Health Innovation Subcommittee

Tuesday, March 10, 2015
9:00 AM - 11:00 AM
306 HOB

Steve Crisafulli
Speaker

Kenneth Roberson
Chair

Committee Meeting Notice

HOUSE OF REPRESENTATIVES

Health Innovation Subcommittee

Start Date and Time:	Tuesday, March 10, 2015 09:00 am
End Date and Time:	Tuesday, March 10, 2015 11:00 am
Location:	306 HOB
Duration:	2.00 hrs

Consideration of the following bill(s):

HB 269 Experimental Treatments for Terminal Conditions by Pilon
HB 279 Pharmacy by Pigman
HB 555 Pharmacy by Gaetz
HB 601 Statewide Prepaid Dental Program by Magar
HB 749 Continuing Care Communities by Van Zant
HB 999 Ambulatory Surgical Centers by Fitzenhagen
HB 1001 Assisted Living Facilities by Ahern

Pursuant to rule 7.12, the deadline for amendments to bills on the agenda by non-appointed members is 6:00 p.m., Monday, March 9, 2015.

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., Monday, March 9, 2015.

NOTICE FINALIZED on 03/06/2015 15:22 by Iseminger.Bobbye

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 269 Experimental Treatments for Terminal Conditions
SPONSOR(S): Pilon
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Innovation Subcommittee		Tuszynski	Poche
2) Insurance & Banking Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

The Food and Drug Administration (FDA) has regulatory authority over what drugs are marketed and sold within the United States. Investigational or experimental drugs are new drugs that are not approved by the FDA and are in the process of being tested for safety and effectiveness. An investigational drug must go through a lengthy and expensive approval process requiring phased clinical trials. Approval of an investigational drug by the FDA can take as long as 11 years.

The FDA has a procedure to gain access to investigational drugs that have not yet been approved by the FDA known as expanded access. Under the FDA's expanded access scheme, physicians can request an investigational drug for a single patient using an emergency use application. However, this process is considered burdensome, time-consuming, and confusing. In February, the FDA announced a draft application that removes many of the burdensome and time-consuming requirements of the old procedure.

HB 269 creates the "Right to Try Act," which establishes a framework in which a manufacturer may provide a post-phase 1 investigational drug, biological product, or device to an eligible patient with a terminal illness, bypassing the FDA's emergency use expanded access program. The bill defines an eligible patient and a terminal illness. The bill also requires certain information and attestations in a written informed consent document, which must be signed by the patient or the patient's parent, guardian, or health care surrogate and provided to the manufacturer, in order to receive a post-phase 1 investigational drug, biological product, or device.

The bill also protects the licenses of physicians who recommend investigational drugs, biological products, or devices from disciplinary action as a result of making the recommendation. The bill also permits insurers to pay for investigational drugs, but does not require such payment. Lastly, the bill provides liability protection for manufacturers, persons, and entities involved in the use of the investigational drug, biological product, or device pursuant to the provisions of the bill.

The bill does not appear to have a fiscal impact on state or local governments.

The bill provides an effective date of July 1, 2015.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Regulation of Drugs

The U.S. Food and Drug Administration (FDA) has wide regulatory authority over what drugs are marketed and sold within the United States. The Pure Food and Drug Act, passed in 1906, was the genesis of the federal regulation of drugs.[1] The responsibility of enforcing this act was given to the Bureau of Chemistry, later renamed the Food and Drug Administration in 1927.[2] The Federal Food, Drug and Cosmetic Act (FFDCA) was passed in 1938 and gave authority to the FDA to oversee the safety of food, drugs, and cosmetics.[3] In 1962, in the wake of deaths and birth defects from the tranquilizer thalidomide marketed in Europe, Congress passed the Kefauver-Harris Drug Amendments to the FFDCA, increasing safety provisions and requiring that drugs be proven effective as well as safe.[4]

Approval Process

Investigational or experimental drugs are new drugs that have yet to be approved by the FDA, or are approved drugs that have not been approved by the FDA for a new use, and are in the process of being tested for safety and effectiveness. To bring a drug to market, an investigational drug's sponsor, typically a pharmaceutical company or research entity, must go through a lengthy approval process. It can take 11 years[5] from the beginning of the FDA's involvement to bring an investigational drug to market; the average time to market is 8 years.[6] The same process applies to new biological products and devices.

The first step in the process, basic laboratory research, occurs prior to FDA involvement. Research often adds years onto the average time it takes a drug to be approved. Basic laboratory research, often funded by the federal government in federal labs or research universities, investigates chemical components and compounds that may have therapeutic efficacy. If research identifies a component that may be promising as an experimental drug, private industry or private research groups continue development of the drug and begin animal testing. When the drug is ready for human trials, an investigational new drug application (IND) is submitted to the FDA,[7] which includes details on the appropriateness of human testing.[8] Once the IND is approved, the sponsor may begin testing to gather evidence as to the safety and effectiveness of the drug.[9]

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[1] Pure Food and Drug Act of 1906, ch. 3915, 34 Stat. 769 (1906) (Repealed by the Federal Food, Drug, and Cosmetic Act of 1938 [21 U.S.C. Sec 329(a)]), http://www.fda.gov/regulatoryinformation/legislation/ucm148690.htm; The Federal Food and Drugs Act of 1906 is called the "Wiley Act."
[2] Federal Food and Drugs Act of 1906, P.L. 59-384, s. 1.
[3] Food, Drug, and Cosmetic Act of 1938 (21 U.S.C. ch. 9 § 301 et seq.)
[4] Kefaver-Harris Drug Amendments to the FFDCA, P.L. 87-781, (1962)
[5] Christopher P. Adams & Van. V. Brantner, *New Drug Development: Estimating Entry From Human Clinical Trials* 9 (Jul. 7, 2003). Available at http://www.ftc.gov/reports/new-drug-development-estimating-entry-human-clinical-trials
[6] Id.
[7] 21 U.S.C. § 355(i)(1); *see also* 21 C.F.R. pt. 312
[8] 21 C.F.R. § 312.23
[9] 21 U.S.C. § 355(d)(5)

Generally, the investigation into experimental drugs, biological products, and devices is divided into three clinical development trials, detailed in the chart below.[10][11]

CLINICAL TRIAL PHASES			
Phase	**Participants**	**Purpose**	**Average Time**
Phase 1	20-80	This is the initial introduction of a new drug into humans. These studies are typically closely monitored and designed to determine the metabolism and pharmacologic action of the treatment, side effects associated with increased dosage, and if possible, to gain early evidence of effectiveness.	1.7 years
Phase 2	Several Hundred	These are the controlled clinical studies conducted to evaluate the effectiveness of the treatment for a particular indication or indications, and to determine common short-term side effects and risks.	2.4 years
Phase 3	Several Thousand	These are performed after preliminary evidence suggesting effectiveness of the treatment has been obtained from Phase 2. This phase is intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the treatment and to provide an adequate basis for physician labeling.	3.7 years

When a sponsor believes there is "substantial evidence"[12] of safety and effectiveness, they submit a new drug application (NDA) to the FDA for approval.[13] The application must contain full reports of the phased clinical trials detailing the safety and effectiveness of the drug.[14] During the NDA review, the FDA evaluates the clinical trial data, analyzes samples, inspects the facilities where the finished product will be made, and checks the proposed labeling for accuracy.[15] Once the FDA determines that there is substantial evidence of safety and effectiveness, the NDA is approved and the sponsor is allowed to bring the drug to market.

Expanded Access

The FDA established regulations allowing expanded access to, or "compassionate use" of, experimental drugs, biological products, and devices in 1987, and individual patient "emergency use" expanded access in 1997. These regulations provide access to:

1. Individuals on a case-by-case basis, known as "individual patient access";[16]

[10] Supra. at FN 5.
[11] Phase 4 trials are post-approval clinical trials to test the long term effects of investigational drugs, biological products, and devices.
[12] 21 U.S.C. § 355(d)(5)
[13] 21 U.S.C. § 355(a)
[14] Id. at § 355(b)(1)(a)
[15] Supra. at FN 5.
[16] U.S. Food and Drug Administration, *Expanded Access Categories for Drugs*, http://www.fda.gov/NewsEvents/PublicHealthFocus/ExpandedAccessCompassionateUse/ucm431774.htm. (last visited March 4, 2015).

2. Intermediate sized groups of patients with similar treatment needs who otherwise do not qualify to participate in a clinical trial;[17] and
3. Large groups of patients who do not have other treatment options available.[18]

The access routes for intermediate and large groups are essentially expanded clinical trials. If enough patients are outside of the geographical area of a clinical trial, or were unable to meet the criteria of the specific trial, the FDA can approve concurrent trials.

Individual patient access includes "emergency use." Emergency use requests can be made by phone or other means of electronic communication. A patient may start using the investigational drug, biological product, or device immediately upon FDA authorization of the request.[19] The written emergency use request must be received by the FDA within 15 business days of the telephone authorization.[20] The written emergency use request requires physicians to submit 26 distinct fields of information and seven attachments.[21] This process can take upwards of 100 hours to gather and submit the required information.[22]

The FDA reviews emergency use requests and makes the determination whether to approve the request based on the following factors:

- The patient has a serious or immediately life-threatening disease or condition, and there is no comparable or satisfactory alternative therapy.[23]
- The potential benefit justifies the potential risks, and that those risks are not unreasonable.[24]
- Provision of the treatment will not interfere with the initiation, conduct, or completion of clinical investigations that could support marketing approval of the expanded access use or otherwise compromise the development of the expanded access use.[25]
- A determination by the patient's physician that the probable risk to the person is not greater than the risk of the disease or condition.[26]
- A determination by the FDA that the patient cannot obtain the treatment under another IND or protocol.[27]

Between October 1, 2013 and September 30, 2014, the FDA approved 1,066 of the 1,069 emergency use requests it received. [28]

"Right to Try" Laws and FDA Response

Five states have passed laws in the past 12 months allowing terminally ill patients access to experimental drugs outside of the FDA's normal regulatory scheme:

- Colorado[29]
- Louisiana[30]

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[17] 21 U.S.C. § 312.315
[18] Id. at § 312.320
[19] Jacobson, PD, Parmet WE. A New Era of Unapproved Drugs: The Case of Abigail Alliance v. Von Eschenbach. *JAMA*. 2007;297(2):206.
[20] Id.
[21] Peter Lurie, M.D., M.P.H., *A Big step to help the patients most in need*, FDA Voice, February 4, 2015, *available at* http://blogs.fda.gov/fdavoice/index.php/tag/individual-patient-expanded-access-applications-form-fda-3926/. (last visited February 17, 2015).
[22] Id.
[23] 21 U.S.C. § 312.305(a)(1)
[24] Id. at § 312.305(a)(2)
[25] Id. at § 312.305(a)(3)
[26] Id. at § 312.310(a)(1)
[27] Id. at § 312.310(a)(2)
[28] Expanded Access Submission Receipts Report: Oct 1, 2013 - Sep 30, 2014, http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/DrugandBiologicApprovalReports/INDActivityReports/UCM430188.pdf (last viewed February 10, 2015).
[29] Colo. R.S.A. §§ 25-45-101 to -108
[30] La. R.S. § 1300.381-386

- Missouri[31]
- Arizona[32]
- Michigan[33]

These state laws allow, but do not require, manufacturers of experimental treatments to make these treatments available to eligible patients with terminal illnesses. The laws also require written informed consent from patients stating that they are aware of the dangers associated with the experimental treatment. The laws also include provisions that protect the licenses of physicians who recommend or prescribe experimental treatments; exempt insurers from having to pay for experimental treatment; and provide liability protection to manufacturers and distributors of experimental treatments.

On February 4, 2015, the FDA issued new draft guidance for Individual Patient Expanded Access, or "compassionate use", applications. The draft guidance addresses a new "compassionate use" form, a streamlined alternative for submitting an IND application for use in cases requesting individual patient expanded access to an investigational drug, biological product, or device. The old form, FDA 1571, was designed for large experimental drug sponsors and manufacturers to apply for expanded access, not physicians.[34] The new form, FDA 3926, is designed for physicians seeking authorization on behalf of an individual patient. The form requires only eight distinct fields of information and one attachment.[35] The FDA estimates that it will take approximately 45 minutes to complete the new form.[36]

Abigail Alliance Case

In 1999, Abigail Burroughs, a 19 year old college student, was diagnosed with head and neck cancer. Despite undergoing chemotherapy and radiation therapy, her tumor showed increased expression of the cell surface membrane receptor EGFR[37]. She did not meet the inclusion criteria for either of the two clinical trials targeting EGFR at the time. Shortly after her death in 2001, her father formed the Abigail Alliance for Better Access to Developmental Drugs[38] and, in 2003, sued the FDA. The Abigail Alliance argued that terminal cancer patients have a constitutional right to experimental drugs, positing self-defense theories as well as 5th amendment substantive due process claims, and that the FDA should grant access to experimental drugs for use by terminally ill patients.

In 2007, after years of protracted litigation, the U.S. Court of Appeals for the District of Columbia, sitting *en banc*, upheld the previous trial court decision finding no constitutional right to unapproved drugs by terminally ill patients. The Supreme Court of the United States declined to review the case.

Dispensing in an Approved Clinical Trial in Florida

Section 465.0276, F.S., limits dispensing to a licensed pharmacist, unless otherwise authorized by the statute. The statute allows dispensing pursuant to an approved clinical trial.[39] An "approved clinical trial" is defined as a clinical research study or clinical investigation that, in whole or in part, is state or federally funded or is conducted under an investigational new drug application that is reviewed by the FDA.[40]

[31] V.A. Mo. S. § 191.480
[32] Ariz. R.S.A. §36-1311 to -1314
[33] Mich. C.L.A. §§ 16221, 26451
[34] Supra. at FN 20.
[35] Id.
[36] Id.
[37] Supra. at FN 18.
[38] Id.
[39] S. 465.0276(1)(b)(4), F.S.
[40] S. 465.0276(1)(b)(4), F.S.

Effect of Proposed Changes

HB 269 creates the "Right to Try Act" (Act), establishing a framework in which a manufacturer may provide an investigational drug, biological product, or device to an eligible patient with a terminal illness without utilizing the FDA's emergency use expanded access program.

The bill defines the following terms as used in the Act:

- An "eligible patient" is a person with a terminal illness, attested to by the patient's treating physician, who has considered all other approved treatment options currently available, has given written informed consent, and has documentation from his or her physician that the patient meets the requirements of the Act.
- An "investigational drug, biological product, or device" is any drug, biological product, or device that has successfully completed a phase 1 clinical trial, is currently undergoing an approved clinical trial, and has not yet been approved for general use by the FDA.
- A "terminal illness" is a progressive disease or medical or surgical condition that causes significant functional impairment, is not considered reversible with the available treatments currently approved by the FDA, and, without the administration of life-sustaining procedures, will result in death.

The bill requires the patient, a parent of a minor patient, a court-appointed guardian for the patient, or a health care surrogate designated by the patient to provide written informed consent prior to accessing an investigational drug, biological product, or device under the Act. The written informed consent must include:

- An explanation of the currently approved products and treatments for the patient's disease or condition;
- An attestation that the patient agrees with his or her physician in believing that all currently approved treatments are unlikely to prolong the patient's life;
- The specific name of the investigational drug, biological product, or device;
- A description, based on the physician's knowledge of the proposed treatment and the patient's condition, of:
    - The best and worst outcomes of use of the investigational drug, biological product, or device; and
    - A realistic description of the most likely outcome, detailing the possibility of unanticipated or worse symptoms.
- A statement that death could be hastened by use of the investigational drug, biologic product, or device.
- A statement that the patient's health plan or third-party administrator and health care provider are not obligated to pay for treatment consequent to the use of the investigational drug, biological product, or device, unless required to do so by law;
- A statement that the patient's eligibility for hospice care may be withdrawn if the patient begins curative treatment, and reinstated if curative treatment ends and the patient meets hospice eligibility requirements; and
- A statement that the patient understands that he or she is liable for all expenses consequent to the use of the investigational drug, biological product, or device and that this liability extends to the patient's estate, unless negotiated otherwise.

There is no obligation on the part of any manufacturer to provide a requested investigational drug, biologic product, or device under the Act, but a manufacturer may do so with or without compensation. The eligible patient may be required to pay the costs of, or associated with, the manufacture of the investigational drug, biological product, or device.

The bill allows a health plan, third-party administrator, or governmental agency to cover the cost of an investigational drug, biological product, or device. The bill does not mandate insurance coverage for an investigational drug, biological product, or device, nor does it affect any mandatory coverage for participation in clinical trials.

The bill states that health care facilities are not required to provide new or additional services associated with a patient's use of an investigational drug, biologic product, or device under the Act, unless it is approved by the health care facility.

The bill exempts a patient's heirs from any outstanding debt associated with the patient's use of the investigational drug, biological product, or device.

The bill prohibits a regulatory board from revoking, suspending, or denying renewal of a health care provider's license based solely on the provider's recommendation to an eligible patient regarding access to or treatment with an investigational drug, biological product, or device. The bill also prohibits action against a health care provider's Medicare certification for the same reason.

The bill prohibits the state from blocking or attempting to block an eligible patient's access to an investigational drug.

The bill states that the Act does not create a private cause of action against a manufacturer, person, or entity involved in the use of an investigational drug, biological product, or device by an eligible patient for any harm as a result of that use, as long as the manufacturer, person, or entity complies in good faith with the Act and exercises reasonable care.

The bill provides an effective date of July 1, 2015

B. SECTION DIRECTORY:

Section 1: Creates s. 499.0295, relating to the "Right to Try Act" and access to investigational drugs.

Section 2: Provides for an effective date.

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:

The bill permits manufacturers of investigational drugs, biologic products, and devices to provide such drugs, products, and devices to terminally ill patients without the approval of the FDA. A manufacturer can track the safety and effectiveness of the drug, biologic product, or device on a human subject much earlier than through the traditional FDA approval process, which may quicken the development process and the shorten the amount of time it takes for a drug, biologic product, or device to get to market.

The bill also permits a manufacturer to charge a terminally ill patient for use of the investigational drug, biologic product, or device.

The bill provides liability protection to manufacturers, persons, and entities involved with the use of an investigational drug, biologic product, or device.

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:

Access to and use of investigational drugs are controlled by the FDA through the "expanded access" provisions of 21 U.S.C. §360bbb and 21 C.F.R. 312. The language of this bill creates a framework that bypasses this federal regulatory scheme.

B. RULE-MAKING AUTHORITY:

Not applicable.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The bill language protects a physician's license and Medicare certification from action for recommending an investigational drug, biological product, or device, but not for administering the same investigational drug, biological product, or device.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to experimental treatments for terminal conditions; creating s. 499.0295, F.S.; providing a short title; providing definitions; providing conditions for a manufacturer to provide certain drugs, products, or devices to a patient; specifying insurance coverage requirements and exceptions; providing conditions for provision of certain services by a hospital or health care facility; providing immunity from liability; providing protection from disciplinary or legal action against a health care provider who makes certain treatment recommendations; prohibiting state interference with a patient's access to certain drugs, products, or devices; providing that a cause of action may not be asserted against the manufacturer of certain drugs, products, or devices or a person or entity caring for a patient using such drug, product, or device; providing applicability; providing an effective date.

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

Section 1. Section 499.0295, Florida Statutes, is created to read:

499.0295 Experimental treatments for terminal conditions.—

(1) This section may be cited as the "Right to Try Act."

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

(a) "Eligible patient" means a person who:

1. Has a terminal illness, attested to by the patient's treating physician.

2. Has considered all other treatment options currently approved by the United States Food and Drug Administration.

3. Has given written, informed consent for the use of an investigational drug, biological product, or device.

4. Has documentation from his or her physician that the patient meets the requirements of this paragraph.

(b) "Investigational drug, biological product, or device" means a drug, biological product, or device that has successfully completed phase 1 of a clinical trial but has not been approved for general use by the United States Food and Drug Administration and remains under investigation in a clinical trial approved by the United States Food and Drug Administration.

(c) "Terminal illness" means a progressive disease or medical or surgical condition that causes significant functional impairment, is not considered by a treating physician to be reversible even with the administration of available treatments currently approved by the United States Food and Drug Administration, and, without the administration of life-sustaining procedures, will soon result in death.

(d) "Written informed consent" means a document that is signed by the patient, a parent of a minor patient, a court-

appointed guardian for the patient, or a health care surrogate designated by the patient. Written informed consent must include:

1. An explanation of the currently approved products and treatments for the disease or condition from which the patient suffers.

2. An attestation that the patient concurs with his or her physician in believing that all currently approved and conventionally recognized treatments are unlikely to prolong the patient's life.

3. Clear identification of the specific proposed investigational drug, biological product, or device that the patient is seeking to use.

4. A description of the potentially best and worst outcomes of using the investigational drug, biological product, or device and a realistic description of the most likely outcome. The description shall include the possibility that new, unanticipated, different, or worse symptoms might result and that death could be hastened by the proposed treatment. The description shall be based on the physician's knowledge of the proposed treatment in conjunction with an awareness of the patient's condition.

5. A statement that the patient's health plan or third-party administrator and health care provider are not obligated to pay for care or treatment consequent to the use of the investigational drug, biological product, or device unless they

are specifically required to do so by law or contract.

6. A statement that the patient's eligibility for hospice care may be withdrawn if the patient begins curative treatment with the investigational drug, biological product, or device and that hospice care may be reinstated if this treatment ends and the patient meets hospice eligibility requirements.

7. A statement that the patient understands that he or she is liable for all expenses consequent to the use of the investigational drug, biological product, or device and that this liability extends to the patient's estate, unless a contract between the patient and the manufacturer of the investigational drug, biological product, or device states otherwise.

(3) A manufacturer may make available, and an eligible patient may request, the manufacturer's investigational drug, biological product, or device under this section. A manufacturer is not required to make an investigational drug, biological product, or device available to a patient.

(4) A manufacturer may:

(a) Provide an investigational drug, biological product, or device to an eligible patient without receiving compensation.

(b) Require an eligible patient to pay the costs of, or the costs associated with, the manufacture of the investigational drug, biological product, or device.

(5) A health plan, third-party administrator, or governmental agency may provide coverage for the cost of, or the

cost of services related to the use of, an investigational drug, biological product, or device.

(6) A governmental agency is not required to pay the costs associated with providing an investigational drug, biological product, or device or the care or treatment of a patient who uses such drug, product, or device.

(7) A hospital or health care facility licensed under chapter 395 is not required to provide new or additional services unless those services are approved by the hospital or health care facility.

(8) If a patient dies while being treated by an investigational drug, biological product, or device, the patient's heirs are not liable for any outstanding debt related to the treatment or lack of insurance due to the treatment.

(9) A licensing board or disciplinary subcommittee may not revoke, fail to renew, suspend, or take any action against a health care provider's license issued under chapter 458 or chapter 459 based solely on the health care provider's recommendations to an eligible patient regarding access to or treatment with an investigational drug, biological product, or device. An entity responsible for Medicare certification may not take action against a health care provider's Medicare certification based solely on the health care provider's recommendation that a patient have access to an investigational drug, biological product, or device.

(10) An official, employee, or agent of the state may not

block or attempt to block an eligible patient's access to an investigational drug, biological product, or device. Counseling, advice, or a recommendation consistent with medical standards of care from a licensed health care provider is not a violation of this section.

(11) This section does not create a private cause of action against the manufacturer of an investigational drug, biological product, or device; against a person or entity involved in the care of an eligible patient who is using the investigational drug, biological product, or device; or for any harm to the eligible patient that is a result of the use of the investigational drug, biological product, or device if the manufacturer or other person or entity complies in good faith with the terms of this section and exercises reasonable care.

(12) This section does not expand the coverage an insurer must provide under the Florida Insurance Code.

(13) This section does not affect mandatory health care coverage for participation in clinical trials.

Section 2. This act shall take effect July 1, 2015.

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 Innovation Subcommittee

Representative Pilon offered the following:

Amendment (with title amendment)

Remove everything after the enacting clause and insert:

Section 1. Section 499.0295, Florida Statutes, is created to read:

499.0295 Experimental treatments for terminal conditions.—

(1) This section may be cited as the "Right to Try Act."

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

(a) "Eligible patient" means a person who:

1. Has a terminal condition, attested to by the patient's physician, and confirmed by a second independent evaluation by a board-certified physician in an appropriate specialty for that condition;

2. Has considered all other treatment options for the terminal condition currently approved by the United States Food and Drug Administration;

3. Has given written informed consent for the use of an investigational drug, biological product, or device; and

4. Has documentation from his or her treating physician that the patient meets the requirements of this paragraph.

(b) "Investigational drug, biological product, or device" means a drug, biological product, or device that has successfully completed phase 1 of a clinical trial but has not been approved for general use by the United States Food and Drug Administration and remains under investigation in a clinical trial approved by the United States Food and Drug Administration.

(c) "Terminal condition" means a progressive disease or medical or surgical condition that causes significant functional impairment, is not considered by a treating physician to be reversible even with the administration of available treatment options currently approved by the United States Food and Drug Administration, and, without the administration of life-sustaining procedures, will result in death within one year of diagnosis if the condition runs its normal course.

(d) "Written informed consent" means a document that is signed by a patient, a parent of a minor patient, a court-appointed guardian for a patient, or a health care surrogate designated by a patient and includes:

1. An explanation of the currently approved products and treatments for the patient's terminal condition.

2. An attestation that the patient concurs with his or her physician in believing that all currently approved products and treatments are unlikely to prolong the patient's life.

3. Identification of the specific investigational drug, biological product, or device that the patient is seeking to use.

4. A realistic description of the most likely outcomes of using the investigational drug, biological product, or device. The description shall include the possibility that new, unanticipated, different, or worse symptoms might result and death could be hastened by the proposed treatment. The description shall be based on the physician's knowledge of the proposed treatment for the patient's terminal condition.

5. A statement that the patient's health plan or third-party administrator and physician are not obligated to pay for care or treatment consequent to the use of the investigational drug, biological product, or device unless required to do so by law or contract.

6. A statement that the patient's eligibility for hospice care may be withdrawn if the patient begins treatment with the investigational drug, biological product, or device and that hospice care may be reinstated if the treatment ends and the patient meets hospice eligibility requirements.

7. A statement that the patient understands he or she is liable for all expenses consequent to the use of the investigational drug, biological product, or device and that liability extends to the patient's estate, unless a contract between the patient and the manufacturer of the investigational drug, biological product, or device states otherwise.

(3) Upon the request of an eligible patient, a manufacturer may:

(a) Make available the manufacturer's investigational drug, biological product, or device under this section.

(b) Provide an investigational drug, biological product, or device to an eligible patient without receiving compensation.

(c) Require an eligible patient to pay the costs of, or the costs associated with, the manufacture of the investigational drug, biological product, or device.

(4) A health plan, third-party administrator, or governmental agency may provide coverage for the cost of, or the cost of services related to the use of, an investigational drug, biological product, or device.

(5) A hospital or health care facility licensed under chapter 395 is not required to provide new or additional services unless those services are approved by the hospital or health care facility.

(6) If an eligible patient dies while using an investigational drug, biological product, or device pursuant to this section, the patient's heirs are not liable for any

outstanding debt related to the patient's use of the investigational drug, biologic product, or device.

(7) A licensing board may not revoke, fail to renew, suspend, or take any action against a physician's license issued under chapter 458 or chapter 459 based solely on the physician's recommendations to an eligible patient regarding access to or treatment with an investigational drug, biological product, or device. A state entity responsible for Medicare certification may not take action against a physician's Medicare certification based solely on the physician's recommendation that an eligible patient have access to an investigational drug, biological product, or device.

(8) There shall be no liability on the part of, and no cause of action of any nature shall arise against, any person, including a physician, pharmacist, manufacturer, or distributor who possesses, stores, or administers an investigational drug, biological product, or device in compliance with this section. Such immunity does not apply to any willful tort.

(9) This section does not expand the coverage an insurer must provide under the Florida Insurance Code and does not affect mandatory health coverage for participation in clinical trials.

Section 2. This act shall take effect July 1, 2015.

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

Amendment No.

Remove everything before the enacting clause and insert:

A bill to be entitled

An act relating to experimental treatments for terminal conditions; creating s. 499.0295, F.S.; providing a short title; providing definitions; providing conditions for a manufacturer to provide certain drugs, products, or devices to an eligible patient; specifying insurance coverage requirements and exceptions; providing conditions for provision of certain services by a hospital or health care facility; providing immunity from liability; providing protection from disciplinary or legal action against a physician who makes certain treatment recommendations; providing that a cause of action may not be asserted against the manufacturer of certain drugs, products, or devices or a person or entity caring for a patient using such drug, product, or device; providing applicability; providing an effective date.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 279 Pharmacy
SPONSOR(S): Pigman
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Innovation Subcommittee		Castagna	Poche
2) Health & Human Services Committee			

SUMMARY ANALYSIS

Section 465.189, F.S., authorizes pharmacists to administer the influenza, pneumococcal, meningococcal, and shingles vaccines to adults within an established protocol with a supervising physician. Before administering a vaccine, a pharmacist must apply to the Board of Pharmacy (Board), under the Department of Health's (DOH) Division of Medical Quality Assurance, for immunization certification and pay a $55 fee. To obtain certification, a pharmacist must demonstrate that he or she has successfully completed a Board-approved 20-hour vaccine administration certification program regarding the safe and effective administration of vaccines.

