The Florida Senate

COMMITTEE MEETING EXPANDED AGENDA

HEALTH POLICY
Senator Bean, Chair
Senator Sobel, Vice Chair

MEETING DATE: Wednesday, January 8, 2014
TIME: 4:00 —6:00 p.m.
PLACE: *Pat Thomas Committee Room,* 412 Knott Building

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

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
1	**A proposed committee substitute** for the following bill (SB 248) is expected to be considered:		
	SB 248 Children, Families, and Elder Affairs (Compare H 91, H 263, S 186, S 508)	Assisted Living Facilities; Providing that Medicaid prepaid behavioral health 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 prepaid behavioral health plan; requiring that an extended congregate care license be issued to certain facilities that have been licensed as assisted living facilities under certain circumstances and authorizing the issuance of such license if a specified condition is met, etc. HP 01/08/2014 Fav/CS JU	Fav/CS Yeas 9 Nays 0
2	**SB 268** Grimsley (Identical H 287)	Certificates of Need; Decreasing the subdistrict average occupancy rate that the Agency for Health Care Administration is required to maintain as a goal of its nursing-home-bed-need methodology; providing that, under certain circumstances, replacement of a nursing home is a health-care-related project subject to expedited review; repealing provisions relating to the moratorium on the approval of certificates of need for additional community nursing home beds, etc. HP 01/08/2014 Fav/CS CF AHS AP	Fav/CS Yeas 9 Nays 0

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
3	**SB 344** Flores	Dentists; Establishing the Dental Student Loan Repayment Program in order to encourage dentists to work in underserved areas or public health programs; requiring the Department of Health, certain universities, and the Florida Dental Association to develop the program; providing sanctions for failure to comply with loan requirements, etc. HP 01/08/2014 Favorable ED AED AP	Favorable Yeas 9 Nays 0
4	**SB 340** Flores (Similar H 27)	Prepaid Dental Plans; Postponing the scheduled repeal of a provision requiring the Agency for Health Care Administration to contract with dental plans for dental services on a prepaid or fixed-sum basis; authorizing the agency to provide a prepaid dental health program in Miami-Dade County on a permanent basis; requiring an annual report to the Governor and Legislature; authorizing the agency to seek any necessary revisions to the state plan or federal waivers, etc. HP 01/08/2014 Favorable CA AHS AP	Favorable Yeas 7 Nays 2
5	**SB 380** Bean (Similar H 373)	Hospitals; Requiring certain hospitals to notify obstetrical physicians before the hospitals close their obstetrical departments or cease to provide obstetrical services, etc. HP 01/08/2014 Fav/CS CA AHS AP	Fav/CS Yeas 9 Nays 0
6	Consideration of proposed committee bill:		
	SPB 7010	Health Access Dental Licenses; Deleting the requirement that a license applicant or renewing licensee not have been reported to the National Practitioner Data Bank; authorizing the Board of Dentistry to deny licensure to an applicant or renewing licensee who has committed or is under investigation or prosecution for certain violations; repealing provisions relating to the future repeal of provisions authorizing the health access dental license, etc.	Not Considered
7	Consideration of proposed committee bill:		

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
	SPB 7008	Nonresident Pharmacies; Deleting a requirement that the Board of Pharmacy refer regulatory issues affecting a nonresident pharmacy to the state where the pharmacy is located; requiring registered nonresident pharmacies to obtain a permit in order to ship, mail, deliver, or dispense compounded sterile products into this state; authorizing the department to inspect registered nonresident pharmacies, etc.	Not Considered
8	Presentation on System Enhancements for the Children's Health Insurance Program (CHIP) by Rich Robleto, Executive Director, Florida Healthy Kids Corporation		Presented
	Other Related Meeting Documents		

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

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

BILL:	PCS/SB 248 (877366)
INTRODUCER:	Children, Families, and Elder Affairs Committee
SUBJECT:	Assisted Living Facilities
DATE:	December 18, 2013 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Daniel	Hendon		**CF SPB 7000 as introduced**
2.	Looke	Stovall	HP	**Pre-meeting**
3.			JU	

I. Summary:

PCS/SB 248 strengthens the enforcement of current regulations for Assisted Living Facilities (ALF or facility) by revising fines imposed for licensure violations, clarifying existing enforcement tools, and requiring an additional inspection for facilities with significant violations. Specifically, the bill:

- Specifies who is responsible for assuring that mental health residents in an ALF receive necessary services.
- Clarifies the duties of the state Long-Term Care Ombudsman Program.
- Amends language related to ALF specialty licenses by:
  - Creating a provisional Extended Congregate Care (ECC) license for new ALFs and specifying when the Agency for Health Care Administration (AHCA or agency) may deny or revoke a facility's ECC license.
  - Reducing the number of monitoring visits the AHCA must conduct for ALFs with Limited Nursing Services (LNS) licenses and ECC licenses.
  - Specifying when the AHCA may waive a monitoring visit in facilities with an ECC or LNS license.
  - Requiring that facilities with one or more state supported mental health residents obtain a limited mental health (LMH) license. Current law only requires an LMH license for facilities with three or more mental health residents.
- Allows the AHCA to revoke the license of a facility with a controlling interest that has or had a 25 percent or greater financial or ownership interest in a second facility that closed due to financial inability to operate or that was the subject of other specified administrative sanctions. Current law allows the AHCA to deny such a facility's license during the renewal process.
- Clarifies the criteria under which the AHCA must revoke or deny a facility's license.
- Specifies circumstances under which the AHCA must impose an immediate moratorium[1] on a facility.

[1] "Moratorium" means a prohibition on the acceptance of new clients. Section 408.803(10), F.S.

- Amends fine amounts by:
  - Setting fines for all classes of violations[2] to a fixed amount at the midpoint of the current range and multiplying these new fine amounts by 1.5 for facilities licensed for 100 or more beds.
  - Allowing the AHCA to impose a fine for a class I violation even if it is corrected before the AHCA inspects a facility.
  - Doubling fines for repeated serious violations.
  - Requiring that fines be imposed for repeat minor violations[3] regardless of correction.
  - Doubling the fines for minor violations if a facility is cited for the same minor violation during the previous two licensure inspections.
  - Requiring the AHCA to impose a $2,500 fine against a facility that does not show good cause for terminating the residency of an individual.
- Amends the definition of "assistance with self-administration of medication" to add several actions to the list of services in which unlicensed staff can assist residents.
- 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' (DCF or department) central abuse hotline.
- Requires an additional inspection, paid for by the facility, within 6 months, of a facility cited for specified serious violations.
- Clarifies that in a continuing care facility or retirement community, ALF staffing requirements apply only to residents of units designated for independent living as an ALF.
- Requires new facility staff, who have not previously completed core training, to attend a two-hour pre-service orientation before interacting with residents.
- Requires the Office of Program Policy Analysis and Government Accountability (OPPAGA) to conduct a study of inter-surveyor reliability in order to determine the consistency with which the AHCA applies regulations to facilities, and requires OPPAGA to report its findings and recommendations by November 1, 2014.
- Requires the AHCA to implement an ALF rating system by March 1, 2015.
- Requires the AHCA to add certain content to its website by November 1, 2014, to help consumers select an ALF.

II. Present Situation:

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.[4] A personal service is direct physical assistance with, or supervision of, the activities of daily living and the self-administration of medication.[5] Activities of daily living include ambulation, bathing, dressing, eating, grooming, toileting, and other similar tasks.[6]

[2] The classes of violations can be found in s. 408.813, F.S.
[3] Class III and class IV violations.
[4] Section 429.02(5), F.S. An ALF does not include an adult family-care home or a non-transient public lodging establishment.
[5] Section 429.02(16), F.S.
[6] Section 429.02(1), F.S.

An ALF is required to provide care and services appropriate to the needs of the residents accepted for admission to the facility.[7] The owner or facility administrator determines whether an individual is appropriate for admission to the facility based on a number of criteria.[8] If, as determined by the facility administrator or health care provider, a resident no longer meets the criteria for continued residency or the facility is unable to meet the resident's needs, the resident must be discharged in accordance with the Resident Bill of Rights.[9]

As of November 1, 2013, there were 3,042 licensed ALFs in Florida with a total of 86,455 beds.[10] An ALF must have a standard license issued by the AHCA, pursuant to part I of ch. 429, F.S., and part II of ch. 408, F.S. 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,[11] limited mental health services,[12] and extended congregate care services.[13] There are 1,020 facilities with LNS specialty licenses, 274 with ECC licenses, and 1,040 with LMH specialty licenses.[14]

Limited Nursing Services Specialty License

An LNS specialty license enables an ALF to provide, directly or through contract, a select number of nursing services in addition to the personal services that are authorized under the standard license. The nursing services are limited to acts specified in administrative rules, may only be provided as authorized by a health care provider's order, and must be conducted and supervised in accordance with ch. 464, F.S., relating to nursing, and the prevailing standard of practice in the nursing community.

Extended Congregate Care Specialty License

The primary purpose of ECC services is to allow residents to remain in a familiar setting as they become more impaired with physical or mental limitations. An ECC specialty license enables a facility to provide, directly or through contract, services performed by licensed nurses and supportive services[15] to persons who otherwise would be disqualified from continued residence in an ALF.[16] A facility licensed to provide ECC services may also admit an individual who

[7] For specific minimum standards see Rule 58A-5.0182, F.A.C.
[8] Section 429.26, F.S., and Rule 58A-5.0181, F.A.C.
[9] Section 429.28, F.S.
[10] Fla. Agency for Health Care Admin., *Assisted Living Facility Directory* (Oct. 1, 2013), http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Assisted_Living/docs/alf/Directory_ALF.pdf (last visited Nov. 15, 2013).
[11] Section 429.07(3)(c), F.S.
[12] Section 429.075, F.S.
[13] Section 429.07(3)(b), F.S.
[14] *See* Fla. Agency for Health Care Admin., *Assisted Living Facility*, http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Assisted_Living/alf.shtml (follow the hyperlinks for the ALF directories found under the "Notices/Updates" heading) (last visited Nov. 15, 2013).
[15] Supportive services include social service needs, counseling, emotional support, networking, assistance with securing social and leisure services, shopping service, escort service, companionship, family support, information and referral, assistance in developing and implementing self-directed activities, and volunteer services. Rule 58A-5.030(8)(a), F.A.C.
[16] An ECC program may provide additional services, such as the following: 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; assisting with self-administered medications or administering medications and treatments

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, a facility with an ECC license still may not serve residents who require 24-hour nursing supervision.[17]

Limited Mental Health Specialty License

An ALF that serves three or more mental health residents must obtain an LMH specialty license.[18] A mental health resident is an individual who receives social security disability income (SSDI) due to a mental disorder or supplemental security income (SSI) due to a mental disorder, and receives optional state supplementation (OSS).[19] The department must ensure that a mental health resident is assessed and determined able to live in an ALF with an LMH license.[20]

The administrator of a LMH facility must consult with a mental health resident and the resident's case manager to develop and help execute a community living support plan for the resident detailing the specific needs and services the resident requires.[21] The LMH licensee must also execute a cooperative agreement with the mental health care services provider. The cooperative agreement specifies, among other things, directions for the ALF accessing emergency and after-hours care for the mental health resident.

Department of Elder Affairs Rules

In addition to ch. 429, F.S., ALFs are also subject to regulation under Rule 58A-5 of the Florida Administrative Code (F.A.C.). These rules are adopted by the Department of Elder Affairs (DOEA) in consultation with the AHCA, the DCF, and the Department of Health (DOH).[22] In June 2012, the DOEA initiated a process of negotiated rulemaking to revise many of its rules regarding ALFs. After multiple meetings, a committee that consisted of agency staff, consumer advocates, and industry representatives voted on numerous changes to Rule 58A-5, F.A.C. On November 28, 2012, the DOEA issued a proposed rule and held several public hearings on the proposed rule.[23] In June 2013, the DOEA withdrew the proposed rule in order to get a revised Statement of Estimated Regulatory Costs, and it plans to move forward with the rule, including seeking ratification from the Legislature on the portions of the rule that require it.[24]

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pursuant to a health care provider's order; supervising residents with dementia and cognitive impairments; health education, counseling, and implementing health-promoting programs; rehabilitative services; and escort services related to health-related appointments. Section 429.07(3)(b), F.S., and Rule 58A-5.030, F.A.C.

[17] Section 429.07(3)(b), F.S.

[18] Section 429.075, F.S.

[19] Section 429.02(15), F.S. Optional State Supplementation is a cash assistance program. Its purpose is to supplement a person's income to help pay for costs in an assisted living facility, mental health residential treatment facility, or adult family care home, but it is not a Medicaid program. Dep't of Elder Affairs, *Florida Affordable Assisted Living: Optional State Supplementation (OSS)*, http://elderaffairs.state.fl.us/faal/operator/statesupp.html (last visited Nov. 22, 2013).

[20] Section 394.4574, F.S., requires a mental health resident to be assessed by a psychiatrist, clinical psychologist, clinical social worker, psychiatric nurse, or an individual who is supervised by one of these professionals to determine whether it is appropriate for the person to reside in an ALF.

[21] Rule 58A-5.029(2)(c)3., F.A.C.

[22] Section 429.41(1), F.S.

[23] *See* Dep't of Elder Affairs, *Assisted Living Facility (ALF) Negotiated Rulemaking*, http://elderaffairs.state.fl.us/doea/alf_rulemaking.php (last visited Nov. 18, 2013).

[24] Conversation with Adam Lovejoy, Legislative Affairs Director, Department of Elder Affairs (Sept. 17, 2013).

ALF Staff Training

Administrators and Managers

Administrators and other ALF staff must meet minimum training and education requirements established in rule by the DOEA.[25] This training and education is intended to assist facilities in appropriately responding to the needs of residents, maintaining resident care and facility standards, and meeting licensure requirements.[26]

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.[27]

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.[28]

Staff with Direct Care Responsibilities

Facility administrators or managers are required to provide or arrange for six hours of in-service training for facility staff who provide direct care to residents which covers various topics as mandated in rule.[29] 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. 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 complete 1 hour of elopement training and one hour of training on do not resuscitate orders. The staff may be required to complete training on special topics such as self-administration of medication and 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 either prior to the facility receiving its ECC license or within 3 months after beginning employment in the facility as an administrator or ECC supervisor. The administrator and ECC supervisor must also complete a minimum of 4 hours of continuing education every 2 years in topics relating to the physical, psychological, or

[25] Rule 58A-5.0191, F.A.C. Many of the training requirements in rule may be subject to change due to the DOEA negotiated rulemaking process.
[26] Section 429.52(1), F.S.
[27] 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.
[28] Rule 58A-5.0191, F.A.C.
[29] Rule 58A-5.0191, F.A.C.

social needs of frail elderly and disabled persons, or persons with Alzheimer's disease or related disorders.[30]

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 statutory and rule requirements and the delivery of personal care and supportive services in an ECC facility.[31]

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 having mental health diagnoses and a minimum of 3 hours of continuing education dealing with mental health diagnoses or mental health treatment every 2 years.[32]

Inspections and Surveys

The agency 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
- To monitor facilities cited in the previous year for a class I or class II, or four or more uncorrected class III, violations.[33]
- Upon receipt of an oral or written complaint of practices that threaten the health, safety, or welfare of residents.
- If the 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.[34]

Abbreviated Surveys

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

- Class I, class II, or uncorrected class III violations.
- Confirmed long-term care ombudsman council complaints reported to the AHCA by the council.

[30] Rule 58A-5.0191(7)(b), F.A.C.
[31] Rule 58A-5.0191(7)(c), F.A.C.
[32] Section 429.075, F.S. and Rule 58A-5.0191(8), F.A.C.
[33] See "Violations and Penalties" subheading below for a description of the violations.
[34] See s. 429.34, F.S., and Rule 58A-5.033, F.A.C.

- Confirmed licensing complaints within the two licensing periods immediately preceding the current renewal date.[35]

An abbreviated survey allows for a quicker and less intrusive survey by narrowing the range of items the agency must inspect.[36] The agency must expand an abbreviated survey or conduct a full survey if violations that threaten or potentially threaten the health, safety, or security of residents are identified during an abbreviated survey.[37]

Monitoring Visits

Facilities with LNS or ECC licenses are subject to monitoring visits by the AHCA in which the agency inspects the facility for compliance with the requirements of the specialty license. 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 services and to determine if the facility is complying with applicable regulatory requirements.[38] An ECC licensee is subject to quarterly monitoring inspections. At least one registered nurse must be included in the inspection team. The agency 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.[39]

Violations and Penalties

Part II of ch. 408, F.S., provides general licensure standards for all facilities regulated by the AHCA. Under s. 408.813, F.S., ALFs may be subject to administrative fines imposed by the 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 the 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.
  - The agency must fine a facility between $5,000 and $10,000 for each class I violation.
  - During fiscal years 2011-2013, the AHCA entered 115 final orders for class I violations with an average fine amount of $6,585 for facilities with less than 100 beds and $7,454 for facilities with 100 or more beds.

- **Class II violations** are those conditions that the AHCA determines directly threaten the physical or emotional health, safety, or security of the clients.

[35] Rule 58A-5.033(2), F.A.C.
[36] Rule 58A-5.033(2)(b).
[37] *Id.*
[38] Section 429.07(3)(c), F.S.
[39] Section 429.07(3)(b), F.S.

- Examples include 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 a food storage area.
- The agency must fine a facility between $1,000 and $5,000 for each violation.
- During fiscal years 2011-2013, the AHCA entered 749 final orders for class II violations with an average fine amount of $1,542 for facilities with less than 100 beds and $1,843 for facilities with 100 or more beds.

- **Class III violations** are those conditions that the 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.
  - The agency must fine a facility between $500 and $1,000 for each violation, but no fine may be imposed if the facility corrects the violation.
  - During fiscal years 2011-2013, the AHCA entered 507 final orders for uncorrected class III violations with an average fine amount of $766 for facilities with less than 100 beds and $614 for facilities with 100 or more beds.

- **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.
  - The agency can only fine a facility (between $100 and $200 for each violation) if the problem is not corrected.
  - During fiscal years 2011-2013, the AHCA entered 18 final orders for uncorrected class IV violations with an average fine amount of $165 for facilities with less than 100 beds and $100 for facilities with 100 or more beds.[40,41,42]

In addition to financial penalties, the AHCA can take other actions against a facility. The agency may deny, revoke, and suspend any license for any of the actions listed in s. 429.14(1)(a)-(k), F.S. The agency 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.[43] The agency may also impose an immediate moratorium or emergency suspension on any provider if it determines that any condition that presents a threat to the health, safety, or welfare of a client.[44] The agency is required to publicly post notification of a license suspension, revocation, or denial of a license

[40] 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. Section 429.19(3), F.S.
[41] Section 429.19(2), F.S.
[42] *AHCA bill analysis for SB 248*, dated November 26, 2013. On file with the Senate Committee on Health Policy.
[43] Section 429.14(4), F.S.
[44] Section 408.814, F.S.

renewal, at the facility.[45] Finally, ch. 825, F.S., Florida's Criminal Code, provides criminal penalties for the abuse, neglect, and exploitation of elderly persons[46] and disabled adults.[47]

Central Abuse Hotline

The department 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[48] at any hour of the day or night, any day of the week.[49] 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.[50]

Florida's 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.[51] 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.[52] 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.[53] The names or identities of the complainants or residents involved in a complaint, including any problem identified by an ombudsman council as a result

[45] Section 429.14(7), F.S.
[46] "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. Section 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. Section 825.104, F.S.
[47] "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. Section 825.101(4), F.S.
[48] "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. Section 415.102(27), F.S.
[49] 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.
[50] Section 415.1034, F.S.
[51] 42 U.S.C. 3058. *See also* s. 400.0061(1), F.S.
[52] Section 400.0063, F.S.
[53] Section 400.0078, F.S.

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.[54] In addition to investigating and resolving complaints, ombudsmen conduct unannounced visits to assess the quality of care in facilities, referred to as administrative assessments.

Consumer Information

Section 400.191, F.S., requires the AHCA to provide information to the public about all licensed nursing homes in the state. The information must be provided in a consumer-friendly electronic format to assist consumers and their families in comparing and evaluating nursing homes. Under s. 400.191(2), F.S., the agency must provide an Internet site that includes information such as a list by name and address of all nursing homes in the state, the total number of beds in each facility, and survey and deficiency information. Additional information that the agency may provide on the site includes the licensure status history of each facility, the rating history of each facility, and the regulatory history of each facility.

There is no similar requirement in law to provide certain consumer information to the public on the licensed ALFs in the state.

The Miami Herald Articles and the Governor's Assisted Living Workgroup

Beginning on April 30, 2011, the Miami Herald published a four-part series, titled "Neglected to Death," which detailed abuses occurring in ALFs and the state regulatory responses to such cases. The paper spent a year examining thousands of state inspections, police reports, court cases, autopsy files, e-mails, and death certificates and conducting dozens of interviews with operators and residents throughout Florida. The series detailed examples of abuses, neglect, and even death that took place in facilities.[55] The series also criticized the state's regulatory and law enforcement agencies' responses to the problems. The paper concluded that the state's agencies, and in particular the AHCA, failed to enforce existing laws designed to protect Florida's citizens who reside in ALFs.[56]

Soon after the Miami Herald series, Governor Rick Scott vetoed HB 4045,[57] which reduced requirements relating to ALFs. The Governor then directed the AHCA to form a task force for the purpose of examining current assisted living regulations and oversight.[58] The task force

[54] Section 400.0077(1)(b), F.S.
[55] Rob Barry, Michael Sallah and Carol Marbin Miller, *Neglected to Death, Parts 1-3*, THE MIAMI HERALD, April 30, 2011 *available at* http://www.miamiherald.com/2011/04/30/2194842/once-pride-of-florida-now-scenes.html and http://www.miamiherald.com/2011/05/03/2199747/key-medical-logs-doctored-missing.html (see left side of article to access weblinks to the three-part series) (Last visited on Nov. 20, 2013).
[56] *Id.*
[57] House Bill 4045 (2011) repealed a requirement for the annual dissemination of a list of ALFs that had been sanctioned or fined, a requirement for an ALF to report monthly any liability claims filed against it, a requirement to disseminate the results of the inspection of each ALF, provisions concerning rule promulgation for ALFs by the DOEA, provisions concerning the collection of information regarding the cost of care in ALFs, and the authority for local governments or organizations to contribute to the cost of care of local facility residents.
[58] Membership details of the task force are available at Fla. Agency for Health Care Admin., *Assisted Living Workgroup Members*, http://ahca.myflorida.com/SCHS/CommiteesCouncils/ALWG/wgmembers.shtml (last visited Nov. 20, 2013).

referred to as the Assisted Living Workgroup, held meetings and produced two reports, one in August of 2011 and one in October of 2012. In addition to public testimony and presentations, the Assisted Living Workgroup focused on assisted living regulation, consumer information and choice, and long term care services and access.[59] The workgroup made numerous recommendations in its two reports.[60]

III. Effect of Proposed Changes:

Section 1 of 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 mental health residents who are not enrolled with a Medicaid managed care plan. This section requires a mental health resident's community living support plan to 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. Finally, this section charges the entity 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.

Section 2 of the bill amends s. 400.0074, F.S., to require the Long-Term Care Ombudsman Program's administrative assessments of facilities be comprehensive in nature. This section also requires ombudsmen to conduct an exit consultation with the facility administrator to discuss issues and concerns from the visit.

Section 3 of the bill amends s. 400.0078, F.S., to require an ALF to include a statement that retaliatory action cannot be taken against a resident for presenting grievances when that ALF provides the required information to new residents upon admission to the facility about the purpose of the Long-Term Care Ombudsman Program.

Section 4 of 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 a full ECC license.
- Clarifying under what circumstances the 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.

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[59] *See* Fla. Agency for Health Care Admin., *Assisted Living Workgroup, Phase I*, http://ahca.myflorida.com/SCHS/CommiteesCouncils/ALWG/archived/ALWG2011.shtml (last visited Nov. 20, 2013); Fla. Agency for Health Care Admin., *Assisted Living Workgroup, Phase II*, http://ahca.myflorida.com/SCHS/CommiteesCouncils/ALWG/index.shtml (last visited Nov. 20, 2013).

[60] See Fla. Agency for Health Care Admin., *Florida Assisted Living Workgroup, Phase II Recommendations* (Nov. 26, 2012), http://ahca.myflorida.com/SCHS/CommiteesCouncils/ALWG/docs/ALF-FinalReportandRecommendationsPhaseII.pdf (last visited Nov. 20, 2013); Fla. Agency for Health Care Admin., *Florida Assisted Living Workshop, Final Report and Recommendations*, http://ahca.myflorida.com/SCHS/CommiteesCouncils/ALWG/archived/docs/2011/ALWorkgroupFinalReport.pdf (last visited Nov. 20, 2013).

  - The facility must inform the AHCA when it has admitted one or more residents requiring ECC services, after which the 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, the AHCA must grant the facility a full 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 provisional ECC license expires.
- 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 the AHCA may waive one of the required monitoring visits for facilities with ECC licenses and also allowing the AHCA to waive the required monitoring visit for facilities with an LNS license under the same conditions.

Section 5 of the bill amends s. 429.075, F.S., to require facilities with one or more state supported mental health residents to obtain a LMH license. Current law only requires an ALF to obtain an LMH license if they have three or more state supported mental health residents.

Section 6 of the bill amends s. 429.14, F.S., to clarify the use of administrative penalties, to:

- Allow the AHCA to revoke, rather than only deny,[61] a facility's or a controlling interest's license if that facility or controlling interest has, or had, a 25 percent or greater financial or ownership interest in a second facility that closed due to financial inability to operate or was the subject of other specified administrative sanctions.
- Add additional criteria under which the AHCA must deny or revoke a facility's license.
- Require that the AHCA impose an immediate moratorium on a facility that fails to provide the AHCA with access to the facility, prohibits a regulatory inspection, denies access to records, or prohibits the confidential interview of facility staff or residents.

This section of the bill also clarifies that if a facility is required to relocate its residents due to agency action, the facility does not have to give residents 45 days' notice as required under s. 429.28(1)(k), F.S.

Section 7 of the bill amends s. 429.178, F.S., to make technical changes and to conform with changes to other parts of the bill.

Section 8 of the bill amends s. 429.19, F.S., relating to the impositions of fines. Specifically, the bill:

- Sets the dollar amount of fines for facilities with fewer than 100 beds at $7,500 for class I violations, $3,000 for class II violations, $750 for class III violations, and $150 for class IV violations. This is the midpoint of the current ranges for fines in current law.
- Sets the dollar amount of fines for facilities with 100 or more beds at $11,250 for class I violations, $4,500 for class II violations, $1,125 for class III violations, and $225 for class IV

[61] Denial of a license occurs when the Agency refuses to renew the facilities license at the end of the 2-year period the license was issued for.

violations. These fines are 1.5 times the amount of the fines for facilities with fewer than 100 beds.
- Requires the AHCA to impose a fine on a facility for a class I violation, even if the facility corrects the violation before the AHCA conducts an investigation. Facilities can still challenge such fines through an administrative hearing pursuant to ch. 120, F.S.
- Doubles the fines for facilities with repeat class I and class II violations.
- Imposes a fine on facilities with repeat class III and class IV violations, regardless of correction. Current law prohibits the AHCA from assessing fines for corrected class III and class IV violations. Current law would still apply for the first class III or class IV violation.
- Doubles the fines for class III or class IV violations if a facility is cited for one or more such violations, stemming from the same regulation, upon the third licensure inspection if they were previously cited for the same violations over the course of the last two licensure inspections.

Section 9 of the bill amends s. 429.256, F.S., to allow unlicensed staff to assist with several additional services that fall under the category of assistance with self-administration of medication. Specifically, unlicensed staff will be allowed to assist with:

- Taking a prefilled insulin syringe to a resident.
- The resident's use of a nebulizer, including removing the cap of a nebulizer, opening the unit dose of nebulizer solution, and pouring the prescribed premeasured dose into the dispensing cup.
- The resident's use of a glucometer to perform blood-glucose level checks.
- Putting on and taking off antiembolism stockings.
- Applying and removing an oxygen cannula, but not titrating the oxygen levels.
- The resident's use of a continuous positive airway pressure device, but not titrating the device.
- Measuring vital signs.
- The resident's use of colostomy bags.

Section 10 of the bill amends s. 429.28, F.S., to require the posted notice of a resident's rights, obligations, and prohibitions, to specify that complaints made to the ombudsman program, as well as the names and identities of the complainant and any residents involved, are confidential. 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.

Section 11 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 provides that a facility with 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 licensee must pay a fee to the AHCA to cover the cost of the additional inspection.

Section 12 of the bill amends s. 429.41, F.S., to provide that if a continuing care facility or a retirement community licenses part of a building for ALF services the staffing requirements established in rule only apply to the residents receiving assisted living services.

Section 13 of the bill amends s. 429.52, F.S., to require that facilities provide a two 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 requiring that it be provided by a trainer registered with the DOEA.

The bill also increases the training requirements for staff who assist residents with medication from four to six hours.

Section 14 of the bill creates a new, unnumbered section of the Florida Statutes which requires the OPPAGA to conduct a study of inter-surveyor reliability to determine if different surveyors consistently apply licensure standards. The OPPAGA must report its findings and make recommendations to the Governor, the President of the Senate, and the Speaker of the House by November 1, 2014.

Section 15 of the bill creates a new, unnumbered section of the Florida Statutes which finds that consumers need additional information in order to select an ALF. To facilitate this, the bill requires the AHCA to implement a rating system for ALFs by March 1, 2015. This section also requires the AHCA to create a consumer guide website with information on ALFs by November 1, 2014. At a minimum, the website must include:

- Information on each licensed ALF such as the number and type of licensed beds, the types of licenses held by the facility, and the expiration date of the facility's license.
- A list of the facility's violations including a summary of the violation, any sanctions imposed, and the date of any corrective action taken by the facility.
- Links to inspection reports.
- A monitored comment page to help inform consumers of the quality and care of services in ALFs. The comment page must allow members of the public to post comments on their experiences with, or observations of, an ALF. A controlling interest in an ALF or an employee or owner of an ALF may not post comments on the page; however, a controlling interest, employee, or owner may respond to comments on the page, and the AHCA shall ensure that the responses are identified as being from a representative of the facility.

Section 16 of the bill provides an effective date of July 1, 2014.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. Other Constitutional Issues:

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

PCS/SB 248 requires the AHCA to conduct a new survey of an ALF within 6 months after finding a class I violation or two or more class II violations. Facilities that require the additional survey will be charged a fee to cover the cost of the additional survey. According to the AHCA, current fees and fines from ALFs do not cover the cost of regulating such facilities statewide.

B. Private Sector Impact:

The bill revises the fine amounts for each of the four classes of violations. Specifically, the bill sets the dollar amount of fines for facilities with fewer than 100 beds at $7,500 for class I violations, $3,000 for class II violations, $750 for class III violations, and $150 for class IV violations. Current law provides for a range of fine amounts, for example a facility cited for a class I violation can be fined between $5,000 and $10,000. Fines are multiplied by 1.5 for facilities with 100 or more beds to help resolve an inequity in penalties whereby small facilities can pay the same fine amount as much larger facilities. Fixing the fine amounts at the mid-point of each range will provide for more predictable outcomes for facilities that are cited for violations.

Additionally, the bill provides for the following changes to the fine amounts:

- A $2,500 fine if a facility removes a resident without cause, as determined by a state court.
- A doubling of fines for class I or II violations if the facility was previously cited for one or more class I or II violations during the last licensure inspection.
- An imposition of a fine for class I violations regardless of whether they were corrected prior to being cited by the Agency.

The AHCA estimates that the new fine structure will initially cost facilities cited for violations a total of approximately $1.3 million per year. However, these increased costs

could be reduced by increased compliance with ALF regulations and a corresponding reduction in the number of cited violations.[62]

All fines are subject to challenge through an administrative hearing under ch. 120, F.S.

Facilities with significant uncorrected violations would be more likely to see their licenses suspended or revoked under the bill. Closing facilities with significant problems would improve the public's assessment of ALFs and could improve the financial success of those facilities that meet licensure standards.

Facilities with any state supported mental health residents would have to meet limited mental health licensure requirements with one or more mental health residents. Facilities that currently have less than three state supported mental health residents and do not meet these requirements may see increased costs to comply.

Facilities with specialty licenses that meet licensure standards will have 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.

The bill requires facilities to provide all new employees who have not already gone through the ALF core training program with a two hour pre-service training session before they work with residents. Additionally, the bill increases the training requirements for staff who assist residents with medication from 4 to 6 hours. The cost of both of these training requirements is not expected to be significant.

C. Government Sector Impact:

The AHCA estimates that the bill will generate approximately $1.1 million of additional net revenues for the agency per year which could be available to cover any additional costs generated by the bill. According to the agency, there will be approximately $100,000 of start-up costs to implement the ALF website and rating system and approximately $250,000 of yearly recurring costs due to new FTE and contract positions.[63] These costs will likely be offset, and additional revenue will likely be generated, through the increased fines. The agency estimates, based on the number of violations cited over the past 2 years, that the new fine structure in the bill will generate approximately $1.3 million additional revenue per year. However, this amount could decrease if the new fine amounts result in increased compliance and fewer cited violations.[64]

VI. Technical Deficiencies:

None.

[62] *AHCA bill analysis for SB 248*, dated November, 26, 2013. On file with the Senate Committee on Health Policy.
[63] AHCA will require one new Health Services and Facilities Consultant FTE position to create and monitor the comment page created in section 17 and two new senior attorney FTE positions to process these additional legal cases resulting from an increased number of administrative fines. See Id. pg. 18.
[64] Id.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 394.4574, 400.0074, 400.0078, 429.02, 429.07, 429.075, 429.14, 429.178, 429.19, 429.256, 429.28, 429.34, 429.41, 429.52.

This bill creates the following sections of the Florida Statutes: 429.55.

The bill creates two new unnumbered sections of the Florida Statutes.

