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 CD	O'Callaghan mo
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]

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[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.

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[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.ashx (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

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

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

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

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

Section 1. Community Health Worker Task Force.—

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

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

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

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

2. Performs the following activities in a community setting:

a. Provides information regarding available resources.

b. Provides social support.

c. Advocates for individuals and their health care needs.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3. One state official appointed by the Governor.

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

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

(c) The task force shall develop recommendations for:

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

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

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

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

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

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

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

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

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

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

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

Amendment No.

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

Committee/Subcommittee hearing bill: Health Quality Subcommittee

Representative Watson, C. offered the following:

Amendment

Remove lines 105-109 and insert:

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

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 TG	O'Callaghan MO
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

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[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 DOH[12], 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

health.

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

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

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

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

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

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

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

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

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

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		

Committee/Subcommittee hearing bill: Health Quality Subcommittee

Representative Adkins offered the following:

Amendment (with title amendment)

Remove everything after the enacting clause and insert:

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

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

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

Section 2. 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 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 communicable and other diseases, illnesses, injuries, and hazards to human health.

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

(5) Provide for the dissemination of information to the

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

(6) Act as registrar of vital statistics.

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

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

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

Remove everything before the enacting clause and insert:

A bill to be entitled

An act relating to communicable disease control; amending s. 154.001; F.S.; providing for coordination of services relating to control of communicable diseases and antibiotic-resistant threats by county health departments; amending s. 381.0011, F.S.; providing duties of the Department of Health relating to the dissemination of information regarding antibiotic-resistant threat outbreaks; providing an 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
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 paper[3] 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.

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[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 permit[17] or an out-of-state prescription drug wholesale distributor permit[18] is required.

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

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[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 FDA[19] 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 Act[26] in s. 499.01211, F.S. The Council reviews the Florida Drug and Cosmetic Act[27] 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]

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[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 Pharmacopeia and The National Formulary (USP–NF) is a book of public pharmacopeial 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

A bill to be entitled

An act relating to the Florida Drug and Cosmetic Act; reordering and amending s. 499.003, F.S.; revising definitions; amending s. 499.01, F.S.; deleting permit requirements for medical oxygen retail establishments, compressed medical gas wholesale distributors, and compressed medical gas manufacturers; conforming cross-references; amending s. 499.0121, F.S.; deleting reference to establishments that handle medical oxygen; amending s. 499.01211, F.S.; revising membership of the Drug Wholesale Distributor Advisory Council; conforming cross-references; amending s. 499.041, F.S.; deleting certain permitting fees for compressed medical gas manufacturers, medical gas wholesale distributors, or medical oxygen retail establishments; amending ss. 499.051, 499.066, 499.0661, and 499.067, F.S.; conforming provisions to changes made by the act; creating part III of chapter 499, F.S., relating to medical gases; providing for applicability and preemption; authorizing the department to administer and enforce the part; requiring a state, county, or municipal attorney to institute appropriate proceedings for a violation; providing notice requirements for the department; providing definitions; requiring a permit for distribution of medical gas as a wholesale

distributor, manufacturer, or medical oxygen retail establishment; authorizing the department to adopt rules; providing permitting standards; providing requirements to obtain a permit; providing for permit renewal; providing guidelines to change certain information; authorizing the department to revoke permits for failure to comply; requiring certain distributors of medical gases to obtain a permit and maintain permit renewal; requiring an applicant to provide a sworn statement disclosing certain information; providing minimum qualifications for licensure; requiring an applicant or licensee to designate and maintain a registered agent for service of process; providing minimum requirements for the storage and handling of gases and patient information; requiring a facility of wholesale distribution of medical gases to secure the facility from unauthorized entry; providing recommended security measures; requiring medical gases to be stored and packaged in accordance with certain regulations or standards; requiring a visual examination of a medical gas container upon receipt; requiring that a damaged or unfit medical gas be quarantined; requiring inspection of outgoing shipments; requiring a wholesale distributor of medical gases to review the records that accompany a medical gas received by the

distributor; requiring returned medical gases to be reprocessed for resale; requiring certain medical gases to be quarantined; requiring an acquiring distributor or manufacturer to provide notice of adulteration, misbranding, or suspected adulteration or misbranding; requiring certain medical gases to be retained; requiring a wholesale distributor of medical gases to comply with certain due diligence requirements; requiring that certain information must be provided by the supplying distributor to the acquiring distributor; providing an exception; requiring a wholesale distribution of medical gases to establish and maintain certain records; requiring the records to be made available for a certain amount of time; requiring a wholesale distributor to establish, maintain, and adhere to written policies and procedures; providing certain mandatory policies; prohibiting certain acts; providing that certain acts are felonies of the third degree; providing additional penalties of forfeiture; providing requirements related to salvaging and reprocessing; authorizing the department to recognize a third party inspection of wholesale distributors of medical gases or recognize other states inspections; providing for a right of review; providing notice requirements; providing for the deposit of fees in a trust fund and authorizing

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

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

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

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

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

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

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

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

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

499.01 Permits.—

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

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

~~(n) A compressed medical gas wholesale distributor;~~

~~(o) A compressed medical gas manufacturer;~~

(2) The following permits are established:

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

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

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

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

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

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

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

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

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

(g) Restricted prescription drug distributor permit.—

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

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

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

the manufacturer of the drug.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

good manufacturing practices; and

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

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

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

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

(2) SECURITY.—

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

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

2. A security system that will provide suitable protection

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

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

499.01211 Drug Wholesale Distributor Advisory Council.—

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

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

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

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

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

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

chapter 458 or chapter 459.

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

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

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

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

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

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

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

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

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

~~annually.~~

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

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

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

499.051 Inspections and investigations.—

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

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

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

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

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

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

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

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

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

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

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

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

(a) The severity of the violation;

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

(c) Any previous violations.

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

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

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

(1) CEASE AND DESIST ORDERS.—

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

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

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

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

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

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

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

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

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

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

notice, to correct the violation and has failed to do so;

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

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

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

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

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

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

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

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

1. The applicant is not of good moral character or that it would be a danger or not in the best interest of the public

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

PART III

MEDICAL GASES

499.81 Administration and enforcement.—

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

provisions of this part shall control over any conflicting provisions.

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

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

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

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

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

(1) "Adulterated" means:

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

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

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

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

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

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

term does not include:

(a) The dispensation or administration of medical gas;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(11) "USP" means United States Pharmacopeia.

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

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

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

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

(c) Intracompany transactions;

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

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

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

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

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

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

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

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

medical gas warehouses.

499.831 Permits.—

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

(a) A medical gas wholesale distributor;

(b) A medical gas manufacturer; or

(c) A medical oxygen retail establishment.

(2) The following permits are established:

(a) Medical gas wholesale distributor permit.—A medical gas wholesale distributor permit is required for the wholesale distribution of medical gases, whether in or into this state. The medical gas must be in the original container obtained by the wholesale distributor without further manufacturing operations. A medical gas wholesale distributor may not possess or engage in the wholesale distribution of a prescription drug that is not a medical gas. The department shall adopt rules to govern the wholesale distribution of prescription medical oxygen for emergency use and to persons authorized to receive emergency use oxygen. Rules regarding the emergency use of prescription medical oxygen may not be inconsistent with rules and regulations of federal agencies unless the Legislature specifically directs otherwise.

(b) Medical gas manufacturer permit.—A medical gas manufacturer permit is required for a person that engages in the

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

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

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

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

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

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

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

a practitioner authorized by law to prescribe.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

a. Return the permit to the department.

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

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

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

499.841 Additional requirements for licensure of a wholesale distributor of medical gases.—

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

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

499.85 Minimum qualifications.—

(1) The department shall consider the following factors in determining the eligibility for, and renewal of, licensure of persons who engage in the wholesale distribution of medical gas:

(a) A finding by the department that the applicant has violated or been disciplined by a regulatory agency in any state for violating a federal, state, or local law relating to the wholesale distribution of medical gases.

(b) A criminal conviction of the applicant under a federal, state, or local law.

(c) The applicant's past experience in the manufacture or wholesale distribution of medical gases.

(d) False or fraudulent material provided by the applicant in an application made in connection with the manufacturing or wholesale distribution of medical gases.

(e) A suspension, sanction, or revocation by a federal, state, or local government against a license currently or previously held by the applicant or its owners for violations of a federal, state, or local law regarding medical gas.

(f) Compliance with previously granted licenses.

(g) Compliance with the requirements of wholesale distributors to medical gases to maintain records or make records available to the department licensing authority or federal, state, or local law enforcement officials.

(h) Other factors or qualifications the department considers relevant to and consistent with the public health and

safety.

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

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

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

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

agents, representatives, and employees.

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

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

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

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

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

(e) Be maintained in an orderly condition.

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

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

confidentiality of the patient information.