HB 279 adds the following vaccines to the list of vaccines a certified pharmacist may provide:

- Vaccines listed in the Centers for Disease Control and Prevention's (CDC) Adult Immunization Schedule (Schedule);
- Vaccines listed in the CDC's Health Information for International Travel; and
- Vaccines approved by the Board in response to a state of emergency declared by the Governor.

The bill authorizes pharmacy interns to administer vaccines upon completion of a 20-hour Board-approved vaccine administration certification program and payment of a $55 fee. A pharmacy intern must be under the supervision of a pharmacist to be authorized to administer vaccines.

The bill has a significant positive fiscal impact on the DOH.

The bill provides an effective date of July 1, 2015.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current situation

Department of Health – Division of Medical Quality Assurance

The Department of Health's (DOH) Division of Medical Quality Assurance (MQA) regulates health care practitioners to ensure the health, safety and welfare of the public. There are 22 boards and 8 councils under the MQA, and the MQA licenses 7 types of facilities and 200-plus occupations in more than 40 health care professions.[1] MQA is responsible for the licensure of health care practitioners and facilities, the enforcement of law and rules governing practitioners and facilities, and providing information and data to the public.[2]

Boards

A board is a statutorily created entity that is authorized to exercise regulatory or rulemaking authority over practitioners within the MQA.[3] A board is responsible for approving or denying applications for licensure and making disciplinary decisions on whether a health care practitioner is acting within the authority of the applicable practice act. Practice acts refer to the legal authority in state statute that grants a profession the authority to provide services to the public. The range of disciplinary actions taken by a board includes citations, suspensions, reprimands, probations, and revocations.

Pharmacy Practice in Florida

Chapter 465, F.S., governs the practice of pharmacy in Florida. The Board of Pharmacy (Board) is authorized to adopt rules to implement the provisions of the Florida Pharmacy Act.[4]

Section 465.003(13), F.S., defines the "practice of the profession of pharmacy" to include:

- Compounding, dispensing, and consulting concerning contents, therapeutic values, and uses of any medicinal drug;
- Consulting concerning therapeutic values and interactions of patent and proprietary preparations, whether pursuant to prescriptions or in the absence and entirely independent of such prescriptions or orders;
- Any other act, service, operation, research, or transaction incidental to any authorized acts involving or employing the practice or science of the pharmaceutical profession, study, or training; and
- Transmitting information from persons authorized to prescribe medicinal drugs to their patients.

To become a licensed pharmacist, a person must submit:

- An application form and the required fees to DOH;
- Satisfactory proof that the applicant:
    - Is at least 18 years of age;
    - Received a degree from an accredited school or college of pharmacy; or

[1] Florida Department of Health, *Florida Health Source*, accessible at http://www.flhealthsource.gov/ (last visited February 20, 2015).
[2] Id.
[3] S. 456.001, F.S.
[4] S. 465.005, F.S.

    - Graduated from a 4-year undergraduate pharmacy program of a school or college of pharmacy located outside the United States, has demonstrated proficiency in English, has passed the Foreign Pharmacy Graduate Equivalency Examination, and
    - Has completed a minimum of 500 hours in a supervised work activity program within Florida under the supervision of a pharmacist licensed by the DOH;
- Satisfactory proof that the applicant has completed an internship program, which must not exceed 2,080 hours; and
- Proof of successful completion of the licensure examination.[5]

A pharmacy license is renewed every two years by submitting an application, paying a $205 renewal fee, [6][7] and submitting proof of completion of at least 30 hours of continuing professional pharmaceutical education during the two years prior to application for renewal.[8] If a pharmacist is certified to administer vaccines, 3 completed continuing education hours must cover the safe and effective administration of vaccines and epinephrine autoinjection.[9]

Florida Pharmacy Interns

To become a pharmacy intern, a person must be certified by the Board as enrolled in an intern program at an accredited school or college of pharmacy or as a graduate of an accredited school or college of pharmacy and not yet licensed as a pharmacist in Florida.[10] The Board's rules outline the registration process for pharmacy interns and the internship program requirements for U.S. pharmacy students or graduates and foreign pharmacy graduates.[11] There were 10,319 registered pharmacy interns in 2014.[12]

A pharmacist is responsible for any delegated act performed by a registered pharmacy intern employed or supervised by the pharmacist.[13]

Requirements for Pharmacist Vaccine Administration

A pharmacist may become certified to administer the influenza, pneumococcal, meningococcal, and shingles vaccine to adults within an established protocol under a licensed supervising physician. A pharmacist is permitted to administer epinephrine to treat any allergic reaction resulting from a vaccine. The protocol between the pharmacist and the supervising physician dictates which types of patients to whom the pharmacist may administer allowable vaccines.[14] The terms, scope, and conditions set forth in the protocol must be appropriate to the pharmacist's training and certification. A supervising physician must review the administration of vaccines by the pharmacist.[15] A pharmacist is required to provide the Board a copy of the protocol.[16]

To be certified to administer vaccines, a pharmacist must successfully complete a Board-approved vaccine administration certification program. The certification program requires pharmacists to submit an application, pay a $55 fee to the Board, and complete 20 hours of Board-approved continuing education classes.[17] The continuing education classes must cover:

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[5] S. 465.007, F.S.
[6] Florida Board of Pharmacy, *Pharmacist*, available at http://floridaspharmacy.gov/renewals/pharmacist/ (last visited March 7, 2015).
[7] S. 465.008(1), F.S.
[8] S. 465.009, F.S.
[9] S. 465.009(6)(a), F.S.
[10] S. 465.013, F.S.
[11] Rule 64B16-26.2032, F.A.C. (U.S. pharmacy students/graduates); Rule 64B16-26.2033, F.A.C. (foreign pharmacy graduates).
[12] Florida Dep't of Health, *2015 Agency Legislative Bill Analysis HB 279,* February 9, 2015 (on file with committee staff).
[13] Rule 64B16-27.430, F.A.C.
[14] S. 465.189(7), F.S.
[15] Id.
[16] Id.
[17] Rule 64B16-26.1031, F.A.C.

- Mechanisms of action for vaccines, contraindications, drug interactions, and monitoring after vaccine administration;
- Immunization schedules;
- Immunization screening questions, provision of risk/benefit information, informed consent, recordkeeping, and electronic reporting into the statewide immunization registry maintained by DOH;
- Vaccine storage and handling;
- Bio-hazardous waste disposal and sterile technique;
- Entering, negotiating, and performing pursuant to physician oversight protocols;
- Community immunization resources and programs;
- Identifying, managing and responding to adverse incidents including but not limited to potential allergic reactions associated with vaccine administration;
- Procedures and policies for reporting adverse incidents to the Vaccine Adverse Event Reporting System;
- Reimbursement procedures and vaccine coverage by federal, state, and local governmental jurisdictions and private third party payers;
- Administration techniques;
- Administration of epinephrine using an autoinjector delivery system;
- Current CDC immunization guidelines and recommendations for influenza, pneumococcal, meningococcal, and shingles vaccinations;
- Review of the current law permitting a pharmacist to administer vaccinations and epinephrine; and
- CPR training.[18]

A pharmacist must also pass an examination and demonstrate vaccine administration technique.[19]

Pharmacists who are certified to administer vaccines must also maintain at least $200,000 of professional liability insurance.[20] A certified pharmacist is required to report all administered vaccinations to the state registry of immunization information, Florida SHOTS.[21] Approximately 11,323, or 37 percent, of active licensed pharmacists in Florida are certified to administer vaccines.[22]

Other State Laws on Pharmacist Vaccination

In the United States pharmacists are authorized to administer vaccinations in addition to traditional roles such as medication preparation and dispensing. Pharmacists are typically required to complete specific certification or training in the administration of vaccines prior to authorization. Depending on patient age and vaccine type, most states require pharmacists to have formal permission to administer certain vaccines.[23] Some states require a patient-specific prescription, a protocol with a supervising physician or public health official, or both, before a pharmacist can administer certain vaccinations.[24]

All 50 states have laws authorizing pharmacists to administer vaccines to adults.[25] Forty two states authorize pharmacists to administer all Centers for Disease Control and Prevention (CDC)

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[18] Id.
[19] Id.
[20] S. 465.189(3), F.S.
[21] Florida SHOTS is a statewide centralized online immunization registry that assists health-care providers and schools in keeping track of immunization records administered by the Florida Dep't of Health. Florida Shots, *Florida SHOTS Facts,* accessible at http://www.flshots.com/what/ (last visited March 4, 2015).
[22] Supra at FN 12.
[23] Association of State and Territorial Health Officials, *Pharmacy Legal Toolkit,* accessible at http://www.astho.org/infectious-disease/pharmacy-legal-toolkit/.(last visited March 2, 2015).
[24] Id.
[25] Id.

recommended vaccines.[2627] Eight states, including Florida, limit pharmacists' vaccination authority to only a few CDC recommended vaccines. In addition, 39 states and U.S. territories allow pharmacy interns to administer vaccines under the supervision of a pharmacist.[28]

CDC Immunization Recommendations

Advisory Committee on Immunization Practices

Since 1964, the Advisory Committee on Immunization Practices (ACIP) has provided guidance on immunization policy to the CDC. ACIP members are selected by the Secretary of the U.S. Department of Health and Human Services and have expertise in fields such as vaccinology, immunology, pediatrics, internal medicine, and infectious disease. ACIP guidance includes scheduling of vaccine doses, specific risk groups for whom vaccinations are recommended, and vaccine contraindications and precautions. [29]

Adult Immunization Schedule

ACIP annually issues the Adult Immunization Schedule (Schedule) which is the official federal guideline for the use of vaccines in the United States.[30] The Schedule provides a summary of ACIP [31] recommendations for vaccines routinely administered to adults and ensures current vaccination practices for specific indications such as age, immunosuppressant medical conditions, pregnancy, and chronic diseases.

Although some vaccines listed on the Schedule have been recommended since the 1940s, the official, annually endorsed Schedule was not introduced until 1995.[32] The Schedule has been continuously updated as more vaccines are developed. The current version of the Schedule, issued February 2015, includes the following vaccines: [33]

- Influenza;
- Tetanus, diphtheria, pertussis (Td/Tdap), a combination vaccine, which prevents disease complications such as: [34]
    - Whooping cough, a highly contagious infection that can lead to pneumonia;
    - Lockjaw and muscle spasms; and
    - Breathing problems;
- Varicella, which prevents chickenpox;[35]

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[26] Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, District of Columbia, Delaware, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Massachusetts, Maryland, Maine, Michigan, Minnesota, Mississippi, Montana, Nebraska, Nevada, New Jersey, New Mexico, North Carolina, North Dakota, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Utah, Vermont, Virginia, Washington, and Wisconsin allow pharmacists to administer any CDC recommended vaccine. American Pharmacists Association, *Pharmacist Administered Vaccines,* available at http://www.pharmacist.com/types-vaccines-pharmacists-are-authorized-administer (last visited March 3, 2015).

[27] Association of State and Territorial Health Officials, *2013 State Immunization Legislation Summary,* available at http://www.astho.org/Programs/Immunization/Legislative-Tracking/ (last visited March 3, 2015).

[28] Supra at FN 26.

[29] Centers for Disease Control and Prevention, *Structure, Role, and Procedures of the ACIP,* available at http://www.cdc.gov/vaccines/acip/committee/structure-role.html (last visited March 5, 2015).

[30] Immunization Action Coalition, *Vaccine Policy and Licensing,* available at http://www.immunize.org/vacpolicy/ (last visited February 13, 2015).

[31] The Schedule is also endorsed by the American Academy of Family Physicians, The American College of Physicians, American College of Obstetricians and Gynecologists and American College of Nurse-Midwives.

[32] College of Physicians of Philadelphia, *The History of Vaccines, The Development of the Immunization Schedule,* available at http://www.historyofvaccines.org/content/articles/development-immunization-schedule (last visited February 13, 2015).

[33] Centers for Disease Control and Prevention, *Adult Immunization Schedules*, available at http://www.cdc.gov/vaccines/schedules/hcp/adult.html (last visited March 4, 2015).

[34] There are 4 combination vaccines used to prevent diphtheria, tetanus, and pertussis. DTap and DT are given to children under 7 and Tdap and Td are given to older children and adults. Centers for Disease Control and Prevention, *Tetanus (Lockjaw) Vaccination,* available at http://www.cdc.gov/vaccines/vpd-vac/tetanus/ (last visited March 4, 2015).

[35] Varicella vaccines are recommended for adults who have never had chickenpox or shingles. Supra at FN 33.

- Human Papillomavirus (for females and males), which prevents cervical cancer in women;
- Zoster, which prevents shingles;[36]
- Measles, Mumps, and Rubella (MMR), a combination vaccine, which prevents viral infections;[37]
- Pneumococcal,[38] which prevents pneumococcal bacterial disease and resulting complications such as:
    - Pneumonia, which causes inflammation in the lungs; and
    - Bacteremia, which causes bacteria to enter the blood stream;
- Meningococcal, which prevents meningococcal bacterial disease and resulting complications such as meningitis;
- Hepatitis A and Hepatitis B;[39] and
- Haemophilus influenza type b (Hib).[40]

New vaccines are considered for addition to the schedule after licensure by the United States Food and Drug Administration. Not all newly licensed vaccines are added to the Schedule. Some licensed vaccines are only recommended for people who are traveling to areas where other vaccine preventable diseases, such as typhoid fever, occur.[41]

CDC Health Information for International Travel

CDC's Health Information for International Travel, commonly called the Yellow Book (Book), is published biannually by the CDC as a reference for those who advise international travelers about health risks.[42] The Book includes a complete catalog of travel-related diseases, up-to-date vaccine and booster recommendations, and destination specific environmental health information. The Book also includes advice on preventing and treating common travel-related ailments and tips for individuals traveling with special needs.[43] A team of approximately 200 experts update the Book to provide the latest CDC recommendations.[44]

Vaccinations are recommended by the CDC to protect international travelers from illness and prevent the importation of infectious diseases across international borders. The Book recommends that persons traveling internationally should be up to date on all CDC recommended vaccines.[45] The Book includes an immunization schedule that recommends additional vaccines that are not listed in the Schedule, including yellow fever, rotavirus, and polio vaccines.[46] The specific vaccinations recommended depend on the traveler's destination and other factors. Some of the most common vaccinations considered for travelers include hepatitis A, hepatitis B, meningococcal, polio (adult booster), rabies, typhoid fever, and yellow fever.[47]

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[36] A single dose of zoster vaccine is recommended for adults aged 60 years or older regardless of whether they report a prior episode of zoster (shingles). Id.
[37] Children are the primary recipients of the MMR vaccine, but it is also recommended for adults, born after 1956, who have not been previously vaccinated as these diseases can cause serious health complications. Id.
[38] Two types of pneumococcal vaccines are recommended by the CDC for adults aged 65 and older, the pneuomoccocal13-valent conjugate and the pneumococcal polysaccharide vaccines. Id.
[39] Hepatitis A causes an acute, treatable infection while Hepatitis B can cause chronic and serious health complications such as cirrhosis, liver cancer, and death. A combination vaccine is available for Hepatitis A and B. Centers for Disease Control and Prevention, *Hepatitis A FAQs for the Public*, available at http://www.cdc.gov/hepatitis/A/aFAQ.htm#overview (last visited March 4, 2015).
[40] The Meningococcal vaccine, along with Hepatitis A and B, pneumococcal, and Hib are recommended for subgroups of the adult population based on pre-existing medical conditions, occupation, or lifestyle. Supra at FN 33.
[41] Supra at FN 32.
[42] Centers for Disease Control and Prevention. *CDC Health Information for International Travel 2014* (online version). New York: Oxford University Press; 2014. available at http://wwwnc.cdc.gov/travel/yellowbook/2014/table-of-contents (last visited March 4, 2015).
[43] Centers for Disease Control and Prevention, *CDC Releases 2014 Edition of the "Yellow Book"* available at http://www.cdc.gov/media/releases/2013/p0806-2014-yellow-book.html (last visited March 4, 2015).
[44] Id.
[45] Supra at FN 42, ch. 2.
[46] Id. at ch. 2, Table 2-04.
[47] Id. At ch. 4.

State of Emergency

The scope of practice of certain regulated healthcare practitioners may be modified for emergency situations to meet the increased demand for services.[48] The legal authorities and mechanisms for modifying health care scope of practice for a state of emergency vary among states. Various states have permanently authorized modified scopes of practice during emergencies for pharmacists and other health care practitioners, either by statute or regulation. In this instance, these provisions may be activated by an emergency declaration by a governor, state health officer, or other authorized officials.[49]

Florida State of Emergency

Section 252.36, F.S., describes the powers of the Governor in a state of emergency. In the event an emergency or disaster is beyond local control, the Governor may assume direct operational control over all or any part of the emergency management functions within the state.[50] The Governor is authorized to delegate such powers as he or she may deem prudent.[51] A state of emergency must be declared by executive order or proclamation by the Governor when an emergency or disaster has occurred or the threat of occurrence is imminent. [52]

Effect of Proposed Changes

HB 279 amends s.465.189, F.S., to authorize licensed pharmacists and registered pharmacy interns, who are certified with the Board to administer vaccines, to administer those vaccines:

- Listed in the CDC's Adult Immunization Schedule;
- Recommended in the CDC's Health Information for International Travel; and
- Approved by the Board in response to a state of emergency declared by the Governor.

A registered pharmacy intern who is authorized to administer vaccinations must be under the supervision of a pharmacist.

The bill requires a pharmacy intern to meet the same vaccine administration certification requirements as a pharmacist. To be certified, a pharmacy intern must complete 20 hours of coursework approved by the Board concerning the safe and effective administration of the vaccines listed in the bill and pay a fee of $55.

In addition to the vaccines that pharmacists are currently authorized to administer in s. 465.189, F.S., the inclusion of the CDC's official immunization recommendations in s. 465.189, F.S., also authorizes:

- Measles, mumps, rubella (MMR);
- Tetanus, diphtheria, pertussis (Td/Tdap);
- Varicella;
- Human Papillomavirus (HPV);
- Hepatitis A;
- Hepatitis B;
- Haemophilus influenza type b (Hib); and
- Vaccines recommended for international travel such as yellow fever and typhoid fever.

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[48] Association of State and Territorial Health Officials, *Scope of Practice Issues in Public Health Emergencies,* available at http://www.astho.org/Programs/Preparedness/Public-Health-Emergency-Law/Scope-of-Practice-Toolkit/Scope-of-Practice-Issues-in-Public-Health-Emergencies-Fact-Sheet/ (last viewed March 4, 2015).
[49] Id.
[50] S. 252.36(1)(a), F.S
[51] Id.
[52] S. 252.36(1)(b), F.S

The bill provides an effective date of July 1, 2015.

B. SECTION DIRECTORY:

Section 1: Amends s. 465.189, F.S., relating to administration of vaccines and epinephrine autoinjection.

Section 2: Provides an effective date of July 1, 2015.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   Based on Fiscal Year 2013-14 data, there are 30,636 pharmacists registered by the Board, and 11,323, or 37 percent, are currently certified to administer vaccines. There are 10,914 registered pharmacy interns. It is assumed that 4,038 (10,914 X 37 percent) of the current registered pharmacy interns will apply for certification to administer vaccines. There were 1,855 applications seeking intern registration in the Fiscal Year 2013-14. It is assumed that 686 (1,855 x 37 percent) pharmacy interns will apply for vaccine administration certification.

   Revenues collected from the $55 certification fee are calculated based on an estimated 4,724 (4,038 current registered interns + 686 newly registered interns) applications for certification totaling $259,820 (4,724 x $55). The fees collected are subject to the 8 percent general revenue surcharge and $20,786 ($259,820 x .08) is deducted from the estimated amounts to be collected by DOH to be deposited in the General Revenue Fund. The total estimated revenue for the DOH for first biennium is $239,034 ($259,820 - $20,786).[53]

2. Expenditures:

   The bill will cause the DOH to experience a recurring increase in workload, associated with processing applications for vaccine certification for pharmacy interns, which can be absorbed within current resources.

   DOH will incur a non-recurring increase in workload, associated with updating the Licensing and Enforcement Information Database System, modifying the pharmacy intern application, updating the Pharmacy website, and rulemaking. This can be absorbed within current resources.

   DOH may experience an increase in workload costs associated with the receipt and processing of certification applications for registered pharmacy interns. The processing cost per application is $7.69. It is estimated that 4,724 applicants for certification will be submitted for processing equating to a cost of $36,328.[54]

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

[53] Supra at FN 12
[54] Id.

Pharmacies that opt to allow pharmacists and pharmacy interns to administer the vaccinations may see an increase in customers seeking vaccinations.

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 gives the DOH rulemaking authority to authorize additional immunizations or vaccines as they are added to the CDC Adult Immunization Schedule and to approve immunizations in response to a state of emergency declared by the Governor.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to pharmacy; amending s. 465.189, F.S.; authorizing a registered intern under the supervision of a pharmacist to administer specified vaccines to an adult; revising which vaccines may be administered by a pharmacist or registered intern under the supervision of a pharmacist; requiring a registered intern seeking to administer vaccines to be certified to administer such vaccines and to complete a minimum amount of coursework; providing an effective date.

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

Section 1. Subsections (1) and (6) of section 465.189, Florida Statutes, are amended to read:

465.189 Administration of vaccines and epinephrine autoinjection.—

(1) In accordance with guidelines of the Centers for Disease Control and Prevention for each recommended immunization or vaccine, a pharmacist, or a registered intern under the supervision of a pharmacist, may administer the following vaccines to an adult within the framework of an established protocol under a supervising physician licensed under chapter 458 or chapter 459:

(a) Immunizations or vaccines listed in the Adult

Immunization Schedule as of February 1, 2014, by the United States Centers for Disease Control and Prevention. The board may authorize, by rule, additional immunizations or vaccines as they are added to the Adult Immunization Schedule I~~nfluenza vaccine~~.

(b) Immunizations or vaccines recommended by the United States Centers for Disease Control and Prevention for international travel as of July 1, 2015. The board may authorize, by rule, additional immunizations or vaccines as they are recommended by the United States Centers for Disease Control and Prevention for international travel ~~Pneumococcal vaccine~~.

(c) Immunizations or vaccines approved by the board in response to a state of emergency declared by the Governor pursuant to s. 252.36 ~~Meningococcal vaccine~~.

~~(d) Shingles vaccine.~~

(6) Any pharmacist or registered intern seeking to administer vaccines to adults under this section must be certified to administer such vaccines pursuant to a certification program approved by the Board of Pharmacy in consultation with the Board of Medicine and the Board of Osteopathic Medicine. The certification program shall, at a minimum, require that the pharmacist attend at least 20 hours of continuing education classes approved by the board and the registered intern complete at least 20 hours of coursework approved by the board. The program shall have a curriculum of instruction concerning the safe and effective administration of such vaccines, including, but not limited to, potential allergic

reactions to such vaccines.

Section 2. This act shall take effect July 1, 2015.

COMMITTEE/SUBCOMMITTEE AMENDMENT

Bill No. HB 279 (2015)

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 Innovation Subcommittee

Representative Pigman offered the following:

Amendment

Remove lines 22-26 and insert:

supervision of a pharmacist who is certified under subsection (6), may administer the following vaccines to an adult within the framework of an established protocol under a supervising physician licensed under chapter 458 or chapter 459:

(a) Immunizations or vaccines listed in the February 2015 Adult

HB 555

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 555 Pharmacy
SPONSOR(S): Gaetz
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Innovation Subcommittee		Tuszynski	Poche
2) Insurance & Banking Subcommittee			
3) Appropriations Committee			
4) Health & Human Services Committee			

SUMMARY ANALYSIS

Pharmacy benefit managers (PBM) provide a variety of services, including developing and managing pharmacy networks, developing drug formularies, providing mail order and specialty pharmacy services, rebate negotiation, therapeutic substitution, disease management, utilization review, support services for physicians and beneficiaries, and processing and auditing claims. Health plan sponsors contract with PBMs to provide these services, and payment terms are established in the contract.

In recent years, federal and state litigants and various stakeholders in the prescription drug industry have alleged that PBMs sometimes engage in unfair business practices that have resulted in excessive profits at the expense of health plan members, sponsors, or pharmacies. In response, PBMs have begun to offer health plan sponsors contracts that provide more transparency than traditional contracts. These contracts give health plan sponsors access to information about contractual and financial arrangements with drug manufacturers and pharmacies.

HB 555 builds on this trend of transparency in contracts between PBMs, plan sponsors, including employers and insurers, and contracting pharmacies. The bill requires that such contracts include specific terms related to disclosure of information, timeframes for providing such information, and providing notice of changes to the plan sponsor or contracting pharmacy. The bill establishes criteria that must be met for a PBM to place a generic drug on the MAC list, requiring at least three nationally available equivalent multiple-source generic drugs that meet certain requirements.

The bill requires that a contract between a PBM and a plan sponsor disclose the methodology used to establish MAC (MAC) pricing for generic drugs and brand name drugs with generic equivalents. A PBM is required to promptly provide the plan sponsor with an updated list when MAC pricing changes. The contract must disclose if the PBM uses a MAC pricing list for drugs dispensed at retail, but not for drugs dispensed by mail order. The contract must also disclose whether the PBM uses the same MAC pricing list to bill the plan sponsor as it uses to reimburse a contracted pharmacy. If a PBM does not use the same MAC list to bill a plan sponsor and reimburse a contracted pharmacy, the bill requires the contract to disclose the pricing differences.

The bill requires that contracts between a PBM and a pharmacy contain a process for an appeal, investigation, and resolution of disputes relating to MAC pricing. If an appeal is denied, the PBM must provide the reason for denial and identify an alternative drug that may be purchased at a price at or below the MAC. If an appeal is upheld, the PBM must make an adjustment retroactive to the date the claim was adjudicated for all similarly situated contracted pharmacies.

There is an anticipated significant negative fiscal impact on the state group health plan. See fiscal comments.

The bill provides an effective date of July 1, 2015.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Pharmacy Regulation

Pharmacies and pharmacists are regulated under the Florida Pharmacy Act (the Act) in Chapter 465, F.S. The Board of Pharmacy (the board) was created within the Department of Health (DOH) to adopt rules to implement provisions of the Act and take other actions as required in the Act.[1]

Several pharmacy types are specified in law and are required to be permitted or registered under the Act:

- Community pharmacy[2] – A location where medicinal drugs are compounded, dispensed, stored, or sold or where prescriptions are filled or dispensed on an outpatient basis.
- Institutional pharmacy[3] – A location in a hospital, clinic, nursing home, dispensary, sanitarium, extended care facility, or other facility where medical drugs are compounded, dispensed, stored, or sold. The Act further classifies institutional pharmacies according to the type of facility or activities within the facility.
- Nuclear pharmacy[4] – A location where radioactive drugs and chemicals within the classification of medicinal drugs are compounded, dispensed, stored, or sold. The Act excludes hospitals or the nuclear medicine facilities of hospitals.
- Internet pharmacy[5] – A location, whether within or outside the state, which uses the internet to communicate with or obtain information from consumers in order to fill or refill prescriptions or to dispense, distribute, or otherwise engage in the practice of pharmacy in Florida.
- Non-resident pharmacy[6] – A location outside the state, which ships, mails, or delivers, in any manner, a dispensed drug into the state.
- Special pharmacy[7] – A location where medicinal drugs are compounded, dispensed, stored, or sold and which provides miscellaneous specialized pharmacy service functions.