IX. Additional Information:

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

PCS/SB 248 (877366) by Health Policy:
The PCS amends SB 248 to:

- Delete language related to flexible bed licenses while retaining language clarifying that a continuing care facility or retirement community which licenses a part of a building for ALF services must only comply with ALF staffing requirements for those residents who are receiving ALF services;
- Delete language setting a fine amount of $500 for violations of ALF employee background screening requirements;
- Require an ALF administrator to sign a statement, rather than attest under penalty of perjury, that a new employee has completed a pre-service orientation;
- Change the date by which the AHCA must implement a rating system for ALFs from November 1, 2014 to March 1, 2015;
- Change the date by which the AHCA must create a website with ALF content from January 1, 2015 to November 1, 2014;
- Require the AHCA to post the date that an ALF corrects a cited violation, rather than a summary of the corrective action taken;
- Rename "Medicaid prepaid behavioral health plans" to "Medicaid managed care plans;" and
- Clarify:
  - That a provisional ECC license expires if the ALF fails to admit an ECC resident within 3 months after receiving the provisional license;
  - That ombudsman council complaints resulting in licensure citations need not be confirmed before they require the AHCA to perform the full number of licensure inspections for ECC and LNS licenses.
  - Language requiring the AHCA to impose fines for class I violations that are corrected before a licensure inspection.
  - That assisting a resident with applying and removing an oxygen cannula or a CPAP device does not include titrating the cannula or device.

B. Amendments:

730014

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
01/08/2014	.	
	.	
	.	
	.	

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

Senate Amendment

Between lines 750 and 751
insert:
(g) 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.


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Proposed Committee Substitute by the Committee on Health Policy

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; deleting a provision to conform to changes made by the act; requiring that the community living support plan be completed and provided to the administrator of a facility upon the mental health resident's admission; requiring the community living support plan to be updated when there is a significant change to the mental health resident's behavioral health; requiring the case manager assigned to a mental health resident of an assisted living facility that holds a limited mental health license to keep a record of the date and time of face-to-face interactions with the resident and to make the record available to the responsible entity for inspection; requiring that the record be maintained for a specified time; requiring the responsible entity to ensure that there is adequate and consistent monitoring and enforcement of community living support plans and cooperative agreements and that concerns are reported to the appropriate regulatory oversight organization under certain circumstances; amending s.

400.0074, F.S.; requiring that an administrative assessment conducted by a local council be comprehensive in nature and focus on factors affecting the rights, health, safety, and welfare of nursing home residents; requiring a local council to conduct an exit consultation with the facility administrator or administrator designee to discuss issues and concerns in areas affecting the rights, health, safety, and welfare of residents and make recommendations for improvement; amending s. 400.0078, F.S.; requiring that a resident or a representative of a resident of a long-term care facility be informed that retaliatory action cannot be taken against a resident for presenting grievances or for exercising any other resident right; amending s. 429.07, F.S.; requiring that an extended congregate care license be issued to certain facilities that have been licensed as assisted living facilities under certain circumstances and authorizing the issuance of such license if a specified condition is met; providing the purpose of an extended congregate care license; providing that the initial extended congregate care license of an assisted living facility is provisional under certain circumstances; requiring a licensee to notify the Agency for Health Care Administration if it accepts a resident who qualifies for extended congregate care services; requiring the agency to inspect the facility for compliance with the requirements of an extended congregate care license;


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requiring the issuance of an extended congregate care license under certain circumstances; requiring the licensee to immediately suspend extended congregate care services under certain circumstances; requiring a registered nurse representing the agency to visit the facility at least twice a year, rather than quarterly, to monitor residents who are receiving extended congregate care services; authorizing the agency to waive one of the required yearly monitoring visits under certain circumstances; authorizing the agency to deny or revoke a facility's extended congregate care license; requiring a registered nurse representing the agency to visit the facility at least annually, rather than twice a year, to monitor residents who are receiving limited nursing services; providing that such monitoring visits may be conducted in conjunction with other agency inspections; 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 one or more mental health residents to obtain a limited mental health license; amending s. 429.14, F.S.; revising the circumstances under which the agency may deny, revoke, or suspend the license of an assisted living facility and impose an administrative fine; 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 provision requiring the agency to 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 some or all of its residents; amending s. 429.178, F.S.; conforming cross-references; amending s. 429.19, F.S.; revising the amounts and uses of administrative fines; requiring the agency to levy a fine for violations that are corrected before an inspection if noncompliance occurred within a specified period of time; deleting factors that the agency is required to consider in determining penalties and fines; 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. 429.28, F.S.; providing notice requirements to inform facility residents that the identity of the resident and complainant in any complaint made to the State Long-Term Care Ombudsman Program or a local long-term care ombudsman council is confidential and that retaliatory action cannot be taken against a resident for presenting grievances or for exercising any other resident right; requiring that a facility that terminates an individual's residency after the filing of a complaint be fined if good cause is not shown for the termination; amending

s. 429.34, F.S.; requiring certain persons to report elder abuse in assisted living facilities; requiring the agency to regularly inspect every licensed assisted living facility; requiring the agency to conduct more frequent inspections under certain circumstances; requiring the licensee to pay a fee for the cost of additional inspections; requiring the agency to annually adjust the fee; amending s. 429.41, F.S.; providing that certain staffing requirements apply only to residents in continuing care facilities who are receiving the relevant service; amending s. 429.52, F.S.; requiring each newly hired employee of an assisted living facility to attend a preservice orientation provided by the assisted living facility; requiring the employee and administrator to sign a statement that the employee completed the required pre-service orientation and keep the signed statement in the employee’s personnel record; requiring two additional hours of training for assistance with medication; conforming a cross-reference; creating s. 429.55, F.S.; 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; requiring the agency to implement a rating system of assisted living facilities by a specified date, adopt rules, and create content for the agency’s website that makes available to consumers information regarding assisted living facilities;

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providing criteria for the content; 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" ~~"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, as appropriate, 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


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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 upon the resident's admission. The support plan and the agreement may be in one document.


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(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, such as an inpatient admission or a change in medication, level of service, or residence. 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) Adequate and consistent monitoring and enforcement 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 ~~Family Services~~, 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

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~~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) The local council shall conduct an exit consultation with the facility administrator or administrator designee to

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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. 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


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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


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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. Within

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the first 3 months after the provisional license is issued, 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 requirements of an extended congregate care license. Failure to admit an extended congregate care resident within the first 3 months shall render the extended congregate care license void. A licensee with a provisional extended congregate care license that demonstrates compliance with all of 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 requirements during a follow-up 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 one month in order to complete a follow-up 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


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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

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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 5. 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

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of Children and Families ~~Family Services~~.

(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. The support plan and the agreement may be combined.

(b) Have documentation ~~that is~~ provided by the Department of Children and Families ~~Family Services~~ 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.

(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 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 6. Section 429.14, Florida Statutes, is amended to

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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.


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(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 or revoke a license of an ~~to any~~ applicant or 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, must 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

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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 access to the facility or prohibits the agency from conducting a regulatory inspection. The licensee may not restrict agency staff in accessing and copying records or in 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-days' 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 7. 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


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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) ~~s. 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) ~~s. 429.52(2)(g)~~.

Section 8. Section 429.19, Florida Statutes, is amended to read:

429.19 Violations; imposition of administrative fines; grounds.—

(1) In addition to the requirements of part II of chapter 408, the agency shall impose an administrative fine in the manner provided in chapter 120 for the violation of any provision of this part, part II of chapter 408, and applicable rules by an assisted living facility, for the actions of any person subject to level 2 background screening under s. 408.809, for the actions of any facility employee, or for an intentional or negligent act seriously affecting the health, safety, or welfare of a resident of the facility.

(2) Each violation of this part and adopted rules must ~~shall~~ be classified according to the nature of the violation and the gravity of its probable effect on facility residents. The


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agency shall indicate the classification on the written notice of the violation as follows:

(a) Class "I" violations are defined in s. 408.813. The agency shall impose an administrative fine of $7,500 for each ~~a~~ cited class I violation in a facility that is licensed for fewer than 100 beds at the time of the violation ~~in an amount not less than $5,000 and not exceeding $10,000 for each violation~~. The agency shall impose an administrative fine of $11,250 for each cited class I violation in a facility that is licensed for 100 or more beds at the time of the violation. If the agency has knowledge of a class I violation which occurred within 12 months prior to an inspection, a fine must be levied for that violation whether or not the noncompliance was corrected before the inspection.

(b) Class "II" violations are defined in s. 408.813. The agency shall impose an administrative fine of $3,000 for each ~~a~~ cited class II violation in a facility that is licensed for fewer than 100 beds at the time of the violation ~~in an amount not less than $1,000 and not exceeding $5,000 for each violation~~. The agency shall impose an administrative fine of $4,500 for each cited class II violation in a facility that is licensed for 100 or more beds at the time of the violation.

(c) Class "III" violations are defined in s. 408.813. The agency shall impose an administrative fine of $750 for each ~~a~~ cited class III violation in a facility that is licensed for fewer than 100 beds at the time of the violation ~~in an amount not less than $500 and not exceeding $1,000 for each violation~~. The agency shall impose an administrative fine of $1,125 for each cited class III violation in a facility that is licensed


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for 100 or more beds at the time of the violation.

(d) Class "IV" violations are defined in s. 408.813. The agency shall impose an administrative fine of $150 for each ~~a~~ cited class IV violation in a facility that is licensed for fewer than 100 beds at the time of the violation ~~in an amount not less than $100 and not exceeding $200 for each violation~~. The agency shall impose an administrative fine of $225 for each cited class IV violation in a facility that is licensed for 100 or more beds at the time of the violation.

(e) Any fine imposed for a class I violation or a class II violation must be doubled if a facility was previously cited for one or more class I or class II violations during the agency's last licensure inspection or any inspection or complaint investigation since the last licensure inspection.

(f) Notwithstanding s. 408.813(2)(c) and (d) and s. 408.832, a fine must be imposed for each class III or class IV violation, regardless of correction, if a facility was previously cited for one or more class III or class IV violations during the agency's last licensure inspection or any inspection or complaint investigation since the last licensure inspection for the same regulatory violation. A fine imposed for class III or class IV violations must be doubled if a facility was previously cited for one or more class III or class IV violations during the agency's last two licensure inspections for the same regulatory violation.

~~(3) For purposes of this section, in determining if a penalty is to be imposed and in fixing the amount of the fine, the agency shall consider the following factors:~~

~~(a) The gravity of the violation, including the probability~~


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~~that death or serious physical or emotional harm to a resident will result or has resulted, the severity of the action or potential harm, and the extent to which the provisions of the applicable laws or rules were violated.~~

~~(b) Actions taken by the owner or administrator to correct violations.~~

~~(c) Any previous violations.~~

~~(d) The financial benefit to the facility of committing or continuing the violation.~~

~~(e) The licensed capacity of the facility.~~

(3) ~~(4)~~ Each day of continuing violation after the date established by the agency ~~fixed~~ for correction ~~termination~~ of the violation~~, as ordered by the agency,~~ constitutes an additional, separate, and distinct violation.

(4) ~~(5)~~ An ~~Any~~ action taken to correct a violation shall be documented in writing by the owner or administrator of the facility and verified through followup visits by agency personnel. The agency may impose a fine and, in the case of an owner-operated facility, revoke or deny a facility's license when a facility administrator fraudulently misrepresents action taken to correct a violation.

(5) ~~(6)~~ A ~~Any~~ facility whose owner fails to apply for a change-of-ownership license in accordance with part II of chapter 408 and operates the facility under the new ownership is subject to a fine of $5,000.

(6) ~~(7)~~ In addition to any administrative fines imposed, the agency may assess a survey fee, equal to the lesser of one half of the facility's biennial license and bed fee or $500, to cover the cost of conducting initial complaint investigations that

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result in the finding of a violation that was the subject of the complaint or monitoring visits conducted under s. 429.28(3)(c) to verify the correction of the violations.

(7) ~~(8)~~ During an inspection, the agency shall make a reasonable attempt to discuss each violation with the owner or administrator of the facility, prior to written notification.

(8) ~~(9)~~ The agency shall develop and disseminate an annual list of all facilities sanctioned or fined for violations of state standards, the number and class of violations involved, the penalties imposed, and the current status of cases. The list shall be disseminated, at no charge, to the Department of Elderly Affairs, the Department of Health, the Department of Children and Families ~~Family Services~~, the Agency for Persons with Disabilities, the area agencies on aging, the Florida Statewide Advocacy Council, and the state and local ombudsman councils. The Department of Children and Families ~~Family Services~~ shall disseminate the list to service providers under contract to the department who are responsible for referring persons to a facility for residency. The agency may charge a fee commensurate with the cost of printing and postage to other interested parties requesting a copy of this list. This information may be provided electronically or through the agency's website ~~Internet site~~.

Section 9. 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,

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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 (CPAP) device, but not with titrating the prescribed setting of the device.

(l) Assisting with measuring vital signs.

(m) Assisting with colostomy bags.


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

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

Section 10. 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~~.

(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:

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(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 11. 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 ~~Family Services~~, 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 one or more class I violations 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. In addition to any fines imposed on the facility under s. 429.19, the licensee shall pay a fee for the cost of the additional inspection equivalent to the standard assisted living facility license and per-bed fees, without exception for beds designated for recipients of optional state supplementation. The agency shall adjust the fee in accordance with s. 408.805.

Section 12. 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


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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 13. Present subsections (1) through (11) of section 429.52, Florida Statutes, are renumbered as subsections (2) through (12), respectively, a new subsection (1) is added to that section, and present subsections (5) and (9) of that

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section are amended, to read:

429.52 Staff training and educational programs; core educational requirement.—

(1) Effective October 1, 2014, 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 pre-service 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)~~.


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Section 14. 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 (OPPAGA) shall conduct a study of intersurveyor reliability for assisted living facilities. By November 1, 2014, OPPAGA shall report 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 15. 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:

(1) Implement a rating system for assisted living facilities by March 1, 2015 . The agency shall adopt rules to administer this subsection.

(2) By November 1, 2014 create content that is easily accessible through the front page of the agency’s website. At a minimum, the content must include:

(a) Information on each licensed assisted living facility, including, but not limited to:

1. The name and address of the facility.

2. The number and type of licensed beds in the facility.

3. The types of licenses held by the facility.

4. The facility’s license expiration date and status.

5. Other relevant information that the agency currently collects.

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(b) A list of the facility's violations, including, for each violation:

1. A summary of the violation which is presented in a manner understandable by the general public;

2. Any sanctions imposed by final order; and

3. The date the corrective action was confirmed by the agency.

(c) Links to inspection reports that the agency has on file.

(d) A monitored comment page, maintained by the agency, which allows members of the public to anonymously comment on assisted living facilities that are licensed to operate in this state. This comment page must, at a minimum, allow members of the public to post comments on their experiences with, or observations of, an assisted living facility and to review other people's comments. Comments posted to the agency's comment page may not contain profanity and are intended to provide meaningful feedback about the assisted living facility. The agency shall review comments for profane content before the comments are posted to the page. A controlling interest, as defined in s. 408.803, Florida Statutes, in an assisted living facility, or an employee or owner of an assisted living facility, is prohibited from posting comments on the page, except that a controlling interest, employee, or owner may respond to comments on the page, and the agency shall ensure that the responses are identified as being from a representative of the facility.

Section 16. This act shall take effect July 1, 2014.

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

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

BILL:	CS/SB 248
INTRODUCER:	Health Policy Committee and Children, Families, and Elder Affairs Committee
SUBJECT:	Assisted Living Facilities
DATE:	January 9, 2014 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Stovall	HP	**Fav/CS**
2.			JU	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 248 strengthens the enforcement of current regulations for Assisted Living Facilities (ALF or facility) by revising fines imposed for licensure violations, clarifying existing enforcement tools, and requiring an additional inspection for facilities with significant violations. Specifically, the bill:

- Specifies who is responsible for assuring that mental health residents in an ALF receive necessary services.
- Clarifies the duties of the state Long-Term Care Ombudsman Program.
- Amends language related to ALF specialty licenses by:
  - Creating a provisional Extended Congregate Care (ECC) license for new ALFs and specifying when the Agency for Health Care Administration (AHCA or agency) may deny or revoke a facility's ECC license.
  - Reducing the number of monitoring visits the AHCA must conduct for ALFs with Limited Nursing Services (LNS) licenses and ECC licenses.
  - Specifying when the AHCA may waive a monitoring visit in facilities with an ECC or LNS license.
  - Requiring that facilities with one or more state supported mental health residents obtain a limited mental health (LMH) license. Current law only requires an LMH license for facilities with three or more mental health residents.
- Allows the AHCA to revoke the license of a facility with a controlling interest that has or had a 25 percent or greater financial or ownership interest in a second facility that closed due to financial inability to operate or that was the subject of other specified administrative

sanctions. Current law allows the AHCA to deny such a facility's license during the renewal process.

- Clarifies the criteria under which the AHCA must revoke or deny a facility's license.
- Specifies circumstances under which the AHCA must impose an immediate moratorium[1] on a facility.
- Amends fine amounts by:
  - Setting fines for all classes of violations[2] to a fixed amount at the midpoint of the current range and multiplying these new fine amounts by 1.5 for facilities licensed for 100 or more beds.
  - Allowing the AHCA to impose a fine for a class I violation even if it is corrected before the AHCA inspects a facility.
  - Doubling fines for repeated serious violations.
  - Requiring that fines be imposed for repeat minor violations[3] regardless of correction.
  - Doubling the fines for minor violations if a facility is cited for the same minor violation during the previous two licensure inspections.
  - Specifying a fine amount of $500 for ALFs that are not in compliance with background screening requirements.[4]
  - Requiring the AHCA to impose a $2,500 fine against a facility that does not show good cause for terminating the residency of an individual.
- Amends the definition of "assistance with self-administration of medication" to add several actions to the list of services in which unlicensed staff can assist residents.
- 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' (DCF or department) central abuse hotline.
- Requires an additional inspection, paid for by the facility, within 6 months, of a facility cited for specified serious violations.
- Clarifies that in a continuing care facility or retirement community, ALF staffing requirements apply only to residents of units designated for independent living as an ALF.
- Requires new facility staff, who 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 (OPPAGA) to conduct a study of inter-surveyor reliability in order to determine the consistency with which the AHCA applies regulations to facilities, and requires OPPAGA to report its findings and recommendations by November 1, 2014.
- Requires the AHCA to implement an ALF rating system by March 1, 2015.
- Requires the AHCA to add certain content to its website by November 1, 2014, to help consumers select an ALF.

II. Present Situation:

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

[1] "Moratorium" means a prohibition on the acceptance of new clients. Section 408.803(10), F.S.
[2] The classes of violations can be found in s. 408.813, F.S.
[3] Class III and class IV violations.
[4] Background screening requirements are found in s. 408.809, F.S.

more adults who are not relatives of the owner or administrator.[5] A personal service is direct physical assistance with, or supervision of, the activities of daily living and the self-administration of medication.[6] Activities of daily living include ambulation, bathing, dressing, eating, grooming, toileting, and other similar tasks.[7]

An ALF is required to provide care and services appropriate to the needs of the residents accepted for admission to the facility.[8] The owner or facility administrator determines whether an individual is appropriate for admission to the facility based on a number of criteria.[9] If, as determined by the facility administrator or health care provider, a resident no longer meets the criteria for continued residency or the facility is unable to meet the resident's needs, the resident must be discharged in accordance with the Resident Bill of Rights.[10]

As of November 1, 2013, there were 3,042 licensed ALFs in Florida with a total of 86,455 beds.[11] An ALF must have a standard license issued by the AHCA, pursuant to part I of ch. 429, F.S., and part II of ch. 408, F.S. 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,[12] limited mental health services,[13] and extended congregate care services.[14] There are 1,020 facilities with LNS specialty licenses, 274 with ECC licenses, and 1,040 with LMH specialty licenses.[15]

Limited Nursing Services Specialty License

An LNS specialty license enables an ALF to provide, directly or through contract, a select number of nursing services in addition to the personal services that are authorized under the standard license. The nursing services are limited to acts specified in administrative rules, may only be provided as authorized by a health care provider's order, and must be conducted and supervised in accordance with ch. 464, F.S., relating to nursing, and the prevailing standard of practice in the nursing community.

Extended Congregate Care Specialty License

The primary purpose of ECC services is to allow residents to remain in a familiar setting as they become more impaired with physical or mental limitations. An ECC specialty license enables a facility to provide, directly or through contract, services performed by licensed nurses and

[5] Section 429.02(5), F.S. An ALF does not include an adult family-care home or a non-transient public lodging establishment.
[6] Section 429.02(16), F.S.
[7] Section 429.02(1), F.S.
[8] For specific minimum standards see Rule 58A-5.0182, F.A.C.
[9] Section 429.26, F.S., and Rule 58A-5.0181, F.A.C.
[10] Section 429.28, F.S.
[11] Fla. Agency for Health Care Admin., *Assisted Living Facility Directory* (Oct. 1, 2013), http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Assisted_Living/docs/alf/Directory_ALF.pdf (last visited Nov. 15, 2013).
[12] Section 429.07(3)(c), F.S.
[13] Section 429.075, F.S.
[14] Section 429.07(3)(b), F.S.
[15] *See* Fla. Agency for Health Care Admin., *Assisted Living Facility*, http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Assisted_Living/alf.shtml (follow the hyperlinks for the ALF directories found under the "Notices/Updates" heading) (last visited Nov. 15, 2013).

supportive services[16] to persons who otherwise would be disqualified from continued residence in an ALF.[17] A facility 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, a facility with an ECC license still may not serve residents who require 24-hour nursing supervision.[18]

Limited Mental Health Specialty License

An ALF that serves three or more mental health residents must obtain an LMH specialty license.[19] A mental health resident is an individual who receives social security disability income (SSDI) due to a mental disorder or supplemental security income (SSI) due to a mental disorder, and receives optional state supplementation (OSS).[20] The department must ensure that a mental health resident is assessed and determined able to live in an ALF with an LMH license.[21]

The administrator of a LMH facility must consult with a mental health resident and the resident's case manager to develop and help execute a community living support plan for the resident detailing the specific needs and services the resident requires.[22] The LMH licensee must also execute a cooperative agreement with the mental health care services provider. The cooperative agreement specifies, among other things, directions for the ALF accessing emergency and after-hours care for the mental health resident.

Department of Elder Affairs Rules

In addition to ch. 429, F.S., ALFs are also subject to regulation under Rule 58A-5 of the Florida Administrative Code (F.A.C.). These rules are adopted by the Department of Elder Affairs (DOEA) in consultation with the AHCA, the DCF, and the Department of Health (DOH).[23] In June 2012, the DOEA initiated a process of negotiated rulemaking to revise many of its rules regarding ALFs. After multiple meetings, a committee that consisted of agency staff, consumer

[16] Supportive services include social service needs, counseling, emotional support, networking, assistance with securing social and leisure services, shopping service, escort service, companionship, family support, information and referral, assistance in developing and implementing self-directed activities, and volunteer services. Rule 58A-5.030(8)(a), F.A.C.
[17] An ECC program may provide additional services, such as the following: 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; assisting with self-administered medications or administering medications and treatments pursuant to a health care provider's order; supervising residents with dementia and cognitive impairments; health education, counseling, and implementing health-promoting programs; rehabilitative services; and escort services related to health-related appointments. Section 429.07(3)(b), F.S., and Rule 58A-5.030, F.A.C.
[18] Section 429.07(3)(b), F.S.
[19] Section 429.075, F.S.
[20] Section 429.02(15), F.S. Optional State Supplementation is a cash assistance program. Its purpose is to supplement a person's income to help pay for costs in an assisted living facility, mental health residential treatment facility, or adult family care home, but it is not a Medicaid program. Dep't of Elder Affairs, *Florida Affordable Assisted Living: Optional State Supplementation (OSS)*, http://elderaffairs.state.fl.us/faal/operator/statesupp.html (last visited Nov. 22, 2013).
[21] Section 394.4574, F.S., requires a mental health resident to be assessed by a psychiatrist, clinical psychologist, clinical social worker, psychiatric nurse, or an individual who is supervised by one of these professionals to determine whether it is appropriate for the person to reside in an ALF.
[22] Rule 58A-5.029(2)(c)3., F.A.C.
[23] Section 429.41(1), F.S.

advocates, and industry representatives voted on numerous changes to Rule 58A-5, F.A.C. On November 28, 2012, the DOEA issued a proposed rule and held several public hearings on the proposed rule.[24] In June 2013, the DOEA withdrew the proposed rule in order to get a revised Statement of Estimated Regulatory Costs, and it plans to move forward with the rule, including seeking ratification from the Legislature on the portions of the rule that require it.[25]

ALF Staff Training

Administrators and Managers

Administrators and other ALF staff must meet minimum training and education requirements established in rule by the DOEA.[26] This training and education is intended to assist facilities in appropriately responding to the needs of residents, maintaining resident care and facility standards, and meeting licensure requirements.[27]

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.[28]

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.[29]

Staff with Direct Care Responsibilities

Facility administrators or managers are required to provide or arrange for six hours of in-service training for facility staff who provide direct care to residents which covers various topics as mandated in rule.[30] 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. 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 complete 1 hour of elopement training and one hour of training on do not resuscitate orders. The staff may be required to complete training on special topics such as self-administration of medication and Alzheimer's disease, if applicable.

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[24] *See* Dep't of Elder Affairs, *Assisted Living Facility (ALF) Negotiated Rulemaking*, http://elderaffairs.state.fl.us/doea/alf_rulemaking.php (last visited Nov. 18, 2013).
[25] Conversation with Adam Lovejoy, Legislative Affairs Director, Department of Elder Affairs (Sept. 17, 2013).
[26] Rule 58A-5.0191, F.A.C. Many of the training requirements in rule may be subject to change due to the DOEA negotiated rulemaking process.
[27] Section 429.52(1), F.S.
[28] 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.
[29] Rule 58A-5.0191, F.A.C.
[30] Rule 58A-5.0191, F.A.C.

ECC Specific Training

The administrator and ECC supervisor, if different from the administrator, must complete 4 hours of initial training in extended congregate care either prior to the facility receiving its ECC license or within 3 months after beginning employment in the facility as an administrator or ECC supervisor. The administrator and ECC supervisor 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.[31]

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 statutory and rule requirements and the delivery of personal care and supportive services in an ECC facility.[32]

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 having mental health diagnoses and a minimum of 3 hours of continuing education dealing with mental health diagnoses or mental health treatment every 2 years.[33]

Inspections and Surveys

The agency 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
- To monitor facilities cited in the previous year for a class I or class II, or four or more uncorrected class III, violations.[34]
- Upon receipt of an oral or written complaint of practices that threaten the health, safety, or welfare of residents.
- If the 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.[35]

[31] Rule 58A-5.0191(7)(b), F.A.C.
[32] Rule 58A-5.0191(7)(c), F.A.C.
[33] Section 429.075, F.S. and Rule 58A-5.0191(8), F.A.C.
[34] See "Violations and Penalties" subheading below for a description of the violations.
[35] See 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 the AHCA if the applicant does not have any:

- Class I, class II, or uncorrected class III violations.
- Confirmed long-term care ombudsman council complaints reported to the AHCA by the council.
- Confirmed licensing complaints within the two licensing periods immediately preceding the current renewal date.[36]

An abbreviated survey allows for a quicker and less intrusive survey by narrowing the range of items the agency must inspect.[37] The agency must expand an abbreviated survey or conduct a full survey if violations that threaten or potentially threaten the health, safety, or security of residents are identified during an abbreviated survey.[38]

Monitoring Visits

Facilities with LNS or ECC licenses are subject to monitoring visits by the AHCA in which the agency inspects the facility for compliance with the requirements of the specialty license. 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 services and to determine if the facility is complying with applicable regulatory requirements.[39] An ECC licensee is subject to quarterly monitoring inspections. At least one registered nurse must be included in the inspection team. The agency 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.[40]

Violations and Penalties

Part II of ch. 408, F.S., provides general licensure standards for all facilities regulated by the AHCA. Under s. 408.813, F.S., ALFs may be subject to administrative fines imposed by the 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 the 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.
  - The agency must fine a facility between $5,000 and $10,000 for each class I violation.

[36] Rule 58A-5.033(2), F.A.C.
[37] Rule 58A-5.033(2)(b).
[38] *Id.*
[39] Section 429.07(3)(c), F.S.
[40] Section 429.07(3)(b), F.S.

- During fiscal years 2011-2013, the AHCA entered 115 final orders for class I violations with an average fine amount of $6,585 for facilities with less than 100 beds and $7,454 for facilities with 100 or more beds.

- **Class II violations** are those conditions that the AHCA determines directly threaten the physical or emotional health, safety, or security of the clients.
  - Examples include 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 a food storage area.
  - The agency must fine a facility between $1,000 and $5,000 for each violation.
  - During fiscal years 2011-2013, the AHCA entered 749 final orders for class II violations with an average fine amount of $1,542 for facilities with less than 100 beds and $1,843 for facilities with 100 or more beds.

- **Class III violations** are those conditions that the 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.
  - The agency must fine a facility between $500 and $1,000 for each violation, but no fine may be imposed if the facility corrects the violation.
  - During fiscal years 2011-2013, the AHCA entered 507 final orders for uncorrected class III violations with an average fine amount of $766 for facilities with less than 100 beds and $614 for facilities with 100 or more beds.

- **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.
  - The agency can only fine a facility (between $100 and $200 for each violation) if the problem is not corrected.
  - During fiscal years 2011-2013, the AHCA entered 18 final orders for uncorrected class IV violations with an average fine amount of $165 for facilities with less than 100 beds and $100 for facilities with 100 or more beds.[41,42,43]

In addition to financial penalties, the AHCA can take other actions against a facility. The agency may deny, revoke, and suspend any license for any of the actions listed in s. 429.14(1)(a)-(k), F.S. The agency 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.[44] The agency may also impose an immediate moratorium or emergency suspension on any provider if it determines that any

[41] 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. Section 429.19(3), F.S.
[42] Section 429.19(2), F.S.
[43] *AHCA bill analysis for SB 248*, dated November 26, 2013. On file with the Senate Committee on Health Policy.
[44] Section 429.14(4), F.S.

condition that presents a threat to the health, safety, or welfare of a client.[45] The agency is required to publicly post notification of a license suspension, revocation, or denial of a license renewal, at the facility.[46] Finally, ch. 825, F.S., Florida's Criminal Code, provides criminal penalties for the abuse, neglect, and exploitation of elderly persons[47] and disabled adults.[48]

Central Abuse Hotline

The department 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[49] at any hour of the day or night, any day of the week.[50] 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.[51]

Florida's 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.[52] 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.[53] 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

[45] Section 408.814, F.S.
[46] Section 429.14(7), F.S.
[47] "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. Section 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. Section 825.104, F.S.
[48] "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. Section 825.101(4), F.S.
[49] "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. Section 415.102(27), F.S.
[50] 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.
[51] Section 415.1034, F.S.
[52] 42 U.S.C. 3058. *See also* s. 400.0061(1), F.S.
[53] Section 400.0063, F.S.

number for receiving complaints.[54] 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.[55] In addition to investigating and resolving complaints, ombudsmen conduct unannounced visits to assess the quality of care in facilities, referred to as administrative assessments.

Consumer Information

Section 400.191, F.S., requires the AHCA to provide information to the public about all licensed nursing homes in the state. The information must be provided in a consumer-friendly electronic format to assist consumers and their families in comparing and evaluating nursing homes. Under s. 400.191(2), F.S., the agency must provide an Internet site that includes information such as a list by name and address of all nursing homes in the state, the total number of beds in each facility, and survey and deficiency information. Additional information that the agency may provide on the site includes the licensure status history of each facility, the rating history of each facility, and the regulatory history of each facility.

There is no similar requirement in law to provide certain consumer information to the public on the licensed ALFs in the state.

The Miami Herald Articles and the Governor's Assisted Living Workgroup

Beginning on April 30, 2011, the Miami Herald published a four-part series, titled "Neglected to Death," which detailed abuses occurring in ALFs and the state regulatory responses to such cases. The paper spent a year examining thousands of state inspections, police reports, court cases, autopsy files, e-mails, and death certificates and conducting dozens of interviews with operators and residents throughout Florida. The series detailed examples of abuses, neglect, and even death that took place in facilities.[56] The series also criticized the state's regulatory and law enforcement agencies' responses to the problems. The paper concluded that the state's agencies, and in particular the AHCA, failed to enforce existing laws designed to protect Florida's citizens who reside in ALFs.[57]

Soon after the Miami Herald series, Governor Rick Scott vetoed HB 4045,[58] which reduced requirements relating to ALFs. The Governor then directed the AHCA to form a task force for

[54] Section 400.0078, F.S.
[55] Section 400.0077(1)(b), F.S.
[56] Rob Barry, Michael Sallah and Carol Marbin Miller, *Neglected to Death, Parts 1-3*, THE MIAMI HERALD, April 30, 2011 *available at* http://www.miamiherald.com/2011/04/30/2194842/once-pride-of-florida-now-scenes.html and http://www.miamiherald.com/2011/05/03/2199747/key-medical-logs-doctored-missing.html (see left side of article to access weblinks to the three-part series) (Last visited on Nov. 20, 2013).
[57] *Id.*
[58] House Bill 4045 (2011) repealed a requirement for the annual dissemination of a list of ALFs that had been sanctioned or fined, a requirement for an ALF to report monthly any liability claims filed against it, a requirement to disseminate the results of the inspection of each ALF, provisions concerning rule promulgation for ALFs by the DOEA, provisions concerning the collection of information regarding the cost of care in ALFs, and the authority for local governments or organizations to contribute to the cost of care of local facility residents.

the purpose of examining current assisted living regulations and oversight.[59] The task force referred to as the Assisted Living Workgroup, held meetings and produced two reports, one in August of 2011 and one in October of 2012. In addition to public testimony and presentations, the Assisted Living Workgroup focused on assisted living regulation, consumer information and choice, and long term care services and access.[60] The workgroup made numerous recommendations in its two reports.[61]

III. Effect of Proposed Changes:

Section 1 of 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 mental health residents who are not enrolled with a Medicaid managed care plan. This section requires a mental health resident's community living support plan to 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. Finally, this section charges the entity 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.