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

499.88 Security.—

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

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

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

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

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

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

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

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

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

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

499.89 Storage.—

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

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

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

499.90 Examination of materials.—

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

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

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

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

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

499.91 Returned, damaged, and outdated medical gases.—

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

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

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

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

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

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

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

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

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

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

Administration.

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

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

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

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

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

(a) Proof of such registration.

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

under this part.

499.93 Recordkeeping.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

499.95 Prohibited acts.—

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

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

(b) A wholesale distributor of medical gases;

(c) A home respiratory care company;

(d) A pharmacy or health care entity;

(e) A person authorized to receive emergency use oxygen

without a prescription;

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

(g) 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.

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

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

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

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

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

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

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

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

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

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

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

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

3. Stolen or obtained by fraud or deceit.

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

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

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

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

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

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

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

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

499.96 Criminal acts.—

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

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

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

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

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

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

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

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

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

499.97 Salvaging and reprocessing.—

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

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

499.98 Inspections.—

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

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

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

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

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

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

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

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

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

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

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

409.9201 Medicaid fraud.—

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

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

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

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

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

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

(9)

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

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

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

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

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

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

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

465.0265 Centralized prescription filling.—

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

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

499.01212 Pedigree paper.—

(2) FORMAT.—A pedigree paper must contain the following information:

(b) For all other wholesale distributions of prescription

drugs:

1. The quantity, dosage form, and strength of the prescription drugs.

2. The lot numbers of the prescription drugs.

3. The name and address of each owner of the prescription drug and his or her signature.

4. Shipping information, including the name and address of each person certifying delivery or receipt of the prescription drug.

5. An invoice number, a shipping document number, or another number uniquely identifying the transaction.

6. A certification that the recipient wholesale distributor has authenticated the pedigree papers.

7. The unique serialization of the prescription drug, if the manufacturer or repackager has uniquely serialized the individual prescription drug unit.

8. The name, address, telephone number, and, if available, e-mail contact information of each wholesale distributor involved in the chain of the prescription drug's custody.

When an affiliated group member obtains title to a prescription drug before distributing the prescription drug as the manufacturer under s. 499.003(30)(e) ~~499.003(31)(e)~~, information regarding the distribution between those affiliated group members may be omitted from a pedigree paper required under this paragraph for subsequent distributions of that prescription

drug.

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

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

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

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

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

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

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

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

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

499.05 Rules.—

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

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

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

Section 18. This act shall take effect October 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	_____

Committee/Subcommittee hearing bill: Health Quality Subcommittee

Representative Magar offered the following:

Amendment

Remove everything after the enacting clause and insert:

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

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

(32) ~~(11)~~ "~~Compressed~~ Medical gas" means any liquefied or vaporized gas that is a prescription drug, whether ~~it is~~ alone

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

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

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

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

499.01 Permits.—

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

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

~~(n) A compressed medical gas wholesale distributor;~~

~~(o) A compressed medical gas manufacturer;~~

(2) The following permits are established:

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

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

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

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

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

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

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

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

(g) Restricted prescription drug distributor permit.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(2) SECURITY.—

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

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

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

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

499.01211 Drug Wholesale Distributor Advisory Council.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

499.051 Inspections and investigations.—

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

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

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

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

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

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

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

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

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

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

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

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

(a) The severity of the violation;

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

(c) Any previous violations.

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

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

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

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

(1) CEASE AND DESIST ORDERS.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

PART III

MEDICAL GASES

499.81 Administration and enforcement.—

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

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

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

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

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

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

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

(1) "Adulterated" means:

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

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

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

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

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

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

(a) The dispensation or administration of medical gas;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(12) "USP" means United States Pharmacopeia.

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

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

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

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

(c) Intracompany transactions;

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

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

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

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

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

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

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

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

499.831 Permits.—

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

(a) A medical gas wholesale distributor;

(b) A medical gas manufacturer; or

(c) A medical oxygen retail establishment.

(2) The following permits are established:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

4. The full name and business address of the sole proprietor and the name and federal employer identification number of the business entity, if the permittee is a sole proprietorship.

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

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

(d) An address and description of each facility and warehouse, including all locations used for medical gas storage

or wholesale distribution including a description of the security system.

(4) A permit issued pursuant to this part may be issued to a natural person who is at least 18 years of age or to an applicant who is not a natural person if the person who, directly or indirectly, manages, controls, or oversees the operation of that applicant is at least 18 years of age.

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

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

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

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

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

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

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

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

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

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

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

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

(10)(a) A permit issued by the department is valid only for the person or governmental unit to which it is issued and is not subject to sale, assignment, or other transfer, voluntarily or involuntarily, and is not valid for any establishment other than the establishment for which it was originally issued except as provided in this part. The department is authorized to approve a change of the permit holder.

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

1. A person permitted under this part must notify the department 30 days before making a change of location. The department shall set a change of location fee not to exceed $100.

2. When a majority of the ownership or controlling interest of a permitted establishment is transferred or assigned, or when a lessee agrees to undertake or provide services to the extent that legal liability for operation of the establishment will rest with the lessee, an application for a new permit shall be required. The application for the new permit must be made 30 days before the change of ownership. If the application for the new permit is not made 30 days before the change of ownership, and if the new owner acquires a permitted wholesale distributor or manufacturer and the new owner has held another permit under this chapter for at least 18 months and has not been found to have violated the provisions of this chapter in the preceding 18 months, then the new owner can operate under

the permit of the acquired entity, provided the application for a new permit is made no later than the first business day after ownership is transferred or assigned. The new owner is responsible for compliance with all laws and regulations governing medical gas. If the application is denied, the new owner shall immediately cease operation at the establishment until a permit is issued to the new owner.

3. A permit holder may make a change of business name without submitting a new permit application and must notify the department 30 days before making the name change. The permit holder may continue to operate the establishment under the old name until the department approves of the name change and issues a permit under the new name.

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

a. Return the permit to the department.

b. If the permittee is authorized to distribute medical gas, indicate the disposition of such medical gas, including the name, address, and inventory, and provide the name and address of a contact with access to records that are required to be maintained under this part. Transfer of ownership of medical gas may be made only to persons authorized to possess medical gas under this part.

(11) Any change in information required under this section shall be submitted to the department 30 days before such change.

The department may revoke the permit of any person that fails to comply with this part.

499.841 Additional requirements for licensure of a wholesale distributor of medical gases.—

(1) A wholesale distributor of medical gases that resides in the state or provides services within or into this state must obtain a permit from the department and must renew the permit with the department biennially on an application provided by the department. In order to distribute medical gases into this state pursuant to this subsection, out-of-state medical gas wholesale distributors must maintain a valid license or permit in the state in which they reside, if required, and proof of registration set forth in s. 499.98(4)(a), if required.

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

499.85 Minimum qualifications.—

(1) The department shall consider the following factors in determining the eligibility for, and renewal of, a permit of persons who engage in the wholesale distribution of medical gas:

(a) A finding by the department that the applicant has violated or been disciplined by a regulatory agency in any state

for violating a federal, state, or local law relating to the wholesale distribution of medical gases.

(b) A criminal conviction of the applicant under a federal, state, or local law.

(c) The applicant's past experience in the manufacture or wholesale distribution of medical gases.

(d) False or fraudulent material provided by the applicant in an application made in connection with the manufacturing or wholesale distribution of medical gases.

(e) A suspension, sanction, or revocation by a federal, state, or local government against a license or permit currently or previously held by the applicant or its owners for violations of a federal, state, or local law regarding medical gas.

(f) Compliance with previously granted licenses or permits.

(g) Compliance with the requirements of wholesale distributors to medical gases to maintain records or make records available to the department licensing authority or federal, state, or local law enforcement officials.

(h) Other factors or qualifications the department considers relevant to and consistent with the public health and safety.

(2) The applicant shall provide a sworn statement providing complete disclosure of any past criminal convictions and violations of federal, state, or local laws regarding medical gases or a sworn statement that the applicant has not

been convicted of or disciplined for any criminal or prohibited acts.

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

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

(1) Minimum requirements shall be established for the storage, handling, transport, and shipment of medical gases and for the maintenance of wholesale distribution records by wholesale distributors of medical gases and their officers, agents, representatives, and employees.

(2) A facility at which a medical gas is received, stored, warehoused, handled, held, offered, marketed, displayed, or transported from, as necessary to avoid a negative effect on the

identity, strength, quality, or purity of the medical gas, shall:

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

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

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

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

(e) Be maintained in an orderly condition.

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

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

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

499.88 Security.—

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

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

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

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

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

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

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

(4) Where a wholesale distributor of medical gases uses electronic distribution records, the wholesale distributor shall employ, train, and document the training of personnel in the proper use of such technology and equipment.

(5) Vehicles used for on-call delivery of oxygen USP and oxygen related equipment for home care use by home care

providers may be parked at a place of residence and must be locked and equipped with an audible alarm when not attended.