Each pharmacy is subject to inspection[8] and discipline[9] by DOH for violations of applicable state or federal laws relating to a pharmacy. Any pharmacy located outside of this state which ships, mails, or delivers, in any manner, a dispensed drug into this state is considered a nonresident pharmacy, and must register with the board as a nonresident pharmacy.[10,11]

Pharmacy Benefit Managers and Pharmacies

Advances in pharmaceuticals have transformed health care over the last several decades. Many health care problems are prevented, cured, or managed effectively using prescription drugs. As a result, national expenditures for retail prescription drugs have grown from $120.9 billion in 2000 to $271.1

[1] S. 465.005, F.S.
[2] S. 465.003(11)(a)(1), F.S.
[3] S. 465.003(11)(a)(2), F.S.
[4] S. 465.003(11)(a)(3), F.S.
[5] S. 465.003(11)(a)(5), F.S.
[6] S. 465.0156(1), F.S.
[7] S. 465.003(11)(a)(4), F.S.
[8] S. 465.017, F.S.
[9] S. 465.016, F.S.
[10] S. 465.0156, F.S.
[11] However, the board may grant an exemption from the registration requirements to any nonresident pharmacy, which confines its dispensing activity to isolated transactions. *See* s. 465.0156(2), F.S.

billion in 2013.[12] Health plan sponsors, which include commercial insurers, private employers, and government plans, such as Medicaid and Medicare, spent $222.6 billion on prescription drugs in 2013 and consumers paid $45.9 billion out of pocket for prescription drugs that year.[13]

Health plan sponsors contract with pharmacy benefit managers (PBMs) to provide specified services, which may include developing and managing pharmacy networks, developing drug formularies, providing mail order and specialty pharmacy services, rebate negotiation, therapeutic substitution, disease management, utilization review, support services for physicians and beneficiaries, and processing claims.[14] Payments for the services are established in contracts between health plan sponsors and PBMs.[15] For example, contracts will specify how much health plan sponsors will pay PBMs for brand name and generic drugs. These prices are typically set as a discount off the average wholesale price[16] for brand-name drugs and a MAC (MAC)[17] for generic drugs (and sometimes brand drugs that have generic versions), plus a dispensing fee.[18]

The shift to generic drugs has saved consumers more than a $1 trillion over a decade[19], but it has adversely affected independent pharmacists according to recent news articles. In 2000, about 50 percent of U.S. prescription drugs were generic. Now, generics represent about 84 percent of the market, according to IMS Health Incorporated.[20] The increasing use of generics is pushing the dollar volume of prescription-drug sales down. In response, drugstores want lawmakers to require the PBMs to share pricing information that would help drugstores negotiate bigger reimbursements and avoid dispensing drugs that are money losers.[21] Contracts also generally include fees for processing claims submitted by pharmacies (usually based on a rate per claim) and fees for providing services such as disease management or utilization review.[22] In addition, contracts generally specify whether and how the PBM will pass manufacturer rebates on to the health plan sponsors.[23] The contracts can also include performance guarantees, such as claims processing accuracy or amount of rebates received.[24]

Federal Pharmacy Benefits Managers Transparency Requirements

On March 23, 2010, President Obama signed into law Public Law No. 111-148, the Patient Protection and Affordable Care Act (PPACA), and on March 30, 2010, President Obama signed into law Public Law No. 111-152, the Health Care and Education Affordability Reconciliation Act of 2010, amending PPACA. The law requires Medicare Part D plans and qualified health plan issuers who have their own PBM or contract with a PBM to report to the federal Department of Health and Human Services (HHS) aggregate information about rebates, discounts, or price concessions that are passed through to the plan sponsor or retained by the PBM. [25] In addition, the plans must report the difference between the amount the plan pays the PBM and the amount that the PBM pays its suppliers.[26] The reported information is confidential, subject to certain limited exceptions.[27]

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[12] Centers for Medicare and Medicaid Services, *National Health Expenditure Data, Historical, available at* https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ (last visited March 8, 2015).
[13] Id.
[14] Program Policy Analysis & Government Accountability. (Office of Program Policy Analysis & Government Accountability, *Legislature Could Consider Options to Address Pharmacy Benefit Manager Business Practices*, Report No. 07-08 (Feb. 2007), *available at* http://www.oppaga.state.fl.us/MonitorDocs/Reports/pdf/0708rpt.pdf (last visited March 7, 2015).
[15] Id.
[16] Average wholesale price is the retail list price (sticker price) or the average price that manufacturers recommend wholesalers sell to physicians, pharmacies and others, such as hospitals.
[17] MAC is a price set for generic drugs and is the maximum amount that the plan sponsor will pay for a specific drug.
[18] Supra. at FN 14
[19] Timothy W. Martin, *Drugstores Press for Pricing Data,* Wall Street Journal, March 27, 2013. *available at* http://www.wsj.com/articles/SB10001424127887323466204578382990730159644 (last visited March 4, 2015)
[20] Id.
[21] Id.
[22] If the PBM owns the mail order or specialty pharmacy, claims processing fees may not be applied.
[23] Contracts may specify a fixed amount per prescription or a percentage of the total rebates received by a PBM.
[24] Supra. at FN 14.
[25] 42 U.S.C. s. 1320b-23.
[26] Id.
[27] Id.

State and Federal Studies on Pharmacy Benefit Managers

Federal Studies

Concerns have been raised that a PBM that owns a pharmacy (whether retail or mail) may have a greater ability to influence which drugs are dispensed under the plans it administers than a PBM that does not own a pharmacy. If plan sponsor contracts with PBMs do not properly align the incentives of PBMs with those of the plans, this lack of alignment could create a conflict of interest. Potential conflicts of interest should be rare, however, if competition among PBMs provides plan sponsors with alternatives. At the request of Congress, the Federal Trade Commission (FTC) collected aggregate data on prices, generic substitution and dispensing rates, savings due to therapeutic drug switches, and repackaging practices. The study examined whether PBM ownership of mail-order pharmacies served to maximize competition and lower prescription drug prices for plan sponsors. In its 2005 report based on the study, the FTC found, among other things, that the prices for a common basket of prescription drugs dispensed by PBM-owned mail order pharmacies were typically lower than the prices charged by retail pharmacies. The study also found competition affords health plans substantial tools with which to safeguard their interests.[28]

The 2005 study continued the FTC's ongoing review of PBMs. The PBM practices were a particular focus of hearings on health care markets jointly conducted by the FTC and the Department of Justice Antitrust Division in 2003.[29] In 2004, the FTC and DOJ issued a report based on the hearings, a Commission-sponsored workshop, and independent research.[30]

State Study

Pursuant to a legislative request, the Office of Program Policy Analysis & Government Accountability (OPPAGA) reviewed pharmacy benefit managers in a report released in 2007. The report addressed concerns relating to PBM business practices, actions by states, PBMs, and plan sponsors, and gave possible legislative options. Relevant portions of the report are summarized below.[31]

Concern with PBM business practices

In recent years, federal and state litigants and various stakeholders in the prescription drug industry have alleged that PBMs sometimes engage in unfair business practices that have resulted in excessive profits at the expense of health plan members, sponsors, or pharmacies. These include allegations that PBMs:

- Have excessively profited by accepting secret monetary incentives from drug manufacturers, such as incentives for increasing a manufacturer's drug sales that are not shared with health plan sponsors.
- Have increased rebates by changing patient prescriptions to drugs that receive higher rebates.
- Have excessively profited from the price spread created by the difference between pharmacy reimbursements and plan sponsor drug prices.
- Have realized high profits by charging health plan sponsors significantly higher drug prices than prices at which they reimburse pharmacies.
- Have not provided sponsors access to information on PBM transactions or negotiations with manufacturers and pharmacies.

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[28] Federal Trade Commission, *Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies* (August 2005). Available at: https://www.ftc.gov/reports/pharmacy-benefit-managers-ownership-mail-order-pharmacies-federal-trade-commission-report (last visited March 3, 2015).

[29] *See* Hearings on Health Care and Competition Law and Policy, June 26, 2003, *available at* http://www.justice.gov/atr/public/health_care/204694.pdf (last visited March 4, 2015).

[30] *See* Federal Trade Commission, and Department of Justice, *Improving Health Care: A Dose of Competition* (2004), available at http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf (last visited March 4, 2015).

[31] Supra. at FN 13.

- Prevented health plan sponsors and pharmacies from receiving a fair share of the profits realized by PBMs in their negotiations with drug manufacturers.

How have states, PBMs, and health plan sponsors addressed these concerns?

As of December 2006, three states and the District of Columbia had passed legislation that addresses certain contractual issues.[32] In addition, two states had passed legislation to regulate PBMs by requiring licensure or oversight by state insurance departments or pharmacy boards. The PBMs, health plans sponsors, and other stakeholders have taken steps to change business practices and increase transparency.

To create more transparency in their business practices, PBMs have begun to offer health plan sponsors contracts that provide more transparency than traditional contracts. These contracts give health plan sponsors access to information about contractual and financial arrangements with drug manufacturers and pharmacies. Some PBMs negotiate contracts that establish drug prices for health plan sponsors equal to the price at which PBMs reimburse pharmacies. In addition to these voluntary steps, the provisions of settled lawsuits require defendant PBMs to adhere to specific transparency practices.[33]

What options could the Legislature consider to address PBM business practices?

In 2007, OPPAGA suggested that prior to considering statutory actions, the Legislature may wish to give market forces time to further influence efforts by PBMs, health plan sponsors, and other stakeholders to change PBM business practices and establish contracts that are more transparent. If the Legislature wishes to enact statutory provisions to regulate PBMs, the OPPAGA suggested it could consider options adopted in other states such as establishing transparency guidelines or licensing or certifying PBMs.

Effect of Proposed Changes

HB 555 establishes contractual requirements between a PBM and a contracted pharmacy and between a PBM and a plan sponsor. The requirements include updating the MAC pricing information every seven calendar days; establishing a reasonable process for prompt notice of MAC pricing updates to the contracted pharmacy; and maintaining a procedure to remain consistent with pricing changes in the marketplace. A contract must allow for prompt modification of the MAC pricing information or elimination of products from the MAC pricing list, if necessary, within three calendar days after a change, if such products no longer meet the requirements included in the bill.

To place a prescription drug on a MAC pricing list, the bill requires a PBM to ensure that the drug has at least three or more nationally available, therapeutically equivalent, multiple-source generic drugs that:

- Have a significant cost difference;
- Are listed as therapeutically and pharmaceutically equivalent or "A" or "B" rated in the most recent version of Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations published by the United States Food and Drug Administration;
- Are available for purchase without limitations from national or regional wholesalers without limitation by all pharmacies in the state; and
- Are not obsolete or temporarily unavailable.

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[32] At least 21 states and the District of Columbia have now enacted laws imposing some form of regulation on pharmacy benefit managers, including Arkansas, Connecticut, Florida (Medicaid audits), Georgia, Indiana, Iowa, Kansas, Kentucky, Maryland, Mississippi, Missouri, New Mexico, North Carolina, North Dakota, Oklahoma, Rhode Island, South Dakota, Tennessee, Texas, Utah, Vermont, and the District of Columbia. (National Community Pharmacy Association, *Laws that Provide Regulation of the Business Practices of Pharmacy Benefit Managers*, available at http://www.ncpanet.org/pdf/leg/leg_pbm_business_practice_regulation.pdf (last visited March 5, 2015).

[33] For example, the settlement agreement between 20 state attorneys general against Medco arising from litigation in 2003 prohibits Medco from soliciting drug switches when the net drug cost of the proposed drug exceeds the cost of the prescribed drug. It also requires Medco to disclose financial incentives for switching drugs.

A contract between a plan sponsor and a PBM must disclose the basis of the methodology and sources used to establish MAC pricing. The contract must also require that the PBM promptly update the plan sponsor with an updated list when MAC pricing changes. The contract must disclose whether the PBM uses a MAC pricing list for drugs dispensed at retail, but not for drugs dispensed by mail order. Also, the contract must disclose whether the PBM uses the same MAC pricing list to bill the plan sponsor as it uses to reimburse a contracted pharmacy. If a PBM does not use the same MAC list to bill a plan sponsor and reimburse a contracted pharmacy, the bill requires the contract to disclose the pricing differences.

The bill requires that a contract between a PBM and pharmacy contain a process for the appeal, investigation, and resolution of disputes regarding MAC pricing. If an appeal is denied, the contract must require a PBM to provide the reason for denial and identify an alternative drug that may be purchased at a price at or below the MAC. If an appeal is upheld, the PBM must make an adjustment retroactive to the date the claim was adjudicated for all similarly situated contracted pharmacies.

The bill defines contracted pharmacy, MAC, pharmacy benefit manager, and plan sponsor.

The bill provides an effective date of July 1, 2015.

B. SECTION DIRECTORY:

Section 1: Creates s. 465.1862, F.S., relating to pharmacy benefit managers
Section 2: Provides an effective date of July 1, 2015.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   The Division of State Group Insurance anticipates a negative fiscal impact of $3,000,000 to the state group health plan as a result of increased administrative costs and changes to MAC pricing required by the bill.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The changes to MAC pricing may impact the operations of PBMs and the terms of contracts with plan sponsors and contracted pharmacies.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to pharmacy; creating s. 465.1862, F.S.; defining terms; providing requirements for contracts between pharmacy benefit managers and contracted pharmacies; requiring a pharmacy benefit manager to ensure that a prescription drug has met certain requirements to be placed on a maximum allowable cost pricing list; requiring the pharmacy benefit manager to disclose certain information to a plan sponsor; requiring a contract between a pharmacy benefit manager and a pharmacy to include an appeal process; providing an effective date.

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

Section 1. Section 465.1862, Florida Statutes, is created to read:

465.1862 Pharmacy benefit managers.—

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

(a) "Contracted pharmacy" means a pharmacy or network of pharmacies that has executed a contract, which includes maximum allowable cost pricing requirements, with a pharmacy benefit manager and acts on behalf of a plan sponsor.

(b) "Maximum allowable cost" means the upper limit or maximum amount that an insurer or managed care plan will pay for generic prescription drugs or brand-name prescription drugs with

available generic versions, which are included on a list of products generated by the pharmacy benefit manager.

(c) "Pharmacy benefit manager" means a person, business, or other entity that provides administrative services related to processing and paying prescription claims for pharmacy benefit and coverage programs. Such services may include, but are not limited to, contracting with a pharmacy or network of pharmacies; establishing payment levels for pharmacies; dispensing prescription drugs to plan sponsor beneficiaries; negotiating discounts and rebate arrangements with drug manufacturers; developing and managing prescription formularies, preferred drug lists, and prior authorization programs; ensuring audit compliance; and providing management reports.

(d) "Plan sponsor" means an employer, insurer, managed care organization, prepaid limited health service organization, third-party administrator, or other entity contracting for pharmacy benefit manager services.

(2) A contract between a pharmacy benefit manager and a contracted pharmacy must require the pharmacy benefit manager to:

(a) Update the maximum allowable cost pricing information at least every 7 calendar days and establish a reasonable process for the prompt notification of any pricing updates to the contracted pharmacy.

(b) Maintain a procedure to remain consistent with pricing changes in the marketplace by promptly modifying the maximum

allowable cost pricing information or, if necessary, eliminating products from the cost pricing list within 3 calendar days after a change if such products no longer meet the requirements of this section.

(3) A pharmacy benefit manager, to place a prescription drug on a maximum allowable cost pricing list, at a minimum, must ensure that the drug has at least three or more nationally available, therapeutically equivalent, multiple-source generic drugs that:

(a) Have a significant cost difference.

(b) Are listed as therapeutically and pharmaceutically equivalent or "A" or "B" rated in the most recent version of Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations published by the United States Food and Drug Administration.

(c) Are available for purchase from national or regional wholesalers without limitation by all pharmacies in the state.

(d) Are not obsolete or temporarily unavailable.

(4) In a contract between a pharmacy benefit manager and a plan sponsor, the pharmacy benefit manager must disclose the following to the plan sponsor:

(a) The basis of the methodology and sources used to establish applicable maximum allowable cost pricing. A pharmacy benefit manager shall promptly update applicable maximum allowable cost pricing lists and provide the plan sponsor with an updated list upon any pricing change.

(b) Whether the pharmacy benefit manager uses a maximum allowable cost pricing list for drugs dispensed at retail but does not use such a list for drugs dispensed by mail order. If such practice is adopted after a contract is executed, the pharmacy benefit manager shall disclose such practice to the plan sponsor within 21 business days after implementation of the practice.

(c) Whether the pharmacy benefit manager uses an identical maximum allowable cost pricing list to bill the plan sponsor and to reimburse a contracted pharmacy. If more than one maximum allowable cost pricing list is used, the pharmacy benefit manager shall disclose to the contracted pharmacy any difference between the amount billed to the plan sponsor and the amount paid as reimbursement to a contracted pharmacy.

(5)(a) Each contract between a pharmacy benefit manager and a contracted pharmacy must include a process for appeal, investigation, and resolution of disputes regarding maximum allowable cost pricing. The process must:

1. Limit the right to appeal to 90 calendar days after an initial claim is made by the contracted pharmacy.

2. Require investigation and resolution of a dispute within 7 days after an appeal is received by the pharmacy benefit manager.

3. Include a telephone number at which a contracted pharmacy may contact the pharmacy benefit manager regarding an appeal.

(b) If an appeal is denied, the pharmacy benefit manager shall provide the reasons for denial and shall identify the national drug code for the prescription drug that may be purchased by the contracted pharmacy at a price at or below the disputed maximum allowable cost pricing.

(c) If an appeal is upheld, the pharmacy benefit manager shall adjust the maximum allowable cost pricing retroactive to the date that the claim was adjudicated. The pharmacy benefit manager shall apply the adjustment retroactively to any similarly situated contracted pharmacy.

Section 2. This act shall take effect July 1, 2015.

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 Innovation Subcommittee

Representative Gaetz offered the following:

Amendment

Remove everything after the enacting clause and insert:

Section 1. Section 465.1862, Florida Statutes, is created to read:

465.1862 Section 465.1862, Florida Statutes, is created to read:

465.1862 Pharmacy benefit managers.—

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

(a) "Contracted pharmacy" means a pharmacy or network of pharmacies that has executed a contract, which includes maximum allowable cost pricing requirements, with a pharmacy benefit manager and acts on behalf of a plan sponsor.

(b) "Maximum allowable cost" means the upper limit or maximum amount that an insurer or managed care plan will pay for generic prescription drugs or brand-name prescription drugs with available generic versions, which are included on a list of products generated by the pharmacy benefit manager.

(c) "Pharmacy benefit manager" means a person, business, or other entity that provides administrative services related to processing and paying prescription claims for pharmacy benefit and coverage programs. Such services may include, but are not limited to, contracting with a pharmacy or network of pharmacies; establishing payment levels for pharmacies; dispensing prescription drugs to plan sponsor beneficiaries; negotiating discounts and rebate arrangements with drug manufacturers; developing and managing prescription formularies, preferred drug lists, and prior authorization programs; ensuring audit compliance; and providing management reports.

(d) "Plan sponsor" means an employer, insurer, managed care organization, prepaid limited health service organization, third-party administrator, or other entity contracting for pharmacy benefit manager services.

(2) A contract between a pharmacy benefit manager and a contracted pharmacy must require the pharmacy benefit manager to update the maximum allowable cost pricing information at least every 7 calendar days and establish a reasonable process for the prompt notification of any pricing updates to the contracted pharmacy.

(3) A pharmacy benefit manager, to place a prescription drug on a maximum allowable cost pricing list, at a minimum, must ensure that the drug has at least two or more nationally available, therapeutically equivalent, multiple-source generic drugs that:

(a) Have a significant cost difference.

(b) Are listed as therapeutically and pharmaceutically equivalent or "A" or "AB" rated in the most recent version of Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations published by the United States Food and Drug Administration.

(c) Are available for purchase from national or regional wholesalers without limitation by all pharmacies in the state.

(d) Are not obsolete or temporarily unavailable.

(4) In a contract between a pharmacy benefit manager and a plan sponsor, the pharmacy benefit manager must disclose the following to the plan sponsor:

(a) Whether the pharmacy benefit manager uses a maximum allowable cost pricing list for drugs dispensed at retail but does not use such a list for drugs dispensed by mail order. If such practice is adopted after a contract is executed, the pharmacy benefit manager shall disclose such practice to the plan sponsor within 21 business days after implementation of the practice.

(b) Whether the pharmacy benefit manager uses an identical maximum allowable cost pricing list to bill the plan sponsor and

to reimburse a contracted pharmacy. If more than one maximum allowable cost pricing list is used, the pharmacy benefit manager shall disclose to the contracted pharmacy any difference between the amount billed to the plan sponsor and the amount paid as reimbursement to a contracted pharmacy.

(5)(a) Each contract between a pharmacy benefit manager and a contracted pharmacy must include a process for appeal, investigation, and resolution of disputes regarding maximum allowable cost pricing. The process must:

1. Limit the right to appeal to 30 calendar days after an initial claim is made by the contracted pharmacy.

2. Require investigation and resolution of a dispute within 14 days after an appeal is received by the pharmacy benefit manager.

3. Include a telephone number at which a contracted pharmacy may contact the pharmacy benefit manager regarding an appeal.

(b) If an appeal is denied, the pharmacy benefit manager shall provide the reasons for denial and shall identify the national drug code for the prescription drug that may be purchased by the contracted pharmacy at a price at or below the disputed maximum allowable cost pricing.

(c) If an appeal is upheld, the pharmacy benefit manager shall adjust the maximum allowable cost pricing retroactive to the date that the claim was adjudicated. The pharmacy benefit

manager shall apply the adjustment retroactively to any similarly situated contracted pharmacy.

Section 2. This act shall take effect July 1, 2015.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 601 Statewide Prepaid Dental Program
SPONSOR(S): Magar
TIED BILLS: **IDEN./SIM. BILLS:** SB 350

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Innovation Subcommittee		McElroy	Poche
2) Health & Human Services Committee			

SUMMARY ANALYSIS

In 2011, Florida established the Statewide Medicaid Managed Care (SMMC) program. The SMMC program requires the Agency for Health Care Administration (AHCA) to create an integrated managed care program for Medicaid enrollees to provide all the mandatory and optional Medicaid benefits for primary and acute care, including pediatric dental services, in a Managed Medical Assistance (MMA) program. In February 2014, AHCA executed 5-year contracts for the MMA program, and began implementation, which was completed August 1, 2014. As of February 2015, over 2.9 million Medicaid recipients enrolled in the MMA program receive their dental services through managed care plans that offer a full array of medical, behavioral, and dental health benefits.

HB 601 removes pediatric dental services from the otherwise integrated SMMC program by creating a new statewide prepaid dental program. Adult dental services will remain with the MMA plans. The bill directs AHCA to contract with at least two prepaid dental health plans (PDHP) on a statewide basis. The statewide prepaid dental program will begin no later than September 1, 2016, or when AHCA receives the necessary federal authority to implement the program.

The bill gives AHCA authority to seek any state plan amendments or waiver authority necessary to implement the program. To remove dental services from the SMMC program, AHCA will have to apply for an amendment of the approved section 1115 waiver, and will likely also have to apply for a new 1915(b) waiver to have authority to use a PDHP model to deliver dental services. The federal government has no deadline for acting on a section 1115 waiver application.

The bill requires that any child who becomes eligible for Medicaid benefits between the effective date of the act and implementation of the statewide prepaid dental program must receive dental services through the SMMC program. The child will be removed from the SMMC plan and enrolled in the statewide prepaid dental program once it is implemented. The bill requires AHCA to provide recipients with all required notices regarding this transition. The bill authorizes AHCA to assess the costs incurred in providing a notice to the participating plans.

The bill requires a medical loss ratio of 85 percent for prepaid dental plans participating in the statewide prepaid dental program.

The bill requires AHCA to provide an annual report to the Governor and Legislature which compares the utilization, benefit and cost data from Medicaid dental contractors as well as compliance reports and access to care to the state's overall Medicaid dental population.

The bill has a significant negative fiscal impact on the Medicaid program.

The bill provides that the act will take effect upon becoming a law.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Medicaid

Medicaid is a joint federal- and state-funded program that provides health care for low-income Floridians, administered by AHCA under ch. 409, F.S. Federal law establishes the mandatory services to be covered in order to receive federal matching funds. Benefit requirements can vary by eligibility category. For example, more benefits are required for children than for the adult population. Florida's mandatory and optional benefits are prescribed in state law under ss. 409.905, and 409.906 F.S., respectively.

Dental services are an optional Medicaid benefit. Florida provides full dental services for children and only dentures and medically necessary, emergency dental procedures to alleviate pain or infection for adults.[1]

The delivery of Medicaid services through managed care is not expressly authorized by federal law. If a state wants to use a managed care delivery system, it must seek a waiver of certain requirements of Title XIX of the Social Security Act (Medicaid). Section 1915(b) of the Social Security Act provides authority for Secretary of Health and Human Services to waive requirements of the Act to the extent she "finds it to be cost-effective and efficient and not inconsistent with the purposes of this title."

Florida previously had waiver authority for Medicaid recipients receive dental benefits through a managed care delivery system using prepaid dental health plans.

Prepaid Dental Health Plans

A Medicaid prepaid dental health plan (PDHP) is a risk-bearing entity paid a prospective per-member, per-month payment by AHCA to provide dental services.

In 2001, the state began using PDHPs to deliver dental services to children as a pilot program in Miami-Dade County[2]. In 2003, the Legislature expanded the PDHP initiative beyond Miami-Dade County by authorizing AHCA to contract with PDHPs in other areas.[3] The statutory authority excluded Miami-Dade County from this contracting process but did permit AHCA the option[4] of including the Medicaid reform pilot counties.[5] Similar language was enacted in s. 409.912(41)(a), F.S. However, these provisions made PDHP contracting mandatory, not discretionary, outside the reform counties (and Miami-Dade County). Section 409.912(41)(b), F.S., limited the use of PHDPs by requiring that AHCA may not limit dental services to PDHPs and must allow dental services to be provided on a fee-for-service basis as well.

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[1] S. 409.906(1), (6), F.S.

[2] Proviso language in the 2001 General Appropriations Act (GAA) authorized AHCA to initiate a PDHP pilot program in Miami-Dade County. Similar statutory authority was provided in 2003.

[3] S. 409.912(42), F.S. (2003). The 2010-2011 GAA proviso specifically authorized AHCA to contract with PDHPs on either a regional or statewide basis.

[4] AHCA elected not to include those counties (children enrolled in managed care plans in the reform counties receive their dental benefits through comprehensive managed care plans; not through PDHPs).

[5] In 2005, the Legislature enacted laws to reform the delivery and payment of services through the Medicaid program and directed AHCA to seek a federal waiver for a Medicaid managed care pilot program over five years. The program began in Broward and Duval counties in 2006 and later expanded to Baker, Clay and Nassau counties in 2007, as authorized in statute. The five-year waiver was set to expire June 30, 2011, but was renewed through June 30, 2014.

Pursuant to the above statutory provisions, and the 2010-2011 General Appropriations Act, AHCA issued a competitive procurement for the statewide PDHP program in 2011 and awarded contracts to two PDHPs to provide dental services to Medicaid recipients in all Florida counties with the exceptions noted above.[6] The original procurement period was December 1, 2011 through September 30, 2013. The program was renewed once, which extended the contracts through September 30, 2014. DentaQuest and MCNA were the PDHP contractors when the contracts expired on September 30, 2014.

PDHP Accountability and Performance

The PDHP contracts imposed various accountability provisions and performance measures on the PDHP contractors.

The PDHP contracts imposed specific requirements for network adequacy, to ensure a sufficient number of primary and specialty dental care providers were available to meet the needs of plan enrollees.[7] This included having at least one full time primary dental provider per service area and at least one full time primary dental provider per every 1500 enrollees.[8]

AHCA required the PDHPs to meet a specific medical loss ratio. Under the terms of the contract, an 85 percent of the capitation paid to a PDHP must be expended on dental care services. If the MLR is not met, the PDHP was required to pay the difference back to AHCA. In calendar year 2013, both PDHPs failed to meet the MLR and were required to repay AHCA an estimated $20 million.[9]

Each PDHP was required to provide a Child Health Check-Up to enrollees. [10]The Check-Up includes dental screenings and referral starting at age 3, or earlier if indicated.[11] The PDHPs were required to achieve an annual screening and participation Check-Up rate of 80%.[12] PDHPs which failed to achieve this rate were required to file a corrective action plan (CAP) with ACHA.[13]

The PDHP contracts included incentive payments for providers if certain preventive dental service utilization criteria were met.[14] Specifically, providers who met or exceeded a 60% utilization rate for preventive dental services during a six month reporting period were entitled to receive incentive payments.[15]

AHCA measured the performance of PDHPs based on standards established by the National Committee for Quality Assurance called the Healthcare Effectiveness Data and Information Set (HEDIS). PDHPs that failed to achieve acceptable HEDIS scores were potentially subject to unspecified monetary damages. "Acceptable HEDIS score" was not defined in the PDHP contracts.[16] Annual HEDIS pediatric dental visits in Miami-Dade, statewide, and in the reform pilot counties are reflected below.

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[6] During 2012, the Agency implemented the statewide PDHP program in Medicaid Area 9 on January 1; Areas 5, 6, and 7 on October 1; and Areas 1, 2, 3, 4, 8, and 11 (Monroe County only) on December 1, 2012.
[7] Medicaid Prepaid Dental Health Plan Contract, Attachment II, Agency for Health Care Administration, January, 2012, available at http://www.fdhc.state.fl.us/MCHQ/Managed_Health_Care/MHMO/PDHP_prov.shtml (last visited on March 9, 2015).
[8] Id.
[9] AHCA 2015 Agency Legislative Bill Analysis for HB 601, January 28, 2015 (on file with the Health Innovation Subcommittee).
[10] Medicaid Prepaid Dental Health Plan Contract at 53-54.
[11] Id.
[12] Id.
[13] Id.
[14] Medicaid Prepaid Dental Health Plan Contract at 64.
[15] Id.
[16] Medicaid Prepaid Dental Health Plan Contract at 83.