Section 2 of the bill amends s. 400.0074, F.S., to require the Long-Term Care Ombudsman Program's administrative assessments of facilities be comprehensive in nature. This section also requires ombudsmen to conduct an exit consultation with the facility administrator to discuss issues and concerns from the visit.

Section 3 of the bill amends s. 400.0078, F.S., to require an ALF to include a statement that retaliatory action cannot be taken against a resident for presenting grievances when that ALF provides the required information to new residents upon admission to the facility about the purpose of the Long-Term Care Ombudsman Program.

Section 4 of 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 a full ECC license.

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[59] Membership details of the task force are available at Fla. Agency for Health Care Admin., *Assisted Living Workgroup Members*, http://ahca.myflorida.com/SCHS/CommiteesCouncils/ALWG/wgmembers.shtml (last visited Nov. 20, 2013).
[60] *See* Fla. Agency for Health Care Admin., *Assisted Living Workgroup, Phase I*, http://ahca.myflorida.com/SCHS/CommiteesCouncils/ALWG/archived/ALWG2011.shtml (last visited Nov. 20, 2013); Fla. Agency for Health Care Admin., *Assisted Living Workgroup, Phase II*, http://ahca.myflorida.com/SCHS/CommiteesCouncils/ALWG/index.shtml (last visited Nov. 20, 2013).
[61] See Fla. Agency for Health Care Admin., *Florida Assisted Living Workgroup, Phase II Recommendations* (Nov. 26, 2012), http://ahca.myflorida.com/SCHS/CommiteesCouncils/ALWG/docs/ALF-FinalReportandRecommendationsPhaseII.pdf (last visited Nov. 20, 2013); Fla. Agency for Health Care Admin., *Florida Assisted Living Workshop, Final Report and Recommendations*, http://ahca.myflorida.com/SCHS/CommiteesCouncils/ALWG/archived/docs/2011/ALWorkgroupFinalReport.pdf (last visited Nov. 20, 2013).

- Clarifying under what circumstances the 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 the AHCA when it has admitted one or more residents requiring ECC services, after which the 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, the AHCA must grant the facility a full 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 provisional ECC license expires.
- 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 the AHCA may waive one of the required monitoring visits for facilities with ECC licenses and also allowing the AHCA to waive the required monitoring visit for facilities with an LNS license under the same conditions.

Section 5 of the bill amends s. 429.075, F.S., to require facilities with one or more state supported mental health residents to obtain a LMH license. Current law only requires an ALF to obtain an LMH license if they have three or more state supported mental health residents.

Section 6 of the bill amends s. 429.14, F.S., to clarify the use of administrative penalties, to:

- Allow the AHCA to revoke, rather than only deny,[62] a facility's or a controlling interest's license if that facility or controlling interest has, or had, a 25 percent or greater financial or ownership interest in a second facility that closed due to financial inability to operate or was the subject of other specified administrative sanctions.
- Add additional criteria under which the AHCA must deny or revoke a facility's license.
- Require that the AHCA impose an immediate moratorium on a facility that fails to provide the AHCA with access to the facility, prohibits a regulatory inspection, denies access to records, or prohibits the confidential interview of facility staff or residents.

This section of the bill also clarifies that if a facility is required to relocate its residents due to agency action, the facility does not have to give residents 45 days' notice as required under s. 429.28(1)(k), F.S.

Section 7 of the bill amends s. 429.178, F.S., to make technical changes and to conform with changes to other parts of the bill.

Section 8 of the bill amends s. 429.19, F.S., relating to the impositions of fines. Specifically, the bill:

- Sets the dollar amount of fines for facilities with fewer than 100 beds at $7,500 for class I violations, $3,000 for class II violations, $750 for class III violations, and $150 for class IV violations. This is the midpoint of the current ranges for fines in current law.

[62] Denial of a license occurs when the Agency refuses to renew the facilities license at the end of the 2-year period the license was issued for.

- Sets the dollar amount of fines for facilities with 100 or more beds at $11,250 for class I violations, $4,500 for class II violations, $1,125 for class III violations, and $225 for class IV violations. These fines are 1.5 times the amount of the fines for facilities with fewer than 100 beds.
- Requires the AHCA to impose a fine on a facility for a class I violation, even if the facility corrects the violation before the AHCA conducts an investigation. Facilities can still challenge such fines through an administrative hearing pursuant to ch. 120, F.S.
- Doubles the fines for facilities with repeat class I and class II violations.
- Imposes a fine on facilities with repeat class III and class IV violations, regardless of correction. Current law prohibits the AHCA from assessing fines for corrected class III and class IV violations. Current law would still apply for the first class III or class IV violation.
- Doubles the fines for class III or class IV violations if a facility is cited for one or more such violations, stemming from the same regulation, upon the third licensure inspection if they were previously cited for the same violations over the course of the last two licensure inspections.
- Substitutes a fine of $500 for failure to comply with background screening requirements. This fine will take the place of any fine assessed based on the class of violation.

Section 9 of the bill amends s. 429.256, F.S., to allow unlicensed staff to assist with several additional services that fall under the category of assistance with self-administration of medication. Specifically, unlicensed staff will be allowed to assist with:

- Taking a prefilled insulin syringe to a resident.
- The resident's use of a nebulizer, including removing the cap of a nebulizer, opening the unit dose of nebulizer solution, and pouring the prescribed premeasured dose into the dispensing cup.
- The resident's use of a glucometer to perform blood-glucose level checks.
- Putting on and taking off antiembolism stockings.
- Applying and removing an oxygen cannula, but not titrating the oxygen levels.
- The resident's use of a continuous positive airway pressure device, but not titrating the device.
- Measuring vital signs.
- The resident's use of colostomy bags.

Section 10 of the bill amends s. 429.28, F.S., to require the posted notice of a resident's rights, obligations, and prohibitions, to specify that complaints made to the ombudsman program, as well as the names and identities of the complainant and any residents involved, are confidential. 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.

Section 11 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 provides that a facility with 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 licensee must pay a fee to the AHCA to cover the cost of the additional inspection.

Section 12 of the bill amends s. 429.41, F.S., to provide that if a continuing care facility or a retirement community licenses part of a building for ALF services the staffing requirements established in rule only apply to the residents receiving assisted living services.

Section 13 of the bill amends s. 429.52, F.S., to require that facilities provide a two 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 requiring that it be provided by a trainer registered with the DOEA.

The bill also increases the training requirements for staff who assist residents with medication from four to six hours.

Section 14 of the bill creates a new, unnumbered section of the Florida Statutes which requires the OPPAGA to conduct a study of inter-surveyor reliability to determine if different surveyors consistently apply licensure standards. The OPPAGA must report its findings and make recommendations to the Governor, the President of the Senate, and the Speaker of the House by November 1, 2014.

Section 15 of the bill creates a new, unnumbered section of the Florida Statutes which finds that consumers need additional information in order to select an ALF. To facilitate this, the bill requires the AHCA to implement a rating system for ALFs by March 1, 2015. This section also requires the AHCA to create a consumer guide website with information on ALFs by November 1, 2014. At a minimum, the website must include:

- Information on each licensed ALF such as the number and type of licensed beds, the types of licenses held by the facility, and the expiration date of the facility's license.
- A list of the facility's violations including a summary of the violation, any sanctions imposed, and the date of any corrective action taken by the facility.
- Links to inspection reports.
- A monitored comment page to help inform consumers of the quality and care of services in ALFs. The comment page must allow members of the public to post comments on their experiences with, or observations of, an ALF. A controlling interest in an ALF or an employee or owner of an ALF may not post comments on the page; however, a controlling interest, employee, or owner may respond to comments on the page, and the AHCA shall ensure that the responses are identified as being from a representative of the facility.

Section 16 of the bill provides an effective date of July 1, 2014.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. Other Constitutional Issues:

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

CS/SB 248 requires the AHCA to conduct a new survey of an ALF within 6 months after finding a class I violation or two or more class II violations. Facilities that require the additional survey will be charged a fee to cover the cost of the additional survey. According to the AHCA, current fees and fines from ALFs do not cover the cost of regulating such facilities statewide.

B. Private Sector Impact:

The bill revises the fine amounts for each of the four classes of violations. Specifically, the bill sets the dollar amount of fines for facilities with fewer than 100 beds at $7,500 for class I violations, $3,000 for class II violations, $750 for class III violations, and $150 for class IV violations. Current law provides for a range of fine amounts, for example a facility cited for a class I violation can be fined between $5,000 and $10,000. Fines are multiplied by 1.5 for facilities with 100 or more beds to help resolve an inequity in penalties whereby small facilities can pay the same fine amount as much larger facilities. Fixing the fine amounts at the mid-point of each range will provide for more predictable outcomes for facilities that are cited for violations.

Additionally, the bill provides for the following changes to the fine amounts:

- A $2,500 fine if a facility removes a resident without cause, as determined by a state court.
- A doubling of fines for class I or II violations if the facility was previously cited for one or more class I or II violations during the last licensure inspection.
- An imposition of a fine for class I violations regardless of whether they were corrected prior to being cited by the Agency.

The AHCA estimates that the new fine structure will initially cost facilities cited for violations a total of approximately $1.3 million per year. However, these increased costs could be reduced by increased compliance with ALF regulations and a corresponding reduction in the number of cited violations.[63]

All fines are subject to challenge through an administrative hearing under ch. 120, F.S.

Facilities with significant uncorrected violations would be more likely to see their licenses suspended or revoked under the bill. Closing facilities with significant problems would improve the public's assessment of ALFs and could improve the financial success of those facilities that meet licensure standards.

Facilities with any state supported mental health residents would have to meet limited mental health licensure requirements with one or more mental health residents. Facilities that currently have less than three state supported mental health residents and do not meet these requirements may see increased costs to comply.

Facilities with specialty licenses that meet licensure standards will have 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.

The bill requires facilities to provide all new employees who have not already gone through the ALF core training program with a two hour pre-service training session before they work with residents. Additionally, the bill increases the training requirements for staff who assist residents with medication from 4 to 6 hours. The cost of both of these training requirements is not expected to be significant.

C. Government Sector Impact:

The AHCA estimates that the bill will generate approximately $1.1 million of additional net revenues for the agency per year which could be available to cover any additional costs generated by the bill. According to the agency, there will be approximately $100,000 of start-up costs to implement the ALF website and rating system and approximately $250,000 of yearly recurring costs due to new FTE and contract positions.[64] These costs will likely be offset, and additional revenue will likely be generated, through the increased fines. The agency estimates, based on the number of violations cited over the past 2 years, that the new fine structure in the bill will generate approximately $1.3 million additional revenue per year. However, this amount could decrease if the new fine amounts result in increased compliance and fewer cited violations.[65]

[63] *AHCA bill analysis for SB 248*, dated November, 26, 2013. On file with the Senate Committee on Health Policy.
[64] AHCA will require one new Health Services and Facilities Consultant FTE position to create and monitor the comment page created in section 17 and two new senior attorney FTE positions to process these additional legal cases resulting from an increased number of administrative fines. See Id. pg. 18.
[65] Id.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 394.4574, 400.0074, 400.0078, 429.02, 429.07, 429.075, 429.14, 429.178, 429.19, 429.256, 429.28, 429.34, 429.41, 429.52.

This bill creates the following sections of the Florida Statutes: 429.55.

The bill creates two new unnumbered sections of the Florida Statutes.

IX. Additional Information:

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

CS by Health Policy on January 8, 2014:
The CS amends SB 248 to:

- Delete language related to flexible bed licenses while retaining language clarifying that a continuing care facility or retirement community which licenses a part of a building for ALF services must only comply with ALF staffing requirements for those residents who are receiving ALF services;
- Require an ALF administrator to sign a statement, rather than attest under penalty of perjury, that a new employee has completed a pre-service orientation;
- Change the date by which the AHCA must implement a rating system for ALFs from November 1, 2014 to March 1, 2015;
- Change the date by which the AHCA must create a website with ALF content from January 1, 2015 to November 1, 2014;
- Require the AHCA to post the date that an ALF corrects a cited violation, rather than a summary of the corrective action taken;
- Rename "Medicaid prepaid behavioral health plans" to "Medicaid managed care plans;" and
- Clarify:
  - That a provisional ECC license expires if the ALF fails to admit an ECC resident within 3 months after receiving the provisional license;
  - That ombudsman council complaints resulting in licensure citations need not be confirmed before they require the AHCA to perform the full number of licensure inspections for ECC and LNS licenses.
  - Language requiring the AHCA to impose fines for class I violations that are corrected before a licensure inspection.

- That assisting a resident with applying and removing an oxygen cannula or a CPAP device does not include titrating the cannula or device.

B. Amendments:

None.

By the Committee on Children, Families, and Elder Affairs

586-00461-14 2014248__

A bill to be entitled

An act relating to assisted living facilities; amending s. 394.4574, F.S.; providing that Medicaid prepaid behavioral health 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 prepaid behavioral health plan; deleting a provision to conform to changes made by the act; requiring that the community living support plan be completed and provided to the administrator of a facility upon the mental health resident's admission; requiring the community living support plan to be updated when there is a significant change to the mental health resident's behavioral health; requiring the case manager assigned to a mental health resident of an assisted living facility that holds a limited mental health license to keep a record of the date and time of face-to-face interactions with the resident and to make the record available to the responsible entity for inspection; requiring that the record be maintained for a specified time; requiring the responsible entity to ensure that there is adequate and consistent monitoring and enforcement of community living support plans and cooperative agreements and that concerns are reported to the appropriate regulatory oversight organization under certain circumstances; amending s. 400.0074, F.S.; requiring

that an administrative assessment conducted by a local council be comprehensive in nature and focus on factors affecting the rights, health, safety, and welfare of nursing home residents; requiring a local council to conduct an exit consultation with the facility administrator or administrator designee to discuss issues and concerns in areas affecting the rights, health, safety, and welfare of residents and make recommendations for improvement; amending s. 400.0078, F.S.; requiring that a resident or a representative of a resident of a long-term care facility be informed that retaliatory action cannot be taken against a resident for presenting grievances or for exercising any other resident right; amending s. 429.02, F.S.; conforming a cross-reference; providing a definition; amending s. 429.07, F.S.; requiring that an extended congregate care license be issued to certain facilities that have been licensed as assisted living facilities under certain circumstances and authorizing the issuance of such license if a specified condition is met; providing the purpose of an extended congregate care license; providing that the initial extended congregate care license of an assisted living facility is provisional under certain circumstances; requiring a licensee to notify the Agency for Health Care Administration if it accepts a resident who qualifies for extended congregate care services; requiring the agency to inspect the facility for compliance with the requirements of an extended

congregate care license; requiring the issuance of an extended congregate care license under certain circumstances; requiring the licensee to immediately suspend extended congregate care services under certain circumstances; requiring a registered nurse representing the agency to visit the facility at least twice a year, rather than quarterly, to monitor residents who are receiving extended congregate care services; authorizing the agency to waive one of the required yearly monitoring visits under certain circumstances; authorizing the agency to deny or revoke a facility's extended congregate care license; requiring a registered nurse representing the agency to visit the facility at least annually, rather than twice a year, to monitor residents who are receiving limited nursing services; providing that such monitoring visits may be conducted in conjunction with other agency inspections; 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 one or more mental health residents to obtain a limited mental health license; amending s. 429.14, F.S.; revising the circumstances under which the agency may deny, revoke, or suspend the license of an assisted living facility and impose an administrative fine; 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 provision requiring the agency to 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 some or all of its residents; amending s. 429.178, F.S.; conforming cross-references; amending s. 429.19, F.S.; revising the amounts and uses of administrative fines; requiring the agency to levy a fine for violations that are corrected before an inspection if noncompliance occurred within a specified period of time; deleting factors that the agency is required to consider in determining penalties and fines; 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. 429.28, F.S.; providing notice requirements to inform facility residents that the identity of the resident and complainant in any complaint made to the State Long-Term Care Ombudsman Program or a local long-term care ombudsman council is confidential and that retaliatory action cannot be taken against a resident for presenting grievances or for exercising any other resident right; requiring that a facility that terminates an individual's residency after the filing of a complaint be fined if

good cause is not shown for the termination; amending s. 429.34, F.S.; requiring certain persons to report elder abuse in assisted living facilities; requiring the agency to regularly inspect every licensed assisted living facility; requiring the agency to conduct more frequent inspections under certain circumstances; requiring the licensee to pay a fee for the cost of additional inspections; requiring the agency to annually adjust the fee; amending s. 429.41, F.S.; providing that certain staffing requirements apply only to residents in continuing care facilities who are receiving the relevant service; amending s. 429.52, F.S.; requiring each newly hired employee of an assisted living facility to attend a preservice orientation provided by the assisted living facility; requiring the administrator to attest to the completion of the preservice orientation; requiring two additional hours of training for assistance with medication; conforming a cross-reference; creating s. 429.55, F.S.; providing that a facility may apply for a flexible bed license; requiring a facility that has a flexible bed license to keep a log, specify certain information in a flexible bed contract, and retain certain records; requiring a licensed flexible bed facility to provide state surveyors with access to the log and certain independent living units; authorizing state surveyors to interview certain residents; providing that a flexible bed license does not preclude a resident from obtaining certain services;

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; requiring the agency to implement a rating system of assisted living facilities by a specified date, adopt rules, and create content for the agency's website that makes available to consumers information regarding assisted living facilities; providing criteria for the content; 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" ~~"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 prepaid behavioral health plans are responsible for enrolled mental health residents, and managing entities under contract with the department are responsible for

mental health residents who are not enrolled with a Medicaid prepaid behavioral health plan. A Medicaid prepaid behavioral health plan or a managing entity, as appropriate, 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 upon 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, such as an inpatient admission or a change in medication, level of service, or residence. 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) Adequate and consistent monitoring and enforcement 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 ~~Family Services~~, 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) The local council shall conduct an exit consultation with the facility administrator or administrator designee 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. Subsection (11) of section 429.02, Florida

Statutes, is amended, present subsections (12) through (26) of that section are redesignated as subsections (13) through (27), respectively, and a new subsection (12) is added to that section, to read:

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

(11) "Extended congregate care" means acts beyond those authorized in subsection (17) which ~~(16) that~~ may be performed by persons licensed under ~~pursuant to~~ part I of chapter 464 ~~by persons licensed thereunder~~ while carrying out their professional duties, and other supportive services which may be specified by rule. The purpose of such services is to enable residents to age in place in a residential environment despite mental or physical limitations that might otherwise disqualify them from residency in a facility licensed under this part.

(12) "Flexible bed" means a licensed bed designated to allow a continuing care facility licensed under chapter 651 or a retirement community that offers other services pursuant to this part in addition to nursing home, home health, or adult day care services licensed under this chapter or chapter 400 on a single campus to provide assisted living services for up to 15 percent of independent living residents residing in residential units designated for independent living on the campus. A flexible bed allows a resident who needs personal care services, but who does not require a secure care setting, to age in place. A flexible bed is reserved for individuals who have been a contract holder of a facility licensed under chapter 651 or a resident of a retirement community for at least 6 months.

Section 5. 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 but meets all other licensure requirements for an extended congregate care license, it shall be issued a provisional extended congregate care license for a period of 6 months. Within the first 3 months after the provisional license is issued, the licensee shall notify the agency when it has admitted an extended congregate care resident, after which an unannounced inspection shall be made to determine compliance with requirements of an extended congregate care license. If the licensee demonstrates compliance with all of the requirements of an extended congregate care license during the inspection, the licensee 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 requirements during a followup inspection, the licensee shall immediately suspend extended congregate care services, and the provisional extended congregate care license expires.

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 confirmed 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 confirmed 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 6. 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 ~~Family Services~~.

(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. The support plan and the agreement may be combined.

(b) Have documentation ~~that is~~ provided by the Department of Children and Families ~~Family Services~~ 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.

(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 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 7. 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 or revoke a license of an ~~to any~~ applicant or 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, must 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 access to the facility or prohibits the agency from conducting a regulatory inspection. The licensee may not restrict agency staff in accessing and copying records or in 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-days' 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 8. 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) ~~s. 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) ~~s. 429.52(2)(g)~~.

Section 9. Section 429.19, Florida Statutes, is amended to read:

429.19 Violations; imposition of administrative fines; grounds.—

(1) In addition to the requirements of part II of chapter 408, the agency shall impose an administrative fine in the manner provided in chapter 120 for the violation of any provision of this part, part II of chapter 408, and applicable rules by an assisted living facility, for the actions of any person subject to level 2 background screening under s. 408.809, for the actions of any facility employee, or for an intentional or negligent act seriously affecting the health, safety, or

welfare of a resident of the facility.

(2) Each violation of this part and adopted rules must ~~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:

(a) Class "I" violations are defined in s. 408.813. The agency shall impose an administrative fine of $7,500 for each ~~a~~ cited class I violation in a facility that is licensed for fewer than 100 beds at the time of the violation ~~in an amount not less than $5,000 and not exceeding $10,000 for each violation~~. The agency shall impose an administrative fine of $11,250 for each cited class I violation in a facility that is licensed for 100 or more beds at the time of the violation. If the noncompliance occurred within the prior 12 months, the fine must be levied for violations that are corrected before an inspection.

(b) Class "II" violations are defined in s. 408.813. The agency shall impose an administrative fine of $3,000 for each ~~a~~ cited class II violation in a facility that is licensed for fewer than 100 beds at the time of the violation ~~in an amount not less than $1,000 and not exceeding $5,000 for each violation~~. The agency shall impose an administrative fine of $4,500 for each cited class II violation in a facility that is licensed for 100 or more beds at the time of the violation.

(c) Class "III" violations are defined in s. 408.813. The agency shall impose an administrative fine of $750 for each ~~a~~ cited class III violation in a facility that is licensed for fewer than 100 beds at the time of the violation ~~in an amount not less than $500 and not exceeding $1,000 for each violation~~.

The agency shall impose an administrative fine of $1,125 for each cited class III violation in a facility that is licensed for 100 or more beds at the time of the violation.

(d) Class "IV" violations are defined in s. 408.813. The agency shall impose an administrative fine of $150 for each ~~a~~ cited class IV violation in a facility that is licensed for fewer than 100 beds at the time of the violation ~~in an amount not less than $100 and not exceeding $200 for each violation~~. The agency shall impose an administrative fine of $225 for each cited class IV violation in a facility that is licensed for 100 or more beds at the time of the violation.

(e) Any fine imposed for a class I violation or a class II violation must be doubled if a facility was previously cited for one or more class I or class II violations during the agency's last licensure inspection or any inspection or complaint investigation since the last licensure inspection.

(f) Notwithstanding s. 408.813(2)(c) and (d) and s. 408.832, a fine must be imposed for each class III or class IV violation, regardless of correction, if a facility was previously cited for one or more class III or class IV violations during the agency's last licensure inspection or any inspection or complaint investigation since the last licensure inspection for the same regulatory violation. A fine imposed for class III or class IV violations must be doubled if a facility was previously cited for one or more class III or class IV violations during the agency's last two licensure inspections for the same regulatory violation.

(g) 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.

~~(3) For purposes of this section, in determining if a penalty is to be imposed and in fixing the amount of the fine, the agency shall consider the following factors:~~

~~(a) The gravity of the violation, including the probability that death or serious physical or emotional harm to a resident will result or has resulted, the severity of the action or potential harm, and the extent to which the provisions of the applicable laws or rules were violated.~~

~~(b) Actions taken by the owner or administrator to correct violations.~~

~~(c) Any previous violations.~~

~~(d) The financial benefit to the facility of committing or continuing the violation.~~

~~(e) The licensed capacity of the facility.~~

(3) ~~(4)~~ Each day of continuing violation after the date established by the agency ~~fixed~~ for correction ~~termination~~ of the violation~~, as ordered by the agency,~~ constitutes an additional, separate, and distinct violation.

(4) ~~(5)~~ An ~~Any~~ action taken to correct a violation shall be documented in writing by the owner or administrator of the facility and verified through followup visits by agency personnel. The agency may impose a fine and, in the case of an owner-operated facility, revoke or deny a facility's license when a facility administrator fraudulently misrepresents action taken to correct a violation.

(5) ~~(6)~~ A ~~Any~~ facility whose owner fails to apply for a

change-of-ownership license in accordance with part II of chapter 408 and operates the facility under the new ownership is subject to a fine of $5,000.

(6)~~(7)~~ In addition to any administrative fines imposed, the agency may assess a survey fee, equal to the lesser of one half of the facility's biennial license and bed fee or $500, to cover the cost of conducting initial complaint investigations that result in the finding of a violation that was the subject of the complaint or monitoring visits conducted under s. 429.28(3)(c) to verify the correction of the violations.

(7)~~(8)~~ During an inspection, the agency shall make a reasonable attempt to discuss each violation with the owner or administrator of the facility, prior to written notification.

(8)~~(9)~~ The agency shall develop and disseminate an annual list of all facilities sanctioned or fined for violations of state standards, the number and class of violations involved, the penalties imposed, and the current status of cases. The list shall be disseminated, at no charge, to the Department of Elderly Affairs, the Department of Health, the Department of Children and Families ~~Family Services~~, the Agency for Persons with Disabilities, the area agencies on aging, the Florida Statewide Advocacy Council, and the state and local ombudsman councils. The Department of Children and Families ~~Family Services~~ shall disseminate the list to service providers under contract to the department who are responsible for referring persons to a facility for residency. The agency may charge a fee commensurate with the cost of printing and postage to other interested parties requesting a copy of this list. This information may be provided electronically or through the

agency's website ~~Internet site~~.

Section 10. 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, 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.

(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.

(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.

(k) Assisting with the use of a continuous positive airway pressure (CPAP) 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 11. 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~~.

(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 12. 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 ~~Family Services~~, 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 one or more class I violations 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. In addition to any fines imposed on the facility under s. 429.19, the licensee shall pay a fee for the cost of the additional inspection equivalent to the standard assisted living facility license and per-bed fees, without exception for beds designated for recipients of optional state supplementation. The agency shall adjust the fee in accordance with s. 408.805.

Section 13. 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 authorizes assisted living services in a building or part of a building designated for independent living, staffing requirements established in rule apply only to residents who have contracted for, and are receiving, assisted living services. If a facility uses flexible beds, staffing requirements established in rule apply only to residents receiving services through the flexible bed license provided for by department rule. 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 14. Present subsections (1) through (11) of section 429.52, Florida Statutes, are renumbered as subsections (2) through (12), respectively, a new subsection (1) is added to that section, and present subsections (5) and (9) of that section are amended, to read:

429.52 Staff training and educational programs; core educational requirement.—

(1) Effective October 1, 2014, 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. At the time of license renewal and as part of the license renewal application, each administrator of a facility licensed by the agency must attest, under penalty of perjury, to compliance with the provisions of this subsection.

(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 15. Section 429.55, Florida Statutes, is created to read:

429.55 Facilities licensed for flexible beds.—

(1) Beginning January 1, 2015, a facility may apply for a flexible bed license.

(2) A facility that has a flexible bed license shall:

(a) Retain a log that lists the name of each resident who has contracted for and is receiving assisted living services in flexible bed living units, the unit number in which the resident resides, the date the contract for the services commenced, the date that services ended in the flexible bed living unit if applicable, and documentation to demonstrate that minimum staffing standards are met;

(b) Specify in the flexible bed contract the process that will be used to determine when a resident is no longer eligible for services provided through the flexible bed license. This contract for services must also outline if the delivery of services in a flexible bed living unit will be covered under the existing residency agreement or will require a fee for service payment; and

(c) Retain each flexible bed contract for 5 years after the assisted living services end. All other records must be retained for at least 2 years from the date of termination of the services.

(3) Upon request, a facility that has a flexible bed

license must provide state surveyors with access to the log described in paragraph (2)(a). State surveyors shall also have access to independent living units occupied by residents who are receiving services through the flexible bed license at the time of any survey. State surveyors may interview any resident who has received services through the flexible bed license since the last biennial survey, but who is no longer receiving such services.

(4) A flexible bed license does not preclude a resident who lives in a building that has such a license from obtaining home health services in accordance with the policies of the facility.

Section 16. 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 (OPPAGA) shall conduct a study of intersurveyor reliability for assisted living facilities. By November 1, 2014, OPPAGA shall report 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 17. 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:

(1) Implement a rating system for assisted living facilities by November 1, 2014. The agency shall adopt rules to administer this subsection.

(2) By January 1, 2015, create content that is easily accessible through the front page of the agency's website. At a minimum, the content must include:

(a) Information on each licensed assisted living facility, including, but not limited to:

1. The name and address of the facility.

2. The number and type of licensed beds in the facility.

3. The types of licenses held by the facility.

4. The facility's license expiration date and status.

5. Other relevant information that the agency currently collects.

(b) A list of the facility's violations, including, for each violation:

1. A summary of the violation which is presented in a manner understandable by the general public;

2. Any sanctions imposed by final order; and

3. A summary of any corrective action taken by the facility.

(c) Links to inspection reports that the agency has on file.

(d) A monitored comment page, maintained by the agency, which allows members of the public to anonymously comment on assisted living facilities that are licensed to operate in this state. This comment page must, at a minimum, allow members of the public to post comments on their experiences with, or observations of, an assisted living facility and to review other people's comments. Comments posted to the agency's comment page may not contain profanity and are intended to provide meaningful feedback about the assisted living facility. The agency shall

review comments for profane content before the comments are posted to the page. A controlling interest, as defined in s. 408.803, Florida Statutes, in an assisted living facility, or an employee or owner of an assisted living facility, is prohibited from posting comments on the page, except that a controlling interest, employee, or owner may respond to comments on the page, and the agency shall ensure that the responses are identified as being from a representative of the facility.

Section 18. This act shall take effect July 1, 2014.

THE FLORIDA SENATE

APPEARANCE RECORD

1/8/14 (Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

Meeting Date

Topic ACF

Bill Number SB 248 *(if applicable)*

Name Carol Berkowitz

Amendment Barcode *(if applicable)*

Job Title SR. Director

Address 1812 Riggins Rd *Street*

Phone 850.671.3700

City Tallahassee *State* FL *Zip* 32309

E-mail cberkowitz@leadingagefloridaorg

Speaking: ☑ For ☐ Against ☐ Information

Representing LeadingAge Florida

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

1/8/14
Meeting Date

Topic ALF

Bill Number 248 *(if applicable)*

Name JACK McRAY

Amendment Barcode 277366 *(if applicable)*

Job Title

Address 200 W. COLLEGE ST, # 304
Street

TLH FL 32301
City *State* *Zip*

Phone

E-mail

Speaking: ☑ For ☐ Against ☐ Information

Representing AARP

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

January 8, 2014
Meeting Date

Topic ALF

Bill Number 248 *(if applicable)*

Name Brian Jogerst

Amendment Barcode _____ *(if applicable)*

Job Title _____

Address 215 South Monroe Street, Suite 703
Street

Tallahassee FL 32301
City *State* *Zip*

Phone 850.222.0191

E-mail brian@bhandassociates.com

Speaking: ☑ For ☐ Against ☐ Information

Representing Florida Health Care Association

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

1/8/14
Meeting Date

Topic _____ Bill Number SB 248 *(if applicable)*

Name Bobby Brantley Amendment Barcode _____ *(if applicable)*

Job Title Lobbyist

Address ~~[illegible]~~ 215 S. Monroe St Suite 804 Phone 850-521-0600
Street

Tallahassee, FL 32301 E-mail bbrantley@Stutts.com
City *State* *Zip*

Speaking: ☐ For ☐ Against ☐ Information

Representing Florida Lifecare Residents Association (FLICRA)

Appearing at request of Chair: ☐ Yes ☑ No Lobbyist registered with Legislature: ☑ Yes ☐ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

1/8/2014
Meeting Date

Topic _____ Bill Number 298 *(if applicable)*

Name BRIAN PITTS Amendment Barcode _____ *(if applicable)*

Job Title TRUSTEE

Address 1119 NEWTON AVNUE SOUTH Phone 727-897-9291
Street

SAINT PETERSBURG FLORIDA 33705 E-mail JUSTICE2JESUS@YAHOO.COM
City *State* *Zip*

Speaking: ☐ For ☐ Against ☑ Information

Representing JUSTICE-2-JESUS

Appearing at request of Chair: ☐ Yes ☑ No Lobbyist registered with Legislature: ☐ Yes ☑ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/20/11)

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

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

BILL:	CS/SB 268
INTRODUCER:	Health Policy Committee and Senator Grimsley
SUBJECT:	Certificates of Need
DATE:	January 8, 2014 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Stovall	HP	**Fav/CS**
2.			CF	
3.			AHS	
4.			AP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 268 amends various sections of the Florida Statutes related to nursing home certificates of need (CON) in order to:

- Repeal the moratorium on CONs for new community nursing homes and for adding additional community nursing home beds to an existing nursing home.
- Establish a positive CON application factor for CON applications in subdistricts with bed need if the applicant relinquishes nursing home beds in one or more subdistricts without need.
- Decrease the statutorily set goal minimum average sub-district nursing home occupancy rate from 94 to 92 percent.
- Allow contiguous sub-districts that each have nursing-home-bed-need to aggregate their need for the construction of one nursing home.
- Allow for an expedited review of a CON application for the replacement of a nursing home:
  - Within a 30-mile radius of the existing nursing home regardless of healthcare planning districts or the geographic location of the majority of the current nursing home's residents.
  - Outside of a 30-mile radius of the existing nursing home if the new nursing home is within the same sub-district or a contiguous sub-district within the same district.
  - If the nursing home is moved to a contiguous sub-district with either provision, existing nursing homes in that sub-district must have at least an 85 percent occupancy rate.

- Allow an expedited CON review for a nursing home to relocate a portion of its beds to an existing facility or a new facility in the same district, or a contiguous district, if the total number of beds in the state does not increase.
- Create a new exemption to the CON process for a nursing home that is adding up to either 30 beds or 25 percent of its current beds, whichever is less, when replacing its facility.
- Amend several existing provisions granting exemptions to the nursing home CON process, without increasing the number of nursing home beds.
- Restrict the Agency for Healthcare Administration (AHCA or agency) from issuing any further CONs for nursing home beds once 5,000 total new beds have been approved. This provision expires on July 1, 2019.