499.89 Storage.—

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

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

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

499.90 Examination of materials.—

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

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

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

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

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

499.91 Returned, damaged, and outdated medical gases.—

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

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

(3) When medical gas is adulterated, misbranded, or suspected of being adulterated or misbranded, notice shall be provided to the manufacturer or wholesale distributer from which they were acquired and the appropriate boards and federal regulatory bodies.

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

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

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

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

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

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

(b) If a wholesale distributor is distributing to a wholesale distributor, evidence that the wholesale distributor

supplying the medical gas is licensed or permitted to distribute product into the state.

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

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

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

(3) A wholesale distributor of medical gases is exempt from obtaining the information from a manufacturer as required under subsection (1) if the manufacturer is registered with the United States Food and Drug Administration in accordance with s. 510 of the federal act and the manufacturer provides:

(a) Proof of such registration.

(b) Proof of inspection by the United States Food and Drug Administration or other regulatory body within the past 3 years demonstrating substantial compliance with current good manufacturing practices applicable to medical gases.

499.93 Recordkeeping.—

(1) A wholesale distributor of medical gases shall establish and maintain records of all transactions regarding the receipt and wholesale distribution or other disposition of

medical gases. These records shall include the following, which need not appear on the same document:

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

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

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

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

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

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

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

(3) Records kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within 2 working days of a request

by an authorized official of any state or federal governmental agency charged with enforcement of these rules.

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

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

499.931 Trade secret information.—The department shall ensure that information required to be provided as part of the application process or information obtained pursuant to an investigation by the department, which are trade secret, as defined in s. 812.081, and designated as trade secret by the entity supplying the information to the department, shall be maintained by the department as trade secret as provided in ss. 499.012(8)(g) and 499.051(7).

499.94 Policies and procedures.—A wholesale distributor of medical gases shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, transport, and shipping and wholesale distribution of medical gases, including policies and procedures for maintaining inventories, identifying, recording, and reporting losses or thefts and for correcting all errors and inaccuracies in inventories associated with nitrous oxide. A

wholesale distributor of medical gases shall include the following in the written policies and procedures:

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

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

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

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

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

499.95 Prohibited acts.—It is unlawful for a person to perform, cause the performance of, or aid and abet the following acts in this state:

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

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

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

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

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

(f) The knowing and willful sale or transfer of a medical gas to a person or other recipient who is not legally authorized to receive a medical gas, except that no violation shall exist if a permitted wholesale distributor, at its location, provides oxygen to a medical oxygen retail establishment permit holder that is out of compliance with the notice of location change requirements of s. 499.831(10)(b)1., provided that the wholesale distributor with knowledge of the violation notifies the department of the transaction by the next business day;

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

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

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

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

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

3. Stolen or obtained by fraud or deceit.

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

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

(l) Except for oxygen USP in emergency situations, distribution of a medical gas to a patient without a prescription or prescription order from a practitioner licensed by law to use or prescribe the medical gas;

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

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

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

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

499.96 Criminal acts.—

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

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

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

(c) Engages in the wholesale distribution and knowingly sells, barters, brokers, or transfers medical gases to a person not legally authorized to purchase medical gases under the jurisdiction in which the person receives the medical gas, except that no violation shall exist if a permitted wholesale distributor, at its location, provides oxygen to a medical oxygen retail establishment permit holder that is out of

compliance with the notice of location change requirements of s. 499.831(10)(b)1., provided that the wholesale distributor with knowledge of the violation notifies the department of the transaction by the next business day.

(d) Knowingly creates a false label for a medical gas or who falsely represents factual matter contained in a medical gas label.

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

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

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

official use by the department or the agencies involved in the investigation and prosecution that led to the conviction.

499.97 Salvaging and reprocessing.—

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

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

499.98 Inspections.—

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

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

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

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

(a) The manufacturing facility is currently registered with the United States Food and Drug Administration under s. 510

of the federal act and can provide proof of registration, such as a copy of the internet verification page.

(b) The manufacturing facility can provide proof of inspection by the Food and Drug Administration, or if the facility is located in another state, inspection by the Food and Drug Administration or other governmental entity charged with regulation of good manufacturing practices related to medical gases within the past 3 years.

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

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

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

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

409.9201 Medicaid fraud.—

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

(a) "Prescription drug" means any drug, including, but not limited to, finished dosage forms or active ingredients that are subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act or by s. 465.003(8), s. 499.003(52), ~~499.003(46) or (53)~~ or s. 499.007(13).

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

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

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

(9)

(c)1. Chiropractic physicians may adjust, manipulate, or treat the human body by manual, mechanical, electrical, or natural methods; by the use of physical means or physiotherapy, including light, heat, water, or exercise; by the use of acupuncture; or by the administration of foods, food concentrates, food extracts, and items for which a prescription is not required and may apply first aid and hygiene, but chiropractic physicians are expressly prohibited from prescribing or administering to any person any legend drug

except as authorized under subparagraph 2., from performing any surgery except as stated herein, or from practicing obstetrics.

2. Notwithstanding the prohibition against prescribing and administering legend drugs under subparagraph 1. ~~or s. 499.01(2)(m)~~, pursuant to board rule chiropractic physicians may order, store, and administer, for emergency purposes only at the chiropractic physician's office or place of business, prescription medical oxygen and may also order, store, and administer the following topical anesthetics in aerosol form:

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

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

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

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

465.0265 Centralized prescription filling.—

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

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

499.01212 Pedigree paper.—

(2) FORMAT.—A pedigree paper must contain the following information:

(b) For all other wholesale distributions of prescription drugs:

1. The quantity, dosage form, and strength of the prescription drugs.

2. The lot numbers of the prescription drugs.

3. The name and address of each owner of the prescription drug and his or her signature.

4. Shipping information, including the name and address of each person certifying delivery or receipt of the prescription drug.

5. An invoice number, a shipping document number, or another number uniquely identifying the transaction.

6. A certification that the recipient wholesale distributor has authenticated the pedigree papers.

7. The unique serialization of the prescription drug, if the manufacturer or repackager has uniquely serialized the individual prescription drug unit.

8. The name, address, telephone number, and, if available, e-mail contact information of each wholesale distributor involved in the chain of the prescription drug's custody.

When an affiliated group member obtains title to a prescription drug before distributing the prescription drug as the manufacturer under s. 499.003(30)(e) ~~499.003(31)(e)~~, information regarding the distribution between those affiliated group members may be omitted from a pedigree paper required under this paragraph for subsequent distributions of that prescription drug.

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

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

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

(3) Except for those persons exempted from the definition of manufacturer in s. 499.003(30) ~~499.003(31)~~, a person may not sell any product that he or she has failed to register in conformity with this section. Such failure to register subjects such drug, device, or cosmetic product to seizure and

condemnation as provided in s. 499.062, and subjects such person to the penalties and remedies provided in this part.

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

499.024 Drug product classification.—The department shall adopt rules to classify drug products intended for use by humans which the United States Food and Drug Administration has not classified in the federal act or the Code of Federal Regulations.

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

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

499.05 Rules.—

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

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

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

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

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	O'Callaghan
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 disorders[5] 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

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[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 states[9] 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

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[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 2008[15] 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 Questionnaire[19] 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 BCBAs 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 BCBAs 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 by 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 MQA[28] will also be assessed upon initial licensure and renewal. FABA 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]

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[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:

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[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.*

A bill to be entitled

An act relating to behavior analysts; creating ch. 470, F.S.; entitling the chapter; creating s. 470.40, F.S.; providing a purpose; creating s. 470.41, F.S.; defining terms; creating s. 470.415, F.S.; creating the Board of Applied Behavior Analysis; creating s. 470.42, F.S.; specifying the authority and duties of the board; creating s. 470.43, F.S.; providing requirements for licensure and renewal; creating s. 470.44, F.S.; establishing maximum fees for applications, initial licenses, and license renewals; creating s. 470.45, F.S.; providing grounds for disciplinary action by the board; providing for reinstatement of a license; creating s. 470.46, F.S.; requiring a licensee or his or her employer to report to the board certain felony convictions on the part of a licensee or suspicions that a licensee has committed fraud or deceit; creating s. 470.47, F.S.; providing penalties for practicing applied behavior analysis without a license or wrongfully identifying oneself as a licensed behavior analyst; creating s. 470.48, F.S.; providing exceptions to the chapter; amending s. 456.001, F.S.; including licensed behavior analysts and licensed assistant behavior analysts in the definition of "health care practitioner"; providing an effective date.

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.

(3) "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.

(4) "Board-certified assistant behavior analyst" means a practitioner who is certified by the national Behavior Analyst Certification Board, or its successor pursuant to s. 470.42, as a Board Certified Assistant Behavior Analyst.

(5) "Department" means the Department of Health.

(6) "Licensed behavior analyst" means an individual who is licensed by the board and meets the requirements of this chapter.

(7) "Licensed assistant behavior analyst" means an individual who:

(a) Is licensed by the board as an assistant behavior analyst and meets the requirements of this chapter; and

(b) Works under the supervision of a licensed behavior analyst.