HEDIS Annual Dental Visit Scores for Reform Plans and PDHPs[17]

Calendar Year	Reform Plans 5 Counties	DentaQuest Statewide	MCNA Statewide
2012	40.4%	47.3%	39.3%
2013	42.3%	37.2%	34.3%

HEDIS annual dental visit scores are also available for the original Miami-Dade County pilot for 2005-2013 (pilot began in 2001).[18] The data indicate an initial improvement from 2005-2010, followed by relatively static numbers over the next few years.[19]

Miami Dade PDHP (ADV)	2005	2006	2007	2008	2009	2010	2011	2012	2013
DentaQuest	20.0%	25.7%	30.0%	31.5%	32.9%	37.7%	39.1%	41.4%	43.3%
MCNA						34.81%	35.63%	36.8%	39.9%

Statewide Medicaid Managed Care

In 2011, the Legislature established the Statewide Medicaid Managed Care (SMMC) program as Part IV of Chapter 409, F.S. The SMMC program is an integrated managed care program for Medicaid enrollees to provide all the mandatory and optional Medicaid benefits. Within the SMMC program, the Managed Medical Assistance (MMA) program provides primary and acute medical assistance and related services, including dental services[20].

The SMMC program reflects a deliberate policy shift away from the isolated silos of care embodied by the dental-specific PDHP contracts, toward a model of fully integrated, comprehensive, coordinated care. In the SMMC program, each Medicaid recipient has one managed care organization to coordinate all health care services, rather than various entities.[21] Such coordinated care is particularly important in the area of oral health, which is connected to overall health outcomes.[22]

In December, 2012, AHCA released an Invitation to Negotiate (ITN) to competitively procure managed care plans on a regional basis for the MMA program.[23] AHCA selected 19 managed care plans and executed 5-year contracts in February, 2014. The MMA program was fully implemented statewide by of August 1, 2014.

Dental Care in the MMA Program

The last remaining contracts with the PDHP providers (DentaQuest and MCNA) expired on September 30, 2014. On October 1, 2014, the statutory authority for the AHCA to contract with PDHPs to provide dental services to eligible Medicaid recipients expired.

[17] Information provided by AHCA and on file with the Health Innovation Subcommittee.
[18] The 2005-2011 data for PDHPs was self-reported by the plans. 2012 was the first year the PDHPs submitted performance measures that were audited by an NCQA-certified HEDIS auditor.
[19] AHCA, *supra,* note 17.
[20] The other component of the SMMC program is the Long-Term Care Managed Care Program.
[21] This comprehensive coordinated system of care was successfully implemented in the 5-county Medicaid reform pilot program, 2006-2014.
[22] U.S. Department of Health and Human Services. *Oral Health in America: A Report of the Surgeon General.* Rockville, MD: U.S. Department of Health and Human Services, National Institute of Dental and Craniofacial Research, National Institutes of Health, 2000. http://profiles.nlm.nih.gov/ps/retrieve/ResourceMetadata/NNBBJT/ (last viewed March 7, 2015).
[23] AHCA Invitation to Negotiate, *Statewide Medicaid Managed Care, Addendum 2* Solicitations Number: AHCA ITN 017-12/13; dated February 26, 2013 http://www.govcb.com/Statewide-Medicaid-Managed-Care-ADP13619273520001182.htm (March 6, 2015); AHCA Invitation to Negotiate, *Statewide Medicaid Managed Care*, Solicitation Number: AHCA ITN 017-12/13; dated December 28, 2012 http://www.govcb.com/Statewide-Medicaid-Managed-Care-ADP13619273520001182.htm (March 6, 2015).

As of February 2015, over 2.9 million Medicaid recipients are enrolled in the MMA program and receive their dental services through managed care plans that offer a full array of medical, behavioral, and dental health benefits.[24]

Under the MMA contracts, all managed care plans are required to provide comprehensive Medicaid services, including all Medicaid covered dental services, to their enrollees. Most of MMA managed care plans also provide full adult dental services at no additional cost to the state. Full adult dental services have never before been offered by Florida Medicaid. Examples of these additional benefits include twice-yearly exams and cleanings, fluoride treatments, fillings, and yearly x-rays.[25] These additional services are valued at over $100 million over the 5-year duration of the MMA contracts.[26] This unusual offering may be due to two factors: Consumer choice drove plans to offer more competitive benefit packages, and the risk-adjusted capitated payment model ensures plans will bear the cost of dental emergencies, which gives them an incentive to avoid costly crisis events with preventive care. Since July 2014, 72,552 adult enrollees have received dental benefits under the MMA program.

The Managed Care Plans participating in the SMMC have developed their dental networks both by subcontracting with PDHPs and directly contracting with dentists. Both DentaQuest and MCNA, the former PDHP contractors, have subcontracts in a majority of regions of the state, while two other plans, Liberty Dental Plan and Dental Benefits Provider, Inc., also have subcontracts.[27]

Dental Subcontractor	MMA Region
DentaQuest	1, 4, 5, 6, 7, 9, 10, 11
MCNA	2, 3, 4, 5, 6, 7, 8, 9, 10, 11
Liberty Dental Plan	2, 3, 4, 6, 7, 8, 11
Dental Benefits Provider, Inc.	3, 7,11

Dental Service Accountability and Performance in the MMA Program

The MMA program contracts impose various accountability provisions and performance measures on the MMA plans, specific to dental services.

First, the MMA contracts impose specific requirements for network adequacy, to ensure a sufficient number of primary and specialty dental care providers are available to meet the needs of plan enrollees.[28] This includes having at least one full time primary dental provider per service area and at least one full time primary dental provider per every 1500 enrollees.[29] Dentist participation in Medicaid has increased 17 percent since the implementation of the MMA program.[30]

Dentists Participating in Medicaid

Nov.2013	Jan.2015	Total Percent Change
1,884	2,203	17%

[24] Comprehensive Medicaid Managed Care Enrollment Reports, AHCHA, February 2015. http://www.fdhc.state.fl.us/MCHQ/Managed_Health_Care/MHMO/med_data.shtml (last viewed March 8, 2015).
[25] Information provided by AHCA and on file with the Health Innovation Subcommittee.
[26] AHCA 2014 Agency Legislative Bill Analysis for HB 27, dated November 25, 2013 (on file with the Health Innovation Subcommittee).
[27] AHCA, *supra,* note 17.
[28] MMA Model Agreement, Attachment II, Exhibit II-A, pp. 83-85.
[29] Id.
[30] Id.

Second, the contracts require managed care plans to maintain an annual medical loss ratio of a minimum of 85 percent for the first full year of MMA program operation.[31]

In addition, under the federal terms and conditions of the 1115 waiver, AHCA must work with MMA plans on an oral health quality improvement initiative. For this initiative, the MMA contracts[32] have specific performance goals for pediatric dental and penalties for not reaching the performance standards.

Each MMA plan is required to provide a Child Health Check-Up to enrollees. The Check-Up includes dental screenings and referral starting at age 3, or earlier if indicated. The MMA plans must achieve a Check-Up (including dental screening) rate of at least 80 percent for children enrolled for eight continuous months. A plan that fails to meet this goal is subject to a corrective action plan and liquidated damages of $50,000 per occurrence in addition to $10,000 for each percentage point less than the target.[33] As part of the integration of care, the MMA plan must provide transportation to and from the child's Check-Up, if needed.

The MMA plans are required to achieve a preventive dental services rate of at least 28 percent for children enrolled for 90 continuous days. A plan that fails to meet this goal is subject to a corrective action plan and liquidated damages of $50,000 per occurrence in addition to $10,000 for each percentage point less than the target.[34] As part of the integration of care, the MMA plan must provide transportation to and from the child's dental appointment, if needed.

Additionally, the Managed Care Plans are required to have HEDIS scores above 50 percent for pediatric dental or be subject liquidated damages. This requires a significant improvement over current PDHPs and reform county plans. The liquidated damages will be calculated based on the number of members enrolled in the Managed Care Plan as follows:

PM Ranking	Amount per Member
40th-49th percentile	$1.25
25th-39th percentile	$2.00
10th-24th percentile	$2.75
< 10th percentile	$3.50

Federal Waiver Authority

To use the PDHP model to deliver dental services to Medicaid recipients, AHCA had to obtain section 1915(b) waiver authority. This waiver authority expired on January 31, 2014. AHCA did not seek renewal of the waiver. Instead, the federal government agreed to give a series of temporary extensions to the 1915(b) waiver as AHCA implemented the SMMC program, allowing dental services to be gradually folded into the SMMC program and then letting the section 1915(b) waiver expire.[35]

To implement the SMMC program, AHCA applied for and obtained section 1115 waiver authority. Section 1115 of the Social Security Act allows states to use innovative service delivery systems that improve care, increase efficiency, and reduce costs. Federal authority for including dental services in the SMMC program is in the approved section 1115 waiver.[36]

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[31] MMA Model Agreement, Attachment II, Exhibit II A, Medicaid Managed Medical Assistance Program, Agency for Health Care Administration, February, 2014, available at http://ahca.myflorida.com/Medicaid/statewide_mc/plans.shtml (last viewed March 7, 2015).
[32] The Managed Medical Assistance Model Contract is available at: http://ahca.myflorida.com/Medicaid/statewide_mc/plans.shtml (last viewed March 7, 2015).
[33] MMA Model Agreement, Attachment II, Exhibit II-A, pp. 22, 109.
[34] MMA Model Agreement, Attachment II, Exhibit II-A, pp. 22, 110.
[35] AHCA, *supra,* note 26.
[36] AHCA, *supra,* note 9.

Currently, Florida only has federal authority to provide dental services to Medicaid recipients as an integrated component of the SMMC program.

Effect of the Proposed Changes

The bill removes pediatric dental services from the integrated MMA program by creating a new statewide prepaid dental program. AHCA is directed to contract with at least two PDHPs on a statewide basis to provide dental services to children enrolled in Medicaid. The bill requires AHCA to contract only with PDHPs that have experience maintaining statewide dental provider networks for Medicaid programs.

To remove dental services from the SMMC program, AHCA will have to apply for an amendment of the approved section 1115 waiver to remove pediatric dental services from the SMMC program's covered benefits. AHCA will likely also have to seek 1915(b) waiver authority to utilize the PDHP model to deliver dental services, because the prior waiver authority expired September 30, 2014. AHCA will have to either apply for a new 1915(b) waiver or seek an amendment to the approved section 1115 waiver to reestablish this authority. The bill gives AHCA the authority to seek any state plan amendments or waiver authority necessary to implement the program.

The federal government has no time limits for reviewing a request for a section 1115 waiver. The bill delays enrollment in the PDHPs until all necessary state plan amendments or federal waivers have been obtained. However, the bill intends that enrollment begin no later than September 1, 2016.

The bill requires that any child who is eligible for Medicaid benefits between the effective date of the act and implementation of the PDHP receive dental services through the MMA program. The child will be removed from the MMA plan and enrolled in a PDHP once the PDHP program is implemented. The bill requires AHCA to provide recipients with all required notices regarding this transition, and allows AHCA to assess the PDHPs for the costs of this notification.

Because AHCA and the MMA plans based their contract negotiations and capitated rates on the current law that requires coverage of pediatric dental services, AHCA may be required to renegotiate rates with all the MMA plans and amend contract terms, including network adequacy requirements and performance measures. Similarly, because the SMMC plans based their provider payment and network development on the current law requirement to cover pediatric dental services, the SMMC plans may have to renegotiate with dental providers to reflect the lower volume of (adult only) care.

The bill requires a medical loss ratio of 85 percent for prepaid dental plans participating in the PDHP. This is identical to the medical loss ratio requirement for MMA.

The bill requires AHCA to provide an annual report to the Governor and Legislature which compares the utilization, benefit and cost data from Medicaid dental contractors as well as compliance reports and access to care to the state's overall Medicaid dental population.

The bill amends s. s. 409.973, F.S., remove pediatric dental services from the MMA program and to provide that only adult dental services[37] are the only dental services available in that program.

B. SECTION DIRECTORY:

Section 1: Creating s. 409.91205, F.S., relating to statewide prepaid dental program.
Section 2: Amending s. 409.973, F.S., relating to social and economic assistance benefits.
Section 3: Providing that the act shall take effect upon becoming a law.

[37] Adult dental services include only dentures and medically necessary, emergency dental procedures to alleviate pain or infection. S. 409.906(1), (6), F.S

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   AHCA anticipates the need for an additional five (5) FTEs, pay grade 24, employees to implement this bill. AHCA will need: (a) an FTE to develop the competitive procurement document and manage the contracts, (b) three (3) FTEs to monitor the contracts, and (c) an FTE to prepare and manage the new Section 1915(b) waiver including all required federal reporting. Expenditures for these activities will be $21,315 nonrecurring (AHCA standard expense package), $191,544 in FY 2015-16 and $230,927 annually thereafter. Expenditures related to the five additional positions and the cost implied from FY 2016-17 would be funded using General Revenue and federal match dollars

   A procurement defense of specifications and bid awards, through appeal, will cost approximately $100,000.00 in contract services dollars for outside counsel representation.

   There are indeterminate, but likely significant, costs related to re-negotiation of the MMA contracts, re-procurement of the SMMC program, re-procurement of the PDHPs, legal challenges and system changes required to implement the exclusion of dental services from the MMA program.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

For the majority of adult Medicaid enrollees, current dental benefits are extremely limited. Under MMA, AHCA negotiated expanded dental benefits with the managed care organizations at no cost to AHCA. AHCA estimates the value of these additional benefits at $100 million over 5 years, at no additional cost to taxpayers.[38] However, if the pediatric enrollees are carved out of the MMA contracts, AHCA believes that the managed care organizations will lose leverage with the dental providers and existing dental provider networks resulting in the loss of the expanded benefit for the adults.[39] In all likelihood, adult Medicaid enrollees will lose access to expanded dental benefits, dental providers will lose the opportunity for increased patients and revenue, and taxpayers will not have the benefit of a no-cost $100 million negotiated contract term.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

[38] AHCA, *supra,* note 26.
[39] AHCA, *supra,* note 9.

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

   Requiring AHCA to contract with licensed prepaid dental health plans for Medicaid dental services after October 1, 2014, could implicate constitutional prohibitions against impairment of contracts.

   On December 28, 2012, AHCA released an Invitation to Negotiate (ITN) to competitively procure managed care plans on a statewide basis.[40] Dental services were included in the ITN as one of the enumerated services to be provided under the MMA program. On February 6, 2014, AHCA executed contracts with the managed care plans selected to provide care, including dental services, under the MMA program.

   The United States Constitution and the Florida Constitution prohibit the state from passing any law impairing the obligation of contracts.[41] The courts will subject state actions that impact state-held contracts to an elevated form of scrutiny when the Legislature passes laws that impact such contracts. *Cf. Chiles v. United Faculty of Fla.*, 615 So.2d 671 (Fla. 1993). "[T]he first inquiry must be whether the state law has, in fact, operated as a substantial impairment of a contractual relationship. The severity of the impairment measures the height of the hurdle the state legislation must clear."[42]

   The estimated annualized value of the MMA contracts is approximately $70 billion over 5 years. The change in the value of these MMA contracts due to the value of removing the dental benefit may be deemed substantial if AHCA must re-negotiate these contracts or re-procure due to severing dental benefits from the benefits to be provided.

   If a law does impair contracts, the courts will assess whether the law is reasonable and necessary to serve an important public purpose.[43] The court will also consider three factors when balancing the impairment of contracts with the important public purpose:

   - Whether the law was enacted to deal with a broad economic or social problem;
   - Whether the law operates in an area that was already subject to state regulation at the time the contract was entered into; and
   - Whether the effect on the contractual relationship is temporary; not severe, permanent, immediate, and retroactive.[44]

   A law that is deemed to be an impairment of contract will be deemed to be invalid as it applies to any contracts entered into prior to the effective date of the act.

B. RULE-MAKING AUTHORITY:

   None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

   There is a potential that non-winning vendors of the MMA procurement might initiate litigation. Non-winning vendors which had not included comparable adult dental benefits might challenge the change in terms and argue a different approach would have been taken if they had known that dental would be

[40] Id.
[41] U.S. Const. art. I, § 10; art. I, s. 10, Fla. Const.
[42] *Pomponio v. Claridge of Pompano Condominium, Inc.*, 378 So. 2d 774 (Fla. 1980). *See also General Motors Corp. v. Romein*, 503 U.S. 181 (1992).
[43] *Park Benzinger & Co. v. Southern Wine & Spirits, Inc.*, 391 So. 2d 681 (Fla. 1980); *Yellow Cab C., v. Dade County*, 412 So. 2d 395 (Fla. 3rd DCA 1982). *See also Exxon Corp. v. Eagerton*, 462 U.S. 176 (1983).
[44] *Pomponio v. Cladridge of Pompanio Condo., Inc.*, 378 So. 2d 774 (Fla. 1980).

carved out later. Similarly, some vendors that may have chosen not to compete due to an inadequate dental network might challenge a re-negotiation.

On December 28, 2012, AHCA released an Invitation to Negotiate (ITN) to competitively procure managed care plans on a statewide basis. Dental services were included in the ITN as one of the enumerated services to be provided under the SMMC. On February 6, 2014, AHCA executed contracts with the managed care plans selected to provide care, including dental services, under the SMMC. Legal challenges could result to due to the change in the term of the contracts. The contracts were negotiated, rates were set, and provider networks were established based on the requirement that dental services be included. The contacted rates and networks would not be valid under the bill; therefore, AHCA may have to reopen rate negotiations prior to implementing the SMMC program.

AHCA previously noted that creating a carve-out for any single service would set a bad precedent for the future of the new, reformed Medicaid program, and expects other service providers to seek carve-outs from the Legislature. [45] AHCA additionally notes that there is no data or evidence to suggest that the current approach to providing children's dental services through the MMA program is flawed in design, network adequacy, quality, or implementation.[46] A unified, coordinated system of care is a primary characteristic of Medicaid reform, in part because it solves the problem of complexity with which Florida's Medicaid program has been plagued for decades. In 2010, the Florida House of Representatives contracted with a consultant to analyze Florida's Medicaid program and identify problems and possible solutions. One of the consultant's conclusions was that Florida Medicaid's fragmented, complex system makes it difficult to improve value for patients and taxpayers.[47]

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

[45] AHCA, *supra,* note 26.
[46] AHCA, *supra,* note 9.
[47] Medicaid Managed Care Study, Pacific Health Policy Group, p. 73, March 2010

A bill to be entitled

An act relating to the statewide prepaid dental program; creating s. 409.91205, F.S.; providing legislative findings and intent; creating the Medicaid statewide prepaid dental program; directing the Agency for Health Care Administration to contract with prepaid dental health plans meeting specified criteria; directing the agency to apply for and implement state plan amendments or waivers of applicable federal laws and regulations necessary to implement the statewide prepaid dental program; directing the agency to competitively procure licensed prepaid dental health plans; prohibiting the agency from extending certain existing contracts; providing that enrollment in the statewide prepaid dental program shall not begin until the necessary state plan amendments or waivers of applicable federal laws and regulations are obtained and implemented; providing that a child who is eligible to receive Medicaid benefits during a specified period shall receive dental services through the Medicaid managed medical assistance program; directing the agency to provide any required notice to recipients regarding the transition from the Medicaid managed medical assistance program to the statewide prepaid dental program; providing that the agency may assess the

costs incurred in providing the notice to plans participating in the statewide prepaid dental program; requiring prepaid dental plans participating in the statewide prepaid dental program to submit encounter data; providing that the agency shall require a medical loss ratio for prepaid dental plans participating in the statewide prepaid dental program; requiring the agency to submit an annual report to the Governor and Legislature; specifying the contents of the report; amending s. 409.973, F.S.; removing the requirement that managed care plans participating in the Medicaid managed assistance program provide pediatric dental services; providing an effective date.

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

Section 1. Section 409.91205, Florida Statutes, is created to read:

409.91205 Statewide prepaid dental program.—

(1) The Legislature finds and declares that the design and delivery of children's Medicaid dental services should be directed by the principle that the health of children is an overriding concern. The Legislature also finds that the delivery of dental services as compared to other health care services is considerably different and, considering the historical

shortcomings of access to dental care in Florida, special attention must be given to children's accessibility to dental care and provider network sustainability. Therefore, it is the intent of the Legislature that a Medicaid prepaid dental program be established, on a statewide basis in all counties, separate and apart from the Medicaid managed medical assistance program described in ss. 409.961-409.985. Further, the Legislature finds that it is of paramount interest to the Medicaid program that continuous and high-quality dental care be provided to Medicaid recipients, and thus the agency shall ensure a seamless transition of the responsibility for the provision of dental services to children from the managed medical assistance program to the statewide prepaid dental program.

(2) Notwithstanding ss. 409.961-409.985, the agency shall implement the statewide prepaid dental program by contracting on a prepaid or fixed-sum basis with at least two appropriately licensed prepaid dental health plans to provide dental services to children statewide that demonstrate extensive experience in administering dental benefits for children enrolled in Medicaid and that have experience in constructing and maintaining statewide dental and specialty dental provider networks for Medicaid programs.

(a) The agency shall apply for and implement state plan amendments or waivers of applicable federal laws and regulations necessary to implement the statewide prepaid dental program.

(b) The agency shall competitively procure at least two appropriately licensed prepaid dental health plans to provide dental services to children statewide.

(c) Enrollment in the statewide prepaid dental program shall not begin until the necessary state plan amendments or waivers of applicable federal laws and regulations are obtained and implemented; however, it is the intent of the Legislature that enrollment should begin no later than September 1, 2016.

(d) A child who is eligible to receive Medicaid benefits between the date that this act takes effect and the implementation of the statewide prepaid dental program shall receive dental services as provided in ss. 409.961-409.985 until the child is eligible to enroll in the statewide prepaid dental program.

(e) Before enrollment in the statewide prepaid dental program, the agency shall provide any required notice to recipients regarding the transition. The agency may assess the costs incurred in providing the notice to the plans participating in the statewide prepaid dental program.

(f) The prepaid dental plans participating in the statewide prepaid dental program shall be required by contract to submit encounter data as described in s. 409.967(2)(d).

(g) The agency shall require a medical loss ratio of 85 percent for prepaid dental plans participating in the statewide prepaid dental program. The calculation shall use uniform financial data collected from all plans and shall be computed

for each plan on a statewide basis. The method for calculating the medical loss ratio shall require that expenditures be classified in a manner consistent with 45 C.F.R. part 158.

(3) The agency shall submit a report by January 15 of each year on operation of the statewide prepaid dental program to the Governor, the President of the Senate, and the Speaker of the House of Representatives that compares the combined annual benefits utilization and encounter data reported by all participating prepaid dental plans, along with the agency's findings with respect to projected and budgeted annual program costs, the extent to which each plan is complying with all contract terms and conditions, the effect that each plan's operation is having on access to care for Medicaid recipients in the plan's service area, and the statistical trends associated with indicators of good oral health among all recipients served in comparison with the state's population as a whole.

Section 2. Paragraph (e) of subsection (1) of section 409.973, Florida Statutes, is amended to read:

409.973 Benefits.—

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

(e) Adult dental services as described in s. 409.906(1).

Section 3. This act shall take effect upon becoming a law.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 749 Continuing Care Communities
SPONSOR(S): Van Zant and others
TIED BILLS: **IDEN./SIM. BILLS:** SB 1126

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Innovation Subcommittee		Guzzo	Poche
2) Insurance & Banking Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

Continuing Care Communities (CCCs) are retirement facilities that furnish residents with shelter and health care for an entrance fee and monthly payments. CCCs are regulated by the Department of Financial Services, the Agency for Health Care Administration and the Office of Insurance Regulation (OIR). Pursuant to chapter 651, F.S., CCCs are governed by a contract between the facility and the resident. In Florida, continuing care contracts are considered an insurance product and are reviewed and approved by OIR. The OIR authorizes and monitors a facility's operation as well as determines the facility's financial status and the management capabilities of its managers and owners. Currently, there are 71 CCCs in Florida.

A resident of a CCC is required to pay an entry fee upon entering a contract with a facility. The contract must include the terms for which a resident is due a refund of any portion of the entrance fee. If the contract provides that the resident does not receive a transferable membership or ownership right in the facility, and the resident has occupied his or her unit, the refund must be calculated on a pro-rata basis with the facility retaining up to two-percent per month of occupancy by the resident and up to a five-percent processing fee, the balance of which must be paid within 120 days after the resident gives notice of intent to cancel. Similarly, a contract may provide a one-percent declining-scale refund, but the refund must be paid from the proceeds of the next entrance fees received by the provider for units for which there are no prior claims.

The bill makes several changes to chapter 651, F.S. Specifically, the bill:

- Requires a CCC contract, paying a two-percent refund, to provide for payment to a resident within 90 days after the contract is terminated and the unit is vacated, instead of 120 days after notice of intent to cancel;
- Requires a CCC contract, paying a one-percent refund, to provide for payment to a resident for the unit that is vacated, or a like or similar unit, whichever is applicable, by specified time frames;
- Clarifies that CCCs must be accredited for OIR to waive equivalent requirements in rule or law;
- Makes a continuing care at-home contract a preferred claim against a provider in bankruptcy proceedings;
- Requires OIR to notify the executive office of the governing body of the CCC provider about all deficiencies found as part of an examination;
- Requires a CCC to provide a copy of any final examination report and corrective action plan to the executive officer of the governing body of the provider within 60 days after issuance of the report;
- Requires each CCC to establish a resident's council to provide input on subjects that impact the general residential quality of life;
- Authorizes the board of directors or governing board of a provider to allow a facility resident to be a voting member of the board or governing body of the facility; and
- Requires all CCCs to provide a copy of the most recent third-party financial audit to the president or chair of the resident's council within 30 days of filing the annual report with OIR.

The bill does not appear to have a fiscal impact on state or local government.

The bill provides an effective date of October 1, 2015.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Continuing Care Communities (CCCs)

A CCC is a residential alternative for older adults (usually age 65 and older) that provides flexible housing options, a coordinated system of services and amenities, and a lifetime continuum of care that addresses the varying health and wellness needs of residents as they grow older.[1] The foundation of the CCC model is based on enabling residents to move within the community if their health care needs change and they require supervision.[2] The services provided by the CCC and purchased by the resident are governed by contract, or resident service agreement. Entry fees can range from $20,000 to more than $1 million, depending on the geographic location of the CCC, features of the living space, size of the living unit, additional services and amenities selected, whether one or two individuals receive services, and the type of service contract.[3]

There are 1,926 CCCs in the United States.[4] The average number of units in a CCC is 280.[5] Over eighty-percent of CCCs are not-for-profit sponsored, and roughly half of CCCs are faith-based.[6] CCCs feature a combination of living arrangements and nursing beds. There are 71 CCCs in Florida, and a total of 24,775 CCC residents.[7]

The typical accommodations and services include:

- Independent living units – a cottage, townhouse, cluster home, or apartment; the resident is generally healthy and requires little, or no, assistance with activities of daily living.
- Assisted living – a studio or one-bedroom apartment designed for frail individuals who can still maintain a level of independence but need some assistance with activities of daily living.
- Nursing – nursing services are offered on-site or nearby the CCC to provide constant care for recovery from a short-term injury or illness, treatment of a chronic condition, or higher levels of services.
- Memory-care support – offers dedicated cognitive support care with the goal of maximizing function, maintaining dignity, preserving sense of self, and optimizing independence.[8]

In order to offer continuing care[9] services in Florida, a provider must be licensed by obtaining a certificate of authority (COA).[10] To obtain a COA, each applicant must first apply for and obtain a provisional COA.[11] The OIR is responsible for receiving, reviewing and approving or denying

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[1] Continuing Care Retirement Community Task Force, Leading Age, American Seniors Housing Association, *Today's Continuing Care Retirement Community*, at page 2 (Jane E. Zarem ed. 2010).
[2] Id.
[3] Id., at page 9.
[4] Ziegler, *Senior Living Overview* (October 8, 2014) , at page 26, available at www.flicra.com/pdfs/FLiCRA%20Presentation%2010-8-14.pdf (last visited March 7, 2015).
[5] Id.
[6] Id.
[7] Presentation to the Governor's Continuing Care Advisory Council, September 29, 2014, available at http://www.floir.com/siteDocuments/CouncilPresentation.pdf. (last visited March 7, 2015).
[8] See supra, FN 1, at 4.
[9] S. 651.011(2), F.S., "...furnishing shelter or nursing care or personal services to a resident who resides in a facility, whether such nursing care or personal services are provided in the facility or in another setting designated in the contract for continuing care, by an individual not related by consanguinity or affinity to the resident, upon payment of an entrance fee."
[10] S. 651.011(9), F.S.
[11] S. 651.022, F.S.; *see also* s. 651.022(2) and (3), F.S., for detailed description of information, reports and studies required to be submitted with an application for a provisional COA.

applications for provisional COAs within a specified time period.[12] Upon receipt of a provisional COA, a provider may collect entrance fees and reservation deposits from prospective residents of a proposed continuing care facility.[13]

To obtain a COA, each provider holding a provisional COA must submit additional documentation regarding financing of the proposed facility, receipt of aggregate entrance fees from prospective residents, completed financial audit statements, and other specific information.[14] The OIR is required to issue a COA once it determines that a provider meets all requirements of law, has submitted all necessary information required by statute, has met all escrow requirements, and has paid appropriate fees set out in s. 651.015(2), F.S.[15] Further, a COA will only be issued once a provider submits proof to OIR that a minimum of fifty-percent of the units available, for which entrance fees are being charged, are reserved.[16] Upon receiving a COA, a provider may request the release of entrance fees held in escrow.[17]

Pursuant to s. 651.028, F.S., if a provider is accredited by a process found by the OIR to be acceptable and substantially equivalent to the provisions of chapter 651, F.S., the office may, pursuant to rule of the commission, waive any requirements of chapter 651, F.S., with respect to the provider if the OIR finds that such waivers are not inconsistent with the security protections of chapter 651, F.S.