II. Present Situation:

Certificates of Need

A CON is a written statement issued by the AHCA evidencing community need for a new, converted, expanded, or otherwise significantly modified health care facility, health service, or hospice.[1] Under this regulatory program, the Agency must provide approval through the CON review and approval process prior to a provider establishing a new nursing home or adding nursing home beds.

The Florida CON program has three levels of review: full, expedited, and exempt.[2] The nursing home projects that require CONs are as follows:

Projects Subject to Full Comparative Review

- Adding beds in community nursing homes; and
- Constructing or establishing new health care facilities, which include skilled nursing facilities (SNF).[3]

Projects Subject to Expedited Review

- Replacing a nursing home within the same district;
- Relocating a portion of a nursing home's licensed beds to a facility within the same district; or
- The new construction of a nursing home in a retirement community if certain population and bed need criteria are met.[4]

Exemptions from CON Review

- Converting licensed acute care hospital beds to Medicare and Medicaid certified skilled nursing beds in a rural hospital;

[1] S. 408.032(3), F.S.
[2] S. 408.036, F.S.
[3] S. 408.032(16), F.S., defines an SNF as an institution, or a distinct part of an institution, which is primarily engaged in providing, to inpatients, skilled nursing care and related services for patients who require medical or nursing care, or rehabilitation services for the rehabilitation of injured, disabled, or sick persons.
[4] These provisions, laid out in s. 408.036(2)(d), F.S., are excepted from the moratorium on CONs for new nursing homes in s. 408.0435, F.S.

- Adding nursing home beds at a SNF that is part of a retirement community which had been in operation on or before July 1, 1949, for the exclusive use of the community residents;
- Combining licensed beds from two or more licensed nursing homes within a district into a single nursing home within that district if 50 percent of the beds are transferred from the only nursing home in a county and that nursing home had less than a 75 percent occupancy rate;[5]
- State veteran's nursing homes operated by or on behalf of the Florida Department of Veterans' Affairs;
- Combining the beds or services authorized by two or more CONs issued in the same planning sub-district into one nursing home;
- Separating the beds or services that are authorized by one CON into two or more nursing homes in the sub-district;
- Adding no more than 10 total beds or 10 percent of the licensed nursing home beds of that facility, whichever is greater; or if the nursing home is designated as a Gold Seal nursing home, no more than 20 total beds or 10 percent of the licensed nursing home beds of that facility for a facility with a prior 12-month occupancy rate of 96 percent or greater; and
- Replacing a licensed nursing home on the same site, or within three miles, if the number of licensed beds does not increase.

The CON program applies to all nursing home beds, regardless of the source of payment for the beds (private funds, insurance, Medicare, Medicaid, or other funding sources).

Determination of Need

Granting a CON is predicated on a determination of need. The future need for community nursing home beds is determined twice a year and published by the agency as a fixed bed need pool for the applicable planning horizon. The planning horizon for CON applications is 3 years. Need determinations are calculated for sub-districts within the Agency's 11 service districts[6] based on a formula[7] and estimates of current and projected population as published by the Executive Office of the Governor.

Moratorium on Nursing Home CONs

Under the provisions of s. 408.0435, F.S., no CONs for additional community nursing home beds may be approved by the Agency until the moratorium on nursing home CONs expires. The Legislature first enacted this moratorium in 2001 which was slated to last until July 1, 2006.[8] The Legislature then reenacted the moratorium in 2006,[9] and again in 2011.[10] The current moratorium lasts until October 1, 2016, or until Medicaid managed care is implemented statewide. Full implementation of the statewide Medicaid managed care program is statutorily required to be completed by October 1, 2014.[11]

[5] This exemption is repealed upon the expiration of the moratorium by operation of s. 408.036(3)(f), F.S.
[6] The nursing home subdistricts are set forth in Rule 59C-2.200, F.A.C. and generally consist of 1 to 2 counties. Duval County is divided between several subdistricts of district 4.
[7] Rule 59C-1.036, F.A.C.
[8] Ch. 2001-45, L.O.F. s. 52.
[9] Ch. 2006-161, L.O.F.
[10] Ch. 2011-135, L.O.F.
[11] ss. 409.971 and 409.978, F.S.

The Legislature provided for additional exceptions to the moratorium to address occupancy needs that might arise including:

- Adding sheltered nursing home beds;
- Beds may be added in a county that has no community nursing home beds and the lack of beds is the result of the closure of nursing homes that were licensed on July 1, 2001;[12]
- Adding the greater of no more than 10 total beds or 10 percent of the licensed nursing home beds of a nursing home located in a county having up to 50,000 residents, if:
  - The nursing home has not had any class I or class II deficiencies within the 30 months preceding the request for addition;
  - The prior 12-month average occupancy rate for the nursing home beds at the facility meets or exceeds 94 percent and the facility has not had any class I or class II deficiencies since its initial licensure; or
  - For a facility that has been licensed for less than 24 months, the prior 6-month average occupancy rate for the nursing home beds at the facility meets or exceeds 94 percent and the facility has not had any class I or class II deficiencies since its initial licensure;
- Adding the greater of no more than 10 total beds or 10 percent of the number of licensed nursing home beds if:
  - The facility has not had any class I or class II deficiencies within the 30 months preceding the request for addition;
  - The prior 12-month average occupancy rate for the nursing home beds at the facility meets or exceeds 96 percent;
  - The prior 12-month occupancy rate for the nursing home beds in the sub-district is 94 percent or greater;
  - Any beds authorized for the facility under this exception in a prior request have been licensed and operational for at least 12 months;[13] and
- The new construction of a nursing home in a retirement community if certain population and bed need criteria are met.

III. Effect of Proposed Changes:

Section 1 of the bill amends s. 408.034, F.S., to reduce the average sub-district nursing home occupancy rate which the AHCA must attempt to maintain by rule from 94 to 92 percent. Potentially, this could result in an increase in nursing home beds. Statewide bed occupancy rates have remained around 88.5 percent since fiscal year 2004-05.[14]

The bill allows an applicant applying for a CON for the construction of a new community nursing home to aggregate bed need from two or more contiguous sub-districts if:

- The proposed nursing home will be located in the sub-district with the greater need when only two sub-districts are aggregated, or

[12] The request to add beds under this exception to the moratorium is subject to the full competitive review process for CONs.
[13] The request to add beds under the exception to the moratorium is subject to the procedures related to an exemption to the CON requirements.
[14] *AHCA bill analysis for SB 268*, December 20, 2013, on file with the Senate Health Policy Committee.

- The proposed nursing home will be located at a site that provides reasonable geographic access for residents in each sub-district respective of that sub-district's bed need when more than two sub-districts are aggregated.

Contiguous sub-districts where the nursing home is not built will continue to show bed need in subsequent batching cycles.

The bill allows for an additional positive CON application factor for an applicant applying for a CON in a subdistrict where nursing home bed need has been determined to exist if that applicant voluntarily relinquishes licensed nursing home beds in one or more subdistricts where there is no calculated bed need. The applicant must be able to demonstrate that it operates, controls, or has an agreement with another licensed nursing home to ensure that the beds are relinquished.

The bill deletes obsolete language related to pilot nursing home diversion projects.

Section 2 of the bill amends s. 408.036, F.S., to allow for an expedited review of a CON application for the replacement of a nursing home either:

- Within a 30-mile radius of the existing nursing home regardless of healthcare planning districts or the geographic location of the majority of the current nursing home's residents, or
- Outside of a 30-mile radius of the existing nursing home if the new nursing home will be within the same sub-district or a contiguous sub-district.

If the nursing home is moved to a contiguous sub-district, existing nursing homes in that sub-district must have at least an 85 percent occupancy rate.

The bill also allows for an expedited CON review for a nursing home that is relocating a portion of its beds, within the same district or a contiguous district, to an established facility or to a new facility. Such a relocation cannot cause the total number of nursing home beds in the state to increase.

The bill makes the following changes to the allowed CON exemptions:

- Creates a new CON exemption for a nursing home that is adding up to either 30 beds or 25 percent of its current beds, whichever is less, when replacing its facility;
- Reduces the required average occupancy rate from 96 to 94 percent for a facility to add a number of beds equal to the greater of no more than 10 beds or 10 percent of the facility's current licensed beds;
- Increases the distance a replacement nursing home may be located from the current nursing home to up to 5, rather than 3, miles and clarifies that such a move must remain within the same subdistrict; and
- Allows the consolidation of multiple licensed nursing homes with any shared controlled interest or the transfer of beds between such nursing homes if all of the nursing homes are within the same planning district, rather than sub-district. The site of relocation must be within 30 miles of the original sites and the total number of nursing home beds in the planning district may not increase.

The bill also makes technical and conforming changes to this section.

Section 3 of the bill repeals s. 408.0435, F.S., which establishes the moratorium on nursing home CONs.

Section 4 of the bill creates s. 408.0436, F.S., restricting the AHCA from issuing any CONs for new nursing home beds following the batching cycle in which the total number of new community nursing home beds approved between July 1, 2014, and June 30, 2019, meets or exceeds 5,000. The bill also defines "batching cycle" as the grouping for comparative review of CON applications submitted for beds, services, or programs having a like CON need methodology or licensing category in the same planning horizon and the same applicable district or subdistrict.

The bill provides a repeal date for this section of July 1, 2019.

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

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

CS/SB 268 repeals the moratorium preventing the AHCA from issuing CONs for new community nursing home beds in most instances. Repealing this moratorium will allow the AHCA to grant new CONs for the construction of new community nursing homes and the addition of community nursing home beds to existing nursing homes when need is determined. The bill also eases some of the guidelines that the AHCA must follow when issuing new nursing home CONs. Most significantly, the bill allows for a reduced minimum occupancy rate for existing nursing homes and allows CON applicants to aggregate bed need between sub-districts to qualify for the CON.

When taken together, the provisions of the bill will allow for the construction of new nursing homes and the expansion of existing nursing homes where such construction or expansion would have been previously restricted. This new construction will likely have indeterminate positive effects on the parts of the private sector responsible for such construction, but may also have indeterminate negative effects on existing nursing homes in or around areas where such new construction is allowed.

C. Government Sector Impact:

According to the agency's bill analysis,[15] the AHCA will need to amend its CON rules and revise the bed need formula to comply with the reduced average sub-district nursing home occupancy rate. Rewriting these rules will produce a minor indeterminate fiscal impact for the agency.

VI. Technical Deficiencies:

None.

VII. Related Issues:

The term "reasonable geographic access for residents in the respective sub-districts" on line 46 may prove difficult to define by rule since several of the state's contiguous sub-districts cover large geographic areas. For example, District 3 has seven sub-districts and consists of 16 counties ranging from Hamilton County to Hernando County, District 8 has six sub-districts and includes seven counties, and District 4 has four sub-districts and includes seven counties.[16]

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 408.034, 408.036.

This bill creates the following sections of the Florida Statutes: 408.0436

This bill repeals the following section of the Florida Statutes: 408.0435.

IX. Additional Information:

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

CS by Health Policy on January 8, 2014, amends SB 268 to:

- Establish a positive CON application factor for CON applications in sub-districts with bed need if an applicant relinquishes nursing home beds in one or more sub-districts without need.

[15] *Supra, 14.*
[16] *Supra, 14.*

- Restrict a nursing home moving to a new location within 30 miles of the original nursing home from moving into a new sub-district unless that sub-district has had at least an 85 percent occupancy rate for the prior 6 months.
- Allow an expedited CON review for a nursing home to relocate a portion of its beds to an existing facility or a new facility in the same district, or a contiguous district, if the total number of beds in the state does not increase.
- Add language granting a CON exemption to a nursing home that is adding up to either 30 beds or 25 percent of its current beds, whichever is less, when replacing its facility.
- Create section 4 to restrict the AHCA from issuing any further CONs for nursing home beds once 5,000 total new beds have been approved. This provision expires on June 30, 2019.
- Make other technical, clarifying, and conforming changes.

B. Amendments:

None.

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
01/08/2014	.	
	.	
	.	
	.	

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

Senate Amendment (with title amendment)

Delete everything after the enacting clause and insert:

Section 1. Subsection (5) of section 408.034, Florida Statutes, is amended, present subsection (6) of that section is redesignated as subsection (8), and a new subsection (6) and subsection (7) are added to that section, to read:

408.034 Duties and responsibilities of agency; rules.—

(5) The agency shall establish by rule a nursing-home-bed-

need methodology that has a goal of maintaining a subdistrict average occupancy rate of 92 ~~94~~ percent ~~and that reduces the community nursing home bed need for the areas of the state where the agency establishes pilot community diversion programs through the Title XIX aging waiver program~~.

(6) If nursing home bed need is determined to exist in geographically contiguous subdistricts within a district, an applicant may aggregate the subdistricts' need for a new community nursing home in one of the subdistricts. If need is aggregated from two subdistricts, the proposed nursing home site must be located in the subdistrict with the greater need as published by the agency in the Florida Administrative Register. However, if need is aggregated from more than two subdistricts, the location of the proposed nursing home site must provide reasonable geographic access for residents in the respective subdistricts given the relative bed need in each.

(7) If nursing home bed need is determined to exist in a subdistrict, an additional positive application factor may be recognized in the application review process for an applicant who agrees to voluntarily relinquish licensed nursing home beds in one or more subdistricts where there is no calculated need. The applicant must demonstrate that it operates, controls, or has an agreement with another licensed community nursing home to ensure that beds are voluntarily relinquished if the application is approved and the applicant is licensed.

Section 2. Subsection (2) and paragraphs (f), (k), (p), and (q) of subsection (3) of section 408.036, Florida Statutes, are amended to read:

408.036 Projects subject to review; exemptions.—

(2) PROJECTS SUBJECT TO EXPEDITED REVIEW.—Unless exempt pursuant to subsection (3), the following projects are subject to ~~an~~ expedited review ~~shall include, but not be limited to~~:

(a) ~~A~~ Transfer of a certificate of need, except that when an existing hospital is acquired by a purchaser, all certificates of need issued to the hospital which are not yet operational shall be acquired by the purchaser~~,~~ without need for a transfer.

(b) Replacement of a nursing home ~~within the same district~~, if the proposed project site is ~~located within a geographic area that contains at least 65 percent of the facility's current residents and is~~ within a 30-mile radius of the replaced nursing home. If the proposed project site is outside the subdistrict where the replaced nursing home is located, the prior 6-month occupancy rate for licensed community nursing homes in the proposed subdistrict must be at least 85 percent in accordance with the agency's most recently published inventory.

(c) Replacement of a nursing home within the same district, if the proposed project site is outside a 30-mile radius of the replaced nursing home but within the same subdistrict or a geographically contiguous subdistrict. If the proposed project site is in the geographically contiguous subdistrict, the prior 6-month occupancy rate for licensed community nursing homes for that subdistrict must be at least 85 percent in accordance with the agency's most recently published inventory.

(d) ~~(c)~~ Relocation of a portion of a nursing home's licensed beds to another ~~a~~ facility or to establish a new facility within the same district or within a geographically contiguous district, if the relocation is within a 30-mile radius of the

existing facility and the total number of nursing home beds in the state ~~district~~ does not increase.

(e) ~~(d) The~~ New construction of a community nursing home in a retirement community as further provided in this paragraph.

1. Expedited review under this paragraph is available if all of the following criteria are met:

a. The residential use area of the retirement community is deed-restricted as housing for older persons as defined in s. 760.29(4)(b).

b. The retirement community is located in a county in which 25 percent or more of its population is age 65 and older.

c. The retirement community is located in a county that has a rate of no more than 16.1 beds per 1,000 persons age 65 years or older. The rate shall be determined by using the current number of licensed and approved community nursing home beds in the county per the agency's most recent published inventory.

d. The retirement community has a population of at least 8,000 residents within the county, based on a population data source accepted by the agency.

e. The number of proposed community nursing home beds in an application does not exceed the projected bed need after applying the rate of 16.1 beds per 1,000 persons aged 65 years and older projected for the county 3 years into the future using the estimates adopted by the agency reduced by~~, after subtracting~~ the agency's most recently published inventory of licensed and approved community nursing home beds in the county ~~per the agency's most recent published inventory~~.

2. No more than 120 community nursing home beds shall be approved for a qualified retirement community under each request

~~for application~~ for expedited review. Subsequent requests for expedited review under this process may ~~shall~~ not be made until 2 years after construction of the facility has commenced or 1 year after the beds approved through the initial request are licensed, whichever occurs first.

3. The total number of community nursing home beds which may be approved for any single deed-restricted community pursuant to this paragraph may ~~shall~~ not exceed 240, regardless of whether the retirement community is located in more than one qualifying county.

4. Each nursing home facility approved under this paragraph must ~~shall~~ be dually certified for participation in the Medicare and Medicaid programs.

5. Each nursing home facility approved under this paragraph must ~~shall~~ be at least 1 mile, as measured over publicly owned roadways, from an existing approved and licensed community nursing home~~, measured over publicly owned roadways~~.

~~6. Section 408.0435 does not apply to this paragraph.~~

6.~~7.~~ A retirement community requesting expedited review under this paragraph shall submit a written request to the agency for ~~an~~ expedited review. The request must ~~shall~~ include the number of beds to be added and provide evidence of compliance with the criteria specified in subparagraph 1.

7.~~8.~~ After verifying that the retirement community meets the criteria for expedited review specified in subparagraph 1., the agency shall publicly notice in the Florida Administrative Register that a request for an expedited review has been submitted by a qualifying retirement community and that the qualifying retirement community intends to make land available

for the construction and operation of a community nursing home. The agency's notice must ~~shall~~ identify where potential applicants can obtain information describing the sales price of, or terms of the land lease for, the property on which the project will be located and the requirements established by the retirement community. The agency notice must ~~shall~~ also specify the deadline for submission of the ~~any~~ certificate-of-need application, which may ~~shall~~ not be earlier than the 91st day or ~~and not be~~ later than the 125th day after the date the notice appears in the Florida Administrative Register.

8.~~9.~~ The qualified retirement community shall make land available to applicants it deems to have met its requirements for the construction and operation of a community nursing home but may ~~will~~ sell or lease the land only to the applicant that is issued a certificate of need by the agency under ~~the provisions of~~ this paragraph.

a. A certificate-of-need ~~certificate of need~~ application submitted under ~~pursuant to~~ this paragraph must ~~shall~~ identify the intended site for the project within the retirement community and the anticipated costs for the project based on that site. The application must ~~shall~~ also include written evidence that the retirement community has determined that both the provider submitting the application and the project satisfy ~~proposed by that provider satisfies~~ its requirements for the project.

b. If the retirement community determines ~~community's determination~~ that more than one provider satisfies its requirements for the project, it may notify ~~does not preclude the retirement community from notifying~~ the agency of the

provider it prefers.

9.~~10.~~ The agency shall review each submitted application ~~submitted shall be reviewed by the agency~~. If multiple applications are submitted for a ~~the~~ project ~~as~~ published pursuant to subparagraph 7. ~~8.~~, ~~then~~ the agency shall review the competing applications ~~shall be reviewed by the agency~~.

The agency shall develop rules to implement the ~~provisions for~~ expedited review process, including time schedule, application content that ~~which~~ may be reduced from the full requirements of s. 408.037(1), and application processing.

(3) EXEMPTIONS.—Upon request, the following projects are subject to exemption from the provisions of subsection (1):

(f) For the addition of nursing home beds licensed under chapter 400 in a number not exceeding 30 total beds or 25 percent of the number of beds licensed in the facility being replaced under paragraph (2)(b), paragraph (2)(c), or paragraph (p), whichever is less ~~For the creation of a single nursing home within a district by combining licensed beds from two or more licensed nursing homes within such district, regardless of subdistrict boundaries, if 50 percent of the beds in the created nursing home are transferred from the only nursing home in a county and its utilization data demonstrate that it had an occupancy rate of less than 75 percent for the 12-month period ending 90 days before the request for the exemption~~. ~~This paragraph is repealed upon the expiration of the moratorium established in s. 408.0435(1).~~

(k) For the addition of nursing home beds licensed under chapter 400 in a number not exceeding 10 total beds or 10

percent of the number of beds licensed in the facility being expanded, whichever is greater; or, for the addition of nursing home beds licensed under chapter 400 at a facility that has been designated as a Gold Seal nursing home under s. 400.235 in a number not exceeding 20 total beds or 10 percent of the number of licensed beds in the facility being expanded, whichever is greater.

1. In addition to any other documentation required by the agency, a request for exemption submitted under this paragraph must certify that:

a. ~~Certify that~~ The facility has not had any class I or class II deficiencies within the 30 months preceding the request ~~for addition~~.

b. ~~Certify that~~ The prior 12-month average occupancy rate for the nursing home beds at the facility meets or exceeds 94 ~~96~~ percent.

c. ~~Certify that~~ Any beds authorized for the facility under this paragraph before the date of the current request for an exemption have been licensed and operational for at least 12 months.

2. The timeframes and monitoring process specified in s. 408.040(2)(a)-(c) apply to any exemption issued under this paragraph.

3. The agency shall count beds authorized under this paragraph as approved beds in the published inventory of nursing home beds until the beds are licensed.

(p) For replacement of a licensed nursing home on the same site, or within 5 ~~3~~ miles of the same site, if the number of licensed beds does not increase.

(q) For consolidation or combination of licensed nursing homes or transfer of beds between licensed nursing homes within the same planning district ~~subdistrict~~, by ~~providers that operate multiple~~ nursing homes with any shared controlled interest within that planning district ~~subdistrict~~, if there is no increase in the planning district ~~subdistrict~~ total number of nursing home beds and the site of the relocation is not more than 30 miles from the original location.

Section 3. Section 408.0435, Florida Statutes, is repealed.

Section 4. Section 408.0436, Florida Statutes, is created to read:

408.0436 Limitation on nursing home certificates of need.—Notwithstanding the establishment of need as provided in this chapter, the agency may not approve a certificate-of-need application for new community nursing home beds following the batching cycle in which the total number of new community nursing home beds approved from July 1, 2014, to June 30, 2019, equals or exceeds 5,000. As used in this section and provided in rule 59C-1.002, Florida Administrative Code, the term "batching cycle" means the grouping for comparative review of certificate-of-need applications submitted for beds, services, or programs having a like certificate-of-need need methodology or licensing category in the same planning horizon and the same applicable district or subdistrict. This section repeals on July 1, 2019.

Section 5. This act shall take effect July 1, 2014.

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

And the title is amended as follows:

Delete everything before the enacting clause and insert:

A bill to be entitled

An act relating to certificates of need; amending s. 408.034, F.S.; decreasing the subdistrict average occupancy rate that the Agency for Health Care Administration is required to maintain as a goal of its nursing-home-bed-need methodology; conforming a provision to changes made by the act; authorizing an applicant to aggregate the need of geographically contiguous subdistricts within a district for a proposed community nursing home under certain circumstances; requiring the proposed nursing home site to be located in the subdistrict with the greater need under certain circumstances; recognizing an additional positive application factor for an applicant who voluntarily relinquishes certain nursing home beds; requiring the applicant to demonstrate that it meets certain requirements; amending s. 408.036, F.S.; providing that, under certain circumstances, replacement of a nursing home and relocation of a portion of a nursing home's licensed beds to another facility, or to establish a new facility, is a health-care-related project subject to expedited review; conforming a cross-reference; revising the requirements for projects that are exempted from applying for a certificate of need; repealing s. 408.0435, F.S., relating to the moratorium on the approval of certificates of need for additional community nursing home beds; creating s. 408.0436, F.S.; prohibiting the agency from approving a

certificate-of-need application for new community nursing home beds under certain circumstances; defining the term "batching cycle"; providing a repeal; providing an effective date.

667212

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
01/08/2014	.	
	.	
	.	
	.	

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

Senate Amendment to Amendment (756214)

Delete lines 229 - 232
and insert:
batching cycle in which the cumulative number of new community nursing home beds approved from July 1, 2014, to June 30, 2019, equals or exceeds 5,000. As used in this section, the term "batching

391926

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
01/08/2014	.	
	.	
	.	
	.	

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

Senate Amendment to Amendment (756214)

Delete lines 212 - 213

and insert:

site, or within 5 ~~3~~ miles of the same site if within the same subdistrict, if the number of licensed beds does not increase except as allowed by paragraph (f).

By Senator Grimsley

21-00284A-14 2014268__

A bill to be entitled

An act relating to certificates of need; amending s. 408.034, F.S.; decreasing the subdistrict average occupancy rate that the Agency for Health Care Administration is required to maintain as a goal of its nursing-home-bed-need methodology; conforming a provision to changes made by the act; authorizing an applicant to aggregate the need of geographically contiguous subdistricts within a district for a proposed community nursing home under certain circumstances; requiring the proposed nursing home site to be located in the subdistrict with the greater need under certain circumstances; amending s. 408.036, F.S.; providing that, under certain circumstances, replacement of a nursing home is a health-care-related project subject to expedited review; conforming a cross-reference; revising the requirements for projects that are exempted from applying for a certificate of need; repealing s. 408.0435, F.S., relating to the moratorium on the approval of certificates of need for additional community nursing home beds; providing an effective date.

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

Section 1. Subsection (5) of section 408.034, Florida Statutes, is amended, present subsection (6) of that section is redesignated as subsection (7), and a new subsection (6) is added to that section, to read:

408.034 Duties and responsibilities of agency; rules.—

(5) The agency shall establish by rule a nursing-home-bed-need methodology that has a goal of maintaining a subdistrict average occupancy rate of 92 ~~94~~ percent ~~and that reduces the community nursing home bed need for the areas of the state where the agency establishes pilot community diversion programs through the Title XIX aging waiver program~~.

(6) If nursing home bed need is determined to exist in geographically contiguous subdistricts within a district, an applicant may aggregate the subdistricts' need for a new community nursing home in one of the subdistricts. If need is aggregated from two subdistricts, the proposed nursing home site must be located in the subdistrict with the greater need as published by the agency in the Florida Administrative Register. However, if need is aggregated from more than two subdistricts, the location of the proposed nursing home site must provide reasonable geographic access for residents in the respective subdistricts given the relative bed need in each.

Section 2. Subsection (2) and paragraphs (f), (k), (p), and (q) of subsection (3) of section 408.036, Florida Statutes, are amended to read:

408.036 Projects subject to review; exemptions.—

(2) PROJECTS SUBJECT TO EXPEDITED REVIEW.—Unless exempt pursuant to subsection (3), the following projects are subject to ~~an~~ expedited review ~~shall include, but not be limited to~~:

(a) A transfer of a certificate of need, except that when an existing hospital is acquired by a purchaser, all certificates of need issued to the hospital which are not yet operational shall be acquired by the purchaser~~,~~ without need for

a transfer.

(b) Replacement of a nursing home, if the proposed project site ~~within the same district, if the proposed project site is located within a geographic area that contains at least 65 percent of the facility's current residents and~~ is within a 30-mile radius of the replaced nursing home.

(c) Replacement of a nursing home within the same district, if the proposed project site is outside a 30-mile radius of the replaced nursing home but within the same subdistrict or a geographically contiguous subdistrict. If the proposed project site is in the geographically contiguous subdistrict, the prior 6-month occupancy rate for licensed community nursing homes for that subdistrict must be at least 85 percent in accordance with the agency's most recently published inventory.

(d) ~~(c)~~ Relocation of a portion of a nursing home's licensed beds to a facility within the same district, if the relocation is within a 30-mile radius of the existing facility and the total number of nursing home beds in the district does not increase.

(e) ~~(d)~~ The new construction of a community nursing home in a retirement community as further provided in this paragraph.

1. Expedited review under this paragraph is available if all of the following criteria are met:

a. The residential use area of the retirement community is deed-restricted as housing for older persons as defined in s. 760.29(4)(b).

b. The retirement community is located in a county in which 25 percent or more of its population is age 65 and older.

c. The retirement community is located in a county that has

a rate of no more than 16.1 beds per 1,000 persons age 65 years or older. The rate shall be determined by using the current number of licensed and approved community nursing home beds in the county per the agency's most recent published inventory.

d. The retirement community has a population of at least 8,000 residents within the county, based on a population data source accepted by the agency.

e. The number of proposed community nursing home beds in an application does not exceed the projected bed need after applying the rate of 16.1 beds per 1,000 persons aged 65 years and older projected for the county 3 years into the future using the estimates adopted by the agency reduced by~~, after subtracting~~ the agency's most recent published inventory of licensed and approved community nursing home beds in the county ~~per the agency's most recent published inventory~~.

2. No more than 120 community nursing home beds shall be approved for a qualified retirement community under each request ~~for application~~ for expedited review. Subsequent requests for expedited review under this process may ~~shall~~ not be made until 2 years after construction of the facility has commenced or 1 year after the beds approved through the initial request are licensed, whichever occurs first.

3. The total number of community nursing home beds which may be approved for any single deed-restricted community pursuant to this paragraph may ~~shall~~ not exceed 240, regardless of whether the retirement community is located in more than one qualifying county.

4. Each nursing home facility approved under this paragraph must ~~shall~~ be dually certified for participation in the Medicare

and Medicaid programs.

5. Each nursing home facility approved under this paragraph must ~~shall~~ be at least 1 mile, as measured over publicly owned roadways, from an existing approved and licensed community nursing home~~, measured over publicly owned roadways~~.

~~6. Section 408.0435 does not apply to this paragraph.~~

6.~~7.~~ A retirement community requesting expedited review under this paragraph shall submit a written request to the agency for ~~an~~ expedited review. The request must ~~shall~~ include the number of beds to be added and provide evidence of compliance with the criteria specified in subparagraph 1.

7.~~8.~~ After verifying that the retirement community meets the criteria for expedited review specified in subparagraph 1., the agency shall publicly notice in the Florida Administrative Register that a request for an expedited review has been submitted by a qualifying retirement community and that the qualifying retirement community intends to make land available for the construction and operation of a community nursing home. The agency's notice must ~~shall~~ identify where potential applicants can obtain information describing the sales price of, or terms of the land lease for, the property on which the project will be located and the requirements established by the retirement community. The agency notice must ~~shall~~ also specify the deadline for submission of the ~~any~~ certificate-of-need application, which may ~~shall~~ not be earlier than the 91st day or ~~and not be~~ later than the 125th day after the date the notice appears in the Florida Administrative Register.

8.~~9.~~ The qualified retirement community shall make land available to applicants it deems to have met its requirements

for the construction and operation of a community nursing home but may ~~will~~ sell or lease the land only to the applicant that is issued a certificate of need by the agency under ~~the provisions of~~ this paragraph.

a. A certificate of need application submitted under ~~pursuant to~~ this paragraph must ~~shall~~ identify the intended site for the project within the retirement community and the anticipated costs for the project based on that site. The application must ~~shall~~ also include written evidence that the retirement community has determined that both the provider submitting the application and the project satisfy ~~proposed by that provider satisfies~~ its requirements for the project.

b. If the retirement community determines ~~community's determination~~ that more than one provider satisfies its requirements for the project, it may notify ~~does not preclude the retirement community from notifying~~ the agency of the provider it prefers.

9.~~10.~~ The agency shall review each submitted application ~~submitted shall be reviewed by the agency~~. If multiple applications are submitted for a ~~the~~ project ~~as~~ published pursuant to subparagraph 7. ~~8.~~, ~~then~~ the agency shall review the competing applications ~~shall be reviewed by the agency~~.

The agency shall develop rules to implement the ~~provisions for~~ expedited review process, including time schedule, application content that ~~which~~ may be reduced from the full requirements of s. 408.037(1), and application processing.

(3) EXEMPTIONS.—Upon request, the following projects are subject to exemption from the provisions of subsection (1):

~~(f) For the creation of a single nursing home within a district by combining licensed beds from two or more licensed nursing homes within such district, regardless of subdistrict boundaries, if 50 percent of the beds in the created nursing home are transferred from the only nursing home in a county and its utilization data demonstrate that it had an occupancy rate of less than 75 percent for the 12-month period ending 90 days before the request for the exemption. This paragraph is repealed upon the expiration of the moratorium established in s. 408.0435(1).~~

(j) ~~(k)~~ For the addition of nursing home beds licensed under chapter 400 in a number not exceeding 10 total beds or 10 percent of the number of beds licensed in the facility being expanded, whichever is greater; or, for the addition of nursing home beds licensed under chapter 400 at a facility that has been designated as a Gold Seal nursing home under s. 400.235 in a number not exceeding 20 total beds or 10 percent of the number of licensed beds in the facility being expanded, whichever is greater.

1. In addition to any other documentation required by the agency, a request for exemption submitted under this paragraph must certify that:

a. ~~Certify that~~ The facility has not had any class I or class II deficiencies within the 30 months preceding the request ~~for addition~~.

b. ~~Certify that~~ The prior 12-month average occupancy rate for the nursing home beds at the facility meets or exceeds 94 ~~96~~ percent.

c. ~~Certify that~~ Any beds authorized for the facility under

this paragraph before the date of the current request for an exemption have been licensed and operational for at least 12 months.

2. The timeframes and monitoring process specified in s. 408.040(2)(a)-(c) apply to any exemption issued under this paragraph.

3. The agency shall count beds authorized under this paragraph as approved beds in the published inventory of nursing home beds until the beds are licensed.

(o) ~~(p)~~ For replacement of a licensed nursing home on the same site, or within 5 ~~3~~ miles of the same site, if the number of licensed beds does not increase.

(p) ~~(q)~~ For consolidation or combination of licensed nursing homes or transfer of beds between licensed nursing homes within the same planning district ~~subdistrict~~, by ~~providers that operate multiple~~ nursing homes with any shared controlled interest within that planning district ~~subdistrict~~, if there is no increase in the planning district ~~subdistrict~~ total number of nursing home beds and the site of the relocation is not more than 30 miles from the original location.

Section 3. Section 408.0435, Florida Statutes, is repealed.

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

GEORGIADES.CELIA

From: MIELKE.MARTY
Sent: Wednesday, November 20, 2013 11:15 AM
To: GEORGIADES.CELIA
Subject: Request to Agenda SB 268, Certificates of Need

Senator Grimsley respectfully requests that Senate Bill 268, relating to Certificates of Need, be considered for the agenda of the next Health Policy meeting.

If you have any questions, please don't hesitate to call.

