the implementation of best practices for preventing healthcare-associated infections.⁸

Disease Control Tools

Nationally recognized guidelines are available for health care facilities to improve treatment and control of infections and communicable diseases. The guidelines are available from CDC, Healthcare Infection Control Practices Advisory Committee (HICPAC), the Society for Healthcare Epidemiology of America, and the Infectious Disease Society of America. These nationally recognized groups also provide tools for outbreak response and provide guidance on what should be included in health care facility protocols for responding to an outbreak.⁹

Further, nationally recognized guidelines are available for health care facilities to assist in developing protocols for responding to outbreaks of multi-drug resistant organisms and treatment-resistant bacteria. For example, the CDC has published a toolkit for preventing the spread of certain treatment resistant bacteria and has developed a toolkit and resources for responding to outbreaks. The HICPAC has published research-based guidelines for preventing the spread of multi-drug resistant organisms.¹⁰

Disease Investigation and Outbreak Response

At the local and state level, DOH currently conducts activities tailored to prevention and control of diseases of public health significance. DOH has existing teams of epidemiologists, statisticians and clinicians who utilize the disease monitoring information reported by hospitals, laboratories and physicians to investigate disease cases and outbreaks, document outbreaks per established protocols, and make infection control recommendations to control the spread of disease. Currently, DOH has emergency response teams located across the state to control disease outbreaks deemed significant to public health. The processes and protocols used by DOH disease control emergency response teams are integrated with existing systems for reporting to the CDC.¹¹

Effect of Proposed Changes

Current law requires DOH to administer and enforce laws and rules relating to “communicable” diseases. The bill amends s. 381.0011, F.S., to replace the word “communicable” with “infectious”.

The bill also requires DOH to develop an internet website to collect information related to treatment-resistant bacterial infections to be disseminated to the public. Physicians, osteopathic physicians, physician assistants, nurses, and advanced registered nurse practitioners licensed in Florida must report confirmed treatment-resistant bacterial infections and their location using the website. Certain information is exempt from public access on the website, including the identity of the health care practitioner reporting and protected patient health information.

Finally, the bill requires DOH to create:

- A research panel tasked with making recommendations to state agencies on needed research programs and developing protocols for control of treatment-resistant bacterial infections;
- An interagency task force to identify emergency response protocols for the 29 types of healthcare facilities licensed by the Agency for Health Care Administration; and
- A volunteer response team to investigate, and report outbreaks of treatment-resistant bacterial infections to the CDC.

⁸ *Id.*

⁹ *Id.*

¹⁰ *Id.*

¹¹ *Id.*

B. SECTION DIRECTORY:

Section 1: Amends s. 381.0011, F.S., relating to duties and powers of the Department of Health.

Section 2: Provides an effective date of July 1, 2014.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

The bill is expected to have a negative fiscal impact on DOH. According to DOH¹², resources will be needed to develop, test, and maintain a new website, database and searchable interface, and provide training.

Additional expenditures are expected from supporting and staffing both a research panel and an interagency task force.

Total Expenditures

Year 1: \$869,463

Year 2: \$690,121

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

¹² *Id.*

B. RULE-MAKING AUTHORITY:

No additional rule-making authority is necessary to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to infectious disease control;
 amending s. 381.0011, F.S.; providing duties of the
 Department of Health relating to the dissemination of
 information regarding treatment-resistant bacterial
 infections; providing for the establishment of a
 research panel and an interagency task force;
 requiring the department to adopt and enforce minimum
 standards for infection control practices in certain
 licensed facilities; providing an effective date.

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

Section 1. Section 381.0011, Florida Statutes, is amended
 to read:

381.0011 Duties and powers of the Department of Health.—It
 is the duty of the Department of Health to:

(1) Assess the public health status and needs of the
 state.

(2) Administer and enforce laws and rules relating to
 sanitation, control of infectious ~~communicable~~ diseases,
 illnesses and hazards to health among humans and from animals to
 humans, and the general health of the people of the state.

(3) Coordinate with federal, state, and local officials
 for the prevention and suppression of infectious ~~communicable~~
 and other diseases, illnesses, injuries, and hazards to human

27 health.

28 (4) Provide for a thorough investigation and study of the
 29 incidence, causes, modes of propagation and transmission, and
 30 means of prevention, control, and cure of diseases, illnesses,
 31 and hazards to human health.

32 (5) Provide for the dissemination of information to the
 33 public relating ~~relative~~ to the prevention, control, and cure of
 34 diseases, illnesses, and hazards to human health, including
 35 information reported by licensed health care practitioners under
 36 subsection (6).

37 (6) Establish an Internet website for health care
 38 practitioners licensed under chapter 458, chapter 459, or
 39 chapter 464 to report the presence of confirmed treatment-
 40 resistant bacterial infections. The website shall require the
 41 practitioner to enter his or her license number, the location of
 42 the confirmed treatment-resistant bacterial infection, and the
 43 type of bacterial infection. The department shall adopt rules
 44 establishing a method to ensure that only one report per
 45 confirmed case is displayed on the publicly accessible part of
 46 the website. The department shall adopt rules requiring that the
 47 identity of the practitioner not be displayed on the publicly
 48 accessible part of the website and that the report not disclose
 49 protected health information but only documents the presence,
 50 type, and location of a confirmed treatment-resistant bacterial
 51 infection.

52 ~~(7)~~(6) Act as registrar of vital statistics.

53 ~~(8)(7)~~ Manage and coordinate emergency preparedness and
 54 disaster response functions to: investigate and control the
 55 spread of disease; coordinate the availability and staffing of
 56 special needs shelters; support patient evacuation; ensure the
 57 safety of food and drugs; provide critical incident stress
 58 debriefing; and provide surveillance and control of
 59 radiological, chemical, biological, and other environmental
 60 hazards.

61 (9) Establish a research panel composed of experts in the
 62 field of treatment-resistant bacterial infections, which shall
 63 make recommendations to state agencies regarding biomedical
 64 research programs designed to improve treatment outcomes and
 65 develop protocols to control the incidence of treatment-
 66 resistant bacterial infections.

67 (10) Establish and lead an interagency task force that
 68 includes representatives from health care providers, interested
 69 trade associations, and other state agencies to:

70 (a) Identify emergency response protocols for facilities
 71 licensed under part II of chapter 408 when an outbreak of a
 72 treatment-resistant bacterial infection occurs in such a
 73 facility.

74 (b) Establish a volunteer statewide emergency response
 75 team to investigate, document, and report the presence and
 76 outbreak of a treatment-resistant bacterial infection to the
 77 department and the Centers for Disease Control and Prevention.

78 Section 2. This act shall take effect July 1, 2014.



Amendment No.

COMMITTEE/SUBCOMMITTEE ACTION

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

1 Committee/Subcommittee hearing bill: Health Quality
 2 Subcommittee

3 Representative Adkins offered the following:

4

5 **Amendment (with title amendment)**

6 Remove everything after the enacting clause and insert:

7 Section 1. Section 154.001, Florida Statutes, is amended
 8 to read:

9 154.001 System of coordinated county health department
 10 services; legislative intent.—It is the intent of the
 11 Legislature to promote, protect, maintain, and improve the
 12 health and safety of all citizens and visitors of this state
 13 through a system of coordinated county health department
 14 services, which shall include the control of communicable
 15 diseases and antibiotic-resistant threats, as defined and
 16 prioritized by the Centers for Disease Control and Prevention
 17 and as specified in s. 381.0011(5). The Legislature recognizes



Amendment No.

18 the unique partnership which necessarily exists between the
19 state and its counties in meeting the public health needs of the
20 state. To strengthen this partnership, the Legislature intends
21 that the public health needs of the several counties be provided
22 through contractual arrangements between the state and each
23 county. The Legislature also recognizes the importance of
24 meeting the educational needs of Florida's public health
25 professionals.

26 Section 2. Section 381.0011, Florida Statutes, is amended
27 to read:

28 381.0011 Duties and powers of the Department of Health.—It
29 is the duty of the Department of Health to:

30 (1) Assess the public health status and needs of the
31 state.

32 (2) Administer and enforce laws and rules relating to
33 sanitation, control of communicable diseases, illnesses and
34 hazards to health among humans and from animals to humans, and
35 the general health of the people of the state.

36 (3) Coordinate with federal, state, and local officials
37 for the prevention and suppression of communicable and other
38 diseases, illnesses, injuries, and hazards to human health.

39 (4) Provide for a thorough investigation and study of the
40 incidence, causes, modes of propagation and transmission, and
41 means of prevention, control, and cure of diseases, illnesses,
42 and hazards to human health.

43 (5) Provide for the dissemination of information to the



Amendment No.

44 public relating ~~relative~~ to the prevention, control, and cure of
 45 diseases, illnesses, and hazards to human health, and
 46 antibiotic-resistant threat outbreaks, as defined and
 47 prioritized by the Centers for Disease Control and Prevention in
 48 the report entitled "Antibiotic Resistance Threats in the United
 49 States, 2013." The department shall document on its website the
 50 presence, type, and location of an antibiotic resistant threat
 51 outbreak.

52 (6) Act as registrar of vital statistics.

53 (7) Manage and coordinate emergency preparedness and
 54 disaster response functions to: serve as the lead agency for the
 55 investigation of antibiotic resistant outbreak threats included
 56 in the report referenced in subsection (5); investigate and
 57 control the spread of disease; coordinate the availability and
 58 staffing of special needs shelters; support patient evacuation;
 59 ensure the safety of food and drugs; provide critical incident
 60 stress debriefing; and provide surveillance and control of
 61 radiological, chemical, biological, and other environmental
 62 hazards.

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

64
 65 -----

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

67 Remove everything before the enacting clause and insert:

68 A bill to be entitled




Amendment No.

69 | An act relating to communicable disease control;
70 | amending s. 154.001; F.S.; providing for coordination
71 | of services relating to control of communicable
72 | diseases and antibiotic-resistant threats by county
73 | health departments; amending s. 381.0011, F.S.;
74 | providing duties of the Department of Health relating
75 | to the dissemination of information regarding
76 | antibiotic-resistant threat outbreaks; providing an
77 | effective date.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 687 Florida Drug and Cosmetic Act
SPONSOR(S): Magar
TIED BILLS: HB 689 **IDEN./SIM. BILLS:** SB 836

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

SUMMARY ANALYSIS

Part I of chapter 499, F.S., requires the Department of Business and Professional Regulation (DBPR) to regulate drugs, devices, and cosmetics. Most of the regulations relate to the distribution of prescription drugs into and within Florida. In particular, the regulations require various entities in the distribution chain, such as prescription drug manufacturers and prescription drug wholesale distributors, to obtain permits to operate in the state.

In Florida, medical gases, such as oxygen, nitrous oxide, nitrogen, and helium, are prescription drugs and subject to regulation under part I of chapter 499, F.S., and the rules adopted thereunder in chapter 61N-1, F.A.C. However, many of the provisions and requirements of part I are difficult to apply to medical gases because of the nature of storage, shipment, and maintenance of medical gas, primarily in large tanks or canisters.

House Bill 687 creates part III of chapter 499, F.S., which separates the regulation, including permit requirements, of manufacturers and wholesale distributors of medical gases, as well as medical oxygen retail establishments, from the provisions of part I and part II of the chapter, which regulate the manufacturers and distributors of other drugs, devices, and cosmetics. The bill includes many provisions governing medical gases that are substantially similar to existing provisions in part I, but revises those provisions for applicability to medical gases. The provisions of new part III require:

- Permits for medical gas manufacturers and wholesale distributors and medical oxygen retail establishments;
- Minimum qualifications for obtaining a permit to deal in medical gases;
- Certain procedures to change a permit;
- Security and storage of medical gases;
- Returned, damaged, and outdated medical gases to be handled in a certain manner;
- Penalties for committing prohibited and criminal acts associated with medical gases; and
- Inspections of facilities that manufacture medical gases.

The bill has an indeterminate, but likely insignificant, fiscal impact on the DBPR.

The bill provides an effective date of October 1, 2014.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Regulation of Drugs, Devices, and Cosmetics

Part I of Chapter 499, F.S., requires the Department of Business and Professional Regulation (DBPR) to regulate drugs, devices, and cosmetics.¹ Most of the regulations relate to the distribution of prescription drugs into and within Florida. In particular, the regulations require various entities in the distribution chain, such as prescription drug manufacturers and prescription drug wholesale distributors, to obtain permits. In total, Florida has 20 distinct permits for these entities. Among many other provisions, the chapter provides for:

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

Many of these regulations have been significantly strengthened in recent years, including:

- More stringent requirements to obtain a wholesale distributor permit, requiring, among other items, a posting of a bond and extensive background information for various employees of the wholesale distributor;²
- More thorough documentation requirements for the distribution of prescription drugs, including broader application of the pedigree paper³ to most wholesale distributions;⁴
- Enhanced criminal penalties for, among other things, distribution of contraband prescription drugs;⁵ and
- Stronger departmental enforcement authority to protect the prescription drug supply chain.⁶

Compressed medical gases are also regulated under part I of chapter 499, F.S.

¹ S. 27, ch. 2010-161, Law of Fla., shifted responsibility for operation and enforcement of the Florida Drugs, Devices, and Cosmetics Act from the Department of Health to the Department of Business and Professional Regulation.

² S. 499.01(2)(d), F.S. (requiring a bond of \$100,000 or other means of equivalent security) and s. 499.012(8) and (9), F.S. (requiring, in addition to other information, place of residence for the past 7 years, fingerprints, photograph taken within 30 days, and name, address, occupation, and date and place of birth of each member of the person's immediate family who is 18 years of age or older).

³ A pedigree paper is a record that documents the movement of drugs, devices or cosmetics through the chain of commerce. A pedigree paper must provide a complete audit trail from a person's receipt or acquisition to sale or other disposition of the product or component. Rule 61N-1.012(1)(a), F.A.C.

⁴ S. 499.01212, F.S. ("Each person who is engaged in the wholesale distribution of a prescription drug must, prior to or simultaneous with each wholesale distribution, provide a pedigree paper to the person who receives the drug.")

⁵ S. 499.0051(6), F.S. (imposing a second degree felony for "a person who is knowingly in actual or constructive possession of any amount of contraband prescription drugs, who knowingly sells or delivers, or who possesses with intent to sell or deliver any amount of contraband prescription drugs").

⁶ S. 499.0051(12) and (13), F.S.

Medical Gases

According to the United States Food and Drug Administration (FDA), medical gases include:

- Oxygen;
- Nitrogen;
- Nitrous oxide;
- Carbon dioxide;
- Helium;
- Medical air;⁷ and
- Any mixture of these gases or other gas products approved under a New Drug Application.⁸

Medical gases have a variety of uses. For example, nitrous oxide, a clear and colorless gas with a slightly sweet odor, is blended with oxygen for use as medical or dental anesthesia or analgesia.⁹ Over 80 percent of manufactured nitrous oxide is used in medicine or dentistry.¹⁰ Helium, due to its light weight, is used as a therapy in many respiratory conditions, such as asthma, chronic obstructive pulmonary disorder (COPD), and croup.¹¹ Helium has also been used as a more effective treatment of decompression illness, or “the bends.”¹² Xenon, a colorless, heavy, and odorless noble gas, is used in anesthesia and in medical imaging, such as enhanced CT scans.¹³

Regulation of Medical Gases in Florida

In Florida, compressed medical gases are prescription drugs,¹⁴ and fall under the regulatory provisions of part I of chapter 499, F.S., and the rules adopted thereunder in chapter 61N-1, F.A.C. A permit is required to manufacture or repackage, or to wholesale distribute, compressed medical gases within the state.¹⁵ A business seeking either permit must submit an application, pass an onsite inspection by the DBPR, and pay the appropriate fee.¹⁶ For a business located outside of Florida that wishes to manufacture and distribute or wholesale distribute compressed medical gases into the state, a nonresident prescription drug manufacturer permit¹⁷ or an out-of-state prescription drug wholesale distributor permit¹⁸ is required.

A compressed medical gases manufacturer or a medical oxygen retailer who manufactures or refills compressed medical gases must comply with the current good manufacturing practice regulations

⁷ Medical air is a nonflammable, colorless, and odorless gas consisting of a mixture of various elements, mostly nitrogen and oxygen. Medical air is most often used for respiratory therapy and to power pneumatic medical devices. Airgas, *Medical Air U.S.P.*, available at www.airgas.com/content/products.aspx?id=9002003001003 (last viewed on March 21, 2014).

⁸ U.S. Food and Drug Administration, Center for Drug Evaluation and Research, *About FDA-Questions and Answers on the Proposed Rule for Medical Gas Containers (2006)*, available at www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm096373.htm (last viewed on March 21, 2014).

⁹ Compressed Gas Association, *Nitrous oxide fact sheet*, available at www.cganet.com/n20guidelines.php (last viewed on March 21, 2014).

¹⁰ Norco, Inc., *Medical Gases-Nitrous Oxide*, available at www.norco-inc.com/content/medical-gases (last viewed on March 21, 2014).

¹¹ Berganza, C., and Zhang, J., *The role of helium gas in medicine*, Medical Gas Research 2013, 3:18, page 2, available at www.medicalgasresearch.com/content/pdf/2045-9912-3-18.pdf (last viewed on March 21, 2014).

¹² *Id.* at page 1.

¹³ Esencan, E., Yuksel, S., et al., *Xenon in medical area: emphasis on neuroprotection in hypoxia and anesthesia*, Medical Gas Research 2013, 3:4, pages 2, 6, available at www.medicalgasresearch.com/content/pdf/2045-9912-3-4.pdf (last viewed on March 21, 2014).

¹⁴ S. 499.003(11), F.S., see also s. 499.003(46), F.S. (defining “prescription medical oxygen”).

¹⁵ S. 499.01(2)(o), F.S., and s. 499.01(2)(n), F.S., respectively.

¹⁶ Applications require detailed information pursuant to Rule 61N-1.015(1) and (7)(d), F.A.C. An onsite inspection is required pursuant to Rule 61N-1.015(3), F.A.C. Appropriate fees are outlined in Rule 61N-1.018, F.A.C.

¹⁷ S. 499.01(2)(c), F.S.

¹⁸ S. 499.01(2)(d), F.S.

promulgated by the FDA¹⁹ and the “Compressed Medical Gases Guideline”²⁰ issued by the Center for Drug Evaluation and Research at the FDA.²¹

A medical oxygen retail establishment permit is required for any person that sells medical oxygen only to patients.²² A sale of medical oxygen under the permit must be based on an order from health care practitioner authorized to prescribe medical oxygen.²³ A permittee must comply with all state and federal good manufacturing practices and all of the wholesale distribution requirements in s. 499.0121, F.S.²⁴ An applicant for this permit must submit an application, submit to and pass a fire inspection and DBPR inspection, and pay the appropriate fee.²⁵

Drug Wholesale Distributor Advisory Council

The Drug Wholesale Distributor Advisory Council (Council) was established by the Prescription Drug Protection Act²⁶ in s. 499.01211, F.S. The Council reviews the Florida Drug and Cosmetic Act²⁷ and associated rules and:

- Provides input to the DBPR regarding all proposed rules;
- Makes recommendations to the Secretary of the DBPR regarding the listing of all specified drugs;²⁸
- Makes recommendations to improve the protection of prescription drugs and public health;
- Makes recommendations to improve coordination with other states’ regulatory agencies and the federal government concerning the wholesale distribution of drugs; and
- Makes recommendations to minimize the impact of regulation of the wholesale distribution industry while ensuring protection of the public health.²⁹

The Secretary of the DBPR, or her or his designee, and the Secretary of the Agency for Health Care Administration, or her or his designee, both serve as members of the Council.³⁰ The Secretary of the DBPR appoints nine members to the Council to serve 4 year terms.³¹ The remaining nine members of the Council are:

- 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;
- One person employed by a licensed prescription drug wholesale distributor which is a secondary wholesale distributor;
- One person employed by a retail pharmacy chain;
- One member of the Florida Board of Pharmacy who is a licensed pharmacist;
- One licensed physician;
- One person who is an employee of a hospital who is a licensed pharmacist; and
- One person who is an employee of a pharmaceutical manufacturer.³²

¹⁹ 21 C.F.R. Parts 200-299

²⁰ Available at www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm124716.htm (last viewed on March 21, 2014).

²¹ Rule 61N-1.007(1), F.A.C.

²² S. 499.01(2)(m), F.S.

²³ S. 499.01(2)(m)2., F.S.

²⁴ S. 499.01(2)(m)2. and 3., F.S.

²⁵ Rules 61N-1.015(1) and (3), F.A.C. and Rule 61N-1.018(4), F.A.C.

²⁶ Ch. 2003-155, Laws of Fla.

²⁷ Chapter 499, F.S.

²⁸ S. 499.0121(6)(e), F.S.

²⁹ S. 499.01211(3), F.S.

³⁰ S. 499.01211(2), F.S.

³¹ Id.

³² S. 499.01211(2)(a)-(g), F.S.

Effect of Proposed Changes

The bill creates part III of chapter 499, F.S., which separates the regulation of manufacturers and wholesale distributors of medical gases, as well as medical oxygen retail establishments, from the provisions of part I and part II of the chapter, which regulate the manufacturers and distributors of other drugs, devices, and cosmetics. The bill creates the following new sections of law.

Definitions

The bill revises the current definition of “compressed medical gas” to “medical gas” in part I and refers to the definition of the term in the federal Food, Drug, and Cosmetic Act. The bill deletes the definition of “prescription medical oxygen” in part I.

The following terms are defined for part III: “adulterated,” “distribution,” “emergency,” “emergency use oxygen,” “federal act,” “medical gas,” “misbranded,” “prescription medical oxygen,” “product labeling,” “USP,”³³ “USP-NF,”³⁴ “wholesale distribution,” and “wholesale distributor.” Under the definition of “wholesale distribution,” the bill provides several exceptions that do not constitute wholesale distribution, including the sale, purchase, or trade of a medical gas, or the offer to do so, pursuant to a prescription or for emergency medical reasons; intracompany transactions; activities exempt from wholesale distribution as defined in s. 499.003(54), F.S., in part I; and other transactions exempted from the definition of wholesale distribution in the federal act or federal regulations adopted pursuant to the federal act.

Administration and Enforcement

The bill asserts that the provisions of part III regulating medical gas control over any other provision purporting to regulate medical gas. The bill grants power to the DBPR to administer and enforce part III and grants specific authority to the DBPR to, during the course of an investigation or proceeding regarding a violation of part III, administer oaths, take depositions, subpoena witnesses, and conduct discovery. The bill also requires each state, county, or municipal attorney to investigate and, if proper, prosecute any report made by the DBPR relating to a violation of the part. Minor violations may be disposed by written notice or warning.

Permits

The bill deletes the medical oxygen retail establishment permit, the compressed medical gas wholesale distributor permit, and the compressed medical gas manufacturer from s. 499.01, F.S., and moves them to s. 499.831, F.S. The provision for the medical gas wholesale distributor permit is substantially similar to the same provision in current law at s. 499.01(2)(n), F.S.

The provision for the medical gas manufacturer permit is similar to the same provision in current law at s. 499.01(2)(o), F.S. However, the new law allows a medical gas manufacturer to manufacture or possess a prescription drug other than a medical gas if the appropriate permit is obtained. Current law prohibits the manufacture or possession of a prescription drug other than a medical gas by a medical gas manufacturer permittee. The new law also expressly permits the wholesale distribution of medical gas by a medical gas manufacturer permittee without a medical gas wholesale distributor permit.

The provision for the medical oxygen retail establishment permit is substantially similar to the same provision in current law at s. 499.01(2)(m), F.S. However, the new law allows a retail establishment permittee to possess, purchase, sell, or trade a prescription drug other than medical oxygen if it obtains

³³ 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.

³⁴ The United States Pharmacopoeia and The National Formulary (USP–NF) is a book of public pharmacopoeial standards. It is available at <http://www.usp.org/usp-nf> (last viewed on March 22, 2014).

the appropriate permit. Similar to the case of a medical gas manufacturer permit, a medical oxygen retail establishment permittee is prohibited from possessing, purchasing, selling, or trading any prescription drug other than medical oxygen.

The bill provides for specific information that must be included in an application for permit under the section, which is similar to the provisions in current law in s. 499.012(3) and (4), F.S. The bill outlines the fee structure for each permit, which is identical to current law in s. 499.041(1)(e), (2)(b), and (3)(b), F.S. The permit renewal process and fee is similar to current law in s. 499.012(5)(c), F.S. Also, the expiration date of a permit 2 years after the last day of the month it was issued and the process for reapplying for a permit after failing to timely renew it is identical to the provisions of current law in s. 499.012(5)(c) and (d), F.S.

The bill includes the same process for changing a permit type for a permittee in good standing, which exists in s. 499.012(2), F.S. However, the bill establishes a new expiration date for a change in permit type. Current law sets the expiration date as the date the original permit was to expire or 1 year from the date the new permit was issued, whichever is earlier. The bill sets the expiration date as the date the original permit was to expire, eliminating the earlier expiration date provision.

The bill contains similar language to current law in s. 499.012(6), F.S., regarding non-transferability of medical gas-related permits issued by the DBPR, but adds language authorizing the DBPR to approve a change in permit holder. The bill retains the change of location provision and the \$100 fee for doing so.

The bill adds a new provision of law allowing a permit holder to make a change in name prior to informing the DBPR and operate while the notice is being processed and without submitting a new permit application. The bill also includes new language requiring 30-days' notice after any change of information required by the new section.

Additional Requirements for Licensure of a Wholesale Distributor of Medical Gas

The bill includes similar language as found in s. 499.01(13), F.S., which requires permitting and biennially renewal to wholesale distribute medical gas within or into the state. The bill requires out-of-state wholesale distributors to maintain permit requirements in the state where they are located and all other states in which they distribute, if applicable. If the state where an out-of-state wholesale distributor of medical gas is located does not require a permit to engage in wholesale distributing, the wholesale distributor will not be required to obtain a permit to operate in Florida.

The bill includes substantially similar provisions related to minimum qualifications of persons seeking a permit to engage in the wholesale distribution of medical gas as is currently found in s. 499.012(4)(d), F.S.

Registered Agent

The bill includes new language that requires each applicant or licensee under part III to designate and maintain a registered agent in Florida for purposes of service of process. If an applicant or licensee does not have a registered agent in Florida or, if after reasonable diligence, service of process cannot be completed, service may be made on the Secretary of State and relevant information regarding service mailed to the applicant or licensee.

Minimum Requirements for the Storage and Handling of Medical Gases; Establishment and Maintenance of Medical Gas Records

The bill includes minimum requirements for the storage, handling, transport, and shipment of medical gases that are substantially similar to the requirements found in current law at s. 499.0121(1)-(3), F.S.

The bill also includes the following requirements for a facility handling medical gas to ensure the identity, strength, quality, or purity of the medical gas:

- The facility must be of suitable construction to ensure the medical gas is maintained according to the label instructions or in compliance with the USP-NF.
- The facility must be a commercial location and not a residence, except that a personal residence may be used for on-call delivery of medical oxygen for home use pursuant to a permit.
- The facility must protect and keep confidential patient information.
- The facility must have appropriate inventory controls to detect and document the theft of nitrous oxide.

The bill requires that medical gases be packaged according to applicable guidelines in the USP-NF.

Security

The bill requires strict security measures to protect medical gases from unauthorized entry into a facility that stores medical gases. The provisions are substantially similar to the security measures included in s. 499.0121(2), F.S. The bill adds a provision for on-call delivery of medical oxygen which requires a vehicle containing the medical oxygen to be parked at a residence and be equipped with an audible alarm when not attended.

Examination of Materials

The bill includes requirements for inspection of medical gases containers that are similar to provisions in current law in s. 499.0121(4) and (5)(b), F.S., that require the examination of containers of prescription drugs to reveal damage that may compromise the prescription drugs in the container. The bill adds provisions to this section that have particular application to the containers for medical gases, which are typically metal tanks or canisters. The bill requires a damaged or unfit container to be quarantined in a separate area of the facility until a more thorough inspection can be done to determine if the medical gas has been misbranded or adulterated by the damage to the container. Also, a pedigree paper is not required for the wholesale distribution of medical gas, with is consistent with current law.

Returned, Damaged, and Outdated Medical Gases

The bill establishes procedures for handling returned, damaged, and outdated medical gases that are substantially similar to the procedures found in s. 499.0121(5), F.S., for handling prescription drugs that have been returned or damaged or are outdated. The bill includes a new provision that requires a medical gas, its container, or associated documentation and labeling that is suspected of being involved in criminal activity must be preserved until law enforcement or the DBPR directs its disposition.

Salvaging and Reprocessing

The bill prohibits the salvaging or reprocessing of a medical gas that has been subject to improper conditions such as fire, accident, or natural disaster. The bill also permits the return of a medical gas container to the manufacturer and reprocessed if the manufacturer has appropriate controls in place to confirm the identity, strength, quality, and purity of the reprocessed gas.

Due Diligence

The bill establishes due diligence requirements for a wholesale distributor or manufacturer seeking to acquire medical gas and for a wholesale distributor or manufacturer seeking to supply medical gas. These provisions are similar to the requirements in current law in s. 499.0121(13) and (15), F.S. The bill exempts a wholesale distributor from the due diligence requirements in this section if the

manufacturer from whom medical gas is received is registered with the FDA under s. 501 of the federal Food, Drug, and Cosmetics Act, can provide proof of registration, and can provide proof of an inspection by the FD within the past 3 years. If an inspection was not completed in the last 3 years, the bill allows the manufacturer to attest to its conformance with industry standards or guidelines, as identified by the DBPR or under part III.

Recordkeeping

The bill includes provisions for the establishment and maintenance of certain records by a wholesale distributor of medical gas. The provisions are substantially similar to the recordkeeping requirements in current law in s. 499.0121(6), F.S., but slightly changed to account for the difference between medical gas and prescription drugs. For example, the bill requires certain records for high pressure medical gas to be kept for 3 years, while records for cryogenic or refrigerated liquid medical gas must be kept for 1 year. Also, the bill requires a wholesale distributor to maintain sufficient records to aid in the reporting of any loss of theft, or suspected theft, of nitrous oxide to the DBPR or an appropriate law enforcement agency.

Policies and Procedures

The bill mandates the creation and maintenance of policies and procedures by a wholesale distributor of medical gas to handle certain circumstances, such as the recall of a medical gas, an action initiated by the FDA, or the security or operation of a facility during a natural disaster or other emergency. The provisions are substantially similar to the requirements in current law in s. 499.0121(8), F.S. The bill adds a provision that requires a wholesale distributor to have policies and procedures in place for reporting criminal activities involving nitrous oxide to the DBPR and law enforcement within 3 days of becoming aware of, or suspecting, criminal activity.

Prohibited Acts

While a section of the new law is entitled, "Prohibited acts," subsection (1) of the new law lists the persons legally authorized to receive a medical gas, to include:

- A licensed manufacturer of medical gases or medical gas related equipment;
- A wholesale distributor of medical gases;
- A home respiratory care company;
- A pharmacy or health care entity;
- A person authorized to receive emergency use oxygen without a prescription;
- A location with automated external defibrillation machines where emergency use oxygen is intended to be used with such machines; and
- A company that requires the use of a medical gas in the installation and refurbishment of piping and equipment, including medical gas related equipment that will be used to contain or administer a medical gas.

Subsection (2) of the new law includes a list of prohibited acts associated with medical gas. The prohibitions are substantially similar to those that are found in s. 499.005, F.S., and are revised to apply to circumstances involving medical gas.

Criminal Acts

The bill provides a list of criminal acts associated with medical gas. The provisions are substantially similar to those provisions that appear in current law in s. 499.0051, F.S., and are revised to apply to circumstances involving medical gas. The bill includes a provision that requires the forfeiture to the state, upon a finding of guilt for any criminal act in the section, any real or personal property used to commit, facilitate, or promote the crime. The provision includes the forfeiture of property or assets

purchased or obtained using the proceeds of the criminal act. Lastly, the subsection provides for the disposition of property or assets to the DBPR, law enforcement, or other agencies involved in the investigation and prosecution of the criminal act that resulted in conviction.

Inspections

The bill allows the DBPR to recognize the inspection of a wholesale distributor by a third party in another state. The bill also authorizes the DBPR to recognize the inspection of a wholesale distributor by another state agency, if the DBPR determines the laws of the state are substantially equivalent to Florida law.

The bill provides an exemption from DBPR inspection to a manufacturing facility if the following conditions are met:

- The facility is registered with the FDA under s. 510 of the federal Act;
- The facility provides proof of FDA registration; and
- The facility provides proof of inspection by the FDA within the last 3 years or, if the facility is in another state, proof of inspection by the FDA or another governmental agency which regulates current good manufacturing processes within the same timeframe.

The bill requires a wholesale distributor to exhibit or have readily available all state licenses and the most recent inspection report from the DBPR. Lastly, the bill gives the DBPR discretion to issue a written notice of minor violations of part III if it determines the public interest is served by doing so.

Deposit of Fees

The bill requires all fees for licenses and permits collected under part III to be deposited into the Professional Regulation Trust Fund, in a separate account for the Drug, Devices, and Cosmetics program, for administration of part III.

Drug Wholesale Distributor Advisory Council

The bill adds another member to the Council, bringing the total number of members to 12. The new member must be an employee of either a medical gas manufacturer or a medical gas wholesale distributor and must be named by the Compressed Gas Association.

Conforming Changes

The bill conforms cross-references in ss. 409.9201, 460.403, 465.0265, 499.01, 499.01211, 499.01212, 499.015, 499.024, and 499.05. The bill also changes references to the term "part" to "chapter" to reflect application of provisions in part I of chapter 499, F.S., to the new part III, regarding medical gases.

B. SECTION DIRECTORY:

Section 1: Amends s. 499.03, F.S., relating to definitions of terms used in this part.

Section 2: Amends s. 499.01, F.S., relating to permits.

Section 3: Amends s. 499.0121, F.S., relating to storage and handling of prescription drugs; recordkeeping.

Section 4: Amends s. 499.01211, F.S., relating to Drug Wholesale Distributor Advisory Council.

Section 5: Amends s. 499.041, F.S., relating to schedule of fees for drug, device, and cosmetic applications and permits, product registrations, and free-sale certificates.

Section 6: Amends s. 499.051, F.S., relating to inspections and investigations.

Section 7: Amends s. 499.066, F.S., relating to penalties; remedies.

Section 8: Amends s. 499.0661, F.S., relating to cease and desist orders; removal of certain persons.