CCC Contracts

Continuing care services are governed by a contract between the facility and the resident of a CCC. In Florida, continuing care contracts are considered an insurance product, and are reviewed and approved for the market by the OIR.[18] Each contract for continuing care services must:

- Provide for continuing care of one resident, or two residents living in a double occupancy room, under regulations established by the provider;
- List all properties transferred to the facility and their market value at the time of transfer;
- Specify all services to be provided to each resident;
- Describe terms and conditions for cancellation of the contract;
- Describe the health and financial conditions required for a person to be accepted as a resident and to continue as a resident;
- Describe the circumstances under which the resident will be permitted to remain in the facility in the event of financial difficulties of the resident; and
- Provide the fees that will be charged if the resident marries while at the designated facility, the terms concerning the entry of a spouse to the facility, and the consequences if the spouse does not meet the requirements for entry.[19]

The contract is also required to provide that it may be canceled by giving at least 30 days' written notice by the provider, the resident, or the person who provided the transfer of property or funds for the care of such resident.[20]

In the event of receivership or liquidation proceedings against a provider, all continuing care contracts executed by a provider must be deemed preferred claims against all assets owned by the provider.

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[12] S. 651.022(5) and (6), F.S.
[13] S. 651.022(7), F.S., which requires the fee to be deposited into escrow or placed in deposit with the department of financial services until a COA is issued by OIR.
[14] S. 651.023(1), F.S.
[15] S 651.023(4), F.S.
[16] S. 651.023(4)(a), F.S.
[17] S. 651.023(6), F.S.
[18] S. 651.055(1), F.S.
[19] Id.
[20] S. 651.055(1)(g), F.S.

Entrance Fee Refunds

A resident of a CCC is required to pay an entry fee upon entering a contract with a facility. The contract must include the terms for which a resident is due a refund of any portion of the entrance fee.[21] If the contract provides that the resident does not receive a transferable membership or ownership right in the facility, and the resident has occupied his or her unit, the refund must be calculated on a pro-rata basis with the facility retaining up to two-percent per month of occupancy by the resident and up to a five-percent processing fee, the balance of which must be paid within 120 days after the resident gives notice of intent to cancel. This is known as a two-percent declining-scale refund and provides a resident with up to 47.5 months of residency before the refund is reduced to zero. Similarly, a contract may provide a one-percent declining-scale refund and is allowed to have the timing of any resident refund dependent on the resale of any unit but are not allowed to make the timing dependent on the resale of a particular unit or type of units.[22]

Resident's Council

Section 651.081, F.S., provides for the creation of a single statewide resident's council. Section 651.085, F.S., requires the governing body of a provider, or the designated representative of the provider, to hold quarterly meeting with the residents of the CCC for the purpose of free discussion of issues and concerns of residents. The resident's council is tasked with different duties associated with the quarterly meetings between residents and the governing body of the provider, as provided in s. 651.085, F.S. References to the resident's council in s. 651.085, F.S., may be confused or misinterpreted to allow for multiple councils instead of the the singular council as created by s. 651.081, F.S.

Examinations and Inspections

The OIR is authorized to examine at any time, and at least once every three years, the business of any applicant for a certificate of authority and any provider engaged in the execution of care contracts in the same manner as provided for the examination of insurance companies[23] pursuant to s. 624.316, F.S.[24] The OIR is required to notify the provider in writing of all deficiencies in its compliance with the provisions of chapter 651, F.S., and must set a reasonable length of time for compliance by the provider.[25] At the time of routine examination, OIR must determine if all disclosures required under chapter 651, F.S., have been made to the president or chair of the resident's council.

Effect of Proposed Changes

The bill modifies the timing of refunds paid by CCCs to their residents for certain contracts. A CCC contract, paying a two-percent declining-scale refund, must provide for payment to a resident within 90 days after the contract is terminated and the unit is vacated, instead of 120 days after notice of intent to cancel as required by current law. Similarly, the bill requires a CCC contract, paying a one-percent declining-scale refund, to provide for payment to a resident from:

- The proceeds of the next entrance fees received by the provider for units for which there are no prior claims by any resident;

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[21] Id.
[22] Id.
[23] S. 624.316, F.S., "...The office shall examine the affairs, transactions, accounts, records, and assets of each authorized insurer and of the attorney in fact of a reciprocal insurer as to its transactions affecting the insurer as often as it deems advisable, except as provided in this section. The examination may include examination of the affairs, transactions, accounts, and records relating directly or indirectly to the insurer and of the assets of the insurer's managing general agents and controlling or controlled person, as defined in s. 625.012. The examination shall be pursuant to a written order of the office. Such order shall expire upon receipt by the office of the written report of the examination."
[24] S. 651.105(1), F.S.
[25] S. 651.105(4), F.S.

- The proceeds of the next entrance fee received by the provider for a like or similar unit as specified in the residency or reservation contract signed by the resident for which there are no prior claims by any resident until paid in full; or
- The proceeds of the next entrance fee received by the provider for the unit that is vacated if the contract is approved by the OIR before October 1, 2015. Providers may not use this refund option after October 1, 2016, and must submit a new or amended contract with an alternative refund provision to the office for approval by August 2, 2016.

For contracts entered into on or after January 1, 2016, that provide for a refund from the proceeds of the next entrance fee received by the provider for a like or similar unit, the bill requires any refund that is due upon the resident's death or relocation of the resident to another level of care that results in the termination of the contract to be paid the earlier of:

- Thirty days after receipt by the provider of the next entrance fee received for a like or similar unit for which there is no prior claim by any resident until paid in full; or
- No later than a specified maximum number of months or years, determined by the provider and specified in the contract, after the contract is terminated and the unit is vacated.

Further, the bill requires any refund that is due to be paid to a resident who vacates the unit and voluntarily terminates a contract after the seven-day rescission period, to be paid within thirty days of receipt by the provider of the next entrance fee for a like or similar unit for which there are no prior claims. A contract is voluntarily terminated when a resident provides written notice of intent to leave and moves out of the CCC after the seven-day rescission period. The bill defines the term "like or similar units" to mean a residential dwelling categorized into a group of units which have similar characteristics such as comparable square footage, number of bedrooms, location, age of construction, or a combination of one or more of these features. A CCC that offers such contracts must have a minimum of the lesser of five-percent of the total number of independent living units or ten units in each category unless the category consists of single family home, in which case there is no limit.

The bill requires the OIR to notify the executive office of the governing body of the CCC provider about all deficiencies found as part of an examination, and requires a CCC to provide a copy of any final examination report and corrective action plan to the executive officer of the governing body of the provider within 60 days after issuance of the report.

The bill requires each CCC to establish a resident's council to provide input on subjects that impact the general residential quality of life; authorizes the board of directors or governing board of a licensed provider to allow a facility resident to be a voting member of the board or governing body of the facility; and requires all CCCs to provide a copy of the most recent third-party financial audit to the president or chair of the resident's council within 30 days of filing the annual report to OIR.

The bill makes a continuing care at-home contract a preferred claim against a provider in bankruptcy proceedings. It also requires that a CCC must be accredited without stipulations or conditions for the OIR to waive any statutory requirements under chapter 651, F.S.

The bill provides an effective date of October 1, 2015.

B. SECTION DIRECTORY:

Section 1: Amends s. 651.055, F.S., relating to continuing care contracts; right to rescind.
Section 2: Amends s. 651.028, F.S., relating to accredited facilities.
Section 3: Amends s. 651.071, F.S., relating to contracts as preferred claims on liquidation or receivership.
Section 4: Amends s. 651.105, F.S., relating to examination and inspections.
Section 5: Amends s. 651.081, F.S., relating to resident's council.

Section 6: Amends s. 651.085, F.S., relating to quarterly meetings between residents and the governing body of the provider; resident representation before the governing body of the provider.

Section 7: Amends s. 651.091, F.S., relating to availability, distribution, and posting of reports and records; requirement of full disclosure.

Section 8: Provides an effective date of October 1, 2015.

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. The bill does not appear to affect county or municipal governments.

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

No additional rulemaking 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 continuing care communities; amending s. 651.055, F.S.; revising requirements for continuing care contracts; amending s. 651.028, F.S.; revising authority of the Office of Insurance Regulation to waive requirements for accredited facilities; amending s. 651.071, F.S.; providing that continuing care and continuing care at-home contracts are preferred claims in the event of bankruptcy proceedings against a provider; revising subordination of claims; amending s. 651.105, F.S.; revising notice requirements; revising duties of the office; requiring an agent of a provider to provide a copy of an examination report and corrective action plan under certain conditions; amending s. 651.081, F.S.; requiring a residents' council to provide a forum for certain purposes; requiring a residents' council to adopt its own bylaws and governance documents; amending s. 651.085, F.S.; revising provisions relating to quarterly meetings between residents and the governing body of the provider; revising powers of the residents' council; amending s. 651.091, F.S.; revising continuing care facility reporting requirements; providing an effective date.

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

Section 1. Paragraphs (g) through (k) of subsection (1) of section 651.055, Florida Statutes, are amended to read:

651.055 Continuing care contracts; right to rescind.—

(1) Each continuing care contract and each addendum to such contract shall be submitted to and approved by the office before its use in this state. Thereafter, no other form of contract shall be used by the provider until it has been submitted to and approved by the office. Each contract must:

(g) Provide that the contract may be canceled by giving at least 30 days' written notice of cancellation by the provider, the resident, or the person who provided the transfer of property or funds for the care of such resident. However, if a contract is canceled because there has been a good faith determination that a resident is a danger to himself or herself or others, only such notice as is reasonable under the circumstances is required.

(h)~~1.~~ Describe ~~The contract must also provide~~ in clear and understandable language, in print no smaller than the largest type used in the body of the contract, the terms governing the refund of any portion of the entrance fee.

1.~~2.~~ For a resident whose contract with the facility provides that the resident does not receive a transferable membership or ownership right in the facility, and who has occupied his or her unit, the refund shall be calculated on a pro rata basis with the facility retaining up to 2 percent per

month of occupancy by the resident and up to a 5 percent processing fee. Such refund must be paid within 120 days after giving the notice of intention to cancel. For contracts entered into on or after January 1, 2016, refunds must be made within 90 days after the contract is terminated and the unit is vacated. A resident who enters into a contract before January 1, 2016, may voluntarily sign a contract addendum approved by the office that provides for such revised refund requirement.

2.~~3.~~ In addition to a processing fee not to exceed 5 percent, if the contract provides for the facility to retain no more than ~~up to~~ 1 percent per month of occupancy by the resident and the resident does not receive a transferable membership or ownership right in the facility, the contract shall~~, it may~~ provide that such refund will be paid from one of the following:

a. The proceeds of the next entrance fees received by the provider for units for which there are no prior claims by any resident until paid in full;

b. The proceeds of the next entrance fee received by the provider for a like or similar unit as specified in the residency or reservation contract signed by the resident for which there are no prior claims by any resident until paid in full; or

c. The proceeds of the next entrance fee received by the provider for the unit that is vacated if the contract is approved by the office before October 1, 2015. Providers may not use this refund option after October 1, 2016, and must submit a

new or amended contract with an alternative refund provision to the office for approval by August 2, 2016~~, if the provider has discontinued marketing continuing care contracts, within 200 days after the date of notice~~.

3. For contracts entered into on or after January 1, 2016, that provide for a refund in accordance with sub-subparagraph 2.b., the following provisions apply:

a. Any refund that is due upon the resident's death or relocation of the resident to another level of care that results in the termination of the contract must be paid the earlier of:

(I) Thirty days after receipt by the provider of the next entrance fee received for a like or similar unit for which there is no prior claim by any resident until paid in full; or

(II) No later than a specified maximum number of months or years, determined by the provider and specified in the contract, after the contract is terminated and the unit is vacated.

b. Any refund that is due to a resident who vacates the unit and voluntarily terminates a contract after the 7-day rescission period required in subsection (2) must be paid within 30 days after receipt by the provider of the next entrance fee for a like or similar unit for which there are no prior claims by any resident until paid in full and is not subject to the provisions in sub-subparagraph a. A contract is voluntarily terminated when a resident provides written notice of intent to leave and moves out of the continuing care facility after the 7-day rescission period.

4. For purposes of this paragraph, the term "like or similar unit" means a residential dwelling categorized into a group of units which have similar characteristics such as comparable square footage, number of bedrooms, location, age of construction, or a combination of one or more of these features as specified in the residency or reservation contract. Each category must consist of at least 5 percent of the total number of residential units designated for independent living or 10 residential units designated for independent living, whichever is less. However, a group of units consisting of single family homes may contain fewer than 10 units.

5. If the provider has discontinued marketing continuing care contracts, any refund due a resident must be paid within 200 days after the contract is terminated and the unit is vacated.

6.~~4.~~ Unless subsection (5) applies, for any prospective resident, regardless of whether or not such a resident receives a transferable membership or ownership right in the facility, who cancels the contract before occupancy of the unit, the entire amount paid toward the entrance fee shall be refunded, less a processing fee of up to 5 percent of the entire entrance fee; however, the processing fee may not exceed the amount paid by the prospective resident. Such refund must be paid within 60 days after the resident gives ~~giving~~ notice of intention to cancel. For a resident who has occupied his or her unit and who has received a transferable membership or ownership right in the

facility, the foregoing refund provisions do not apply but are deemed satisfied by the acquisition or receipt of a transferable membership or an ownership right in the facility. The provider may not charge any fee for the transfer of membership or sale of an ownership right.

(i) ~~(h)~~ State the terms under which a contract is canceled by the death of the resident. These terms may contain a provision that, upon the death of a resident, the entrance fee of such resident is considered earned and becomes the property of the provider. If the unit is shared, the conditions with respect to the effect of the death or removal of one of the residents must be included in the contract.

(j) ~~(i)~~ Describe the policies that may lead to changes in monthly recurring and nonrecurring charges or fees for goods and services received. The contract must provide for advance notice to the resident, of at least 60 days, before any change in fees or charges or the scope of care or services is effective, except for changes required by state or federal assistance programs.

(k) ~~(j)~~ Provide that charges for care paid in one lump sum may not be increased or changed during the duration of the agreed upon care, except for changes required by state or federal assistance programs.

(l) ~~(k)~~ Specify whether the facility is, or is affiliated with, a religious, nonprofit, or proprietary organization or management entity; the extent to which the affiliate organization will be responsible for the financial and

contractual obligations of the provider; and the provisions of the federal Internal Revenue Code, if any, under which the provider or affiliate is exempt from the payment of federal income tax.

Section 2. Section 651.028, Florida Statutes, is amended to read:

651.028 Accredited facilities.—If a provider is accredited <u>without stipulations or conditions</u> by a process found by the office to be acceptable and substantially equivalent to the provisions of this chapter, the office may, pursuant to rule of the commission, waive any requirements of this chapter with respect to the provider if the office finds that such waivers are not inconsistent with the security protections intended by this chapter.

Section 3. Subsection (1) of section 651.071, Florida Statutes, is amended to read:

651.071 Contracts as preferred claims on liquidation or receivership.—

(1) In the event of <u>bankruptcy,</u> receivership or liquidation proceedings against a provider, all continuing care and continuing care at-home contracts executed by a provider shall be deemed preferred claims against all assets owned by the provider; however, such claims are subordinate to ~~those priority claims set forth in s. 631.271 and~~ any secured claim.

Section 4. Subsections (4) and (5) of section 651.105, Florida Statutes, are amended, and subsection (6) is added to

that section, to read:

651.105 Examination and inspections.—

(4) The office shall notify the provider and the executive officer of the governing body of the provider in writing of all deficiencies in its compliance with the provisions of this chapter and the rules adopted pursuant to this chapter and shall set a reasonable length of time for compliance by the provider. In addition, the office shall require corrective action or request a corrective action plan from the provider which plan demonstrates a good faith attempt to remedy the deficiencies by a specified date. If the provider fails to comply within the established length of time, the office may initiate action against the provider in accordance with the provisions of this chapter.

(5) At the time of the routine examination, the office shall determine if all disclosures required under this chapter have been made to the president or chair of the residents' council and the executive officer of the governing body of the provider.

(6) A representative of the provider must give a copy of the final examination report and corrective action plan, if one is required by the office, to the executive officer of the governing body of the provider within 60 days after issuance of the report.

Section 5. Section 651.081, Florida Statutes, is amended to read:

651.081 Residents' council.—

(1) Residents living in a facility holding a valid certificate of authority under this chapter have the right of self-organization, the right to be represented by an individual of their own choosing, and the right to engage in concerted activities for the purpose of keeping informed on the operation of the facility that is caring for them or for the purpose of other mutual aid or protection.

(2)(a) Each facility shall establish a residents' council created for the purpose of representing residents on matters set forth in s. 651.085. The residents' council shall ~~may~~ be established through an election in which the residents, as defined in s. 651.011, vote by ballot, physically or by proxy. If the election is to be held during a meeting, a notice of the organizational meeting must be provided to all residents of the community at least 10 business days before the meeting. Notice may be given through internal mailboxes, communitywide newsletters, bulletin boards, in-house television stations, and other similar means of communication. An election creating a residents' council is valid if at least 40 percent of the total resident population participates in the election and a majority of the participants vote affirmatively for the council. The initial residents' council created under this section is valid for at least 12 months. A residents' organization formalized by bylaws and elected officials must be recognized as the residents' council under this section and s. 651.085. Within 30

days after the election of a newly elected president or chair of the residents' council, the provider shall give the president or chair a copy of this chapter and rules adopted thereunder, or direct him or her to the appropriate public website to obtain this information. Only one residents' council may represent residents before the governing body of the provider as described in s. 651.085(2).

(b) In addition to those matters provided in s. 651.085, a residents' council shall provide a forum in which a resident may submit issues or make inquiries related to, but not limited to, subjects that impact the general residential quality of life and cultural environment. The residents' council shall serve as a formal liaison to provide input related to such matters to the appropriate representative of the provider.

(c) The activities of a residents' council are independent of the provider. The provider is not responsible for ensuring, or for the associated costs of, compliance of the residents' council with the provisions of this section with respect to the operation of a resident's council.

(d) A residents' council shall adopt its own bylaws and governance documents. The residents' council shall provide for open meetings when appropriate. The governing documents shall define the manner in which residents may submit an issue to the council and define a reasonable timeframe in which the residents' council shall respond to a resident submission or inquiry. A residents' council may include term limits in its

governing documents to ensure consistent integration of new leaders. If a licensed facility files for bankruptcy under chapter 11 of the United States Bankruptcy Code, 11 U.S.C. chapter 11, the facility, in its required filing of the 20 largest unsecured creditors with the United States Trustee, shall include the name and contact information of a designated resident selected by the residents' council, and a statement explaining that the designated resident was chosen by the residents' council to serve as a representative of the residents' interest on the creditors' committee, if appropriate.

Section 6. Section 651.085, Florida Statutes, is amended to read:

651.085 Quarterly meetings between residents and the governing body of the provider; resident representation before the governing body of the provider.—

(1) The governing body of a provider, or the designated representative of the provider, shall hold quarterly meetings with the residents of the continuing care facility for the purpose of free discussion of subjects including, but not limited to, income, expenditures, and financial trends and problems as they apply to the facility, as well as a discussion on proposed changes in policies, programs, and services. At quarterly meetings where monthly maintenance fee increases are discussed, a summary of the reasons for raising the fee as specified in subsection (4) must be provided in writing to the president or chair of the residents' council. Upon request of

the residents' council, a member of the governing body of the provider, such as a board member, general partner, principal owner, or designated representative shall attend such meetings. Residents are entitled to at least 7 days' advance notice of each quarterly meeting. An agenda and any materials that will be distributed by the governing body or representative of the provider shall be posted in a conspicuous place at the facility and shall be available upon request to residents of the facility. The office shall request verification from a facility that quarterly meetings are held and open to all residents ~~if it receives a complaint from the residents' council that a facility is not in compliance with this subsection~~. In addition, a facility shall report to the office in the annual report required under s. 651.026 the dates on which quarterly meetings were held during the reporting period.

(2) A residents' council formed pursuant to s. 651.081, members of which are elected by the residents, shall ~~may~~ designate a resident to represent them before the governing body of the provider o~~r organize a meeting or ballot election of the residents to determine whether to elect a resident to represent them before the governing body of the provider. If a residents' council does not exist, any resident may organize a meeting or ballot election of the residents of the facility to determine whether to elect a resident to represent them before the governing body and, if applicable, elect the representative. The residents' council, or the resident that organizes a meeting or~~

~~ballot election to elect a representative, shall give all residents notice at least 10 business days before the meeting or election. Notice may be given through internal mailboxes, communitywide newsletters, bulletin boards, in-house television stations, and other similar means of communication. An election of the representative is valid if at least 40 percent of the total resident population participates in the election and a majority of the participants vote affirmatively for the representative.~~ The initial designated representative elected under this section shall be elected to serve at least 12 months.

(3) The designated representative shall be notified at least 14 days in advance of any meeting of the full governing body at which proposed changes in resident fees or services will be discussed. The representative shall be invited to attend and participate in that portion of the meeting designated for the discussion of such changes.

(4) At a quarterly meeting prior to the implementation of any increase in the monthly maintenance fee, the designated representative of the provider must provide the reasons, by department cost centers, for any increase in the fee that exceeds the most recently published Consumer Price Index for All Urban Consumers, all items, Class A Areas of the Southern Region. Nothing in this subsection shall be construed as placing a cap or limitation on the amount of any increase in the monthly maintenance fee, establishing a presumption of the appropriateness of the Consumer Price Index as the basis for any

increase in the monthly maintenance fee, or limiting or restricting the right of a provider to establish or set monthly maintenance fee increases.

(5) The board of directors or governing board of a licensed provider may at its sole discretion allow a resident of the facility to be a voting member of the board or governing body of the facility. The board of directors or governing board of a licensed provider may establish specific criteria for the nomination, selection, and term of a resident as a member of the board or governing body. If the board or governing body of a licensed provider operates more than one licensed facility, regardless of whether the facility is in-state or out-of-state, the board or governing body may select at its sole discretion one resident from among its facilities to serve on the board of directors or governing body on a rotating basis.

Section 7. Paragraph (d) of subsection (2) of section 651.091, Florida Statutes, is amended to read:

651.091 Availability, distribution, and posting of reports and records; requirement of full disclosure.—

(2) Every continuing care facility shall:

(d) Distribute a copy of the full annual statement and a copy of the most recent third party financial audit filed with the annual report to the president or chair of the residents' council within 30 days after filing the annual report with the office, and designate a staff person to provide explanation thereof.

Section 8. This act shall take effect October 1, 2015.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 999 Ambulatory Surgical Centers
SPONSOR(S): Fitzenhagen
TIED BILLS: **IDEN./SIM. BILLS:** SB 1394

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Innovation Subcommittee		Guzzo	Poche
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

Pursuant to s. 395.002, F.S., an ambulatory surgical center (ASC) is a facility, that is not a part of a hospital, the primary purpose of which is to provide elective surgical care, in which the patient is admitted and discharged within the same working day and is not permitted to stay overnight. Federal law prohibits a patient from staying longer than 24 hours after admission.

The bill changes the allowable length of stay in an ASC from less than one working day to no more than 24 hours, which is the Federal length of stay standard.

The bill does not appear to have a fiscal impact on state or local government.

The bill provides an effective date of July 1, 2015.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Ambulatory Surgical Centers (ASCs)

An ASC is a facility, that is not a part of a hospital, the primary purpose of which is to provide elective surgical care, in which the patient is admitted and discharged within the same working day and is not permitted to stay overnight.[1]

In Florida, ambulatory procedures are performed in two settings, hospital-based outpatient facilities and freestanding ASCs. Currently, there are 607 ASCs in Florida, including 402 freestanding ASCs and 205 hospital-based facilities.[2]

In 2013, there were 2,899,326 visits to ASCs in Florida.[3] Hospital outpatient facilities accounted for 46 percent and free standing ASCs accounted for 54 percent of the total number of visits. However, the breakdown of the $31.3 billion in total charges shows that hospital-based facilities accounted for 76 percent of the charges, while ASCs accounted for 24 percent.[4] The average charge at the hospital-based facilities ($17,721) was larger than the average charge at the freestanding ASCs ($4,844).[5] These visits and charges were paid mainly by commercial Insurance and Medicare. Commercial insurance paid for 39 percent of all charges (a total of $12.3 billion), while Medicare paid for 30 percent ($9.5 billion).[6] The next three top payer groups (Medicare Managed Care, Medicaid, and Medicaid Managed Care) accounted for a total of 19 percent ($6.3 billion) of the charge total.[7]

In 2013, the top three procedures accounting for the highest percentage of visits to ASCs were upper gastrointestinal endoscopy, cataract removal, and colonoscopy.[8]

ASC Licensure

ASCs are licensed and regulated by the Agency for Health Care Administration (AHCA) under the same regulatory framework as hospitals.[9]

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[1] Section 395.002(3), F.S. "Ambulatory surgical center" or "mobile surgical facility" means a facility the primary purpose of which is to provide elective surgical care, in which the patient is admitted to and discharged from such facility within the same working day and is not permitted to stay overnight, and which is not part of a hospital. However, a facility existing for the primary purpose of performing terminations of pregnancy, an office maintained by a physician for the practice of medicine, or an office maintained for the practice of dentistry shall not be construed to be an ambulatory surgical center, provided that any facility or office which is certified or seeks certification as a Medicare ambulatory surgical center shall be licensed as an ambulatory surgical center pursuant to s. 395.003. Any structure or vehicle in which a physician maintains an office and practices surgery, and which can appear to the public to be a mobile office because the structure or vehicle operates at more than one address, shall be construed to be a mobile surgical facility.

[2] Agency for Health Care Administration, *Facilities: All Florida Outpatient Ambulatory Surgical Centers*, available at http://www.floridahealthfinder.gov/CompareCare/ListFacilities.aspx (report generated March 6, 2015).

[3] Agency for Health Care Administration, *Ambulatory Facility Type Visits, 1992-2013*, available at http://floridahealthfinderstore.blob.core.windows.net/documents/researchers/QuickStat/documents/AMBULATORY%20FACILITY%20TYPE%20VISITS%201992-2013.xls (last viewed on March 7, 2015).

[4] Agency for Health Care Administration, *Ambulatory (Outpatient) Surgery Query Results, By Facility Type and Average Charges,* available at http://www.floridahealthfinder.gov/QueryTool/QTResults.aspx (last viewed on March 7, 2015).

[5] Id.

[6] Id., *By Patient, Primary Payer, and Average Charges* (last viewed on March 7, 2015).

[7] Id.

[8] Agency for Health Care Administration, *Ambulatory Surgery and Outpatient Procedures, Visits by Top CPT Codes, 2013*, page 6, available at http://floridahealthfinderstore.blob.core.windows.net/documents/researchers/QuickStat/documents/2013%20Ambulatory%20Quick%20Summary.net.

[9] Sections 395.001-395.1065, F.S., and Part II, Chapter 408, F.S.