(8) "Supervised experience" means an individual has completed the training necessary to satisfy the eligibility requirements for BACB certification.

Section 4. Section 470.415, Florida Statutes, is created to read:

470.415 Board of Applied Behavior Analysis.—

(1) The Board of Applied Behavior Analysis is created within the department. The board consists of seven members who

must be appointed by the Governor and confirmed by the Senate.

(2) The initial board members, who are not required to be licensed as a condition of appointment, shall be appointed as follows:

(a) Three board-certified behavior analysts, which may include board-certified behavior analysts who are at the doctoral level, two of whom shall be selected from a list of six nominations submitted by the Florida Association for Behavior Analysis. One shall be appointed to a 1-year term, and two shall be appointed to 3-year terms;

(b) One board-certified assistant behavior analyst, who shall be appointed to a 1-year term;

(c) One health care provider licensed in this state, who shall be appointed to a 2-year term. The majority of the appointed health care provider's practice must be related to the treatment of behavior disorders, including, but not limited to, autism spectrum disorders; and

(d) Two laypersons, who may include a parent or guardian of an individual who is a recipient of applied behavior analysis services, one of whom shall serve a 1-year term, and one of whom shall serve a 2-year term.

(3) As the terms of the initial members expire, the Governor shall appoint successors for 3-year terms. Each successor, except for the laypersons, must be licensed. A member may not serve more than two consecutive terms.

(4) All provisions of chapter 456 relating to the board

apply.

Section 5. Section 470.42, Florida Statutes, is created to read:

470.42 Authority of the board; duties.—

(1) The board may adopt rules pursuant to ss. 120.536(1) and 120.54 to implement the provisions of this chapter conferring duties upon it. Such rules must include, but are not limited to, rules relating to all of the following:

(a) Standards of practice.

(b) Licensure, including the suspension and revocation of a license and the refusal to issue or renew a license.

(c) Limitations of activities.

(d) Supervision.

(e) Educational qualifications and continuing education requirements.

(f) The number of persons that a licensed behavior analyst or licensed assistant behavior analyst may supervise at one time.

(g) The competency of a person to receive or renew his or her license.

(h) 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.

(2) The board shall perform all of the following:

(a) Adopt a code of ethical standards and standards of

practice for licensed behavior analysts and licensed assistant behavior analysts.

(b) Keep a minute book containing a record of all meetings of the board.

(c) Maintain a registry of all persons licensed under this chapter. This registry must show the name of every licensee in this state, his or her current business and residence address and telephone number, and his or her licensure date and license number. A licensee shall notify the board of a change of name, address, or telephone number within 30 days after the change.

(d) Update its records annually.

(e) Publish annually and make available a current directory of all licensed behavior analysts and licensed assistant behavior analysts in this state.

(f) Adopt a seal and affix it to every license granted by the board.

(g) Maintain its official headquarters in Tallahassee.

(3) If the Behavior Analyst Certification Board stops certifying practitioners of applied behavior analysis in this state, the board shall approve a successor certification board that is accredited by the National Commission for Certifying Agencies or the American National Standards Institute to certify applied behavior analysts.

Section 6. Section 470.43, Florida Statutes, is created to read:

470.43 Licensure and renewal.—

(1) A person applying for an initial or renewal license as a licensed behavior analyst or licensed assistant behavior analyst shall apply to the board on such form and in such manner as the board prescribes. The person shall furnish evidence to the board that he or she:

(a) Is a board-certified behavior analyst;

(b) Conducts his or her professional activities in accordance with accepted standards as required by rule;

(c) Complies with all applicable rules adopted by the board;

(d) Has paid the licensure fee or the biennial renewal fee; and

(e) Has passed a criminal background check, as determined by the board.

(2) A person applying for an initial or renewal license as an assistant behavior analyst shall apply to the board upon such form and in such manner as the board prescribes and shall furnish evidence to the board that such person:

(a) Is a board-certified assistant behavior analyst;

(b) Conducts his or her professional activities in accordance with accepted standards, as required by rule;

(c) Complies with all applicable rules promulgated by the board;

(d) Is supervised by a licensed behavior analyst in a manner consistent with BACB requirements and this chapter;

(e) Has paid the licensure fee or the biennial renewal

fee; and

(f) Has passed a criminal background check, as determined by the board.

(3) 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 to those imposed by this state and that offers reciprocity to individuals licensed under this chapter. Applicants for reciprocity must:

(a) Submit proof of licensure and board certification;

(b) Pass a criminal background check, as determined by the board; and

(c) Pay the licensure fee.

Section 7. Section 470.44, Florida Statutes, is created to read:

470.44 Fees.—

(1) The board shall establish by rule a fee not to exceed $100 for an application and a fee not to exceed $300 for an initial license or license renewal.

(2) In establishing fees pursuant to subsection (1), the board shall consider the actual costs incurred in carrying out its duties under this chapter.

(3) All moneys collected by the department under this chapter shall be deposited as provided under s. 456.025.

Section 8. Section 470.45, Florida Statutes, is created to read:

470.45 Disciplinary grounds and actions; reinstatement.—

(1) The board may enter an order imposing any of the penalties provided under s. 456.072(2) against a licensee who violates any provision of s. 456.072(1), except that the board may not do any of the following:

(a) Place a licensee on probation for more than 5 years.

(b) Impose a fine that exceeds $2,500.

(c) Suspend a license for more than 5 years.

(d) Limit or restrict a license for an indefinite period.

(2) The board may reinstate a license that has been suspended or revoked if, after a hearing conducted pursuant to s. 120.54, the board determines that the applicant is able to practice his or her profession with reasonable competency and in accordance with the code of ethics and standards of practice established by rule under s. 470.42. As a condition of reinstatement, the board may impose reasonable restrictions on the licensee's license to practice.

Section 9. Section 470.46, Florida Statutes, is created to read:

470.46 Duty to report felony or suspicion of fraud or deceit.—A licensee or employer of a licensee having actual or direct knowledge of facts shall report to the board a behavior analyst or assistant behavior analyst who:

(1) Has been charged or convicted of a felony that involved any act that bears directly on his or her qualifications or ability to practice applied behavior analysis

or any act that bears directly on the public health, safety, or welfare;

(2) Is suspected of fraud or deceit in procuring or attempting to procure a license to practice applied behavior analysis or of negligently performing actions that justify action against the license of the behavior analyst or assistant behavior analyst;

(3) Has had a board certification or a license to practice as a behavior analyst or assistant behavior analyst denied, limited, suspended, placed on probation, or revoked in another jurisdiction on grounds sufficient to cause a license or certificate to be denied, limited, suspended, placed on probation, or revoked in this state; or

(4) Is practicing applied behavior analysis without a license issued by the board unless specifically exempted in this chapter.

Section 10. Section 470.47, Florida Statutes, is created to read:

470.47 Violations and penalties.—

(1) Unless licensed or authorized under this chapter, a person who engages in the practice of applied behavior analysis, assists in the practice of applied behavior analysis, renders services designated as applied behavior analysis, or represents himself or herself as a practitioner of applied behavior analysis in this state commits a felony of the third degree, punishable as provided under s. 775.082, s. 775.083, or s.

775.084.

(2) Unless licensed or authorized under this chapter, a person who uses the title "licensed behavior analyst," "licensed assistant behavior analyst," or any other title that is substantially similar commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083.

Section 11. Section 470.48, Florida Statutes, is created to read:

470.48 Exceptions to applicability.—This chapter does not prohibit or restrict the practice of the following:

(1) An individual licensed under chapter 490 to practice psychology if the applied behavior analysis services he or she provides are within the scope of chapter 490 and his or her education, training, and experience.

(2) A certified teacher authorized to practice in this state who is not a behavior analyst if he or she does not represent himself or herself as a behavior analyst. The services provided by a certified teacher must be within his or her authorized scope of practice and within the scope of his or her education, training, and experience and must be provided in the course of his or her employment in a program approved by the Department of Education. Teaching assistants, other than those engaged in pupil personnel services, and student support professionals are exempt from the requirements of this chapter if they provide behavior analysis services under the supervision of a certified teacher who meets the requirements of this

paragraph.

(3) A behavior analyst who practices with nonhuman clients, including, but not limited to, applied animal behaviorists and animal trainers.

(4) An unlicensed individual who provides applied behavior analysis services under the extended authority and direction of a licensed behavior analyst or licensed assistant behavior analyst.

(5) An individual who teaches applied behavior analysis or who conducts behavior analytic research if such teaching or research does not involve the delivery of direct behavior analysis interventions to individuals.

(6) A matriculated college or university student or postdoctoral fellow whose activities are part of a defined behavior analysis program of study, practicum, or intensive practicum if his or her practice under this subsection is directly supervised by a licensed behavior analyst or an instructor of an accredited course sequence approved by the Behavior Analyst Certification Board (BACB). A student or intern may not represent himself or herself as a professional behavior analyst but may use a title indicating his or her trainee status, such as "behavior analyst student," "behavior analyst intern," or "behavior analyst trainee."