- Section 9:** Amends s. 499.067, F.S., relating to denial, suspension, or revocation of permit, certification, or registration.
- Section 10:** Creates Part III of chapter 499, F.S., relating to medical gases.
- Section 11:** Amends s. 409.9201, F.S., relating to Medicaid fraud.
- Section 12:** Amends s. 460.403, F.S., relating to definitions.
- Section 13:** Amends s. 465.0265, F.S., relating to centralized prescription filling.
- Section 14:** Amends s. 499.01212, F.S., relating to pedigree paper.
- Section 15:** Amends s. 499.015, F.S., relating to registration of drugs, devices, and cosmetics; issuance of certificates of free sale.
- Section 16:** Amends s. 499.024, F.S., relating to drug product classification.
- Section 17:** Amends s. 499.05, F.S., relating to rules.
- Section 18:** Provides an effective date of October 1, 2014.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

The additional member of the Council will minimally increase costs associated with Council meetings.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The revision of the permitting process and the easing of other regulations for medical gas manufacturers and wholesale distributors and medical oxygen retail establishments may result in lower administrative costs for these entities. Also, a revised permitting process and less regulation may prove attractive for medical gas manufacturers, medical gas wholesale distributors, and medical oxygen retail establishments to relocate to Florida.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill provides sufficient rule-making authority to the DBPR to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The bill add one member to the Council who is an employee of either a medical gas manufacturer or a medical gas wholesale distributor and has been named to the Council by the Compressed Gas Association, an industry advocacy group. Currently, only the Secretary of the DBPR has the right to name members to the Council. It is suggested that the term "named" be changed to "recommended," so as not to grant one industry group the right to assign a member to the Council. Also, the additional member brings the total number to 12, which could result in tie votes on the business of the Council. It is recommended that another member of the Council be removed to keep the number of members at 11.

The term "intracompany transaction" is used in the bill, but is not defined. It is recommended that a definition of the term be included in s. 499.82, F.S., as created.

Section 499.95, F.S., is entitled "Prohibited acts." However, the section includes a list of persons legally authorized to possess medical gas, along with a list of prohibited acts associated with medical gas. It is recommended that subsection (1), including the list of persons legally authorized to possess medical gas, and subsection (2), including the list of prohibited acts associated with medical gas, be separated into individual sections, such as s. 499.95, F.S., and s. 499.951, F.S.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

27 distributor, manufacturer, or medical oxygen retail
 28 establishment; authorizing the department to adopt
 29 rules; providing permitting standards; providing
 30 requirements to obtain a permit; providing for permit
 31 renewal; providing guidelines to change certain
 32 information; authorizing the department to revoke
 33 permits for failure to comply; requiring certain
 34 distributors of medical gases to obtain a permit and
 35 maintain permit renewal; requiring an applicant to
 36 provide a sworn statement disclosing certain
 37 information; providing minimum qualifications for
 38 licensure; requiring an applicant or licensee to
 39 designate and maintain a registered agent for service
 40 of process; providing minimum requirements for the
 41 storage and handling of gases and patient information;
 42 requiring a facility of wholesale distribution of
 43 medical gases to secure the facility from unauthorized
 44 entry; providing recommended security measures;
 45 requiring medical gases to be stored and packaged in
 46 accordance with certain regulations or standards;
 47 requiring a visual examination of a medical gas
 48 container upon receipt; requiring that a damaged or
 49 unfit medical gas be quarantined; requiring inspection
 50 of outgoing shipments; requiring a wholesale
 51 distributor of medical gases to review the records
 52 that accompany a medical gas received by the

53 distributor; requiring returned medical gases to be
 54 reprocessed for resale; requiring certain medical
 55 gases to be quarantined; requiring an acquiring
 56 distributor or manufacturer to provide notice of
 57 adulteration, misbranding, or suspected adulteration
 58 or misbranding; requiring certain medical gases to be
 59 retained; requiring a wholesale distributor of medical
 60 gases to comply with certain due diligence
 61 requirements; requiring that certain information must
 62 be provided by the supplying distributor to the
 63 acquiring distributor; providing an exception;
 64 requiring a wholesale distribution of medical gases to
 65 establish and maintain certain records; requiring the
 66 records to be made available for a certain amount of
 67 time; requiring a wholesale distributor to establish,
 68 maintain, and adhere to written policies and
 69 procedures; providing certain mandatory policies;
 70 prohibiting certain acts; providing that certain acts
 71 are felonies of the third degree; providing additional
 72 penalties of forfeiture; providing requirements
 73 related to salvaging and reprocessing; authorizing the
 74 department to recognize a third party inspection of
 75 wholesale distributors of medical gases or recognize
 76 other states inspections; providing for a right of
 77 review; providing notice requirements; providing for
 78 the deposit of fees in a trust fund and authorizing

79 the department to use such funds; amending ss.
 80 409.9201, 460.403, 465.0265, 499.01212, 499.015,
 81 499.024, and 499.05, F.S.; conforming cross-
 82 references; providing an effective date.
 83

84 Be It Enacted by the Legislature of the State of Florida:
 85

86 Section 1. Subsections (12) through (32) and subsections
 87 (47) through (55) of section 499.003, Florida Statutes are
 88 renumbered as sections (11) through (31) and subsections (46)
 89 through (54), respectively, present subsection (11) is reordered
 90 and amended, and present subsections (43) and (46) of that
 91 section are amended, to read:

92 499.003 Definitions of terms used in this part.—As used in
 93 this part, the term:

94 (32) ~~(11)~~ "Compressed Medical gas" means any liquefied or
 95 vaporized gas that is a prescription drug, whether ~~it is~~ alone
 96 or in combination with other gases, and as defined in the
 97 federal act.

98 (43) "Prescription drug" means a prescription, medicinal,
 99 or legend drug, including, but not limited to, finished dosage
 100 forms or active pharmaceutical ingredients subject to, defined
 101 by, or described by s. 503(b) of the federal ~~Food, Drug, and~~
 102 ~~Cosmetic~~ act or s. 465.003(8), s. 499.007(13), or subsection
 103 (32) ~~(11)~~, ~~subsection (46)~~, or subsection (52) ~~(53)~~, except that
 104 an active pharmaceutical ingredient is a prescription drug only

105 if substantially all finished dosage forms in which it may be
 106 lawfully dispensed or administered in this state are also
 107 prescription drugs.

108 ~~(46) "Prescription medical oxygen" means oxygen USP which~~
 109 ~~is a drug that can only be sold on the order or prescription of~~
 110 ~~a practitioner authorized by law to prescribe. The label of~~
 111 ~~prescription medical oxygen must comply with current labeling~~
 112 ~~requirements for oxygen under the Federal Food, Drug, and~~
 113 ~~Cosmetic Act.~~

114 Section 2. Paragraphs (m), (n), and (o) of subsection (1),
 115 paragraphs (a), (c), (g), (m), (n), and (o) of subsection (2),
 116 and subsection (5) of section 499.01, Florida Statutes, are
 117 amended to read:

118 499.01 Permits.—

119 (1) Prior to operating, a permit is required for each
 120 person and establishment that intends to operate as:

- 121 ~~(m) A medical oxygen retail establishment;~~
- 122 ~~(n) A compressed medical gas wholesale distributor;~~
- 123 ~~(o) A compressed medical gas manufacturer;~~

124 (2) The following permits are established:

125 (a) Prescription drug manufacturer permit.—A prescription
 126 drug manufacturer permit is required for any person that is a
 127 manufacturer of a prescription drug and that manufactures or
 128 distributes such prescription drugs in this state.

129 1. A person that operates an establishment permitted as a
 130 prescription drug manufacturer may engage in wholesale

131 distribution of prescription drugs manufactured at that
 132 establishment and must comply with all of the provisions of this
 133 part, except s. 499.01212, and the rules adopted under this
 134 part, except s. 499.01212, which apply to a wholesale
 135 distributor.

136 2. A prescription drug manufacturer must comply with all
 137 appropriate state and federal good manufacturing practices.

138 3. A blood establishment, as defined in s. 381.06014,
 139 operating in a manner consistent with the provisions of 21
 140 C.F.R. parts 211 and 600-640, and manufacturing only the
 141 prescription drugs described in s. 499.003(53)(d) ~~499.003(54)(d)~~
 142 is not required to be permitted as a prescription drug
 143 manufacturer under this paragraph or to register products under
 144 s. 499.015.

145 (c) Nonresident prescription drug manufacturer permit.—A
 146 nonresident prescription drug manufacturer permit is required
 147 for any person that is a manufacturer of prescription drugs,
 148 unless permitted as a third party logistics provider, located
 149 outside of this state or outside the United States and that
 150 engages in the wholesale distribution in this state of such
 151 prescription drugs. Each such manufacturer must be permitted by
 152 the department and comply with all of the provisions required of
 153 a wholesale distributor under this part, except s. 499.01212.

154 1. A person that distributes prescription drugs for which
 155 the person is not the manufacturer must also obtain an out-of-
 156 state prescription drug wholesale distributor permit or third

157 party logistics provider permit pursuant to this section to
 158 engage in the wholesale distribution of such prescription drugs.
 159 This subparagraph does not apply to a manufacturer as defined in
 160 s. 499.003(30)(e) ~~499.003(31)(e)~~.

161 2. Any such person must comply with the licensing or
 162 permitting requirements of the jurisdiction in which the
 163 establishment is located and the federal act, and any product
 164 wholesaled into this state must comply with this part. If a
 165 person intends to import prescription drugs from a foreign
 166 country into this state, the nonresident prescription drug
 167 manufacturer must provide to the department a list identifying
 168 each prescription drug it intends to import and document
 169 approval by the United States Food and Drug Administration for
 170 such importation.

171 (g) Restricted prescription drug distributor permit.—

172 1. A restricted prescription drug distributor permit is
 173 required for:

174 a. Any person located in this state who engages in the
 175 distribution of a prescription drug, which distribution is not
 176 considered "wholesale distribution" under s. 499.003(53)(a)
 177 ~~499.003(54)(a)~~.

178 b. Any person located in this state who engages in the
 179 receipt or distribution of a prescription drug in this state for
 180 the purpose of processing its return or its destruction if such
 181 person is not the person initiating the return, the prescription
 182 drug wholesale supplier of the person initiating the return, or

183 the manufacturer of the drug.

184 c. A blood establishment located in this state which
 185 collects blood and blood components only from volunteer donors
 186 as defined in s. 381.06014 or pursuant to an authorized
 187 practitioner's order for medical treatment or therapy and
 188 engages in the wholesale distribution of a prescription drug not
 189 described in s. 499.003(53)(d) ~~499.003(54)(d)~~ to a health care
 190 entity. A mobile blood unit operated by a blood establishment
 191 permitted under this sub-subparagraph is not required to be
 192 separately permitted. The health care entity receiving a
 193 prescription drug distributed under this sub-subparagraph must
 194 be licensed as a closed pharmacy or provide health care services
 195 at that establishment. The blood establishment must operate in
 196 accordance with s. 381.06014 and may distribute only:

197 (I) Prescription drugs indicated for a bleeding or
 198 clotting disorder or anemia;

199 (II) Blood-collection containers approved under s. 505 of
 200 the federal act;

201 (III) Drugs that are blood derivatives, or a recombinant
 202 or synthetic form of a blood derivative;

203 (IV) Prescription drugs that are identified in rules
 204 adopted by the department and that are essential to services
 205 performed or provided by blood establishments and authorized for
 206 distribution by blood establishments under federal law; or

207 (V) To the extent authorized by federal law, drugs
 208 necessary to collect blood or blood components from volunteer

209 blood donors; for blood establishment personnel to perform
 210 therapeutic procedures under the direction and supervision of a
 211 licensed physician; and to diagnose, treat, manage, and prevent
 212 any reaction of a volunteer blood donor or a patient undergoing
 213 a therapeutic procedure performed under the direction and
 214 supervision of a licensed physician,

215

216 as long as all of the health care services provided by the blood
 217 establishment are related to its activities as a registered
 218 blood establishment or the health care services consist of
 219 collecting, processing, storing, or administering human
 220 hematopoietic stem cells or progenitor cells or performing
 221 diagnostic testing of specimens if such specimens are tested
 222 together with specimens undergoing routine donor testing. The
 223 blood establishment may purchase and possess the drugs described
 224 in this sub-subparagraph without a health care clinic
 225 establishment permit.

226 2. Storage, handling, and recordkeeping of these
 227 distributions by a person required to be permitted as a
 228 restricted prescription drug distributor must be in accordance
 229 with the requirements for wholesale distributors under s.
 230 499.0121, but not those set forth in s. 499.01212 if the
 231 distribution occurs pursuant to sub-subparagraph 1.a. or sub-
 232 subparagraph 1.b.

233 3. A person who applies for a permit as a restricted
 234 prescription drug distributor, or for the renewal of such a

235 permit, must provide to the department the information required
 236 under s. 499.012.

237 4. The department may adopt rules regarding the
 238 distribution of prescription drugs by hospitals, health care
 239 entities, charitable organizations, other persons not involved
 240 in wholesale distribution, and blood establishments, which rules
 241 are necessary for the protection of the public health, safety,
 242 and welfare.

243 ~~(m) Medical oxygen retail establishment permit. A medical~~
 244 ~~oxygen retail establishment permit is required for any person~~
 245 ~~that sells medical oxygen to patients only. The sale must be~~
 246 ~~based on an order from a practitioner authorized by law to~~
 247 ~~prescribe. The term does not include a pharmacy licensed under~~
 248 ~~chapter 465.~~

249 ~~1. A medical oxygen retail establishment may not possess,~~
 250 ~~purchase, sell, or trade any prescription drug other than~~
 251 ~~medical oxygen.~~

252 ~~2. A medical oxygen retail establishment may refill~~
 253 ~~medical oxygen for an individual patient based on an order from~~
 254 ~~a practitioner authorized by law to prescribe. A medical oxygen~~
 255 ~~retail establishment that refills medical oxygen must comply~~
 256 ~~with all appropriate state and federal good manufacturing~~
 257 ~~practices.~~

258 ~~3. A medical oxygen retail establishment must comply with~~
 259 ~~all of the wholesale distribution requirements of s. 499.0121.~~

260 ~~4. Prescription medical oxygen sold by a medical oxygen~~

261 ~~retail establishment pursuant to a practitioner's order may not~~
 262 ~~be returned into the retail establishment's inventory.~~

263 ~~(n) Compressed medical gas wholesale distributor permit. A~~
 264 ~~compressed medical gas wholesale distributor is a wholesale~~
 265 ~~distributor that is limited to the wholesale distribution of~~
 266 ~~compressed medical gases to other than the consumer or patient.~~
 267 ~~The compressed medical gas must be in the original sealed~~
 268 ~~container that was purchased by that wholesale distributor. A~~
 269 ~~compressed medical gas wholesale distributor may not possess or~~
 270 ~~engage in the wholesale distribution of any prescription drug~~
 271 ~~other than compressed medical gases. The department shall adopt~~
 272 ~~rules that govern the wholesale distribution of prescription~~
 273 ~~medical oxygen for emergency use. With respect to the emergency~~
 274 ~~use of prescription medical oxygen, those rules may not be~~
 275 ~~inconsistent with rules and regulations of federal agencies~~
 276 ~~unless the Legislature specifically directs otherwise.~~

277 ~~(o) Compressed medical gas manufacturer permit. A~~
 278 ~~compressed medical gas manufacturer permit is required for any~~
 279 ~~person that engages in the manufacture of compressed medical~~
 280 ~~gases or repackages compressed medical gases from one container~~
 281 ~~to another.~~

282 ~~1. A compressed medical gas manufacturer may not~~
 283 ~~manufacture or possess any prescription drug other than~~
 284 ~~compressed medical gases.~~

285 ~~2. A compressed medical gas manufacturer may engage in~~
 286 ~~wholesale distribution of compressed medical gases manufactured~~

287 ~~at that establishment and must comply with all the provisions of~~
 288 ~~this part and the rules adopted under this part that apply to a~~
 289 ~~wholesale distributor.~~

290 ~~3. A compressed medical gas manufacturer must comply with~~
 291 ~~all appropriate state and federal good manufacturing practices.~~

292 (5) A prescription drug repackager permit issued under
 293 this part is not required for a restricted prescription drug
 294 distributor permitholder that is a health care entity to
 295 repackage prescription drugs in this state for its own use or
 296 for distribution to hospitals or other health care entities in
 297 the state for their own use, pursuant to s. 499.003(53)(a)3.
 298 ~~499.003(54)(a)3.~~, if:

299 (a) The prescription drug distributor notifies the
 300 department, in writing, of its intention to engage in
 301 repackaging under this exemption, 30 days before engaging in the
 302 repackaging of prescription drugs at the permitted
 303 establishment;

304 (b) The prescription drug distributor is under common
 305 control with the hospitals or other health care entities to
 306 which the prescription drug distributor is distributing
 307 prescription drugs. As used in this paragraph, "common control"
 308 means the power to direct or cause the direction of the
 309 management and policies of a person or an organization, whether
 310 by ownership of stock, voting rights, contract, or otherwise;

311 (c) The prescription drug distributor repackages the
 312 prescription drugs in accordance with current state and federal

313 good manufacturing practices; and

314 (d) The prescription drug distributor labels the
 315 prescription drug it repackages in accordance with state and
 316 federal laws and rules.

317
 318 The prescription drug distributor is exempt from the product
 319 registration requirements of s. 499.015 with regard to the
 320 prescription drugs that it repackages and distributes under this
 321 subsection.

322 Section 3. Paragraph (b) of subsection (2) of section
 323 499.0121, Florida Statutes, is amended to read:

324 499.0121 Storage and handling of prescription drugs;
 325 recordkeeping.—The department shall adopt rules to implement
 326 this section as necessary to protect the public health, safety,
 327 and welfare. Such rules shall include, but not be limited to,
 328 requirements for the storage and handling of prescription drugs
 329 and for the establishment and maintenance of prescription drug
 330 distribution records.

331 (2) SECURITY.—

332 (b) An establishment that is used for wholesale drug
 333 distribution must be equipped with:

334 1. An alarm system to detect entry after hours; however,
 335 the department may exempt by rule establishments that only hold
 336 a permit as prescription drug wholesale distributor-brokers. and
 337 ~~establishments that only handle medical oxygen; and~~

338 2. A security system that will provide suitable protection

339 against theft and diversion. When appropriate, the security
 340 system must provide protection against theft or diversion that
 341 is facilitated or hidden by tampering with computers or
 342 electronic records.

343 Section 4. Subsection (2) of section 499.01211, Florida
 344 Statutes, is amended, and paragraph (h) is added to that
 345 subsection, to read:

346 499.01211 Drug Wholesale Distributor Advisory Council.—

347 (2) The Secretary of Business and Professional Regulation
 348 or his or her designee and the Secretary of Health Care
 349 Administration or her or his designee shall be members of the
 350 council. The Secretary of Business and Professional Regulation
 351 shall appoint 10 ~~nine~~ additional members to the council who
 352 shall be appointed to a term of 4 years each, as follows:

353 (a) Three different persons each of whom is employed by a
 354 different prescription drug wholesale distributor licensed under
 355 this part which operates nationally and is a primary wholesale
 356 distributor, as defined in s. 499.003(46) ~~499.003(47)~~.

357 (b) One person employed by a prescription drug wholesale
 358 distributor licensed under this part which is a secondary
 359 wholesale distributor, as defined in s. 499.003(51) ~~499.003(52)~~.

360 (c) One person employed by a retail pharmacy chain located
 361 in this state.

362 (d) One person who is a member of the Board of Pharmacy
 363 and is a pharmacist licensed under chapter 465.

364 (e) One person who is a physician licensed pursuant to

365 chapter 458 or chapter 459.

366 (f) One person who is an employee of a hospital licensed
 367 pursuant to chapter 395 and is a pharmacist licensed pursuant to
 368 chapter 465.

369 (g) One person who is an employee of a pharmaceutical
 370 manufacturer.

371 (h) One person who is an employee of a medical gas
 372 manufacturer or medical gas wholesale distributor and who has
 373 been named by the Compressed Gas Association.

374 Section 5. Paragraph (e) of subsection (1), paragraph (b)
 375 of subsection (2), and paragraph (b) of subsection (3) of
 376 section 499.041, Florida Statutes, are amended to read:

377 499.041 Schedule of fees for drug, device, and cosmetic
 378 applications and permits, product registrations, and free-sale
 379 certificates.—

380 (1) The department shall assess applicants requiring a
 381 manufacturing permit an annual fee within the ranges established
 382 in this section for the specific type of manufacturer.

383 ~~(c) The fee for a compressed medical gas manufacturer~~
 384 ~~permit may not be less than \$400 or more than \$500 annually.~~

385 (2) The department shall assess an applicant that is
 386 required to have a wholesaling permit an annual fee within the
 387 ranges established in this section for the specific type of
 388 wholesaling.

389 ~~(b) The fee for a compressed medical gas wholesale~~
 390 ~~distributor permit may not be less than \$200 or more than \$300~~

391 ~~annually.~~

392 (3) The department shall assess an applicant that is
 393 required to have a retail establishment permit an annual fee
 394 within the ranges established in this section for the specific
 395 type of retail establishment.

396 ~~(b) The fee for a medical oxygen retail establishment~~
 397 ~~permit may not be less than \$200 or more than \$300 annually.~~

398 Section 6. Subsections (1) through (4) of section 499.051,
 399 Florida Statutes, are amended to read:

400 499.051 Inspections and investigations.—

401 (1) The agents of the department and of the Department of
 402 Law Enforcement, after they present proper identification, may
 403 inspect, monitor, and investigate any establishment permitted
 404 pursuant to this chapter part during business hours for the
 405 purpose of enforcing this chapter part, chapters 465, 501, and
 406 893, and the rules of the department that protect the public
 407 health, safety, and welfare.

408 (2) In addition to the authority set forth in subsection
 409 (1), the department and any duly designated officer or employee
 410 of the department may enter and inspect any other establishment
 411 for the purpose of determining compliance with this part and
 412 rules adopted under this chapter part regarding any drug,
 413 device, or cosmetic product.

414 (3) Any application for a permit or product registration
 415 or for renewal of such permit or registration made pursuant to
 416 this chapter part and rules adopted under this chapter part

417 constitutes permission for any entry or inspection of the
 418 premises in order to verify compliance with this chapter part
 419 and rules; to discover, investigate, and determine the existence
 420 of compliance; or to elicit, receive, respond to, and resolve
 421 complaints and violations.

422 (4) Any application for a permit made pursuant to s.
 423 499.012 or s. 499.831 and rules adopted under those sections
 424 ~~that section~~ constitutes permission for agents of the department
 425 and the Department of Law Enforcement, after presenting proper
 426 identification, to inspect, review, and copy any financial
 427 document or record related to the manufacture, repackaging, or
 428 distribution of a drug as is necessary to verify compliance with
 429 this chapter part and the rules adopted by the department to
 430 administer this chapter part, in order to discover, investigate,
 431 and determine the existence of compliance, or to elicit,
 432 receive, respond to, and resolve complaints and violations.

433 Section 7. Subsections (1) through (4) of section 499.066,
 434 Florida Statutes, are amended to read:

435 499.066 Penalties; remedies.—In addition to other
 436 penalties and other enforcement provisions:

437 (1) The department may institute such suits or other legal
 438 proceedings as are required to enforce any provision of this
 439 chapter part. If it appears that a person has violated any
 440 provision of this chapter part for which criminal prosecution is
 441 provided, the department may provide the appropriate state
 442 attorney or other prosecuting agency having jurisdiction with

443 respect to such prosecution with the relevant information in the
 444 department's possession.

445 (2) If any person engaged in any activity covered by this
 446 chapter part violates any provision of this chapter part, any
 447 rule adopted under this chapter part, or a cease and desist
 448 order as provided by this chapter part, the department may
 449 obtain an injunction in the circuit court of the county in which
 450 the violation occurred or in which the person resides or has its
 451 principal place of business, and may apply in that court for
 452 such temporary and permanent orders as the department considers
 453 necessary to restrain the person from engaging in any such
 454 activities until the person complies with this chapter part, the
 455 rules adopted under this chapter part, and the orders of the
 456 department authorized by this chapter part or to mandate
 457 compliance with this chapter part, the rules adopted under this
 458 chapter part, and any order or permit issued by the department
 459 under this chapter part.

460 (3) The department may impose an administrative fine, not
 461 to exceed \$5,000 per violation per day, for the violation of any
 462 provision of this chapter part or rules adopted under this
 463 chapter part. Each day a violation continues constitutes a
 464 separate violation, and each separate violation is subject to a
 465 separate fine. All amounts collected pursuant to this section
 466 shall be deposited into the Professional Regulation Trust Fund
 467 and are appropriated for the use of the department in
 468 administering this chapter part. In determining the amount of

469 the fine to be levied for a violation, the department shall
 470 consider:

471 (a) The severity of the violation;

472 (b) Any actions taken by the person to correct the
 473 violation or to remedy complaints; and

474 (c) Any previous violations.

475 (4) The department shall deposit any rewards, fines, or
 476 collections that are due the department and which derive from
 477 joint enforcement activities with other state and federal
 478 agencies which relate to this chapter ~~part~~, chapter 893, or the
 479 federal act, into the Professional Regulation Trust Fund. The
 480 proceeds of those rewards, fines, and collections are
 481 appropriated for the use of the department in administering this
 482 chapter ~~part~~.

483 Section 8. Paragraph (a) of subsection (1) and paragraph
 484 (a) of subsection (2) of section 499.0661, Florida Statutes, are
 485 amended to read:

486 499.0661 Cease and desist orders; removal of certain
 487 persons.—

488 (1) CEASE AND DESIST ORDERS.—

489 (a) In addition to any authority otherwise provided in
 490 this chapter, the department may issue and serve a complaint
 491 stating charges upon a any permittee or upon an ~~any~~ affiliated
 492 party, whenever the department has reasonable cause to believe
 493 that the person or individual named therein is engaging in or
 494 has engaged in conduct that is:

495 1. An act that demonstrates a lack of fitness or
 496 trustworthiness to engage in the business authorized under the
 497 permit issued pursuant to this chapter part, is hazardous to the
 498 public health, or constitutes business operations that are a
 499 detriment to the public health;

500 2. A violation of a ~~any~~ provision of this chapter part;

501 3. A violation of a ~~any~~ rule of the department;

502 4. A violation of an ~~any~~ order of the department; or

503 5. A breach of a ~~any~~ written agreement with the
 504 department.

505 (2) REMOVAL OF AFFILIATED PARTIES BY THE DEPARTMENT.—

506 (a) The department may issue and serve a complaint stating
 507 charges upon an ~~any~~ affiliated party and upon the permittee
 508 involved whenever the department has reason to believe that an
 509 affiliated party is engaging in or has engaged in conduct that
 510 constitutes:

511 1. An act that demonstrates a lack of fitness or
 512 trustworthiness to engage in the business authorized under the
 513 permit issued pursuant to this chapter part, is hazardous to the
 514 public health, or constitutes business operations that are a
 515 detriment to the public health;

516 2. A willful violation of this chapter part; however, if
 517 the violation constitutes a misdemeanor, a complaint may not be
 518 served as provided in this section until the affiliated party is
 519 notified in writing of the matter of the violation and has been
 520 afforded a reasonable period of time, as set forth in the

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521 notice, to correct the violation and has failed to do so;
 522 3. A violation of a ~~any other~~ law involving fraud or moral
 523 turpitude which constitutes a felony;
 524 4. A willful violation of a ~~any~~ rule of the department;
 525 5. A willful violation of an ~~any~~ order of the department;
 526 or
 527 6. A material misrepresentation of fact, made knowingly
 528 and willfully or made with reckless disregard for the truth of
 529 the matter.
 530 Section 9. Subsections (1) and (2), paragraph (c) of
 531 subsection (3), and subsections (4) through (9) of section
 532 499.067, Florida Statutes, are amended to read:
 533 499.067 Denial, suspension, or revocation of permit,
 534 certification, or registration.—
 535 (1)(a) The department may deny, suspend, or revoke a
 536 permit if it finds that there has been a substantial failure to
 537 comply with this chapter ~~part~~ or chapter 465, chapter 501, or
 538 chapter 893, the rules adopted under ~~this part~~ or those
 539 chapters, any final order of the department, or applicable
 540 federal laws or regulations or other state laws or rules
 541 governing drugs, devices, or cosmetics.
 542 (b) The department may deny an application for a permit or
 543 certification, or suspend or revoke a permit or certification,
 544 if the department finds that:
 545 1. The applicant is not of good moral character or that it
 546 would be a danger or not in the best interest of the public

547 health, safety, and welfare if the applicant were issued a
 548 permit or certification.

549 2. The applicant has not met the requirements for the
 550 permit or certification.

551 3. The applicant is not eligible for a permit or
 552 certification for any of the reasons enumerated in s. 499.012.

553 4. The applicant, permittee, or person certified under s.
 554 499.012(16) demonstrates any of the conditions enumerated in s.
 555 499.012.

556 5. The applicant, permittee, or person certified under s.
 557 499.012(16) has committed any violation of ss. 499.005-499.0054
 558 or this chapter.

559 (2) The department may deny, suspend, or revoke any
 560 registration required by the provisions of this chapter part for
 561 the violation of any provision of this chapter part or of any
 562 rules adopted under this chapter part.

563 (3) The department may revoke or suspend a permit:

564 (c) If the permittee has violated a ~~any~~ provision of this
 565 chapter part or rules adopted under this chapter part.

566 (4) If a ~~any~~ permit issued under this chapter part is
 567 revoked or suspended, the owner, manager, operator, or
 568 proprietor of the establishment shall cease to operate as the
 569 permit authorized, from the effective date of the suspension or
 570 revocation until the person is again registered with the
 571 department and possesses the required permit. If a permit is
 572 revoked or suspended, the owner, manager, or proprietor shall

573 remove all signs and symbols that identify the operation as
 574 premises permitted as a drug wholesaling establishment; drug,
 575 device, or cosmetic manufacturing establishment; or retail
 576 establishment. The department shall determine the length of time
 577 for which the permit is to be suspended. If a permit is revoked,
 578 the person that owns or operates the establishment may not apply
 579 for a ~~any~~ permit under this chapter ~~part~~ for a period of 1 year
 580 after the date of the revocation. A revocation of a permit may
 581 be permanent if the department considers that to be in the best
 582 interest of the public health.

583 (5) The department may deny, suspend, or revoke a permit
 584 issued under this part which authorizes the permittee to
 585 purchase prescription drugs if an ~~any~~ owner, officer, employee,
 586 or other person who participates in administering or operating
 587 the establishment has been found guilty of a ~~any~~ violation of
 588 this chapter ~~part~~ or chapter 465, chapter 501, or chapter 893,
 589 any rules adopted under ~~this part~~ or those chapters, or any
 590 federal or state drug law, regardless of whether the person has
 591 been pardoned, had her or his civil rights restored, or had
 592 adjudication withheld.

593 (6) The department shall deny, suspend, or revoke the
 594 permit of a ~~any~~ person or establishment if the assignment, sale,
 595 transfer, or lease of an establishment permitted under this
 596 chapter ~~part~~ will avoid an administrative penalty, civil action,
 597 or criminal prosecution.

598 (7) Notwithstanding s. 120.60(5), if a permittee fails to

599 comply with s. 499.012(6) or s. 499.831, as applicable, the
 600 department may revoke the permit of the permittee and shall
 601 provide notice of the intended agency action by posting a notice
 602 at the department's headquarters and by mailing a copy of the
 603 notice of intended agency action by certified mail to the most
 604 recent mailing address on record with the department and, if the
 605 permittee is not a natural person, to the permittee's registered
 606 agent on file with the Department of State.

607 (8) The department may deny, suspend, or revoke a permit
 608 under this part if it finds the permittee has not complied with
 609 the credentialing requirements of s. 499.0121(15).

610 (9) The department may deny, suspend, or revoke a permit
 611 under this part if it finds the permittee has not complied with
 612 the reporting requirements of, or knowingly made a false
 613 statement in a report required by, s. 499.0121(14).

614 Section 10. Part III of chapter 499, Florida Statutes,
 615 consisting of sections 499.81 through 499.99, is created to
 616 read:

617 PART III

618 MEDICAL GASES

619 499.81 Administration and enforcement.-

620 (1) The provisions of this part are cumulative and shall
 621 be construed and applied as being in addition to, and not in
 622 substitution for or limitation of, any powers, duties, or
 623 authority of the department under any other law of this state;
 624 except that, with respect to the regulation of medical gas, the

625 provisions of this part shall control over any conflicting
 626 provisions.

627 (2) The department shall administer and enforce this part
 628 to prevent fraud, adulteration, misbranding, or false
 629 advertising in the manufacture or distribution of medical gas.

630 (3) For the purpose of an investigation or proceeding
 631 conducted by the department under this part, the department may
 632 administer oaths, take depositions, subpoena witnesses, and
 633 compel the production of books, papers, documents, or other
 634 records. Challenges to, and enforcement of, subpoenas and orders
 635 shall be handled as provided in s. 120.569.

636 (4) Each state attorney, county attorney, or municipal
 637 attorney to whom the department or its designated agent reports
 638 a violation of this part shall cause appropriate proceedings to
 639 be instituted in the proper courts without delay and prosecuted
 640 in the manner required by law.

641 (5) This part does not require the department to report,
 642 for the institution of proceedings under this part, minor
 643 violations of this part when the department believes that the
 644 public interest will be adequately served by a written notice or
 645 warning.

646 499.82 Definitions.—As used in this part, the term:

647 (1) "Adulterated" means:

648 (a) Consisting in whole or in part of impurities or
 649 deleterious substances exceeding normal specifications;

650 (b) Produced, prepared, packed, or held under conditions

651 whereby the medical gas may have been contaminated causing it to
 652 be rendered injurious to health; or if the methods used in, or
 653 the facilities or controls used for, its manufacture,
 654 processing, packing, or holding do not conform to or are not
 655 operated or administered in conformity with current good
 656 manufacturing practices to ensure that the medical gas meets the
 657 requirements of this part as to safety and has the identity and
 658 strength, and meets the quality and purity characteristics that
 659 it is represented to possess;

660 (c) Having a container interior that is composed in whole
 661 or in part of a poisonous or deleterious substance which may
 662 render the contents injurious to health; or

663 (d) Represented as a medical gas, with strength differing
 664 from, or quality or purity falling below, the standard set forth
 665 in the USP-NF. Such determination shall be made in accordance
 666 with the tests or methods of assay in the USP-NF, or validated
 667 equivalent, or in the absence of or inadequacy of these tests or
 668 methods of assay, tests or methods of assay prescribed under the
 669 federal act. No medical gas defined in USP-NF shall be deemed to
 670 be adulterated under this paragraph because it differs from the
 671 standard of strength, quality, or purity set forth in the USP-
 672 NF, if its difference in strength, quality, or purity from that
 673 standard is plainly stated on its label.

674 (2) "Distribution" means to sell, offer to sell, deliver,
 675 offer to deliver, broker, give away, or transfer a medical gas,
 676 whether by passage of title, physical movement, or both. The

677 term does not include:

678 (a) The dispensation or administration of medical gas;

679 (b) The delivery of, or an offer to deliver, a medical gas
 680 by a common carrier in the usual course of business as a common
 681 carrier; or

682 (c) Sales activities taking place in a location owned or
 683 controlled by, or staffed by persons employed by, a person or
 684 entity licensed in this state to distribute medical gas, where
 685 the locations where such sales activities are taking place do
 686 not physically store or move medical gas.

687 (3) "Emergency" includes, but is not limited, to:

688 (a) Transfer of a medical gas between wholesale
 689 distributors of medical gases or between a wholesale distributor
 690 of medical gases and a retail pharmacy or health care entity to
 691 alleviate a temporary shortage of a medical gas arising from a
 692 delay in or interruption of regular distribution schedules.

693 (b) Sales to licensed emergency medical services,
 694 including ambulance companies and firefighting organizations in
 695 this state, or licensed practitioners allowed to dispense
 696 medical gases in the treatment of acutely ill or injured
 697 persons.