Applicants for ASC licensure must submit certain information to AHCA prior to accepting patients for care or treatment, including the:

- Affidavit of compliance with fictitious name;
- Registration of articles of incorporation; and
- ASC's zoning certificate or proof of compliance with zoning requirements.[10]

Upon receipt of an initial application, AHCA is required to conduct a survey to determine compliance with all laws and rules. ASCs are required to provide certain information during the initial inspection, including the:

- Governing body bylaws, rules and regulations;
- Roster of registered nurses and licensed practical nurses with current license numbers;
- Fire plan; and
- Comprehensive Emergency Management Plan.[11]

Rules for ASCs

Pursuant to s. 395.1055, F.S., AHCA is authorized to adopt rules for hospitals and ASCs. Separate standards may be provided for general and specialty hospitals, ASCs, mobile surgical facilities, and statutory rural hospitals, but the rules for all hospitals and ASCs must include minimum standards for ensuring that:

- A sufficient number of qualified types of personnel and occupational disciplines are on duty and available at all times to provide necessary and adequate patient care;
- Infection control, housekeeping, sanitary conditions, and medical record procedures are established and implemented to adequately protect patients;
- A comprehensive emergency management plan is prepared and updated annually;
- Licensed facilities are established, organized, and operated consistent with established standards and rules; and
- Licensed facility beds conform to minimum space, equipment, and furnishing standards

AHCA adopted rule 59A-5, F.A.C., to implement the minimum standards for ASCs.

Staff and Personnel Rules

ASCs are required to have written policies and procedures for surgical services, anesthesia services, nursing services, pharmaceutical services, and laboratory and radiologic services. In providing these services, ACSs are required to have certain professional staff available, including:

- A Registered nurse to serve as operating room circulating nurse;
- An Anesthesiologist or other physician, or a certified registered nurse anesthetist under the on-site medical direction of a licensed physician in the ASC during the anesthesia and post-anesthesia recovery period until all patients are alert or discharged; and
- A Registered professional nurse in the recovery area during the patient's recovery period.[12]

Infection Control Rules

ASCs are required to establish an infection control program, which must include written policies and procedures reflecting the scope of the infection control program. The written policies and procedures

[10] Rule 59A-5.003(4), F.A.C.
[11] Rule 59A-5.003(5), F.A.C.
[12] Rule 59A-5.0085, F.A.C.

must be reviewed at least every two years by the infection control program members. The infection control program must include:

- Surveillance, prevention, and control of infection among patients and personnel;
- A system for identifying, reporting, evaluating and maintaining records of infections;
- Ongoing review and evaluation of aseptic, isolation and sanitation techniques employed by the ASC; and
- Development and coordination of training programs in infection control for all personnel.[13]

Emergency Management Plan Rules

ASCs are required to develop and adopt a written comprehensive emergency management plan for emergency care during an internal or external disaster or emergency. The ASC must review the plan and update it annually.

Accreditation

ASCs may seek voluntary accreditation by the Joint Commission for Health Care Organizations or the Accreditation Association for Ambulatory Health Care. AHCA is required to conduct an annual licensure inspection survey for non-accredited ASCs. AHCA is authorized to accept survey reports of accredited ASCs from accrediting organizations if the standards included in the survey report are determined to document that the ASC is in substantial compliance with state licensure requirements. AHCA is required to conduct annual validation inspections on a minimum of 5 percent of the ASCs which were inspected by an accreditation organization.[14]

AHCA is required to conduct annual life safety inspections of all ASCs to ensure compliance with life safety codes and disaster preparedness requirements. However, the life-safety inspection may be waived if an accreditation inspection was conducted on an ASC by a certified life safety inspector and the ASC was found to be in compliance with the life safety requirements.[15]

In 2014, 373 licensed ASCs in Florida were accredited by a national accrediting organization.[16]

Federal Requirements

Medicare

ASCs are required to have an agreement with the Centers for Medicare and Medicaid Services (CMS) to participate in Medicare. ASCs are also required to comply with specific conditions for coverage. CMS defines "ASC" as any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization and in which the expected duration of services would not exceed 24 hours[17] following an admission.[18]

CMS may deem an ASC to be in compliance with all of the conditions for coverage if the ASC is accredited by a national accrediting body, or licensed by a state agency, that CMS determines provides

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[13] Rule 59A-5.011, F.A.C.
[14] Rule 59A-5.004, F.A.C.
[15] Id.
[16] Agency for Health Care Administration, *Ambulatory Surgical Center Regulatory Overview,* March 2014 (on file with subcommittee staff).
[17] State Operations Manual Appendix L, *Guidance for Surveyors: Ambulatory Surgical Centers* (Rev. 99, 01-31-14) exceeding the 24-hour time frame is expected to be a rare occurrence, and each rare occurrence is expected to be demonstrated to have been something which ordinarily could not have been foreseen. Not meeting this requirement constitutes condition-level noncompliance with §416.25. In addition, review of the cases that exceed the time frame may also reveal noncompliance with CfCs related to surgical services, patient admission and assessment, and quality assurance/performance improvement.
[18] 42 C.F.R. §416.2

reasonable assurance that the conditions are met.[19] All of the CMS conditions for coverage requirements are specifically required in AHCA rule 59A-5, F.A.C., and apply to all ASCs in Florida. The conditions for coverage require ASCs to have a:

- Governing body that assumes full legal responsibility for determining, implementing, and monitoring policies governing the ASC's total operation;
- Quality assessment and performance improvement program;
- Transfer agreement with one or more acute care general hospitals, which will admit any patient referred who requires continuing care;
- Disaster preparedness plan;
- Organized medical staff;
- Fire control plan;
- Sanitary environment;
- Infection control program; and
- Procedure for patient admission, assessment and discharge.

Effect of Proposed Changes

Pursuant to s. 395.002(3), F.S., patients receiving services in an ASC must be discharged on the same working day that they were admitted and they are not permitted to stay overnight. Federal regulations limit the length of stay in an ASC to 24 hours following admission. The bill amends s. 395.002(3), F.S., to reference the federal definition of an ambulatory surgical center in 42 C.F.R. 416.2, which includes a provision that permits a patient to stay at an ASC for no longer than 24 hours. The change conforms to the Medicare length of stay requirement.

B. SECTION DIRECTORY:

Section 1: Amends s. 395.002, F.S., related to definitions.
Section 2: Provides an effective date of July 1, 2015.

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.

[19] 42 C.F.R. §416.26(1)

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Individuals needing surgery may save money by being able to stay longer in an ASC.

An ASC may realize a positive fiscal impact by being able to perform more complex procedures and keep patients longer.

Hospitals may experience a negative fiscal impact if patients receive care in an ASC.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

Not applicable.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to ambulatory surgical centers; amending s. 395.002, F.S.; providing for patient discharge within a specified number of hours after admission to an ambulatory surgical center in conformance with federal law; providing an effective date.

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

Section 1. Subsection (3) of section 395.002, Florida Statutes, is amended to read:

395.002 Definitions.—As used in this chapter:

(3) "Ambulatory surgical center" or "mobile surgical facility" means a facility the primary purpose of which is to provide elective surgical care, in which the patient is admitted to and discharged from such facility pursuant to 42 C.F.R. s. 416.2 ~~within the same working day and is not permitted to stay overnight~~, and which is not part of a hospital. However, a facility existing for the primary purpose of performing terminations of pregnancy, an office maintained by a physician for the practice of medicine, or an office maintained for the practice of dentistry shall not be construed to be an ambulatory surgical center, provided that any facility or office which is certified or seeks certification as a Medicare ambulatory surgical center shall be licensed as an ambulatory surgical

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

center pursuant to s. 395.003. Any structure or vehicle in which a physician maintains an office and practices surgery, and which can appear to the public to be a mobile office because the structure or vehicle operates at more than one address, shall be construed to be a mobile surgical facility.

Section 2. This act shall take effect July 1, 2015.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1001 Assisted Living Facilities
SPONSOR(S): Ahern
TIED BILLS: **IDEN./SIM. BILLS:** CS/SB 382

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Innovation Subcommittee		Guzzo	Poche
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

HB 1001 strengthens the regulation of Assisted Living Facilities (ALFs) and makes other regulatory changes to improve the quality of ALFs. Specifically, the bill:

- Clarifies who is responsible for assuring that mental health residents in an ALF receive necessary services.
- Requires ALFs to provide information to new residents upon admission that retaliatory action cannot be taken against a resident for presenting grievances or for exercising any other resident right.
- Allows licensed register nurses to practice to the full scope of their professional license in ALFs that have a Limited Nursing Services specialty license.
- Creates a provisional Extended Congregate Care (ECC) license for new ALFs and specifies when the Agency for Health Care Administration (AHCA) may deny or revoke a facility's ECC license.
- Requires facilities with one or more, rather than three or more, state supported mental health residents obtain a Limited Mental Health (LMH) license.
- Specifies circumstances under which AHCA must impose an immediate moratorium on a facility.
- Requires AHCA to impose a $500 fine against a facility that does not comply with the background screening requirements of s. 408.809, F.S.
- Allows AHCA to impose a $2,500 fine against a facility that does not show good cause for terminating the residency of an individual.
- Authorizes ALF staff to perform certain additional duties to assist with self-administration of medication and increases the applicable staff training requirements from 4 hours to 6 hours.
- Adds certain responsible parties and agency personnel to the list of people who must report abuse or neglect to the Department of Children and Families' central abuse hotline.
- Requires AHCA to conduct an additional inspection of a facility cited for certain serious violations.
- Requires new facility staff that have not previously completed core training to attend a 2 hour pre-service orientation before interacting with residents.
- Requires the Office of Program Policy Analysis and Government Accountability to conduct a study of inter-surveyor reliability in order to determine the consistency with which regulations are applied to facilities.
- Requires AHCA to add certain content to its website by November 1, 2015, to assist consumers in selecting an ALF.

The bill appears to have a negative fiscal impact on AHCA to enact and enforce the provisions of the bill. However, the bill appropriates $159,308 and 2 FTEs to assist in carrying out the regulatory activities.

The bill provides an effective date of July 1, 2015.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Assisted Living Facility Reform

In April of 2011, the Miami Herald completed a three part investigative series relating to assisted living facilities (ALFs). This series highlighted concerns with the management and administration of ALFs and garnered the attention of not only the public, but many state lawmakers, stakeholders, and facility residents and their families.

Assisted Living Facility Workgroups

In July 2011, Governor Rick Scott directed AHCA to examine the regulation and oversight of ALFs. In response, AHCA created the ALF workgroup. The workgroup's objective was to make recommendations to the Governor and Legislature that would improve the monitoring of safety in ALFs to help ensure the well-being of residents. After a series of meetings, the workgroup produced a final report and recommendations that they felt could strengthen oversight and reassure the public that ALFs are safe. Such recommendations included increasing administrator qualifications, expanding training for administrators and other staff, increasing survey inspection activity, and improving the integration of information among all agencies involved in the regulation of ALFs. The workgroup also noted several other issues that would require more time to evaluate and recommended they be examined by a Phase II workgroup.

Phase II of the workgroup began meeting in June 2012 to resume examining those issues not addressed by Phase I of the workgroup. Phase II of the workgroup will concluded in October, 2012 and produced a final report and recommendations to the Governor and the Legislature on November 26, 2012.

The issue of improving inter-agency communication was included in the workgroup's recommendations. Specifically, the workgroup recommended improving coordination between various federal, state and local agencies with any role in long-term care facilities oversight, especially ALFs. This includes AHCA, the Long Term Care Ombudsman Program, local fire authorities, local health departments, the Department of Children and Families (DCF), the Department of Elder Affairs (DOEA), local law enforcement and the Attorney General's Office.[1]

Assisted Living Facility Negotiated Rulemaking Committee

In June, 2012, DOEA, in consultation with AHCA, DCF, and DOH, began conducting negotiated rulemaking meetings to address ALF regulation. The purpose of the meetings was to draft and amend mutually acceptable proposed rules addressing the safety and quality of services and care provided to residents within ALFs. Most of the issues addressed by the Committee were identified by Phase I of the workgroup as areas of concern that could be reformed via the rulemaking process. The Committee produced a Final Summary Report containing all the proposed rule changes agreed upon by the Committee. These proposed rule changes are currently in the final stages of the standard proposed rule making process required by law.

[1] Florida Assisted Living Workgroup, Phase II Recommendations, November 26, 2012, available at http://www.ahca.myflorida.com/SCHSCommitteesCouncils/ALWG/index.shtm.

Assisted Living Facilities - General

An ALF is a residential establishment, or part of a residential establishment, that provides housing, meals, and one or more personal services for a period exceeding 24 hours to one or more adults who are not relatives of the owner or administrator.[2,3] A personal service is direct physical assistance with, or supervision of, the activities of daily living and the self-administration of medication.[4] Activities of daily living include: ambulation, bathing, dressing, eating, grooming, toileting, and other similar tasks.[5]

An ALF is required to provide care and services appropriate to the needs of the residents accepted for admission to the facility.[6] The owner or facility administrator determines whether an individual is appropriate for admission to the facility based on certain criteria.[7] If a resident no longer meets the criteria for continued residency, or the facility is unable to meet the resident's needs, as determined by the facility administrator or health care provider, the resident must be discharged in accordance with the Resident Bill of Rights.[8]

As of March 7, 2015, there are 3,042 licensed ALFs in Florida with 88,879 beds.[9] An ALF must have a standard license issued by AHCA, pursuant to part I of ch. 429, F.S., and part II of ch. 408, F.S.

Specialty Licensed Facilities

In addition to a standard license, an ALF may have one or more specialty licenses that allow the ALF to provide additional care. These specialty licenses include: limited nursing services,[10] limited mental health services,[11] and extended congregate care services.[12]

Limited Mental Health License

A mental health resident is "an individual who receives social security disability income due to a mental disorder as determined by the Social Security Administration or receives supplemental security income due to a mental disorder as determined by the Social Security Administration and receives optional state supplementation."[13] A LMH license is required for any facility serving 3 or more mental health residents. [14] To obtain this license, the facility may not have any current uncorrected deficiencies or violations and facility administrator, as well as staff providing direct care to residents must complete 6 hours of training related to LMH duties, which is either provided by or approved by DCF.[15] A LMH license can be obtained during initial licensure, during relicensure, or upon request of the licensee.[16] There are 913 facilities with LMH licenses, providing 14,172 beds.[17]

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[2] S. 429.02(5), F.S.
[3] An ALF does not include an adult family-care home or a non-transient public lodging establishment.
[4] S. 429.02(16), F.S.
[5] S. 429.02(1), F.S.
[6] For specific minimum standards see Rule 58A-5.0182, F.A.C.
[7] S. 429.26, F.S., and Rule 58A-5.0181, F.A.C.
[8] S. 429.28, F.S.
[9] Agency for Health Care Administration, *Facility/Provider Search Results-Assisted Living Facilities*, available at http://www.floridahealthfinder.gov/facilitylocator/ListFacilities.aspx (report generated on March 7, 2015).
[10] S. 429.07(3)(c), F.S.
[11] S. 429.075, F.S.
[12] S. 429.07(3)(b), F.S.
[13] S. 429.02, F.S.
[14] S. 429.075, F.S.
[15] S. 429.075, F.S.
[16] S. 429.075, F.S.
[17] Agency for Health Care Administration, *Assisted Living Facilities with Limited Mental Health*, as of March 2, 2015, available at http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Assisted_Living/docs/alf/Directory_ALF_LMH.pdf (last viewed on March 7, 2015).

Extended Congregate Care License

The ECC specialty license allows an ALF to provide, directly or through contract, services performed by licensed nurses and supportive services to individuals who would otherwise be disqualified from continued residency in an ALF.[18] There are 261 facilities with ECC licenses, providing 16,161 beds.[19]

In order for ECC services to be provided, AHCA must first determine that all requirements in law and rule are met. ECC licensure is regulated pursuant to s. 429.07, F.S., and Rule 58A-5, F.A.C.

The primary purpose of ECC services is to allow residents, as their acuity level rises, to remain in a familiar setting. An ALF licensed to provide ECC services may also admit an individual who exceeds the admission criteria for a facility with a standard license, if the individual is determined appropriate for admission to the ECC facility. A licensed facility must adopt its own requirements within guidelines for continued residency set forth by rule. However, the facility may not serve residents who require 24-hour supervision.

Licensed ECC facilities may provide the following additional services:

- Total help with bathing, dressing, grooming, and toileting;
- Nursing assessments conducted more frequently than monthly;
- Measuring and recording basic vital functions and weight;
- Dietary management, including providing special diets, monitoring nutrition, and observing the resident's food and fluid intake and output;
- Assisting with self-administered medications;
- Supervising residents with dementia and cognitive impairments;
- Health education, counseling, and implementing health-promoting programs;
- Rehabilitative services; and
- Escort services to health-related appointments.[20]

Before being admitted to an ECC licensed facility to receive ECC services, the prospective resident must undergo a medical examination.[21] The ALF must develop a service plan that sets forth how the facility will meet the resident's needs and must maintain a written progress report on each resident who receives ECC services.

ALFs with an ECC license must meet the following staffing requirements:

- Specify a staff member to serve as the ECC supervisor if the administrator does not perform this function;
- The administrator of an ECC licensed facility must have a minimum of 2 years of managerial, nursing, social work, therapeutic recreation, or counseling experience in a residential, long-term care, or acute care setting; and
- A baccalaureate degree may be substituted for one year of the required experience and a nursing home administrator licensed under chapter 468, F.S., shall be considered qualified.[22]

An ECC administrator or supervisor, if different from the administrator, must complete the core training required of a standard licensed ALF administrator (26 hours plus a competency test), and 4 hours of

[18] S. 429.07(3)(b), F.S.
[19] Agency for Health Care Administration, *Assisted Living Facilities with Extended Congregate Care*, as of March 2, 2015, available at http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Assisted_Living/docs/alf/Directory_ALF_ECC.pdf (last viewed on March 7, 2015).
[20] Rule 58A-5.030(8)(b), F.A.C.
[21] Rule 58A-5.030(6), F.A.C.
[22] Rule 58A-5.030(4), F.A.C.

initial training in ECC care within 3 months of beginning employment. The administrator must complete a minimum of 4 hours of continued education every 2 years. [23]

All staff providing direct ECC care to residents must complete at least 2 hours of initial service training, provided by the administrator, within 6 months of beginning employment.[24]

ALFs with a standard license must pay a biennial license fee of $300 per license, with an additional fee of $50 per resident. The total fee may not exceed $10,000. In addition to the total fee assessed for standard licensed ALFs, facilities providing ECC services must pay an additional fee of $400 per license, with an additional fee of $10 per resident.[25]

Limited Nursing Services License

Limited nursing services are services beyond those provided by standard licensed ALFs. A licensed registered nurse in a facility with a LNS specialty license may only perform certain acts, as specified by rule.[26] Pursuant to Rule 58A-5.031, F.A.C., a licensed registered nurse may provide the following services in an ALF with an LNS license:

- Passive range of motion exercises;
- Ice caps or heat relief;
- Cutting toenails of diabetic residents;
- Ear and Eye irrigations;
- Urine dipstick tests;
- Replacement of urinary catheters;
- Digital stool removal therapies;
- Applying and changing routine dressings that do not require packing or irrigation;
- Care for stage 2 pressure sores;
- Caring for casts, braces and splints;
- Conducting nursing assessments;
- Caring for and monitoring the application of anti-embolism stockings or hosiery;
- Administration and regulation of portable oxygen;
- Applying, caring for and monitoring a transcutaneous electric nerve stimulator; and
- Catheter, colostomy, ileostomy care and maintenance.

A facility holding only a standard or LNS license must meet the admission and continued residency criteria contained in Rule 59A-5.0181, F.A.C.[27] The following admission and continued residency criteria for potential residents must be met:

- Be at least 18 years of age;
- Be free from signs and symptoms of any communicable disease;
- Be able to perform the activities of daily living;
- Be able to transfer, with assistance if necessary;
- Be capable of taking their own medications with assistance from staff if necessary;
- Not be a danger to themselves or others;
- Not require licensed professional mental health treatment on a 24-hour a day basis;
- Not be bedridden;
- Not have any stage 3 or 4 pressure sores;

[23] Rule 58A-5.0191(7), F.A.C.
[24] Id.
[25] S.429.07(4), F.S.
[26] S. 429.02(13), F.S.
[27] Rule 58A-5.031(2), F.A.C.

- Not require nursing services for oral or other suctioning, assistance with tube feeding, monitoring of blood gases, intermittent positive pressure breathing therapy, or treatment of surgical incisions or wounds;
- Not require 24-hour nursing supervision;
- Not require skilled rehabilitative services; and
- Have been determined by the administrator to be appropriate for admission to the facility.[28]

Facilities licensed to provide limited nursing services must employ or contract with a nurse to provide necessary services to facility residents.[29] Licensed LNS facilities must maintain written progress reports on each resident receiving LNS. A registered nurse representing AHCA must visit these facilities at least twice a year to monitor residents and determine compliance.[30] A nursing assessment must be conducted at least monthly on each resident receiving limited nursing services.[31]

Facilities licensed to provide LNS must pay the standard licensure fee of $300 per license, with an additional fee of $50 per resident and the total fee may not exceed $10,000. In addition to the standard fee, in order to obtain the LNS specialty license facilities must pay an additional biennial fee of $250 per license, with an additional fee of $10 per bed.[32] There are 775 facilities with LNS licenses, offering 31,062 slots.[33]

Staff Training

Administrators and Managers

Administrators and other ALF staff must meet minimum training and education requirements established by the DOEA by rule.[34,35] This training and education is intended to assist facilities to appropriately respond to the needs of residents, maintain resident care and facility standards, and meet licensure requirements.[36]

The current ALF core training requirements established by the DOEA consist of a minimum of 26 hours of training and passing a competency test. Administrators and managers must successfully complete the core training requirements within 3 months after becoming a facility administrator or manager. The minimum passing score for the competency test is 75 percent.[37]

Administrators and managers must participate in 12 hours of continuing education in topics related to assisted living every 2 years. A newly hired administrator or manager, who has successfully completed the ALF core training and continuing education requirements, is not required to retake the core training. An administrator or manager, who has successfully completed the core training but has not maintained the continuing education requirements, must retake the ALF core training and retake the competency test.[38]

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[28] Rule 58A-5.0181(1), F.A.C.
[29] Rule 58A-5.031(2), F.A.C.
[30] S. 429.07(2)(c), F.S.
[31] Id.
[32] S. 429.07(4)(c), F.S.
[33] Agency for Health Care Administration, *Assisted Living Facilities with Limited Nursing Services*, as of March 2, 2015, available at http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Assisted_Living/docs/alf/Directory_ALF_LNS.pdf (last viewed on March 7, 2015).
[34] Rule 58A-5.0191, F.A.C.
[35] Many of the training requirements in rule may be subject to change due to the recent DOEA negotiated rulemaking process.
[36] S. 429.52(1), F.S.
[37] Administrators who have attended core training prior to July 1, 1997, and managers who attended the core training program prior to April 20, 1998, are not required to take the competency test. Administrators licensed as nursing home administrators in accordance with Part II of Chapter 468, F.S., are exempt from this requirement.
[38] Rule 58A-5.0191, F.A.C.

Staff with Direct Care Responsibilities

Facility administrators or managers are required to provide or arrange for 6 hours of in-service training for facility staff who provide direct care to residents. The training covers a variety of topics as provided by rule.[39] Staff training requirements must generally be met within 30 days after staff begin employment at the facility, however, staff must have at least 1 hour of infection control training before providing direct care to residents. Also, nurses, certified nursing assistants, and home health aides who are on staff with an ALF are exempt from many of the training requirements. In addition to the standard 6 hours of in-service training, staff must also complete 1 hour of elopement training and 1 hour of training on do not resuscitate orders, and may have to complete training on special topics such as self-administration of medication and persons with Alzheimer's disease, if applicable.

ECC Specific Training

The administrator and ECC supervisor, if different from the administrator, must complete 4 hours of initial training in extended congregate care prior to the facility receiving its ECC license or within 3 months after beginning employment in the facility as an administrator or ECC supervisor. They must also complete a minimum of 4 hours of continuing education every 2 years in topics relating to the physical, psychological, or social needs of frail elderly and disabled persons, or persons with Alzheimer's disease or related disorders.[40]

All direct care staff providing care to residents in an ECC program must complete at least 2 hours of in-service training, provided by the facility administrator or ECC supervisor, within 6 months after beginning employment in the facility. The training must address ECC concepts and requirements, including the delivery of personal care and supportive services in an ECC facility.[41]

LMH Specific Training

Administrators, managers, and staff, who have direct contact with mental health residents in a licensed LMH facility must receive a minimum of 6 hours of specialized training in working with individuals with mental health diagnoses and a minimum of 3 hours of continuing education dealing with mental health diagnoses or mental health treatment every 2 years.[42]

Inspections and Surveys

AHCA is required to conduct a survey, investigation, or monitoring visit of an ALF:

- Prior to the issuance of a license.
- Prior to biennial renewal of a license.
- When there is a change of ownership.
- To monitor facilities licensed to provide LNS or ECC services, or facilities cited in the previous year for a class I or class II, or four or more uncorrected class III, violations.[43]
- Upon receipt of an oral or written complaint of practices that threaten the health, safety, or welfare of residents.
- If AHCA has reason to believe a facility is violating a provision of part III of ch. 429, F.S., relating to adult day care centers, or an administrative rule.
- To determine if cited deficiencies have been corrected.
- To determine if a facility is operating without a license.[44]

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[39] See supra, FN 26.
[40] Rule 58A-5.0191(7)(b), F.A.C.
[41] Rule 58A-5.0191(7)(c), F.A.C.
[42] S. 429.075, F.S. and Rule 58A-5.0191(8), F.A.C.
[43] *See below* information under subheading "Violations and Penalties" for a description of each class of violation.
[44] S. 429.34, F.S., and Rule 58A-5.033, F.A.C.

Abbreviated Surveys

An applicant for licensure renewal is eligible for an abbreviated biennial survey by AHCA if the applicant does not have any:

- Class I or class II violations or uncorrected class III violations.
- Confirmed long-term care ombudsman council complaints reported to AHCA by the council.
- Confirmed licensing complaints within the two licensing periods immediately preceding the current renewal date.[45]

An abbreviated survey allows for a quicker and less intrusive survey by narrowing the range of items that AHCA must inspect.[46] AHCA is required to expand an abbreviated survey or conduct a full survey if violations which threaten or potentially threaten the health, safety, or security of residents are identified during an abbreviated survey.[47]

Monitoring Visits

Facilities with LNS or ECC licenses are subject to monitoring visits by AHCA in which the agency inspects the facility for compliance with the requirements of the specialty license type. An LNS licensee is subject to monitoring inspections at least twice a year. At least one registered nurse must be included in the inspection team to monitor residents receiving LNS and to determine if the facility is complying with applicable regulatory requirements.[48] An ECC licensee is subject to quarterly monitoring inspections. At least one registered nurse must be included in the inspection team. AHCA may waive one of the required yearly monitoring visits for an ECC facility that has been licensed for at least 24 months, if the registered nurse who participated in the monitoring inspections determines that the ECC services are being provided appropriately, and there are no serious violations or substantiated complaints about the quality of service or care.[49]

Violations and Penalties

Part II of ch. 408, F.S., provides general licensure standards for all facilities regulated by AHCA. Under s. 408.813, F.S., ALFs may be subject to administrative fines imposed by AHCA for certain types of violations. Violations are categorized into four classes according to the nature of the violation and the gravity of its probable effect on residents.

- Class I violations are those conditions that AHCA determines present an imminent danger to residents or a substantial probability of death or serious physical or emotional harm. Examples include resident death due to medical neglect, risk of resident death due to inability to exit in an emergency, and the suicide of a mental health resident in an ALF licensed for Limited Mental Health. AHCA must issue a fine between $5,000 and $10,000 for each violation.
- Class II violations are those conditions that AHCA determines directly threaten the physical or emotional health, safety, or security of the clients. Examples include having no qualified staff in the facility, the failure to call 911 in a timely manner for resident in a semi-comatose state, and rodents in food storage area. AHCA must issue a fine between $1,000 and $5,000 for each violation.
- Class III violations are those conditions that AHCA determines indirectly or potentially threaten the physical or emotional health, safety, or security of clients. Examples include missing or incomplete resident assessments, erroneous documentation of medication administration, and failure to correct unsatisfactory DOH food service inspection findings in a timely manner. AHCA

[45] Rule 58A-5.033(2), F.A.C.
[46] Rule 58A-5.033(2)(b)
[47] Id.
[48] S. 429.07(3)(c), F.S.
[49] S. 429.07(3)(b), F.S.

must issue a fine between $500 and $1,000 for each violation, but no fine may be imposed if the facility corrects the violation.