(7) An unlicensed individual pursuing supervised experiential training to meet eligibility requirements for BACB certification if such training is supervised by an individual

who is licensed to practice applied behavior analysis and who meets BACB supervisor requirements and if the supervised experience is conducted in accordance with other BACB standards and requirements.

(8) A board-certified behavior analyst, a doctoral level board-certified behavior analyst, or an individual licensed to practice applied behavior analysis in another state who resides in another state and provides applied behavior analysis in this state or to a resident of this state for less than 12 days per year.

(9) A Florida-certified behavior analyst who is in good standing with the Behavior Analyst Certification Board and who is not a board-certified behavior analyst.

(10) A family member of a recipient of applied behavior analysis services who implements certain procedures with the recipient under the extended authority and direction of a licensed behavior analyst or licensed assistant behavior analyst. Such a family member may not represent himself or herself as a professional behavior analyst.

(11) A behavior analyst who provides general behavior analysis services to organizations if the services are for the benefit of the organizations and do not involve direct services to individuals.

(12) A physician licensed pursuant to chapter 458 or chapter 459 if he or she does not represent himself or herself as a professional behavior analyst.

(13) An individual licensed pursuant to chapter 491 as a clinical social worker, marriage and family therapist, or mental health counselor if he or she does not represent himself or herself as a professional behavior analyst.

(14) A salaried employee of a private, nonprofit organization providing behavior analysis services to children, youth, and families if the services are provided for no charge, the employee is performing duties for which he or she was trained and hired, and the employee does not represent himself or herself as a professional behavior analyst.

(15) A school psychologist certified in school psychology by the Department of Education who performs behavior analysis services as an employee of a public or private educational institution. Such exemption does not authorize unlicensed practice that is not performed directly as an employee of an educational institution.

(16) A rabbi, priest, minister, or member of the clergy of a religious denomination or sect if engaging in activities that are within the scope of the performance of his or her regular or specialized ministerial duties and for which no separate fee is charged, or if such activities are performed, with or without a fee, for or under the auspices or sponsorship, individually or in conjunction with others, of an established and legally cognizable church, denomination, or sect; and if the person rendering service remains accountable to the established authority thereof.

Section 12. Subsection (4) of section 456.001, Florida Statutes, is amended to read:

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

(4) "Health care practitioner" means any person licensed under chapter 457; chapter 458; chapter 459; chapter 460; chapter 461; chapter 462; chapter 463; chapter 464; chapter 465; chapter 466; chapter 467; part I, part II, part III, part V, part X, part XIII, or part XIV of chapter 468; chapter 470; chapter 478; chapter 480; part III or part IV of chapter 483; chapter 484; chapter 486; chapter 490; or chapter 491.

Section 13. This act shall take effect October 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	_____

Committee/Subcommittee hearing bill: Health Quality Subcommittee

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.

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.

(3) "Board-certified behavior analyst" means a practitioner who is certified as a Board Certified Behavior Analyst, or is recognized as a "Florida-certified behavior analyst," by the national Behavior Analyst Certification Board (BACB), or its successor pursuant to s. 470.42.

(4) "Board-certified assistant behavior analyst" means a practitioner who is certified by the national Behavior Analyst Certification Board, or its successor pursuant to s. 470.42, as a Board Certified Assistant Behavior Analyst.

(5) "Department" means the Department of Health.

(6) "Licensed behavior analyst" means an individual who is licensed by the board and meets the requirements of this chapter.

(7) "Licensed assistant behavior analyst" means an individual who:

(a) Is licensed by the board as an assistant behavior analyst and meets the requirements of this chapter; and

(b) Works under the supervision of a licensed behavior analyst.

(8) "Supervised experience" means an individual has completed the training necessary to satisfy the eligibility requirements for BACB certification.

Section 4. Section 470.415, Florida Statutes, is created to read:

470.415 Board of Applied Behavior Analysis.—

(1) The Board of Applied Behavior Analysis is created within the department. The board consists of seven members who must be appointed by the Governor and confirmed by the Senate.

(2) The initial board members, who are not required to be licensed as a condition of appointment, shall be appointed as follows:

(a) Three board-certified behavior analysts, which may include board-certified behavior analysts who are at the doctoral level, two of whom shall be selected from a list of six nominations submitted by the Florida Association for Behavior

Analysis. One shall be appointed to a 1-year term, and two shall be appointed to 3-year terms;

(b) One board-certified assistant behavior analyst, who shall be appointed to a 1-year term;

(c) One health care practitioner licensed in this state, who shall be appointed to a 2-year term. The majority of the appointed health care practitioner's practice must be related to the treatment of behavior disorders, including, but not limited to, autism spectrum disorders; and

(d) Two laypersons, who may include a parent or guardian of an individual who is a recipient of applied behavior analysis services, one of whom shall serve a 1-year term, and one of whom shall serve a 2-year term.

(3) As the terms of the initial members expire, the Governor shall appoint successors for 4-year terms. Each successor, except for the laypersons, must be licensed. A member may not serve more than two consecutive terms.

Section 5. Section 470.42, Florida Statutes, is created to read:

470.42 Authority of the board; board duties; authority of the department.—

(1) The board may adopt rules pursuant to ss. 120.536(1) and 120.54 to implement the provisions of this chapter conferring duties upon it. Such rules must include, but are not limited to, rules relating to all of the following:

(a) Standards of practice for licensed behavior analysts and licensed assistant behavior analysts.

(b) The competency of a person to receive or renew his or her license.

(c) 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.

(d) Supervision of licensed assistant behavior analysts or students in training to be licensed behavior analysts, including the number of persons that a licensed behavior analyst or licensed assistant behavior analyst may supervise at one time.

(2) If the Behavior Analyst Certification Board stops certifying practitioners of applied behavior analysis in this state, the board shall approve a successor certification board that is accredited by the National Commission for Certifying Agencies or the American National Standards Institute to certify applied behavior analysts.

(3) The department may adopt rules pursuant to ss. 120.536(1) and 120.54 to implement the provisions of this chapter conferring duties upon it. Such rules must include, but are not limited to, rules relating to all of the following:

(a) Licensure and licensure renewal applications and processes, including licensure fees.

(b) Educational qualifications for licensure.

(c) Continuing education requirements for biennial renewal of licensure not to exceed 30 hours biennially as a condition for renewal of a license.

Section 6. Section 470.43, Florida Statutes, is created to read:

470.43 Licensure and renewal.—

(1) A person applying for an initial or renewal license as a licensed behavior analyst or licensed assistant behavior analyst shall apply to the department on such form and in such manner as the department prescribes. The person shall furnish evidence to the department that he or she:

(a) Is a board-certified behavior analyst;

(b) Conducts his or her professional activities in accordance with accepted standards as required by rule;

(c) Complies with all applicable rules adopted by the board;

(d) Has paid the licensure fee or the biennial renewal fee; and

(e) Has passed a criminal background check after submitting fingerprints and a fee pursuant to s. 456.0135.

(2) A person applying for an initial or renewal license as an assistant behavior analyst shall apply to the department upon such form and in such manner as the department prescribes and shall furnish evidence to the department that such person:

(a) Is a board-certified assistant behavior analyst;

(b) Conducts his or her professional activities in accordance with accepted standards, as required by rule;

(c) Complies with all applicable rules promulgated by the board;

(d) Is supervised by a licensed behavior analyst in a manner consistent with BACB requirements and this chapter;

(e) Has paid the licensure fee or the biennial renewal fee; and

(f) Has passed a criminal background check after submitting fingerprints and a fee pursuant to s. 456.0135.

(3) 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 and:

(a) Submits proof of licensure and board certification;

(b) Passes a criminal background check after submitting fingerprints and a fee pursuant to s. 456.0135; and

(c) Pays the licensure fee.

Section 7. Section 470.44, Florida Statutes, is created to read:

470.44 Fees.—

(1) The board shall establish by rule a fee not to exceed $100 for an application and a fee not to exceed $300 for an initial license or license renewal.

(2) In establishing fees pursuant to subsection (1), the board shall consider the actual costs incurred in carrying out its duties under this chapter.

(3) All moneys collected by the department under this chapter shall be deposited as provided under s. 456.025.

Section 8. Section 470.45, Florida Statutes, is created to read:

470.45 Disciplinary grounds and actions; reinstatement.—The board may enter an order imposing any of the penalties provided under s. 456.072(2) against a licensee who violates any provision of s. 456.072(1), except that the board may not do any of the following:

(1) Place a licensee on probation for more than 5 years.

(2) Impose a fine that exceeds $2,500.

(3) Suspend a license for more than 5 years.

(4) Limit or restrict a license for an indefinite period.