698 (c) Provision of emergency supplies of medical gases to
 699 nursing homes during hours of the day when necessary medical
 700 gases cannot be obtained.

701 (d) Transfer of medical gases between retail pharmacies to
 702 alleviate a temporary shortage.

703 (4) "Emergency use oxygen" means oxygen USP administered
 704 in emergency situations without a prescription for oxygen
 705 deficiency and resuscitation. The container must be labeled in
 706 accordance with requirements of the United States Food and Drug
 707 Administration.

708 (5) "Federal act" means the Federal Food, Drug, and
 709 Cosmetic Act.

710 (6) "Medical gas" means a liquefied or vaporized gas that
 711 is a prescription drug, whether alone or in combination with
 712 other gases, and as defined in the federal act.

713 (7) "Medical gas related equipment" means a device used as
 714 a component part or accessory used to contain or control the
 715 flow, delivery, or pressure during the administration of a
 716 medical gas, such as liquid oxygen base and portable units,
 717 pressure regulators and flow meters, and oxygen concentrators.

718 (8) "Misbranded " means having a label that is false or
 719 misleading; a label without the name and address of the
 720 manufacturer, packer, or distributor and without an accurate
 721 statement of the quantities of active ingredients; or a label
 722 without an accurate monograph for the medical gas, except in the
 723 case of mixtures of designated medical gases where the label
 724 identifies the component percentages of each designated medical
 725 gas used to make the mixture.

726 (9) "Prescription medical oxygen" means oxygen USP which
 727 can only be sold on the order or prescription of a practitioner
 728 authorized to prescribe. The label of prescription medical

729 oxygen must comply with labeling requirements for oxygen under
 730 the federal act.

731 (10) "Product labeling" means the labels and other
 732 written, printed, or graphic matter upon an article, or the
 733 containers or wrappers that accompany an article, except for
 734 letters, numbers, and symbols stamped into the container as
 735 required by the federal Department of Transportation.

736 (11) "USP" means United States Pharmacopeia.

737 (12) "USP-NF" means United States Pharmacopeia-National
 738 Formulary.

739 (13) "Wholesale distribution" means the distribution of
 740 medical gas by a wholesale distributor of medical gases to a
 741 person other than a consumer or patient. Wholesale distribution
 742 of medical gases does not include:

743 (a) The sale, purchase, or trade of a medical gas, an
 744 offer to sell, purchase, or trade a prescription drug or device,
 745 or the dispensing of a medical gas pursuant to a prescription;

746 (b) The sale, purchase, or trade of a medical gas or an
 747 offer to sell, purchase, or trade a medical gas for emergency
 748 medical reasons;

749 (c) Intracompany transactions;

750 (d) The sale, purchase, or trade of a medical gas or an
 751 offer to sell, purchase, or trade a medical gas among hospitals,
 752 pharmacies, or other health care entities that are under common
 753 control;

754 (e) The sale, purchase, or trade of a medical gas or the

755 offer to sell, purchase, or trade a medical gas by a charitable
756 organization described in s. 501(c)(3) of the Internal Revenue
757 Code of 1986, as amended, to a nonprofit affiliate of the
758 organization to the extent otherwise permitted by law;

759 (f) The purchase or other acquisition by a hospital or
760 other similar health care entity that is a member of a group
761 purchasing organization of a medical gas for its own use from
762 the group purchasing organization or from other hospitals or
763 similar health care entities that are members of such
764 organizations;

765 (g) The return of residual medical gas that may be
766 reprocessed in accordance with manufacturer's procedures, or the
767 return of recalled, expired, damaged, or otherwise nonsalable
768 medical gas, when conducted by a hospital, health care entity,
769 pharmacy, or charitable institution to a wholesale distributor
770 of medical gases;

771 (h) Activities exempt from wholesale distribution as
772 defined in s. 499.003(53); or

773 (i) Other transactions excluded from the definition of
774 wholesale distribution under the federal act or regulations
775 implemented under the federal act related to medical gas.

776 (14) "Wholesale distributor" means any person engaged in
777 wholesale distribution of medical gas in or into this state,
778 including, but not limited to, manufacturers, own-label
779 distributors, private-label distributors, warehouses, including
780 manufacturers' and distributors' warehouses, and wholesale

781 medical gas warehouses.
 782 499.831 Permits.-
 783 (1) Before operating, unless exempted under this part, a
 784 permit is required for each person and establishment, whether
 785 inside or outside of this state, that intends to distribute
 786 medical gas in or into this state and operate as:
 787 (a) A medical gas wholesale distributor;
 788 (b) A medical gas manufacturer; or
 789 (c) A medical oxygen retail establishment.
 790 (2) The following permits are established:
 791 (a) Medical gas wholesale distributor permit.-A medical
 792 gas wholesale distributor permit is required for the wholesale
 793 distribution of medical gases, whether in or into this state.
 794 The medical gas must be in the original container obtained by
 795 the wholesale distributor without further manufacturing
 796 operations. A medical gas wholesale distributor may not possess
 797 or engage in the wholesale distribution of a prescription drug
 798 that is not a medical gas. The department shall adopt rules to
 799 govern the wholesale distribution of prescription medical oxygen
 800 for emergency use and to persons authorized to receive emergency
 801 use oxygen. Rules regarding the emergency use of prescription
 802 medical oxygen may not be inconsistent with rules and
 803 regulations of federal agencies unless the Legislature
 804 specifically directs otherwise.
 805 (b) Medical gas manufacturer permit.-A medical gas
 806 manufacturer permit is required for a person that engages in the

807 manufacture of medical gases by physical air separation,
 808 chemical action, purification, or filling containers by a liquid
 809 to liquid, liquid to gas, or gas to gas process and that
 810 distributes those medical gases in or into this state.

811 1. A medical gas manufacturer may not manufacture or
 812 possess a prescription drug that is not a medical gas, unless
 813 the medical gas manufacturer obtains the appropriate permit
 814 under this paragraph.

815 2. A medical gas manufacturer may engage in wholesale
 816 distribution of medical gases manufactured without a medical gas
 817 wholesale distributor permit, but must comply with the
 818 provisions of this part and the rules adopted under this part
 819 that apply to a wholesale distributor.

820 3. A medical gas manufacturer shall comply with all
 821 appropriate state and federal good manufacturing practices.

822 (c) Medical oxygen retail establishment permit.—A medical
 823 oxygen retail establishment permit is required for a person that
 824 sells medical oxygen directly to patients. The sale must be
 825 based on an order from a practitioner authorized by law to
 826 prescribe. The medical oxygen retail establishment permit
 827 excludes a pharmacy licensed under chapter 465.

828 1. A medical oxygen retail establishment may not possess,
 829 purchase, sell, or trade a prescription drug that is not medical
 830 oxygen unless the establishment obtains the appropriate permit.

831 2. A medical oxygen retail establishment may refill
 832 medical oxygen for an individual patient based on an order from

833 a practitioner authorized by law to prescribe.

834 3. Prescription medical oxygen sold by a medical oxygen
 835 retail establishment pursuant to an order from a practitioner
 836 may not be returned into the retail establishment's inventory.

837 4. A medical oxygen retail establishment that refills
 838 medical oxygen shall comply with all appropriate state and
 839 federal good manufacturing practices.

840 5. A medical oxygen retail establishment shall comply with
 841 the requirements of s. 499.87.

842 (3) The department shall adopt rules establishing the form
 843 and content of the application to obtain or renew a permit. The
 844 applicant must submit to the department with the application a
 845 statement that swears or affirms that the information is true
 846 and correct. An application for a permit must include:

847 (a) All trade or business terms used by the licensee,
 848 including "doing business as (d/b/a)" and "formerly known as,"
 849 which cannot be identical to the name used by an unrelated
 850 wholesale distributor licensed to purchase medical gas in the
 851 state;

852 (b) The name of the owner and operator of the licensee
 853 including:

854 1. The name, business address, and date of birth, if the
 855 licensee is an individual.

856 2. The name, business address, date of birth of each
 857 partner, the name of the partnership, and federal employer
 858 identification number, if the licensee is a partnership.

859 3. The name, business address, and title of each corporate
 860 officer and director, the corporate names, the state of
 861 incorporation, the federal employer identification number, and
 862 the name and business address of the parent company, if one
 863 exists, if the licensee is a corporation.

864 4. The full name and business address of the sole
 865 proprietor and the name and federal employer identification
 866 number of the business entity, if the licensee is a sole
 867 proprietorship.

868 5. The name, business address, and title of each company
 869 officer, the name of the limited liability company and federal
 870 employer identification number, and the name of the state in
 871 which the limited liability company was organized, if the
 872 licensee is a limited liability company.

873 (c) A list of all disciplinary actions pertinent to
 874 wholesale distributors of prescription drugs or controlled
 875 substances by any state and federal agencies against the
 876 wholesale distributor distributing medical gas into the state
 877 and any disciplinary actions against principals, owners,
 878 directors, or officers; and

879 (d) An address and description of each facility and
 880 warehouse, including all locations used for medical gas storage
 881 or wholesale distribution including a description of the
 882 security system.

883 (4) A permit issued pursuant to this part may be issued to
 884 a natural person who is at least 18 years of age or to an

885 applicant who is not a natural person if the person who,
 886 directly or indirectly, manages, controls, or oversees the
 887 operation of that applicant is at least 18 years of age.

888 (5) An applicant for a permit shall submit the appropriate
 889 fee for the permit for which he or she is applying. The fee
 890 shall be determined by the department.

891 (a) The fee for a medical gas wholesale distributor permit
 892 may not be less than \$200 or more than \$300 annually.

893 (b) The fee for a medical gas manufacturer permit may not
 894 be less than \$400 or more than \$500 annually.

895 (c) The fee for a medical oxygen retail establishment
 896 permit may not be less than \$200 or more than \$300 annually.

897 (6) Upon approval of the application by the department and
 898 payment of the required fee, the department shall issue a permit
 899 to the applicant pursuant to the rules adopted under this part.

900 (7)(a) A permit issued under this part may be renewed by
 901 submitting an application for renewal on a form furnished by the
 902 department and paying the appropriate fee.

903 (b) If a renewal application and fee are submitted and
 904 postmarked after expiration of the permit, a late renewal
 905 delinquent fee of \$100, plus the required renewal fee must be
 906 paid within 60 days after expiration of the permit.

907 (c) Upon approval of the renewal application by the
 908 department and payment of the required renewal fee, the
 909 department shall issue a permit to the applicant pursuant to the
 910 rules adopted under this part.

911 (d) The department shall adopt rules for the biennial
 912 renewal of permits.

913 (8)(a) A permit, unless suspended or revoked,
 914 automatically expires 2 years after the last day of the month in
 915 which the permit was issued.

916 (b) Failure to renew a permit in accordance with this
 917 section precludes any future renewal of that permit. If a permit
 918 issued pursuant to this part has expired and cannot be renewed,
 919 the establishment must submit an application for a new permit,
 920 pay the application fee, the initial permit fee, and all
 921 applicable penalties, and be issued a new permit by the
 922 department before the establishment may engage in activities
 923 that require a permit under this part.

924 (9) A permitted person in good standing may change permit
 925 type to a different permit under s. 499.831 by completing a new
 926 application for the requested permit, paying the additional
 927 amount due for the permit fee if the fee for the new permit is
 928 more than the fee for the original permit, and meeting the
 929 applicable permitting conditions for the new permit type. The
 930 new permit shall expire on the expiration date of the original
 931 permit. A refund may not be issued if the fee for the new permit
 932 is less than the fee that was paid for the original permit.

933 (10)(a) A permit issued by the department is valid only
 934 for the person or governmental unit to which it is issued and is
 935 not subject to sale, assignment, or other transfer, voluntarily
 936 or involuntarily, and is not valid for any establishment other

937 than the establishment for which it was originally issued except
 938 as provided in this part. The department is authorized to
 939 approve a change of the permit holder.

940 (b) Changes by authorized persons are permitted as
 941 follows:

942 1. A person permitted under this part must notify the
 943 department before making a change of location. The department
 944 shall set a change of location fee not to exceed \$100.

945 2. When a majority of the ownership or controlling
 946 interest of a permitted establishment is transferred or
 947 assigned, or when a lessee agrees to undertake or provide
 948 services to the extent that legal liability for operation of the
 949 establishment will rest with the lessee, an application for a
 950 new permit shall be required. The application for the new permit
 951 must be made before the change of ownership.

952 3. A permit holder may make a change of name without
 953 submitting a new permit application and must notify the
 954 department before making the name change. The permit holder may
 955 continue to operate the establishment while the notification is
 956 processed.

957 4. If an establishment permitted under this part closes,
 958 the owner must notify the department in writing before the
 959 effective date of the closure and must:

960 a. Return the permit to the department.

961 b. If the permittee is authorized to distribute medical
 962 gas, indicate the disposition of such medical gas, including the

963 name, address, and inventory, and provide the name and address
 964 of a contact with access to records that are required to be
 965 maintained under this part. Transfer of ownership of medical gas
 966 may be made only to persons authorized to possess medical gas
 967 under this part.

968 (11) Any change in information required under this section
 969 shall be submitted to the department within 30 days after such
 970 change. The department may revoke the permit of any person that
 971 fails to comply with this section.

972 499.841 Additional requirements for licensure of a
 973 wholesale distributor of medical gases.-

974 (1) A wholesale distributor of medical gases that resides
 975 in the state or provides services in or into this state must
 976 obtain a permit from the department and must renew the permit
 977 with the department biennially on an application provided by the
 978 department. Out-of-state wholesale distributors of medical gases
 979 that provide services into this state must also maintain permit
 980 requirements in the state in which they reside and in all states
 981 in which they distribute, if applicable.

982 (2) Wholesale distributors may not operate from or receive
 983 a permit for a residence, except that a place of residence may
 984 be used for on call delivery of homecare oxygen by a home
 985 respiratory care technician. If wholesale distribution
 986 operations are conducted at more than one location within the
 987 state or distributed from more than one location into the state,
 988 each location must be licensed by the department.

989 | 499.85 Minimum qualifications.-
 990 | (1) The department shall consider the following factors in
 991 | determining the eligibility for, and renewal of, licensure of
 992 | persons who engage in the wholesale distribution of medical gas:
 993 | (a) A finding by the department that the applicant has
 994 | violated or been disciplined by a regulatory agency in any state
 995 | for violating a federal, state, or local law relating to the
 996 | wholesale distribution of medical gases.
 997 | (b) A criminal conviction of the applicant under a
 998 | federal, state, or local law.
 999 | (c) The applicant's past experience in the manufacture or
 1000 | wholesale distribution of medical gases.
 1001 | (d) False or fraudulent material provided by the applicant
 1002 | in an application made in connection with the manufacturing or
 1003 | wholesale distribution of medical gases.
 1004 | (e) A suspension, sanction, or revocation by a federal,
 1005 | state, or local government against a license currently or
 1006 | previously held by the applicant or its owners for violations of
 1007 | a federal, state, or local law regarding medical gas.
 1008 | (f) Compliance with previously granted licenses.
 1009 | (g) Compliance with the requirements of wholesale
 1010 | distributors to medical gases to maintain records or make
 1011 | records available to the department licensing authority or
 1012 | federal, state, or local law enforcement officials.
 1013 | (h) Other factors or qualifications the department
 1014 | considers relevant to and consistent with the public health and

1015 safety.

1016 (2) The applicant shall provide a sworn statement
 1017 providing complete disclosure of any past criminal convictions
 1018 and violations of federal, state, or local laws regarding
 1019 medical gases or a sworn statement that the applicant has not
 1020 been convicted of or disciplined for any criminal or prohibited
 1021 acts.

1022 499.86 Registered agent.—Each applicant or licensee under
 1023 this part shall designate and maintain a registered agent in
 1024 this state for service of process. If an applicant or licensee
 1025 does not designate a registered agent, or if, after reasonable
 1026 diligence, service of process cannot be completed, service of
 1027 process may be effected by service upon the Secretary of State
 1028 as agent of the applicant or licensee. A copy of the service of
 1029 process shall be mailed to the applicant or licensee by the
 1030 department by certified mail, return receipt requested, or
 1031 postage prepaid, at the address such applicant or licensee has
 1032 designated on the applicant's or licensee's application for
 1033 licensure in this state.

1034 499.87 Minimum requirements for the storage and handling
 1035 of medical gases; establishment and maintenance of medical gas
 1036 records.—

1037 (1) Minimum requirements shall be established for the
 1038 storage, handling, transport, and shipment of medical gases and
 1039 for the maintenance of wholesale distribution records by
 1040 wholesale distributors of medical gases and their officers,

1041 agents, representatives, and employees.

1042 (2) A facility at which a medical gas is received, stored,
 1043 warehoused, handled, held, offered, marketed, displayed, or
 1044 transported from, as necessary to avoid a negative effect on the
 1045 identity, strength, quality, or purity of the medical gas,
 1046 shall:

1047 (a) Be of suitable construction to ensure that medical
 1048 gases are maintained in accordance with the product labeling of
 1049 the medical gas or in compliance with the USP-NF.

1050 (b) Be of suitable size and construction to facilitate
 1051 cleaning, maintenance, and proper wholesale distribution
 1052 operations.

1053 (c) Have adequate storage areas with appropriate lighting,
 1054 ventilation, space, equipment, and security conditions.

1055 (d) Have a quarantined area for storage of medical gases
 1056 that are suspected of being misbranded, adulterated, or
 1057 otherwise unfit for distribution.

1058 (e) Be maintained in an orderly condition.

1059 (f) Be a commercial location and not a personal dwelling
 1060 or residence location, except for a personal dwelling location
 1061 used for on-call delivery of oxygen USP for homecare use where
 1062 the person providing on-call delivery is employed by or acting
 1063 under a written contract with a permittee.

1064 (g) Provide for the secure and confidential storage of
 1065 patient information, if applicable, with restricted access and
 1066 policies and procedures to protect the integrity and

1067 confidentiality of the patient information.

1068 (h) Provide and maintain appropriate inventory controls to
 1069 detect and document any theft of nitrous oxide.

1070 499.88 Security.—

1071 (1) A facility used for wholesale distribution of medical
 1072 gases shall protect such gases within the facility from
 1073 unauthorized entry by using the following security measures:

1074 (a) Keep access from outside the premises well-controlled
 1075 and to a minimum.

1076 (b) Ensure the outside perimeter of the premises is well-
 1077 lit.

1078 (c) Limit entry into areas where medical gas is held to
 1079 authorized personnel.

1080 (d) Equip all facilities with a fence or other system to
 1081 detect or deter entry after hours.

1082 (2) A facility used for wholesale distribution of medical
 1083 gases shall be equipped with a system that will provide suitable
 1084 protection against theft, including when appropriate, protection
 1085 against theft of computers or electronic records and that will
 1086 protect the integrity and confidentiality of data and documents.

1087 (3) A facility used for wholesale distribution of medical
 1088 gases shall be equipped with inventory management and control
 1089 systems that protect against, detect, and document any instances
 1090 of theft of nitrous oxide.

1091 (4) Where a wholesale distributor of medical gases uses
 1092 electronic distribution records, the wholesale distributor shall

1093 employ, train, and document the training of personnel in the
 1094 proper use of such technology and equipment.

1095 (5) Vehicles used for on-call delivery of oxygen USP and
 1096 oxygen related equipment for home care use by home care
 1097 providers may be parked at a place of residence and must be
 1098 locked and equipped with an audible alarm when not attended.

1099 499.89 Storage.—

1100 (1) All medical gases shall be stored under appropriate
 1101 conditions in accordance with regulations created by the
 1102 department or, in the absence of regulations, in accordance with
 1103 applicable industry standards and the manufacturers'
 1104 recommendations on the product labeling.

1105 (2) Packaging of medical gas shall be in accordance with
 1106 the USP-NF, if applicable.

1107 (3) The record keeping requirements in s. 499.93 shall be
 1108 followed for the wholesale distribution of all medical gases.

1109 499.90 Examination of materials.—

1110 (1) Upon receipt of a medical gas container, the container
 1111 shall be visually examined to determine identity and whether the
 1112 container is damaged or otherwise unfit for wholesale
 1113 distribution.

1114 (2) A medical gas container that is found to be damaged or
 1115 unfit under subsection (1) shall be quarantined from the
 1116 remaining stock until an examination is conducted and a
 1117 determination is made that the medical gas is not misbranded or
 1118 adulterated.

1119 (3) Each outgoing shipment shall be carefully inspected
 1120 for the identity of the medical gas and to ensure that no
 1121 medical gas shipment has been damaged in storage or held under
 1122 improper conditions.

1123 (4) Upon receipt of a medical gas, a wholesale distributor
 1124 of medical gases must review the accompanying records for
 1125 accuracy and completeness. A pedigree paper is not required for
 1126 the wholesale distribution of a medical gas.

1127 (5) The record keeping requirements in s. 499.93 shall be
 1128 followed for all incoming and outgoing medical gases.

1129 499.91 Returned, damaged, and outdated medical gases.—

1130 (1) Medical gas that has left the control of the wholesale
 1131 distributor may be returned to the wholesale distributor or
 1132 manufacturer from which it was acquired but may not be resold as
 1133 a medical gas unless it is reprocessed by the manufacturer using
 1134 proper and adequate controls to ensure the identity, strength,
 1135 quality, and purity of the reprocessed medical gas.

1136 (2) A medical gas, including its container, that is
 1137 damaged, misbranded, or adulterated shall be quarantined and
 1138 physically separated from other medical gases until it is
 1139 destroyed or returned to either the manufacturer or wholesale
 1140 distributor from which it was acquired. External contamination
 1141 of medical gas containers or the container's closure system, not
 1142 impacting the integrity of the medical gas, is not considered
 1143 damage or adulteration for purposes of this paragraph.

1144 (3) When medical gas is adulterated, misbranded, or

1145 suspected of being adulterated or misbranded, notice shall be
 1146 provided to the manufacturer or wholesale distributor from which
 1147 they were acquired and the appropriate boards and federal
 1148 regulatory bodies.

1149 (4) A medical gas container that has been opened or used,
 1150 but is not adulterated or misbranded, shall be considered empty,
 1151 quarantined, and physically separated from nonempty medical gas
 1152 containers and returned to the manufacturer for destruction or
 1153 reprocessing.

1154 (5) A medical gas, its container, or its associated
 1155 documentation or labeling, that is suspected of being involved
 1156 in a criminal activity shall be retained and not destroyed until
 1157 its disposition is authorized by the department or applicable
 1158 law enforcement agency.

1159 (6) The record keeping requirements in s. 499.93 shall be
 1160 followed for all misbranded or adulterated medical gases.

1161 499.92 Due diligence.—A wholesale distributor of medical
 1162 gases shall comply with the following due diligence
 1163 requirements:

1164 (1) Before the initial acquisition of medical gases from a
 1165 wholesale distributor, including a manufacturer, the supplying
 1166 wholesale distributor shall provide the following information to
 1167 the acquiring wholesale distributor or manufacturer:

1168 (a) If a manufacturer is distributing to a wholesale
 1169 distributor, evidence that the manufacturer is registered and
 1170 the medical gas is listed with the United States Food and Drug

1171 Administration.

1172 (b) If a wholesale distributor is distributing to a
 1173 wholesale distributor, evidence that the wholesale distributor
 1174 supplying the medical gas is licensed to distribute product into
 1175 the state.

1176 (c) The name of the responsible facility contact person at
 1177 the supplying manufacturer or wholesale distributor.

1178 (d) A certification that the manufacturer or wholesale
 1179 distributor's policies and procedures comply with this part.

1180 (2) A manufacturer or wholesale distributor that
 1181 distributes or acquires medical gases to or from another
 1182 wholesale distributor of medical gases shall provide to or
 1183 obtain from the distributing or acquiring entities, as
 1184 applicable, the information set forth in s. 499.93(1).

1185 (3) A wholesale distributor of medical gases is exempt
 1186 from inspection of the facilities and review of the information
 1187 obtained from a manufacturer of medical gases, as required in
 1188 this section, when the manufacturer is registered with the
 1189 United States Food and Drug Administration in accordance with s.
 1190 510 of the federal act and the wholesale distributor provides:

1191 (a) Proof of such registration.

1192 (b) Proof of inspection by the Food and Drug
 1193 Administration or other regulatory body within the past 3 years,
 1194 or in the event that no regulatory body has inspected the
 1195 facility within the past 3 years, conformance with industry
 1196 standards or guidelines, as identified by the department or

1197 under this part.

1198 499.93 Recordkeeping.—

1199 (1) A wholesale distributor of medical gases shall
 1200 establish and maintain records of all transactions regarding the
 1201 receipt and wholesale distribution or other disposition of
 1202 medical gases. These records shall include the following, which
 1203 need not appear on the same document:

1204 (a) Dates of receipt and wholesale distribution or other
 1205 disposition of the medical gas.

1206 (b) The name, address, license number, and license
 1207 expiration date of the entity purchasing the medical gas.

1208 (c) The name, address, license number, and license
 1209 expiration date of the entity receiving the medical gas, if
 1210 different from paragraph (b).

1211 (d) Information sufficient to perform a recall of medical
 1212 gases received and distributed.

1213 (2) Such records shall be made available for inspection
 1214 and copying by an authorized official of any federal, state, or
 1215 local governmental agency for a period of:

1216 (a) Three years following the creation date of high
 1217 pressure medical gases.

1218 (b) One year following the creation date for cryogenic or
 1219 refrigerated liquid medical gases.

1220 (3) Records kept at the inspection site or that can be
 1221 immediately retrieved by computer or other electronic means
 1222 shall be readily available for authorized inspection during the

1223 retention period. Records kept at a central location apart from
 1224 the inspection site and not electronically retrievable shall be
 1225 made available for inspection within 2 working days of a request
 1226 by an authorized official of any state or federal governmental
 1227 agency charged with enforcement of these rules.

1228 (4) A wholesale distributor or manufacturers of medical
 1229 gases shall maintain an ongoing list of persons from whom they
 1230 receive or to whom they distribute medical gases.

1231 (5) A wholesale distributor of medical gases shall
 1232 maintain records sufficient to aid in the mandatory reporting of
 1233 any theft, suspected theft, or other significant loss of nitrous
 1234 oxide to the department and other appropriate law enforcement
 1235 agencies.

1236 499.94 Policies and procedures.—A wholesale distributor of
 1237 medical gases shall establish, maintain, and adhere to written
 1238 policies and procedures, which shall be followed for the
 1239 receipt, security, storage, transport, and shipping and
 1240 wholesale distribution of medical gases, including policies and
 1241 procedures for maintaining inventories, identifying, recording,
 1242 and reporting losses or thefts and for correcting all errors and
 1243 inaccuracies in inventories associated with nitrous oxide. A
 1244 wholesale distributor of medical gases shall include the
 1245 following in the written policies and procedures:

1246 (1) A process for handling recalls and withdrawals of
 1247 medical gases. The process shall be adequate to deal with
 1248 recalls and withdrawals due to:

1249 (a) An action initiated at the request of the United
 1250 States Food and Drug Administration or other federal, state, or
 1251 local law enforcement or other government agency, including the
 1252 department; or

1253 (b) A volunteer action by the manufacturer of medical
 1254 gases to remove defective or potentially defective medical gases
 1255 from the market.

1256 (2) A procedure to ensure that wholesale distributors of
 1257 medical gases prepare for, protect against, and handle a crisis
 1258 that affects the security or operation of any facility in the
 1259 event of a strike, fire, flood, or other natural disaster, or
 1260 other situations of local, state, or national emergency.

1261 (3) A procedure for reporting criminal or suspected
 1262 criminal activities involving the inventory of nitrous oxide to
 1263 the department and applicable law enforcement agencies within 3
 1264 business days of becoming aware of the criminal or suspect
 1265 criminal activity.

1266 499.95 Prohibited acts.-

1267 (1) For the purposes of this section, a person who is
 1268 legally authorized to receive a medical gas includes:

1269 (a) A licensed manufacturer of medical gases or medical
 1270 gas related equipment;

1271 (b) A wholesale distributor of medical gases;

1272 (c) A home respiratory care company;

1273 (d) A pharmacy or health care entity;

1274 (e) A person authorized to receive emergency use oxygen

1275 without a prescription;

1276 (f) A location with automated external defibrillation
 1277 machines where emergency use oxygen is intended to be used with
 1278 such machines; or

1279 (g) A company that requires the use of a medical gas in
 1280 the installation and refurbishment of piping and equipment,
 1281 including medical gas related equipment that will be used to
 1282 contain or administer a medical gas.

1283 (2) It is unlawful for a person to perform, cause the
 1284 performance of, or aid and abet the following acts in this
 1285 state:

1286 (a) The manufacture sale, delivery, or holding or offering
 1287 for sale of a medical gas that is adulterated, misbranded, or
 1288 has otherwise been rendered unfit for distribution or wholesale
 1289 distribution;

1290 (b) The adulteration or misbranding of a medical gas;

1291 (c) The receipt of a medical gas that is adulterated,
 1292 misbranded, stolen, obtained by fraud or deceit, or the delivery
 1293 or proffered delivery of such medical gas for pay or otherwise;

1294 (d) The alteration, mutilation, destruction, obliteration,
 1295 or removal of the whole or a part of the product labeling of a
 1296 medical gas or the willful commission of an act with respect to
 1297 a medical gas that results in the medical gas being misbranded;

1298 (e) The purchase or receipt of a medical gas from a person
 1299 that is not licensed, or exempt from licensure, to distribute
 1300 wholesale medical gas to that purchaser or recipient;

1301 (f) The knowing and willful sale or transfer of a medical
 1302 gas to a person or other recipient who is not legally authorized
 1303 to receive a medical gas;

1304 (g) The failure to maintain or provide records as required
 1305 by this part and its implementing regulations;

1306 (h) Providing the department or its representatives or any
 1307 federal, state, or local official with false or fraudulent
 1308 records or making false or fraudulent statements regarding a
 1309 matter within the provisions of this part and its implementing
 1310 regulations;

1311 (i) The wholesale distribution of any medical gas that
 1312 was:

1313 1. Purchased by a public or private hospital or other
 1314 health care entity, except for physical distribution of such
 1315 medical gas to an authorized recipient at the direction of the
 1316 hospital or other health care entity;

1317 2. Donated or supplied at a reduced price to a charitable
 1318 organization; or

1319 3. Stolen or obtained by fraud or deceit.

1320 (j) The failure to obtain a license or operating without a
 1321 valid license when a license is required;

1322 (k) The obtaining of or attempting to obtain a medical gas
 1323 by fraud, deceit, or misrepresentation in the distribution of a
 1324 medical gas;

1325 (l) Except for oxygen USP in emergency situations,
 1326 distribution of a medical gas to a patient without a

1327 prescription or prescription order from a practitioner licensed
 1328 by law to use or prescribe the medical gas;

1329 (m) Distribution of a medical gas that was previously
 1330 dispensed by a pharmacy or distributed by a practitioner;

1331 (n) Distribution of a medical gas or medical gas related
 1332 equipment to a patient, unless the patient has been provided
 1333 with appropriate information and counseling on use, storage, and
 1334 disposal;

1335 (o) The failure to report an act prohibited by this part
 1336 and its implementing regulations; or

1337 (p) The failure to exercise due diligence as provided in
 1338 s. 499.92.

1339 499.96 Criminal acts.—

1340 (1) A person commits a felony of the third degree,
 1341 punishable as provided in s. 775.082, s. 775.083, or s. 775.084,
 1342 if he or she:

1343 (a) With intent to defraud or deceive, adulterates or
 1344 misbrands a medical gas.

1345 (b) Engages in wholesale distribution and knowingly
 1346 purchases or receives medical gas from a person not legally
 1347 authorized to distribute medical gas.

1348 (c) Engages in the wholesale distribution and knowingly
 1349 sells, barter, brokers, or transfers medical gases to a person
 1350 not legally authorized to purchase medical gases under the
 1351 jurisdiction in which the person receives the medical gas.

1352 (d) Knowingly creates a false label for a medical gas or

1353 who falsely represents factual matter contained in a medical gas
 1354 label.

1355 (2) A person found guilty of an offense under this
 1356 section, under the authority of the court convicting and
 1357 sentencing the person, shall be ordered to forfeit to the state
 1358 any real or personal property:

1359 (a) Used or intended to be used to commit, to facilitate,
 1360 or to promote the commission of such offense; and

1361 (b) Constituting, derived from, or traceable to the gross
 1362 proceeds that the defendant obtained directly or indirectly as a
 1363 result of the offense. Property or assets subject to forfeiture
 1364 under this section may be seized pursuant to a warrant obtained
 1365 in the same manner as a search warrant or as otherwise permitted
 1366 by law, and held until the case against a defendant is
 1367 adjudicated. Monies ordered forfeited, or proceeds from the sale
 1368 of other assets ordered forfeited, shall be equitably divided
 1369 between the department and other agencies involved in the
 1370 investigation and prosecution that led to the conviction. Other
 1371 property ordered forfeited after conviction of a defendant may,
 1372 at the discretion of the investigating agencies, be placed into
 1373 official use by the department or the agencies involved in the
 1374 investigation and prosecution that led to the conviction.

1375 499.97 Salvaging and reprocessing.—

1376 (1) Medical gas that has been subjected to improper
 1377 conditions such as a fire, accident or natural disaster, may not
 1378 be salvaged or reprocessed.

1379 (2) Medical gas in a container that has left the control
 1380 of the wholesale distributor may be returned to the manufacturer
 1381 and reprocessed if the manufacturer employs proper and adequate
 1382 controls to ensure the identity, strength, quality, and purity
 1383 of the reprocessed medical gas.

1384 499.98 Inspections.—

1385 (1) The department is authorized to recognize a third
 1386 party to inspect wholesale distributors of medical gases in that
 1387 state or in other states pursuant to a schedule to be determined
 1388 by the department.

1389 (2) The department is authorized to recognize state
 1390 inspections of wholesale distributors of medical gases
 1391 operations in another state, if the state's laws are deemed to
 1392 be substantially equivalent by the department.

1393 (3) The department's decision to deny issuance of a
 1394 license to an applicant is subject to review pursuant to chapter
 1395 120.

1396 (4) A manufacturing facility of medical gases is exempt
 1397 from inspection by the department if:

1398 (a) The manufacturing facility is currently registered
 1399 with the United States Food and Drug Administration under s. 510
 1400 of the federal act and can provide proof of registration, such
 1401 as a copy of the internet verification page.

1402 (b) The manufacturing facility can provide proof of
 1403 inspection by the Food and Drug Administration, or if the
 1404 facility is located in another state, inspection by the Food and

1405 Drug Administration or other governmental entity charged with
 1406 regulation of good manufacturing practices related to medical
 1407 gases within the past 3 years.

1408 (5) A wholesale distributor of medical gases must exhibit
 1409 or have readily available all state licenses and the most recent
 1410 inspection report administered by the department.

1411 (6) This part does not require the department to report
 1412 minor violations of this part, including variances in good
 1413 manufacturing practices, for the institution of proceedings
 1414 under this part when the department believes that the public
 1415 interest will be adequately served in the circumstances by
 1416 written notice.