Marty Mielke
Chief Legislative Assistant
Senator Denise Grimsley, District 21
205 S. Commerce Avenue, Suite A
Sebring, FL 33870
(863) 386-6016
Fax Number 888-263-3869

ENTERED

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

1/8/14
Meeting Date

Topic SB 268 CON

Bill Number 268 *(if applicable)*

Name Chris Hudson

Amendment Barcode _____ *(if applicable)*

Job Title Govt Relations

Address _____ *Street*

Phone 2392405658

Naples FL 34117
City *State* *Zip*

E-mail chudson@aflaw.com

Speaking: ☒ For ☐ Against ☐ Information

Representing Foundation for Government Accountability

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

_____
Meeting Date

Topic COW Bill Number 268 *(if applicable)*

Name JACK MCRAY Amendment Barcode 756214 *(if applicable)*

Job Title _____

Address 200 W. COLLEGE ST #304 Phone _____
Street

TLH FL 32301 E-mail _____
City *State* *Zip*

Speaking: ☑ For ☐ Against ☐ Information

Representing AARP

Appearing at request of Chair: ☐ Yes ☐ No Lobbyist registered with Legislature: ☑ Yes ☐ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

1/8/14
Meeting Date

Topic CAN

Bill Number 268 *(if applicable)*

Name TONY MARSHALL

Amendment Barcode *(if applicable)*

Job Title SR. DIRECTOR OF REIMBURSEMENT

Address 307 W. PARK AVE *Street*

Phone 850 224 3907

TALLAHASSEE, FL 32301 *City* *State* *Zip*

E-mail tmarshall@fhca.org

Speaking: ☑ For ☐ Against ☐ Information

Representing FLORIDA HEALTH CARE ASSOCIATION

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

1/8/14
Meeting Date

Topic LOM

Bill Number SB 268 *(if applicable)*

Name Carol Berkowitz

Amendment Barcode *(if applicable)*

Job Title SR. Director

Address 1812 Riggins Rd
Street
Tallahassee, FL 32308
City *State* *Zip*

Phone 850.671.3700

E-mail Cberkowitz@leadingfloridaors.com

Speaking: ☐ For ☐ Against ☐ Information

Representing Leading Age Florida

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/20/11)

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

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

BILL:	SB 344
INTRODUCER:	Senator Flores
SUBJECT:	Dentists
DATE:	December 16, 2013
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Peterson	Stovall	HP	**Favorable**
2.			ED	
3.			AED	
4.			AP	

I. Summary:

SB 344 creates the Dental Student Loan Repayment Program as an incentive to encourage Florida-licensed dentists to practice in medically underserved areas where there is a shortage of practitioners or public health programs that serve Medicaid or other low income patients. The bill creates definitions of "medically underserved area" and "public health program." A practitioner may receive funds for up to 4 years, subject to availability. A practitioner who fails to comply with program requirements will be ineligible for license renewal.

II. Present Situation:

The Dental Workforce

Nationally, the pool of dentists to serve a growing population of Americans is shrinking. The American Dental Association has found that 6,000 dentists retire each year in the U.S., while there are only 4,000 dental school graduates each year to replace them. The projected shortage of dentists is even greater in rural America. Of the approximately 150,000 general dentists in practice in the U.S., only 14 percent practice in rural areas, 7.7 percent in large rural areas, 3.7 percent in small rural areas, and 2.2 percent in isolated rural areas. In 2003, there were 2,235 federally designated dental health professional shortage areas (HPSAs)[1] —74 percent of which

[1] HPSAs are designated by the U.S. Dept. of Health and Human Services, Health Resources and Services Administration according to criteria developed in accordance with Section 332 of the Public Health Services Act. HPSA designations are used to identify areas and population groups within the United States that are experiencing a shortage of health professionals. There are three categories of HPSA designation: 1) primary medical; 2) dental; and 3) mental health. For each discipline category, there are three types of HPSA designations based on the area or population group that is experiencing the shortage: 1) geographic area; 2) population group; and 3) facility. A geographic HPSA indicates that the entire area may experience barriers in accessing care, while a population HPSA indicates that a particular subpopulation of an area (e.g., homeless or low-income) may be underserved. Finally, a facility HPSA is granted to a unique facility that primarily cares for an underserved population. The primary factor used to determine a HPSA designation is the number of health professionals

were located in non-metropolitan areas.[2] Today, the number of dental HPSAs has increased to 4,563 — 58 percent of which are located in non-metropolitan areas. The Health Resources and Services Administration (HRSA) estimates that 6,636 dentists are required to meet the dental service needs of people living in designated underserved areas.[3]

Contrast Florida, where the workforce projections for dentists through 2050 indicate that new dentists entering the profession more than offset attrition associated with retirement, assuming current entry levels into the field are sustained. In fact, only an estimated 926 dentists, roughly 10 percent of Florida's currently practicing dental workforce, plan to retire within the next 3 years. In addition, 97 percent of dentists in general practice and those having specializations are currently accepting new patients, indicating that supply is meeting the demand for services. However, similar to the national trend, most dentists in Florida are concentrated in the more populous areas of the state, while rural areas, especially the central Panhandle counties and interior counties of south Florida, have a noticeable dearth of dentists. [4]

Not only is there a shortage of dentists in rural areas, but only a small portion of dentists in Florida practice in dental public health (1.4 percent). Most dentists, 74.1 percent, practice in general dentistry.[5] In many rural communities, the county health department may be the primary provider of health care services, including dental care. Florida currently has 218 designated dental HPSAs, which have only enough dentists to serve 17 percent of the population living within them. HRSA estimates that 853 additional dentists are required to meet the total need.[6] This puts Florida among the states with the highest proportion of their population that are deemed underserved.[7]

Children are acutely affected by the shortage of dentists to serve low income patients. In 2011, 76 percent of Medicaid-enrolled children in Florida did not receive dental care, a figure which ranked Florida last in the nation in performance.[8] In 2010, only 15 percent of dentists in Florida accepted Medicaid patients.[9]

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relative to the population with consideration of high need. The threshold for a dental HPSA is a population-to-provider ratio of at least 5,000:1 (4,000:1 in high need communities).

[2] National Rural Health Association, *Issue Paper: Recruitment and Retention of a Quality Health Workforce in Rural Areas*, (November 2006) (on file with the Senate Health Policy Committee).

[3] U.S. Dept. of Health and Human Services, Health Resources and Services Administration, *Designated Health Professional Shortage Areas Statistics*, 1 (as of Nov. 27, 2013) (on file with the Senate Health Policy Committee).

[4] Florida Dept. of Health, *Report on the 2009-2010 Workforce Survey of Dentists*, (March 2011) (on file with the Senate Health Policy Committee). In 2009, the Department of Health developed this workforce survey for dentists. The survey was administered on a voluntary basis in conjunction with biennial renewal of dental licenses and 89 % of dentists with an active Florida license responded to the survey.

[5] *Id.*

[6] U.S. Dept. of Health and Human Services, Health Resources and Services Administration, *supra* note 3, at 2.

[7] The Pew Charitable Trusts, *In Search of Dental Care*, 3 (June 2013), *available at* http://www.pewstates.org/uploadedFiles/PCS_Assets/2013/In_search_of_dental_care.pdf (last visited Nov. 26, 2013). According to analysis by the The Pew Charitable Trusts, Florida ranks 8th behind only Mississippi (36.3%), Louisiana (24.4%), Alabama (24.4%), New Mexico (24.2%), Delaware (21.9%), South Carolina (20.6%), and Tennessee (19.8%).

[8] *Id.*, at 5, 10.

[9] *Id.*

In 2011, the Legislature passed HB 7107[10] creating the Statewide Medicaid Managed Care (SMMC) program as part IV of ch. 409, F.S. The program has two primary components: Managed Medical Assistance Program (MMAP) and Long Term Care Program. To implement MMAP, the law requires the AHCA to create an integrated managed care program for Medicaid enrollees that incorporates all of the minimum benefits, for the delivery of primary and acute care, including dental.[11] Medicaid recipients who are enrolled in the MMAP program will receive their dental services through the fully integrated managed care plans. Although most dental services are designated as a minimum benefit for Medicaid recipients under age 21, many of the managed care plans expected to contract with the AHCA will provide, as an enhanced benefit, dental services for adults. The enabling statute requires statewide implementation of MMAP to be completed by October 1, 2014.

The Cost of Dental Education

Among U.S. dental schools, the cost of a 4-year degree has risen dramatically over the last 10 years — by 93 percent for in-state residents (from about $89,000 to $171,000) and by 82 percent for out-of-state residents (from $128,000 to $234,000). Dental school debt has increased proportionately. Combined undergraduate and dental school debt jumped from $106,000 in 2000 to more than $220,000 in 2012 — an increase of 109 percent in 12 years.[12] Approximately two-thirds of all undergraduates and 90 percent of dental students rely on student loans to finance their degrees.[13]

Of concern is whether such high debt loads limit a graduate's ability to choose from starting a private practice, entering the public practice, joining academic dentistry, or serving low-income patients. A second concern is whether rising costs and indebtedness discourage economically disadvantaged and minority students from pursuing dentistry as a career. Some studies suggest that minority dentists are more likely to provide care to minority patients. Thus, increased educational costs and indebtedness could further erode access to care for vulnerable, underserved populations.[14]

[10] *See* ch. 2011-134, L.O.F.
[11] Health and Human Services Committee, Fla. House of Representatives, *PCB HHSC 11-01 Staff Analysis*, 25 (Mar. 25, 2011).
[12] American Dental Education Association, *A Report of the ADEA Presidential Task Force on the Cost of Higher Education and Student Borrowing*,17 (March 2013), *available at* http://www.adea.org/uploadedFiles/ADEA/Content_Conversion_Final/publications/Documents/ADEACostandBorrowingReportMarch2013.pdf (last visited Nov. 27, 2013).
[13] *Id.*at 15.
[14] *Id.*at 17 - 18. *See also* U.S. Dept. of Health and Human Services, Health Resources and Services Administration, *Financing Dental Education: Public Policy Interests, Issues and Strategic Considerations*, 39 (2005), *available at* http://bhpr.hrsa.gov/healthworkforce1/reports/financedentaledu.pdf (last visited Nov. 27, 2013).

At least three studies, including a 2011 Florida Senate Report,[15] have recommended consideration of loan forgiveness programs as one strategy for addressing dental workforce shortage concerns.[16]

Florida Health Services Corps

In 1992, the Legislature created the Florida Health Services Corps (FHSC), administered by the Department of Health (DOH), to encourage medical professionals to practice in locations that are underserved because of a shortage of qualified professionals.[17] The FHSC was defined[18] as a program that offered scholarships to allopathic, osteopathic, chiropractic, podiatric, dental, physician assistant, and nursing students, and loan repayment assistance and travel and relocation expenses to allopathic and osteopathic residents and physicians, chiropractic physicians, podiatric physicians, nurse practitioners, dentists, and physician assistants, in return for service in a public health care program[19] or in a medically underserved area.[20] Membership in the FHSC could be extended to any health care practitioner who provided uncompensated care to medically indigent patients.[21] All FHSC members were required to enroll in Medicaid and to accept all patients referred by the DOH pursuant to the program agreement.[22] In exchange for this service, an FHSC member was made an agent of the state and granted sovereign immunity under s. 768.28(9), F.S., when providing uncompensated care to medically indigent patients referred for treatment by the DOH.[23]

The statute authorized the DOH to provide loan repayment assistance and travel and relocation reimbursement to allopathic and osteopathic medical residents with primary care specialties during their last 2 years of residency training or upon completion of residency training, and to

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[15] The Florida Senate, *Review Eligibility of Dentist Licensure in Florida and Other Jurisdictions*, Interim Report No. 2012-127, 15 (Sept. 2011), *available at* http://www.flsenate.gov/PublishedContent/Session/2012/InterimReports/2012-127hr.pdf (last visited Nov. 27, 2013). The report concluded, in part: "Florida may become more competitive in its recruitment of dentists in rural areas and may enhance Florida's dental care for underserved populations if it offers a loan forgiveness program. The program could require dentists seeking loan assistance to serve in a rural area (the Panhandle or central, south Florida) and require dentists to serve a certain percentage of Medicaid recipients or participate in the provider network of managed care entities participating in the Medicaid program for a particular period of time. Considering the current lack of state resources, it may be beneficial to limit the number of dentists that may apply to the loan forgiveness program and target resources to areas with the most need for general dentists or specialists." At the time, Florida was one of only 8 states that did not have a state loan forgiveness program. Now it is one of only 11 states: Arkansas, Connecticut, Florida, Georgia, Hawaii, Indiana, New York, North Carolina, Rhode Island, South Carolina, Texas, and Utah.

[16] American Dental Education Association, *supra* note 13, at 26; *Financing Dental Education*, *supra* note 15, at 40.

[17] Ch. 92-33, s. 111, Laws of Fla. (creating s. 381.0302, F.S., effective July 1, 1992).

[18] Section 381.0302(2)(b)1., F.S. (2011).

[19] "Public health program" was defined to include a county health department, a children's medical services program, a federally funded community health center, a federally funded migrant health center, or other publicly funded or nonprofit health care program designated by the DOH. Section 381.0302(2)(e), F.S. (2011).

[20] "Medically underserved area" was defined to include: a geographic area, a special population, or a facility that has a shortage of health professionals as defined by federal regulations; a county health department, community health center, or migrant health center; or a geographic area or facility designated by rule of the DOH that has a shortage of health care practitioners who serve Medicaid and other low-income patients. Section 381.0302(2)(c), F.S. (2011).

[21] "Medically indigent person" was defined as a person who lacks public or private health insurance, is unable to pay for care, and is a member of a family with income at or below 185 percent of the Federal Poverty Level. Section 381.0302(2)(d), F.S. (2011).

[22] Section 381.0302(10), F.S. (2011).

[23] Section 381.0302(11), F.S. (2011).

physician assistants and nurse practitioners with primary care specialties, in return for an agreement to serve a minimum of 2 years in the FHSC. During the period of service, the maximum amount of annual financial payments was limited to no more than the annual total of loan repayment assistance and tax subsidies authorized by the National Health Services Corps loan repayment program.[24]

During the twenty years the program was in statute, it was funded only three times. A total of $3,684,000 was appropriated in FY 1994-95, FY 1995-96, and FY 1996-97 for loan assistance payments to all categories of eligible health care practitioners. Of that amount, $971,664 was directed to 18 dentists for an average award of $25,570 per year of service in the program.[25] The 2007 Legislature attempted to reinvigorate the program by appropriating $700,000 to fund loan repayment assistance for dentists, only.[26] However, the appropriation and a related substantive bill were vetoed by the Governor.[27] The Legislature repealed the program in 2012.[28]

National Health Service Corps

The National Health Service Corps (NHSC) programs provide scholarships and educational loan repayment to primary care providers[29] who agree to practice in areas that are medically underserved. NHSC loan repayment program (LRP) participants fulfill their service requirement by working at NHSC-approved sites in HPSAs. The NHSC-approved sites are community-based health care facilities that provide comprehensive outpatient, ambulatory, primary health care services. Eligible dental facilities must be located in a dental HPSA and offer comprehensive primary dental health services. NHSC-approved sites (with the exception of correctional facilities and free clinics) are required to provide services for free or on a sliding fee scale (SFS) or discounted fee schedule for low-income individuals. The SFS or discounted fee schedule is based upon the Federal Poverty Guidelines, and patient eligibility is determined by annual income and family size.[30]

The LRP provides funds to participants to repay their outstanding qualifying educational loans. Maximum loan reimbursement under the program is $60,000 for either a 2-year, full-time[31] or 4-year, half-time[32] clinical practice, although participants may be eligible to continue loan repayment beyond the initial term. Participants who breach their LRP agreement are subject to damages, which are the sum of the amount of assistance received by the participant representing any period of obligated service not completed, a penalty, and interest. Loan repayments are

[24] Section 381.0302(6), F.S. (2011).
[25] E-mail from Karen Lundberg, Florida Dept. of Health, to Joe Anne Hart, Florida Dental Association (Sept. 16, 2005) (on file with the Senate Health Policy Committee).
[26] Ch. 2007-72, Laws of Fla. The funding was contained in Specific Appropriations 677A of the General Appropriation Act, but later vetoed pursuant to the Governor's line item veto authority.
[27] *Journal of the Florida Senate*, at 3 (June 12, 2007).
[28] Ch. 2012-184, s. 45, Laws of Fla.
[29] Primary care physicians, nurse practitioners, certified nurse midwives, physician assistants, dentists, dental hygienists, and behavioral and mental health providers, including health service psychologists, licensed clinical social workers, marriage and family therapists, psychiatrist nurse specialists, and licensed professional counselors.
[30] U.S. Dept. of Health and Human Services, Health Resources and Services Administration, *National Health Service Corps Site Reference Guide*, (Sept. 2013), *available at* http://nhsc.hrsa.gov/downloads/sitereference.pdf (last visited Nov. 26, 2013).
[31] Full-time clinical practice is defined as no less than 40 hours per week, for a minimum of 45 weeks per year.
[32] Half-time clinical practice is defined as a minimum of 20 hours per week (not to exceed 39 hours per week), for a minimum of 45 weeks per year.

exempt from federal income and employment taxes and are not included as wages when determining benefits under the Social Security Act.[33] There are currently 38.5 full time equivalent NHSC dentists in Florida.[34]

A second NHSC program, the State Loan Repayment Program (SLRP) offers cost-sharing grants to states to operate their own state educational loan repayment programs for primary care providers working in HPSAs within the state. The SLRP varies from state-to-state, and may differ in eligible categories of providers, practice sites, length of required service commitment, and the amount of loan repayment assistance offered. However, there are certain statutory requirements SLRP grantees must meet. Any SLRP program participant must practice at an eligible site located in a federally-designated HPSA. Like the NHSC loan repayment program awards, assistance provided through a SLRP is not taxable.

In addition, the SLRP requires a $1 state match for every $1 provided under the federal grant. While the SLRP does not limit award amounts, the maximum award amount per provider that the federal government will support through its grant is $50,000 per year, with a minimum service commitment of 2 years. A state may offer awards to providers above $50,000 per year; however, any awards that exceed that amount must be funded entirely by the state.[35]

Currently, Florida is one of only 14 states which do not receive a SLRP grant.[36]

III. Effect of Proposed Changes:

SB 344 creates the Dental Student Loan Repayment Program. The program is conditioned on the availability of funds and is intended to encourage dentists to practice in medically underserved areas or public health programs. The bill defines "medically underserved area" as a designated health professional shortage area that lacks an adequate number of dental health professionals to serve Medicaid and other low income patients. "Public health program" is defined to include a county health department, the Children's Medical Services program, a federally funded community health center, a federally funded migrant health center, or other publicly funded or nonprofit health care program designated by the DOH.

The program will be developed by the DOH, in cooperation with the state's three dental schools and the Florida Dental Association. A Florida licensed dentist who commits to service under the program is eligible for 1 to 4 years of funding. A participating dentist who defaults on his or her obligation is ineligible for license renewal unless default is the result of disability. The DOH

[33] U.S. Dept. of Health and Human Services, Health Resources and Services Administration, *National Health Service Corps Loan Repayment Program, Fiscal Year 2013 Application & Program Guidance*, (Feb. 2013), *available at* http://nhsc.hrsa.gov/downloads/lrpapplicationguidance.pdf (last visited Nov. 26, 2013).
[34] E-mail from Philip Street, Senior Policy Coordinator, Health Statistics and Performance Management, Florida Dept. of Health (Nov. 19, 2013) (on file with the Senate Committee on Health Policy).
[35] U.S. Dept. of Health and Human Services, Health Resources and Services Administration, *SLRP Grantees*, http://nhsc.hrsa.gov/currentmembers/stateloanrepaymentprogram/index.html (last visited Dec. 3, 2013).
[36] Arkansas, Connecticut, Idaho, Mississippi, Nebraska, New Hampshire, North Carolina, Oklahoma, South Carolina, Texas, Utah, Vermont, and Wyoming are the others. U.S. Dept. of Health and Human Services, Health Resources and Services Administration, *National Health Service Corps Program & Updates*,(March 13, 2013), *available at* http://www.nhchc.org/wp-content/uploads/2012/11/National-Health-Service-Corps-Kleine.pdf (last visited Dec. 3, 2013).

must adopt rules to administer the program that, at a minimum, establish the maximum amount a participant may receive each year.

The effective date of the bill is July 1, 2014.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Dentists who qualify for loan repayment assistance will benefit from a reduction in their student loan debt. Residents of HPSAs where program dentists practice will benefit from increased access to care.

C. Government Sector Impact:

Public health programs, as defined by the bill, or other public providers that meet the definition of "medically underserved area," such as correctional facilities, will benefit from an increased number of eligible dentists to provide care. According to the DOH, county health departments historically have experienced a shortage of dentists to provide care to the low income and Medicaid populations.

VI. Technical Deficiencies:

The statement of intent, definition of "medically underserved area," and language authorizing awards are not consistent or clear in how they describe where dentists must work and what populations they must serve in order to be eligible for loan repayment assistance. As written, a dentist could work in a geographic location that meets the definition of a medically underserved area, but provide services to patients other than Medicaid or low income patients.

The bill directs the DOH to develop the program "in cooperation with" the state's dental schools and the Florida Dental Association. The DOH has expressed concern that the language does not give it clear authority to make final decisions.

The bill is silent regarding the maximum amount of loan repayment assistance that may be awarded to a dentist annually. Instead, it directs the DOH to establish this by rule. Without more specific guidance from the Legislature, this may result in an unconstitutional delegation of authority.[37]

The bill does not establish a clear requirement for a dentist to enter into an agreement that would be enforceable by the DOH. Likewise, it does not give the DOH clear authority to recover the loan assistance provided to a dentist who defaults on the agreement for reasons other than disability.

If the intent of the bill is to create authority for the state to obtain SLRP grant assistance, then the DOH should be given specific authority to use funds for this purpose.

VII. Related Issues:

The bill amends ch. 381, F.S., relating to Public Health, and assigns responsibility for administration of the program to the DOH. Florida has two other health care loan forgiveness programs, both of which are contained within ch. 1009, F.S., relating to Educational Scholarships, Fees, and Financial Assistance. The Medical Education Reimbursement and Loan Repayment Program (MERLP) is administered by the DOH. The Nursing Student Loan Forgiveness Program (NSLFP) is administered by the Department of Education. The MERLP is similar to the program that is proposed by SB 344 in that it seeks to create an incentive for eligible practitioners to serve underserved populations and communities. It gives the DOH responsibility for designating appropriate practice settings. In contrast, the NSLFP creates an incentive for nurses to serve in facilities that are experiencing a shortage of nurses, regardless of the economic status of the patients the facilities serve. Both programs condition assistance payments on proof of continued practice in the designated setting.

The bill uses the terminology "federally funded community health center" and "federally funded migrant health center." Under federal law, a federally qualified health center (FQHC) is one of three types of organizations: a health center (defined as organizations receiving grants under section 330 of the Public Health Service Act, including, community health centers, migrant health centers, health care for the homeless health centers, and public housing primary care centers), a health center-look alike, and certain tribal programs and facilities. The bill appears to carve out only two of the federally-funded facilities that serve Medicaid and low income patients.

VIII. Statutes Affected:

This bill creates the following section of the Florida Statutes: 381.4019.

[37] Under the "non-delegation doctrine," the Legislature may not delegate the power to enact a law or the right to exercise unrestricted discretion in applying the law. *See, e.g., Bush v. Schiavo,* 885 So. 2d 321 (Fla. 2004).

IX. Additional Information:

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

None.

B. Amendments:

None.

By Senator Flores

37-00468-14 2014344__

A bill to be entitled

An act relating to dentists; creating s. 381.4019, F.S.; establishing the Dental Student Loan Repayment Program in order to encourage dentists to work in underserved areas or public health programs; providing definitions; requiring the Department of Health, certain universities, and the Florida Dental Association to develop the program; providing for the award of funds; providing the maximum number of years funds may be awarded to a dentist; providing sanctions for failure to comply with loan requirements; requiring the department to adopt rules; providing an effective date.

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

Section 1. Section 381.4019, Florida Statutes, is created to read:

381.4019 Dental Student Loan Repayment Program.—Subject to the availability of funds, the Legislature establishes the Dental Student Loan Repayment Program in order to encourage qualified dentists to practice in medically underserved areas or public health programs in the state in which there are shortages of such practitioners.

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

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

(b) "Loan program" means the Dental Student Loan Repayment Program.

(c) "Medically underserved area" means a geographic area,

an area having a special population, or a facility as designated by department rule which is a health professional shortage area as defined by federal regulations and which has a shortage of dental health professionals who serve Medicaid and other low-income patients.

(d) "Public health program" means a county health department, the Children's Medical Services program, a federally funded community health center, a federally funded migrant health center, or other publicly funded or nonprofit health care program designated by the department.

(2) The loan program shall be developed by the department in cooperation with the University of Florida College of Dentistry, the Nova Southeastern University College of Dental Medicine, the Lake Erie College of Osteopathic Medicine School of Dental Medicine, and the Florida Dental Association.

(3) The department shall award funds from the loan program to repay the student loans of state-licensed dentists who commit to practice in a medically underserved area or in a public health program to serve Medicaid recipients and other low-income patients in this state.

(4) A participant in the loan program may receive funds for at least 1 year, up to a maximum of 4 years. The period of obligated service begins when the dentist is employed in the medically underserved area or by a public health program.

(5) Failure to comply with the participation requirements of the loan program shall result in ineligibility for license renewal under chapter 466. If a dentist is unable to participate for reasons of disability, the penalty is the actual amount of financial assistance provided to the dentist. Financial

penalties shall be deposited into the loan program and used to provide additional funding for program participants.

(6) The department shall adopt rules to administer the loan program. The rules must quantify the amount of funds each dentist may receive per year of participation in the loan program.

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

The Florida Senate

Committee Agenda Request

To: Senator Aaron Bean, Chair
Committee on Health Policy

Subject: Committee Agenda Request

Date: November 7, 2013

I respectfully request that **Senate Bill #344**, relating to Dentists, be placed on the:

☐ committee agenda at your earliest possible convenience.

☒ next committee agenda.

Anitere Flores

Senator Anitere Flores
Florida Senate, District 37

FLORIDA SENATE
NOV 12 2013
Health Policy Committee

File signed original with committee office

S-020 (03/2004)

ENTERED

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

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

BILL:	SB 340
INTRODUCER:	Senator Flores
SUBJECT:	Prepaid Dental Plans
DATE:	December 23, 2013
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Lloyd	Stovall	HP	**Favorable**
2.			CA	
3.			AHS	
4.			AP	
5.				
6.				

I. Summary:

SB 340 postpones the scheduled repeal of a provision that requires the Agency for Health Administration (AHCA) to contract separately with prepaid dental health plans on a prepaid or fixed sum basis for Medicaid recipients. The bill requires the AHCA to contract with such prepaid dental health plans notwithstanding certain other statutory provisions.

The AHCA is also authorized to provide a Medicaid prepaid dental program in Miami-Dade County on an indefinite basis. Obsolete provisions requiring the AHCA to allow other qualified dental providers to participate in the Medicaid dental program on a fee-for-service basis are deleted.

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

The AHCA is directed to seek any necessary revisions or amendments to the Medicaid state plan in order to implement SB 340's provisions.

The bill has an estimated annualized fiscal impact of at least $20 million in lost enhanced adult dental benefits and $138,489 in administrative costs to the AHCA.

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

II. Present Situation:

Medicaid is a joint federal and state funded program that provides health care for low income Floridians. The program is administered by the AHCA and financed with federal and state funds. Over 3.3 million Floridians are currently enrolled in Medicaid and the program's estimated expenditures for fiscal year 2012-13 were approximately $21 billion.[1] The statutory authority for the Medicaid program is contained in ch. 409, F.S.

Federal law establishes the minimum benefit levels required to receive federal matching funds. Benefit levels 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 statute under ss. 409.905 and 409.906, F.S., respectively. Comprehensive dental benefit coverage is a mandatory Medicaid service only for children in Florida.

Florida Medicaid recipients currently receive their benefits through a number of different delivery systems. Florida has at least 15 different managed care models,[2] including the model being used for the delivery of dental services, licensed, prepaid dental health plans (PDHP). The PDHPs are classified as prepaid ambulatory health plans by 42 CFR Part 438.[3] The PDHPs are paid on a capitated basis for all covered dental services, meaning that the plans receive a single rate per individual member for all dental costs associated with that member. Currently, two PDHPs serve more than 1.4 million pediatric Medicaid members.[4,5]

History of Prepaid Dental Plans

Proviso language in the 2001-2002 General Appropriations Act (GAA) authorized the AHCA to initiate a PDHP pilot program in Miami-Dade County.[6] The 2003 Legislature authorized the AHCA to contract on a prepaid or fixed sum basis for dental services for Medicaid-eligible recipients specifically using PDHPs.[7] Through a competitive bid process, the AHCA executed its first PDHP contract in 2004 to serve children under age 21 in Miami-Dade County.[8]

The Legislature included proviso in the 2010-11 GAA authorizing the AHCA to contract by competitive procurement with one or more prepaid dental plans on a regional or statewide basis

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[1] Agency for Health Care Administration, *Florida Medicaid*, http://ahca.myflorida.com/Medicaid/index.shtml (last visited Nov. 26, 2013).
[2] Comm. on Health Regulation, Fla. Senate, *Overview of Medicaid Managed Care Programs in Florida*, p.1, (Issue Brief 2011-221) (November 2010).
[3] *See* Agency for Health Care Administration, *Model Statewide Prepaid Dental Health Plan (SPDHP) Contract, Attachment II-Core Contract Provisions*, p. 17, http://ahca.myflorida.com/medicaid/pdhp/docs/120120_Attachment_II_Core.pdf (last visited November 21, 2013).
[4] *See* Agency for Health Care Administration, *Prepaid Dental Health Plans (PDHPs),* http://ahca.myflorida.com/medicaid/pdhp/index.shtml#Home (last visited November 21, 2013).
[5] *See* Agency for Health Care Administration, *Comprehensive Medicaid Managed Care Enrollment Reports, November 2013*, http://ahca.myflorida.com/mchq/Managed_Health_Care/MHMO/med_data.shtml (last visited Dec. 20, 2013).
[6] *See* Specific Proviso 135A, General Appropriations Act 2001-2002 (Conference Report on CS/SB 2C).
[7] Chapter 2003-405, L.O.F.
[8] Agency for Health Care Administration, *2014 Agency Bill Analysis - HB 27*, p. 2, (Nov. 11, 2013) (on file with the Senate Health Policy Committee).

for a period not to exceed 2 years, in all counties except those participating in Miami-Dade County and Medicaid Reform, under a fee-for-service or managed care delivery system.[9]

In the following year, the Legislature included proviso in the 2012-13 GAA requiring that for all counties other than Miami-Dade, the AHCA could not limit Medicaid dental services to prepaid plans and must allow qualified dental providers to provide services on a fee-for-service basis.[10] Similar language was also passed in the 2012-13 appropriations implementing bill, which included additional directives to AHCA to terminate existing contracts, as needed. The 2012-13 implementing bill provisions became obsolete on July 1, 2013.

According to the AHCA website, two vendors were selected for the statewide program and it has been implemented statewide since December 1, 2012.[11] Under the current statewide program, Medicaid recipients may select one of the two PDHPs in their county for dental services. The existing dental plan contracts cover only Medicaid recipients under age 21. Dental care through Medicaid fee for service providers ended July 1, 2013.

The current PDHP contracts were procured through a competitive process beginning in 2011and contracts under that procurement were most recently renewed through September 30, 2014.[12] The Invitation to Negotiate (ITN) for that procurement limited renewal to no more than a 3 year period.[13]

Statewide Medicaid Managed Care

In 2011, the Legislature passed HB 7107[14] creating the Statewide Medicaid Managed Care (SMMC) program as part IV of ch. 409, F.S. The SMMC program requires the AHCA to create an integrated managed care program for Medicaid enrollees that incorporates all of the minimum benefits for the delivery of primary and acute care, including dental services, under the Managed Medical Assistance component (MMA).[15] Instead of being delivered as a separate benefit under a separate contract, dental services are to be incorporated by and be the responsibility of the managed care organization. Medicaid recipients who are enrolled in the MMA program will receive their dental services through fully integrated managed care plans as the program is implemented.[16]

The AHCA released an ITN to competitively procure managed care plans on a statewide basis in December 2012. Plans could supplement the minimum benefits in their bids and offer enhanced

[9] *See* Specific Proviso 204, General Appropriations Act 2010-2011 (Conference Report on HB 5001).
[10] *See* Specific Proviso 186, General Appropriations Act 2012-2013 (Conference Report on HB 5001).
[11] Six counties were excluded from the statewide roll-out. Miami-Dade was excluded because of the prepaid dental program that has been in existence since 2004. Baker, Broward, Clay, Duval and Nassau counties were excluded because the Medicaid Reform Pilot Project has been implemented in those since counties, which requires most Medicaid recipients to enroll in managed care plans that provide dental care as a covered service.
[12] Agency for Health Care Administration, *supra* note 8 at 5.
[13] Agency for Health Care Administration, *supra* note 8 at 5.
[14] *See* ch. 2011-134, L.O.F.
[15] Health and Human Services Committee, Fla. House of Representatives, *PCS HHSC 11-01 Staff Analysis*, p.25, (Mar. 25, 2011).
[16] Agency for Health Care Administration *supra* note 8, at 2.

options.[17] Of the 14 general, non-specialty plans selected for contracts, all but one elected to include adult dental benefits as an enhanced benefit.[18]

The AHCA has released a draft MMA implementation schedule by region with the first roll-out scheduled for May 1, 2014, and the final group for August 1, 2014.[19] The enabling legislation required the statewide roll-out to be completed by October 2014. Existing PDHP enrollees will be transitioned to dental coverage through their managed care plan as the enrollee's region is implemented under MMA.

Final approval by the federal government of the 1915(b) Medicaid waiver for the MMA component of SMMC program was received on June 14, 2013.[20] The AHCA has recently begun the waiver renewal process for the period of July 1, 2014 through June 30, 2017.[21]

III. Effect of Proposed Changes:

Section 1 amends s. 409.912, F.S., to postpone the scheduled repeal of the requirement that the AHCA contract on a fixed-sum or prepaid basis with licensed prepaid dental health plans to provide dental services to Medicaid recipients. The bill extends the repeal date to October 1, 2017. Existing law repeals this contracting requirement effective October 1, 2014.