Section 9. Section 470.47, Florida Statutes, is created to read:

470.47 Violations and penalties.—

(1) Unless licensed or authorized under this chapter, a person who engages in the practice of applied behavior analysis, assists in the practice of applied behavior analysis, renders services designated as applied behavior analysis, or represents himself or herself as a practitioner of applied behavior analysis in this state commits a felony of the third degree, punishable as provided under s. 775.082, s. 775.083, or s. 775.084.

(2) Unless licensed or authorized under this chapter, a person who uses the title "licensed behavior analyst," "licensed

assistant behavior analyst," or any other title that is substantially similar commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083.

Section 10. Section 470.48, Florida Statutes, is created to read:

470.48 Exceptions to applicability.—This chapter does not prohibit or restrict the practice of the following:

(1) An individual licensed under chapter 490 to practice psychology.

(2) A certified teacher authorized to practice in this state who is not a behavior analyst if he or she does not represent himself or herself as a behavior analyst. The services provided by a certified teacher must be within his or her authorized scope of practice and within the scope of his or her education, training, and experience and must be provided in the course of his or her employment in a program approved by the Department of Education. Teaching assistants, other than those engaged in pupil personnel services, and student support professionals are exempt from the requirements of this chapter if they provide applied behavior analysis services under the supervision of a certified teacher who meets the requirements of this paragraph.

(3) A behavior analyst who practices with nonhuman clients, including, but not limited to, applied animal behaviorists and animal trainers.

(4) An individual who teaches applied behavior analysis or who conducts behavior analytic research if such teaching or research does not involve the delivery of applied behavior analysis.

(5) A matriculated college or university student or postdoctoral fellow whose activities are part of a defined behavior analysis program of study, practicum, or intensive practicum if his or her practice under this subsection is directly supervised by a licensed behavior analyst or an instructor of an accredited course sequence approved by the Behavior Analyst Certification Board (BACB). A student or intern may not represent himself or herself as a professional behavior analyst but may use a title indicating his or her trainee status, such as "behavior analyst student," "behavior analyst intern," or "behavior analyst trainee."

(6) An unlicensed individual pursuing supervised experiential training to meet eligibility requirements for BACB certification if such training is supervised by an individual who is licensed to practice applied behavior analysis and who meets BACB supervisor requirements and if the supervised experience is conducted in accordance with other BACB standards and requirements.

(7) A board-certified behavior analyst, a doctoral level board-certified behavior analyst, or an individual licensed to practice applied behavior analysis in another state who resides in another state and provides applied behavior analysis in this

state or to a resident of this state for less than 12 days per year.

(8) A family member of a recipient of applied behavior analysis services who implements certain procedures with the recipient. Such a family member may not represent himself or herself as a professional behavior analyst.

(9) A behavior analyst who provides general behavior analysis services to organizations if the services are for the benefit of the organizations and do not involve direct services to individuals.

(10) A physician licensed pursuant to chapter 458 or chapter 459.

(11) An individual licensed pursuant to chapter 491 as a clinical social worker, marriage and family therapist, or mental health counselor.

(12) A salaried employee of a private, nonprofit organization providing behavior analysis services to children, youth, and families if the services are provided for no charge, the employee is performing duties for which he or she was trained and hired, and the employee does not represent himself or herself as a professional behavior analyst.

(13) A school psychologist certified in school psychology by the Department of Education who performs behavior analysis services as an employee of a public or private educational institution. Such exemption does not authorize unlicensed

practice that is not performed directly as an employee of an educational institution.

(14) A rabbi, priest, minister, or member of the clergy of a religious denomination or sect if engaging in activities that are within the scope of the performance of his or her regular or specialized ministerial duties and for which no separate fee is charged, or if such activities are performed, with or without a fee, for or under the auspices or sponsorship, individually or in conjunction with others, of an established and legally cognizable church, denomination, or sect; and if the person rendering service remains accountable to the established authority thereof.

Section 11. Paragraph (g) of subsection (3) of section 20.43, Florida Statutes, is amended to read:

20.43 Department of Health.—There is created a Department of Health.

(3) The following divisions of the Department of Health are established:

(g) Division of Medical Quality Assurance, which is responsible for the following boards and professions established within the division:

1. The Board of Acupuncture, created under chapter 457.

2. The Board of Medicine, created under chapter 458.

3. The Board of Osteopathic Medicine, created under chapter 459.

4. The Board of Chiropractic Medicine, created under chapter 460.

5. The Board of Podiatric Medicine, created under chapter 461.

6. Naturopathy, as provided under chapter 462.

7. The Board of Optometry, created under chapter 463.

8. The Board of Nursing, created under part I of chapter 464.

9. Nursing assistants, as provided under part II of chapter 464.

10. The Board of Pharmacy, created under chapter 465.

11. The Board of Dentistry, created under chapter 466.

12. Midwifery, as provided under chapter 467.

13. The Board of Speech-Language Pathology and Audiology, created under part I of chapter 468.

14. The Board of Nursing Home Administrators, created under part II of chapter 468.

15. The Board of Occupational Therapy, created under part III of chapter 468.

16. Respiratory therapy, as provided under part V of chapter 468.

17. Dietetics and nutrition practice, as provided under part X of chapter 468.

18. The Board of Athletic Training, created under part XIII of chapter 468.

19. The Board of Orthotists and Prosthetists, created under part XIV of chapter 468.

20. The Board of Applied Behavior Analysis, created under chapter 470.

21.~~20.~~ Electrolysis, as provided under chapter 478.

22.~~21.~~ The Board of Massage Therapy, created under chapter 480.

23.~~22.~~ The Board of Clinical Laboratory Personnel, created under part III of chapter 483.

24.~~23.~~ Medical physicists, as provided under part IV of chapter 483.

25.~~24.~~ The Board of Opticianry, created under part I of chapter 484.

26.~~25.~~ The Board of Hearing Aid Specialists, created under part II of chapter 484.

27.~~26.~~ The Board of Physical Therapy Practice, created under chapter 486.

28.~~27.~~ The Board of Psychology, created under chapter 490.

29.~~28.~~ School psychologists, as provided under chapter 490.

30.~~29.~~ The Board of Clinical Social Work, Marriage and Family Therapy, and Mental Health Counseling, created under chapter 491.

31.~~30.~~ Emergency medical technicians and paramedics, as provided under part III of chapter 401.

Section 12. Subsection (4) of section 456.001, Florida Statutes, is amended to read:

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

(4) "Health care practitioner" means any person licensed under chapter 457; chapter 458; chapter 459; chapter 460; chapter 461; chapter 462; chapter 463; chapter 464; chapter 465; chapter 466; chapter 467; part I, part II, part III, part V, part X, part XIII, or part XIV of chapter 468; chapter 470; chapter 478; chapter 480; part III or part IV of chapter 483; chapter 484; chapter 486; chapter 490; or chapter 491.

Section 13. Section 456.0135, Florida Statutes, is amended to read:

456.0135 General background screening provisions.—

(1) An application for initial licensure received on or after January 1, 2013, under chapter 458, chapter 459, chapter 460, chapter 461, chapter 464, ~~or~~ s. 465.022, or chapter 470 shall include fingerprints pursuant to procedures established by the department through a vendor approved by the Department of Law Enforcement and fees imposed for the initial screening and retention of fingerprints. Fingerprints must be submitted electronically to the Department of Law Enforcement for state processing, and the Department of Law Enforcement shall forward the fingerprints to the Federal Bureau of Investigation for national processing. Each board, or the department if there is no board, shall screen the results to determine if an applicant

meets licensure requirements. For any subsequent renewal of the applicant's license that requires a national criminal history check, the department shall request the Department of Law Enforcement to forward the retained fingerprints of the applicant to the Federal Bureau of Investigation.

(2) All fingerprints submitted to the Department of Law Enforcement as required under subsection (1) shall be retained by the Department of Law Enforcement as provided under s. 943.05(2)(g) and (h) and (3). The department shall notify the Department of Law Enforcement regarding any person whose fingerprints have been retained but who is no longer licensed.

(3) The costs of fingerprint processing, including the cost for retaining fingerprints, shall be borne by the applicant subject to the background screening.

Section 14. This act shall take effect January 1, 2015.

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

Remove everything before the enacting clause and insert: An act relating to behavior analysts; creating ch. 470, F.S.; entitling the chapter; creating s. 470.40, F.S.; providing a purpose; creating s. 470.41, F.S.; defining terms; creating s. 470.415, F.S.; creating the Board of Applied Behavior Analysis; creating s. 470.42, F.S.; specifying the authority and duties of the board; creating s. 470.43, F.S.; providing requirements for

licensure and renewal; creating s. 470.44, F.S.; establishing maximum fees for applications, initial licenses, and license renewals; creating s. 470.45, F.S.; providing grounds for disciplinary action by the board; providing for reinstatement of a license; creating s. 470.46, F.S.; requiring a licensee or his or her employer to report to the board certain felony convictions on the part of a licensee or suspicions that a licensee has committed fraud or deceit; creating s. 470.47, F.S.; providing penalties for practicing applied behavior analysis without a license or wrongfully identifying oneself as a licensed behavior analyst; creating s. 470.48, F.S.; providing exceptions to the chapter; amending s. 456.001, F.S.; including licensed behavior analysts and licensed assistant behavior analysts in the definition of "health care practitioner"; amending s. 456.0135, F.S.; requiring an applicant for licensure under ch. 470, F.S., to submit to certain fingerprinting 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	O'Callaghan
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.