1417 499.99 Deposit of fees.—All fees collected for licenses
 1418 and permits required by this part shall be deposited in the
 1419 Professional Regulation Trust Fund and shall be used by the
 1420 department in the administration of this part. The Department of
 1421 Business and Professional Regulation shall maintain a separate
 1422 account in the Professional Regulation Trust Fund for the Drugs,
 1423 Devices, and Cosmetics program.

1424 Section 11. Paragraph (a) of subsection (1) of section
 1425 409.9201, Florida Statutes, is amended to read:

1426 409.9201 Medicaid fraud.—

1427 (1) As used in this section, the term:

1428 (a) "Prescription drug" means any drug, including, but not
 1429 limited to, finished dosage forms or active ingredients that are
 1430 subject to, defined by, or described by s. 503(b) of the Federal

1431 Food, Drug, and Cosmetic Act or by s. 465.003(8), s.
 1432 499.003(52), ~~499.003(46) or (53)~~ or s. 499.007(13).

1433

1434 The value of individual items of the legend drugs or goods or
 1435 services involved in distinct transactions committed during a
 1436 single scheme or course of conduct, whether involving a single
 1437 person or several persons, may be aggregated when determining
 1438 the punishment for the offense.

1439 Section 12. Paragraph (c) of subsection (9) of section
 1440 460.403, Florida Statutes, is amended to read:

1441 460.403 Definitions.—As used in this chapter, the term:
 1442 (9)

1443 (c)1. Chiropractic physicians may adjust, manipulate, or
 1444 treat the human body by manual, mechanical, electrical, or
 1445 natural methods; by the use of physical means or physiotherapy,
 1446 including light, heat, water, or exercise; by the use of
 1447 acupuncture; or by the administration of foods, food
 1448 concentrates, food extracts, and items for which a prescription
 1449 is not required and may apply first aid and hygiene, but
 1450 chiropractic physicians are expressly prohibited from
 1451 prescribing or administering to any person any legend drug
 1452 except as authorized under subparagraph 2., from performing any
 1453 surgery except as stated herein, or from practicing obstetrics.

1454 2. Notwithstanding the prohibition against prescribing and
 1455 administering legend drugs under subparagraph 1. ~~or s.~~
 1456 ~~499.01(2)(m)~~, pursuant to board rule chiropractic physicians may

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1457 order, store, and administer, for emergency purposes only at the
 1458 chiropractic physician's office or place of business,
 1459 prescription medical oxygen and may also order, store, and
 1460 administer the following topical anesthetics in aerosol form:

1461 a. Any solution consisting of 25 percent ethylchloride and
 1462 75 percent dichlorodifluoromethane.

1463 b. Any solution consisting of 15 percent
 1464 dichlorodifluoromethane and 85 percent
 1465 trichloromonofluoromethane.

1466
 1467 However, this paragraph does not authorize a chiropractic
 1468 physician to prescribe medical oxygen as defined in chapter 499.

1469 Section 13. Subsection (3) of section 465.0265, Florida
 1470 Statutes, is amended to read:

1471 465.0265 Centralized prescription filling.-

1472 (3) The filling, delivery, and return of a prescription by
 1473 one pharmacy for another pursuant to this section shall not be
 1474 construed as the filling of a transferred prescription as set
 1475 forth in s. 465.026 or as a wholesale distribution as set forth
 1476 in s. 499.003(53) ~~499.003(54)~~.

1477 Section 14. Paragraph (b) of subsection (2) of section
 1478 499.01212, Florida Statutes, is amended to read:

1479 499.01212 Pedigree paper.-

1480 (2) FORMAT.-A pedigree paper must contain the following
 1481 information:

1482 (b) For all other wholesale distributions of prescription

1483 | drugs:

1484 | 1. The quantity, dosage form, and strength of the

1485 | prescription drugs.

1486 | 2. The lot numbers of the prescription drugs.

1487 | 3. The name and address of each owner of the prescription

1488 | drug and his or her signature.

1489 | 4. Shipping information, including the name and address of

1490 | each person certifying delivery or receipt of the prescription

1491 | drug.

1492 | 5. An invoice number, a shipping document number, or

1493 | another number uniquely identifying the transaction.

1494 | 6. A certification that the recipient wholesale

1495 | distributor has authenticated the pedigree papers.

1496 | 7. The unique serialization of the prescription drug, if

1497 | the manufacturer or repackager has uniquely serialized the

1498 | individual prescription drug unit.

1499 | 8. The name, address, telephone number, and, if available,

1500 | e-mail contact information of each wholesale distributor

1501 | involved in the chain of the prescription drug's custody.

1502 |

1503 | When an affiliated group member obtains title to a prescription

1504 | drug before distributing the prescription drug as the

1505 | manufacturer under s. 499.003(30)(e) ~~499.003(31)(e)~~, information

1506 | regarding the distribution between those affiliated group

1507 | members may be omitted from a pedigree paper required under this

1508 | paragraph for subsequent distributions of that prescription

1509 drug.

1510 Section 15. Paragraph (a) of subsection (1) and subsection
1511 (3) of section 499.015, Florida Statutes, is amended to read:

1512 499.015 Registration of drugs, devices, and cosmetics;
1513 issuance of certificates of free sale.—

1514 (1)(a) Except for those persons exempted from the
1515 definition of manufacturer in s. 499.003(30) ~~499.003(31)~~, any
1516 person who manufactures, packages, repackages, labels, or
1517 relabels a drug, device, or cosmetic in this state must register
1518 such drug, device, or cosmetic biennially with the department;
1519 pay a fee in accordance with the fee schedule provided by s.
1520 499.041; and comply with this section. The registrant must list
1521 each separate and distinct drug, device, or cosmetic at the time
1522 of registration.

1523 (3) Except for those persons exempted from the definition
1524 of manufacturer in s. 499.003(30) ~~499.003(31)~~, a person may not
1525 sell any product that he or she has failed to register in
1526 conformity with this section. Such failure to register subjects
1527 such drug, device, or cosmetic product to seizure and
1528 condemnation as provided in s. 499.062, and subjects such person
1529 to the penalties and remedies provided in this part.

1530 Section 16. Subsection (3) of section 499.024, Florida
1531 Statutes, is amended to read:

1532 499.024 Drug product classification.—The department shall
1533 adopt rules to classify drug products intended for use by humans
1534 which the United States Food and Drug Administration has not

1535 classified in the federal act or the Code of Federal
 1536 Regulations.

1537 (3) Any product that falls under the definition of drug in
 1538 s. 499.003(18) ~~499.003(19)~~ may be classified under the authority
 1539 of this section. This section does not subject portable
 1540 emergency oxygen inhalators to classification; however, this
 1541 section does not exempt any person from ss. 499.01 and 499.015.

1542 Section 17. Paragraphs (i) and (m) of subsection (1) of
 1543 section 499.05, Florida Statutes, are amended to read:

1544 499.05 Rules.—

1545 (1) The department shall adopt rules to implement and
 1546 enforce this part with respect to:

1547 (i) Additional conditions that qualify as an emergency
 1548 medical reason under s. 499.003(53)(b)2. ~~499.003(54)(b)2.~~

1549 (m) The recordkeeping, storage, and handling with respect
 1550 to each of the distributions of prescription drugs specified in
 1551 s. 499.003(53)(a)-(d) ~~499.003(54)(a)-(d).~~

1552 Section 18. This act shall take effect October 1, 2014.



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COMMITTEE/SUBCOMMITTEE ACTION

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

1 Committee/Subcommittee hearing bill: Health Quality

2 Subcommittee

3 Representative Magar offered the following:

4

5 **Amendment**

6 Remove everything after the enacting clause and insert:

7 Section 1. Subsections (12) through (32) and subsections

8 (47) through (55) of section 499.003, Florida Statutes are

9 renumbered as sections (11) through (31) and subsections (46)

10 through (54), respectively, present subsection (11) is reordered

11 and amended, and present subsections (43) and (46) of that

12 section are amended, to read:

13 499.003 Definitions of terms used in this part.—As used in

14 this part, the term:

15 (32)~~(11)~~ "Compressed Medical gas" means any liquefied or

16 vaporized gas that is a prescription drug, whether ~~it is~~ alone



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17 or in combination with other gases, and as defined in the
18 federal act.

19 (43) "Prescription drug" means a prescription, medicinal,
20 or legend drug, including, but not limited to, finished dosage
21 forms or active pharmaceutical ingredients subject to, defined
22 by, or described by s. 503(b) of the federal ~~Food, Drug, and~~
23 ~~Cosmetic~~ act or s. 465.003(8), s. 499.007(13), or subsection
24 (32) ~~(11)~~, ~~subsection (46)~~, or subsection (52) ~~(53)~~, except that
25 an active pharmaceutical ingredient is a prescription drug only
26 if substantially all finished dosage forms in which it may be
27 lawfully dispensed or administered in this state are also
28 prescription drugs.

29 ~~(46) "Prescription medical oxygen" means oxygen USP which~~
30 ~~is a drug that can only be sold on the order or prescription of~~
31 ~~a practitioner authorized by law to prescribe. The label of~~
32 ~~prescription medical oxygen must comply with current labeling~~
33 ~~requirements for oxygen under the Federal Food, Drug, and~~
34 ~~Cosmetic Act.~~

35 Section 2. Paragraphs (m), (n), and (o) of subsection (1),
36 paragraphs (a), (c), (g), (m), (n), and (o) of subsection (2),
37 and subsection (5) of section 499.01, Florida Statutes, are
38 amended to read:

39 499.01 Permits.—

40 (1) Prior to operating, a permit is required for each
41 person and establishment that intends to operate as:

42 ~~(m) A medical oxygen retail establishment;~~



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43 ~~(n) A compressed medical gas wholesale distributor,~~

44 ~~(o) A compressed medical gas manufacturer,~~

45 (2) The following permits are established:

46 (a) Prescription drug manufacturer permit.—A prescription
47 drug manufacturer permit is required for any person that is a
48 manufacturer of a prescription drug and that manufactures or
49 distributes such prescription drugs in this state.

50 1. A person that operates an establishment permitted as a
51 prescription drug manufacturer may engage in wholesale
52 distribution of prescription drugs manufactured at that
53 establishment and must comply with all of the provisions of this
54 part, except s. 499.01212, and the rules adopted under this
55 part, except s. 499.01212, which apply to a wholesale
56 distributor.

57 2. A prescription drug manufacturer must comply with all
58 appropriate state and federal good manufacturing practices.

59 3. A blood establishment, as defined in s. 381.06014,
60 operating in a manner consistent with the provisions of 21
61 C.F.R. parts 211 and 600-640, and manufacturing only the
62 prescription drugs described in s. 499.003(53)(d) ~~499.003(54)(d)~~
63 is not required to be permitted as a prescription drug
64 manufacturer under this paragraph or to register products under
65 s. 499.015.

66 (c) Nonresident prescription drug manufacturer permit.—A
67 nonresident prescription drug manufacturer permit is required
68 for any person that is a manufacturer of prescription drugs,

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69 unless permitted as a third party logistics provider, located
70 outside of this state or outside the United States and that
71 engages in the wholesale distribution in this state of such
72 prescription drugs. Each such manufacturer must be permitted by
73 the department and comply with all of the provisions required of
74 a wholesale distributor under this part, except s. 499.01212.

75 1. A person that distributes prescription drugs for which
76 the person is not the manufacturer must also obtain an out-of-
77 state prescription drug wholesale distributor permit or third
78 party logistics provider permit pursuant to this section to
79 engage in the wholesale distribution of such prescription drugs.
80 This subparagraph does not apply to a manufacturer as defined in
81 s. 499.003(30)(e) ~~499.003(31)(e)~~.

82 2. Any such person must comply with the licensing or
83 permitting requirements of the jurisdiction in which the
84 establishment is located and the federal act, and any product
85 wholesaled into this state must comply with this part. If a
86 person intends to import prescription drugs from a foreign
87 country into this state, the nonresident prescription drug
88 manufacturer must provide to the department a list identifying
89 each prescription drug it intends to import and document
90 approval by the United States Food and Drug Administration for
91 such importation.

92 (g) Restricted prescription drug distributor permit.—

93 1. A restricted prescription drug distributor permit is
94 required for:



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95 a. Any person located in this state who engages in the
96 distribution of a prescription drug, which distribution is not
97 considered "wholesale distribution" under s. 499.003(53)(a)
98 ~~499.003(54)(a)~~.

99 b. Any person located in this state who engages in the
100 receipt or distribution of a prescription drug in this state for
101 the purpose of processing its return or its destruction if such
102 person is not the person initiating the return, the prescription
103 drug wholesale supplier of the person initiating the return, or
104 the manufacturer of the drug.

105 c. A blood establishment located in this state which
106 collects blood and blood components only from volunteer donors
107 as defined in s. 381.06014 or pursuant to an authorized
108 practitioner's order for medical treatment or therapy and
109 engages in the wholesale distribution of a prescription drug not
110 described in s. 499.003(53)(d) ~~499.003(54)(d)~~ to a health care
111 entity. A mobile blood unit operated by a blood establishment
112 permitted under this sub-subparagraph is not required to be
113 separately permitted. The health care entity receiving a
114 prescription drug distributed under this sub-subparagraph must
115 be licensed as a closed pharmacy or provide health care services
116 at that establishment. The blood establishment must operate in
117 accordance with s. 381.06014 and may distribute only:

118 (I) Prescription drugs indicated for a bleeding or
119 clotting disorder or anemia;



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120 (II) Blood-collection containers approved under s. 505 of
121 the federal act;

122 (III) Drugs that are blood derivatives, or a recombinant
123 or synthetic form of a blood derivative;

124 (IV) Prescription drugs that are identified in rules
125 adopted by the department and that are essential to services
126 performed or provided by blood establishments and authorized for
127 distribution by blood establishments under federal law; or

128 (V) To the extent authorized by federal law, drugs
129 necessary to collect blood or blood components from volunteer
130 blood donors; for blood establishment personnel to perform
131 therapeutic procedures under the direction and supervision of a
132 licensed physician; and to diagnose, treat, manage, and prevent
133 any reaction of a volunteer blood donor or a patient undergoing
134 a therapeutic procedure performed under the direction and
135 supervision of a licensed physician,
136

137 as long as all of the health care services provided by the blood
138 establishment are related to its activities as a registered
139 blood establishment or the health care services consist of
140 collecting, processing, storing, or administering human
141 hematopoietic stem cells or progenitor cells or performing
142 diagnostic testing of specimens if such specimens are tested
143 together with specimens undergoing routine donor testing. The
144 blood establishment may purchase and possess the drugs described



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145 in this sub-subparagraph without a health care clinic
146 establishment permit.

147 2. Storage, handling, and recordkeeping of these
148 distributions by a person required to be permitted as a
149 restricted prescription drug distributor must be in accordance
150 with the requirements for wholesale distributors under s.
151 499.0121, but not those set forth in s. 499.01212 if the
152 distribution occurs pursuant to sub-subparagraph 1.a. or sub-
153 subparagraph 1.b.

154 3. A person who applies for a permit as a restricted
155 prescription drug distributor, or for the renewal of such a
156 permit, must provide to the department the information required
157 under s. 499.012.

158 4. The department may adopt rules regarding the
159 distribution of prescription drugs by hospitals, health care
160 entities, charitable organizations, other persons not involved
161 in wholesale distribution, and blood establishments, which rules
162 are necessary for the protection of the public health, safety,
163 and welfare.

164 ~~(m) Medical oxygen retail establishment permit. A medical~~
165 ~~oxygen retail establishment permit is required for any person~~
166 ~~that sells medical oxygen to patients only. The sale must be~~
167 ~~based on an order from a practitioner authorized by law to~~
168 ~~prescribe. The term does not include a pharmacy licensed under~~
169 ~~chapter 465.~~



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170 ~~1. A medical oxygen retail establishment may not possess,~~
171 ~~purchase, sell, or trade any prescription drug other than~~
172 ~~medical oxygen.~~

173 ~~2. A medical oxygen retail establishment may refill~~
174 ~~medical oxygen for an individual patient based on an order from~~
175 ~~a practitioner authorized by law to prescribe. A medical oxygen~~
176 ~~retail establishment that refills medical oxygen must comply~~
177 ~~with all appropriate state and federal good manufacturing~~
178 ~~practices.~~

179 ~~3. A medical oxygen retail establishment must comply with~~
180 ~~all of the wholesale distribution requirements of s. 499.0121.~~

181 ~~4. Prescription medical oxygen sold by a medical oxygen~~
182 ~~retail establishment pursuant to a practitioner's order may not~~
183 ~~be returned into the retail establishment's inventory.~~

184 ~~(n) Compressed medical gas wholesale distributor permit. A~~
185 ~~compressed medical gas wholesale distributor is a wholesale~~
186 ~~distributor that is limited to the wholesale distribution of~~
187 ~~compressed medical gases to other than the consumer or patient.~~
188 ~~The compressed medical gas must be in the original sealed~~
189 ~~container that was purchased by that wholesale distributor. A~~
190 ~~compressed medical gas wholesale distributor may not possess or~~
191 ~~engage in the wholesale distribution of any prescription drug~~
192 ~~other than compressed medical gases. The department shall adopt~~
193 ~~rules that govern the wholesale distribution of prescription~~
194 ~~medical oxygen for emergency use. With respect to the emergency~~
195 ~~use of prescription medical oxygen, those rules may not be~~



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196 ~~inconsistent with rules and regulations of federal agencies~~
197 ~~unless the Legislature specifically directs otherwise.~~

198 ~~(e) Compressed medical gas manufacturer permit. A~~
199 ~~compressed medical gas manufacturer permit is required for any~~
200 ~~person that engages in the manufacture of compressed medical~~
201 ~~gases or repackages compressed medical gases from one container~~
202 ~~to another.~~

203 ~~1. A compressed medical gas manufacturer may not~~
204 ~~manufacture or possess any prescription drug other than~~
205 ~~compressed medical gases.~~

206 ~~2. A compressed medical gas manufacturer may engage in~~
207 ~~wholesale distribution of compressed medical gases manufactured~~
208 ~~at that establishment and must comply with all the provisions of~~
209 ~~this part and the rules adopted under this part that apply to a~~
210 ~~wholesale distributor.~~

211 ~~3. A compressed medical gas manufacturer must comply with~~
212 ~~all appropriate state and federal good manufacturing practices.~~

213 (5) A prescription drug repackager permit issued under
214 this part is not required for a restricted prescription drug
215 distributor permitholder that is a health care entity to
216 repackage prescription drugs in this state for its own use or
217 for distribution to hospitals or other health care entities in
218 the state for their own use, pursuant to s. 499.003(53)(a)3.
219 ~~499.003(54)(a)3.~~, if:

220 (a) The prescription drug distributor notifies the
221 department, in writing, of its intention to engage in



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222 repackaging under this exemption, 30 days before engaging in the
223 repackaging of prescription drugs at the permitted
224 establishment;

225 (b) The prescription drug distributor is under common
226 control with the hospitals or other health care entities to
227 which the prescription drug distributor is distributing
228 prescription drugs. As used in this paragraph, "common control"
229 means the power to direct or cause the direction of the
230 management and policies of a person or an organization, whether
231 by ownership of stock, voting rights, contract, or otherwise;

232 (c) The prescription drug distributor repackages the
233 prescription drugs in accordance with current state and federal
234 good manufacturing practices; and

235 (d) The prescription drug distributor labels the
236 prescription drug it repackages in accordance with state and
237 federal laws and rules.

238

239 The prescription drug distributor is exempt from the product
240 registration requirements of s. 499.015 with regard to the
241 prescription drugs that it repackages and distributes under this
242 subsection.

243 Section 3. Paragraph (b) of subsection (2) of section
244 499.0121, Florida Statutes, is amended to read:

245 499.0121 Storage and handling of prescription drugs;
246 recordkeeping.—The department shall adopt rules to implement
247 this section as necessary to protect the public health, safety,



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248 and welfare. Such rules shall include, but not be limited to,
249 requirements for the storage and handling of prescription drugs
250 and for the establishment and maintenance of prescription drug
251 distribution records.

252 (2) SECURITY.—

253 (b) An establishment that is used for wholesale drug
254 distribution must be equipped with:

255 1. An alarm system to detect entry after hours; however,
256 the department may exempt by rule establishments that only hold
257 a permit as prescription drug wholesale distributor-brokers. ~~and~~
258 ~~establishments that only handle medical oxygen; and~~

259 2. A security system that will provide suitable protection
260 against theft and diversion. When appropriate, the security
261 system must provide protection against theft or diversion that
262 is facilitated or hidden by tampering with computers or
263 electronic records.

264 Section 4. Subsection (2) of section 499.01211, Florida
265 Statutes, is amended, and paragraph (h) is added to that
266 subsection, to read:

267 499.01211 Drug Wholesale Distributor Advisory Council.—

268 (2) The Secretary of Business and Professional Regulation
269 or his or her designee and the Secretary of Health Care
270 Administration or her or his designee shall be members of the
271 council. The Secretary of Business and Professional Regulation
272 shall appoint 10 ~~nine~~ additional members to the council who
273 shall be appointed to a term of 4 years each, as follows:



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274 (a) Three different persons each of whom is employed by a
275 different prescription drug wholesale distributor permitted
276 ~~licensed~~ under this part which operates nationally and is a
277 primary wholesale distributor, as defined in s. 499.003(46)
278 ~~499.003(47)~~.

279 (b) One person employed by a prescription drug wholesale
280 distributor permitted ~~licensed~~ under this part which is a
281 secondary wholesale distributor, as defined in s. 499.003(51)
282 ~~499.003(52)~~.

283 (c) One person employed by a retail pharmacy chain located
284 in this state.

285 (d) One person who is a member of the Board of Pharmacy
286 and is a pharmacist licensed under chapter 465.

287 (e) One person who is a physician licensed pursuant to
288 chapter 458 or chapter 459.

289 (f) One person who is an employee of a hospital licensed
290 pursuant to chapter 395 and is a pharmacist licensed pursuant to
291 chapter 465.

292 (g) One person who is an employee of a pharmaceutical
293 manufacturer.

294 (h) One person who is an employee of a medical gas
295 manufacturer or medical gas wholesale distributor and who has
296 been recommended by the Compressed Gas Association.

297 Section 5. Paragraph (e) of subsection (1), paragraph (b)
298 of subsection (2), and paragraph (b) of subsection (3) of
299 section 499.041, Florida Statutes, are amended to read:



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300 499.041 Schedule of fees for drug, device, and cosmetic
301 applications and permits, product registrations, and free-sale
302 certificates.-

303 (1) The department shall assess applicants requiring a
304 manufacturing permit an annual fee within the ranges established
305 in this section for the specific type of manufacturer.

306 ~~(e) The fee for a compressed medical gas manufacturer~~
307 ~~permit may not be less than \$400 or more than \$500 annually.~~

308 (2) The department shall assess an applicant that is
309 required to have a wholesaling permit an annual fee within the
310 ranges established in this section for the specific type of
311 wholesaling.

312 ~~(b) The fee for a compressed medical gas wholesale~~
313 ~~distributor permit may not be less than \$200 or more than \$300~~
314 ~~annually.~~

315 (3) The department shall assess an applicant that is
316 required to have a retail establishment permit an annual fee
317 within the ranges established in this section for the specific
318 type of retail establishment.

319 ~~(b) The fee for a medical oxygen retail establishment~~
320 ~~permit may not be less than \$200 or more than \$300 annually.~~

321 Section 6. Subsections (1) through (4) of section 499.051,
322 Florida Statutes, are amended to read:

323 499.051 Inspections and investigations.-

324 (1) The agents of the department and of the Department of
325 Law Enforcement, after they present proper identification, may



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326 inspect, monitor, and investigate any establishment permitted
327 pursuant to this chapter part during business hours for the
328 purpose of enforcing this chapter part, chapters 465, 501, and
329 893, and the rules of the department that protect the public
330 health, safety, and welfare.

331 (2) In addition to the authority set forth in subsection
332 (1), the department and any duly designated officer or employee
333 of the department may enter and inspect any other establishment
334 for the purpose of determining compliance with this chapter part
335 and rules adopted under this chapter part regarding any drug,
336 device, or cosmetic product.

337 (3) Any application for a permit or product registration
338 or for renewal of such permit or registration made pursuant to
339 this chapter part and rules adopted under this chapter part
340 constitutes permission for any entry or inspection of the
341 premises in order to verify compliance with this chapter part
342 and rules; to discover, investigate, and determine the existence
343 of compliance; or to elicit, receive, respond to, and resolve
344 complaints and violations.

345 (4) Any application for a permit made pursuant to s.
346 499.012 or s. 499.831 and rules adopted under those sections
347 ~~that section~~ constitutes permission for agents of the department
348 and the Department of Law Enforcement, after presenting proper
349 identification, to inspect, review, and copy any financial
350 document or record related to the manufacture, repackaging, or
351 distribution of a drug as is necessary to verify compliance with



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352 | this chapter part and the rules adopted by the department to
353 | administer this chapter part, in order to discover, investigate,
354 | and determine the existence of compliance, or to elicit,
355 | receive, respond to, and resolve complaints and violations.

356 | Section 7. Subsections (1) through (4) of section 499.066,
357 | Florida Statutes, are amended to read:

358 | 499.066 Penalties; remedies.—In addition to other
359 | penalties and other enforcement provisions:

360 | (1) The department may institute such suits or other legal
361 | proceedings as are required to enforce any provision of this
362 | chapter part. If it appears that a person has violated any
363 | provision of this chapter part for which criminal prosecution is
364 | provided, the department may provide the appropriate state
365 | attorney or other prosecuting agency having jurisdiction with
366 | respect to such prosecution with the relevant information in the
367 | department's possession.

368 | (2) If any person engaged in any activity covered by this
369 | chapter part violates any provision of this chapter part, any
370 | rule adopted under this chapter part, or a cease and desist
371 | order as provided by this chapter part, the department may
372 | obtain an injunction in the circuit court of the county in which
373 | the violation occurred or in which the person resides or has its
374 | principal place of business, and may apply in that court for
375 | such temporary and permanent orders as the department considers
376 | necessary to restrain the person from engaging in any such
377 | activities until the person complies with this chapter part, the



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378 rules adopted under this chapter part, and the orders of the
379 department authorized by this chapter part or to mandate
380 compliance with this chapter part, the rules adopted under this
381 chapter part, and any order or permit issued by the department
382 under this chapter part.

383 (3) The department may impose an administrative fine, not
384 to exceed \$5,000 per violation per day, for the violation of any
385 provision of this chapter part or rules adopted under this
386 chapter part. Each day a violation continues constitutes a
387 separate violation, and each separate violation is subject to a
388 separate fine. All amounts collected pursuant to this section
389 shall be deposited into the Professional Regulation Trust Fund
390 and are appropriated for the use of the department in
391 administering this chapter part. In determining the amount of
392 the fine to be levied for a violation, the department shall
393 consider:

394 (a) The severity of the violation;

395 (b) Any actions taken by the person to correct the
396 violation or to remedy complaints; and

397 (c) Any previous violations.

398 (4) The department shall deposit any rewards, fines, or
399 collections that are due the department and which derive from
400 joint enforcement activities with other state and federal
401 agencies which relate to this chapter part, chapter 893, or the
402 federal act, into the Professional Regulation Trust Fund. The
403 proceeds of those rewards, fines, and collections are



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404 appropriated for the use of the department in administering this
405 chapter part.

406 Section 8. Paragraph (a) of subsection (1) and paragraph
407 (a) of subsection (2) of section 499.0661, Florida Statutes, are
408 amended to read:

409 499.0661 Cease and desist orders; removal of certain
410 persons.—

411 (1) CEASE AND DESIST ORDERS.—

412 (a) In addition to any authority otherwise provided in
413 this chapter, the department may issue and serve a complaint
414 stating charges upon a any permittee or upon an any affiliated
415 party, whenever the department has reasonable cause to believe
416 that the person or individual named therein is engaging in or
417 has engaged in conduct that is:

418 1. An act that demonstrates a lack of fitness or
419 trustworthiness to engage in the business authorized under the
420 permit issued pursuant to this chapter part, is hazardous to the
421 public health, or constitutes business operations that are a
422 detriment to the public health;

423 2. A violation of a any provision of this chapter part;

424 3. A violation of a any rule of the department;

425 4. A violation of an any order of the department; or

426 5. A breach of a any written agreement with the
427 department.

428 (2) REMOVAL OF AFFILIATED PARTIES BY THE DEPARTMENT.—



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429 (a) The department may issue and serve a complaint stating
430 charges upon an ~~any~~ affiliated party and upon the permittee
431 involved whenever the department has reason to believe that an
432 affiliated party is engaging in or has engaged in conduct that
433 constitutes:

434 1. An act that demonstrates a lack of fitness or
435 trustworthiness to engage in the business authorized under the
436 permit issued pursuant to this chapter ~~part~~, is hazardous to the
437 public health, or constitutes business operations that are a
438 detriment to the public health;

439 2. A willful violation of this chapter ~~part~~; however, if
440 the violation constitutes a misdemeanor, a complaint may not be
441 served as provided in this section until the affiliated party is
442 notified in writing of the matter of the violation and has been
443 afforded a reasonable period of time, as set forth in the
444 notice, to correct the violation and has failed to do so;

445 3. A violation of a ~~any other~~ law involving fraud or moral
446 turpitude which constitutes a felony;

447 4. A willful violation of a ~~any~~ rule of the department;

448 5. A willful violation of an ~~any~~ order of the department;
449 or

450 6. A material misrepresentation of fact, made knowingly
451 and willfully or made with reckless disregard for the truth of
452 the matter.



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453 Section 9. Subsections (1) and (2), paragraph (c) of
454 subsection (3), and subsections (4) through (9) of section
455 499.067, Florida Statutes, are amended to read:

456 499.067 Denial, suspension, or revocation of permit,
457 certification, or registration.—

458 (1) (a) The department may deny, suspend, or revoke a
459 permit if it finds that there has been a substantial failure to
460 comply with this chapter part or chapter 465, chapter 501, or
461 chapter 893, the rules adopted under ~~this part~~ or those
462 chapters, any final order of the department, or applicable
463 federal laws or regulations or other state laws or rules
464 governing drugs, devices, or cosmetics.

465 (b) The department may deny an application for a permit or
466 certification, or suspend or revoke a permit or certification,
467 if the department finds that:

468 1. The applicant is not of good moral character or that it
469 would be a danger or not in the best interest of the public
470 health, safety, and welfare if the applicant were issued a
471 permit or certification.

472 2. The applicant has not met the requirements for the
473 permit or certification.

474 3. The applicant is not eligible for a permit or
475 certification for any of the reasons enumerated in s. 499.012.

476 4. The applicant, permittee, or person certified under s.
477 499.012(16) demonstrates any of the conditions enumerated in s.
478 499.012.

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479 5. The applicant, permittee, or person certified under s.
480 499.012(16) has committed any violation of ss. 499.005-499.0054
481 or this chapter.

482 (2) The department may deny, suspend, or revoke any
483 registration required by the provisions of this chapter part for
484 the violation of any provision of this chapter part or of any
485 rules adopted under this chapter part.

486 (3) The department may revoke or suspend a permit:

487 (c) If the permittee has violated a any provision of this
488 chapter part or rules adopted under this chapter part.

489 (4) If a any permit issued under this chapter part is
490 revoked or suspended, the owner, manager, operator, or
491 proprietor of the establishment shall cease to operate as the
492 permit authorized, from the effective date of the suspension or
493 revocation until the person is again registered with the
494 department and possesses the required permit. If a permit is
495 revoked or suspended, the owner, manager, or proprietor shall
496 remove all signs and symbols that identify the operation as
497 premises permitted as a drug wholesaling establishment; drug,
498 device, or cosmetic manufacturing establishment; or retail
499 establishment. The department shall determine the length of time
500 for which the permit is to be suspended. If a permit is revoked,
501 the person that owns or operates the establishment may not apply
502 for a any permit under this chapter part for a period of 1 year
503 after the date of the revocation. A revocation of a permit may



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504 be permanent if the department considers that to be in the best
505 interest of the public health.

506 (5) The department may deny, suspend, or revoke a permit
507 issued under this part which authorizes the permittee to
508 purchase prescription drugs if an any owner, officer, employee,
509 or other person who participates in administering or operating
510 the establishment has been found guilty of a any violation of
511 this chapter part or chapter 465, chapter 501, or chapter 893,
512 any rules adopted under ~~this part~~ or those chapters, or any
513 federal or state drug law, regardless of whether the person has
514 been pardoned, had her or his civil rights restored, or had
515 adjudication withheld.

516 (6) The department shall deny, suspend, or revoke the
517 permit of a any person or establishment if the assignment, sale,
518 transfer, or lease of an establishment permitted under this
519 chapter part will avoid an administrative penalty, civil action,
520 or criminal prosecution.

521 (7) Notwithstanding s. 120.60(5), if a permittee fails to
522 comply with s. 499.012(6) or s. 499.831, as applicable, the
523 department may revoke the permit of the permittee and shall
524 provide notice of the intended agency action by posting a notice
525 at the department's headquarters and by mailing a copy of the
526 notice of intended agency action by certified mail to the most
527 recent mailing address on record with the department and, if the
528 permittee is not a natural person, to the permittee's registered
529 agent on file with the Department of State.

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530 (8) The department may deny, suspend, or revoke a permit
531 under this part if it finds the permittee has not complied with
532 the credentialing requirements of s. 499.0121(15).

533 (9) The department may deny, suspend, or revoke a permit
534 under this part if it finds the permittee has not complied with
535 the reporting requirements of, or knowingly made a false
536 statement in a report required by, s. 499.0121(14).

537 Section 10. Part III of chapter 499, Florida Statutes,
538 consisting of sections 499.81 through 499.99, is created to
539 read:

540 PART III

541 MEDICAL GASES

542 499.81 Administration and enforcement.—

543 (1) The provisions of this part are cumulative and shall
544 be construed and applied as being in addition to, and not in
545 substitution for or limitation of, any powers, duties, or
546 authority of the department under any other law of this state;
547 except that, with respect to the regulation of medical gas, the
548 provisions of this part shall control over any conflicting
549 provisions.

550 (2) The department shall administer and enforce this part
551 to prevent fraud, adulteration, misbranding, or false
552 advertising in the manufacture or distribution of medical gas.

553 (3) For the purpose of an investigation or proceeding
554 conducted by the department under this part, the department may
555 administer oaths, take depositions, subpoena witnesses, and



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556 compel the production of books, papers, documents, or other
557 records. Challenges to, and enforcement of, subpoenas and orders
558 shall be handled as provided in s. 120.569.

559 (4) Each state attorney, county attorney, or municipal
560 attorney to whom the department or its designated agent reports
561 a violation of this part shall cause appropriate proceedings to
562 be instituted in the proper courts without delay and prosecuted
563 in the manner required by law.

564 (5) This part does not require the department to report,
565 for the institution of proceedings under this part, minor
566 violations of this part when the department believes that the
567 public interest will be adequately served by a written notice or
568 warning.