- Class IV violations are those conditions that do not have the potential of negatively affecting clients. Examples include failure to file an adverse incident report, incorrect phone numbers posted for advocacy resources, and failure to post current menus. AHCA can only fine a facility (between $100 and $200 for each violation) if the problem is not corrected. [50,51]

Violations for Fiscal Years 2011-13

	Class I Violations	Class II Violations	Class III Violations	Class IV Violations
Total Violations	115	749	507	18
Average Fine Amount ALFs With Less than 100 beds	$6,585	$1,542	$766	$165
Average Fine Amount ALFs With More Than 100 Beds	$7,484	$1,843	$614	$100

In addition to financial penalties, AHCA can take other actions against a facility. AHCA may deny, revoke, and suspend any license for any of the actions listed in s. 429.14(1)(a)-(k), F.S. AHCA is required to deny or revoke the license of an ALF that has two or more class I violations that are similar to violations identified during a survey, inspection, monitoring visit, or complaint investigation occurring within the previous 2 years.[52] AHCA may also impose an immediate moratorium or emergency suspension on any provider if it determines that any condition presents a threat to the health, safety, or welfare of a client.[53] AHCA is required to publicly post notification of a license suspension or revocation, or denial of a license renewal, at the facility.[54] Finally, Florida's Criminal Code, under ch. 825, F.S., provides criminal penalties for the abuse, neglect, and exploitation of elderly persons[55] and disabled adults.[56]

ALF License Suspensions, Revocations, Denials, Failed to Renew and Closed

	FY 2008-09	FY 2009-10	FY 2010-11	FY 2011-12	FY 2012-13	Total
Suspensions	2	1	2	5	6	16
Revocations	4	12	7	17	15	55
Denials	11	7	5	9	12	44
Closed/Failed to Renew During Legal Case	37	40	46	38	28	189
Total	54	60	60	69	61	304

[50] When fixing the amount of the fine, AHCA must consider the following factors: the gravity of the violation and the extent to which any laws or rules were violated, actions taken to correct the violations, any previous violations, the financial benefit of committing or continuing the violation, and the licensed capacity of the facility. S. 429.19(3), F.S.

[51] S. 429.19(2), F.S.

[52] S. 429.14(4), F.S.

[53] S. 408.814, F.S.

[54] S. 429.14(7), F.S.

[55] "Elderly person" means a person 60 years of age or older who is suffering from the infirmities of aging as manifested by advanced age or organic brain damage, or other physical, mental, or emotional dysfunction, to the extent that the ability of the person to provide adequately for the person's own care or protection is impaired. S. 825.101(5), F.S. It does not constitute a defense to a prosecution for any violation of this chapter that the accused did not know the age of the victim. S. 825.104, F.S.

[56] "Disabled adult" means a person 18 years of age or older who suffers from a condition of physical or mental incapacitation due to a developmental disability, organic brain damage, or mental illness, or who has one or more physical or mental limitations that restrict the person's ability to perform the normal activities of daily living. S. 825.101(4), F.S.

Central Abuse Hotline

The Department of Children and Families is required under s. 415.103, F.S., to establish and maintain a central abuse hotline to receive reports, in writing or through a single statewide toll-free telephone number, of known or suspected abuse, neglect, or exploitation of a vulnerable adult[57] at any hour of the day or night, any day of the week.[58] Persons listed in s. 415.1034, F.S., who know, or have reasonable cause to suspect, that a vulnerable adult has been or is being abused, neglected, or exploited are required to immediately report such knowledge or suspicion to the central abuse hotline.[59]

Personal Property of Residents

Facilities are required under s. 429.27(3), F.S., upon mutual consent with the resident, to provide for the safekeeping of a resident's personal effects not in excess of $500 and funds not in excess of $200 cash. The facility must keep complete and accurate records of all such funds and personal effects received. If a resident is absent from a facility for 24 hours or more, the facility may provide for the safekeeping of the resident's personal effects in excess of $500.

Long-Term Care Ombudsman Program

The Federal Older Americans Act (OAA) requires each state to create a Long-Term Care Ombudsman Program to be eligible to receive funding associated with programs under the OAA.[60] In Florida, the program is a statewide, volunteer-based system of district councils that protect, defend, and advocate on behalf of long-term care facility residents, including residents of nursing homes, ALFs, and adult family-care homes. The ombudsman program is administratively housed in the DOEA and is headed by the State Long-Term Care Ombudsman, who is appointed by the DOEA Secretary.[61] The ombudsman program is required to establish a statewide toll-free telephone number for receiving complaints concerning matters adversely affecting the health, safety, welfare, or rights of residents of ALFs, nursing homes, and adult family care homes. Every resident or representative of a resident must receive, upon admission to a long-term care facility, information regarding the program and the statewide toll-free telephone number for receiving complaints.[62] The names or identities of the complainants or residents involved in a complaint, including any problem identified by an ombudsman council as a result of an investigation, are confidential and exempt from Florida's public records laws, unless the complainant or resident, or the legal representative of the complainant or resident, consents to the disclosure, or the disclosure is required by court order.[63] In addition to investigating and resolving complaints, ombudsmen conduct unannounced visits to assess the quality of care in facilities, referred to as administrative assessments.

Effect of Proposed Changes

The bill amends s. 394.4574, F.S., to clarify that Medicaid managed care plans are responsible for enrolled state supported mental health residents and that managing entities under contract with the DCF are responsible for such residents who are not enrolled with a Medicaid health plan. This section requires a mental health resident's community living support plan be completed and provided to the

[57] "Vulnerable adult" means a person 18 years of age or older whose ability to perform the normal activities of daily living or to provide for his or her own care or protection is impaired due to a mental, emotional, sensory, long-term physical, or developmental disability or dysfunction, or brain damage, or the infirmities of aging. S. 415.102(27), F.S.

[58] The central abuse hotline is operated by the DCF to: accept reports for investigation when there is a reasonable cause to suspect that a vulnerable adult has been or is being abused, neglected, or exploited; determine whether the allegations require an immediate, 24-hour, or next-working-day response priority; when appropriate, refer calls that do not allege the abuse, neglect, or exploitation of a vulnerable adult to other organizations that might better resolve the reporter's concerns; immediately identify and locate prior reports of abuse, neglect, or exploitation through the central abuse hotline; Section 415.103(1), F.S.

[59] S. 415.1034, F.S.

[60] 42 U.S.C. 3058, et. seq.. *See also* s. 400.0061(1), F.S.

[61] S. 400.0063, F.S.

[62] S. 400.0078(2), F.S.

[63] S. 400.0077(1)(b), F.S.

administrator of the facility within 30 days of admitting a mental health resident and be updated when there is a significant change to the resident's behavioral health status. The resident's case manager must keep a 2-year record of any face-to-face interaction with the resident and make the records available for inspection. Finally, this section charges the case manager responsible for a mental health resident to ensure that there is adequate and consistent monitoring of the community living support plan and to report any concerns about a regulated provider failing to provide services or otherwise acting in a manner with the potential to cause harm to the resident.

The bill amends s. 400.0074, F.S., to require any administrative assessment of an ALF performed by the Long-Term Care Ombudsman to be comprehensive. Further, the bill requires the local Ombudsman to conduct an exit consultation with the long-term care facility administrator to discuss issues and concerns affecting residents and make recommendations for improvement, if necessary.

The bill amends s. 400.0078, F.S., to require that ALFs provide information to new residents upon admission to the facility that retaliatory action cannot be taken against a resident for presenting grievances or for exercising any other resident right. An ALF can also provide this information to the resident's representative.

The bill amends s. 429.07, F.S., to make changes to improve the regulation of facilities with ECC and LNS specialty licenses. These changes include:

- Requiring that an ALF be licensed for 2 or more years before being issued an ECC license that is not provisional.
- Clarifying under what circumstances AHCA may deny or revoke a facility's ECC license.
- Creating a provisional ECC license for ALFs that have been licensed for less than 2 years.
- The provisional license lasts for a period of 6 months.
- The facility must inform AHCA when it has admitted one or more residents requiring ECC services.
- After the facility admits one or more ECC residents, AHCA must inspect the facility for compliance with the requirements of the ECC license.
- If the licensee demonstrates compliance with the requirements of an ECC license, AHCA must grant the facility an ECC license.
- If the licensee fails to demonstrate compliance with the requirements of an ECC license or fails to admit an ECC resident within 3 months, the licensee must immediately suspend ECC services and the provisional ECC license expires.
- Authorizing AHCA to extend a provisional ECC license for 1 month in order to compete a follow-up visit.
- Reducing monitoring visits for facilities with ECC licenses from quarterly to twice a year, and for facilities with LNS licenses from twice a year to once a year.
- Clarifying under what circumstances AHCA may waive one of the required monitoring visits for facilities with ECC licenses and also allowing AHCA to waive the required monitoring visit for facilities with an LNS license under the same conditions.

The bill amends s. 429.075, F.S., to require facilities with one or more, instead of three or more, mental health residents to obtain a LMH license. It also permits a facility with a LMH license, if it does not have a copy of the resident's community living support plan and cooperative agreement, to provide written evidence that it requested the plan and agreement from the Medicaid managed care plan or the managing entity within 72 hours of the resident's admission.

The bill amends s. 429.14, F.S., to:

- Add additional criteria under which AHCA must deny or revoke a facility's license. The criteria include:
    - There are 2 moratoria issued and imposed by final order within a 2-year period.

    - The facility is cited for 2 or more class I violations arising from unrelated circumstances during the same survey or investigation.
    - The facility is cited for 2 or more class I violations within 2 years.
- Require AHCA to impose an immediate moratorium on a facility that fails to provide AHCA with access to the facility or prohibits a regulatory inspection;
- Prohibit a licensee from restricting AHCA staff access to records or prohibiting the confidential interview of facility staff or residents.
- Exempt a facility from the 45-day notice requirement in s. 429.28(k), F.S., if that facility is required to relocate all or some of its residents due to action by AHCA.

The bill amends s. 429.19, F.S., to require AHCA to impose an administrative fine of $500 if a facility is found to be not in compliance with the background screening requirements of s. 408.809, F.S.

The bill amends s. 429.256, F.S., to allow all facility staff who received the required training to provide several additional services in assisting with self-administration of medication.[64] Specifically, the additional duties are:

- Taking a prefilled insulin syringe from its place of storage and bringing it to a resident;
- Removing the cap of a nebulizer, opening the unit dose of nebulizer solution, and pouring the pre-measured dose of medication into the dispensing cup of the nebulizer;
- Assisting a resident in using a nebulizer;
- Using a glucometer to perform blood glucose checks;
- Assisting with anti-embolism stockings;
- Assisting with applying and removing an oxygen cannula;
- Assisting with the use of a continuous positive airway pressure device;
- Assisting with the measuring of vital signs; and
- Assisting with the use of colostomy bags.

The bill amends s. 429.27(3), F.S., to increase the amount of cash that a facility may provide sake-keeping of for a resident from $200 to $500.

The bill amends s. 429.28, F.S., to require that the telephone number of Disability Rights Florida (DRF) be included in the posted notice of a resident's rights, obligations, and prohibitions, and that the facility ensure each resident have access to a telephone call DRF. The notice must also specify that

[64] Staff involved with the management of medications and assisting with the self-administration of medications under s. 429.256, F.S., must complete a minimum of 4 additional hours of training provided by a registered nurse, licensed pharmacist, or department staff. The department shall establish by rule the minimum requirements of this additional training. Section 429.52(5), F.S. Unlicensed persons who will be providing assistance with self-administered medications must meet the training requirements pursuant to s. 429.52(5), F.S., prior to assuming this responsibility. Courses provided in fulfillment of this requirement must meet the following criteria: Training must cover state law and rule requirements with respect to the supervision, assistance, administration, and management of medications in assisted living facilities; procedures and techniques for assisting the resident with self-administration of medication including how to read a prescription label; providing the right medications to the right resident; common medications; the importance of taking medications as prescribed; recognition of side effects and adverse reactions and procedures to follow when residents appear to be experiencing side effects and adverse reactions; documentation and record keeping; and medication storage and disposal. Training shall include demonstrations of proper techniques and provide opportunities for hands-on learning through practice exercises. The training must be provided by a registered nurse or licensed pharmacist who shall issue a training certificate to a trainee who demonstrates an ability to: Read and understand a prescription label; Provide assistance with self-administration in accordance with Section 429.256, F.S., and Rule 58A-5.0185, F.A.C., including: Assist with oral dosage forms, topical dosage forms, and topical ophthalmic, otic and nasal dosage forms; Measure liquid medications, break scored tablets, and crush tablets in accordance with prescription directions; Recognize the need to obtain clarification of an "as needed" prescription order; Recognize a medication order which requires judgment or discretion, and to advise the resident, resident's health care provider or facility employer of inability to assist in the administration of such orders; Complete a medication observation record; Retrieve and store medication; and Recognize the general signs of adverse reactions to medications and report such reactions. Unlicensed persons, as defined in Section 429.256(1)(b), F.S., who provide assistance with self-administered medications and have successfully completed the initial 4 hour training, must obtain, annually, a minimum of 2 hours of continuing education training on providing assistance with self-administered medications and safe medication practices in an assisted living facility. The 2 hours of continuing education training shall only be provided by a licensed registered nurse, or a licensed pharmacist. Rule 58A-5.0191(5), F.A.C.

complaints made to the ombudsman program, as well as the names and identities of the complainant and any residents involved in the complaint, are confidential and that retaliatory action cannot be taken against a resident for presenting a grievance or exercising a right. This section also creates a fine of $2,500, which is imposed if a facility cannot show good cause in state court for terminating the residency of an individual who has exercised an enumerated right.

The bill requires AHCA to adopt rules for uniform standards and criteria that will be used to determine a facility's compliance with facility standards and residents' rights.

The bill amends s. 429.34, F.S., to require certain state officials, such as Medicaid Fraud investigators and state or local fire marshals, to report any knowledge or reasonable suspicion that a vulnerable adult has been or is being abused, neglected, or exploited to the DCF central abuse hotline.

The bill requires AHCA to inspect each licensed ALF at least once every 24 months to determine compliance with statute and rules. The bill provides that a facility having one or more class I violations, two or more class II violations arising from separate surveys within a 60-day period, or two or more unrelated class II violations cited during one survey be subject to an additional inspection within 6 months.

The bill amends s. 429.41, F.S., to clarify that ALF staffing requirements for a continuing care facility or retirement community apply only to residents who receive personal limited nursing services or extended congregate care services. The facility must keep a log of the names and unit numbers of residents receiving such services and make the log available to surveyors upon request.

The bill amends s. 429.52, F.S., to require facilities to provide a 2-hour pre service orientation for all new facility employees who have not previously completed core training. The pre-service orientation must cover topics that help the employee provide responsible care and respond to the needs of the residents. The employee and the facility's administrator must sign a statement that the new ALF staff member has completed the pre-service orientation. The signed statement must be kept in that staff member's file. The bill clarifies that the pre-service orientation can be provided by the ALF instead of a trainer registered with DOEA.

The bill creates s. 429.55, F.S., which provides Legislative findings that consumers need additional information in order to select an ALF. To facilitate this, the bill requires AHCA to create a consumer guide website which contains information on each licensed ALF. By November 1, 2015, the website must include:

- The name and address of the facility;
- The name of the owner or operator of the facility;
- The number and type of licensed beds in the facility;
- The types of licenses held by the facility;
- The facility's license expiration date and status;
- The total number of clients that the facility is licensed to serve and the most recent occupancy levels;
- The number of private and semi-private rooms offered;
- The bed-hold policy;
- The religious affiliation, if any, of the ALF;
- The languages spoken by the staff;
- Availability of nurses;
- Forms of payment accepted;
- Identification if the licensee is operating under bankruptcy protection;
- Recreational and other programs available;
- Special care units or programs offered;
- Whether the facility is part of a retirement community that offers other services;

- Links to the State Long-Term Care Ombudsman Program website and the program's statewide toll-free telephone number;
- Links to the internet websites of the providers;
- Other relevant information currently collected by AHCA; and
- Survey and violation information including a list of the facility's violations committed during the previous 60 months, which must be updated monthly and include for each violation:
    - A summary of the violation, with all licensure, revisit, and complaint survey information;
    - Any sanctions imposed by final order; and
    - The date the corrective action was confirmed by AHCA; and
- Links to inspection reports on file with AHCA.

The bill creates a new, unnumbered section of statute which requires the Office of Program Policy Analysis and Government Accountability (OPPAGA) to conduct a study of inter-surveyor reliability to determine if different surveyors consistently apply licensure standards. The bill requires OPPAGA to report its findings and make recommendations to the Governor, the President of the Senate, and the Speaker of the House by January 1, 2016.

For fiscal year 2015-2016, the bill appropriates $159,308 ($151,322 recurring and $7,986 nonrecurring) and authorizes two FTEs to carry out the regulatory activities provided in the bill.

The bill provides an effective date of July 1, 2015.

B. SECTION DIRECTORY:

Section 1: Amends s. 394.4574, F.S., relating to department responsibilities for a mental health resident who resides in an assisted living facility that holds a limited mental health license.
Section 2: Amends s. 400.0074, F.S., relating to local ombudsman council onsite administrative assessments.
Section 3: Amends s. 400.0078, F.S., relating to citizen access to State Long-Term Care Ombudsman Program services.
Section 4: Amends s. 409.212, F.S., relating to optional supplementation.
Section 5: Amends s. 429.02, F.S., relating to definitions.
Section 6: Amends s. 429.07, F.S., relating to license required; fee.
Section 7: Amends s. 429.075, F.S., relating to limited mental health license.
Section 8: Amends s. 429.14, F.S., relating to administrative penalties.
Section 9: Amends s. 429.178, F.S., relating to special care for persons with Alzheimer's disease or other related disorders.
Section 10: Amends s. 429.19, F.S., relating to violations; imposition of administrative fines; grounds.
Section 11: Amends s. 429.256, F.S., relating to assistance with self-administration of medication.
Section 12: Amends s. 429.27, F.S., relating to property and personal affairs of residents.
Section 13: Amends s. 429.28, F.S., relating to resident bill of rights.
Section 14: Amends s. 429.34, F.S., relating to right of entry and inspection.
Section 15: Amends s. 429.41, F.S., relating to rules establishing standards.
Section 16: Amends s. 429.52, F.S., relating to staff training and educational programs; core educational requirements.
Section 17: Creates s. 429.55, F.S., relating to consumer information website.
Section 18: In an unnamed section of law, requires the Office of Program Policy Analysis and Government Accountability to conduct a study of survey reliability for assisted living facilities and submit a report of its findings to the Governor, the President of the Senate, and the Speaker of the House of Representatives by January 1, 2016.
Section 19: For fiscal year 2015-2016, appropriates $151,322 in recurring funds and $7,986 in non-recurring funds from the Health Care Trust Fund to AHCA and authorizes two FTEs for the purposes of carrying out the regulatory activities provided in the act.
Section 20: Provides an effective date of July 1, 2015.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

The bill provides an appropriation for two full-time equivalent positions and associated salary rate and the sums of $7,986 in nonrecurring funds and $151,322 in recurring funds for AHCA to carry out the regulatory activities included within the bill.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Facilities would be required to provide new employees that have not already gone through the ALF core training program with a 2 hour pre-service training session before they work with residents. The cost of this training is not expected to be significant and in many cases is already provided.

Facilities with specialty licenses that meet licensure standards would see fewer monitoring visits from the AHCA. This will positively impact the facilities as they will have less interruption of staff time due to such visits.

Facilities with any state supported mentally ill residents would have to meet limited mental health licensure requirements with one or more mental health residents. Facilities with one or two state supported mentally ill residents that do not meet these requirements may see increased costs to comply. Some facilities with one or two such residents however, may already meet the requirements for a limited mental health license.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill provides AHCA with sufficient rulemaking authority, as 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 assisted living facilities; amending s. 394.4574, F.S.; providing that Medicaid managed care plans are responsible for enrolled mental health residents; providing that managing entities under contract with the Department of Children and Families are responsible for mental health residents who are not enrolled with a Medicaid managed care plan; requiring that a community living support plan be completed and provided to the administrator of a facility within a specified period after the resident's admission; requiring that the community living support plan be updated when there is a significant change to the mental health resident's behavioral health; requiring a mental health resident case manager to keep certain records of interactions with the resident and to make the records available for inspection; requiring retention of the records for a specified period; requiring the responsible entity to ensure monitoring and implementation of community living support plans and cooperative agreements; amending s. 400.0074, F.S.; requiring a local ombudsman council to conduct comprehensive onsite administrative assessments; requiring a local council to conduct an exit consultation with the facility administrator or administrator designee; amending s.

400.0078, F.S.; requiring that a long-term care resident or resident representative be informed of resident immunity from retaliatory action for presenting grievances or exercising resident rights; amending s. 409.212, F.S.; increasing the cap on additional supplementation that a person may receive under certain conditions; amending s. 429.02, F.S.; revising the definition of the term "limited nursing services"; amending s. 429.07, F.S.; requiring that an extended congregate care license be issued to certain facilities licensed as assisted living facilities under certain circumstances and authorizing the issuance of such license if a specified condition is met; providing that the initial extended congregate care license is provisional under certain circumstances; requiring a licensee to notify the agency of acceptance of a resident who qualifies for extended congregate care services; requiring the agency to inspect the facility for compliance with license requirements; requiring the licensee to suspend extended congregate care services under certain circumstances; revising the frequency of monitoring visits to a facility by a registered nurse representing the agency; authorizing the agency to waive a required yearly monitoring visit under certain circumstances; authorizing the agency to deny or

revoke a facility's extended congregate care license; authorizing the agency to waive the required yearly monitoring visit for a facility that is licensed to provide limited nursing services under certain circumstances; amending s. 429.075, F.S.; requiring an assisted living facility that serves mental health residents to obtain a limited mental health license; requiring a limited mental health facility to provide written evidence that certain documentation was sent to the department within a specified period; amending s. 429.14, F.S.; requiring the agency to deny or revoke the license of an assisted living facility under certain circumstances; requiring the agency to impose an immediate moratorium on the license of an assisted living facility under certain circumstances; deleting a requirement that the agency provide a list of facilities with denied, suspended, or revoked licenses to the Department of Business and Professional Regulation; exempting a facility from the 45-day notice requirement if it is required to relocate residents; amending s. 429.178, F.S.; conforming cross-references; amending s. 429.19, F.S.; requiring the agency to levy a fine for violations that are corrected before an inspection if noncompliance occurred within a specified period of time; amending s. 429.256, F.S.; revising the term

"assistance with self-administration of medication" as it relates to the Assisted Living Facilities Act; amending s. 429.27, F.S.; revising the amount of cash for which a facility may provide safekeeping for a resident; amending s. 429.28, F.S.; providing notice requirements regarding confidentiality of resident identity in a complaint made to the State Long-Term Care Ombudsman Program or a local long-term care ombudsman council and immunity from retaliatory action for presenting grievances or exercising resident rights; providing a fine if a facility terminates an individual's residency after the filing of a complaint if good cause is not shown for the termination; requiring the agency to adopt rules; amending s. 429.34, F.S.; requiring certain persons to report elder abuse in assisted living facilities; requiring the agency to regularly inspect a licensed assisted living facility; requiring the agency to conduct periodic inspections; amending s. 429.41, F.S.; providing that certain staffing requirements apply only to residents in continuing care facilities who are receiving certain services; amending s. 429.52, F.S.; requiring each newly hired employee of an assisted living facility to attend a preservice orientation; requiring the employee and administrator to sign a statement of completion and keep the

statement in the employee's personnel record; requiring additional hours of training for assistance with medication; creating s. 429.55, F.S.; directing the agency to create an assisted living facility consumer information website; providing criteria for webpage content; providing content requirements; authorizing the agency to adopt rules; requiring the Office of Program Policy Analysis and Government Accountability to study the reliability of facility surveys and submit to the Governor and the Legislature its findings and recommendations; providing appropriations and authorizing positions; providing an effective date.

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

Section 1. Section 394.4574, Florida Statutes, is amended to read:

394.4574 ~~Department~~ Responsibilities for coordination of services for a mental health resident who resides in an assisted living facility that holds a limited mental health license.—

(1) As used in this section, the term "mental health resident~~,~~" ~~for purposes of this section,~~ means an individual who receives social security disability income due to a mental disorder as determined by the Social Security Administration or receives supplemental security income due to a mental disorder

as determined by the Social Security Administration and receives optional state supplementation.

(2) Medicaid managed care plans are responsible for Medicaid enrolled mental health residents, and managing entities under contract with the department are responsible for mental health residents who are not enrolled in a Medicaid health plan. A Medicaid managed care plan or a managing entity shall ~~The department must~~ ensure that:

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

(b) A cooperative agreement, as required in s. 429.075, is developed by ~~between~~ the mental health care services provider that serves a mental health resident and the administrator of the assisted living facility with a limited mental health license in which the mental health resident is living. ~~Any entity that provides Medicaid prepaid health plan services shall~~

~~ensure the appropriate coordination of health care services with an assisted living facility in cases where a Medicaid recipient is both a member of the entity's prepaid health plan and a resident of the assisted living facility. If the entity is at risk for Medicaid targeted case management and behavioral health services, the entity shall inform the assisted living facility of the procedures to follow should an emergent condition arise.~~

(c) The community living support plan, as defined in s. 429.02, has been prepared by a mental health resident and his or her ~~a~~ mental health case manager ~~of that resident~~ in consultation with the administrator of the facility or the administrator's designee. The plan must be completed and provided to the administrator of the assisted living facility with a limited mental health license in which the mental health resident lives within 30 days after the resident's admission. The support plan and the agreement may be in one document.

(d) The assisted living facility with a limited mental health license is provided with documentation that the individual meets the definition of a mental health resident.

(e) The mental health services provider assigns a case manager to each mental health resident for whom the entity is responsible ~~who lives in an assisted living facility with a limited mental health license~~. The case manager shall coordinate ~~is responsible for coordinating~~ the development ~~of~~ and implementation of the community living support plan defined in s. 429.02. The plan must be updated at least annually, or when

there is a significant change in the resident's behavioral health status. Each case manager shall keep a record of the date and time of any face-to-face interaction with the resident and make the record available to the responsible entity for inspection. The record must be retained for at least 2 years after the date of the most recent interaction.

(f) Consistent monitoring and implementation of community living support plans and cooperative agreements are conducted by the resident's case manager.

(g) Concerns are reported to the appropriate regulatory oversight organization if a regulated provider fails to deliver appropriate services or otherwise acts in a manner that has the potential to result in harm to the resident.

(3) The Secretary of Children and Families, in consultation with the Agency for Health Care Administration, shall ~~annually~~ require each district administrator to develop, with community input, a detailed annual plan that demonstrates ~~detailed plans that demonstrate~~ how the district will ensure the provision of state-funded mental health and substance abuse treatment services to residents of assisted living facilities that hold a limited mental health license. This plan ~~These plans~~ must be consistent with the substance abuse and mental health district plan developed pursuant to s. 394.75 and must address case management services; access to consumer-operated drop-in centers; access to services during evenings, weekends, and holidays; supervision of the clinical needs of the residents;

and access to emergency psychiatric care.

Section 2. Subsection (1) of section 400.0074, Florida Statutes, is amended, and paragraph (h) is added to subsection (2) of that section, to read:

400.0074 Local ombudsman council onsite administrative assessments.—

(1) In addition to any specific investigation conducted pursuant to a complaint, the local council shall conduct, at least annually, an onsite administrative assessment of each nursing home, assisted living facility, and adult family-care home within its jurisdiction. This administrative assessment must be comprehensive in nature and must ~~shall~~ focus on factors affecting residents' ~~the~~ rights, health, safety, and welfare ~~of the residents~~. Each local council is encouraged to conduct a similar onsite administrative assessment of each additional long-term care facility within its jurisdiction.

(2) An onsite administrative assessment conducted by a local council shall be subject to the following conditions:

(h) Upon completion of an administrative assessment, the local council shall conduct an exit consultation with the facility administrator or a designee representing the facility to discuss issues and concerns in areas affecting residents' rights, health, safety, and welfare and, if needed, make recommendations for improvement.

Section 3. Subsection (2) of section 400.0078, Florida Statutes, is amended to read:

400.0078 Citizen access to State Long-Term Care Ombudsman Program services.—

(2) ~~Every resident or representative of a resident shall receive,~~ Upon admission to a long-term care facility, each resident or representative of a resident must receive information regarding the purpose of the State Long-Term Care Ombudsman Program, the statewide toll-free telephone number for receiving complaints, information that retaliatory action cannot be taken against a resident for presenting grievances or for exercising any other resident right, and other relevant information regarding how to contact the program. Each resident or his or her representative ~~Residents or their representatives~~ must be furnished additional copies of this information upon request.

Section 4. Paragraph (c) of subsection (4) of section 409.212, Florida Statutes, is amended to read:

409.212 Optional supplementation.—

(4) In addition to the amount of optional supplementation provided by the state, a person may receive additional supplementation from third parties to contribute to his or her cost of care. Additional supplementation may be provided under the following conditions:

(c) The additional supplementation shall not exceed four ~~two~~ times the provider rate recognized under the optional state supplementation program.