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[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, Aril 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 consent[10] 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 testing[13] 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. CHDs[15] 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:

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[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 law[16] 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.

[16] Section 381.004 (2)(e), F.S.

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

A bill to be entitled

An act relating to HIV testing; amending s. 381.004, F.S.; revising and adding definitions; differentiating between the notification and consent procedures for performing an HIV test in a health care setting and a nonhealth care setting; deleting the exemption from the requirement to obtain informed consent before testing a pregnant woman; amending s. 456.032, F.S.; conforming a cross-reference; providing an effective date.

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

Section 1. Subsection (1), paragraphs (a), (b), (g), and (h) of subsection (2), and paragraph (d) of subsection (4) of section 381.004, Florida Statutes, are amended, and subsection (1) of that section is reordered, to read:

381.004 HIV testing.—

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

(a) "Health care setting" means a setting devoted to both the diagnosis and care of persons, such as 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.

(b) ~~(a)~~ "HIV test" means a test ordered after July 6, 1988,

to determine the presence of the antibody or antigen to human immunodeficiency virus or the presence of human immunodeficiency virus infection.

(c) ~~(b)~~ "HIV test result" means a laboratory report of a human immunodeficiency virus test result entered into a medical record on or after July 6, 1988, or any report or notation in a medical record of a laboratory report of a human immunodeficiency virus test. ~~As used in this section,~~ The term ~~"HIV test result"~~ does not include test results reported to a health care provider by a patient.

(d) "Nonhealth care setting" means a site that conducts HIV testing for the sole purpose of identifying HIV infection. Such setting does not provide medical treatment but may include community-based organizations, outreach settings, county health department HIV testing programs, and mobile vans.

(f) ~~(c)~~ "Significant exposure" means:

1. Exposure to blood or body fluids through needlestick, instruments, or sharps;

2. Exposure of mucous membranes to visible blood or body fluids~~,~~ to which universal precautions apply according to the National Centers for Disease Control and Prevention, including, without limitations, the following body fluids:

a. Blood.

b. Semen.

c. Vaginal secretions.

d. Cerebrospinal ~~Cerebro-spinal~~ fluid (CSF).

e. Synovial fluid.

f. Pleural fluid.

g. Peritoneal fluid.

h. Pericardial fluid.

i. Amniotic fluid.

j. Laboratory specimens that contain HIV (e.g., suspensions of concentrated virus); or

3. Exposure of skin to visible blood or body fluids, especially when the exposed skin is chapped, abraded, or afflicted with dermatitis or the contact is prolonged or involving an extensive area.

(e) ~~(d)~~ "Preliminary HIV test" means an antibody or antibody-antigen screening test, such as the ~~enzyme-linked~~ immunosorbent assays (IA), or a rapid test approved by the federal Food and Drug Administration ~~(ELISAs) or the Single-Use Diagnostic System (SUDS)~~.

(g) ~~(e)~~ "Test subject" or "subject of the test" means the person upon whom an HIV test is performed, or the person who has legal authority to make health care decisions for the test subject.

(2) HUMAN IMMUNODEFICIENCY VIRUS TESTING; INFORMED CONSENT; RESULTS; COUNSELING; CONFIDENTIALITY.—

(a) Before performing an HIV test:

1. In a health care setting, the health care provider shall notify the person to be tested that the test is planned, provide information about the test, and advise the person that

he or she has the right to decline the test. The health care provider shall also explain the right to confidential treatment of information identifying the subject of the test and the results of the test as provided by law. If a person declines the test, the health care provider shall note that fact in the person's medical record. ~~No person in this state shall order a test designed to identify the human immunodeficiency virus, or its antigen or antibody, without first obtaining the informed consent of the person upon whom the test is being performed, except as specified in paragraph (h). Informed consent shall be preceded by an explanation of the right to confidential treatment of information identifying the subject of the test and the results of the test to the extent provided by law. Information shall also be provided on the fact that a positive HIV test result will be reported to the county health department with sufficient information to identify the test subject and on the availability and location of sites at which anonymous testing is performed. As required in paragraph (3)(c), each county health department shall maintain a list of sites at which anonymous testing is performed, including the locations, phone numbers, and hours of operation of the sites. Consent need not be in writing provided there is documentation in the medical record that the test has been explained and the consent has been obtained~~.

2. In a nonhealth care setting, a provider shall obtain the informed consent of the person upon whom the test is being

performed. Informed consent shall be preceded by an explanation of the right to confidential treatment of information identifying the subject of the test and the results of the test as provided by law.

The test subject shall also be informed that a positive HIV test result will be reported to the county health department with sufficient information to identify the test subject and on the availability and location of sites at which anonymous testing is performed. As required in paragraph (3)(c), each county health department shall maintain a list of sites at which anonymous testing is performed, including the locations, telephone numbers, and hours of operation of the sites.

(b) Except as provided in paragraph (h), informed consent must be obtained from a legal guardian or other person authorized by law if ~~when~~ the person:

1. Is not competent, is incapacitated, or is otherwise unable to make an informed judgment; or

2. Has not reached the age of majority, except as provided in s. 384.30.

(g) Human immunodeficiency virus test results contained in the medical records of a hospital licensed under chapter 395 may be released in accordance with s. 395.3025 without being subject to ~~the requirements of~~ subparagraph (e)2., subparagraph (e)9., or paragraph (f) if~~; provided~~ the hospital has notified the patient of the limited confidentiality protections afforded HIV

test results contained in hospital medical records ~~obtained written informed consent for the HIV test in accordance with provisions of this section~~.

(h) Notwithstanding ~~the provisions of~~ paragraph (a), informed consent is not required:

1. When testing for sexually transmissible diseases is required by state or federal law, or by rule including the following situations:

a. HIV testing pursuant to s. 796.08 of persons convicted of prostitution or of procuring another to commit prostitution.

b. HIV testing of inmates pursuant to s. 945.355 before ~~prior to their~~ release from prison by reason of parole, accumulation of gain-time credits, or expiration of sentence.

c. Testing for HIV by a medical examiner in accordance with s. 406.11.

~~d. HIV testing of pregnant women pursuant to s. 384.31.~~

2. Those exceptions provided for blood, plasma, organs, skin, semen, or other human tissue pursuant to s. 381.0041.

3. For the performance of an HIV-related test by licensed medical personnel in bona fide medical emergencies if ~~when~~ the test results are necessary for medical diagnostic purposes to provide appropriate emergency care or treatment to the person being tested and the patient is unable to consent, as supported by documentation in the medical record. Notification of test results in accordance with paragraph (c) is required.

4. For the performance of an HIV-related test by licensed

medical personnel for medical diagnosis of acute illness where, in the opinion of the attending physician, providing notification ~~obtaining informed consent~~ would be detrimental to the patient, as supported by documentation in the medical record, and the test results are necessary for medical diagnostic purposes to provide appropriate care or treatment to the person being tested. Notification of test results in accordance with paragraph (c) is required if it would not be detrimental to the patient. This subparagraph does not authorize the routine testing of patients for HIV infection without notification ~~informed consent~~.

5. If ~~When~~ HIV testing is performed as part of an autopsy for which consent was obtained pursuant to s. 872.04.

6. For the performance of an HIV test upon a defendant pursuant to the victim's request in a prosecution for any type of sexual battery where a blood sample is taken from the defendant voluntarily, pursuant to court order for any purpose, or pursuant to ~~the provisions of~~ s. 775.0877, s. 951.27, or s. 960.003; however, the results of an ~~any~~ HIV test performed shall be disclosed solely to the victim and the defendant, except as provided in ss. 775.0877, 951.27, and 960.003.

7. If ~~When~~ an HIV test is mandated by court order.

8. For epidemiological research pursuant to s. 381.0031, for research consistent with institutional review boards created by 45 C.F.R. part 46, or for the performance of an HIV-related test for the purpose of research, if the testing is performed in

a manner by which the identity of the test subject is not known and may not be retrieved by the researcher.

9. If ~~When~~ human tissue is collected lawfully without the consent of the donor for corneal removal as authorized by s. 765.5185 or enucleation of the eyes as authorized by s. 765.519.