The AHCA is directed to contract with such prepaid dental health plans notwithstanding the provisions of s. 409.961, F.S. The referenced statute requires that provisions of part IV of chapter 409, F.S., shall control if a conflict exists between part IV and the other parts of chapter 409. Part IV requires the AHCA to contract with managed care plans for comprehensive health care services, including dental services, for most Medicaid recipients.

The bill also adds language permitting the AHCA to provide a Medicaid prepaid dental health program in Miami-Dade County in perpetuity. Language limiting authorization of the Miami-Dade dental program to the 2012-13 fiscal year is deleted.

Obsolete language requiring a fee-for-service option for dental benefits that expired on July 1, 2013 is also deleted.

The AHCA is required to provide the Governor, the President of the Senate, and Speaker of the House of Representatives with an annual report each January 15, that compares utilization and

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[17] *See* Correspondence between Agency for Health Care Administration and the Centers for Medicare and Medicaid Services, *Special Terms and Conditions - Customized Benefit Packages*, p.17, http://ahca.myflorida.com/Medicaid/statewide_mc/pdf/mma/FL_MMA_STCs_CMS_Approved_06-14-2013.pdf, (last visited Dec. 29, 2013).

[18] *See Correspondence* between Agency for Health Care Administration and Senator Anitere Flores, November 21, 2013 (on file with the Senate Health Policy Committee).

[19] Agency for Health Care Administration, *Implementation Plan - Managed Medical Assistance Program*, p.5, http://ahca.myflorida.com/Medicaid/statewide_mc/pdf/mma/FL_1115_MMA_IP_10-30-2013_Final.pdf (last visited Nov. 21, 2013).

[20] *See* Correspondence between Agency for Health Care Administration and the Centers for Medicare and Medicaid Services, http://ahca.myflorida.com/Medicaid/statewide_mc/pdf/mma/06-14-2013_Appproval_Letter.pdf (last visited Nov. 21, 2013).

[21] Agency for Health Care Administration, *Managed Medical Assistance - Federal Authorities*, http://ahca.myflorida.com/Medicaid/statewide_mc/index.shtml#FCA (last visited Nov. 21, 2013).

encounter data of all contractors, along with projected and budgeted program costs, each entity's contract compliance, access to care impact for Medicaid recipients and statistical trends related to good oral health compared to the state's population as a whole.

The bill also directs the AHCA to seek any necessary revisions or amendments to the state plan or federal waivers for implementation.

Section 2 provides an effective date of July 1, 2014.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. Other Constitutional Issues:

Requiring the AHCA to contract with licensed prepaid dental health plans for Medicaid dental services after October 1, 2014, under this bill could result in a challenge to that law as an unconstitutional impairment of contracts. Authorizing the AHCA to provide a Medicaid dental program in Miami-Dade County on an indefinite basis could raise the same constitutional issue.

Section 409.973, F.S., requires the managed care plans to cover all required benefits which includes dental services. The ITN released for this component of SMMC articulated that managed care plans would be responsible for the full list of minimum benefits, including dental services.[22] The bill's provisions severs the children's dental services from the awarded contracts and directs the AHCA to continue the delivery of these services through separate prepaid dental plans through September 30, 2017. In Miami-Dade County, the bill permits the AHCA to provide a prepaid dental health program on an indefinite basis.

The ITN has concluded and 14 standard MMA contracts have been awarded.[23] According to the AHCA, the anticipated contract execution deadline for managed care plans selected under the ITN is January 31, 2014.[24] For 13 of the 14 plans selected, those contracts will

[22] Agency for Health Care Administration, ITN 017-12/13, Attachment D, p.87, http://www.myflorida.com/apps/vbs/adoc/F25820_AttachmentD_Region1.pdf (last visited Dec. 29, 2013)..
[23] Agency for Health Care Administration, *Florida Medicaid - Managed Medical Assistance*, http://ahca.myflorida.com/Medicaid/statewide_mc/index.shtml#mmahome (last visited Dec. 20, 2013).
[24] Telephone conversation with Ashley James, Agency for Health Care Administration, December 20, 2013.

include the mandatory benefit of comprehensive dental benefits for children and an expanded dental benefit for adults, a benefit enhancement that was a negotiated item during the ITN.[25] Implementation activities have begun and an implementation plan has been filed for approval, as required, with the federal Centers for Medicare and Medicaid Services (CMS) that includes these provisions.

The United States Constitution and the Florida Constitution prohibit the state from passing any law impairing the obligation of contracts.[26] 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."[27]

The estimated annualized value of the 14 MMA contracts at stake is approximately $70 billion over 5 years. Extracting just the value of expanded adult dental benefit in those same contracts is estimated at $100 million over the same 5-year period.[28] The value of these MMA contracts may be deemed substantial if the AHCA must re-negotiate these contracts or re-procure due to severing pediatric dental benefits from the benefits to be provided.

If a law does impair contracts, the courts will assess whether the law is deemed reasonable and necessary to serve an important public purpose.[29] 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.[30]

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.

The continued availability or the full value to taxpayer and enrollees of this expanded adult dental benefit is no longer assured should the MMA contracts be re-negotiated.

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[25] Agency for Health Care Administration, *supra* note 18.
[26] U.S. Const. art. I, § 10; art. I, s. 10, Fla. Const.
[27] *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).
[28] Agency for Health Care Administration, *supra* note 8 at 4.
[29] *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).
[30] *Pomponio v. Cladridge of Pompanio Condo., Inc.,* 378 So. 2d 774 (Fla. 1980).

Adults in the Medicaid program could lose the currently bargained for, and now unavailable adult dental benefits, and the state would lose a valuable customized benefit worth over $20 million annually.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

For the majority of adult Medicaid enrollees, current dental benefits are extremely limited. Under MMA, the AHCA negotiated expanded dental benefits with the managed care organizations. The AHCA estimates the value of these additional benefits at $100 million over 5 years, at no additional cost to taxpayers.[31] However, if the pediatric enrollees are carved out of the MMA contracts, the 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.[32] In all likelihood, adult Medicaid enrollees will lose access to expanded dental benefits, dental providers may lose the opportunity for increased patients and revenue, and taxpayers will not have the benefit of a no-cost $100 million negotiated contract term.

The managed care organizations awarded contracts under MMA may incur business costs to re-negotiate rates with the AHCA and with provider networks that must be re-configured due to the loss of pediatric members. Some vendors may elect to discontinue expanded dental benefits if it is no longer cost effective to do so with reduced enrollment.

If re-procurement is necessary in order to implement the provisions of this bill, the private sector managed care plans will incur the business costs related to participation in re-procurement in addition to the costs of an implementation delay. Private sector managed care plans may also incur business costs for any re-negotiation of rates with their network providers based on delayed implementation.

The PDHPs will also be impacted. Under SB 340, the PDHPs continue to contract separately with the AHCA for pediatric dental benefits. The current PDHP contracts cannot be extended beyond September 30, 2016, per previous statutory direction. An additional procurement would be necessary prior to the October 1, 2017 sunset date in SB 340. Some of the same PDHPs that would compete under that procurement may already be under contract with the managed care organizations under MMA to provide these same services, as well as the adult dental benefits.

[31] Agency for Health Care Administration, *supra* note 8 at 4.
[32] Agency for Health Care Administration, *supra* note 8 at 4.

C. Government Sector Impact:

The AHCA has indicated that it is a "logistical impossibility" to implement the bill's provisions prior to MMA implementation, regardless of resources.[33] The impossibility relates to a number of issues, including timing of current SMMC implementation activities, the deadline for requests of federal authority for such actions, the legality of the change in terms, and the programming needed to effectuate the proposed changes.

Secondly, since pediatric dental coverage was a required benefit, all of the contracts include this benefit; therefore, a re-negotiation with all managed care plans will be required to carve this benefit and the associated premium out of their contracts. The CMS will not permit the state to pay twice for the same benefit.

In addition, the AHCA will need to renegotiate rates with those managed care plans that incorporated the expanded adult dental benefit in their rate calculations. It may also become necessary to re-procure statewide without dental benefits. There would be a cost to the AHCA to conduct both of these contract negotiations or a second procurement. While the AHCA has not specifically identified a fiscal impact for an implementation delay, the agency has indicated that a delay results in lost savings to taxpayers for each month that MMA is not implemented.[34]

System change costs to implement the carve-out would also be incurred by the AHCA. The AHCA also requests two additional staff and associated costs for contract monitoring to oversee the PDHP contracts for SFY 2014-15.

Agency for Health Care Administration:

Total Costs for 2 FTEs:	**$131,489**
General Revenue	$65,744.50
Medical Care TF	$65,744.50
Travel Costs for 2 FTEs:	**$7,000**
General Revenue	$3,500
Medical Care TF	$3,500
Total - Agency for Health Care Admin.:	**$138,489**
General Revenue	$69,245
Medical Care TF	$69,245

In addition, as noted above in the Private Sector Impact, the AHCA estimates the value of these additional benefits at $100 million over 5 years, at no additional cost to taxpayers.[35] However, if the pediatric enrollees are carved out of the current MMA contracts, the AHCA believes that the managed care organizations will lose leverage with the dental

[33] Agency for Health Care Administration, *supra* note 8 at 4.
[34] *See Correspondence* between Agency for Health Care Administration and Senator Anitere Flores, November 21, 2013 (on file with the Senate Health Policy Committee).
[35] Agency for Health Care Administration, *supra* note 8 at 4.

providers and existing dental provider networks resulting in the complete loss of the expanded dental benefit for adults.[36]

The AHCA also loses the anticipated savings from the MMA contracts if implementation is delayed. Based on the projected 5 percent aggregate savings per year contemplated in s. 409.966(3)(d), F.S., and the estimated contract value of $70 billion over 5 years, the minimum impact for a 1 year delay is $736 million in lost savings.

An alternative valuation of this benefit by an actuary retained by the Florida Association of Health Plans has estimated the value of the expanded adult dental benefit at full program implementation at $5,765,125 per month or an annualized value of over $69 million.[37] The valuation was based on responses by five of the 13 plans currently participating in Medicaid and awarded contracts under the MMA program component. These plans represent over 58 percent of the November 2013 managed care enrollment.[38]

VI. Technical Deficiencies:

Both paragraph (a) and (b) of 409.912(41), F.S., in the bill begin with the word, "notwithstanding." In the latter paragraph, the notwithstanding reference acts to ignore the statutory provisions of paragraph (a). However, the use of two negatives with a cross-reference by one paragraph to another acts as a double-negative. This incorporation may be viewed as negating the effect of both provisions or, at a minimum, creating ambiguity about the validity of one or both of the provisions.

Additionally, paragraph (b) of ch. 409.912(41), F.S., in the bill references paragraph (a), and indicates that "Notwithstanding paragraph (a), the agency may…" Paragraph (a) includes a sunset provision of October 1, 2017. Without paragraph (a) and its cross reference to s. 409.961, F.S., the provisions of paragraph (b) are in conflict with the requirements of s. 409.961, F.S., which provide that if there is any conflict in the provisions of part IV of chapter 409 and any other parts of this chapter, then the provisions of part IV will control. Once paragraph (a) becomes obsolete after October 1, 2017, then the provisions of paragraph (b) no longer have a cross reference that cures any purported conflict in statutory construction. Section 409.912, F.S., is not part of Part IV of Chapter 409; this section of law is referenced under Part III of Chapter 409. The cross reference in paragraph (a) is needed to cure the conflict.

In addition, paragraph (b) of 409.912(41), F.S., refers to a dental program in Miami-Dade County. Unlike the use of the term "licensed prepaid dental health plan" in paragraph (a), the language in paragraph (b) more broadly permits the provision of a "prepaid dental health program." A "prepaid dental health program" could be achieved through a variety of mechanisms that are pre-paid and not necessarily be the same type of licensed, contractual relationship described in paragraph (a).

[36] Agency for Health Care Administration, *supra* note 8 at 4.
[37] Wakely Consulting Group, *Valuation of Medicaid Managed Medical Assistance Expanded Adult Dental Benefit*, p. 1, December 10, 2013 (on file with the Senate Health Policy Committee).
[38] Wakely Consulting Group, *supra* note 36 at 1.

The language in paragraph (b) grants discretion to the AHCA as to whether or not to provide a prepaid dental health program in Miami-Dade County. The AHCA is not required to implement or continue any dental health program in Miami-Dade County by use of the word "may."

VII. Related Issues:

The AHCA's analysis of the companion House legislation identifies several areas of concern for the implementation of the proposed bill. Carving out the children's dental services component from the MMA program could result in the loss of the expanded dental benefit for adults valued at over $100 million over the life of the 5 year contract.[39] Without the inclusion of the pediatric dental benefit, the agency opines that the adult dental network may no longer be cost effective for the managed care plans jeopardizing the benefit for adult enrollees and undermining the overall dental networks.[40]Adult dental benefits that are not currently covered were negotiated and incorporated as an expanded benefit in the majority of the managed care contracts as part of the recently concluded ITN.[41] A separate analysis of the adult dental benefit by the Florida Association of Health Plans placed the value at over $69 million annually, assuming full implementation.[42]

Carving out the pediatric dental benefit will impact the negotiated rates under MMA because the capitated rate covers all services, including the dental. The CMS will not allow double payment for dental services. With the possibility of invalid rates, the AHCA raises the question of whether or not the agency could engage in rate re-negotiation with the existing winning managed care organizations or if a complete re-procurement must be conducted.[43]

The AHCA's preliminary legal analysis pertaining to re-negotiated rates or re-procurement concern scoring during the bid process since consideration was given for the inclusion of the mandatory pediatric dental benefit as well as the expanded adult benefit. Non-winning vendors who had not included comparable 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 carved out later.[44] Similarly, some vendors that chose not to compete due to an inadequate dental network might challenge a re-negotiation. A total re-procurement for the MMA component, seen by the AHCA as the cleanest route, could delay the implementation by more than a year.[45]

The Agency states that it cannot logistically carve dental services out prior to implementation.[46] The Agency cites the proposed, staggered roll-out schedule for SMMC, the statutory implementation completion date of October 1, 2014, the timeline for choice counseling by mid-February for the first region, and the time needed to re-program enrollment and data systems.[47]

[39] Agency for Health Care Administration, *supra* note 8 at 4.
[40] Agency for Health Care Administration, *supra* note 8 at 4.
[41] Agency for Health Care Administration, *supra* note 8 at 3.
[42] Wakely Consulting Group, *supra* note 36 at 1.
[43] Agency for Health Care Administration, *supra* note 8 at 4.
[44] Agency for Health Care Administration, *supra* note 8 at 3-4.
[45] Agency for Health Care Administration, *supra* note 8 at 4.
[46] Agency for Health Care Administration, *supra* note 8 at 4.
[47] Agency for Health Care Administration, *supra* note 8 at 4.

Implementation of the carve-out is identified to be a "logistical impossibility" prior to roll-out, regardless of the amount of additional resources.[48]

Carving out this benefit from the MMA program could also set a precedent for other services that have been integrated in the managed medical assistance contracts with the managed care organizations, such as behavioral health care, transportation and pharmacy. If one service is successful in achieving a carve-out, this action could be seen as a slippery slope for other benefits seeking the same consideration.

The AHCA also indicates that federal approval would be required before implementation of the dental carve-out.[49] The current waiver that includes prepaid dental plans expires January 31, 2014 and the existing 1915(b) waiver incorporates dental services into the managed care contracts.[50] There are deadlines for seeking waivers and the deadline for seeking renewal of this particular waiver has passed as the AHCA anticipated the inclusion of these benefits under the managed care contracts.[51] The Agency would need to seek a new 1915(b) waiver, or request an amendment to the 1115 waiver that carves dental services out.[52] Under either scenario, the AHCA indicates that there would not be sufficient time to receive approval prior to the rollout of the SMMC.[53]

VIII. Statutes Affected:

The bill substantially amends section 409.912 of the Florida Statutes.

IX. Additional Information:

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

None.

B. Amendments:

None.

[48] Agency for Health Care Administration, *supra* note 8, at 4.
[49] Agency for Health Care Administration, *supra* note 8 at 4.
[50] Agency for Health Care Administration, *supra* note 8 at 4.
[51] Agency for Health Care Administration, *supra* note 8 at 4.
[52] Agency for Health Care Administration, *supra* note 8 at 4.
[53] Agency for Health Care Administration, *supra* note 8 at 4.

By Senator Flores

37-00179-14 2014340__

A bill to be entitled

An act relating to prepaid dental plans; amending s. 409.912, F.S.; postponing the scheduled repeal of a provision requiring the Agency for Health Care Administration to contract with dental plans for dental services on a prepaid or fixed-sum basis; authorizing the agency to provide a prepaid dental health program in Miami-Dade County on a permanent basis; requiring an annual report to the Governor and Legislature; authorizing the agency to seek any necessary revisions to the state plan or federal waivers; providing an effective date.

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

Section 1. Subsection (41) of section 409.912, Florida Statutes, is amended to read:

409.912 Cost-effective purchasing of health care.—The agency shall purchase goods and services for Medicaid recipients in the most cost-effective manner consistent with the delivery of quality medical care. To ensure that medical services are effectively utilized, the agency may, in any case, require a confirmation or second physician’s opinion of the correct diagnosis for purposes of authorizing future services under the Medicaid program. This section does not restrict access to emergency services or poststabilization care services as defined in 42 C.F.R. part 438.114. Such confirmation or second opinion shall be rendered in a manner approved by the agency. The agency shall maximize the use of prepaid per capita and prepaid

aggregate fixed-sum basis services when appropriate and other alternative service delivery and reimbursement methodologies, including competitive bidding pursuant to s. 287.057, designed to facilitate the cost-effective purchase of a case-managed continuum of care. The agency shall also require providers to minimize the exposure of recipients to the need for acute inpatient, custodial, and other institutional care and the inappropriate or unnecessary use of high-cost services. The agency shall contract with a vendor to monitor and evaluate the clinical practice patterns of providers in order to identify trends that are outside the normal practice patterns of a provider's professional peers or the national guidelines of a provider's professional association. The vendor must be able to provide information and counseling to a provider whose practice patterns are outside the norms, in consultation with the agency, to improve patient care and reduce inappropriate utilization. The agency may mandate prior authorization, drug therapy management, or disease management participation for certain populations of Medicaid beneficiaries, certain drug classes, or particular drugs to prevent fraud, abuse, overuse, and possible dangerous drug interactions. The Pharmaceutical and Therapeutics Committee shall make recommendations to the agency on drugs for which prior authorization is required. The agency shall inform the Pharmaceutical and Therapeutics Committee of its decisions regarding drugs subject to prior authorization. The agency is authorized to limit the entities it contracts with or enrolls as Medicaid providers by developing a provider network through provider credentialing. The agency may competitively bid single-source-provider contracts if procurement of goods or services

results in demonstrated cost savings to the state without limiting access to care. The agency may limit its network based on the assessment of beneficiary access to care, provider availability, provider quality standards, time and distance standards for access to care, the cultural competence of the provider network, demographic characteristics of Medicaid beneficiaries, practice and provider-to-beneficiary standards, appointment wait times, beneficiary use of services, provider turnover, provider profiling, provider licensure history, previous program integrity investigations and findings, peer review, provider Medicaid policy and billing compliance records, clinical and medical record audits, and other factors. Providers are not entitled to enrollment in the Medicaid provider network. The agency shall determine instances in which allowing Medicaid beneficiaries to purchase durable medical equipment and other goods is less expensive to the Medicaid program than long-term rental of the equipment or goods. The agency may establish rules to facilitate purchases in lieu of long-term rentals in order to protect against fraud and abuse in the Medicaid program as defined in s. 409.913. The agency may seek federal waivers necessary to administer these policies.

(41)(a) Notwithstanding s. 409.961, the agency shall contract on a prepaid or fixed-sum basis with appropriately licensed prepaid dental health plans to provide dental services. This paragraph expires October 1, 2017 ~~2014~~.

(b) Notwithstanding paragraph (a), the agency may provide a Medicaid prepaid dental health program in Miami-Dade County.

~~(b) Notwithstanding paragraph (a) and for the 2012-2013 fiscal year only, the agency is authorized to provide a Medicaid~~

~~prepaid dental health program in Miami-Dade County. For all other counties, the agency may not limit dental services to prepaid plans and must allow qualified dental providers to provide dental services under Medicaid on a fee-for-service reimbursement methodology. The agency may seek any necessary revisions or amendments to the state plan or federal waivers in order to implement this paragraph. The agency shall terminate existing contracts as needed to implement this paragraph. This paragraph expires July 1, 2013.~~

(c) The agency shall provide a report by January 15 of each year to the Governor, the President of the Senate, and the Speaker of the House of Representatives which compares the combined annual benefits utilization and encounter data reported by all contractors, along with the agency's findings with respect to projected and budgeted annual program costs, the extent to which each contracting entity is complying with all contract terms and conditions, the effect that each entity's operation is having on access to care for Medicaid recipients in the contractor'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.

(d) The agency may seek any necessary revisions or amendments to the state plan or federal waivers in order to implement this subsection.

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

RICK SCOTT
GOVERNOR

FLORIDA AGENCY FOR HEALTH CARE ADMINISTRATION

Better Health Care for all Floridians

ELIZABETH DUDEK
SECRETARY

January 7, 2014

The Honorable Aaron Bean
Chair, Senate Committee on Health Policy
302 Senate Office Building
404 South Monroe Street
Tallahassee, FL 32399-1100

Dear Chairman Bean:

I regret to inform you that I am unable to attend the scheduled meeting of the Senate Health Policy Committee on January 8, 2014, due to an unavoidable conflict. I will be in Baltimore meeting with senior staff of the Federal Centers for Medicare and Medicaid Services (CMS) regarding Florida's request for renewal of the 1115 waiver, specifically relating to the request for continued authority and additional funding for the Low Income Pool (LIP) program. As you are aware, the state is seeking federal authority to extend Florida's 1115 Managed Medical Assistance (MMA) Waiver for the period July 1, 2014 to June 30, 2017, and as part of that extension, is seeking to increase funding for the LIP to $4.5 billion annually, for the upcoming waiver extension period of July 1, 2014 through June 30, 2017.

During the January 8 committee meeting, you will consider SB 340, relating to Prepaid Dental Health Plans. SB 340 postpones the scheduled repeal of a provision requiring the Agency for Health Care Administration to contract with dental plans for dental services on a prepaid or fixed-sum basis; authorizes the Agency to provide a prepaid dental health program in Miami-Dade County on a permanent basis; requires an annual report to the Governor and Legislature; and authorizes the Agency to seek any necessary revisions to the state plan or federal waivers, etc.

SB 340 may carve out dental services from the comprehensive benefit package statutorily established as part of the Managed Medical Assistance component of the Statewide Medicaid Managed Care program.

We appreciate the opportunity to provide clarification on the impact of carving dental services out of the Managed Medical Assistance (MMA) program.

The Agency has received approval from federal CMS to implement the MMA program on a phased basis beginning on May 1, 2014 and ending on August 1, 2014. The first letters to recipients in Regions that will roll-out on May 1, 2014 were mailed on January 2, 2014. In the next 90 days, all recipients will begin receiving information about the service packages available to them, and this will include a description of the dental services covered under the MMA program.

In order to implement SB 340, the Agency will need to accomplish the following:

- Obtain federal authority to run a prepaid dental program
- Re-procure the prepaid dental contracts
- Renegotiate MMA program plan rates
- Reprogram systems to allow for dual enrollment in an MMA and a dental plan
- Public notice/ notice to recipients of change in benefits and choice counseling materials

Pursuant to 409.966(3)(d), Florida Statutes, the Agency has negotiated capitation rates for the MMA plans which will provide the Medicaid program with aggregate savings of 5%. For any delay the state would lose the 5% negotiated savings for each month of delayed implementation. The state loses statutory authority for its current prepaid mental health, Medipass, Reform Pilot and all non-reform managed care programs effective October 1, 2014. We have not determined the cost to the state associated with recipients being required to receive their services via the fee-for-service system should delayed implementation extend past October 2014.

Any further analysis of the benefits or concerns relative to costs, quality, and access of such a carve-out would require a formal study of the issue.

Please feel free to contact Chris Chaney, Legislative Affairs Director, by email at Chris.Chaney@ahca.myflorida.com or by phone at 850-412-3611 if you have any questions or need any additional information.

Sincerely,

Justin M. Senior
Deputy Secretary for Medicaid

JMS/ks
Enclosures

The Florida Senate

Committee Agenda Request

To: Senator Aaron Bean, Chair
Committee on Health Policy

Subject: Committee Agenda Request

Date: November 7, 2013

I respectfully request that **Senate Bill #340**, relating to Prepaid Dental Plans, be placed on the:

☐ committee agenda at your earliest possible convenience.

☒ next committee agenda.

Anitere Flores

Senator Anitere Flores
Florida Senate, District 37

FLORIDA SENATE
NOV 12 2013
Health Policy Committee

File signed original with committee office

S-020 (03/2004)

ENTERED

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

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

BILL:	CS/SB 380
INTRODUCER:	Health Policy Committee and Senators Bean and Brandes
SUBJECT:	Hospitals
DATE:	January 8, 2014
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Stovall	HP	**Fav/CS**
2.			CA	
3.			AHS	
4.			AP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 380 requires a hospital to notify obstetrical physicians at least 120 days before closing its obstetrical department or ceasing to provide obstetrical services.

The bill also repeals s. 383.336, F.S., which designates certain hospitals as "provider hospitals" and requires physicians in those hospitals to follow additional practice parameters when providing cesarean sections paid for by the state. Provider hospitals must also establish a peer review board to review all cesarean sections performed by the hospital and paid for by the state.

II. Present Situation:

Obstetrical Departments in Hospitals

Hospitals are required to report the services which will be provided by the hospital as a requirement of licensure and these services are listed on the hospital's license. Hospitals must notify the Agency for Health Care Administration (AHCA) of any change of service that affects information on that hospital's license by submitting a revised licensure application between 60 and 120 days in advance of the change.[1] The list of services is also used for the AHCA's

[1] *AHCA bill analysis for SB 380*, on file with Health Policy Committee staff. See also ss. 408.806(2)(c) and 395.1041(2), F.S.

inventory of hospital emergency services. According to the AHCA's website, there are currently 139 hospitals in Florida that offer emergency obstetrical services.[2]

Provider Hospitals

Presently s. 383.336, F.S., defines the term "provider hospital" and creates certain requirements for such hospitals. A provider hospital is a hospital in which 30 or more births occur annually that are paid for partly or fully by state funds or federal funds administered by the state.[3] Physicians in such hospitals are required to comply with additional practice parameters[4] designed to reduce the number of unnecessary cesarean sections performed within the hospital. These parameters must be followed by physicians when performing cesarean sections partially or fully paid for by the state. The section also requires provider hospitals to establish a peer review board consisting of obstetric physicians and other persons with credentials to perform cesarean sections within the hospital. The board is required to review, on a monthly basis, all cesarean sections performed within the hospital that were partially or fully funded by the state.

These provisions are not currently implemented and Department of Health (DOH) rules regarding provider hospitals were repealed by sections 9 and 10 of 2012-31, L.O.F.

Closure of an Obstetrical Department in Bartow, Florida

In June of 2007 Bartow Regional Medical Center in Polk County announced to patients and physicians that it would close its obstetrics department at the end of July of the same year.[5] Although many obstetrical physicians could continue to see patients in their offices, they would no longer be able to deliver babies at the hospital.[6] Physicians and the local community protested the short timeframe for ceasing to offer obstetrical services. According to the Florida Medical Association and several physicians who worked at the hospital, the short notice "endangered pregnant women who [were] too close to delivery for obstetricians at other hospitals to want them as patients."[7]

III. Effect of Proposed Changes:

Section 1 of the bill repeals s. 383.336, F.S., relating to provider hospitals.

Section 2 of the bill amends s. 395.1051, F.S. to require hospitals to give at least a 120 day advanced notice to each obstetrical physician with clinical privileges at that hospital if the hospital intends to close its obstetrical department or cease providing obstetrical services unless the hospital can demonstrate that it was impossible to do so within this timeframe. The bill also

[2] Report generated by floridahealthfinder.gov on Dec. 20, 2013. On file with Health Policy Committee staff.
[3] S. 383.336 (1), F.S.
[4] These parameters are established by the Office of the State Surgeon General in consultation with the Board of Medicine and the Florida Obstetric and Gynecologic Society and are required to address, at a minimum, the feasibility of attempting a vaginal delivery, dystocia, fetal distress, and fetal malposition.
[5] *Community Unites Against OB Closure*, The Polk County Democrat, July 12, 2007. Available at http://ufdc.ufl.edu/UF00028292/00258/1x?vo=12, last visited on Dec. 20, 2013.
[6] *Bartow Hospital Plan Criticized*, The Ledger, July 11, 2007. Available at http://www.theledger.com/article/20070711/NEWS/707110433?p=1&tc=pg&tc=ar. Last visited on Dec. 20, 2013.
[7] Id.

provides that if notice cannot be provided at least 120 days in advance, a hospital must provide notice as soon as practicable.

Although specific penalties are not listed for violating the notification provisions, the AHCA has the authority to fine a health care facility up to $500 for a non-designated violation.[8] Such non-designated violations include violating any provision of that health care facility's authorizing statute.[9]

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

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

CS/SB 380 may have a positive fiscal impact for obstetrical physicians who receive this notice to allow them adequate time to ensure that they obtain privileges at another hospital. Advanced notice will also allow the patient to adequately plan for delivery at another location. The bill may have a negative fiscal impact on hospitals that fail to comply due to potential administrative fines.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

[8] A non-designated violation is any violation that is not designated as class I-IV. See s. 408.813(3), F.S.
[9] s. 408.813(3)(b), F.S.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill amends the following sections of the Florida Statutes: 395.1051.

This bill repeals the following sections of the Florida Statutes: 383.336.

IX. Additional Information:

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

CS by Health Policy on January 8, 2014:
The CS amends SB 380 to repeal s. 383.336, F.S., related to provider hospitals; to delete language granting rulemaking authority to the DOH; and to require a hospital to provide notice as soon as practicable if it is impossible for a hospital to provide 120 days' notice.

B. Amendments:

None.

604616

LEGISLATIVE ACTION

Senate	.	House
Comm: RS	.	
01/08/2014	.	
	.	
	.	
	.	

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

Senate Amendment (with title amendment)

Delete everything after the enacting clause
and insert:

Section 1. Section 383.336, Florida Statutes, is repealed.

Section 2. Section 395.1051, Florida Statutes, is amended to read:

395.1051 Duty to notify patients and obstetrical physicians.—

(1) An appropriately trained person designated by each licensed facility shall inform each patient, or an individual

604616

identified pursuant to s. 765.401(1), in person about adverse incidents that result in serious harm to the patient. Notification of outcomes of care which ~~that~~ result in harm to the patient under this section does ~~shall~~ not constitute an acknowledgment or admission of liability and may not~~, nor can it~~ be introduced as evidence.

(2) A hospital shall notify each obstetrical physician who has privileges at the hospital at least 120 days before the hospital closes its obstetrical department or ceases to provide obstetrical services. The agency shall adopt rules to administer this subsection, including rules governing those situations in which it is impossible for the hospital to provide 120 days' notice due to circumstances beyond the control of the hospital or the obstetrical physician.

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

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

And the title is amended as follows:

Delete everything before the enacting clause and insert:

A bill to be entitled

An act relating to obstetrical services at hospitals; repealing s. 383.336, F.S., relating to provider hospitals; amending s. 395.1051, F.S.; requiring a hospital to notify obstetrical physicians before the hospital closes its obstetrical department or ceases to provide obstetrical services; requiring the Agency for Health Care Administration to adopt rules; providing an effective date.

441014

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
01/08/2014	.	
	.	
	.	
	.	

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

Senate Substitute for Amendment (604616) (with title amendment)

Delete everything after the enacting clause and insert:

Section 1. Section 383.336, Florida Statutes, is repealed.

Section 2. Section 395.1051, Florida Statutes, is amended to read:

395.1051 Duty to notify patients and obstetrical physicians.—

(1) An appropriately trained person designated by each

441014

licensed facility shall inform each patient, or an individual identified pursuant to s. 765.401(1), in person about adverse incidents that result in serious harm to the patient. Notification of outcomes of care which ~~that~~ result in harm to the patient under this section does ~~shall~~ not constitute an acknowledgment or admission of liability and may not~~, nor can it~~ be introduced as evidence.

(2) A hospital shall notify each obstetrical physician who has privileges at the hospital at least 120 days before the hospital closes its obstetrical department or ceases to provide obstetrical services, unless the hospital can demonstrate it was impossible for the hospital to provide 120 days' notice due to circumstances beyond the control of the hospital or the obstetrical physician. If a hospital is unable to provide 120 days' notice, the hospital must provide notice as soon as practicable.

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

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

And the title is amended as follows:

Delete everything before the enacting clause

and insert:

A bill to be entitled

An act relating to obstetrical services at hospitals; repealing s. 383.336, F.S., relating to provider hospitals; amending s. 395.1051, F.S.; requiring a hospital to notify obstetrical physicians before the hospital closes its obstetrical department or ceases to provide obstetrical services; providing an

441014

effective date.

By Senator Bean

4-00298B-14 2014380__

A bill to be entitled

An act relating to hospitals; amending ss. 383.336 and 395.1051, F.S.; requiring certain hospitals to notify obstetrical physicians before the hospitals close their obstetrical departments or cease to provide obstetrical services; requiring the Department of Health to adopt rules; providing an effective date.

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

Section 1. Section 383.336, Florida Statutes, is amended to read:

383.336 Provider hospitals; notice to obstetrical physicians; practice parameters; peer review board.—

(1) As used in this section, the term "provider hospital" means a hospital in which there annually occur 30 or more births that are paid for partly or fully by state funds or federal funds administered by the state.