Section 5. Subsection (13) of section 429.02, Florida

Statutes, is amended to read:

429.02 Definitions.—When used in this part, the term:

(13) "Limited nursing services" means acts that may be performed by a person licensed under ~~pursuant to~~ part I of chapter 464 ~~by persons licensed thereunder while carrying out their professional duties but limited to those acts which the department specifies by rule~~. ~~Acts which may be specified by rule as allowable~~ Limited nursing services shall be for persons who meet the admission criteria established by the department for assisted living facilities and shall not be complex enough to require 24-hour nursing supervision and may include such services as the application and care of routine dressings, and care of casts, braces, and splints.

Section 6. Paragraphs (b) and (c) of subsection (3) of section 429.07, Florida Statutes, are amended to read:

429.07 License required; fee.—

(3) In addition to the requirements of s. 408.806, each license granted by the agency must state the type of care for which the license is granted. Licenses shall be issued for one or more of the following categories of care: standard, extended congregate care, limited nursing services, or limited mental health.

(b) An extended congregate care license shall be issued to each facility that has been licensed as an assisted living facility for 2 or more years and that provides services ~~facilities providing~~, directly or through contract, ~~services~~

beyond those authorized in paragraph (a), including services performed by persons licensed under part I of chapter 464 and supportive services, as defined by rule, to persons who would otherwise be disqualified from continued residence in a facility licensed under this part. An extended congregate care license may be issued to a facility that has a provisional extended congregate care license and meets the requirements for licensure under subparagraph 2. The primary purpose of extended congregate care services is to allow residents the option of remaining in a familiar setting from which they would otherwise be disqualified for continued residency as they become more impaired. A facility licensed to provide extended congregate care services may also admit an individual who exceeds the admission criteria for a facility with a standard license, if he or she is determined appropriate for admission to the extended congregate care facility.

1. In order for extended congregate care services to be provided, the agency must first determine that all requirements established in law and rule are met and must specifically designate, on the facility's license, that such services may be provided and whether the designation applies to all or part of the facility. This ~~Such~~ designation may be made at the time of initial licensure or relicensure, or upon request in writing by a licensee under this part and part II of chapter 408. The notification of approval or the denial of the request shall be made in accordance with part II of chapter 408. Each existing

facility that qualifies ~~facilities qualifying~~ to provide extended congregate care services must have maintained a standard license and may not have been subject to administrative sanctions during the previous 2 years, or since initial licensure if the facility has been licensed for less than 2 years, for any of the following reasons:

a. A class I or class II violation;

b. Three or more repeat or recurring class III violations of identical or similar resident care standards from which a pattern of noncompliance is found by the agency;

c. Three or more class III violations that were not corrected in accordance with the corrective action plan approved by the agency;

d. Violation of resident care standards which results in requiring the facility to employ the services of a consultant pharmacist or consultant dietitian;

e. Denial, suspension, or revocation of a license for another facility licensed under this part in which the applicant for an extended congregate care license has at least 25 percent ownership interest; or

f. Imposition of a moratorium pursuant to this part or part II of chapter 408 or initiation of injunctive proceedings.

The agency may deny or revoke a facility's extended congregate care license for not meeting the criteria for an extended congregate care license as provided in this subparagraph.

2. If an assisted living facility has been licensed for less than 2 years, the initial extended congregate care license must be provisional and may not exceed 6 months. The licensee shall notify the agency, in writing, when it has admitted at least one extended congregate care resident, after which an unannounced inspection shall be made to determine compliance with the requirements of an extended congregate care license. A licensee with a provisional extended congregate care license that demonstrates compliance with all the requirements of an extended congregate care license during the inspection shall be issued an extended congregate care license. In addition to sanctions authorized under this part, if violations are found during the inspection and the licensee fails to demonstrate compliance with all assisted living facility requirements during a followup inspection, the licensee shall immediately suspend extended congregate care services, and the provisional extended congregate care license expires. The agency may extend the provisional license for not more than 1 month in order to complete a followup visit.

3.~~2.~~ A facility that is licensed to provide extended congregate care services shall maintain a written progress report on each person who receives services which describes the type, amount, duration, scope, and outcome of services that are rendered and the general status of the resident's health. A registered nurse, or appropriate designee, representing the agency shall visit the facility at least twice a year ~~quarterly~~

to monitor residents who are receiving extended congregate care services and to determine if the facility is in compliance with this part, part II of chapter 408, and relevant rules. One of the visits may be in conjunction with the regular survey. The monitoring visits may be provided through contractual arrangements with appropriate community agencies. A registered nurse shall serve as part of the team that inspects the facility. The agency may waive one of the required yearly monitoring visits for a facility that has:

a. Held an extended congregate care license for at least 24 months; ~~been licensed for at least 24 months to provide extended congregate care services, if, during the inspection, the registered nurse determines that extended congregate care services are being provided appropriately, and if the facility has~~

b. No class I or class II violations and no uncorrected class III violations; and~~.~~

c. No ombudsman council complaints that resulted in a citation for licensure. ~~The agency must first consult with the long-term care ombudsman council for the area in which the facility is located to determine if any complaints have been made and substantiated about the quality of services or care. The agency may not waive one of the required yearly monitoring visits if complaints have been made and substantiated.~~

4.~~3.~~ A facility that is licensed to provide extended congregate care services must:

a. Demonstrate the capability to meet unanticipated resident service needs.

b. Offer a physical environment that promotes a homelike setting, provides for resident privacy, promotes resident independence, and allows sufficient congregate space as defined by rule.

c. Have sufficient staff available, taking into account the physical plant and firesafety features of the building, to assist with the evacuation of residents in an emergency.

d. Adopt and follow policies and procedures that maximize resident independence, dignity, choice, and decisionmaking to permit residents to age in place, so that moves due to changes in functional status are minimized or avoided.

e. Allow residents or, if applicable, a resident's representative, designee, surrogate, guardian, or attorney in fact to make a variety of personal choices, participate in developing service plans, and share responsibility in decisionmaking.

f. Implement the concept of managed risk.

g. Provide, directly or through contract, the services of a person licensed under part I of chapter 464.

h. In addition to the training mandated in s. 429.52, provide specialized training as defined by rule for facility staff.

5.~~4.~~ A facility that is licensed to provide extended congregate care services is exempt from the criteria for

continued residency set forth in rules adopted under s. 429.41. A licensed facility must adopt its own requirements within guidelines for continued residency set forth by rule. However, the facility may not serve residents who require 24-hour nursing supervision. A licensed facility that provides extended congregate care services must also provide each resident with a written copy of facility policies governing admission and retention.

~~5. The primary purpose of extended congregate care services is to allow residents, as they become more impaired, the option of remaining in a familiar setting from which they would otherwise be disqualified for continued residency. A facility licensed to provide extended congregate care services may also admit an individual who exceeds the admission criteria for a facility with a standard license, if the individual is determined appropriate for admission to the extended congregate care facility.~~

6. Before the admission of an individual to a facility licensed to provide extended congregate care services, the individual must undergo a medical examination as provided in s. 429.26(4) and the facility must develop a preliminary service plan for the individual.

7. If ~~When~~ a facility can no longer provide or arrange for services in accordance with the resident's service plan and needs and the facility's policy, the facility must ~~shall~~ make arrangements for relocating the person in accordance with s.

429.28(1)(k).

~~8. Failure to provide extended congregate care services may result in denial of extended congregate care license renewal.~~

(c) A limited nursing services license shall be issued to a facility that provides services beyond those authorized in paragraph (a) and as specified in this paragraph.

1. In order for limited nursing services to be provided in a facility licensed under this part, the agency must first determine that all requirements established in law and rule are met and must specifically designate, on the facility's license, that such services may be provided. This ~~Such~~ designation may be made at the time of initial licensure or licensure renewal ~~relicensure~~, or upon request in writing by a licensee under this part and part II of chapter 408. Notification of approval or denial of such request shall be made in accordance with part II of chapter 408. An existing facility that qualifies ~~facilities qualifying~~ to provide limited nursing services must ~~shall~~ have maintained a standard license and may not have been subject to administrative sanctions that affect the health, safety, and welfare of residents for the previous 2 years or since initial licensure if the facility has been licensed for less than 2 years.

2. A facility ~~Facilities~~ that is ~~are~~ licensed to provide limited nursing services shall maintain a written progress report on each person who receives such nursing services. The~~,~~

~~which~~ report must describe ~~describes~~ the type, amount, duration, scope, and outcome of services that are rendered and the general status of the resident's health. A registered nurse representing the agency shall visit the facility ~~such facilities~~ at least annually ~~twice a year~~ to monitor residents who are receiving limited nursing services and to determine if the facility is in compliance with applicable provisions of this part, part II of chapter 408, and related rules. The monitoring visits may be provided through contractual arrangements with appropriate community agencies. A registered nurse shall also serve as part of the team that inspects such facility. Visits may be in conjunction with other agency inspections. The agency may waive the required yearly monitoring visit for a facility that has:

a. Had a limited nursing services license for at least 24 months;

b. No class I or class II violations and no uncorrected class III violations; and

c. No ombudsman council complaints that resulted in a citation for licensure.

3. A person who receives limited nursing services under this part must meet the admission criteria established by the agency for assisted living facilities. When a resident no longer meets the admission criteria for a facility licensed under this part, arrangements for relocating the person shall be made in accordance with s. 429.28(1)(k), unless the facility is licensed to provide extended congregate care services.

Section 7. Section 429.075, Florida Statutes, is amended to read:

429.075 Limited mental health license.—An assisted living facility that serves one ~~three~~ or more mental health residents must obtain a limited mental health license.

(1) To obtain a limited mental health license, a facility must hold a standard license as an assisted living facility, must not have any current uncorrected ~~deficiencies or~~ violations, and must ensure that, within 6 months after receiving a limited mental health license, the facility administrator and the staff of the facility who are in direct contact with mental health residents must complete training of no less than 6 hours related to their duties. This ~~Such~~ designation may be made at the time of initial licensure or relicensure or upon request in writing by a licensee under this part and part II of chapter 408. Notification of approval or denial of such request shall be made in accordance with this part, part II of chapter 408, and applicable rules. This training must ~~will~~ be provided by or approved by the Department of Children and Families.

(2) A facility that is ~~Facilities~~ licensed to provide services to mental health residents must ~~shall~~ provide appropriate supervision and staffing to provide for the health, safety, and welfare of such residents.

(3) A facility that has a limited mental health license must:

(a) Have a copy of each mental health resident's community living support plan and the cooperative agreement with the mental health care services provider or provide written evidence that a request for the community living support plan and the cooperative agreement was sent to the Medicaid managed care plan or managing entity under contract with the Department of Children and Families within 72 hours after admission. The support plan and the agreement may be combined.

(b) Have documentation ~~that is~~ provided by the department ~~of Children and Families~~ that each mental health resident has been assessed and determined to be able to live in the community in an assisted living facility that has ~~with~~ a limited mental health license or provide written evidence that a request for documentation was sent to the department within 72 hours after admission.

(c) Make the community living support plan available for inspection by the resident, the resident's legal guardian or~~,~~ ~~the resident's~~ health care surrogate, and other individuals who have a lawful basis for reviewing this document.

(d) Assist the mental health resident in carrying out the activities identified in the resident's ~~individual's~~ community living support plan.

(4) A facility that has ~~with~~ a limited mental health license may enter into a cooperative agreement with a private mental health provider. For purposes of the limited mental health license, the private mental health provider may act as

the case manager.

Section 8. Section 429.14, Florida Statutes, is amended to read:

429.14 Administrative penalties.—

(1) In addition to the requirements of part II of chapter 408, the agency may deny, revoke, and suspend any license issued under this part and impose an administrative fine in the manner provided in chapter 120 against a licensee for a violation of any provision of this part, part II of chapter 408, or applicable rules, or for any of the following actions by a licensee, ~~for the actions of~~ any person subject to level 2 background screening under s. 408.809, or ~~for the actions of~~ any facility staff ~~employee~~:

(a) An intentional or negligent act seriously affecting the health, safety, or welfare of a resident of the facility.

(b) A ~~The~~ determination by the agency that the owner lacks the financial ability to provide continuing adequate care to residents.

(c) Misappropriation or conversion of the property of a resident of the facility.

(d) Failure to follow the criteria and procedures provided under part I of chapter 394 relating to the transportation, voluntary admission, and involuntary examination of a facility resident.

(e) A citation for ~~of~~ any of the following violations ~~deficiencies~~ as specified in s. 429.19:

1. One or more cited class I violations ~~deficiencies~~.

2. Three or more cited class II violations ~~deficiencies~~.

3. Five or more cited class III violations ~~deficiencies~~ that have been cited on a single survey and have not been corrected within the times specified.

(f) Failure to comply with the background screening standards of this part, s. 408.809(1), or chapter 435.

(g) Violation of a moratorium.

(h) Failure of the license applicant, the licensee during relicensure, or a licensee that holds a provisional license to meet the minimum license requirements of this part, or related rules, at the time of license application or renewal.

(i) An intentional or negligent life-threatening act in violation of the uniform firesafety standards for assisted living facilities or other firesafety standards which ~~that~~ threatens the health, safety, or welfare of a resident of a facility, as communicated to the agency by the local authority having jurisdiction or the State Fire Marshal.

(j) Knowingly operating any unlicensed facility or providing without a license any service that must be licensed under this chapter or chapter 400.

(k) Any act constituting a ground upon which application for a license may be denied.

(2) Upon notification by the local authority having jurisdiction or by the State Fire Marshal, the agency may deny or revoke the license of an assisted living facility that fails

to correct cited fire code violations that affect or threaten the health, safety, or welfare of a resident of a facility.

(3) The agency may deny a license of an ~~to any~~ applicant or a controlling interest as defined in part II of chapter 408 which has or had a 25 percent ~~25-percent~~ or greater financial or ownership interest in any other facility that is licensed under this part, or in any entity licensed by this state or another state to provide health or residential care, if that ~~which~~ facility or entity during the 5 years prior to the application for a license closed due to financial inability to operate; had a receiver appointed or a license denied, suspended, or revoked; was subject to a moratorium; or had an injunctive proceeding initiated against it.

(4) The agency shall deny or revoke the license of an assisted living facility if:

(a) There are two moratoria, issued pursuant to this part or part II of chapter 408, within a 2-year period which are imposed by final order;

(b) The facility is cited for two or more class I violations arising from unrelated circumstances during the same survey or investigation; or

(c) The facility is cited for two or more class I violations arising from separate surveys or investigations within a 2-year period ~~that has two or more class I violations that are similar or identical to violations identified by the agency during a survey, inspection, monitoring visit, or~~

~~complaint investigation occurring within the previous 2 years~~.

(5) An action taken by the agency to suspend, deny, or revoke a facility's license under this part or part II of chapter 408, in which the agency claims that the facility owner or an employee of the facility has threatened the health, safety, or welfare of a resident of the facility, shall be heard by the Division of Administrative Hearings of the Department of Management Services within 120 days after receipt of the facility's request for a hearing, unless that time limitation is waived by both parties. The administrative law judge shall ~~must~~ render a decision within 30 days after receipt of a proposed recommended order.

(6) As provided under s. 408.814, the agency shall impose an immediate moratorium on an assisted living facility that fails to provide the agency with access to the facility or prohibits the agency from conducting a regulatory inspection. The licensee may not restrict agency staff from accessing and copying records at the agency's expense or from conducting confidential interviews with facility staff or any individual who receives services from the facility ~~provide to the Division of Hotels and Restaurants of the Department of Business and Professional Regulation, on a monthly basis, a list of those assisted living facilities that have had their licenses denied, suspended, or revoked or that are involved in an appellate proceeding pursuant to s. 120.60 related to the denial, suspension, or revocation of a license~~.

(7) Agency notification of a license suspension or revocation, or denial of a license renewal, shall be posted and visible to the public at the facility.

(8) If a facility is required to relocate some or all of its residents due to agency action, that facility is exempt from the 45-day notice requirement imposed under s. 429.28(1)(k). This subsection does not exempt the facility from any deadlines for corrective action set by the agency.

Section 9. Paragraphs (a) and (b) of subsection (2) of section 429.178, Florida Statutes, are amended to read:

429.178 Special care for persons with Alzheimer's disease or other related disorders.—

(2)(a) An individual who is employed by a facility that provides special care for residents who have ~~with~~ Alzheimer's disease or other related disorders, and who has regular contact with such residents, must complete up to 4 hours of initial dementia-specific training developed or approved by the department. The training must ~~shall~~ be completed within 3 months after beginning employment and satisfy ~~shall satisfy~~ the core training requirements of s. 429.52(3)(g) ~~429.52(2)(g)~~.

(b) A direct caregiver who is employed by a facility that provides special care for residents who have ~~with~~ Alzheimer's disease or other related disorders~~,~~ and ~~who~~ provides direct care to such residents~~,~~ must complete the required initial training and 4 additional hours of training developed or approved by the department. The training must ~~shall~~ be completed within 9 months

after beginning employment and satisfy ~~shall satisfy~~ the core training requirements of s. 429.52(3)(g) ~~429.52(2)(g)~~.

Section 10. Paragraph (e) is added to subsection (2) of section 429.19, Florida Statutes, to read:

429.19 Violations; imposition of administrative fines; grounds.—

(2) Each violation of this part and adopted rules shall be classified according to the nature of the violation and the gravity of its probable effect on facility residents. The agency shall indicate the classification on the written notice of the violation as follows:

(e) Regardless of the class of violation cited, instead of the fine amounts listed in paragraphs (a)-(d), the agency shall impose an administrative fine of $500 if a facility is found not to be in compliance with the background screening requirements as provided in s. 408.809.

Section 11. Subsection (3) and paragraph (c) of subsection (4) of section 429.256, Florida Statutes, are amended to read:

429.256 Assistance with self-administration of medication.—

(3) Assistance with self-administration of medication includes:

(a) Taking the medication, in its previously dispensed, properly labeled container, including an insulin syringe that is prefilled with the proper dosage by a pharmacist and an insulin pen that is prefilled by the manufacturer, from where it is

stored, and bringing it to the resident.

(b) In the presence of the resident, reading the label, opening the container, removing a prescribed amount of medication from the container, and closing the container.

(c) Placing an oral dosage in the resident's hand or placing the dosage in another container and helping the resident by lifting the container to his or her mouth.

(d) Applying topical medications.

(e) Returning the medication container to proper storage.

(f) Keeping a record of when a resident receives assistance with self-administration under this section.

(g) Assisting with the use of a nebulizer, including removing the cap of a nebulizer, opening the unit dose of nebulizer solution, and pouring the prescribed premeasured dose of medication into the dispensing cup of the nebulizer.

(h) Using a glucometer to perform blood-glucose level checks.

(i) Assisting with putting on and taking off antiembolism stockings.

(j) Assisting with applying and removing an oxygen cannula but not with titrating the prescribed oxygen settings.

(k) Assisting with the use of a continuous positive airway pressure device but not with titrating the prescribed setting of the device.

(l) Assisting with measuring vital signs.

(m) Assisting with colostomy bags.

(4) Assistance with self-administration does not include:

~~(c) Administration of medications through intermittent positive pressure breathing machines or a nebulizer.~~

Section 12. Subsection (3) of section 429.27, Florida Statutes, is amended to read:

429.27 Property and personal affairs of residents.—

(3) A facility, upon mutual consent with the resident, shall provide for the safekeeping in the facility of personal effects not in excess of $500 and funds of the resident not in excess of $500 ~~$200~~ cash, and shall keep complete and accurate records of all such funds and personal effects received. If a resident is absent from a facility for 24 hours or more, the facility may provide for the safekeeping of the resident's personal effects in excess of $500.

Section 13. Paragraph (a) of subsection (3) and subsections (2), (5), and (6) of section 429.28, Florida Statutes, are amended to read:

429.28 Resident bill of rights.—

(2) The administrator of a facility shall ensure that a written notice of the rights, obligations, and prohibitions set forth in this part is posted in a prominent place in each facility and read or explained to residents who cannot read. The ~~This~~ notice must ~~shall~~ include the name, address, and telephone numbers of the local ombudsman council, the ~~and~~ central abuse hotline, and, if ~~when~~ applicable, Disability Rights Florida ~~the Advocacy Center for Persons with Disabilities, Inc., and the~~

~~Florida local advocacy council~~, where complaints may be lodged. The notice must state that a complaint made to the Office of State Long-Term Care Ombudsman or a local long-term care ombudsman council, the names and identities of the residents involved in the complaint, and the identity of complainants are kept confidential pursuant to s. 400.0077 and that retaliatory action cannot be taken against a resident for presenting grievances or for exercising any other resident right. The facility must ensure a resident's access to a telephone to call the local ombudsman council, central abuse hotline, and Disability Rights Florida ~~Advocacy Center for Persons with Disabilities, Inc., and the Florida local advocacy council~~.

(3)(a) The agency shall conduct a survey to determine general compliance with facility standards and compliance with residents' rights as a prerequisite to initial licensure or licensure renewal. The agency shall adopt rules for uniform standards and criteria that will be used to determine compliance with facility standards and compliance with residents' rights.

(5) A ~~No~~ facility or employee of a facility may not serve notice upon a resident to leave the premises or take any other retaliatory action against any person who:

(a) Exercises any right set forth in this section.

(b) Appears as a witness in any hearing, inside or outside the facility.

(c) Files a civil action alleging a violation of the provisions of this part or notifies a state attorney or the

Attorney General of a possible violation of such provisions.

(6) A ~~Any~~ facility that ~~which~~ terminates the residency of an individual who participated in activities specified in subsection (5) must ~~shall~~ show good cause in a court of competent jurisdiction. If good cause is not shown, the agency shall impose a fine of $2,500 in addition to any other penalty assessed against the facility.

Section 14. Section 429.34, Florida Statutes, is amended to read:

429.34 Right of entry and inspection.—

(1) In addition to the requirements of s. 408.811, any duly designated officer or employee of the department, the Department of Children and Families, the Medicaid Fraud Control Unit of the Office of the Attorney General, the state or local fire marshal, or a member of the state or local long-term care ombudsman council has ~~shall have~~ the right to enter unannounced upon and into the premises of any facility licensed pursuant to this part in order to determine the state of compliance with ~~the provisions of~~ this part, part II of chapter 408, and applicable rules. Data collected by the state or local long-term care ombudsman councils or the state or local advocacy councils may be used by the agency in investigations involving violations of regulatory standards. A person specified in this section who knows or has reasonable cause to suspect that a vulnerable adult has been or is being abused, neglected, or exploited shall immediately report such knowledge or suspicion to the central

abuse hotline pursuant to chapter 415.

(2) The agency shall inspect each licensed assisted living facility at least once every 24 months to determine compliance with this chapter and related rules. If an assisted living facility is cited for a class I violation or two or more class II violations arising from separate surveys within a 60-day period or due to unrelated circumstances during the same survey, the agency must conduct an additional licensure inspection within 6 months.

Section 15. Subsection (2) of section 429.41, Florida Statutes, is amended to read:

429.41 Rules establishing standards.—

(2) In adopting any rules pursuant to this part, the department, in conjunction with the agency, shall make distinct standards for facilities based upon facility size; the types of care provided; the physical and mental capabilities and needs of residents; the type, frequency, and amount of services and care offered; and the staffing characteristics of the facility. Rules developed pursuant to this section may ~~shall~~ not restrict the use of shared staffing and shared programming in facilities that are part of retirement communities that provide multiple levels of care and otherwise meet the requirements of law and rule. If a continuing care facility licensed under chapter 651 or a retirement community offering multiple levels of care licenses a building or part of a building designated for independent living for assisted living, staffing requirements established in rule

apply only to residents who receive personal, limited nursing, or extended congregate care services under this part. Such facilities shall retain a log listing the names and unit number for residents receiving these services. The log must be available to surveyors upon request. Except for uniform firesafety standards, the department shall adopt by rule separate and distinct standards for facilities with 16 or fewer beds and for facilities with 17 or more beds. The standards for facilities with 16 or fewer beds must ~~shall~~ be appropriate for a noninstitutional residential environment; however, ~~provided that~~ the structure may not be ~~is no~~ more than two stories in height and all persons who cannot exit the facility unassisted in an emergency must reside on the first floor. The department, in conjunction with the agency, may make other distinctions among types of facilities as necessary to enforce ~~the provisions of~~ this part. Where appropriate, the agency shall offer alternate solutions for complying with established standards, based on distinctions made by the department and the agency relative to the physical characteristics of facilities and the types of care offered ~~therein~~.

Section 16. Subsections (1) through (11) of section 429.52, Florida Statutes, are renumbered as subsections (2) through (12), respectively, present subsections (5) and (9) are amended, and a new subsection (1) is added to that section, to read:

429.52 Staff training and educational programs; core

educational requirement.—

(1) Effective October 1, 2015, each new assisted living facility employee who has not previously completed core training must attend a preservice orientation provided by the facility before interacting with residents. The preservice orientation must be at least 2 hours in duration and cover topics that help the employee provide responsible care and respond to the needs of facility residents. Upon completion, the employee and the administrator of the facility must sign a statement that the employee completed the required preservice orientation. The facility must keep the signed statement in the employee's personnel record.

(6) ~~(5)~~ Staff involved with the management of medications and assisting with the self-administration of medications under s. 429.256 must complete a minimum of 6 ~~4~~ additional hours of training provided by a registered nurse, licensed pharmacist, or department staff. The department shall establish by rule the minimum requirements of this additional training.

(10) ~~(9)~~ The training required by this section other than the preservice orientation must ~~shall~~ be conducted by persons registered with the department as having the requisite experience and credentials to conduct the training. A person seeking to register as a trainer must provide the department with proof of completion of the minimum core training education requirements, successful passage of the competency test established under this section, and proof of compliance with the

continuing education requirement in subsection (5) ~~(4)~~.

Section 17. Section 429.55, Florida Statutes, is created to read:

429.55 Consumer information website.—The Legislature finds that consumers need additional information on the quality of care and service in assisted living facilities in order to select the best facility for themselves or their loved ones. Therefore, the Agency for Health Care Administration shall create content that is easily accessible through the home page of the agency's website either directly or indirectly through links to one or more other established websites of the agency's choosing. The website must be searchable by facility name, license type, city, or zip code. By November 1, 2015, the agency shall include all content in its possession on the website and add content when received from facilities. At a minimum, the content must include:

(1) Information on each licensed assisted living facility, including, but not limited to:

(a) The name and address of the facility.

(b) The name of the owner or operator of the facility.

(c) The number and type of licensed beds in the facility.

(d) The types of licenses held by the facility.

(e) The facility's license expiration date and status.

(f) The total number of clients that the facility is licensed to serve and the most recently available occupancy levels.

(g) The number of private and semiprivate rooms offered.

(h) The bed-hold policy.

(i) The religious affiliation, if any, of the assisted living facility.

(j) The languages spoken by the staff.

(k) Availability of nurses.

(l) Forms of payment accepted, including, but not limited to, Medicaid, Medicaid long-term managed care, private insurance, health maintenance organization, United States Department of Veterans Affairs, CHAMPUS program, or workers' compensation coverage.

(m) Indication if the licensee is operating under bankruptcy protection.

(n) Recreational and other programs available.

(o) Special care units or programs offered.

(p) Whether the facility is a part of a retirement community that offers other services pursuant to this part or part III of this chapter, part II or part III of chapter 400, or chapter 651.

(q) Links to the State Long-Term Care Ombudsman Program website and the program's statewide toll-free telephone number.

(r) Links to the websites of the providers.

(s) Other relevant information that the agency currently collects.

(2) Survey and violation information for the facility, including a list of the facility's violations committed during

the previous 60 months, which on July 1, 2015, may include violations committed on or after July 1, 2010. The list shall be updated monthly and include for each violation:

(a) A summary of the violation, including all licensure, revisit, and complaint survey information, presented in a manner understandable by the general public.

(b) Any sanctions imposed by final order.

(c) The date the corrective action was confirmed by the agency.

(3) Links to inspection reports that the agency has on file.

(4) The agency may adopt rules to administer this section.

Section 18. The Legislature finds that consistent regulation of assisted living facilities benefits residents and operators of such facilities. To determine whether surveys are consistent between surveys and surveyors, the Office of Program Policy Analysis and Government Accountability shall conduct a study of intersurveyor reliability for assisted living facilities. By January 1, 2016, the Office of Program Policy Analysis and Government Accountability shall submit a report of its findings to the Governor, the President of the Senate, and the Speaker of the House of Representatives and make any recommendations for improving intersurveyor reliability.

Section 19. For fiscal year 2015-2016, the sums of $151,322 in recurring funds and $7,986 in nonrecurring funds from the Health Care Trust Fund are appropriated to the Agency

963 for Health Care Administration, and two full-time equivalent
964 positions with associated salary rate are authorized, for the
965 purpose of carrying out the regulatory activities provided in
966 this act.
967 Section 20. This act shall take effect July 1, 2015.