569 499.82 Definitions.—As used in this part, the term:

570 (1) "Adulterated" means:

571 (a) Consisting in whole or in part of impurities or
572 deleterious substances exceeding normal specifications;

573 (b) Produced, prepared, packed, or held under conditions
574 whereby the medical gas may have been contaminated causing it to
575 be rendered injurious to health; or if the methods used in, or
576 the facilities or controls used for, its manufacture,
577 processing, packing, or holding do not conform to or are not
578 operated or administered in conformity with current good
579 manufacturing practices to ensure that the medical gas meets the
580 requirements of this part as to safety and has the identity and



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581 strength, and meets the quality and purity characteristics that
582 it is represented to possess;

583 (c) Having a container interior that is composed in whole
584 or in part of a poisonous or deleterious substance which may
585 render the contents injurious to health; or

586 (d) Represented as a medical gas, with strength differing
587 from, or quality or purity falling below, the standard set forth
588 in the USP-NF. Such determination shall be made in accordance
589 with the tests or methods of assay in the USP-NF, or validated
590 equivalent, or in the absence of or inadequacy of these tests or
591 methods of assay, tests or methods of assay prescribed under the
592 federal act. No medical gas defined in USP-NF shall be deemed to
593 be adulterated under this paragraph because it differs from the
594 standard of strength, quality, or purity set forth in the USP-
595 NF, if its difference in strength, quality, or purity from that
596 standard is plainly stated on its label.

597 (2) "Distribution" means to sell, offer to sell, deliver,
598 offer to deliver, broker, give away, or transfer a medical gas,
599 whether by passage of title, physical movement, or both. The
600 term does not include:

601 (a) The dispensation or administration of medical gas;

602 (b) The delivery of, or an offer to deliver, a medical gas
603 by a common carrier in the usual course of business as a common
604 carrier; or

605 (c) Sales activities taking place in a location owned or
606 controlled by, or staffed by persons employed by, a person or



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607 entity permitted in this state to distribute medical gas, where
608 the locations where such sales activities are taking place do
609 not physically store or move medical gas.

610 (3) "Emergency" means any act or circumstance during a
611 state of emergency declared pursuant to s. 252.36, including,
612 but not limited to:

613 (a) Transfer of a medical gas between wholesale
614 distributors of medical gases or between a wholesale distributor
615 of medical gases and a retail pharmacy or health care entity to
616 alleviate a temporary shortage of a medical gas arising from a
617 delay in or interruption of regular distribution schedules.

618 (b) Sales to licensed emergency medical services,
619 including ambulance companies and firefighting organizations in
620 this state, or licensed practitioners allowed to dispense
621 medical gases in the treatment of acutely ill or injured
622 persons.

623 (c) Provision of emergency supplies of medical gases to
624 nursing homes during hours of the day when necessary medical
625 gases cannot be obtained.

626 (d) Transfer of medical gases between retail pharmacies to
627 alleviate a temporary shortage.

628 (4) "Emergency use oxygen" means oxygen USP administered
629 in emergency situations without a prescription for oxygen
630 deficiency and resuscitation. The container must be labeled in
631 accordance with requirements of the United States Food and Drug
632 Administration.



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633 (5) "Federal act" means the Federal Food, Drug, and
634 Cosmetic Act.

635 (6) "Intracompany transaction" means any transaction
636 between a division, subsidiary, parent, or affiliated or related
637 company under the common ownership and control of a corporate
638 entity.

639 (7) "Medical gas" means a liquefied or vaporized gas that
640 is a prescription drug, whether alone or in combination with
641 other gases, and as defined in the federal act.

642 (8) "Medical gas related equipment" means a device used as
643 a component part or accessory used to contain or control the
644 flow, delivery, or pressure during the administration of a
645 medical gas, such as liquid oxygen base and portable units,
646 pressure regulators and flow meters, and oxygen concentrators.

647 (9) "Misbranded " means having a label that is false or
648 misleading; a label without the name and address of the
649 manufacturer, packer, or distributor and without an accurate
650 statement of the quantities of active ingredients; or a label
651 without an accurate monograph for the medical gas, except in the
652 case of mixtures of designated medical gases where the label
653 identifies the component percentages of each designated medical
654 gas used to make the mixture.

655 (10) "Prescription medical oxygen" means oxygen USP which
656 can only be sold on the order or prescription of a practitioner
657 authorized to prescribe. The label of prescription medical



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658 oxygen must comply with labeling requirements for oxygen under
659 the federal act.

660 (11) "Product labeling" means the labels and other
661 written, printed, or graphic matter upon an article, or the
662 containers or wrappers that accompany an article, except for
663 letters, numbers, and symbols stamped into the container as
664 required by the federal Department of Transportation.

665 (12) "USP" means United States Pharmacopeia.

666 (13) "USP-NF" means United States Pharmacopeia-National
667 Formulary.

668 (14) "Wholesale distribution" means the distribution of
669 medical gas by a wholesale distributor of medical gases to a
670 person other than a consumer or patient. Wholesale distribution
671 of medical gases does not include:

672 (a) The sale, purchase, or trade of a medical gas, an
673 offer to sell, purchase, or trade a prescription drug or device,
674 or the dispensing of a medical gas pursuant to a prescription;

675 (b) The sale, purchase, or trade of a medical gas or an
676 offer to sell, purchase, or trade a medical gas for emergency
677 medical reasons;

678 (c) Intracompany transactions;

679 (d) The sale, purchase, or trade of a medical gas or an
680 offer to sell, purchase, or trade a medical gas among hospitals,
681 pharmacies, or other health care entities that are under common
682 control;



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683 (e) The sale, purchase, or trade of a medical gas or the
684 offer to sell, purchase, or trade a medical gas by a charitable
685 organization described in s. 501(c)(3) of the Internal Revenue
686 Code of 1986, as amended, to a nonprofit affiliate of the
687 organization to the extent otherwise permitted by law;

688 (f) The purchase or other acquisition by a hospital or
689 other similar health care entity that is a member of a group
690 purchasing organization of a medical gas for its own use from
691 the group purchasing organization or from other hospitals or
692 similar health care entities that are members of such
693 organizations;

694 (g) The return of residual medical gas that may be
695 reprocessed in accordance with manufacturer's procedures, or the
696 return of recalled, expired, damaged, or otherwise nonsalable
697 medical gas, when conducted by a hospital, health care entity,
698 pharmacy, or charitable institution to a wholesale distributor
699 of medical gases;

700 (h) Activities exempt from wholesale distribution as
701 defined in s. 499.003(53); or

702 (i) Other transactions excluded from the definition of
703 wholesale distribution under the federal act or regulations
704 implemented under the federal act related to medical gas.

705 (15) "Wholesale distributor" means any person engaged in
706 wholesale distribution of medical gas within or into this state,
707 including, but not limited to, manufacturers, own-label
708 distributors, private-label distributors, warehouses, including



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709 manufacturers' and distributors' warehouses, and wholesale
710 medical gas warehouses.

711 499.831 Permits.—

712 (1) Before operating, unless exempted under this part, a
713 permit is required for each person and establishment, whether
714 inside or outside of this state, that intends to distribute
715 medical gas within or into this state and operate as:

716 (a) A medical gas wholesale distributor;

717 (b) A medical gas manufacturer; or

718 (c) A medical oxygen retail establishment.

719 (2) The following permits are established:

720 (a) Medical gas wholesale distributor permit.—A medical
721 gas wholesale distributor permit is required for the wholesale
722 distribution of medical gases, whether within or into this
723 state, to other than the consumer or patient. The medical gas
724 must be in the original container obtained by the wholesale
725 distributor without further manufacturing operations. A medical
726 gas wholesale distributor may not possess or engage in the
727 wholesale distribution of a prescription drug that is not a
728 medical gas. The department shall adopt rules to govern the
729 wholesale distribution of prescription medical oxygen for
730 emergency use. Rules regarding the emergency use of prescription
731 medical oxygen may not be inconsistent with rules and
732 regulations of federal agencies unless the Legislature
733 specifically directs otherwise.



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734 (b) Medical gas manufacturer permit.—A medical gas
735 manufacturer permit is required for a person that engages in the
736 manufacture of medical gases by physical air separation,
737 chemical action, purification, or filling containers by a liquid
738 to liquid, liquid to gas, or gas to gas process and that
739 distributes those medical gases within or into this state.

740 1. A medical gas manufacturer may not manufacture or
741 possess a prescription drug that is not a medical gas.

742 2. A medical gas manufacturer may engage in wholesale
743 distribution of medical gases manufactured without a medical gas
744 wholesale distributor permit, but must comply with the
745 provisions of this part and the rules adopted under this part
746 that apply to a wholesale distributor.

747 3. A medical gas manufacturer shall comply with all
748 appropriate state and federal good manufacturing practices.

749 (c) Medical oxygen retail establishment permit.—A medical
750 oxygen retail establishment permit is required for a person that
751 sells medical oxygen directly to patients. The sale must be
752 based on an order from a practitioner authorized by law to
753 prescribe. The medical oxygen retail establishment permit
754 excludes a pharmacy licensed under chapter 465.

755 1. A medical oxygen retail establishment may not possess,
756 purchase, sell, or trade a prescription drug that is not medical
757 oxygen.



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758 2. A medical oxygen retail establishment may refill
759 medical oxygen for an individual patient based on an order from
760 a practitioner authorized by law to prescribe.

761 3. Prescription medical oxygen sold by a medical oxygen
762 retail establishment pursuant to an order from a practitioner
763 may not be returned into the retail establishment's inventory.

764 4. A medical oxygen retail establishment that refills
765 medical oxygen shall comply with all appropriate state and
766 federal good manufacturing practices.

767 5. A medical oxygen retail establishment shall comply with
768 the requirements of s. 499.87.

769 (3) The department shall adopt rules establishing the form
770 and content of the application to obtain or renew a permit. The
771 applicant must submit to the department with the application a
772 statement that swears or affirms that the information is true
773 and correct. An application for a permit must include:

774 (a) All trade or business terms used by the permittee,
775 including "doing business as (d/b/a)" and "formerly known as,"
776 which cannot be identical to the name used by an unrelated
777 wholesale distributor permitted to purchase medical gas in the
778 state;

779 (b) The name of the owner and operator of the permittee
780 including:

781 1. The name, business address, and date of birth, if the
782 permittee is an individual.



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783 2. The name, business address, date of birth of each
784 partner, the name of the partnership, and federal employer
785 identification number, if the permittee is a partnership.

786 3. The name, business address, and title of each corporate
787 officer and director, the corporate names, the state of
788 incorporation, the federal employer identification number, and
789 the name and business address of the parent company, if one
790 exists, if the permittee is a corporation.

791 4. The full name and business address of the sole
792 proprietor and the name and federal employer identification
793 number of the business entity, if the permittee is a sole
794 proprietorship.

795 5. The name, business address, and title of each company
796 officer, the name of the limited liability company and federal
797 employer identification number, and the name of the state in
798 which the limited liability company was organized, if the
799 permittee is a limited liability company.

800 (c) A list of all disciplinary actions pertinent to
801 wholesale distributors of prescription drugs or controlled
802 substances by any state and federal agencies against the
803 wholesale distributor distributing medical gas into the state
804 and any disciplinary actions against principals, owners,
805 directors, or officers; and

806 (d) An address and description of each facility and
807 warehouse, including all locations used for medical gas storage



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808 or wholesale distribution including a description of the
809 security system.

810 (4) A permit issued pursuant to this part may be issued to
811 a natural person who is at least 18 years of age or to an
812 applicant who is not a natural person if the person who,
813 directly or indirectly, manages, controls, or oversees the
814 operation of that applicant is at least 18 years of age.

815 (5) An applicant for a permit shall submit the appropriate
816 fee for the permit for which he or she is applying. The fee
817 shall be determined by the department.

818 (a) The fee for a medical gas wholesale distributor permit
819 may not be less than \$200 or more than \$300 annually.

820 (b) The fee for a medical gas manufacturer permit may not
821 be less than \$400 or more than \$500 annually.

822 (c) The fee for a medical oxygen retail establishment
823 permit may not be less than \$200 or more than \$300 annually.

824 (6) Upon approval of the application by the department and
825 payment of the required fee, the department shall issue a permit
826 to the applicant pursuant to the rules adopted under this part.

827 (7) (a) A permit issued under this part may be renewed by
828 submitting an application for renewal on a form furnished by the
829 department and paying the appropriate fee.

830 (b) If a renewal application and fee are submitted and
831 postmarked after expiration of the permit, a late renewal
832 delinquent fee of \$100, plus the required renewal fee must be
833 paid within 60 days after expiration of the permit.



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834 (c) Upon approval of the renewal application by the
835 department and payment of the required renewal fee, the
836 department shall issue a permit to the applicant pursuant to the
837 rules adopted under this part.

838 (d) The department shall adopt rules for the biennial
839 renewal of permits.

840 (8)(a) A permit, unless suspended or revoked,
841 automatically expires 2 years after the last day of the month in
842 which the permit was issued.

843 (b) Failure to renew a permit in accordance with this
844 section precludes any future renewal of that permit. If a permit
845 issued pursuant to this part has expired and cannot be renewed,
846 the establishment must submit an application for a new permit,
847 pay the application fee, the initial permit fee, and all
848 applicable penalties, and be issued a new permit by the
849 department before the establishment may engage in activities
850 that require a permit under this part.

851 (9) A permitted person in good standing may change permit
852 type to a different permit under s. 499.831 by completing a new
853 application for the requested permit, paying the additional
854 amount due for the permit fee if the fee for the new permit is
855 more than the fee for the original permit, and meeting the
856 applicable permitting conditions for the new permit type. The
857 new permit shall expire on the expiration date of the original
858 permit. A refund may not be issued if the fee for the new permit
859 is less than the fee that was paid for the original permit.



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860 (10) (a) A permit issued by the department is valid only
861 for the person or governmental unit to which it is issued and is
862 not subject to sale, assignment, or other transfer, voluntarily
863 or involuntarily, and is not valid for any establishment other
864 than the establishment for which it was originally issued except
865 as provided in this part. The department is authorized to
866 approve a change of the permit holder.

867 (b) Changes by authorized persons are permitted as
868 follows:

869 1. A person permitted under this part must notify the
870 department 30 days before making a change of location. The
871 department shall set a change of location fee not to exceed
872 \$100.

873 2. When a majority of the ownership or controlling
874 interest of a permitted establishment is transferred or
875 assigned, or when a lessee agrees to undertake or provide
876 services to the extent that legal liability for operation of the
877 establishment will rest with the lessee, an application for a
878 new permit shall be required. The application for the new permit
879 must be made 30 days before the change of ownership. If the
880 application for the new permit is not made 30 days before the
881 change of ownership, and if the new owner acquires a permitted
882 wholesale distributor or manufacturer and the new owner has held
883 another permit under this chapter for at least 18 months and has
884 not been found to have violated the provisions of this chapter
885 in the preceding 18 months, then the new owner can operate under



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886 the permit of the acquired entity, provided the application for
887 a new permit is made no later than the first business day after
888 ownership is transferred or assigned. The new owner is
889 responsible for compliance with all laws and regulations
890 governing medical gas. If the application is denied, the new
891 owner shall immediately cease operation at the establishment
892 until a permit is issued to the new owner.

893 3. A permit holder may make a change of business name
894 without submitting a new permit application and must notify the
895 department 30 days before making the name change. The permit
896 holder may continue to operate the establishment under the old
897 name until the department approves of the name change and issues
898 a permit under the new name.

899 4. If an establishment permitted under this part closes,
900 the owner must notify the department in writing before the
901 effective date of the closure and must:

902 a. Return the permit to the department.

903 b. If the permittee is authorized to distribute medical
904 gas, indicate the disposition of such medical gas, including the
905 name, address, and inventory, and provide the name and address
906 of a contact with access to records that are required to be
907 maintained under this part. Transfer of ownership of medical gas
908 may be made only to persons authorized to possess medical gas
909 under this part.

910 (11) Any change in information required under this section
911 shall be submitted to the department 30 days before such change.



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912 The department may revoke the permit of any person that fails to
913 comply with this part.

914 499.841 Additional requirements for licensure of a
915 wholesale distributor of medical gases.-

916 (1) A wholesale distributor of medical gases that resides
917 in the state or provides services within or into this state must
918 obtain a permit from the department and must renew the permit
919 with the department biennially on an application provided by the
920 department. In order to distribute medical gases into this state
921 pursuant to this subsection, out-of-state medical gas wholesale
922 distributors must maintain a valid license or permit in the
923 state in which they reside, if required, and proof of
924 registration set forth in s. 499.98(4)(a), if required.

925 (2) Wholesale distributors may not operate from or receive
926 a permit for a residence, except that a place of residence may
927 be used for on call delivery of homecare oxygen by a home
928 respiratory care technician. If wholesale distribution
929 operations are conducted at more than one location within the
930 state or distributed from more than one location into the state,
931 each location must be permitted by the department.

932 499.85 Minimum qualifications.-

933 (1) The department shall consider the following factors in
934 determining the eligibility for, and renewal of, a permit of
935 persons who engage in the wholesale distribution of medical gas:

936 (a) A finding by the department that the applicant has
937 violated or been disciplined by a regulatory agency in any state



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938 for violating a federal, state, or local law relating to the
939 wholesale distribution of medical gases.

940 (b) A criminal conviction of the applicant under a
941 federal, state, or local law.

942 (c) The applicant's past experience in the manufacture or
943 wholesale distribution of medical gases.

944 (d) False or fraudulent material provided by the applicant
945 in an application made in connection with the manufacturing or
946 wholesale distribution of medical gases.

947 (e) A suspension, sanction, or revocation by a federal,
948 state, or local government against a license or permit currently
949 or previously held by the applicant or its owners for violations
950 of a federal, state, or local law regarding medical gas.

951 (f) Compliance with previously granted licenses or
952 permits.

953 (g) Compliance with the requirements of wholesale
954 distributors to medical gases to maintain records or make
955 records available to the department licensing authority or
956 federal, state, or local law enforcement officials.

957 (h) Other factors or qualifications the department
958 considers relevant to and consistent with the public health and
959 safety.

960 (2) The applicant shall provide a sworn statement
961 providing complete disclosure of any past criminal convictions
962 and violations of federal, state, or local laws regarding
963 medical gases or a sworn statement that the applicant has not



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964 been convicted of or disciplined for any criminal or prohibited
965 acts.

966 499.86 Registered agent.—Each applicant or permittee under
967 this part shall designate and maintain a registered agent in
968 this state for service of process. If an applicant or permittee
969 does not designate a registered agent, or if, after reasonable
970 diligence, service of process cannot be completed, service of
971 process may be effected by service upon the Secretary of State
972 as agent of the applicant or permittee. A copy of the service of
973 process shall be mailed to the applicant or permittee by the
974 department by certified mail, return receipt requested, or
975 postage prepaid, at the address such applicant or permittee has
976 designated on the applicant's or permittee's application for
977 licensure in this state.

978 499.87 Minimum requirements for the storage and handling
979 of medical gases; establishment and maintenance of medical gas
980 records.—

981 (1) Minimum requirements shall be established for the
982 storage, handling, transport, and shipment of medical gases and
983 for the maintenance of wholesale distribution records by
984 wholesale distributors of medical gases and their officers,
985 agents, representatives, and employees.

986 (2) A facility at which a medical gas is received, stored,
987 warehoused, handled, held, offered, marketed, displayed, or
988 transported from, as necessary to avoid a negative effect on the



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989 identity, strength, quality, or purity of the medical gas,
990 shall:

991 (a) Be of suitable construction to ensure that medical
992 gases are maintained in accordance with the product labeling of
993 the medical gas or in compliance with the USP-NF.

994 (b) Be of suitable size and construction to facilitate
995 cleaning, maintenance, and proper wholesale distribution
996 operations.

997 (c) Have adequate storage areas with appropriate lighting,
998 ventilation, space, equipment, and security conditions.

999 (d) Have a quarantined area for storage of medical gases
1000 that are suspected of being misbranded, adulterated, or
1001 otherwise unfit for distribution.

1002 (e) Be maintained in an orderly condition.

1003 (f) Be a commercial location and not a personal dwelling
1004 or residence location, except for a personal dwelling location
1005 used for on-call delivery of oxygen USP for homecare use where
1006 the person providing on-call delivery is employed by or acting
1007 under a written contract with a permittee.

1008 (g) Provide for the secure and confidential storage of
1009 patient information, if applicable, with restricted access and
1010 policies and procedures to protect the integrity and
1011 confidentiality of the patient information.

1012 (h) Provide and maintain appropriate inventory controls to
1013 detect and document any theft of nitrous oxide.

1014 499.88 Security.—



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1015 (1) A facility used for wholesale distribution of medical
1016 gases shall protect such gases within the facility from
1017 unauthorized entry by using the following security measures:

1018 (a) Keep access from outside the premises well-controlled
1019 and to a minimum.

1020 (b) Ensure the outside perimeter of the premises is well-
1021 lit.

1022 (c) Limit entry into areas where medical gas is held to
1023 authorized personnel.

1024 (d) Equip all facilities with a fence or other system to
1025 detect or deter entry after hours.

1026 (2) A facility used for wholesale distribution of medical
1027 gases shall be equipped with a system that will provide suitable
1028 protection against theft, including when appropriate, protection
1029 against theft of computers or electronic records and that will
1030 protect the integrity and confidentiality of data and documents.

1031 (3) A facility used for wholesale distribution of medical
1032 gases shall be equipped with inventory management and control
1033 systems that protect against, detect, and document any instances
1034 of theft of nitrous oxide.

1035 (4) Where a wholesale distributor of medical gases uses
1036 electronic distribution records, the wholesale distributor shall
1037 employ, train, and document the training of personnel in the
1038 proper use of such technology and equipment.

1039 (5) Vehicles used for on-call delivery of oxygen USP and
1040 oxygen related equipment for home care use by home care



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1041 providers may be parked at a place of residence and must be
1042 locked and equipped with an audible alarm when not attended.

1043 499.89 Storage.-

1044 (1) All medical gases shall be stored under appropriate
1045 conditions in accordance with regulations created by the
1046 department or, in the absence of regulations, in accordance with
1047 applicable industry standards and the manufacturers'
1048 recommendations on the product labeling.

1049 (2) Packaging of medical gas shall be in accordance with
1050 the USP-NF, if applicable.

1051 (3) The record keeping requirements in s. 499.93 shall be
1052 followed for the wholesale distribution of all medical gases.

1053 499.90 Examination of materials.-

1054 (1) Upon receipt of a medical gas container, the container
1055 shall be visually examined to determine identity and whether the
1056 container is damaged or otherwise unfit for wholesale
1057 distribution.

1058 (2) A medical gas container that is found to be damaged or
1059 unfit under subsection (1) shall be quarantined from the
1060 remaining stock until an examination is conducted and a
1061 determination is made that the medical gas is not misbranded or
1062 adulterated.

1063 (3) Each outgoing shipment shall be carefully inspected
1064 for the identity of the medical gas and to ensure that no
1065 medical gas shipment has been damaged in storage or held under
1066 improper conditions.

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1067 (4) Upon receipt of a medical gas, a wholesale distributor
1068 of medical gases must review the accompanying records for
1069 accuracy and completeness. A pedigree paper is not required for
1070 the wholesale distribution of a medical gas.

1071 (5) The record keeping requirements in s. 499.93 shall be
1072 followed for all incoming and outgoing medical gases.

1073 499.91 Returned, damaged, and outdated medical gases.-

1074 (1) Medical gas that has left the control of the wholesale
1075 distributor may be returned to the wholesale distributor or
1076 manufacturer from which it was acquired but may not be resold as
1077 a medical gas unless it is reprocessed by the manufacturer using
1078 proper and adequate controls to ensure the identity, strength,
1079 quality, and purity of the reprocessed medical gas.

1080 (2) A medical gas, including its container, that is
1081 damaged, misbranded, or adulterated shall be quarantined and
1082 physically separated from other medical gases until it is
1083 destroyed or returned to either the manufacturer or wholesale
1084 distributor from which it was acquired. External contamination
1085 of medical gas containers or the container's closure system, not
1086 impacting the integrity of the medical gas, is not considered
1087 damage or adulteration for purposes of this paragraph.

1088 (3) When medical gas is adulterated, misbranded, or
1089 suspected of being adulterated or misbranded, notice shall be
1090 provided to the manufacturer or wholesale distributor from which
1091 they were acquired and the appropriate boards and federal
1092 regulatory bodies.



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1093 (4) A medical gas container that has been opened or used,
1094 but is not adulterated or misbranded, shall be considered empty,
1095 quarantined, and physically separated from nonempty medical gas
1096 containers and returned to the manufacturer for destruction or
1097 reprocessing.

1098 (5) A medical gas, its container, or its associated
1099 documentation or labeling, that is suspected of being involved
1100 in a criminal activity shall be retained and not destroyed until
1101 its disposition is authorized by the department or applicable
1102 law enforcement agency.

1103 (6) The record keeping requirements in s. 499.93 shall be
1104 followed for all misbranded or adulterated medical gases.

1105 499.92 Due diligence.—A wholesale distributor of medical
1106 gases shall comply with the following due diligence
1107 requirements:

1108 (1) Before the initial acquisition of medical gases from a
1109 wholesale distributor, including a manufacturer, the supplying
1110 wholesale distributor shall provide the following information to
1111 the acquiring wholesale distributor or manufacturer:

1112 (a) If a manufacturer is distributing to a wholesale
1113 distributor, evidence that the manufacturer is registered and
1114 the medical gas is listed with the United States Food and Drug
1115 Administration.

1116 (b) If a wholesale distributor is distributing to a
1117 wholesale distributor, evidence that the wholesale distributor



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1118 supplying the medical gas is licensed or permitted to distribute
1119 product into the state.

1120 (c) The name of the responsible facility contact person at
1121 the supplying manufacturer or wholesale distributor.

1122 (d) A certification that the manufacturer or wholesale
1123 distributor's policies and procedures comply with this part.

1124 (2) A manufacturer or wholesale distributor that
1125 distributes or acquires medical gases to or from another
1126 wholesale distributor of medical gases shall provide to or
1127 obtain from the distributing or acquiring entities, as
1128 applicable, the information set forth in s. 499.93(1).

1129 (3) A wholesale distributor of medical gases is exempt
1130 from obtaining the information from a manufacturer as required
1131 under subsection (1) if the manufacturer is registered with the
1132 United States Food and Drug Administration in accordance with s.
1133 510 of the federal act and the manufacturer provides:

1134 (a) Proof of such registration.

1135 (b) Proof of inspection by the United States Food and Drug
1136 Administration or other regulatory body within the past 3 years
1137 demonstrating substantial compliance with current good
1138 manufacturing practices applicable to medical gases.

1139 499.93 Recordkeeping.—

1140 (1) A wholesale distributor of medical gases shall
1141 establish and maintain records of all transactions regarding the
1142 receipt and wholesale distribution or other disposition of



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1143 medical gases. These records shall include the following, which
1144 need not appear on the same document:

1145 (a) Dates of receipt and wholesale distribution or other
1146 disposition of the medical gas.

1147 (b) The name, address, license or permit number, and
1148 license or permit expiration date of the entity purchasing the
1149 medical gas.

1150 (c) The name, address, license or permit number, and
1151 license or permit expiration date of the entity receiving the
1152 medical gas, if different from paragraph (b).

1153 (d) Information sufficient to perform a recall of medical
1154 gases received and distributed.

1155 (2) Such records shall be made available for inspection
1156 and copying by an authorized official of any federal, state, or
1157 local governmental agency for a period of:

1158 (a) Three years following the creation date of high
1159 pressure medical gases.

1160 (b) One year following the creation date for cryogenic or
1161 refrigerated liquid medical gases.

1162 (3) Records kept at the inspection site or that can be
1163 immediately retrieved by computer or other electronic means
1164 shall be readily available for authorized inspection during the
1165 retention period. Records kept at a central location apart from
1166 the inspection site and not electronically retrievable shall be
1167 made available for inspection within 2 working days of a request



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1168 by an authorized official of any state or federal governmental
1169 agency charged with enforcement of these rules.

1170 (4) A wholesale distributor or manufacturers of medical
1171 gases shall maintain an ongoing list of persons from whom they
1172 receive or to whom they distribute medical gases.

1173 (5) A wholesale distributor of medical gases shall
1174 maintain records sufficient to aid in the mandatory reporting of
1175 any theft, suspected theft, or other significant loss of nitrous
1176 oxide to the department and other appropriate law enforcement
1177 agencies.

1178 499.931 Trade secret information.—The department shall
1179 ensure that information required to be provided as part of the
1180 application process or information obtained pursuant to an
1181 investigation by the department, which are trade secret, as
1182 defined in s. 812.081, and designated as trade secret by the
1183 entity supplying the information to the department, shall be
1184 maintained by the department as trade secret as provided in ss.
1185 499.012(8)(g) and 499.051(7).

1186 499.94 Policies and procedures.—A wholesale distributor of
1187 medical gases shall establish, maintain, and adhere to written
1188 policies and procedures, which shall be followed for the
1189 receipt, security, storage, transport, and shipping and
1190 wholesale distribution of medical gases, including policies and
1191 procedures for maintaining inventories, identifying, recording,
1192 and reporting losses or thefts and for correcting all errors and
1193 inaccuracies in inventories associated with nitrous oxide. A



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1194 wholesale distributor of medical gases shall include the
1195 following in the written policies and procedures:

1196 (1) A process for handling recalls and withdrawals of
1197 medical gases. The process shall be adequate to deal with
1198 recalls and withdrawals due to:

1199 (a) An action initiated at the request of the United
1200 States Food and Drug Administration or other federal, state, or
1201 local law enforcement or other government agency, including the
1202 department; or

1203 (b) A volunteer action by the manufacturer of medical
1204 gases to remove defective or potentially defective medical gases
1205 from the market.

1206 (2) A procedure to ensure that wholesale distributors of
1207 medical gases prepare for, protect against, and handle a crisis
1208 that affects the security or operation of any facility in the
1209 event of a strike, fire, flood, or other natural disaster, or
1210 other situations of local, state, or national emergency.

1211 (3) A procedure for reporting criminal or suspected
1212 criminal activities involving the inventory of nitrous oxide to
1213 the department and applicable law enforcement agencies within 3
1214 business days of becoming aware of the criminal or suspect
1215 criminal activity.

1216 499.95 Prohibited acts.—It is unlawful for a person to
1217 perform, cause the performance of, or aid and abet the following
1218 acts in this state:



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1219 (a) The manufacture sale, delivery, or holding or offering
1220 for sale of a medical gas that is adulterated, misbranded, or
1221 has otherwise been rendered unfit for distribution or wholesale
1222 distribution;

1223 (b) The adulteration or misbranding of a medical gas;

1224 (c) The receipt of a medical gas that is adulterated,
1225 misbranded, stolen, obtained by fraud or deceit, or the delivery
1226 or proffered delivery of such medical gas for pay or otherwise;

1227 (d) The alteration, mutilation, destruction, obliteration,
1228 or removal of the whole or a part of the product labeling of a
1229 medical gas or the willful commission of an act with respect to
1230 a medical gas that results in the medical gas being misbranded;

1231 (e) The purchase or receipt of a medical gas from a person
1232 that is not licensed or permitted, or exempt from licensure or
1233 permitting, to distribute wholesale medical gas to that
1234 purchaser or recipient;

1235 (f) The knowing and willful sale or transfer of a medical
1236 gas to a person or other recipient who is not legally authorized
1237 to receive a medical gas, except that no violation shall exist
1238 if a permitted wholesale distributor, at its location, provides
1239 oxygen to a medical oxygen retail establishment permit holder
1240 that is out of compliance with the notice of location change
1241 requirements of s. 499.831(10)(b)1., provided that the wholesale
1242 distributor with knowledge of the violation notifies the
1243 department of the transaction by the next business day;



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1244 (g) The failure to maintain or provide records as required
1245 by this part and its implementing regulations;

1246 (h) Providing the department or its representatives or any
1247 federal, state, or local official with false or fraudulent
1248 records or making false or fraudulent statements regarding a
1249 matter within the provisions of this part and its implementing
1250 regulations;

1251 (i) The wholesale distribution of any medical gas that
1252 was:

1253 1. Purchased by a public or private hospital or other
1254 health care entity, except for physical distribution of such
1255 medical gas to an authorized recipient at the direction of the
1256 hospital or other health care entity;

1257 2. Donated or supplied at a reduced price to a charitable
1258 organization; or

1259 3. Stolen or obtained by fraud or deceit.

1260 (j) The failure to obtain a license or permit or operating
1261 without a valid license or permit when a license or permit is
1262 required;

1263 (k) The obtaining of or attempting to obtain a medical gas
1264 by fraud, deceit, or misrepresentation in the distribution of a
1265 medical gas;

1266 (l) Except for oxygen USP in emergency situations,
1267 distribution of a medical gas to a patient without a
1268 prescription or prescription order from a practitioner licensed
1269 by law to use or prescribe the medical gas;



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- 1270 (m) Distribution of a medical gas that was previously
1271 dispensed by a pharmacy or distributed by a practitioner;
- 1272 (n) Distribution of a medical gas or medical gas related
1273 equipment to a patient, unless the patient has been provided
1274 with appropriate information and counseling on use, storage, and
1275 disposal;
- 1276 (o) The failure to report an act prohibited by this part
1277 and its implementing regulations; or
- 1278 (p) The failure to exercise due diligence as provided in
1279 s. 499.92.
- 1280 499.96 Criminal acts.—
- 1281 (1) A person commits a felony of the third degree,
1282 punishable as provided in s. 775.082, s. 775.083, or s. 775.084,
1283 if he or she:
- 1284 (a) With intent to defraud or deceive, adulterates or
1285 misbrands a medical gas.
- 1286 (b) Engages in wholesale distribution and knowingly
1287 purchases or receives medical gas from a person not legally
1288 authorized to distribute medical gas.
- 1289 (c) Engages in the wholesale distribution and knowingly
1290 sells, barter, brokers, or transfers medical gases to a person
1291 not legally authorized to purchase medical gases under the
1292 jurisdiction in which the person receives the medical gas,
1293 except that no violation shall exist if a permitted wholesale
1294 distributor, at its location, provides oxygen to a medical
1295 oxygen retail establishment permit holder that is out of



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1296 compliance with the notice of location change requirements of s.
1297 499.831(10)(b)1., provided that the wholesale distributor with
1298 knowledge of the violation notifies the department of the
1299 transaction by the next business day.

1300 (d) Knowingly creates a false label for a medical gas or
1301 who falsely represents factual matter contained in a medical gas
1302 label.

1303 (2) A person found guilty of an offense under this
1304 section, under the authority of the court convicting and
1305 sentencing the person, shall be ordered to forfeit to the state
1306 any real or personal property:

1307 (a) Used or intended to be used to commit, to facilitate,
1308 or to promote the commission of such offense; and

1309 (b) Constituting, derived from, or traceable to the gross
1310 proceeds that the defendant obtained directly or indirectly as a
1311 result of the offense. Property or assets subject to forfeiture
1312 under this section may be seized pursuant to a warrant obtained
1313 in the same manner as a search warrant or as otherwise permitted
1314 by law, and held until the case against a defendant is
1315 adjudicated. Monies ordered forfeited, or proceeds from the sale
1316 of other assets ordered forfeited, shall be equitably divided
1317 between the department and other agencies involved in the
1318 investigation and prosecution that led to the conviction. Other
1319 property ordered forfeited after conviction of a defendant may,
1320 at the discretion of the investigating agencies, be placed into



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1321 official use by the department or the agencies involved in the
1322 investigation and prosecution that led to the conviction.