(2) A provider hospital shall notify each obstetrical physician who has clinical privileges at that hospital at least 120 days before the hospital closes its obstetrical department or ceases to provide obstetrical services. The Department of Health shall adopt rules to administer this subsection, including rules governing those situations in which it is impossible for the provider hospital to provide 120 days' notice due to circumstances beyond the control of the hospital or the obstetrical physician.

(3) ~~(2)~~ The Office of the State Surgeon General, in consultation with the Board of Medicine and the Florida

Obstetric and Gynecologic Society, shall ~~is directed to~~ establish practice parameters to be followed by physicians in provider hospitals in performance of a caesarean section delivery when the delivery will be paid partly or fully by state funds or federal funds administered by the state. These parameters must include a reduction in ~~shall be directed to reduce~~ the number of unnecessary caesarean section deliveries and must~~. These practice parameters shall~~ address, at a minimum, the following: feasibility of attempting a vaginal delivery for each patient with a prior caesarean section; dystocia, including arrested dilation and prolonged deceleration phase; fetal distress; and fetal malposition. The Department of Health shall adopt rules to implement ~~the provisions of~~ this subsection.

(4)~~(3)~~ Each provider hospital shall establish a peer review board consisting of obstetrical ~~obstetric~~ physicians and other persons having credentials within that hospital to perform deliveries by caesarean section. This board shall review, at least monthly, every caesarean section performed since the previous review and paid for by state funds or federal funds administered by the state. The board shall conduct its review pursuant to the parameters specified in the rule adopted by the Department of Health pursuant to this section, paying ~~act and shall pay~~ particular attention to electronic fetal monitoring records, umbilical cord gas results, and Apgar scores in determining if the caesarean section delivery was appropriate. The results of this periodic review must be shared with the attending physician. These reviews and the resultant reports must be considered a part of the hospital's quality assurance monitoring and peer review process established pursuant to s.

395.0193.

Section 2. Section 395.1051, Florida Statutes, is amended to read:

395.1051 Duty to notify patients and physicians.—

(1) An appropriately trained person designated by each licensed facility shall inform each patient, or an individual identified pursuant to s. 765.401(1), in person about adverse incidents that result in serious harm to the patient. Notification of outcomes of care which ~~that~~ result in harm to the patient under this section does ~~shall~~ not constitute an acknowledgment or admission of liability and may not~~, nor can it~~ be introduced as evidence.

(2) A hospital shall notify each obstetrical physician who has privileges at the hospital at least 120 days before the hospital closes its obstetrical department or ceases to provide obstetrical services. The Department of Health shall adopt rules to administer this subsection, including rules governing those situations in which it is impossible for the hospital to provide 120 days' notice due to circumstances beyond the control of the hospital or the obstetrical physician.

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

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

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

BILL:	SPB 7010
INTRODUCER:	For consideration by the Health Policy Committee
SUBJECT:	Health Access Dental Licenses
DATE:	December 19, 2013 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Peterson	Stovall		**Pre-meeting**

I. Summary:

SPB 7010 changes the requirements for obtaining a health access dental license. A health access license authorizes out-of-state dentists to practice in designated facilities that serve patients who otherwise would not have access to care. The bill removes language that would render an applicant ineligible based on a report to the National Practitioner Data Bank (NPDB). Instead, the Board of Dentistry (Board) is given authority to deny licensure if the applicant has violated or is being investigated for a violation of chapter 466, Florida Statutes., the dental practice act, or other licensing requirements. The bill also deletes language that sunsets the program on January 1, 2015.

II. Present Situation:

The Importance of Oral Health Care

Mouth and throat diseases, which range from cavities to cancer, cause pain and disability for millions of Americans each year. Ninety-six percent of adults aged 50-64 years have had dental caries (tooth decay, cavities). In children, cavities are the most common form of chronic disease, which often begins at an early age. More than one-fourth of U.S. children aged 2-5 years and half of children aged 12-15 years have been affected by tooth decay. Children and adolescents from low-income families are hardest hit: about two-thirds of those aged 12-19 years have had caries, and one in four has untreated caries. Untreated tooth decay can cause pain, dysfunction, and absence from school, and poor appearance — problems that can greatly affect a child's quality of life.[1]

[1] Centers for Disease Control and Prevention and Nat'l Center for Chronic Disease Prevention and Health Promotion, *Oral Health Program Strategic Plan for 2011-2014*, 5 (March 2011) *available at* http://www.cdc.gov/OralHealth/pdfs/oral_health_strategic_plan.pdf (last visited Nov. 25, 2013).

While progress has been made over the last 40 years, the Healthy People 2010 Final Review[2] noted that during the period from 1988-94 to 1999-2004, there were several instances where caries was increasing. Dental caries and untreated caries increased among children aged 2-4 years. Untreated caries also increased for children aged 6-8 years and for adults aged 35-44 years.[3] Caries remains a problem for the increasing number of older adults who have retained most of their teeth. One-fourth of adults older than age 65 years have lost all of their teeth because of tooth decay and advanced gum disease. Tooth loss can affect a person's self-esteem and may contribute to nutrition problems by limiting the types of food that a person can eat.[4]

Disparities exist in the prevalence of caries across populations. The greatest racial and ethnic disparity among children aged 2-4 years and aged 6-8 years is seen in Mexican American and black, non-Hispanic children. Blacks, non-Hispanics, and Mexican Americans aged 35-44 years, experience untreated tooth decay nearly twice as much as white, non-Hispanics.[5] One of the greatest racial and ethnic disparities exists among adults aged 35-44 years for untreated tooth decay. The prevalence of untreated tooth decay among non-Hispanic blacks is more than twice that of non-Hispanic whites. Twice as many non-Hispanic blacks, and Mexican American adults aged 20-64 have untreated tooth decay as do non-Hispanic white adults.[6]

Disparities in oral health care also exist between geographic areas. Most research and surveillance information indicate that access to dental care is significantly more limited in rural areas than in metropolitan areas. According to the National Rural Health Association:[7]

- Even after controlling for population density and income, non-metropolitan counties have lower dentist-to-population ratios (62 dentists per 100,000 population in large metropolitan areas versus 29 dentists per 100,000 population in the most rural counties). The pattern is the same in Florida. Dentists are disproportionately concentrated in the more populous areas, particularly the coastal counties of south Florida (ratios ranging from 42 to 97 dentists per 100,000 population) versus ratios in the largely rural interior counties, as well as many central Panhandle counties (a range of ratios as low as 10 to 33 dentists per 100,000 population).[8]

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[2] The Healthy People initiative, which is administered by the U.S. Department of Health and Human Services, provides science-based, 10-year national objectives for improving the health of all Americans. Since its inception, Healthy People has established benchmarks and monitored progress over time in order to: encourage collaborations across communities and sectors; empower individuals toward making informed health decisions; and measure the impact of prevention activities. Since 1979, there have been four Healthy People initiatives. U.S. Dept. of Health and Human Services, *About Healthy People*, http://www.healthypeople.gov/2020/about/default.aspx (last visited Nov. 25, 2013).

[3] Nat'l Center for Health Statistics, *Healthy People 2010 Final Review*, 21-9 (Dec. 2012), *available at* www.cdc.gov/nchs/data/hpdata2010/hp2010_final_review.pdf (last visited Nov.25, 2013).

[4] *Strategic Plan*, *supra* note 1, at 5.

[5] Centers for Disease Control and Prevention, *Disparities in Oral Health*, http://www.cdc.gov/OralHealth/oral_health_disparities (last visited Nov. 25, 2013).

[6] *Strategic Plan*, *supra* note 1, at 7.

[7] Nat'l Rural Health Association, *Meeting Oral Health Care Needs in Rural America*, 1 – 2 (April 2005) (on file with the Senate Health Policy Committee).

[8] Florida Dept. of Health, *Report on the 2009-2010 Workforce Survey of Dentists*, 4 & 59 (March 2011) (on file with the Senate Health Policy Committee). In 2009, the Department of Health developed this workforce survey for dentists. The survey was administered on a voluntary basis in conjunction with biennial renewal of dental licenses and 89 percent of dentists with an active Florida license responded to the survey.

- Rural residents are more likely to have lost all their teeth than their non-rural counterparts. In fact, adults aged 18 to 64 are nearly twice as likely to be edentulous if they are rural residents.
- Rural adults are significantly more likely than non-rural adults to have untreated dental decay: 32.6 percent versus 25.7 percent.
- In 2001, 67.1 percent of urban residents had visited a dentist in the previous year, while only 58.3 percent of rural Americans had done so.
- Rural residents are less likely than their urban counterparts to have dental insurance.
- Of the 2,235 Dental Health Professional Shortage Areas, 74 percent are in non-metropolitan areas.

According to the National Advisory Committee on Rural Health and Human Services, several factors contribute to the problems of rural oral health:

- *Geographic isolation*. People in remote rural areas have farther to travel to obtain care and fewer dentists, hygienists, and other professionals to provide it.
- *Lack of adequate transportation.* In many parts of rural America, private automobiles are the only source of transportation. Public transit is non-existent, as are taxicabs and other transportation for hire. Consequently, many rural residents — especially low-income residents — face great difficulty in going to the dentist or any other service provider.
- *Lack of fluoridated community water supplies*. This most basic preventative treatment against tooth decay is unavailable in countless rural communities.
- *Higher rates of poverty*. Low-income status prevents many people from seeking and obtaining oral health care. It also prevents them from purchasing dental insurance. In addition, rural employers are less likely to purchase or offer dental insurance for their employees due to the smaller average size for most rural employers.
- *Larger percentage of elderly population*. With increasing age come increasing dental and oral health problems. The percentages of rural Americans who are older and sicker are greater than those of urban Americans, and Medicare does not provide routine dental benefits.
- *Lower dental insurance rates*. Insurance reimbursement rates — both public and private — for dental procedures are typically lower in rural areas than in urban; however, the actual costs of providing the services are often higher in rural areas.
- *Acute provider shortages*. As indicated above, the ratio of dentists per 100,000 population in non-metropolitan counties is less than half of what it is in metropolitan counties. The acute shortage of dentists nationwide is expected to worsen in coming years as dental schools graduate fewer students, despite the fact that dental school applications were up some 18 percent between 2004 and 2005. With the closing of seven dental schools since 1986, and subsequent opening of only three new ones, more people want to become dentists than there are available slots. On top of that, many dentists are nearing retirement age - especially in rural areas. In addition, it can be predicted that the combination of increasing levels of dental school indebtedness and fee disparities between urban and rural locations will lead to a reduced percentage of the dental school graduates locating in rural locations.
- *Difficulty finding providers willing to treat Medicaid patients*. Because of low reimbursement rates, paperwork burdens, and a perception of a higher percentage of broken appointments, many dentists simply do not accept Medicaid or State Children's Health Insurance Program

(SCHIP) patients, of which there are many in rural America due to the higher proportion of people living in poverty.[9]

Health Access Dental Licensure

In 2008, the Legislature established the health access dental license in order to attract out-of-state dentists to practice in underserved health access settings.[10] With this license, a dentist actively licensed in good standing in another state, the District of Columbia, or a U.S. territory is authorized to practice dentistry in Florida in a health access setting if the dentist:

- Files a Board-approved application and pays the applicable fees;
- Has not been convicted or pled nolo contendre to, regardless of adjudication, any felony or misdemeanor related to the practice of a health care profession;
- Submits proof of graduation from a dental school accredited by the Commission on Dental Accreditation of the American Dental Association;
- Submits documentation that the dentist has completed, or will obtain prior to licensure, a continuing education equivalent to Florida's requirement for dentists for the last full reporting biennium before applying for a health access license;
- Submits proof of her or his successful completion of parts I and II of the National Boards and a state or regional clinical dental license examination that the Board has determined effectively measures the applicant's ability to practice safely;
- Has never had a license revoked from another state, the District of Columbia, or a U.S. territory;
- Has never failed an exam under s. 466.006, F.S., unless the applicant was reexamined and received a license to practice in Florida;
- Has not been reported to the NPDB, unless the applicant successfully appealed to have his or her name removed from the data bank; and,
- Submits proof that he or she has been engaged in the active, clinical practice of dentistry providing direct patient care for 5 years immediately preceding the date of application, or proof of continuous clinical practice providing direct patient care since graduation if the applicant graduated less than 5 years from his or her application.[11]

A health access dental license is subject to biennial renewal. The Board will renew a health access dental license if the applicant:

- Submits a renewal application and pays the required fees;
- Signs and submits a statement attesting that the applicant has completed all continuing education required of a licensed dentist;

[9] *Id.* (citing the National Advisory Committee on Rural Health and Human Services).
[10] A "health access setting" is defined in s. 466.003(14), F.S., as a program or institution of the Department of Children and Family Services, the Department of Health, or the Department of Juvenile Justice, a nonprofit community health center, a Head Start center, a federally qualified health center (FQHC) or FQHC look-alike as defined by federal law, a school-based prevention program, or a clinic operated by an accredited college of dentistry or an accredited dental hygiene program in this state if such community service programs and institutions immediately report to the Board of Dentistry practice act or standard of care violations related to the actions or inactions of a dentist, dental hygienist, or dental assistant engaged in the delivery of dental care in such settings.
[11] Section 466.0067, F. S.

- Submits documentation of continued employment in the health access setting;
- Has not been convicted or pled nolo contendre to, regardless of adjudication, any felony or misdemeanor related to the practice of a health care profession;
- Has never failed an exam under s. 466.006, F.S., since initially receiving a health access dental license or since the last renewal; and,
- Has not been reported to the NPDB, unless the applicant successfully appealed to have his or her name removed from the data bank.[12]

The Board may revoke a health access dental license if the licensee is terminated from employment at the health access setting or practices outside of the health access setting, fails the Florida dental examination, or is found by the Board to have committed a violation of Chapter 466 (the dental practice act), other than a violation that is a citation offense or a minor violation.[13]

Currently, there are a total of 54 health access dental licenses. Of those 31 are in-state active, 5 are in-state delinquent, 13 are out-of-state active, 3 are out-of-state inactive, and 2 are retired.[14] According to data collected by the Department of Health, 14 dentists with health access licenses are currently practicing in county health departments (CHDs). Several CHDs reported they do not think they could have obtained a dentist without the availability of the health access license. CHDs also report that these dentists have been of high quality and have improved access to care on the part of the low income population.[15]

The program is scheduled for repeal effective January 1, 2015, unless reenacted by the Legislature.[16]

National Practitioner Data Bank

The NPDB was originally established by Title IV of the Health Care Quality Improvement Act of 1986, Public Law 99-660. The intent of the act is to improve the quality of health care by encouraging state licensing boards, hospitals and other health care entities, and professional societies to identify and discipline those who engage in unprofessional behavior; and to restrict the ability of physicians, dentists, and other healthcare practitioners to move from state-to-state

[12] Section 466.00671, F.S.
[13] Section 466.00672, F.S.
[14] Florida Dept. of Health, Division of Medical Quality Assurance, *Annual Report and Long Range Plan FY 2012-2013*, 8, *available at* http://www.floridahealth.gov/licensing-and-regulation/reports-and-publications/_documents/annual-report-12-13.pdf (last visited Nov. 25, 2013). "In-State Active" means the licensed practitioner has a Florida mailing address and is authorized to practice. "In-State Delinquent" means the licensed practitioner has a Florida mailing address and is not authorized to practice in the state because of failure to renew the license by the expiration date. "Out-of-State Active" means the licensed practitioner has an out-of-state mailing address and is authorized to practice. "Out-of-State Inactive" means the licensed practitioner has an out-of-state mailing address and is not authorized to practice. "Retired" means the licensed practitioner is not authorized to practice. The practitioner is not obligated to update licensure data. *Id.* at 10. s. 456.036, F.S.
[15] E-mail from Philip Street, Senior Policy Coordinator, Health Statistics and Performance Management, Florida Dept. of Health, (Nov. 19, 2013) (on file with the Senate Health Policy Committee).
[16] Section 466.00673, F.S.

without disclosure or discovery of previous medical malpractice payments and adverse actions. Adverse actions can involve licensure, clinical privileges, or professional society memberships.[17]

Information in the NPDB is available to:

- Hospitals requesting information concerning a practitioner on their medical staff or to whom they have granted clinical privileges, or with respect to peer review.
- Health care entities (including hospitals) that have entered or may be entering employment or affiliation relationships with a practitioner or to which the practitioner has applied for clinical privileges or appointment to the medical staff, or with respect to peer review.
- Practitioners requesting information about themselves.
- Boards of medical examiners or other state licensing boards.
- Attorneys or individuals representing themselves upon submission of proof that a hospital failed to submit a mandatory query.
- Persons or entities requesting information in a form which does not identify any particular practitioner or entity.[18]

Information in the NPDB is confidential. Violations of the confidentiality provisions are subject to civil money penalties.

According to the NPDB Handbook:

> The NPDB is intended to augment, not replace, traditional forms of credentials review. As a nationwide flagging system, it provides another resource to assist state licensing boards, hospitals, and other health care entities in conducting extensive, independent investigations of the qualifications of the health care practitioners they seek to license or hire, or to whom they wish to grant clinical privileges.

Settlement of a medical malpractice claim may occur for a variety of reasons that do not necessarily reflect negatively on the professional competence or conduct of the physician, dentist, or other health care practitioner. **Thus, a payment made in settlement of a medical malpractice action or claim shall not be construed as a presumption that medical malpractice has occurred.[19]**

III. Effect of Proposed Changes:

The bill removes reports to the National Practitioner Data Bank as a condition that renders an applicant ineligible for a health access dental license. The bill substitutes instead authority for the Board of Dentistry to deny initial or renewal licensure to any applicant who has committed or is under investigation or prosecution for an act that is grounds for discipline under chapter 466 or chapter 456. SPB 7010 also deletes language that sunsets the program on January 1, 2015.

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[17] U.S. Dept. of Health and Human Services, Health Resources and Services Administration, *NPDB Guidebook*, A-2 (Sept. 2001) *available at* http://www.npdb-hipdb.hrsa.gov/resources/aboutGuidebooks.jsp (last visited Nov. 25, 2013).
[18] *Id.* at A-5.
[19] *Id.* at A-3 (emphasis in the original).

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

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

Section 466.0067(2), F.S., authorizes the Board of Dentistry to charge an application license fee for a health access dental license, laws-and-rule exam fee, and an initial licensure fee, which are the same as fees charged to an applicant for an unrestricted dental license. Currently, those fees are:

- Application fee: $100.
- Exam Development fee: $80.
- Licensure fee: $305.

Because the effect of the bill is to reenact and continue an existing program, these fees are not new. Thus, the potential fiscal impact remains the same as when the program was created in 2008.

B. Private Sector Impact:

The health access dental license creates an incentive for out-of-state dentists to practice in settings—defined as "health access settings"—that provide dental care to underserved populations or communities. The definition includes certain nonprofit facilities. Thus, both the facilities and patients they serve may benefit from access to additional dentists.

C. Government Sector Impact:

The health access dental license creates an incentive for out-of-state dentists to practice in settings—defined as "health access settings"—that provide dental care to underserved populations or communities. The majority of these settings are publicly-operated. Thus, the facilities may benefit from access to additional dentists.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 466.0067 and 466.00671.

This bill repeals the following section of the Florida Statutes: 466.00673.

IX. Additional Information:

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

None.

B. Amendments:

None.

482994

LEGISLATIVE ACTION

Senate . House

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

Senate Amendment (with title amendment)

Delete lines 117 - 118
and insert:
Section 3. Section 466.00673, Florida Statutes, is amended to read
466.00673 Repeal of a health access dental license.—Effective January 1, 2020 ~~2015~~, ss. 466.0067-466.00673 are repealed unless reenacted by the Legislature. Any health access dental license issued before January 1, 2020 ~~2015~~, shall remain valid according to ss. 466.0067-466.00673, without effect from

repeal.

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

And the title is amended as follows:

Delete line 10

and insert:

amending s. 466.00673, F.S., extending the future

FOR CONSIDERATION By the Committee on Health Policy

588-00677-14 20147010__

A bill to be entitled

An act relating to health access dental licenses; amending ss. 466.0067 and 466.00671, F.S.; deleting the requirement that a license applicant or renewing licensee not have been reported to the National Practitioner Data Bank; authorizing the Board of Dentistry to deny licensure to an applicant or renewing licensee who has committed or is under investigation or prosecution for certain violations; repealing s. 466.00673, F.S., relating to the future repeal of provisions authorizing the health access dental license; providing an effective date.

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

Section 1. Section 466.0067, Florida Statutes, is amended to read:

466.0067 ~~Application for~~ Health access dental license application.—The Legislature finds that there is an important state interest in attracting dentists to ~~practice in~~ underserved health access settings in this state and ~~further,~~ that allowing out-of-state dentists who meet certain criteria to practice in health access settings without the supervision of a dentist licensed in this state is substantially related to achieving this important state interest. ~~Therefore,~~

(1) Notwithstanding the requirements of s. 466.006, the board shall grant a health access dental license to an applicant seeking to practice dentistry in this state in health access settings who meets all of the following requirements ~~as defined~~

~~in s. 466.003 to an applicant that~~:

(a)~~(1)~~ Files an ~~appropriate~~ application approved by the board.~~;~~

(b)~~(2)~~ Pays an application license fee for a health access dental license, a laws-and-rule exam fee, and an initial licensure fee as specified under~~. The fees specified in this subsection may not differ from an applicant seeking licensure pursuant to~~ s. 466.006.~~;~~

(c)~~(3)~~ Has not been convicted of or pled nolo contendere to, regardless of adjudication, any felony or misdemeanor related to the practice of a health care profession.~~;~~

(d)~~(4)~~ Submits proof of graduation from a dental school accredited by the Commission on Dental Accreditation of the American Dental Association or its successor agency.~~;~~

(e)~~(5)~~ Submits documentation that she or he has completed, or will obtain prior to licensure, continuing education equivalent to this state's requirement for dentists licensed under s. 466.006 for the last full reporting biennium before applying for a health access dental license.~~;~~

(f)~~(6)~~ Submits proof of her or his successful completion of parts I and II of the dental examination of ~~by~~ the National Board of Dental Examiners and a state or regional clinical dental licensing examination that the board has determined effectively measures the applicant's ability to practice safely.~~;~~

(g)~~(7)~~ Currently holds a valid, active, dental license in good standing which has not been revoked, suspended, restricted, or otherwise disciplined from another of the United States, the District of Columbia, or a United States territory.~~;~~

(h) ~~(8)~~ Has never had a license revoked from another of the United States, the District of Columbia, or a United States territory. ~~;~~

(i) ~~(9)~~ Has never failed the examination specified in s. 466.006, unless the applicant was reexamined pursuant to s. 466.006 and received a license to practice dentistry in this state. ~~;~~

~~(10) Has not been reported to the National Practitioner Data Bank, unless the applicant successfully appealed to have his or her name removed from the data bank;~~

(j) ~~(11)~~ Submits proof that he or she has been engaged in the active, clinical practice of dentistry providing direct patient care for 5 years immediately preceding the date of application, or if ~~in instances when~~ the applicant ~~has~~ graduated from an accredited dental school within the preceding 5 years, submits proof of continuous clinical practice providing direct patient care since graduation. ~~; and~~

(k) ~~(12)~~ Has passed an examination covering the laws and rules of the practice of dentistry in this state as described in s. 466.006(4)(a).

(2) The board may deny a health access dental license to an applicant who has committed, or is under investigation or prosecution for, an act that would constitute a basis for discipline pursuant to chapter 456 or this chapter.

Section 2. Section 466.00671, Florida Statutes, is amended to read:

466.00671 ~~Renewal of the~~ Health access dental license renewal.—

(1) A health access dental licensee shall apply for renewal

each biennium. At the time of renewal, the licensee shall sign a statement that she or he has complied with all continuing education requirements of an active dentist licensee. The board shall renew a health access dental license for an applicant who meets all of the following requirements ~~that~~:

(a) Submits documentation, as approved by the board, from the employer in the health access setting that the licensee has at all times pertinent remained an employee.~~;~~

(b) Has not been convicted of or pled nolo contendere to, regardless of adjudication, any felony or misdemeanor related to the practice of a health care profession.~~;~~

(c) Has paid a renewal fee identical to the fee set by the board under~~. The fee specified herein may not differ from the renewal fee adopted by the board pursuant to~~ s. 466.013. The department may provide payment for these fees through the dentist's salary, benefits, or other department funds.~~;~~

(d) Has not failed the examination specified in s. 466.006 since initially receiving a health access dental license or since the last renewal.~~; and~~

~~(e) Has not been reported to the National Practitioner Data Bank, unless the applicant successfully appealed to have his or her name removed from the data bank.~~

(2) The board may ~~undertake measures to~~ independently verify the health access dental licensee's ongoing employment status in the health access setting.

(3) The board may deny health access dental licensure renewal to an applicant who has committed, or is under investigation or prosecution for, an act that would constitute a basis for discipline pursuant to chapter 456 or this chapter.

Section 3. Section 466.00673, Florida Statutes, is repealed.

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

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

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

BILL:	SPB 7008
INTRODUCER:	For consideration by the Health Policy Committee
SUBJECT:	Nonresident Pharmacies
DATE:	December 23, 2013 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Stovall	Stovall		

I. Summary:

SPB 7008 requires a pharmacy located in another state (nonresident pharmacy) to obtain a nonresident pharmacy compounded sterile products permit prior to shipping, mailing, delivering, or dispensing a compounded sterile product into Florida. Any sterile compounded product that is sent into Florida must have been compounded in a manner that meets or exceeds the standards for sterile compounding.

The proposed bill authorizes the Department of Health (department) or its agents to inspect any nonresident pharmacy that is registered with the department. The nonresident pharmacy is responsible for the cost of this inspection. The department is also authorized to take regulatory action against a nonresident pharmacy immediately, without waiting 180 days for the pharmacy's home state to act on alleged conduct that causes or could cause serious injury to a human or animal in this state.

II. Present Situation:

Pharmacies and pharmacists are regulated under the Florida Pharmacy Act (the Act) found in ch. 465, F.S.[1] The Board of Pharmacy (the board) is created within the department to adopt rules to implement provisions of the Act and take other actions according to duties conferred on it in the Act.[2]

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

- Community pharmacy – a location where medicinal drugs are compounded, dispensed, stored, or sold or where prescriptions are filled or dispensed on an outpatient basis.

[1] Other pharmacy paraprofessionals, including pharmacy interns and pharmacy technicians, are also regulated under the Act.
[2] Section 465.005, F.S.

- Institutional pharmacy – 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 with respect to the handling of drugs within the facility.
- Nuclear pharmacy – a location where radioactive drugs and chemicals within the classification of medicinal drugs are compounded, dispensed, stored, or sold, excluding hospitals or the nuclear medicine facilities of such hospitals.
- Internet pharmacy – a location not otherwise permitted under the Act, whether within or outside the state, which uses the internet to communicate with or obtain information from consumers in this state in order to fill or refill prescriptions or to dispense, distribute, or otherwise engage in the practice of pharmacy in this state.
- Non-resident pharmacy – a location outside this state which ships, mails, or delivers, in any manner, a dispensed drug into this state.
- Special pharmacy – a location where medicinal drugs are compounded, dispensed, stored, or sold if such location is not otherwise defined which provides miscellaneous specialized pharmacy service functions. Seven special pharmacy permits are established in rule.[3]

Nonresident pharmacy

Any pharmacy located outside this state which ships, mails, or delivers, in any manner, a dispensed drug into this state is required to be registered with the board as a nonresident pharmacy.[4,5] In order to register in this state, a nonresident pharmacy must submit an application fee of $255 and a certified application[6] that documents:

- That the pharmacy maintains a valid, unexpired license, permit, or registration to operate the pharmacy in compliance with the laws of the state in which the dispensing facility is located and from which the drugs are dispensed,
- The identity of the principal corporate officers and the pharmacist who serves as the prescription department manager as well as the criminal and disciplinary history of each,
- That the pharmacy complies with lawful directions and requests for information from applicable regulatory bodies,
- The pharmacy department manager's licensure status,
- The most recent pharmacy inspection report, and
- The availability of the pharmacist and patient records for a minimum of 40 hours per week, 6 days a week.

The board may deny, revoke, or suspend registration of, or fine or reprimand, a nonresident pharmacy for:

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[3] Rule 64B16-28.800, F.A.C., establishes the following special permits: Special-Parenteral and Enteral, Special-Closed System Pharmacy, Special-Non Resident (Mail Service), Special-End Stage Renal Disease, Special-Parenteral/Enteral Extended Scope, Special-ALF, and Special Sterile Compounding.
[4] Section 465.0156, F.S.
[5] 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.
[6] The complete application packet may be found at: http://www.floridaspharmacy.gov/Applications/app-non-resident-parmacy.pdf (last visited Dec. 16, 2013).

- Failure to comply with Florida's drug substitution provisions in s. 465.025, F.S.,
- Failure to comply with the registration requirements,
- Advertising the services of a nonresident pharmacy which has not registered knowing the advertisement will likely induce members of the public in this state to use the pharmacy to fill prescriptions, or
- Conduct which causes serious bodily injury or serious psychological injury to a resident of Florida if the board has referred the matter to the regulatory or licensing agency in the state in which the pharmacy is located and the regulatory or licensing agency fails to act within 180 days of the referral.

Pharmaceutical Compounding

Compounding is the professional act by a pharmacist or other practitioner authorized by law, employing the science or art of any branch of the profession of pharmacy, incorporating prescription or non-prescription ingredients to create a finished product for dispensing to a patient or for administration by a practitioner or the practitioner's agent.[7]

Historically and continuing today, a practitioner might prescribe a compounded preparation when a patient requires a different dosage form, such as turning a pill into a liquid for a patient who cannot swallow pills or into a lollipop or flavored medication for children; a different dosage strength, such as for an infant; or allergen-free medication. Compounding and dispensing in this manner is typically patient-specific. More recently, the practice of compounding medications has evolved and expanded to include compounding for office use. "Office use" means the provision and administration of a compounded drug to a patient by a practitioner in the practitioner's office or by the practitioner in a health care facility or treatment setting, including a hospital, ambulatory surgical center, or pharmacy.[8] Typically a drug compounded for office use is not prepared, labeled, and dispensed for a specific patient.

Under the board's rules, compounding includes:

- The preparation of drugs or devices in anticipation of prescriptions based on routine, regularly observed prescribing patterns.
- The preparation pursuant to a prescription of drugs or devices which are not commercially available.
- The preparation of commercially available products[9] from bulk when the prescribing practitioner has prescribed the compounded product on a per prescription basis and the patient has been made aware that the compounded product will be prepared by the pharmacist. The reconstitution of commercially available products pursuant to the manufacturer's guidelines is permissible without notice to the practitioner.

[7] *See* Rule 64B16-27.700, F.A.C.
[8] *See* Rule 64B16-27.700, F.A.C.
[9] The term "commercially available product" means any medicinal product that is legally distributed in Florida by a drug manufacturer or wholesaler. *See* Rule 64B16-27.700, F.A.C.

Compounded Products

Compounded products may be either sterile or non-sterile. A sterile preparation is defined in the board's rule[10] as any dosage form devoid of viable microorganisms, but does not include commercially manufactured products that do not require compounding prior to dispensing. Compounded sterile preparations include, but are not limited, to the following:

- Injectables;
- Parenterals, including Total Parenteral Nutrition (TPN) solutions, parenteral analgesic drugs, parenteral antibiotics, parenteral antineoplastic agents, parenteral electrolytes, and parenteral vitamins;
- Irrigating fluids;
- Ophthalmic preparations; and
- Aqueous inhalant solutions for respiratory treatments.

A non-sterile compounded product is a compounded preparation that is not a sterile compounded preparation.

The United States Pharmacopeia and the National Formulary (USP–NF) is a book containing standards for chemical and biological drug substances, dosage forms, and compounded preparations, excipients, medical devices, and dietary supplements. The federal Food Drug and Cosmetic Act (FDCA) designates the USP–NF as the official compendium for drugs marketed in the United States. A drug product in the U.S. market must conform to the USP–NF standards for strength, quality, purity, packaging, and labeling of medications to avoid possible charges of adulteration and misbranding.[11] The USP–NF has five chapters specifically related to pharmaceutical compounding, two of which are USP Chapter 795, which addresses compounding for non-sterile preparations, and USP Chapter 797, which addresses compounding for sterile preparations. In addition, USP Chapter 797 requires the use of other general chapters as well.

Safety concerns of compounded drugs

Compounded drugs can pose both direct and indirect health risks. Compounded drugs may be unsafe and pose direct health risks because of the use of poor quality compounding practices. They may be sub- or super-potent, contaminated, or otherwise adulterated. Indirect health risks include the possibility that patients will use ineffective compounded drugs instead of FDA-approved drugs that have been shown to be safe and effective. Some pharmacists are well-trained and well-equipped to compound certain medications safely. But not all pharmacists have the same level of skills and equipment, and some drugs may be inappropriate for compounding. In some cases, compounders may lack sufficient controls (e.g., equipment, training, testing, or facilities) to ensure product quality or to compound complex drugs like sterile or extended-release drugs.

[10] Rule 64B16-27.797, F.A.C.
[11] For additional information on the USP-NP *see* http://www.usp.org/usp-nf (last visited Dec. 17, 2013).

In 2012, the federal Centers for Disease Control and Prevention (CDC), in collaboration with state and local health departments and the Food and Drug Administration (FDA), began investigating a multistate outbreak of fungal meningitis and other infections among patients who received contaminated preservative-free methylprednisolone acetate (MPA) steroid injections from the New England Compounding Center (NECC).[12] As of October 23, 2013, 751 cases were reported nationwide, with 64 deaths attributed to contaminated injectables compounded in the Massachusetts pharmacy.[13] Florida reported 25 cases, with 7 deaths related to persons receiving the medications from the contaminated lots.