10. For the performance of an HIV test upon an individual who comes into contact with medical personnel in such a way that a significant exposure has occurred during the course of employment or within the scope of practice and where a blood sample is available which ~~that~~ was taken from that individual voluntarily by medical personnel for other purposes. The term "medical personnel" includes a licensed or certified health care professional; an employee of a health care professional or health care facility; employees of a laboratory licensed under chapter 483; personnel of a blood bank or plasma center; a medical student or other student who is receiving training as a health care professional at a health care facility; and a paramedic or emergency medical technician certified by the department to perform life-support procedures under s. 401.23.

a. Before performing ~~Prior to performance of~~ an HIV test on a voluntarily obtained blood sample, the individual from whom the blood was obtained shall be requested to consent to the performance of the test and to the release of the results. If consent cannot be obtained within the time necessary to perform the HIV test and begin prophylactic treatment of the exposed medical personnel, all information concerning the performance of

an HIV test and any HIV test result shall be documented only in the medical personnel's record unless the individual gives written consent to entering this information on the individual's medical record.

b. Reasonable attempts to locate the individual and to obtain consent shall be made, and all attempts must be documented. If the individual cannot be found or is incapable of providing consent, an HIV test may be conducted on the available blood sample. If the individual does not voluntarily consent to the performance of an HIV test, the individual shall be informed that an HIV test will be performed, and counseling shall be furnished as provided in this section. However, HIV testing shall be conducted only after appropriate medical personnel under the supervision of a licensed physician documents, in the medical record of the medical personnel, that there has been a significant exposure and that, in accordance with the written protocols based on the National Centers for Disease Control and Prevention guidelines on HIV postexposure prophylaxis and in the physician's medical judgment, the information is medically necessary to determine the course of treatment for the medical personnel.

c. Costs of an ~~any~~ HIV test of a blood sample performed with or without the consent of the individual, as provided in this subparagraph, shall be borne by the medical personnel or the employer of the medical personnel. However, costs of testing or treatment not directly related to the initial HIV tests or

costs of subsequent testing or treatment may not be borne by the medical personnel or the employer of the medical personnel.

d. In order to use ~~utilize~~ the provisions of this subparagraph, the medical personnel must ~~either~~ be tested for HIV pursuant to this section or provide the results of an HIV test taken within 6 months before ~~prior to~~ the significant exposure if such test results are negative.

e. A person who receives the results of an HIV test pursuant to this subparagraph shall maintain the confidentiality of the information received and of the persons tested. Such confidential information is exempt from s. 119.07(1).

f. If the source of the exposure will not voluntarily submit to HIV testing and a blood sample is not available, the medical personnel or the employer of such person acting on behalf of the employee may seek a court order directing the source of the exposure to submit to HIV testing. A sworn statement by a physician licensed under chapter 458 or chapter 459 that a significant exposure has occurred and that, in the physician's medical judgment, testing is medically necessary to determine the course of treatment constitutes probable cause for the issuance of an order by the court. The results of the test shall be released to the source of the exposure and to the person who experienced the exposure.

11. For the performance of an HIV test upon an individual who comes into contact with medical personnel in such a way that a significant exposure has occurred during the course of

employment or within the scope of practice of the medical personnel while the medical personnel provides emergency medical treatment to the individual; or notwithstanding s. 384.287, an individual who comes into contact with nonmedical personnel in such a way that a significant exposure has occurred while the nonmedical personnel provides emergency medical assistance during a medical emergency. For the purposes of this subparagraph, a medical emergency means an emergency medical condition outside of a hospital or health care facility that provides physician care. The test may be performed only during the course of treatment for the medical emergency.

a. An individual who is capable of providing consent shall be requested to consent to an HIV test before ~~prior to the~~ testing. If consent cannot be obtained within the time necessary to perform the HIV test and begin prophylactic treatment of the exposed medical personnel and nonmedical personnel, all information concerning the performance of an HIV test and its result, shall be documented only in the medical personnel's or nonmedical personnel's record unless the individual gives written consent to entering this information in ~~on~~ the individual's medical record.

b. HIV testing shall be conducted only after appropriate medical personnel under the supervision of a licensed physician documents, in the medical record of the medical personnel or nonmedical personnel, that there has been a significant exposure and that, in accordance with the written protocols based on the

National Centers for Disease Control and Prevention guidelines on HIV postexposure prophylaxis and in the physician's medical judgment, the information is medically necessary to determine the course of treatment for the medical personnel or nonmedical personnel.

c. Costs of any HIV test performed with or without the consent of the individual, as provided in this subparagraph, shall be borne by the medical personnel or the employer of the medical personnel or nonmedical personnel. However, costs of testing or treatment not directly related to the initial HIV tests or costs of subsequent testing or treatment may not be borne by the medical personnel or the employer of the medical personnel or nonmedical personnel.

d. In order to use ~~utilize~~ the provisions of this subparagraph, the medical personnel or nonmedical personnel shall be tested for HIV pursuant to this section or shall provide the results of an HIV test taken within 6 months before ~~prior to~~ the significant exposure if such test results are negative.

e. A person who receives the results of an HIV test pursuant to this subparagraph shall maintain the confidentiality of the information received and of the persons tested. Such confidential information is exempt from s. 119.07(1).

f. If the source of the exposure will not voluntarily submit to HIV testing and a blood sample was not obtained during treatment for the medical emergency, the medical personnel, the

employer of the medical personnel acting on behalf of the employee, or the nonmedical personnel may seek a court order directing the source of the exposure to submit to HIV testing. A sworn statement by a physician licensed under chapter 458 or chapter 459 that a significant exposure has occurred and that, in the physician's medical judgment, testing is medically necessary to determine the course of treatment constitutes probable cause for the issuance of an order by the court. The results of the test shall be released to the source of the exposure and to the person who experienced the exposure.

12. For the performance of an HIV test by the medical examiner or attending physician upon an individual who expired or could not be resuscitated while receiving emergency medical assistance or care and who was the source of a significant exposure to medical or nonmedical personnel providing such assistance or care.

a. HIV testing may be conducted only after appropriate medical personnel under the supervision of a licensed physician documents in the medical record of the medical personnel or nonmedical personnel that there has been a significant exposure and that, in accordance with the written protocols based on the National Centers for Disease Control and Prevention guidelines on HIV postexposure prophylaxis and in the physician's medical judgment, the information is medically necessary to determine the course of treatment for the medical personnel or nonmedical personnel.

b. Costs of an ~~any~~ HIV test performed under this subparagraph may not be charged to the deceased or to the family of the deceased person.

c. For ~~the provisions of~~ this subparagraph to be applicable, the medical personnel or nonmedical personnel must be tested for HIV under this section or must provide the results of an HIV test taken within 6 months before the significant exposure if such test results are negative.

d. A person who receives the results of an HIV test pursuant to this subparagraph shall comply with paragraph (e).

13. For the performance of an HIV-related test medically indicated by licensed medical personnel for medical diagnosis of a hospitalized infant as necessary to provide appropriate care and treatment of the infant if ~~when~~, after a reasonable attempt, a parent cannot be contacted to provide consent. The medical records of the infant must ~~shall~~ reflect the reason consent of the parent was not initially obtained. Test results shall be provided to the parent when the parent is located.

14. For the performance of HIV testing conducted to monitor the clinical progress of a patient previously diagnosed to be HIV positive.

15. For the performance of repeated HIV testing conducted to monitor possible conversion from a significant exposure.

(4) HUMAN IMMUNODEFICIENCY VIRUS TESTING REQUIREMENTS; REGISTRATION WITH THE DEPARTMENT OF HEALTH; EXEMPTIONS FROM REGISTRATION.—No county health department and no other person in

this state shall conduct or hold themselves out to the public as conducting a testing program for acquired immune deficiency syndrome or human immunodeficiency virus status without first registering with the Department of Health, reregistering each year, complying with all other applicable provisions of state law, and meeting the following requirements:

(d) A program in a health care setting shall meet the notification criteria contained in subparagraph (2)(a)1. A program in a nonhealth care setting shall meet all informed consent criteria contained in subparagraph (2)(a)2. ~~The program must meet all the informed consent criteria contained in subsection (2).~~

Section 2. Subsection (2) of section 456.032, Florida Statutes, is amended to read:

456.032 Hepatitis B or HIV carriers.—

(2) Any person licensed by the department and any other person employed by a health care facility who contracts a blood-borne infection shall have a rebuttable presumption that the illness was contracted in the course and scope of his or her employment, provided that the person, as soon as practicable, reports to the person's supervisor or the facility's risk manager any significant exposure, as that term is defined in s. 381.004(1)(f) ~~381.004(1)(e)~~, to blood or body fluids. The employer may test the blood or body fluid to determine if it is infected with the same disease contracted by the employee. The employer may rebut the presumption by the preponderance of the

evidence. Except as expressly provided in this subsection, there shall be no presumption that a blood-borne infection is a job-related injury or illness.

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

COMMITTEE/SUBCOMMITTEE AMENDMENT

Bill No. HB 1225 (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	_____

Committee/Subcommittee hearing bill: Health Quality Subcommittee

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.;