1323 499.97 Salvaging and reprocessing.—

1324 (1) Medical gas that has been subjected to improper
1325 conditions such as a fire, accident or natural disaster, may not
1326 be salvaged or reprocessed.

1327 (2) Medical gas in a container that has left the control
1328 of the wholesale distributor may be returned to the manufacturer
1329 and reprocessed if the manufacturer employs proper and adequate
1330 controls to ensure the identity, strength, quality, and purity
1331 of the reprocessed medical gas.

1332 499.98 Inspections.—

1333 (1) The department is authorized to recognize a third
1334 party to inspect wholesale distributors of medical gases in that
1335 state or in other states pursuant to a schedule to be determined
1336 by the department.

1337 (2) The department is authorized to recognize state
1338 inspections of wholesale distributors of medical gases
1339 operations in another state, if the state's laws are deemed to
1340 be substantially equivalent by the department.

1341 (3) The department's decision to deny issuance of a permit
1342 to an applicant is subject to review pursuant to chapter 120.

1343 (4) A manufacturing facility of medical gases is exempt
1344 from inspection by the department if:

1345 (a) The manufacturing facility is currently registered
1346 with the United States Food and Drug Administration under s. 510



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1347 of the federal act and can provide proof of registration, such
1348 as a copy of the internet verification page.

1349 (b) The manufacturing facility can provide proof of
1350 inspection by the Food and Drug Administration, or if the
1351 facility is located in another state, inspection by the Food and
1352 Drug Administration or other governmental entity charged with
1353 regulation of good manufacturing practices related to medical
1354 gases within the past 3 years.

1355 (5) A wholesale distributor of medical gases must exhibit
1356 or have readily available all state licenses or permits and the
1357 most recent inspection report administered by the department.

1358 (6) This part does not require the department to report
1359 minor violations of this part, including variances in good
1360 manufacturing practices, for the institution of proceedings
1361 under this part when the department believes that the public
1362 interest will be adequately served in the circumstances by
1363 written notice.

1364 499.99 Deposit of fees.—All fees collected for licenses
1365 and permits required by this part shall be deposited in the
1366 Professional Regulation Trust Fund and shall be used by the
1367 department in the administration of this part. The Department of
1368 Business and Professional Regulation shall maintain a separate
1369 account in the Professional Regulation Trust Fund for the Drugs,
1370 Devices, and Cosmetics program.

1371 Section 11. Paragraph (a) of subsection (1) of section
1372 409.9201, Florida Statutes, is amended to read:



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1373 409.9201 Medicaid fraud.—

1374 (1) As used in this section, the term:

1375 (a) "Prescription drug" means any drug, including, but not
1376 limited to, finished dosage forms or active ingredients that are
1377 subject to, defined by, or described by s. 503(b) of the Federal
1378 Food, Drug, and Cosmetic Act or by s. 465.003(8), s.
1379 499.003(52), ~~499.003(46)~~ or ~~(53)~~ or s. 499.007(13).

1380

1381 The value of individual items of the legend drugs or goods or
1382 services involved in distinct transactions committed during a
1383 single scheme or course of conduct, whether involving a single
1384 person or several persons, may be aggregated when determining
1385 the punishment for the offense.

1386 Section 12. Paragraph (c) of subsection (9) of section
1387 460.403, Florida Statutes, is amended to read:

1388 460.403 Definitions.—As used in this chapter, the term:

1389 (9)

1390 (c)1. Chiropractic physicians may adjust, manipulate, or
1391 treat the human body by manual, mechanical, electrical, or
1392 natural methods; by the use of physical means or physiotherapy,
1393 including light, heat, water, or exercise; by the use of
1394 acupuncture; or by the administration of foods, food
1395 concentrates, food extracts, and items for which a prescription
1396 is not required and may apply first aid and hygiene, but
1397 chiropractic physicians are expressly prohibited from
1398 prescribing or administering to any person any legend drug



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1399 | except as authorized under subparagraph 2., from performing any
1400 | surgery except as stated herein, or from practicing obstetrics.

1401 | 2. Notwithstanding the prohibition against prescribing and
1402 | administering legend drugs under subparagraph 1. ~~or s.~~

1403 | ~~499.01(2)(m)~~, pursuant to board rule chiropractic physicians may
1404 | order, store, and administer, for emergency purposes only at the
1405 | chiropractic physician's office or place of business,
1406 | prescription medical oxygen and may also order, store, and
1407 | administer the following topical anesthetics in aerosol form:

1408 | a. Any solution consisting of 25 percent ethylchloride and
1409 | 75 percent dichlorodifluoromethane.

1410 | b. Any solution consisting of 15 percent
1411 | dichlorodifluoromethane and 85 percent
1412 | trichloromonofluoromethane.

1413

1414 | However, this paragraph does not authorize a chiropractic
1415 | physician to prescribe medical oxygen as defined in chapter 499.

1416 | Section 13. Subsection (3) of section 465.0265, Florida
1417 | Statutes, is amended to read:

1418 | 465.0265 Centralized prescription filling.—

1419 | (3) The filling, delivery, and return of a prescription by
1420 | one pharmacy for another pursuant to this section shall not be
1421 | construed as the filling of a transferred prescription as set
1422 | forth in s. 465.026 or as a wholesale distribution as set forth
1423 | in s. 499.003(53) ~~499.003(54)~~.



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1424 Section 14. Paragraph (b) of subsection (2) of section
1425 499.01212, Florida Statutes, is amended to read:

1426 499.01212 Pedigree paper.—

1427 (2) FORMAT.—A pedigree paper must contain the following
1428 information:

1429 (b) For all other wholesale distributions of prescription
1430 drugs:

1431 1. The quantity, dosage form, and strength of the
1432 prescription drugs.

1433 2. The lot numbers of the prescription drugs.

1434 3. The name and address of each owner of the prescription
1435 drug and his or her signature.

1436 4. Shipping information, including the name and address of
1437 each person certifying delivery or receipt of the prescription
1438 drug.

1439 5. An invoice number, a shipping document number, or
1440 another number uniquely identifying the transaction.

1441 6. A certification that the recipient wholesale
1442 distributor has authenticated the pedigree papers.

1443 7. The unique serialization of the prescription drug, if
1444 the manufacturer or repackager has uniquely serialized the
1445 individual prescription drug unit.

1446 8. The name, address, telephone number, and, if available,
1447 e-mail contact information of each wholesale distributor
1448 involved in the chain of the prescription drug's custody.

1449

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1450 When an affiliated group member obtains title to a prescription
1451 drug before distributing the prescription drug as the
1452 manufacturer under s. 499.003(30)(e) ~~499.003(31)(e)~~, information
1453 regarding the distribution between those affiliated group
1454 members may be omitted from a pedigree paper required under this
1455 paragraph for subsequent distributions of that prescription
1456 drug.

1457 Section 15. Paragraph (a) of subsection (1) and subsection
1458 (3) of section 499.015, Florida Statutes, is amended to read:

1459 499.015 Registration of drugs, devices, and cosmetics;
1460 issuance of certificates of free sale.-

1461 (1)(a) Except for those persons exempted from the
1462 definition of manufacturer in s. 499.003(30) ~~499.003(31)~~, any
1463 person who manufactures, packages, repackages, labels, or
1464 relabels a drug, device, or cosmetic in this state must register
1465 such drug, device, or cosmetic biennially with the department;
1466 pay a fee in accordance with the fee schedule provided by s.
1467 499.041; and comply with this section. The registrant must list
1468 each separate and distinct drug, device, or cosmetic at the time
1469 of registration.

1470 (3) Except for those persons exempted from the definition
1471 of manufacturer in s. 499.003(30) ~~499.003(31)~~, a person may not
1472 sell any product that he or she has failed to register in
1473 conformity with this section. Such failure to register subjects
1474 such drug, device, or cosmetic product to seizure and



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1475 condemnation as provided in s. 499.062, and subjects such person
1476 to the penalties and remedies provided in this part.

1477 Section 16. Subsection (3) of section 499.024, Florida
1478 Statutes, is amended to read:

1479 499.024 Drug product classification.—The department shall
1480 adopt rules to classify drug products intended for use by humans
1481 which the United States Food and Drug Administration has not
1482 classified in the federal act or the Code of Federal
1483 Regulations.

1484 (3) Any product that falls under the definition of drug in
1485 s. 499.003(18) ~~499.003(19)~~ may be classified under the authority
1486 of this section. This section does not subject portable
1487 emergency oxygen inhalators to classification; however, this
1488 section does not exempt any person from ss. 499.01 and 499.015.

1489 Section 17. Paragraphs (i) and (m) of subsection (1) of
1490 section 499.05, Florida Statutes, are amended to read:

1491 499.05 Rules.—

1492 (1) The department shall adopt rules to implement and
1493 enforce this part with respect to:

1494 (i) Additional conditions that qualify as an emergency
1495 medical reason under s. 499.003(53)(b)2. ~~499.003(54)(b)2.~~

1496 (m) The recordkeeping, storage, and handling with respect
1497 to each of the distributions of prescription drugs specified in
1498 s. 499.003(53)(a)-(d) ~~499.003(54)(a)-(d).~~

1499 Section 18. This act shall take effect October 1, 2014.

1500

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1085 Behavioral Analysts
SPONSOR(S): Rooney, Jr.
TIED BILLS: IDEN./SIM. BILLS: SB 1212

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee		Castagna <i>AC</i>	O'Callaghan <i>MS</i>
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

Section 11.62, F.S., the Sunrise Act, states that a profession or occupation may not be subject to regulation by the state unless the regulation is necessary to protect the public health, safety, or welfare from significant and discernible harm or damage, and a profession or occupation may not be regulated by the state in a manner that unnecessarily restricts entry into the practice of the profession or occupation. The Sunrise Act requires the Legislature to consider several factors when determining whether a profession or occupation should be regulated.

The bill creates new regulations for a profession currently not regulated by law, behavior analysts. Qualified individuals in this profession are to be licensed by the Department of Health's (Department) Division of Medical Quality Assurance and regulated by the Board of Applied Behavior Analysis (board).

The bill grants the board rulemaking authority to adopt rules related to:

- Standards of practice;
- Licensure qualifications;
- Licensure and other fees;
- Renewal of licenses;
- Suspension or revocation of licenses;
- Prohibited activities;
- Continuing education requirements; and
- Supervision requirements.

The bill also establishes requirements for licensure of assistant behavior analysts and exempts certain persons from any licensure requirements.

The bill provides disciplinary grounds and actions that may be taken against a licensee, and provides conditions for reinstatement of a license. The bill provides a duty for licensees and employers of licensees to report to the board certain crimes or prohibited acts committed by a licensee. The bill provides criminal penalties for those who engage in or assist in the practice of applied behavior analysis without a license.

The bill amends s. 456.001, F.S., to include behavior analysts and assistant behavior analysts in the definition of "health care practitioner."

The bill appears to have a significant fiscal impact on the Department; however, the expenditures incurred are expected to be offset by fee revenues collected. There appears to be no fiscal impact on local governments.

The bill provides an effective date of October 1, 2014.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

Department of Health, Division of Medical Quality Assurance

Currently, the Division of Medical Quality Assurance (MQA) within the Department of Health (Department) licenses and the boards under MQA regulate health care practitioners to preserve the health, safety, and welfare of the public. There are 22 boards and 6 councils under the MQA, and the MQA licenses 7 types of facilities and 200-plus occupations in more than 40 health care professions.¹

A board is a statutorily created entity that is authorized to exercise regulatory or rulemaking functions within the MQA.² Boards are responsible for approving or denying applications for licensure, establishing continuing medical education requirements, and are involved in disciplinary hearings. Sections 456.072, 456.073, and 456.074 F.S., provide the authority for a board to take disciplinary action against a licensee. The board can take action for any legally sufficient, written, and signed complaint that is filed before it.³

Applied Behavior Analysis

Applied Behavior Analysis (ABA), is practiced by behavior analysts who seek to change the behaviors of their clients. ABA applies behavioral science in real-world settings and can be differentiated from other areas of psychology in that it is focused on analyzing and modifying behavior using principles of learning and positive reinforcement to improve daily life skills in a wide variety of individuals.⁴ Examples of ABA practice include: building the skills and achievements of children in school settings and enhancing the development, abilities, and choices of children and adults with different kinds of emotional and behavioral disabilities.

A growing demand for effective intervention for individuals diagnosed with autism spectrum disorders⁵ and other behavioral and emotional conditions has driven more consumers and employers to seek ABA services. Colleges and universities have responded to these demands by establishing professional training programs in applied behavior analysis.⁶

Behavior analysts work in a wide variety of settings to impact behavior change. Behavior analysts are employed in schools to work with students with emotional and behavioral disorders that affect their ability to learn in the classroom. They work in home settings to improve basic behavioral and life skills

¹ Florida Health Source, Florida Department of Health, *accessible at: <http://www.flhealthsource.gov/>* (Last accessed February 28, 2014).

² Section 456.001, F.S.

³ Section 456.025(3), F.S., provides that a complaint is legally sufficient if it contains the ultimate facts that show a violation of the relevant practice act or any rule adopted by the Department or the relevant board.

⁴ Psychology: Applied Behavior Analysis, Florida State University, *accessible at: <http://www.pc.fsu.edu/Academics/Graduate-Programs/Psychology-Applied-Behavior-Analysis>* (Last accessed March 22, 2014).

⁵ Autism spectrum disorders (ASDs) are a group of developmental disabilities that can cause significant social, communication and behavioral challenges. People with ASDs handle information in their brain differently than other people. ASDs are “spectrum disorders” meaning ASDs affect each person in different ways, and can range from very mild to severe. People with ASDs share some similar symptoms, such as problems with social interaction, but there are differences in when the symptoms start, how severe they are, and the exact nature of the symptoms. Centers for Disease Control and Prevention, “Autism Spectrum Disorder (ASD): Signs and Symptoms,” *accessible at: <http://www.cdc.gov/ncbddd/autism/signs.html>* (Last accessed March 22, 2014).

⁶ The Behavior Analysis Certification Board has approved 9 Florida Universities as meeting the requirements for coursework and supervised experience. *Infra* fn. 20.

for those persons with autism and instruct caregivers on ways to effectively reinforce positive, sustainable, behavior change.⁷

Certification of Behavior Analysts

The uneven standard of care used by behavior analysts in the practice of applied behavior analysis led to the formation of the private, nonprofit, Behavior Analyst Certification Board (BACB). The BACB teaches methods to best implement ethical and effective behavior analytic interventions based on published research. The BACB administers examinations for behavior analyst credentialing several times each year in over 200 sites within the United States. To effectively serve behavior analysis professionals and consumers, the BACB has developed:⁸

- Eligibility Standards for applicants wishing to take the BACB Certification Examination;
- Renewal and recertification standards to maintain certification;
- Guidelines for responsible conduct for behavior analysts;
- Professional disciplinary standards with appeal procedures;
- A registry of those certified;
- A process to approve university course sequences and practical experience;
- Procedures to approve continuing education providers; and
- Professionally developed and maintained certification examinations.

Since 2008, 13 states⁹ have adopted laws to license behavior analysts in their own right. In all 13 states, BACB certification is accepted as a qualification for licensure.

Under the BACB, certification is currently offered at 2 levels: Board Certified Behavior Analyst (BCBA) and Board Certified Assistant Behavior Analyst (BCaBA), these credentialing programs are accredited by the National Commission for Certifying Agencies.

BCBAs have earned at least a Master's degree and have obtained BACB Certification. They conduct behavioral assessments, functional analyses and provide behavior analytic interpretations of the results. They design and supervise behavior analytic interventions.¹⁰ BCaBAs have earned at least a Bachelor's degree and have obtained BACB certification. They may conduct descriptive behavioral assessments, interpret the results and design behavior analytic interventions under the supervision of a BCBA.¹¹

Florida Behavior Analysts

Behavior analysts have been trained and certified in Florida since 1983.¹² They are recognized in multiple sections of Florida law.¹³ There are currently 1,793 BCBAs and 604 BCaBAs in Florida.

The Florida Association for Behavior Analysis (FABA) has represented Florida behavior analysts for 34 years. FABA was founded to promote the ethical, humane, and effective application of behavior principles in a range of settings across the state. FABA primarily serves to offer continuing education

⁷ *Infra* fn. 20.

⁸ About the BACB, Behavior Analysis Certification Board, *accessible at*: <http://www.bacb.com/index.php?page=1> (last accessed March 22, 2014).

⁹ Arizona, Kentucky, Louisiana, Massachusetts, Missouri, Nevada, New York, North Dakota, Oklahoma, Oregon, Rhode Island, Virginia, and Wisconsin have adopted licensure laws.

¹⁰ About BACB credentials, Behavior Analyst Certification Board, *accessible at*: <http://www.bacb.com/index.php?page=4> (last accessed March 22, 2014).

¹¹ *Id.*

¹² *See infra*, fn. 20.

¹³ Behavior analysts are mentioned in ch. 393, F.S., relating to developmental disabilities, ch. 627, F.S., relating to insurance rates and contracts, and ch. 641, F.S., relating to coverage for individuals with developmental disabilities.

opportunities to BCBAs in Florida and to monitor legislative changes to protect the rights of behavior analysts to practice.¹⁴

An insurance coverage mandate for autism spectrum disorder enacted in Florida in 2008¹⁵ led to the recognition and required certification of behavior analysts providing ABA services for the treatment of autism in Florida.¹⁶ Florida law requires ABA services to be covered by insurance when prescribed by the insurance holder's physician in accordance with a treatment plan.¹⁷ Florida Medicaid covers ABA services for individuals under the age of 21 through a Community Behavioral Health (CBH) provider, an Early Intervention Services (EIS) provider, or an iBudget waiver provider. ABA services must be prior approved by Medicaid.¹⁸

Professional Regulation and the Florida Sunrise Act

Generally, there are 3 different types or levels of regulation:

- Licensure is the most restrictive form of state regulation. Under licensure laws, it is illegal for a person to practice a profession without first meeting all of the standards imposed by the state.
- Certification grants title protection to those who meet training and other standards. Those who do not meet certification standards cannot use the title, but can still perform the services.
- Registration is the least restrictive form of regulation, and usually only requires individuals to file their name, address, and qualifications with a government agency before practicing the occupation.

Section 456.003, F.S., specifies that health care professions may be regulated only for the preservation of the health, safety, and welfare of the public under the police powers of the state. Such professions shall be regulated when:

- Their unregulated practice can harm or endanger the health, safety, and welfare of the public, and when the potential for such harm is recognizable and clearly outweighs any anticompetitive impact which may result from regulation;
- The public is not effectively protected by other means, including, but not limited to, other state statutes, local ordinances, or federal legislation; and
- Less restrictive means of regulation are not available.

Section 11.62, F.S., the Sunrise Act, provides legislative intent regarding the regulation of new professions and occupations, stating that:

- No profession or occupation may be subject to regulation by the state unless the regulation is necessary to protect the public health, safety, or welfare from significant and discernible harm or damage and that the police power of the state may be exercised only to the extent necessary for that purpose; and

¹⁴ About FABA, Florida Association for Behavior Analysis *accessible at*: <http://fabaworld.org/aboutfaba.php>(last accessed March 21, 2014).

¹⁵ Section 4, ch. 2008-30, L.O.F.

¹⁶ See s. 641.31098, F.S., relating to insurance coverage for individuals with developmental disabilities, which states that applied behavior analysis services shall be provided by an individual certified pursuant to s. 393.17, F.S, or an individual licensed under chapter 490, F.S., (psychologists) or chapter 491, F.S., (clinical social workers, marriage and family therapists, or mental health counselors).

¹⁷ *Id.*

¹⁸ Email correspondence with the Agency for Health Care Administration, March 18,2014, (on file with Health Quality Subcommittee).

- No profession or occupation may be regulated by the state in a manner that unnecessarily restricts entry into the practice of the profession or occupation or adversely affects the availability of the professional or occupational services to the public.

In determining whether to regulate a profession or occupation, s. 11.62(3), F.S., requires the Legislature to consider the following:

- Whether the unregulated practice of the profession or occupation will substantially harm or endanger the public health, safety, or welfare, and whether the potential for harm is recognizable and not remote;
- Whether the practice of the profession or occupation requires specialized skill or training, and whether that skill or training is readily measurable or quantifiable so that examination or training requirements would reasonably assure initial and continuing professional or occupational ability;
- Whether the regulation will have an unreasonable effect on job creation or job retention in the state or will place unreasonable restrictions on the ability of individuals who seek to practice or who are practicing a given profession or occupation to find employment;
- Whether the public is or can be effectively protected by other means; and
- Whether the overall cost-effectiveness and economic impact of the proposed regulation, including the indirect costs to consumers, will be favorable.

The Sunrise Act requires proponents of regulation to submit information documenting the need for the proposed regulation. A sunrise questionnaire was submitted by the Florida Association for Behavior Analysis (FABA) to the Legislature. FABA is the only statewide organization representing behavior analysts in Florida. The current membership is between 900-1000 members.

Summary of Sunrise Act Questionnaire and Responses

Substantial Harm or Endangerment

The Sunrise Act Questionnaire¹⁹ requests whether the unregulated practice of the profession or occupation will substantially harm or endanger the public health, safety, or welfare, and whether the potential for harm is recognizable and not remote.

The FABA responded to this question stating that a majority of persons treated by ABA services are highly vulnerable making them susceptible to fraudulent, ineffective practices such as claims of cures, or unethical interventions. Over the past 13 years there have been 26 events of unethical or improper practice that were investigated by the BACB in the state of Florida. These violations involved negligence, incompetence, malpractice, or misconduct.²⁰

Specialized Skill or Training, and Measurability

The Sunrise Questionnaire asks whether the practice of the profession or occupation requires specialized skill or training, and whether that skill or training is readily measurable or quantifiable so that examination or training requirements would reasonably assure initial and continuing professional or occupational ability.

According to FABA, the initial measure of a behavior analysts' ability to engage in competent practice is the examination for board certification. The exam is in multiple-choice format with specific questions in each of the content areas of the BACB's task list. To be eligible for examination, one must have at least

¹⁹ The Sunrise Act Questionnaire is a questionnaire developed by Legislative staff to solicit the responses required by the proponents of the new regulation pursuant to s. 11.62(4), F.S.

²⁰ Completed Sunrise Questionnaire by the Florida Association for Behavior Analysis, on file with Health Quality Subcommittee staff.

a master's degree in behavior analysis or other natural science, education, human services, medicine or a field related to behavior analysis to be approved by the BACB.²¹

Unreasonable Effect on Job Creation or Job Retention

The Sunrise Questionnaire asks whether the regulation will have an unreasonable effect on job creation or job retention in the state or will place unreasonable restrictions on the ability of individuals who seek to practice or who are practicing a given profession or occupation to find employment.

FABA responds that the requirements for licensure under the proposed legislation align with current credentialing requirements required for behavior analysts. Currently the privatized BACB handles all credentialing responsibilities.²²

Other persons who may implement behavioral interventions and provide counseling services similar to that of BCBA's include schoolteachers, school psychologists, parents, physicians, school faculty, priests, and ministers. These persons are not required to obtain BACB certification.²³

Can the Public Be Effectively Protected by Other Means?

The Sunrise Questionnaire asks whether the public is or can be effectively protected by other means.

FABA represents that currently, the BACB addresses complaints against BCBA's and those who are fraudulently claiming to be board certified. Over the past 13 years there have been 26 events of unethical or improper practice that were investigated by the BACB in the state of Florida. The current BACB requirements for making a complaint are time consuming, requiring consumers to produce written records of correspondence to the behavior analyst, correspondence to fiscal agencies or funding sources, and correspondence with state regulatory agencies (which is currently unavailable in Florida). Due to non-existing licensure for behavior analysts in Florida there are no funds to regulate the profession and, according to FABA, effectively preserve the health and safety of those citizens utilizing ABA services.²⁴

Favorable Cost-effectiveness and Economic Impact

The Sunrise Questionnaire asks whether the overall cost-effectiveness and economic impact of the proposed regulation, including the indirect costs to consumers, will be favorable.

FABA does not anticipate that establishing licensure of this profession will make any changes to the current costs of services for consumers. The fees imposed by initial licensure application and license renewal will help to more effectively regulate the profession and better protect consumers. Application fees are not expected to exceed \$100 and licensure and renewal fees are not expected to exceed \$300.²⁵

Effect of Proposed Changes

The bill creates chapter 470, F.S., to establish new regulation over the health care profession of behavior analysts within the Department of Health's (Department) Division of Medical Quality Assurance (MQA).

²¹ *Id.*

²² *Id.*

²³ *Id.*

²⁴ *Id.*

²⁵ *Id.*

The bill specifies that the purpose of the practice of applied behavior analysis is to protect the public from harmful conduct of unqualified, unprofessional or unethical applied behavior analysts.

Definitions

The bill defines several terms related to applied behavior analysis including the following:

- “Applied behavior analysis” means the design, implementation, and evaluation of instructional and environmental modifications to produce socially significant improvements in human behavior and includes functional assessment and analysis. The term does not include psychological testing, the diagnosis of a mental or physical disorder, neuropsychology, psychotherapy, cognitive therapy, sex therapy, psychoanalysis, hypnotherapy, or long-term counseling.
- “Board-certified behavior analyst” means a practitioner who is certified by the national Behavior Analyst Certification Board (BACB), or its successor pursuant to s. 470.42, as a Board Certified Behavior Analyst.
- “Board-certified assistant behavior analyst” means a practitioner who is certified by the national BACB, or its successor pursuant to s. 470.42, as a Board Certified Assistant Behavior Analyst.
- “Supervised experience” means an individual has completed the training necessary to satisfy the eligibility requirements for BACB certification.
- “Licensed behavior analyst” means an individual who is licensed by the Board of Applied Behavior Analysis (board) and meets the requirements of ch. 470, F.S.
- “Licensed assistant behavior analyst” means an individual who is licensed by the board as an assistant behavior analyst, meets the requirements of ch. 470, F.S., and works under the supervision of a licensed behavior analyst.

Board

The bill creates s. 470.415, F.S., to establish and house the Board of Applied Behavior Analysis (board) within the MQA. The bill provides that ch. 456, F.S., relating to general requirements for health care practitioners, applies to the board. The board must consist of 7 members appointed by the Governor and confirmed by the Senate. Specific membership of the board is as follows:

- Three board-certified behavior analysts; 1 of whom will be appointed to a 1-year term and 2 who will be appointed to 3-year terms.
 - Two of the 3 board-certified behavior analysts will be selected from a list of 6 nominations submitted by the Florida Association for Behavior Analysis.
- One health care provider licensed in this state whose practice must be related to the treatment of behavior disorders including autism spectrum disorders and who is to be appointed for a 2-year term.
- Two laypersons, who may be a parent or guardian of an individual who is a recipient of ABA services.
 - 1 of whom shall serve a 1-year term and 1 of whom shall serve a 2-year term.
- One board-certified assistant behavior analyst, who is appointed to a 1-year term.

The Governor’s appointments of successors shall be for 3-year terms and successors must be licensed. Members may not serve more than two consecutive terms.

The bill creates s. 470.42, F.S., providing the board authority to adopt rules pursuant to s. 120.536(1), F.S., and 120.54, F.S. These rules must include, but are not limited to, rules relating to the following:

- Standards of practice;
- Licensure qualifications;
- Licensure and other fees;

- Renewal of licenses;
- Suspension or revocation of licenses;
- Prohibited activities;
- Continuing education requirements; and
- Supervision requirements.

The bill requires the board to:

- Adopt a code of ethical standards and standards of practice for licensed behavior analysts and licensed assistant behavior analysts;
- Update records annually;
- Publish annually and make available a current registry of all licensed behavior analysts and licensed assistant behavior analysts; and
- Maintain its official headquarters in Tallahassee, Florida.

The bill requires a licensee to notify the board when the licensee has had a name, address, or telephone number change within 30 days of the change.

Licensure

The bill creates s. 470.43, F.S., providing for the initial licensure and renewal of license for behavior analysts or licensed assistant behavior analysts. In order to be licensed the applicant shall provide evidence that he or she:

- Is a board-certified behavior analyst or board certified assistant behavior analyst;
- Conducts his or her professional activities in accordance with accepted standards as required by rule;
- Complies with all applicable rules adopted by the board;
- Is supervised by a licensed behavior analyst in a manner consistent with BACB requirements;
- Has paid the licensure fee or the biennial renewal fee; and
- Has passed a criminal background check.

The board may issue a license to a person who holds an active license as a behavior analyst or assistant behavior analyst in another state that imposes comparable licensure requirements if the person:

- Submits proof of licensure and board certification;
- Passes a criminal background check, as determined by the board; and
- Pays the licensure fee.

The bill creates s. 470.44, F.S., providing the board authority to establish, by rule, an application fee not to exceed \$100 and to establish a fee for initial licensure and renewal not to exceed \$300. These fees shall be deposited as provided under s. 456.025, F.S.

The bill provides a list of exceptions to the requirement for licensure stating the following persons will not be prohibited, restricted, or subject to the provisions of the bill, provided false representation as a behavior analyst does not occur:

- An individual licensed under ch. 490, F.S., to practice psychology.
- An individual licensed under ch. 491, F.S., as a clinical social worker, marriage and family therapist, or mental health counselor.
- A certified teacher, teaching assistant, or student support professional performing duties under their scope of practice for which he or she was trained and hired.

- A behavior analyst that practices with non-human clients.
- An unlicensed individual who provides ABA services under the extended authority and direction of a licensed behavior analyst or licensed assistant behavior analyst.
- An individual who teaches ABA or who conducts behavior analytic research if such teaching or research does not involve the delivery of ABA to individuals.
- A college or university student or postdoctoral fellow whose activities are part of a defined behavior analysis program of study and ABA practices are directly supervised under a board certified behavior analyst.
- An unlicensed individual pursuing supervised experimental training to meet eligibility requirements for BACB certification.
- A board certified behavior analyst or an individual licensed to practice ABA in another state who provides ABA services in Florida to a resident of this state for less than 12 days per year.
- A "Florida-certified behavior analyst" who is in good standing with the BACB who is not a board certified behavior analyst.
- A family member of a recipient of ABA services implementing certain ABA procedures with the recipient.
- A behavior analyst who provides general ABA services to organizations if the services do not involve direct services to individuals.
- A physician licensed pursuant to chapters 458 or 459, F.S.,
- An employee of a private non-profit organization providing ABA services to youth and families if the services are provided for no charge and the employee is performing duties for which he or she was hired.
- A school psychologist certified in school psychology by the Department of Education who performs ABA services as an employee of a public or private educational institution. This exemption does not authorize unlicensed practice that is not performed directly as an employee of an educational institution.
- A rabbi, priest, minister, or member of the clergy of a religious denomination or sect if activities are within the scope of performance of his or her regular specialized ministerial duties and for which no separate fee is charged.

Disciplinary Grounds and Action

This bill amends s. 456.001, F.S., to include behavior analysts and assistant behavior analysts under the definition of health care practitioner. This inclusion requires behavior analysts to follow the criteria other health care practitioners must meet to uphold the appropriate standard of care for the respective profession.

The bill creates s. 470.45, F.S., providing the disciplinary grounds and actions that may be taken against a licensee who violates any of the provisions of s. 456.072(2), F.S., and imposes penalties provided under s. 456.072(1), F.S. The bill sets limitations on the board regarding disciplinary action that may be taken by specifying that the board may not:

- Place a licensee on probation for more than 5 years;
- Impose a fine that exceeds \$2,500;
- Suspend a license for more than 5 years; or
- Limit or restrict a license for an indefinite period.

The bill authorizes the board to reinstate a license that has been suspended or revoked if, after a hearing conducted pursuant to s. 120.54, F.S., the board determines the applicant is able to practice with reasonable competency and in accordance with the code of ethics and standards of practice established under board rule. Such reinstatement may be subject to reasonable restrictions on the license imposed by the board.

The bill creates s. 470.46, F.S., providing a duty for licensees and employers of licensees to report to the board felonies or suspicion of fraud or deceit committed by a licensee.

The bill creates s. 470.47, F.S., to provide that a person who engages in or assists in the practice of applied behavior analysis without a license commits a felony of the third degree.²⁶ This section also provides title protection for the following: licensed behavior analysts, licensed assistant behavior analysts, or any other title that is substantially similar. False representation of such titles would constitute a misdemeanor of the second degree.²⁷

B. SECTION DIRECTORY:

Section 1. Creates Chapter 470, F.S., relating to Behavior Analysts.

Section 2. Creates s. 470.40, F.S., relating to the purpose of the act.

Section 3. Creates s. 470.41, F.S., relating to definitions.

Section 4. Creates s. 470.415, F.S., relating to the Board of Applied Behavior Analysis.

Section 5. Creates s. 470.42, F.S., relating to the authority and duties of the Board of Applied Behavioral Analysis.

Section 6. Creates s. 470.43, F.S., relating to licensure and renewal.

Section 7. Creates s. 470.44, F.S., relating to fees.

Section 8. Creates s. 470.45, F.S., relating to disciplinary grounds and actions, and reinstatement.

Section 9. Creates s. 470.46, F.S., relating to duty to report felony or suspicion of fraud or deceit.

Section 10. Creates s. 470.47, F.S., relating to violations and penalties.

Section 11. Creates s. 470.48, F.S., relating to exceptions for applicability.

Section 12. Amends s. 456.001, F.S., relating to definitions.

Section 13. Provides an effective date of October 1, 2014 .

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

The initial application fees for behavior analysts and assistant behavior analysts are to be established by rule, but may not exceed \$100 and initial licensure fees may not exceed \$300. The unlicensed activity fee of \$5 imposed by MQA²⁸ will also be assessed upon initial licensure and renewal. FAB estimates 2,000 new applicants for licensure. The estimated revenue for application fees is \$200,000 and the estimated revenue for initial licensure fees is \$600,000. The estimated revenue from unlicensed activity fees is \$10,000. The total estimated revenue to be gained is \$810,000 using the maximum fees authorized.²⁹

2. Expenditures:

The Department estimates that 1 full time equivalent (FTE) will be required to implement the provisions of this bill. 1 FTE can manage an active/inactive licensure pool size of 2,600 for professionals licensed under ch. 491, F.S.³⁰ Salary and benefits for 1 FTE Regulatory Specialist II, no travel, is \$77,326.³¹

²⁶ A felony of the third degree is punishable by a term of imprisonment not exceeding 5 years and a fine not to exceed \$5,000. Sections 775.082, 775.083, or 775.084, F.S.

²⁷ A misdemeanor of the second degree is punishable by a term of imprisonment not exceeding 60 days and a fine not to exceed \$500. Sections 775.082 and 775.083, F.S.

²⁸ Section 455.2281, F.S., refers to unlicensed activity fee which funds regulation of licensed professions, including investigations of persons conducting unlicensed health care activities.

²⁹ 2014 Department of Health Agency Legislative Bill Analysis for HB 1085, dated February 25, 2014, on file with committee staff.

³⁰ Ch. 491, F.S., relates to the similar fields of clinical social work, marriage and family therapy, and mental health counseling.

³¹ *Supra* fn. 29.

MQA may realize additional FTEs are required for effective enforcement of a new profession. The exact fiscal impact is presently unknown, but the information has been requested from the Department.³²

MQA anticipates holding four, 1.5 day meetings per year with 7 board members and 2 Department staff. The average travel cost for professions licensed under chapter 491, F.S., is \$450 per day for a total cost of \$ \$31,800. The cost for board member compensation at \$50 per day for each board member totals \$2,841. Total estimated meeting costs are \$34,641.³³

The Department currently contracts for the processing of initial and renewal applications and related fees. The cost of the contracted service is based on a \$7.69 per application rate. It is projected that 2,000 new applications will be processed for a cost of \$15,380.³⁴

The Department will incur non-recurring costs for rulemaking, which current budget authority is adequate to absorb.³⁵

Consistent with adding any new profession, the Department will update the Customer Oriented Medical Practitioner Administration System (COMPAS) licensure system to accommodate the new Certified Behavior Analyst and Assistant Behavior Analyst license, which current resources are adequate to absorb.³⁶

The Department will incur an increase in workload associated the development and maintenance of a new website, online renewals, and online applications, which current resources are adequate to absorb.³⁷

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Behavior analysts and assistant behavior analysts currently certified under the BACB will be required to pay the application and initial licensure fee, and other fees required by the Department to obtain initial licensure. The board may not set an application fee to exceed \$100 and the initial licensure fee may not exceed \$300. Licensees will also be required to pay license renewal fees to maintain licensure. The board may not set the licensure renewal fee above \$300.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

³² *Id.*

³³ *Id.*

³⁴ *Id.*

³⁵ *Id.*

³⁶ *Id.*

³⁷ *Id.*

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

This bill grants the board rulemaking authority to adopt rules relating to behavior analysts and assistant behavior analysts, which provide for:

- Standards of practice.
- Licensure, including the suspension and revocation of a license and the refusal to issue or renew a license.
- Fees for licensure and licensure renewal.
- Limitations of activities.
- Supervision.
- Educational qualifications and continuing education requirements.
- The number of persons that a licensed behavior analyst or licensed assistant behavior analyst may supervise at one time.
- The competency of a person to receive or renew his or her license.
- The physical and mental examination of licensed behavior analysts and licensed assistant behavior analysts who may be impaired by reason of a mental, physical, or other condition that impedes their ability to practice competently.

C. DRAFTING ISSUES OR OTHER COMMENTS:

Due to the time required to engage in rulemaking and the fact that the MQA licensure database system is being upgraded and not available for changes until October, 2014, it is suggested that the effective date of this bill be changed to January 1, 2015. This would allow the Department and the Governor additional time to make appointments, time for DOH to hire staff, work with the various sections of MQA to develop online applications, develop a new website, promulgate rules for the required applications, and allow time to educate staff and inform those currently certified of this law and the new requirements.³⁸

The professional board should be added to the list of professions regulated by the Department of Health, Division of Medical Quality Assurance, under s. 20.43(3)(g), F.S., thereby placing behavior analysts and behavior analyst assistants within the definition of professions regulated under ch. 456, F.S.³⁹

On line 91, the term "health care provider" should be replaced with the term "health care practitioner" which is defined in s. 456.001, F.S., and has clear legal meaning.

On line 285, references "behavior analysis services". This term is not defined and should be changed to "applied behavior analysis" services, which is defined in the bill.

On lines 297-298, the term "direct behavior analysis interventions" is used. This term is not defined and should be changed to "applied behavior analysis" services, which is defined in the bill.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

³⁸ *Id.*

³⁹ *Id.*

1 A bill to be entitled
 2 An act relating to behavior analysts; creating ch.
 3 470, F.S.; entitling the chapter; creating s. 470.40,
 4 F.S.; providing a purpose; creating s. 470.41, F.S.;
 5 defining terms; creating s. 470.415, F.S.; creating
 6 the Board of Applied Behavior Analysis; creating s.
 7 470.42, F.S.; specifying the authority and duties of
 8 the board; creating s. 470.43, F.S.; providing
 9 requirements for licensure and renewal; creating s.
 10 470.44, F.S.; establishing maximum fees for
 11 applications, initial licenses, and license renewals;
 12 creating s. 470.45, F.S.; providing grounds for
 13 disciplinary action by the board; providing for
 14 reinstatement of a license; creating s. 470.46, F.S.;
 15 requiring a licensee or his or her employer to report
 16 to the board certain felony convictions on the part of
 17 a licensee or suspicions that a licensee has committed
 18 fraud or deceit; creating s. 470.47, F.S.; providing
 19 penalties for practicing applied behavior analysis
 20 without a license or wrongfully identifying oneself as
 21 a licensed behavior analyst; creating s. 470.48, F.S.;
 22 providing exceptions to the chapter; amending s.
 23 456.001, F.S.; including licensed behavior analysts
 24 and licensed assistant behavior analysts in the
 25 definition of "health care practitioner"; providing an
 26 effective date.

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

Section 1. Chapter 470, Florida Statutes, is created and entitled "Behavior Analysts."

Section 2. Section 470.40, Florida Statutes, is created to read:

470.40 Purpose.—The practice of applied behavior analysis in this state affects the public health, safety, and welfare of its residents, and this act is intended to protect the public from any harmful conduct of unqualified, unprofessional, or unethical applied behavior analysts.

Section 3. Section 470.41, Florida Statutes, is created to read:

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

(1) "Applied behavior analysis" means the design, implementation, and evaluation of instructional and environmental modifications to produce socially significant improvements in human behavior and includes functional assessment and analysis. The term does not include psychological testing, the diagnosis of a mental or physical disorder, neuropsychology, psychotherapy, cognitive therapy, sex therapy, psychoanalysis, hypnotherapy, or long-term counseling.

(2) "Board" means the Board of Applied Behavior Analysis established in s. 470.415, except when the term is used in the context of board certification.

53 (3) "Board-certified behavior analyst" means a
 54 practitioner who is certified by the national Behavior Analyst
 55 Certification Board (BACB), or its successor pursuant to s.
 56 470.42, as a Board Certified Behavior Analyst.

57 (4) "Board-certified assistant behavior analyst" means a
 58 practitioner who is certified by the national Behavior Analyst
 59 Certification Board, or its successor pursuant to s. 470.42, as
 60 a Board Certified Assistant Behavior Analyst.

61 (5) "Department" means the Department of Health.

62 (6) "Licensed behavior analyst" means an individual who is
 63 licensed by the board and meets the requirements of this
 64 chapter.

65 (7) "Licensed assistant behavior analyst" means an
 66 individual who:

67 (a) Is licensed by the board as an assistant behavior
 68 analyst and meets the requirements of this chapter; and

69 (b) Works under the supervision of a licensed behavior
 70 analyst.

71 (8) "Supervised experience" means an individual has
 72 completed the training necessary to satisfy the eligibility
 73 requirements for BACB certification.

74 Section 4. Section 470.415, Florida Statutes, is created
 75 to read:

76 470.415 Board of Applied Behavior Analysis.-

77 (1) The Board of Applied Behavior Analysis is created
 78 within the department. The board consists of seven members who

79 must be appointed by the Governor and confirmed by the Senate.

80 (2) The initial board members, who are not required to be
 81 licensed as a condition of appointment, shall be appointed as
 82 follows:

83 (a) Three board-certified behavior analysts, which may
 84 include board-certified behavior analysts who are at the
 85 doctoral level, two of whom shall be selected from a list of six
 86 nominations submitted by the Florida Association for Behavior
 87 Analysis. One shall be appointed to a 1-year term, and two shall
 88 be appointed to 3-year terms;

89 (b) One board-certified assistant behavior analyst, who
 90 shall be appointed to a 1-year term;

91 (c) One health care provider licensed in this state, who
 92 shall be appointed to a 2-year term. The majority of the
 93 appointed health care provider's practice must be related to the
 94 treatment of behavior disorders, including, but not limited to,
 95 autism spectrum disorders; and

96 (d) Two laypersons, who may include a parent or guardian
 97 of an individual who is a recipient of applied behavior analysis
 98 services, one of whom shall serve a 1-year term, and one of whom
 99 shall serve a 2-year term.

100 (3) As the terms of the initial members expire, the
 101 Governor shall appoint successors for 3-year terms. Each
 102 successor, except for the laypersons, must be licensed. A member
 103 may not serve more than two consecutive terms.

104 (4) All provisions of chapter 456 relating to the board

105 apply.

106 Section 5. Section 470.42, Florida Statutes, is created to
 107 read:

108 470.42 Authority of the board; duties.-

109 (1) The board may adopt rules pursuant to ss. 120.536(1)
 110 and 120.54 to implement the provisions of this chapter
 111 conferring duties upon it. Such rules must include, but are not
 112 limited to, rules relating to all of the following:

113 (a) Standards of practice.

114 (b) Licensure, including the suspension and revocation of
 115 a license and the refusal to issue or renew a license.

116 (c) Limitations of activities.

117 (d) Supervision.

118 (e) Educational qualifications and continuing education
 119 requirements.

120 (f) The number of persons that a licensed behavior analyst
 121 or licensed assistant behavior analyst may supervise at one
 122 time.

123 (g) The competency of a person to receive or renew his or
 124 her license.

125 (h) The physical and mental examination of licensed
 126 behavior analysts and licensed assistant behavior analysts who
 127 may be impaired by reason of a mental, physical, or other
 128 condition that impedes their ability to practice competently.

129 (2) The board shall perform all of the following:

130 (a) Adopt a code of ethical standards and standards of

131 practice for licensed behavior analysts and licensed assistant
 132 behavior analysts.

133 (b) Keep a minute book containing a record of all meetings
 134 of the board.

135 (c) Maintain a registry of all persons licensed under this
 136 chapter. This registry must show the name of every licensee in
 137 this state, his or her current business and residence address
 138 and telephone number, and his or her licensure date and license
 139 number. A licensee shall notify the board of a change of name,
 140 address, or telephone number within 30 days after the change.

141 (d) Update its records annually.

142 (e) Publish annually and make available a current
 143 directory of all licensed behavior analysts and licensed
 144 assistant behavior analysts in this state.

145 (f) Adopt a seal and affix it to every license granted by
 146 the board.

147 (g) Maintain its official headquarters in Tallahassee.

148 (3) If the Behavior Analyst Certification Board stops
 149 certifying practitioners of applied behavior analysis in this
 150 state, the board shall approve a successor certification board
 151 that is accredited by the National Commission for Certifying
 152 Agencies or the American National Standards Institute to certify
 153 applied behavior analysts.

154 Section 6. Section 470.43, Florida Statutes, is created to
 155 read:

156 470.43 Licensure and renewal.—

157 (1) A person applying for an initial or renewal license as
 158 a licensed behavior analyst or licensed assistant behavior
 159 analyst shall apply to the board on such form and in such manner
 160 as the board prescribes. The person shall furnish evidence to
 161 the board that he or she:

162 (a) Is a board-certified behavior analyst;

163 (b) Conducts his or her professional activities in
 164 accordance with accepted standards as required by rule;

165 (c) Complies with all applicable rules adopted by the
 166 board;

167 (d) Has paid the licensure fee or the biennial renewal
 168 fee; and

169 (e) Has passed a criminal background check, as determined
 170 by the board.

171 (2) A person applying for an initial or renewal license as
 172 an assistant behavior analyst shall apply to the board upon such
 173 form and in such manner as the board prescribes and shall
 174 furnish evidence to the board that such person:

175 (a) Is a board-certified assistant behavior analyst;

176 (b) Conducts his or her professional activities in
 177 accordance with accepted standards, as required by rule;

178 (c) Complies with all applicable rules promulgated by the
 179 board;

180 (d) Is supervised by a licensed behavior analyst in a
 181 manner consistent with BACB requirements and this chapter;

182 (e) Has paid the licensure fee or the biennial renewal

183 fee; and

184 (f) Has passed a criminal background check, as determined
 185 by the board.

186 (3) The board may issue a license to a person who holds an
 187 active license as a behavior analyst or assistant behavior
 188 analyst in another state that imposes comparable licensure
 189 requirements to those imposed by this state and that offers
 190 reciprocity to individuals licensed under this chapter.

191 Applicants for reciprocity must:

192 (a) Submit proof of licensure and board certification;

193 (b) Pass a criminal background check, as determined by the
 194 board; and

195 (c) Pay the licensure fee.

196 Section 7. Section 470.44, Florida Statutes, is created to
 197 read:

198 470.44 Fees.—

199 (1) The board shall establish by rule a fee not to exceed
 200 \$100 for an application and a fee not to exceed \$300 for an
 201 initial license or license renewal.

202 (2) In establishing fees pursuant to subsection (1), the
 203 board shall consider the actual costs incurred in carrying out
 204 its duties under this chapter.

205 (3) All moneys collected by the department under this
 206 chapter shall be deposited as provided under s. 456.025.

207 Section 8. Section 470.45, Florida Statutes, is created to
 208 read:

209 470.45 Disciplinary grounds and actions; reinstatement.-

210 (1) The board may enter an order imposing any of the
 211 penalties provided under s. 456.072(2) against a licensee who
 212 violates any provision of s. 456.072(1), except that the board
 213 may not do any of the following:

214 (a) Place a licensee on probation for more than 5 years.

215 (b) Impose a fine that exceeds \$2,500.

216 (c) Suspend a license for more than 5 years.

217 (d) Limit or restrict a license for an indefinite period.

218 (2) The board may reinstate a license that has been
 219 suspended or revoked if, after a hearing conducted pursuant to
 220 s. 120.54, the board determines that the applicant is able to
 221 practice his or her profession with reasonable competency and in
 222 accordance with the code of ethics and standards of practice
 223 established by rule under s. 470.42. As a condition of
 224 reinstatement, the board may impose reasonable restrictions on
 225 the licensee's license to practice.

226 Section 9. Section 470.46, Florida Statutes, is created to
 227 read:

228 470.46 Duty to report felony or suspicion of fraud or
 229 deceit.-A licensee or employer of a licensee having actual or
 230 direct knowledge of facts shall report to the board a behavior
 231 analyst or assistant behavior analyst who:

232 (1) Has been charged or convicted of a felony that
 233 involved any act that bears directly on his or her
 234 qualifications or ability to practice applied behavior analysis

235 or any act that bears directly on the public health, safety, or
 236 welfare;

237 (2) Is suspected of fraud or deceit in procuring or
 238 attempting to procure a license to practice applied behavior
 239 analysis or of negligently performing actions that justify
 240 action against the license of the behavior analyst or assistant
 241 behavior analyst;

242 (3) Has had a board certification or a license to practice
 243 as a behavior analyst or assistant behavior analyst denied,
 244 limited, suspended, placed on probation, or revoked in another
 245 jurisdiction on grounds sufficient to cause a license or
 246 certificate to be denied, limited, suspended, placed on
 247 probation, or revoked in this state; or

248 (4) Is practicing applied behavior analysis without a
 249 license issued by the board unless specifically exempted in this
 250 chapter.

251 Section 10. Section 470.47, Florida Statutes, is created
 252 to read:

253 470.47 Violations and penalties.-

254 (1) Unless licensed or authorized under this chapter, a
 255 person who engages in the practice of applied behavior analysis,
 256 assists in the practice of applied behavior analysis, renders
 257 services designated as applied behavior analysis, or represents
 258 himself or herself as a practitioner of applied behavior
 259 analysis in this state commits a felony of the third degree,
 260 punishable as provided under s. 775.082, s. 775.083, or s.

261 775.084.

262 (2) Unless licensed or authorized under this chapter, a
 263 person who uses the title "licensed behavior analyst," "licensed
 264 assistant behavior analyst," or any other title that is
 265 substantially similar commits a misdemeanor of the second
 266 degree, punishable as provided in s. 775.082 or s. 775.083.

267 Section 11. Section 470.48, Florida Statutes, is created
 268 to read:

269 470.48 Exceptions to applicability.—This chapter does not
 270 prohibit or restrict the practice of the following:

271 (1) An individual licensed under chapter 490 to practice
 272 psychology if the applied behavior analysis services he or she
 273 provides are within the scope of chapter 490 and his or her
 274 education, training, and experience.

275 (2) A certified teacher authorized to practice in this
 276 state who is not a behavior analyst if he or she does not
 277 represent himself or herself as a behavior analyst. The services
 278 provided by a certified teacher must be within his or her
 279 authorized scope of practice and within the scope of his or her
 280 education, training, and experience and must be provided in the
 281 course of his or her employment in a program approved by the
 282 Department of Education. Teaching assistants, other than those
 283 engaged in pupil personnel services, and student support
 284 professionals are exempt from the requirements of this chapter
 285 if they provide behavior analysis services under the supervision
 286 of a certified teacher who meets the requirements of this

287 paragraph.

288 (3) A behavior analyst who practices with nonhuman
 289 clients, including, but not limited to, applied animal
 290 behaviorists and animal trainers.

291 (4) An unlicensed individual who provides applied behavior
 292 analysis services under the extended authority and direction of
 293 a licensed behavior analyst or licensed assistant behavior
 294 analyst.

295 (5) An individual who teaches applied behavior analysis or
 296 who conducts behavior analytic research if such teaching or
 297 research does not involve the delivery of direct behavior
 298 analysis interventions to individuals.

299 (6) A matriculated college or university student or
 300 postdoctoral fellow whose activities are part of a defined
 301 behavior analysis program of study, practicum, or intensive
 302 practicum if his or her practice under this subsection is
 303 directly supervised by a licensed behavior analyst or an
 304 instructor of an accredited course sequence approved by the
 305 Behavior Analyst Certification Board (BACB). A student or intern
 306 may not represent himself or herself as a professional behavior
 307 analyst but may use a title indicating his or her trainee
 308 status, such as "behavior analyst student," "behavior analyst
 309 intern," or "behavior analyst trainee."

310 (7) An unlicensed individual pursuing supervised
 311 experiential training to meet eligibility requirements for BACB
 312 certification if such training is supervised by an individual

313 who is licensed to practice applied behavior analysis and who
 314 meets BACB supervisor requirements and if the supervised
 315 experience is conducted in accordance with other BACB standards
 316 and requirements.

317 (8) A board-certified behavior analyst, a doctoral level
 318 board-certified behavior analyst, or an individual licensed to
 319 practice applied behavior analysis in another state who resides
 320 in another state and provides applied behavior analysis in this
 321 state or to a resident of this state for less than 12 days per
 322 year.

323 (9) A Florida-certified behavior analyst who is in good
 324 standing with the Behavior Analyst Certification Board and who
 325 is not a board-certified behavior analyst.

326 (10) A family member of a recipient of applied behavior
 327 analysis services who implements certain procedures with the
 328 recipient under the extended authority and direction of a
 329 licensed behavior analyst or licensed assistant behavior
 330 analyst. Such a family member may not represent himself or
 331 herself as a professional behavior analyst.

332 (11) A behavior analyst who provides general behavior
 333 analysis services to organizations if the services are for the
 334 benefit of the organizations and do not involve direct services
 335 to individuals.

336 (12) A physician licensed pursuant to chapter 458 or
 337 chapter 459 if he or she does not represent himself or herself
 338 as a professional behavior analyst.

339 (13) An individual licensed pursuant to chapter 491 as a
 340 clinical social worker, marriage and family therapist, or mental
 341 health counselor if he or she does not represent himself or
 342 herself as a professional behavior analyst.

343 (14) A salaried employee of a private, nonprofit
 344 organization providing behavior analysis services to children,
 345 youth, and families if the services are provided for no charge,
 346 the employee is performing duties for which he or she was
 347 trained and hired, and the employee does not represent himself
 348 or herself as a professional behavior analyst.

349 (15) A school psychologist certified in school psychology
 350 by the Department of Education who performs behavior analysis
 351 services as an employee of a public or private educational
 352 institution. Such exemption does not authorize unlicensed
 353 practice that is not performed directly as an employee of an
 354 educational institution.

355 (16) A rabbi, priest, minister, or member of the clergy of
 356 a religious denomination or sect if engaging in activities that
 357 are within the scope of the performance of his or her regular or
 358 specialized ministerial duties and for which no separate fee is
 359 charged, or if such activities are performed, with or without a
 360 fee, for or under the auspices or sponsorship, individually or
 361 in conjunction with others, of an established and legally
 362 cognizable church, denomination, or sect; and if the person
 363 rendering service remains accountable to the established
 364 authority thereof.

365 Section 12. Subsection (4) of section 456.001, Florida
366 Statutes, is amended to read:

367 456.001 Definitions.—As used in this chapter, the term:

368 (4) "Health care practitioner" means any person licensed
369 under chapter 457; chapter 458; chapter 459; chapter 460;
370 chapter 461; chapter 462; chapter 463; chapter 464; chapter 465;
371 chapter 466; chapter 467; part I, part II, part III, part V,
372 part X, part XIII, or part XIV of chapter 468; chapter 470;
373 chapter 478; chapter 480; part III or part IV of chapter 483;
374 chapter 484; chapter 486; chapter 490; or chapter 491.

375 Section 13. This act shall take effect October 1, 2014.



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COMMITTEE/SUBCOMMITTEE ACTION

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

1 Committee/Subcommittee hearing bill: Health Quality
 2 Subcommittee
 3 Representative Rooney offered the following:

Amendment (with title amendment)

Remove everything after the enacting clause and insert:

Section 1. Chapter 470, Florida Statutes, is created and entitled "Behavior Analysts."

Section 2. Section 470.40, Florida Statutes, is created to read:

470.40 Purpose.—The practice of applied behavior analysis in this state affects the public health, safety, and welfare of its residents, and this act is intended to protect the public from any harmful conduct of unqualified, unprofessional, or unethical applied behavior analysts.



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17 Section 3. Section 470.41, Florida Statutes, is created to
18 read:

19 470.41 Definitions.—As used in this chapter, the term:

20 (1) "Applied behavior analysis" means the design,
21 implementation, and evaluation of instructional and
22 environmental modifications to produce socially significant
23 improvements in human behavior and includes functional
24 assessment and analysis. The term does not include psychological
25 testing, the diagnosis of a mental or physical disorder,
26 neuropsychology, psychotherapy, cognitive therapy, sex therapy,
27 psychoanalysis, hypnotherapy, or long-term counseling.

28 (2) "Board" means the Board of Applied Behavior Analysis
29 established in s. 470.415, except when the term is used in the
30 context of board certification.

31 (3) "Board-certified behavior analyst" means a
32 practitioner who is certified as a Board Certified Behavior
33 Analyst, or is recognized as a "Florida-certified behavior
34 analyst," by the national Behavior Analyst Certification Board
35 (BACB), or its successor pursuant to s. 470.42.

36 (4) "Board-certified assistant behavior analyst" means a
37 practitioner who is certified by the national Behavior Analyst
38 Certification Board, or its successor pursuant to s. 470.42, as
39 a Board Certified Assistant Behavior Analyst.

40 (5) "Department" means the Department of Health.



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41 (6) "Licensed behavior analyst" means an individual who is
42 licensed by the board and meets the requirements of this
43 chapter.

44 (7) "Licensed assistant behavior analyst" means an
45 individual who:

46 (a) Is licensed by the board as an assistant behavior
47 analyst and meets the requirements of this chapter; and

48 (b) Works under the supervision of a licensed behavior
49 analyst.

50 (8) "Supervised experience" means an individual has
51 completed the training necessary to satisfy the eligibility
52 requirements for BACB certification.

53 Section 4. Section 470.415, Florida Statutes, is created
54 to read:

55 470.415 Board of Applied Behavior Analysis.—

56 (1) The Board of Applied Behavior Analysis is created
57 within the department. The board consists of seven members who
58 must be appointed by the Governor and confirmed by the Senate.

59 (2) The initial board members, who are not required to be
60 licensed as a condition of appointment, shall be appointed as
61 follows:

62 (a) Three board-certified behavior analysts, which may
63 include board-certified behavior analysts who are at the
64 doctoral level, two of whom shall be selected from a list of six
65 nominations submitted by the Florida Association for Behavior



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66 Analysis. One shall be appointed to a 1-year term, and two shall
67 be appointed to 3-year terms;

68 (b) One board-certified assistant behavior analyst, who
69 shall be appointed to a 1-year term;

70 (c) One health care practitioner licensed in this state,
71 who shall be appointed to a 2-year term. The majority of the
72 appointed health care practitioner's practice must be related to
73 the treatment of behavior disorders, including, but not limited
74 to, autism spectrum disorders; and

75 (d) Two laypersons, who may include a parent or guardian
76 of an individual who is a recipient of applied behavior analysis
77 services, one of whom shall serve a 1-year term, and one of whom
78 shall serve a 2-year term.

79 (3) As the terms of the initial members expire, the
80 Governor shall appoint successors for 4-year terms. Each
81 successor, except for the laypersons, must be licensed. A member
82 may not serve more than two consecutive terms.

83 Section 5. Section 470.42, Florida Statutes, is created to
84 read:

85 470.42 Authority of the board; board duties; authority of
86 the department.—

87 (1) The board may adopt rules pursuant to ss. 120.536(1)
88 and 120.54 to implement the provisions of this chapter
89 conferring duties upon it. Such rules must include, but are not
90 limited to, rules relating to all of the following:



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91 (a) Standards of practice for licensed behavior analysts
92 and licensed assistant behavior analysts.

93 (b) The competency of a person to receive or renew his or
94 her license.

95 (c) The physical and mental examination of licensed
96 behavior analysts and licensed assistant behavior analysts who
97 may be impaired by reason of a mental, physical, or other
98 condition that impedes their ability to practice competently.

99 (d) Supervision of licensed assistant behavior analysts or
100 students in training to be licensed behavior analysts, including
101 the number of persons that a licensed behavior analyst or
102 licensed assistant behavior analyst may supervise at one time.

103 (2) If the Behavior Analyst Certification Board stops
104 certifying practitioners of applied behavior analysis in this
105 state, the board shall approve a successor certification board
106 that is accredited by the National Commission for Certifying
107 Agencies or the American National Standards Institute to certify
108 applied behavior analysts.

109 (3) The department may adopt rules pursuant to ss.
110 120.536(1) and 120.54 to implement the provisions of this
111 chapter conferring duties upon it. Such rules must include, but
112 are not limited to, rules relating to all of the following:

113 (a) Licensure and licensure renewal applications and
114 processes, including licensure fees.

115 (b) Educational qualifications for licensure.



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116 (c) Continuing education requirements for biennial renewal
117 of licensure not to exceed 30 hours biennially as a condition
118 for renewal of a license.

119 Section 6. Section 470.43, Florida Statutes, is created to
120 read:

121 470.43 Licensure and renewal.-

122 (1) A person applying for an initial or renewal license as
123 a licensed behavior analyst or licensed assistant behavior
124 analyst shall apply to the department on such form and in such
125 manner as the department prescribes. The person shall furnish
126 evidence to the department that he or she:

127 (a) Is a board-certified behavior analyst;

128 (b) Conducts his or her professional activities in
129 accordance with accepted standards as required by rule;

130 (c) Complies with all applicable rules adopted by the
131 board;

132 (d) Has paid the licensure fee or the biennial renewal
133 fee; and

134 (e) Has passed a criminal background check after
135 submitting fingerprints and a fee pursuant to s. 456.0135.

136 (2) A person applying for an initial or renewal license as
137 an assistant behavior analyst shall apply to the department upon
138 such form and in such manner as the department prescribes and
139 shall furnish evidence to the department that such person:

140 (a) Is a board-certified assistant behavior analyst;



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- 141 (b) Conducts his or her professional activities in
142 accordance with accepted standards, as required by rule;
- 143 (c) Complies with all applicable rules promulgated by the
144 board;
- 145 (d) Is supervised by a licensed behavior analyst in a
146 manner consistent with BACB requirements and this chapter;
- 147 (e) Has paid the licensure fee or the biennial renewal
148 fee; and
- 149 (f) Has passed a criminal background check after
150 submitting fingerprints and a fee pursuant to s. 456.0135.
- 151 (3) The board may issue a license to a person who holds an
152 active license as a behavior analyst or assistant behavior
153 analyst in another state and:
- 154 (a) Submits proof of licensure and board certification;
- 155 (b) Passes a criminal background check after submitting
156 fingerprints and a fee pursuant to s. 456.0135; and
- 157 (c) Pays the licensure fee.
- 158 Section 7. Section 470.44, Florida Statutes, is created to
159 read:
- 160 470.44 Fees.—
- 161 (1) The board shall establish by rule a fee not to exceed
162 \$100 for an application and a fee not to exceed \$300 for an
163 initial license or license renewal.
- 164 (2) In establishing fees pursuant to subsection (1), the
165 board shall consider the actual costs incurred in carrying out
166 its duties under this chapter.



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167 (3) All moneys collected by the department under this
168 chapter shall be deposited as provided under s. 456.025.

169 Section 8. Section 470.45, Florida Statutes, is created to
170 read:

171 470.45 Disciplinary grounds and actions; reinstatement.-

172 The board may enter an order imposing any of the penalties
173 provided under s. 456.072(2) against a licensee who violates any
174 provision of s. 456.072(1), except that the board may not do any
175 of the following:

176 (1) Place a licensee on probation for more than 5 years.

177 (2) Impose a fine that exceeds \$2,500.

178 (3) Suspend a license for more than 5 years.

179 (4) Limit or restrict a license for an indefinite period.

180 Section 9. Section 470.47, Florida Statutes, is created to
181 read:

182 470.47 Violations and penalties.-

183 (1) Unless licensed or authorized under this chapter, a
184 person who engages in the practice of applied behavior analysis,
185 assists in the practice of applied behavior analysis, renders
186 services designated as applied behavior analysis, or represents
187 himself or herself as a practitioner of applied behavior
188 analysis in this state commits a felony of the third degree,
189 punishable as provided under s. 775.082, s. 775.083, or s.
190 775.084.

191 (2) Unless licensed or authorized under this chapter, a
192 person who uses the title "licensed behavior analyst," "licensed



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193 assistant behavior analyst," or any other title that is
194 substantially similar commits a misdemeanor of the second
195 degree, punishable as provided in s. 775.082 or s. 775.083.

196 Section 10. Section 470.48, Florida Statutes, is created
197 to read:

198 470.48 Exceptions to applicability.—This chapter does not
199 prohibit or restrict the practice of the following:

200 (1) An individual licensed under chapter 490 to practice
201 psychology.

202 (2) A certified teacher authorized to practice in this
203 state who is not a behavior analyst if he or she does not
204 represent himself or herself as a behavior analyst. The services
205 provided by a certified teacher must be within his or her
206 authorized scope of practice and within the scope of his or her
207 education, training, and experience and must be provided in the
208 course of his or her employment in a program approved by the
209 Department of Education. Teaching assistants, other than those
210 engaged in pupil personnel services, and student support
211 professionals are exempt from the requirements of this chapter
212 if they provide applied behavior analysis services under the
213 supervision of a certified teacher who meets the requirements of
214 this paragraph.

215 (3) A behavior analyst who practices with nonhuman
216 clients, including, but not limited to, applied animal
217 behaviorists and animal trainers.



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218 (4) An individual who teaches applied behavior analysis or
219 who conducts behavior analytic research if such teaching or
220 research does not involve the delivery of applied behavior
221 analysis.

222 (5) A matriculated college or university student or
223 postdoctoral fellow whose activities are part of a defined
224 behavior analysis program of study, practicum, or intensive
225 practicum if his or her practice under this subsection is
226 directly supervised by a licensed behavior analyst or an
227 instructor of an accredited course sequence approved by the
228 Behavior Analyst Certification Board (BACB). A student or intern
229 may not represent himself or herself as a professional behavior
230 analyst but may use a title indicating his or her trainee
231 status, such as "behavior analyst student," "behavior analyst
232 intern," or "behavior analyst trainee."

233 (6) An unlicensed individual pursuing supervised
234 experiential training to meet eligibility requirements for BACB
235 certification if such training is supervised by an individual
236 who is licensed to practice applied behavior analysis and who
237 meets BACB supervisor requirements and if the supervised
238 experience is conducted in accordance with other BACB standards
239 and requirements.

240 (7) A board-certified behavior analyst, a doctoral level
241 board-certified behavior analyst, or an individual licensed to
242 practice applied behavior analysis in another state who resides
243 in another state and provides applied behavior analysis in this



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244 state or to a resident of this state for less than 12 days per
245 year.

246 (8) A family member of a recipient of applied behavior
247 analysis services who implements certain procedures with the
248 recipient. Such a family member may not represent himself or
249 herself as a professional behavior analyst.

250 (9) A behavior analyst who provides general behavior
251 analysis services to organizations if the services are for the
252 benefit of the organizations and do not involve direct services
253 to individuals.

254 (10) A physician licensed pursuant to chapter 458 or
255 chapter 459.

256 (11) An individual licensed pursuant to chapter 491 as a
257 clinical social worker, marriage and family therapist, or mental
258 health counselor.

259 (12) A salaried employee of a private, nonprofit
260 organization providing behavior analysis services to children,
261 youth, and families if the services are provided for no charge,
262 the employee is performing duties for which he or she was
263 trained and hired, and the employee does not represent himself
264 or herself as a professional behavior analyst.

265 (13) A school psychologist certified in school psychology
266 by the Department of Education who performs behavior analysis
267 services as an employee of a public or private educational
268 institution. Such exemption does not authorize unlicensed



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269 practice that is not performed directly as an employee of an
270 educational institution.

271 (14) A rabbi, priest, minister, or member of the clergy of
272 a religious denomination or sect if engaging in activities that
273 are within the scope of the performance of his or her regular or
274 specialized ministerial duties and for which no separate fee is
275 charged, or if such activities are performed, with or without a
276 fee, for or under the auspices or sponsorship, individually or
277 in conjunction with others, of an established and legally
278 cognizable church, denomination, or sect; and if the person
279 rendering service remains accountable to the established
280 authority thereof.

281 Section 11. Paragraph (g) of subsection (3) of section
282 20.43, Florida Statutes, is amended to read:

283 20.43 Department of Health.—There is created a Department
284 of Health.

285 (3) The following divisions of the Department of Health
286 are established:

287 (g) Division of Medical Quality Assurance, which is
288 responsible for the following boards and professions established
289 within the division:

- 290 1. The Board of Acupuncture, created under chapter 457.
- 291 2. The Board of Medicine, created under chapter 458.
- 292 3. The Board of Osteopathic Medicine, created under
293 chapter 459.



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- 294 4. The Board of Chiropractic Medicine, created under
295 chapter 460.
- 296 5. The Board of Podiatric Medicine, created under chapter
297 461.
- 298 6. Naturopathy, as provided under chapter 462.
- 299 7. The Board of Optometry, created under chapter 463.
- 300 8. The Board of Nursing, created under part I of chapter
301 464.
- 302 9. Nursing assistants, as provided under part II of
303 chapter 464.
- 304 10. The Board of Pharmacy, created under chapter 465.
- 305 11. The Board of Dentistry, created under chapter 466.
- 306 12. Midwifery, as provided under chapter 467.
- 307 13. The Board of Speech-Language Pathology and Audiology,
308 created under part I of chapter 468.
- 309 14. The Board of Nursing Home Administrators, created
310 under part II of chapter 468.
- 311 15. The Board of Occupational Therapy, created under part
312 III of chapter 468.
- 313 16. Respiratory therapy, as provided under part V of
314 chapter 468.
- 315 17. Dietetics and nutrition practice, as provided under
316 part X of chapter 468.
- 317 18. The Board of Athletic Training, created under part
318 XIII of chapter 468.



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- 319 19. The Board of Orthotists and Prosthetists, created
320 under part XIV of chapter 468.
- 321 20. The Board of Applied Behavior Analysis, created under
322 chapter 470.
- 323 21.20. Electrolysis, as provided under chapter 478.
- 324 22.21. The Board of Massage Therapy, created under chapter
325 480.
- 326 23.22. The Board of Clinical Laboratory Personnel, created
327 under part III of chapter 483.
- 328 24.23. Medical physicists, as provided under part IV of
329 chapter 483.
- 330 25.24. The Board of Opticianry, created under part I of
331 chapter 484.
- 332 26.25. The Board of Hearing Aid Specialists, created under
333 part II of chapter 484.
- 334 27.26. The Board of Physical Therapy Practice, created
335 under chapter 486.
- 336 28.27. The Board of Psychology, created under chapter 490.
- 337 29.28. School psychologists, as provided under chapter
338 490.
- 339 30.29. The Board of Clinical Social Work, Marriage and
340 Family Therapy, and Mental Health Counseling, created under
341 chapter 491.
- 342 31.30. Emergency medical technicians and paramedics, as
343 provided under part III of chapter 401.



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344 Section 12. Subsection (4) of section 456.001, Florida
345 Statutes, is amended to read:

346 456.001 Definitions.—As used in this chapter, the term:

347 (4) "Health care practitioner" means any person licensed
348 under chapter 457; chapter 458; chapter 459; chapter 460;
349 chapter 461; chapter 462; chapter 463; chapter 464; chapter 465;
350 chapter 466; chapter 467; part I, part II, part III, part V,
351 part X, part XIII, or part XIV of chapter 468; chapter 470;
352 chapter 478; chapter 480; part III or part IV of chapter 483;
353 chapter 484; chapter 486; chapter 490; or chapter 491.

354

355 Section 13. Section 456.0135, Florida Statutes, is amended
356 to read:

357 456.0135 General background screening provisions.—

358 (1) An application for initial licensure received on or
359 after January 1, 2013, under chapter 458, chapter 459, chapter
360 460, chapter 461, chapter 464, ~~or~~ s. 465.022, or chapter 470
361 shall include fingerprints pursuant to procedures established by
362 the department through a vendor approved by the Department of
363 Law Enforcement and fees imposed for the initial screening and
364 retention of fingerprints. Fingerprints must be submitted
365 electronically to the Department of Law Enforcement for state
366 processing, and the Department of Law Enforcement shall forward
367 the fingerprints to the Federal Bureau of Investigation for
368 national processing. Each board, or the department if there is
369 no board, shall screen the results to determine if an applicant



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370 meets licensure requirements. For any subsequent renewal of the
371 applicant's license that requires a national criminal history
372 check, the department shall request the Department of Law
373 Enforcement to forward the retained fingerprints of the
374 applicant to the Federal Bureau of Investigation.

375 (2) All fingerprints submitted to the Department of Law
376 Enforcement as required under subsection (1) shall be retained
377 by the Department of Law Enforcement as provided under s.
378 943.05(2)(g) and (h) and (3). The department shall notify the
379 Department of Law Enforcement regarding any person whose
380 fingerprints have been retained but who is no longer licensed.

381 (3) The costs of fingerprint processing, including the
382 cost for retaining fingerprints, shall be borne by the applicant
383 subject to the background screening.

384 Section 14. This act shall take effect January 1, 2015.

387 -----
388 T I T L E A M E N D M E N T

389 Remove everything before the enacting clause and insert:
390 An act relating to behavior analysts; creating ch. 470, F.S.;
391 entitling the chapter; creating s. 470.40, F.S.; providing a
392 purpose; creating s. 470.41, F.S.; defining terms; creating s.
393 470.415, F.S.; creating the Board of Applied Behavior Analysis;
394 creating s. 470.42, F.S.; specifying the authority and duties of
395 the board; creating s. 470.43, F.S.; providing requirements for



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396 licensure and renewal; creating s. 470.44, F.S.; establishing
397 maximum fees for applications, initial licenses, and license
398 renewals; creating s. 470.45, F.S.; providing grounds for
399 disciplinary action by the board; providing for reinstatement of
400 a license; creating s. 470.46, F.S.; requiring a licensee or his
401 or her employer to report to the board certain felony
402 convictions on the part of a licensee or suspicions that a
403 licensee has committed fraud or deceit; creating s. 470.47,
404 F.S.; providing penalties for practicing applied behavior
405 analysis without a license or wrongfully identifying oneself as
406 a licensed behavior analyst; creating s. 470.48, F.S.; providing
407 exceptions to the chapter; amending s. 456.001, F.S.; including
408 licensed behavior analysts and licensed assistant behavior
409 analysts in the definition of "health care practitioner";
410 amending s. 456.0135, F.S.; requiring an applicant for licensure
411 under ch. 470, F.S., to submit to certain fingerprinting
412 requirements; providing an effective date.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1225 HIV Testing
SPONSOR(S): Saunders and others
TIED BILLS: IDEN./SIM. **BILLS:** SB 1470

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee		Castagna <i>JK</i>	O'Callaghan <i>ms</i>
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

The bill relates to testing for Human Immunodeficiency Virus (HIV). HIV is an immune system debilitating virus that can lead to fatal acquired immunodeficiency syndrome (AIDS). Widespread testing prevents new HIV infections through awareness, and allows infected individuals to receive early treatment, which improves the lives of those living with HIV.

The bill defines "health care setting" and a "nonhealth care setting" for the purpose of differentiating HIV testing requirements. The bill updates the definition of "preliminary HIV test" to reflect advances in HIV testing.

The bill revises the HIV testing requirement for health care settings to no longer require informed consent from the HIV test subject and establishes new notification requirements. The bill retains the requirement to obtain informed consent from a test subject when HIV testing is performed in nonhealth care settings.

The bill provides that the Department of Health county health departments (CHDs) can operate as both a health care setting and a nonhealth care setting by recognizing testing programs within CHDs as nonhealth care settings.

The bill removes language regarding the required HIV testing of pregnant women without informed consent.

The bill makes technical changes throughout s. 384.004, F.S., to clarify existing language and makes many conforming changes.

The bill appears to have no fiscal impact on state or local governments.

The bill provides an effective date of July 1, 2014

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

Human Immunodeficiency Virus

Human Immunodeficiency Virus (HIV) is an immune system debilitating virus that can lead to fatal acquired immunodeficiency syndrome (AIDS). HIV affects specific cells of the immune system and over time the virus can destroy so many of these cells that the body cannot fight off infections and disease. There is no cure for HIV, yet with proper medical care, HIV can be controlled. Untreated, HIV is almost always fatal.¹

HIV is typically spread by having unprotected sex with someone who has HIV or sharing needles, syringes, or other equipment used to prepare injection drugs with someone who has HIV.²

HIV Testing

Data from 2009 indicates that of the estimated 1.1 million adults in the United States who are infected with the virus, 18% were unaware of their infection.³ HIV testing is essential for improving the health of people living with HIV and reducing new HIV infections. It is recommended that testing occur as part of a routine healthcare visit. This is especially important for people who may not consider themselves at risk for HIV.⁴ HIV testing is nationally recommended for people ages 15 to 65 and pregnant women, including those in labor who have not been tested and whose HIV status is unknown.⁵

The most common types of HIV tests check for HIV antibodies in the body. In these tests, blood, oral fluid, or urine can be used to obtain results. Antibody tests are considered preliminary; if the result is positive, follow-up diagnostic testing is required to confirm the presence of the virus. Antigen tests are another form of testing, which are not as readily available as antibody tests. Antigen tests can be used to diagnose HIV infection 1 to 3 weeks after a person is first infected with HIV and a blood sample is required to obtain results.⁶

Over the past several decades there have been many advances in medical technology to increase access and utilization of HIV testing. Legal and programmatic advances have streamlined testing services to provide confidentiality, and, in some cases, anonymity to test subjects to encourage widespread testing.

¹ "About HIV/AIDS," Centers for Disease Control and Prevention, *accessible at:* <http://www.cdc.gov/hiv/basics/whatishiv.html#panel0> (last accessed March 19, 2014).

² There are several less common ways HIV can be spread including: being born to an infected mother; being stuck with an HIV contaminated needle (which is a risk mainly for health care workers); and receiving blood transfusions, blood products, or organ/tissue transplants that are contaminated with HIV, *accessible at:* <http://www.cdc.gov/hiv/basics/transmission.html> (last accessed March 19, 2014).

³ "HIV in the United States: At a Glance," *accessible at:* <http://www.cdc.gov/hiv/statistics/basics/ataglance.html> (last accessed March 20, 2014).

⁴ In Florida, only 48% of adults under 65 reported having ever been tested for HIV. Department of Health, Florida Charts, *accessible at:* <http://www.floridacharts.com/charts/Brfss/DataViewer.aspx?bid=29> (last accessed March 20, 2014).

⁵ "Screening for HIV, Current Recommendations," U.S. Preventative Services Task Force, April 2013, *accessible at:* <http://www.uspreventiveservicestaskforce.org/uspstf/uspshivi.htm> (last accessed March 20, 2014).

⁶ "Types of HIV Tests," U.S. Department of Health and Human Services, *accessible at:* <http://aids.gov/hiv-aids-basics/prevention/hiv-testing/hiv-test-types/index.html> (last accessed March 20, 2014).

Florida HIV Testing

Section 381.004, F.S., which governs HIV testing in Florida and requires certain procedures to be followed when tests are given, was enacted to create an environment in Florida in which people will agree to or seek out HIV testing because they are sufficiently informed about HIV infection and assured about the privacy of a decision to be tested.⁷ To promote informed patient decision-making, s. 381.004, F.S., prohibits HIV testing without a person's knowledge and consent, except under certain defined circumstances,⁸ and gives the patient special rights to control who learns of the HIV test results.⁹

As stated in s. 381.004(2)(a), F.S., informed consent¹⁰ must be obtained by all persons receiving an HIV test. Consent must be in writing unless it is documented in the person's medical record that they have been educated about the test and given consent to be tested. The right to confidential treatment of information identifying the subject of the test and the results must then be explained to the test subject.¹¹ The subject of the test must be informed that a positive HIV test result will be reported to the local Department of Health county health department (CHD) with enough information to identify the test subject.¹² The test subject must also be informed about the location of local sites at which anonymous testing¹³ is available.¹⁴

The Department of Health has developed a comprehensive program for preventing the spread of HIV/AIDS with many testing options available throughout the state in a variety of settings. CHDs¹⁵ are the primary outlet for state sponsored HIV programs and in addition to testing services, CHDs provide prevention outreach and education free to the public.

Effect of Proposed Changes

The bill provides a definition for health care setting and nonhealth care setting to differentiate between the two for the purpose of HIV testing.

Health Care Setting

"Health care setting" is defined in the bill as a setting devoted to both the diagnosis and care of persons, such as:

⁷ "Florida's Omnibus AIDS Act," Jack P Hartog, Department of Health, *accessible at*: www.floridahealth.gov/diseases.../Omnibus-booklet-update-2013.pdf (last accessed March 21, 2014).

⁸ Section 381.004(2)(h), F.S., lists the exceptions to the requirement to obtain informed consent, including: when a person is tested for sexually transmitted diseases, when blood, plasma, or other human fluids or tissues are donated, when a determination for appropriate emergency medical care or treatment is required, during an autopsy, when a defendant is charged with sexual battery and is consented to by the defendant, pursuant to court order, or for certain research purposes.

⁹ *Supra* fn. 7.

¹⁰ Informed consent is a process of communication between patient and provider through which an informed patient can choose whether to undergo HIV testing or decline to do so. Elements of informed consent typically include providing oral or written information regarding HIV, the risks and benefits of testing, the implications of HIV test results, how test results will be communicated, and the opportunity to ask questions. Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings, Centers for Disease Control and Prevention, September 22, 2006, *accessible at*: <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm> (last accessed March 19, 2014).

¹¹ Under limited circumstances, test results may be released to certain persons, entities, or the Agency for Health Care Administration pursuant to s. 395.3025, F.S.

¹² HIV is a notifiable disease and positive test results must be reported to the Department of Health to effectively monitor disease trends, assess effectiveness of prevention and control measures, identify populations at a higher risk, and develop public health policies. NNDSS Home, Centers for Disease Control, *accessible at*: <http://wwwn.cdc.gov/nndss/> (last accessed March 20, 2014).

¹³ Anonymous testing is available at some testing sites and does not require test subject to identify themselves. When a person takes an anonymous HIV test, they are given a unique identifier that allows only them to access their test results. Centers for Disease Control and Prevention, Testing, *accessible at*: <http://www.cdc.gov/actagainstaids/basics/testing.html> (last accessed March 20, 2014).

¹⁴ Section 381.004(2)(a), F.S.

¹⁵ County Health Departments are the local sector of the Department of Health, providing public health services in all 67 Florida counties. Their core functions are infectious disease prevention and control, basic family health services, and environmental health services. County Health Departments, Department of Health, *accessible at*: <http://www.floridahealth.gov/public-health-in-your-life/county-health-departments/index.html> (last accessed March 20, 2014).

- County health department clinics,
- Hospital emergency departments,
- Urgent care clinics,
- Substance abuse treatment clinics,
- Primary care settings,
- Community clinics,
- Mobile medical clinics, and
- Correctional health care facilities.

The bill changes the current requirement for informed consent for HIV testing performed in a health care setting by requiring a health care provider to instead notify the test subject that the test is planned, and provide information to the test subject on HIV, the risks of being tested, and implications of HIV test results. The provider must also inform the test subject that they have the right to decline the test. The explanation of the right to confidential treatment of information identifying the test subject and the results of the test as provided in current law¹⁶ is retained. The provider must document in the person's medical record if the test was declined.

Nonhealth Care Setting

"Nonhealth care setting" is defined in the bill as a site that conducts HIV testing for the sole purpose of identifying HIV infection. Such settings do not provide medical treatment but may include:

- Community-based organizations,
- Outreach settings,
- County health department HIV testing programs, and
- Mobile vans.

The bill clarifies that informed consent must remain a requirement for testing performed in nonhealth care settings.

County Health Departments

For purposes of HIV testing, CHDs will operate as both health care and nonhealth care settings. If a person is to be tested at a CHD, or a CHD sponsored outreach event, for HIV testing only, the testing will be conducted following nonhealth care setting testing requirements. If a person is being seen at a CHD clinic, such as an STD or family planning clinic, the provider must meet health care setting notification requirements.

Confidentiality

For both health care and nonhealth care settings, the test subject must be informed that a positive HIV test result will be reported to the local CHD with sufficient information to identify the test subject. The subject must also be informed of the availability of sites at which anonymous testing is performed and requires CHDs to maintain a list of those sites. The sites' locations, telephone numbers, and hours of operation must be kept on file. All of these requirements exist in current law, but the bill ensures these requirements apply to both health care and nonhealth care settings.

The bill authorizes hospitals licensed under chapter 395, F.S., to release HIV test results, as is currently authorized, if the hospital notifies the patient of the confidentiality protections for HIV test results included in medical records. The bill conforms this requirement to the notification requirements in the bill related to health care setting HIV testing.

The bill updates the definition of "preliminary HIV tests" to reflect advances in HIV testing and deletes obsolete language.

The bill removes language regarding the required HIV testing of pregnant women without informed consent.

The bill also makes conforming changes and corrects a cross-reference.

B. SECTION DIRECTORY:

Section 1. Amends s. 381.004, F.S., relating to HIV testing.

Section 2. Amends s. 456.032, F.S., relating to Hepatitis B or HIV carriers.

Section 3. Provides an effective date of July 1, 2014.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill requires the Department to revise rule 64D-2.004, F.A.C.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

27 to determine the presence of the antibody or antigen to human
 28 immunodeficiency virus or the presence of human immunodeficiency
 29 virus infection.

30 (c)~~(b)~~ "HIV test result" means a laboratory report of a
 31 human immunodeficiency virus test result entered into a medical
 32 record on or after July 6, 1988, or any report or notation in a
 33 medical record of a laboratory report of a human
 34 immunodeficiency virus test. ~~As used in this section,~~ The term
 35 ~~"HIV test result"~~ does not include test results reported to a
 36 health care provider by a patient.

37 (d) "Nonhealth care setting" means a site that conducts
 38 HIV testing for the sole purpose of identifying HIV infection.
 39 Such setting does not provide medical treatment but may include
 40 community-based organizations, outreach settings, county health
 41 department HIV testing programs, and mobile vans.

42 (f)~~(e)~~ "Significant exposure" means:

- 43 1. Exposure to blood or body fluids through needlestick,
 44 instruments, or sharps;
- 45 2. Exposure of mucous membranes to visible blood or body
 46 fluids, to which universal precautions apply according to the
 47 National Centers for Disease Control and Prevention, including,
 48 without limitations, the following body fluids:
 - 49 a. Blood.
 - 50 b. Semen.
 - 51 c. Vaginal secretions.
 - 52 d. Cerebrospinal ~~Cerebro-spinal~~ fluid (CSF).

- 53 e. Synovial fluid.
- 54 f. Pleural fluid.
- 55 g. Peritoneal fluid.
- 56 h. Pericardial fluid.
- 57 i. Amniotic fluid.
- 58 j. Laboratory specimens that contain HIV (e.g.,
- 59 suspensions of concentrated virus); or

60 3. Exposure of skin to visible blood or body fluids,

61 especially when the exposed skin is chapped, abraded, or

62 afflicted with dermatitis or the contact is prolonged or

63 involving an extensive area.

64 (e)~~(d)~~ "Preliminary HIV test" means an antibody or

65 antibody-antigen screening test, such as the enzyme-linked

66 immunosorbent assays (IA), or a rapid test approved by the

67 federal Food and Drug Administration (ELISAs) or the Single-Use

68 Diagnostic System (SUDS).

69 (g)~~(e)~~ "Test subject" or "subject of the test" means the

70 person upon whom an HIV test is performed, or the person who has

71 legal authority to make health care decisions for the test

72 subject.

73 (2) HUMAN IMMUNODEFICIENCY VIRUS TESTING; INFORMED

74 CONSENT; RESULTS; COUNSELING; CONFIDENTIALITY.—

75 (a) Before performing an HIV test:

76 1. In a health care setting, the health care provider

77 shall notify the person to be tested that the test is planned,

78 provide information about the test, and advise the person that

79 he or she has the right to decline the test. The health care
 80 provider shall also explain the right to confidential treatment
 81 of information identifying the subject of the test and the
 82 results of the test as provided by law. If a person declines the
 83 test, the health care provider shall note that fact in the
 84 person's medical record. ~~No person in this state shall order a~~
 85 ~~test designed to identify the human immunodeficiency virus, or~~
 86 ~~its antigen or antibody, without first obtaining the informed~~
 87 ~~consent of the person upon whom the test is being performed,~~
 88 ~~except as specified in paragraph (h). Informed consent shall be~~
 89 ~~preceded by an explanation of the right to confidential~~
 90 ~~treatment of information identifying the subject of the test and~~
 91 ~~the results of the test to the extent provided by law.~~
 92 ~~Information shall also be provided on the fact that a positive~~
 93 ~~HIV test result will be reported to the county health department~~
 94 ~~with sufficient information to identify the test subject and on~~
 95 ~~the availability and location of sites at which anonymous~~
 96 ~~testing is performed. As required in paragraph (3)(c), each~~
 97 ~~county health department shall maintain a list of sites at which~~
 98 ~~anonymous testing is performed, including the locations, phone~~
 99 ~~numbers, and hours of operation of the sites. Consent need not~~
 100 ~~be in writing provided there is documentation in the medical~~
 101 ~~record that the test has been explained and the consent has been~~
 102 ~~obtained.~~

103 2. In a nonhealth care setting, a provider shall obtain
 104 the informed consent of the person upon whom the test is being

105 performed. Informed consent shall be preceded by an explanation
 106 of the right to confidential treatment of information
 107 identifying the subject of the test and the results of the test
 108 as provided by law.

109
 110 The test subject shall also be informed that a positive HIV test
 111 result will be reported to the county health department with
 112 sufficient information to identify the test subject and on the
 113 availability and location of sites at which anonymous testing is
 114 performed. As required in paragraph (3)(c), each county health
 115 department shall maintain a list of sites at which anonymous
 116 testing is performed, including the locations, telephone
 117 numbers, and hours of operation of the sites.

118 (b) Except as provided in paragraph (h), informed consent
 119 must be obtained from a legal guardian or other person
 120 authorized by law if ~~when~~ the person:

- 121 1. Is not competent, is incapacitated, or is otherwise
 122 unable to make an informed judgment; or
 123 2. Has not reached the age of majority, except as provided
 124 in s. 384.30.

125 (g) Human immunodeficiency virus test results contained in
 126 the medical records of a hospital licensed under chapter 395 may
 127 be released in accordance with s. 395.3025 without being subject
 128 to ~~the requirements of~~ subparagraph (e)2., subparagraph (e)9.,
 129 or paragraph (f) if; ~~provided~~ the hospital has notified the
 130 patient of the limited confidentiality protections afforded HIV

131 test results contained in hospital medical records ~~obtained~~
 132 ~~written informed consent for the HIV test in accordance with~~
 133 ~~provisions of this section.~~

134 (h) Notwithstanding ~~the provisions of~~ paragraph (a),
 135 informed consent is not required:

136 1. When testing for sexually transmissible diseases is
 137 required by state or federal law, or by rule including the
 138 following situations:

139 a. HIV testing pursuant to s. 796.08 of persons convicted
 140 of prostitution or of procuring another to commit prostitution.

141 b. HIV testing of inmates pursuant to s. 945.355 before
 142 ~~prior to their~~ release from prison by reason of parole,
 143 accumulation of gain-time credits, or expiration of sentence.

144 c. Testing for HIV by a medical examiner in accordance
 145 with s. 406.11.

146 ~~d. HIV testing of pregnant women pursuant to s. 384.31.~~

147 2. Those exceptions provided for blood, plasma, organs,
 148 skin, semen, or other human tissue pursuant to s. 381.0041.

149 3. For the performance of an HIV-related test by licensed
 150 medical personnel in bona fide medical emergencies if ~~when~~ the
 151 test results are necessary for medical diagnostic purposes to
 152 provide appropriate emergency care or treatment to the person
 153 being tested and the patient is unable to consent, as supported
 154 by documentation in the medical record. Notification of test
 155 results in accordance with paragraph (c) is required.

156 4. For the performance of an HIV-related test by licensed

157 medical personnel for medical diagnosis of acute illness where,
 158 in the opinion of the attending physician, providing
 159 notification ~~obtaining informed consent~~ would be detrimental to
 160 the patient, as supported by documentation in the medical
 161 record, and the test results are necessary for medical
 162 diagnostic purposes to provide appropriate care or treatment to
 163 the person being tested. Notification of test results in
 164 accordance with paragraph (c) is required if it would not be
 165 detrimental to the patient. This subparagraph does not authorize
 166 the routine testing of patients for HIV infection without
 167 notification ~~informed consent~~.

168 5. If ~~When~~ HIV testing is performed as part of an autopsy
 169 for which consent was obtained pursuant to s. 872.04.

170 6. For the performance of an HIV test upon a defendant
 171 pursuant to the victim's request in a prosecution for any type
 172 of sexual battery where a blood sample is taken from the
 173 defendant voluntarily, pursuant to court order for any purpose,
 174 or pursuant to ~~the provisions of~~ s. 775.0877, s. 951.27, or s.
 175 960.003; however, the results of an any HIV test performed shall
 176 be disclosed solely to the victim and the defendant, except as
 177 provided in ss. 775.0877, 951.27, and 960.003.

178 7. If ~~When~~ an HIV test is mandated by court order.

179 8. For epidemiological research pursuant to s. 381.0031,
 180 for research consistent with institutional review boards created
 181 by 45 C.F.R. part 46, or for the performance of an HIV-related
 182 test for the purpose of research, if the testing is performed in

183 a manner by which the identity of the test subject is not known
 184 and may not be retrieved by the researcher.

185 9. If ~~When~~ human tissue is collected lawfully without the
 186 consent of the donor for corneal removal as authorized by s.
 187 765.5185 or enucleation of the eyes as authorized by s. 765.519.

188 10. For the performance of an HIV test upon an individual
 189 who comes into contact with medical personnel in such a way that
 190 a significant exposure has occurred during the course of
 191 employment or within the scope of practice and where a blood
 192 sample is available which ~~that~~ was taken from that individual
 193 voluntarily by medical personnel for other purposes. The term
 194 "medical personnel" includes a licensed or certified health care
 195 professional; an employee of a health care professional or
 196 health care facility; employees of a laboratory licensed under
 197 chapter 483; personnel of a blood bank or plasma center; a
 198 medical student or other student who is receiving training as a
 199 health care professional at a health care facility; and a
 200 paramedic or emergency medical technician certified by the
 201 department to perform life-support procedures under s. 401.23.

202 a. Before performing ~~Prior to performance of~~ an HIV test
 203 on a voluntarily obtained blood sample, the individual from whom
 204 the blood was obtained shall be requested to consent to the
 205 performance of the test and to the release of the results. If
 206 consent cannot be obtained within the time necessary to perform
 207 the HIV test and begin prophylactic treatment of the exposed
 208 medical personnel, all information concerning the performance of

209 an HIV test and any HIV test result shall be documented only in
210 the medical personnel's record unless the individual gives
211 written consent to entering this information on the individual's
212 medical record.

213 b. Reasonable attempts to locate the individual and to
214 obtain consent shall be made, and all attempts must be
215 documented. If the individual cannot be found or is incapable of
216 providing consent, an HIV test may be conducted on the available
217 blood sample. If the individual does not voluntarily consent to
218 the performance of an HIV test, the individual shall be informed
219 that an HIV test will be performed, and counseling shall be
220 furnished as provided in this section. However, HIV testing
221 shall be conducted only after appropriate medical personnel
222 under the supervision of a licensed physician documents, in the
223 medical record of the medical personnel, that there has been a
224 significant exposure and that, in accordance with the written
225 protocols based on the National Centers for Disease Control and
226 Prevention guidelines on HIV postexposure prophylaxis and in the
227 physician's medical judgment, the information is medically
228 necessary to determine the course of treatment for the medical
229 personnel.

230 c. Costs of an ~~any~~ HIV test of a blood sample performed
231 with or without the consent of the individual, as provided in
232 this subparagraph, shall be borne by the medical personnel or
233 the employer of the medical personnel. However, costs of testing
234 or treatment not directly related to the initial HIV tests or

235 costs of subsequent testing or treatment may not be borne by the
 236 medical personnel or the employer of the medical personnel.

237 d. In order to use ~~utilize~~ the provisions of this
 238 subparagraph, the medical personnel must ~~either~~ be tested for
 239 HIV pursuant to this section or provide the results of an HIV
 240 test taken within 6 months before ~~prior to~~ the significant
 241 exposure if such test results are negative.

242 e. A person who receives the results of an HIV test
 243 pursuant to this subparagraph shall maintain the confidentiality
 244 of the information received and of the persons tested. Such
 245 confidential information is exempt from s. 119.07(1).

246 f. If the source of the exposure will not voluntarily
 247 submit to HIV testing and a blood sample is not available, the
 248 medical personnel or the employer of such person acting on
 249 behalf of the employee may seek a court order directing the
 250 source of the exposure to submit to HIV testing. A sworn
 251 statement by a physician licensed under chapter 458 or chapter
 252 459 that a significant exposure has occurred and that, in the
 253 physician's medical judgment, testing is medically necessary to
 254 determine the course of treatment constitutes probable cause for
 255 the issuance of an order by the court. The results of the test
 256 shall be released to the source of the exposure and to the
 257 person who experienced the exposure.

258 11. For the performance of an HIV test upon an individual
 259 who comes into contact with medical personnel in such a way that
 260 a significant exposure has occurred during the course of

261 | employment or within the scope of practice of the medical
 262 | personnel while the medical personnel provides emergency medical
 263 | treatment to the individual; or notwithstanding s. 384.287, an
 264 | individual who comes into contact with nonmedical personnel in
 265 | such a way that a significant exposure has occurred while the
 266 | nonmedical personnel provides emergency medical assistance
 267 | during a medical emergency. For the purposes of this
 268 | subparagraph, a medical emergency means an emergency medical
 269 | condition outside of a hospital or health care facility that
 270 | provides physician care. The test may be performed only during
 271 | the course of treatment for the medical emergency.

272 | a. An individual who is capable of providing consent shall
 273 | be requested to consent to an HIV test before ~~prior to the~~
 274 | testing. If consent cannot be obtained within the time necessary
 275 | to perform the HIV test and begin prophylactic treatment of the
 276 | exposed medical personnel and nonmedical personnel, all
 277 | information concerning the performance of an HIV test and its
 278 | result, shall be documented only in the medical personnel's or
 279 | nonmedical personnel's record unless the individual gives
 280 | written consent to entering this information in ~~on~~ the
 281 | individual's medical record.

282 | b. HIV testing shall be conducted only after appropriate
 283 | medical personnel under the supervision of a licensed physician
 284 | documents, in the medical record of the medical personnel or
 285 | nonmedical personnel, that there has been a significant exposure
 286 | and that, in accordance with the written protocols based on the

287 National Centers for Disease Control and Prevention guidelines
 288 on HIV postexposure prophylaxis and in the physician's medical
 289 judgment, the information is medically necessary to determine
 290 the course of treatment for the medical personnel or nonmedical
 291 personnel.

292 c. Costs of any HIV test performed with or without the
 293 consent of the individual, as provided in this subparagraph,
 294 shall be borne by the medical personnel or the employer of the
 295 medical personnel or nonmedical personnel. However, costs of
 296 testing or treatment not directly related to the initial HIV
 297 tests or costs of subsequent testing or treatment may not be
 298 borne by the medical personnel or the employer of the medical
 299 personnel or nonmedical personnel.

300 d. In order to use ~~utilize~~ the provisions of this
 301 subparagraph, the medical personnel or nonmedical personnel
 302 shall be tested for HIV pursuant to this section or shall
 303 provide the results of an HIV test taken within 6 months before
 304 ~~prior to~~ the significant exposure if such test results are
 305 negative.

306 e. A person who receives the results of an HIV test
 307 pursuant to this subparagraph shall maintain the confidentiality
 308 of the information received and of the persons tested. Such
 309 confidential information is exempt from s. 119.07(1).

310 f. If the source of the exposure will not voluntarily
 311 submit to HIV testing and a blood sample was not obtained during
 312 treatment for the medical emergency, the medical personnel, the

313 employer of the medical personnel acting on behalf of the
 314 employee, or the nonmedical personnel may seek a court order
 315 directing the source of the exposure to submit to HIV testing. A
 316 sworn statement by a physician licensed under chapter 458 or
 317 chapter 459 that a significant exposure has occurred and that,
 318 in the physician's medical judgment, testing is medically
 319 necessary to determine the course of treatment constitutes
 320 probable cause for the issuance of an order by the court. The
 321 results of the test shall be released to the source of the
 322 exposure and to the person who experienced the exposure.

323 12. For the performance of an HIV test by the medical
 324 examiner or attending physician upon an individual who expired
 325 or could not be resuscitated while receiving emergency medical
 326 assistance or care and who was the source of a significant
 327 exposure to medical or nonmedical personnel providing such
 328 assistance or care.

329 a. HIV testing may be conducted only after appropriate
 330 medical personnel under the supervision of a licensed physician
 331 documents in the medical record of the medical personnel or
 332 nonmedical personnel that there has been a significant exposure
 333 and that, in accordance with the written protocols based on the
 334 National Centers for Disease Control and Prevention guidelines
 335 on HIV postexposure prophylaxis and in the physician's medical
 336 judgment, the information is medically necessary to determine
 337 the course of treatment for the medical personnel or nonmedical
 338 personnel.

339 b. Costs of an ~~any~~ HIV test performed under this
 340 subparagraph may not be charged to the deceased or to the family
 341 of the deceased person.

342 c. For ~~the provisions of~~ this subparagraph to be
 343 applicable, the medical personnel or nonmedical personnel must
 344 be tested for HIV under this section or must provide the results
 345 of an HIV test taken within 6 months before the significant
 346 exposure if such test results are negative.

347 d. A person who receives the results of an HIV test
 348 pursuant to this subparagraph shall comply with paragraph (e).

349 13. For the performance of an HIV-related test medically
 350 indicated by licensed medical personnel for medical diagnosis of
 351 a hospitalized infant as necessary to provide appropriate care
 352 and treatment of the infant if ~~when~~, after a reasonable attempt,
 353 a parent cannot be contacted to provide consent. The medical
 354 records of the infant must ~~shall~~ reflect the reason consent of
 355 the parent was not initially obtained. Test results shall be
 356 provided to the parent when the parent is located.

357 14. For the performance of HIV testing conducted to
 358 monitor the clinical progress of a patient previously diagnosed
 359 to be HIV positive.

360 15. For the performance of repeated HIV testing conducted
 361 to monitor possible conversion from a significant exposure.

362 (4) HUMAN IMMUNODEFICIENCY VIRUS TESTING REQUIREMENTS;
 363 REGISTRATION WITH THE DEPARTMENT OF HEALTH; EXEMPTIONS FROM
 364 REGISTRATION.—No county health department and no other person in

365 | this state shall conduct or hold themselves out to the public as
 366 | conducting a testing program for acquired immune deficiency
 367 | syndrome or human immunodeficiency virus status without first
 368 | registering with the Department of Health, reregistering each
 369 | year, complying with all other applicable provisions of state
 370 | law, and meeting the following requirements:

371 | (d) A program in a health care setting shall meet the
 372 | notification criteria contained in subparagraph (2)(a)1. A
 373 | program in a nonhealth care setting shall meet all informed
 374 | consent criteria contained in subparagraph (2)(a)2. ~~The program~~
 375 | ~~must meet all the informed consent criteria contained in~~
 376 | ~~subsection (2).~~

377 | Section 2. Subsection (2) of section 456.032, Florida
 378 | Statutes, is amended to read:

379 | 456.032 Hepatitis B or HIV carriers.—

380 | (2) Any person licensed by the department and any other
 381 | person employed by a health care facility who contracts a blood-
 382 | borne infection shall have a rebuttable presumption that the
 383 | illness was contracted in the course and scope of his or her
 384 | employment, provided that the person, as soon as practicable,
 385 | reports to the person's supervisor or the facility's risk
 386 | manager any significant exposure, as that term is defined in s.
 387 | 381.004(1)(f) ~~381.004(1)(e)~~, to blood or body fluids. The
 388 | employer may test the blood or body fluid to determine if it is
 389 | infected with the same disease contracted by the employee. The
 390 | employer may rebut the presumption by the preponderance of the

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391 | evidence. Except as expressly provided in this subsection, there
392 | shall be no presumption that a blood-borne infection is a job-
393 | related injury or illness.

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



Amendment No.

COMMITTEE/SUBCOMMITTEE ACTION

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

1 Committee/Subcommittee hearing bill: Health Quality
2 Subcommittee
3 Representative Saunders offered the following:

Amendment (with title amendment)

Remove line 146 and insert:

d. HIV testing of pregnant women pursuant to s. 384.31.

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

Remove lines 6-8 and insert:

nonhealth care setting; amending s. 456.032, F.S.;