The FDA continues to inform the public about recalls, inspections, and regulatory enforcement action related to compounded medications.[14]

State and Federal Oversight of Compounded Medications

Until recently, the regulation of compounded medications was murky, without clear guidelines and oversight responsibility by the FDA or state agencies.[15,16] The FDA traditionally regulated the manufacture of prescription drugs, which typically includes making drugs (preparation, deriving, compounding, propagation, processing, producing, or fabrication) on a large scale for marketing and distribution of the product for unidentified patients. State boards of pharmacy historically have regulated the compounding of medications by a pharmacy under the practice of pharmacy.[17] However, compounding standards, inspector competency, and inspectional frequency and resources in the states, if existent, vary considerably.[18]

On November 27, 2013, President Obama signed the Drug Quality and Security Act (DQSA),[19] legislation to enhance the oversight of the compounding of human drugs. This law creates a new section 503B in the FDCA. Under section 503B, a compounder can become an "outsourcing facility." An outsourcing facility is not required to also be a state-licensed pharmacy. An

[12] The Centers for Disease Control and Prevention Multistate Fungal Meningitis Outbreak Investigation, available at: http://www.cdc.gov/hai/outbreaks/meningitis.html (last visited Dec. 27, 2013).
[13] The Centers for Disease Control and Prevention Multistate Fungal Meningitis Outbreak Investigation, available at: http://www.cdc.gov/hai/outbreaks/meningitis-map-large.html#casecount_table (last visited Dec. 27, 2013).
[14] *See* the FDA website at: http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339771.htm (last visited Dec. 27, 2013).
[15] The U.S. Supreme Court had found certain provisions relating to the advertising and promotion of certain human compounded drugs in section 503A of the FDCA to be unconstitutional in 2002 and struck the entire section of law dealing with the remaining provisions related to compliance with current good manufacturing practices, labeling, and FDA approval prior to marketing. In subsequent opinions, lower courts split on whether the remaining provisions remained intact and enforceable.
[16] In some instances, the FDA was refused admittance to conduct an inspection of compounders, which necessitated obtaining an administrative warrant to gain access to the firm and make copies of the firm's records. *See* http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm347722.htm (last visited Dec. 27, 2013).
[17] *See generally* U.S. Food and Drug Administration, Regulatory Guidance for Compounded Drugs, available at: http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339764.htm (last visited Dec, 27, 2013).
[18] House Democrats Release Report on Flawed Compounding Pharmacy Oversight, April 15, 2013, available at: http://dingell.house.gov/press-release/house-democrats-release-report-flawed-compounding-pharmacy-oversight (last visited Dec. 27, 2013).
[19] H.R. 3204, 113th Congress.

outsourcing facility will be able to qualify for exemptions from the FDA approval requirements for new drugs and the requirement to label products with adequate directions for use. Outsourcing facilities:

- Must comply with current good manufacturing practices (CGMP) requirements,
- Will be inspected by FDA according to a risk-based schedule, and
- Must meet certain other conditions, such as reporting adverse events and providing FDA with certain information about the products they compound.

This law provides the framework such that if compounders register with the FDA as outsourcing facilities, hospitals and other health care providers can lawfully provide their patients with drugs that were compounded in outsourcing facilities that are subject to CGMP requirements and federal oversight.

A compounder that chooses not to register as an outsourcing facility and qualify for the exemptions under section 503B, may qualify for the exemptions under section 503A of the FDCA relating to traditional compounding for patient-specific medications. Otherwise, the compounder is subject to all of the requirements in the FDCA applicable to conventional manufacturers.

The FDA anticipates that state boards of pharmacy will continue their oversight and regulation of the practice of pharmacy, including traditional pharmacy compounding. The FDA has also indicated it intends to continue to cooperate with state authorities to address pharmacy compounding activities that may be violative of the FDCA.[20]

With the nationwide fungal meningitis outbreak caused by contaminated compounded products, the Florida Board of Pharmacy adopted Emergency Rule 64B16ER12-1, Florida Administrative Code. This Emergency Rule required all Florida licensed pharmacy permit holders, including non-residents, to complete a mandatory survey to inform the board of their compounding activities. The goal of this mandatory survey was to determine the scope of sterile and non-sterile compounding within Florida licensed pharmacies –whether physically located in or out-of-state. Of the 8,981 permitted pharmacies, 8,294 (92 percent) responded. The board published the compounding survey results in January 2013.[21]

Key results relating to non-sterile compounding:

- 55 percent (4,494) compound non-sterile products; 9 percent (382) of these are nonresident pharmacies.
- 54 percent (4,380) compound non-sterile products pursuant to a patient-specific prescription; 9 percent (373) of these are nonresident pharmacies.
- 6 percent (459) compound non-sterile products in bulk; 81 percent (373) of these are nonresident pharmacies.

[20] *Supra*, 16.
[21] Florida Board of Pharmacy compounding Survey Report, January 23, 2013 is available at: http://www.floridaspharmacy.gov/Forms/info-compounding-survey-report.pdf, (last visited Dec. 27, 2013).

- 1 percent (119) compound non-sterile products in bulk for office use; 50 percent (59) of these are nonresident pharmacies.
- 5 percent (382) ship compounded non-sterile products to other states; 80 percent (307) of these are nonresident pharmacies.

Key results relating to sterile compounding:

- 12 percent (946) compound sterile products; 32 percent (301) of these are nonresident pharmacies. Some of these in-state pharmacies may hold other permit types as well, such as an institutional permit or a special permit that authorizes compounding.
- 11 percent (913) compound sterile products pursuant to a patient-specific prescription; 32 percent (289) of these are nonresident pharmacies.
- 4 percent (348) compound sterile products in bulk and/or in bulk for office use; 45 percent (155) of these are nonresident pharmacies. Eighty-three of these 348 pharmacies (22 in-state and 61 nonresident) compound greater than 100 doses from a single batch.
- 4 percent (307) ship compounded sterile products to other states; 177 of these are nonresident pharmacies that ship sterile compounded products to Florida.

Effective September 23, 2013, the board adopted a rule requiring most pharmacies that engage or intend to engage in the preparation of sterile compounded products within the state to obtain a Special Sterile Compounding permit.[22] Pharmacies required to obtain this permit must compound sterile products in strict compliance with the standards set forth in board rules.[23] These rules address, among other things, compounding for office use, including the quantity of product that may be safely compounded for office use, execution of an agreement between the pharmacist and practitioner outlining responsibilities of the practitioner, and labeling. Compliance with additional standards based on the risk level for contamination in the practice of compounding sterile preparations is also required. The rule addressing standards of practice for compounding sterile preparations was first adopted in 2008 and amended in January of 2010. These standards apply to all sterile pharmaceuticals, regardless of the location of the patient, e.g., home, hospital, nursing home, hospice, or doctor's office.[24]

There is no statutory authority to require nonresident pharmacies to register or obtain a separate sterile compounding permit in Florida.

Compounding Pharmacy Accreditation

The Pharmacy Compounding Accreditation Board (PCAB) is a nationally recognized organization that issues a voluntary quality accreditation designation for the compounding industry. Founders of the organization include the American College of Apothecaries, National Community Pharmacists Association, American Pharmacists Association, National Alliance of State Pharmacy Associations, International Academy of Compounding Pharmacists, National Association of Boards of Pharmacy, National Home Infusion Association, and United States Pharmacopeia.

[22] Rule 64B16-28.100(8), F.A.C.
[23] Rules 64B16-27.797 and 64B16-27.700, F.A.C.
[24] Rule 64B16-27.700, F.A.C.

The PCAB accreditation means the pharmacy has independent, outside validation that it meets nationally accepted quality assurance, quality control, and quality improvement standards. In order to demonstrate compliance with PCAB standards and earn PCAB accreditation, pharmacies participate in an off-site and on-site evaluation process that includes:[25]

- Verification by PCAB that the pharmacy is not on probation for issues related to compounding quality, public safety or controlled substances.
- Verification that the pharmacy is properly licensed in each state it does business in.
- An extensive on-site evaluation by a PCAB surveyor, all of whom are compounding pharmacists trained in evaluating compliance with PCAB's quality standards. For example, this evaluation includes:
  - An assessment of the pharmacy's system for assuring and maintaining staff competency.
  - A review of facilities and equipment.
  - Review of records and procedures required to prepare quality compounded medications.
  - Verification that the pharmacy uses ingredients from FDA registered and or licensed sources.
  - Review of the pharmacy's program for testing compounded preparations.

Currently, 187 pharmacies hold PCAB accreditation, 15 of which are located in Florida.[26]

III. Effect of Proposed Changes:

Section 1 amends s. 465.0156, F.S., to authorize the department to take regulatory action against a nonresident pharmacy immediately, without waiting 180 days for the pharmacy's home state to act on alleged conduct that causes or could cause serious injury to a human or animal in this state. Authorized regulatory action is expanded to include conduct that could cause serious injury, without demonstrating that the conduct actually injured a person. Regulatory enforcement action may also occur for conduct that causes or could cause serious bodily injury to an animal in this state or for noncompliance with the requirements of the newly established nonresident pharmacy compounded sterile products permit.

Section 2 creates s. 465.0158, F.S., to establish the nonresident pharmacy compounded sterile products permit. A pharmacy located in another state is required to obtain a nonresident pharmacy compounded sterile products permit prior to shipping, mailing, delivering, or dispensing a compounded sterile product into Florida. This permit is a supplemental permit to registration as a nonresident pharmacy.

The proposed bill allows a registered nonresident pharmacy until January 31, 2015 to become permitted, while continuing to send compounded sterile products into this state, if the products meet or exceed the standards required in the proposed bill. However, if a nonresident pharmacy is not registered by July 1, 2014, it must seek registration and obtain the nonresident pharmacy compounded sterile products permit prior to sending compounded sterile products to Florida.

[25] Pharmacy Compounding Accreditation Board, http://www.pcab.org/prescribers, (last visited Dec. 27, 2013).
[26] *See* http://www.pcab.org/pharmacy, (last visited Dec. 27, 2013.

Any sterile compounded product that is sent into this state must have been compounded in a manner that meets or exceeds the standards for sterile compounding in Florida. The owners, officers, and prescription department manager or pharmacist in charge must attest that he or she understands Florida's laws and rules governing sterile compounding and that any compounded sterile products sent into this state will comply with those standards, unless the board has granted an exemption due to conflicting standards where the nonresident pharmacy is located.

The department is required to notify the permittee when Florida's laws or rules for sterile compounding change. However, if notification does not occur, the permittee remains obligated to comply with Florida's standards.

The department is directed to schedule the biennial permit renewal concurrent with the nonresident pharmacy's biennial registration. The board is authorized to adopt in rule a permit fee that will not exceed $250.

Section 3 amends s. 465.017, F.S., to authorize the department or its agents to inspect any nonresident pharmacy that is registered with the department. The nonresident pharmacy is responsible for the actual costs incurred by the department for this inspection. Grammatical changes are also made to this section.

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

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

A biennial permit fee in an amount not to exceed $250 is authorized. According to the board's compounding survey results, 177 nonresident pharmacies ship sterile compounded products to Florida. Assuming all 177 nonresident pharmacies seek a permit to continue shipping sterile compounded products to Florida, the biennial revenue from the permit, plus the $5 unlicensed activity fee,[27] is estimated at $45,135.

[27] The $5 unlicensed activity fee is required by s. 456.065(3), F.S.

B. Private Sector Impact:

SPB 7008 enhances the regulation of pharmacies that are located in other states and provide medication to persons in this state. These pharmacies that compound sterile products for patients in Florida may experience increased costs related to additional permit fees as discussed above and compliance with greater compounding practice standards, if the pharmacy is located in a state with lesser practice standards. All registered nonresident pharmacies may experience on-site inspections and regulatory enforcement for non-compliance with Florida-specific practice requirements.

Patients receiving compounded sterile products from other states might experience increased medication costs to offset any costs of compliance with safer compounding standards. The overall health care market might experience reduced utilization to the extent that adverse health consequences are minimized from safer compounded medications. The fiscal impact of these factors is indeterminate.

C. Government Sector Impact:

The department will incur additional costs related to rule adoption, permitting activities, and regulatory enforcement actions. An analysis from the department was not available; however, frequently the department indicates these costs can be absorbed within existing resources. Costs incurred for inspections of nonresident pharmacies will be reimbursed by the nonresident pharmacy.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 465.0156 and 465.017.

This bill creates the following section of the Florida Statutes: 465.0158.

IX. Additional Information:

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

None.

B. Amendments:

None.

634504

LEGISLATIVE ACTION

Senate . House

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

Senate Amendment

Delete line 83

and insert:

the state in which the nonresident pharmacy is located; or

FOR CONSIDERATION By the Committee on Health Policy

588-00653A-14 20147008__

A bill to be entitled

An act relating to nonresident pharmacies; amending s. 465.0156, F.S.; conforming provisions to changes made by the act; deleting a requirement that the Board of Pharmacy refer regulatory issues affecting a nonresident pharmacy to the state where the pharmacy is located; creating s. 465.0158, F.S.; requiring registered nonresident pharmacies to obtain a permit in order to ship, mail, deliver, or dispense compounded sterile products into this state; requiring submission of an application and a nonrefundable fee; specifying requirements; requiring the Department of Health to inform permittees of any law or rule changes; authorizing the board to deny, revoke, or suspend a permit for certain actions; providing dates by which certain registered and unregistered nonresident pharmacies must obtain a permit; authorizing the Board of Pharmacy to adopt rules; amending s. 465.017, F.S.; authorizing the department to inspect registered nonresident pharmacies; requiring nonresident pharmacies to pay for the costs of such inspections; providing an effective date.

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

Section 1. Subsections (4) and (5) of section 465.0156, Florida Statutes, are amended to read:

465.0156 Registration of nonresident pharmacies.—

(4) The board may deny, revoke, or suspend registration of,

or fine or reprimand, a nonresident pharmacy for failure to comply with s. 465.025, s. 465.0158, or ~~with~~ any requirement of this section in accordance with ~~the provisions of~~ this chapter.

(5) In addition to the prohibitions of subsection (4), the board may deny, revoke, or suspend registration of, or fine or reprimand, a nonresident pharmacy in accordance with ~~the provisions of~~ this chapter for conduct that ~~which~~ causes or could cause serious bodily injury or serious psychological injury to a human or animal in ~~resident of~~ this state ~~if the board has referred the matter to the regulatory or licensing agency in the state in which the pharmacy is located and the regulatory or licensing agency fails to investigate within 180 days of the referral~~.

Section 2. Section 465.0158, Florida Statutes, is created to read:

465.0158 Nonresident pharmacy compounded sterile products permit.—A nonresident pharmacy registered under s. 465.0156 must also hold a compounded sterile products permit issued under this section in order to ship, mail, deliver, or dispense, in any manner, a compounded sterile product into this state.

(1) Application for a permit shall be submitted on a form furnished by the board, together with a nonrefundable permit fee as provided under s. 465.022(14). The board may require such information as it deems reasonably necessary to carry out the purposes of this section, including information pertaining to registration as an outsourcing facility with the Secretary of the United States Department of Health and Human Services.

(2) As a condition of initial permitting and permit renewal, the owners, officers, and prescription department

manager or pharmacist in charge of the nonresident pharmacy must attest in writing that they have read and understand the laws and rules governing sterile compounding in this state and that any compounded sterile product shipped, mailed, delivered, or dispensed into this state will meet or exceed this state's standards for sterile compounding.

(a) The department shall notify all compounded sterile products permittees when state laws or rules affecting the standards for sterile compounding in this state are adopted or revised, along with the effective date of the law or rule.

(b) If the department fails to notify a permittee of a change in state laws or rules, or the permittee does not receive notification of applicable rules, the permittee remains legally obligated to meet or exceed this state's standards with respect to any compounded sterile product shipped, mailed, delivered, or dispensed into this state. The board may provide an exception to this requirement by rule if the sterile compounding laws and rules of the state in which the nonresident pharmacy is located directly conflict with a board rule for sterile compounding in this state but provide a comparable standard of product safety and integrity.

(3) A nonresident pharmacy may not ship, mail, deliver, or dispense any compounded sterile product into this state which:

(a) Was compounded in violation of the laws and rules of the state in which the nonresident pharmacy is located; and

(b) Does not meet or exceed this state's sterile compounding standards as provided in subsection (2).

(4) To the extent feasible, biennial permit renewal shall be timed to coincide with nonresident pharmacies' registration

renewal under s. 465.0156.

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

(a) Failure to comply with the requirements of this section; or

(b) Conduct that causes or could cause serious bodily injury or serious psychological injury to a human or animal in this state.

(6) A registered nonresident pharmacy that is currently shipping, mailing, delivering, or dispensing compounded sterile products into this state may continue to do so if such products meet or exceed the standards for sterile compounding in this state and the pharmacy is issued a nonresident pharmacy compounded sterile products permit on or before January 31, 2015.

(7) A nonresident pharmacy seeking registration in this state under s. 465.0156 on or after July 1, 2014, may not ship, mail, deliver, or dispense a compounded sterile product into this state until it has received the sterile compounded products permit required under this section.

(8) The board shall adopt rules necessary to administer this section.

Section 3. Section 465.017, Florida Statutes, is amended to read:

465.017 Authority to inspect; disposal.—

(1) Duly authorized agents and employees of the department may ~~shall have the power to~~ inspect in a lawful manner at all reasonable hours any pharmacy, including a nonresident pharmacy

registered under s. 465.0156, and any~~,~~ hospital, clinic, wholesale establishment, manufacturer, physician's office, or any other place in the state in which drugs and medical supplies are manufactured, packed, packaged, made, stored, sold, offered for sale, exposed for sale, or kept for sale for the purpose of:

(a) Determining if any provision ~~of the provisions~~ of this chapter or any rule adopted ~~promulgated~~ under its authority is being violated;

(b) Securing samples or specimens of any drug or medical supply after paying or offering to pay for such sample or specimen; or

(c) Securing such other evidence as may be needed for prosecution under this chapter.

(2) The cost for inspecting a nonresident pharmacy shall be reimbursed by the pharmacy. The cost to the pharmacy is limited to the actual costs incurred by the department.

(3)~~(2)(a)~~ Except as permitted by this chapter~~,~~ and chapters 406, 409, 456, 499, and 893 or upon the written authorization of the patient, records maintained in a pharmacy relating to the filling of prescriptions and the dispensing of medicinal drugs may ~~shall not~~ be furnished only ~~to any person other than~~ to the patient for whom the drugs were dispensed, or her or his legal representative, ~~or~~ to the department pursuant to existing law, or if~~, in the event that~~ the patient is incapacitated or unable to request such ~~said~~ records, her or his spouse ~~except upon the written authorization of such patient~~.

(a) Such records may be furnished in any civil or criminal proceeding, upon the issuance of a subpoena from a court of competent jurisdiction and proper notice to the patient or her

or his legal representative by the party seeking such records.

(b) The board shall adopt rules <u>establishing</u> ~~to establish~~ practice guidelines for pharmacies to dispose of records maintained in a pharmacy relating to the filling of prescriptions and the dispensing of medicinal drugs. Such rules <u>must</u> ~~shall~~ be consistent with the duty to preserve the confidentiality of such records in accordance with applicable state and federal law.

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

The Florida Senate

Issue Brief 2009-330 *October 2008*

Committee on Health Regulation

PHARMACY COMPOUNDING: NON-PATIENT SPECIFIC

Statement of the Issue

Periodically, interest arises in legislation that would authorize a pharmacy licensed in Florida to compound prescription drugs that are not to be dispensed by the pharmacy to a named patient but are to be provided to a hospital, ambulatory surgical center, or physician's office for administration to a patient who is unknown at the time the medication is provided to the hospital, ambulatory surgical center, or physician's office. This practice is commonly referred to as compounding for office use.

The current regulatory environment accommodates compounding on a per-prescription basis or in anticipation of receipt of a prescription when a drug that is not commercially available is needed for a specified patient. This regulatory environment is intended to balance the potential health risks associated with pharmaceutical compounding while meeting specific patient medication needs.

The federal and state laws and enforcement efforts concerning pharmacy compounding conflict, and are at best, confusing. This brief sets forth regulatory and other considerations applicable to pharmacy compounding, focusing on issues related to pharmacy compounding for office use.

Discussion

Summary

Compounding is the process of combining, mixing, or altering ingredients, or preparing drugs by a pharmacist (or physician) to fit the unique needs of an individual patient.[1] Compounding does not include mixing, reconstituting, or other acts that are performed in accordance with directions contained in approved labeling or other directions provided by the product's manufacturer. A health care practitioner might prescribe a compounded preparation rather than a commercially available drug in several situations. For example, a practitioner might prescribe a compounded preparation when a patient requires a different dosage form, such as turning a pill into a liquid for a patient who cannot swallow pills or into a lollipop or flavored medication for children; a different dosage strength, such as for an infant; or allergen-free medication. In addition, the practitioner might want a pharmacist to compound medications that are not commercially available.

The Federal Food, Drug, and Cosmetic Act (FDCA) and federal regulations establish the minimum standards for drug products in this country. Specifically, the FDCA regulates the manufacture and distribution of drugs. The regulation of the professional practices of medicine and pharmacy is deferred to the states. In most instances the FDCA does not pre-empt states from enacting duplicative or more stringent licensure and regulatory provisions for activities involving drugs and drug products. Pharmacists and pharmacies are also subject to regulation under The Florida Pharmacy Act[2] and The Florida Drug and Cosmetic Act[3] (The Florida Act).

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[1] United States Food and Drug Administration Consumer Update: The Special Risks of Pharmacy Compounding, found at: <http://www.fda.gov/consumer/updates/compounding053107.html> (Last visited on September 23, 2008).

[2] Chapter 465, Florida Statutes (F.S.).

[3] Part I of ch. 499, F.S.

Drugs for animals may be compounded and although many of the issues are similar, this paper concentrates on drugs intended for human use.[4]

Historical Overview of Drug Regulation

Before mass production of medications (manufacturing) became commonplace, compounding was a routine activity of physicians and pharmacists. The art of pharmaceutical compounding has ancient roots.

Federal controls over the drug supply in this country began in 1848 with the Drug Importation Act, which required U.S. Customs inspection to stop entry of adulterated drugs from overseas. Congress enacted the original Food and Drugs Act in 1906. It prohibited misbranded and adulterated foods, drinks, and drugs in interstate commerce. No government pre-approval was granted; the federal government could act only after products were on the market. Major revisions to drug regulation occurred in the FDCA of 1938, which started a new system of drug regulation – requiring new drugs to be shown safe before marketing via submission of a new drug application[5] to the Food and Drug Administration (FDA).[6] Then in 1962, in addition to demonstrating a new drug's safety, drug manufacturers were required to prove to the FDA the effectiveness of their products before marketing them. The Food and Drug Administration Modernization Act of 1997 (FDAMA) amended numerous provisions of the FDCA, one of which specifically addressed pharmacy compounding.[7]

Specific Drug Regulations

New Drug Approval

The FDCA requires new drugs to undergo an approval process demonstrating that the drug is safe and effective for its intended use.[8] A new drug is defined in the FDCA and in the Florida Act as any drug that is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof.[9] Both the FDCA and the Florida Act[10] prohibit a person from selling … or distributing any new drug unless an approved application has become effective under s. 505 of the FDCA. The Florida Act continues with the phrase, "… or unless otherwise permitted by the Secretary of the United States Department of Health and Human Services for shipment in interstate commerce."[11]

The FDA approval means not only that the drug has been reviewed for safety and effectiveness, it means that the FDA has reviewed manufacturing quality, inspected manufacturing controls, and has reviewed the product labeling to ensure it adequately conveys the drug's benefits and risks. It also means that the drug product is consistently monitored for safety, effectiveness, and adherence with manufacturing quality standards.[12] Accordingly, manufacturing establishments must register with the FDA, including facilities located in other countries if the drugs manufactured in those establishments are to be marketed in this country. Most states also license and inspect facilities that manufacture drugs within their state for compliance with good manufacturing practices.

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[4] New animal drugs are regulated in 21 U.S.C. §360(b)(1).
[5] If a drug obtained approval, the FDA allowed drugs that were identical, related, or similar (IRS) to the approved drug to be covered by that approval and they could be marketed without independent approval. Source: Marketed Unapproved Drugs – Compliance Policy Guide, June 2006, found at: <http://www.fda.gov/cder/guidance/6911fnl.pdf> (Last visited on September 23, 2008).
[6] The FDA had been created in 1927 under a different organizational name.
[7] 21 U.S.C. 353a or Sec. 503A of the FDCA, effective November 21, 1998.
[8] 21 U.S.C. 355 or Sec. 505 of the FDCA. There are various procedures to obtain drug approval.
[9] For the complete definition see 21 USC 321(p) or Sec. 201(p) of the FDCA and s. 499.003(32), F.S.
[10] Section 499.023, F.S.
[11] This phrase is significant because it authorizes compounding in accordance with the exercise of FDA's enforcement discretion as discussed later in this brief.
[12] FDA's Questions and Answers for Consumers about Unapproved Drugs, found at: <http://www.fda.gov/cder/drug/unapproved_drugs/qaConsumers.pdf> (Last visited on September 23, 2008).

Adulteration

Under the FDCA and the Florida Act, a drug is adulterated if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the safety requirements of the FDCA and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess.[13] Current good manufacturing practice standards address personnel; facilities; equipment; control of components, drug product containers, and closures; packaging and labeling control; holding and distribution; laboratory controls; records and reports; and returned and salvaged drug products.[14]

Misbranding

A drug is misbranded under the FDCA and the Florida Act if its labeling is false or misleading in any way and if its labeling fails to bear adequate directions for use. Additionally, the FDCA and the Florida Act require a drug label to include, among other things, the name and place of business of the manufacturer, repackager, or distributor of the drug unless the drug is dispensed pursuant to a prescription of a practitioner licensed by law to prescribe such drug. If the drug is dispensed, the label must, among other things, identify the pharmacy as well as the name of the patient to whom the drug is dispensed.[15]

Status of Compounded Drugs Under Federal Law

In the early 1990s, the FDA became concerned that some pharmacies were purchasing bulk quantities of drug substances, "compounding" them into specific drug products before receiving individual prescriptions, and marketing those drugs to doctors and patients. Although the FDA had long refrained from regulating pharmacist compounding, it believed that pharmacies engaging in large-scale bulk compounding were effectively manufacturing drugs under the guise of compounding them.

In 1992, the FDA issued a Compliance Policy Guide[16] asserting the applicability of the FDCA to compounded drugs, but declaring its intention to generally defer to state regulation of the day-to-day practice of retail pharmacy and related activities. Nevertheless, the FDA warned that it may, in the exercise of its enforcement discretion, initiate federal enforcement actions when the scope and nature of a pharmacy's activity raises the kind of concerns normally associated with a manufacturer. Compounding pharmacies were concerned about relying on the largess of the FDA's enforcement discretion with respect to pharmacy compounding. As a result, in 1997 Congress amended the FDCA by enacting the FDAMA.[17]

The FDAMA exempts drug products that are compounded by a pharmacist or physician on a customized basis for an individual patient from three key provisions of the FDCA: the adulteration provision concerning the good manufacturing practice requirements; the misbranding provision concerning the labeling of drugs with adequate directions for use; and the new drug provision concerning the approval of drugs under new drug or abbreviated new drug applications so long as the provider of the compounded drug abides by certain restrictions.

Soon after enactment of the FDAMA, several licensed pharmacies brought action challenging a restriction in the FDAMA that prohibited the advertising and promotion of particular compounded drugs. The United States Supreme Court held[18] in 2002 that these provisions were unconstitutional restrictions of commercial speech. However, the lower court, the Court of Appeals for the Ninth Circuit, had also determined that the other restrictions related to compounding in the FDAMA could not be severed from the unconstitutional advertising and promotional restrictions. The severability issue was not brought before the Supreme Court, and accordingly, the Supreme Court did not rule on that

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[13] For the complete definition see 21 USC 351 or Sec. 501 of the FDCA found at: <http://www.fda.gov/opacom/laws/fdcact/fdcact5a.htm#ftn1> (Last visited on September 23, 2008) and s. 499.006, F.S.
[14] 21 C.F.R. 211.
[15] 21 USC 352 or Section 502(a) of the FDCA, s. 499.007, F.S., and s. 893.04(1)(e), F.S., for controlled substances.
[16] Compliance Policy Guide No. 7132.16 (Mar. 1992).
[17] Pharmacies characterized Congress' action as a "reaction to the FDA's 1992 policy" and the FDA characterized it as "a confirmation of it." From *Medical Center Pharmacy, et. al. vs. Mukasey536 F.3rd383, 390 (5th Cir. 2008)*.
[18] *Thompson v. Western States Medical Center, et.al.*, 535 U.S. 357 (2002)

issue. The FDA shares the Ninth Circuit's view that this entire compounding section in the FDAMA is now void[19] and compounded drugs are subject to all provisions of the FDCA.

Accordingly, the FDA determined that it needed to issue guidance to the compounding industry on what factors the FDA would consider in exercising its enforcement discretion regarding pharmacy compounding. The FDA's enforcement policy, with respect to the compounding of human drugs, is articulated in Compliance Policy Guide (CPG) section 460.200, issued by the FDA on May 29, 2002. [20] The following includes key provisions from this CPG:

> The FDA recognizes that pharmacists traditionally have extemporaneously compounded and manipulated reasonable quantities of human drugs upon receipt of a valid prescription *for an individually identified patient* from a licensed practitioner. The FDA stated that this traditional activity is not the subject of the guidance. Generally, the FDA will continue to defer to state authorities regarding less significant violations of the FDCA related to pharmacy compounding of human drugs. However, when the scope and nature of a pharmacy's activities raise the kinds of concerns normally associated with a drug manufacturer and result in significant violations of the new drug, adulteration, or misbranding provisions of the FDCA, the FDA has determined that it should seriously consider enforcement action. In determining whether to initiate such action, the FDA will consider whether the pharmacy engages in any of the following acts:[21]
>
> - Compounding drugs in anticipation of receiving prescriptions, except in very limited quantities in relation to the amount of drugs compounded after receiving valid prescriptions;
> - Compounding drugs that were withdrawn or removed from the market for safety reasons;[22]
> - Compounding finished drugs from bulk active ingredients that are not components of FDA approved drugs without an FDA sanctioned investigational new drug application;
> - Receiving, storing, or using drug substances without first obtaining written assurance from the supplier that each lot of the drug substance has been made in an FDA-registered facility;
> - Receiving, storing, or using drug components not guaranteed or otherwise determined to meet official compendia requirements;
> - Using commercial scale manufacturing or testing equipment for compounding drug products;
> - Compounding drugs for third parties who resell to individual patients or offering compounded drug products at wholesale to other state licensed persons or commercial entities for resale;
> - Compounding drug products that are commercially available in the marketplace or that are essentially copies of commercially available FDA-approved drug products unless there is documentation of the medical need for the particular variation of the compound for the particular patient; and
> - Failing to operate in conformance with applicable state law regulating the practice of pharmacy.

Although there are some differences in the set of restrictions between the FDAMA and the FDA's CPG, the major difference is that the FDAMA specifically exempts pharmacies that compound in accordance with the specified criteria from violating the adulteration, misbranding, and new drug provisions of the FDCA. On the other hand, the CPG articulates that compounding is subject to regulation under the FDCA but that the FDA may exercise enforcement discretion with respect to taking action against a pharmacy for violating the adulteration, misbranding, and new drug provisions of the FDCA for compounded products.

On July 18, 2008, the United States Court of Appeals for the Fifth Circuit opined[23] that the other restrictions related to compounding in the FDAMA could be severed from the unconstitutional advertising and promotional restrictions so

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[19] Footnote 2 in seven FDA Warning Letters dated January 7, 2008, related to compounded menopause hormone therapy drugs, found at <http://www.fda.gov/cder/pharmcomp/> (Last visited on September 23, 2008).

[20] Found at:< http://www.fda.gov/ora/compliance_ref/cpg/cpgdrg/cpg460-200.html> (Last visited on September 23, 2008)

[21] The CPG states that the list of factors is not intended to be exhaustive and that other factors may be appropriate for consideration in a particular case. The CPG also provides that other FDA guidance interprets or clarifies the FDA's positions concerning nuclear pharmacy, hospital pharmacy, shared service operations, mail order pharmacy, and the manipulation of approved drug products.

[22] The CPG provides a list of drugs, which is also in 21 C.F.R. 216.24. The CPG provides that this list will be updated in the future, as appropriate.

[23] *Medical Center Pharmacy v. Mukasey*, 536F.3d 383, (5th Cir. 2008).

that a compounding pharmacy that complies with the remaining restrictions in the FDAMA does not violate the adulteration, misbranding, and new drug provisions of the FDCA. Since a split in decisions by the circuit courts of appeal exists, in all likelihood the U.S. Supreme Court will take up the matter at some point in the future.

Wholesale Distribution

Wholesale distribution means distribution of prescription drugs to persons other than a consumer or patient, with certain exemptions. Both federal and state laws distinguish and specifically exempt dispensing a prescription drug from the licensure laws regulating the wholesale distribution of prescription drugs.[24] Under Florida law, dispensing involves a pharmacist or licensed practitioner transferring possession of a properly labeled prescription drug to a patient or patient's agent.[25] Compounded drugs may be delivered to a practitioner's office for administration to the patient if the drug is dispensed for a specified patient at the time of delivery; this is not considered a wholesale distribution. However, if the drug is not so dispensed, the distribution of the compounded drug to the practitioner is a wholesale distribution under both the FDCA and the Florida Act.

Although the distribution of prescription drugs to practitioners for office use constitutes wholesale distribution under the FDCA, federal regulations exempt the sale of minimal quantities of drugs by retail pharmacies to licensed practitioners for office use. In this context, sales of prescription drugs by a retail pharmacy to licensed practitioners for office use are considered to be minimal if the total annual dollar volume of prescription drugs sold to licensed practitioners does not exceed 5 percent of the dollar volume of that retail pharmacy's annual prescription drug sales.[26]

Florida's law does not have a similar exemption and requires a retail pharmacy drug wholesale distributor permit for the wholesale distribution of prescription drugs by a retail pharmacy up to a certain level of sales, and if the sales volume for wholesale distributions exceeds that threshold, then a prescription drug wholesale distributor permit is required.[27,28] However, a pharmacy in Florida that compounds sterile products, such as eye drops and parenteral/enteral nutritional preparations or other injectables, must be licensed by the Board of Pharmacy in a manner that makes the pharmacy ineligible for a permit under the Florida Act that authorizes the wholesale distribution of prescription drugs. This type of compounding pharmacy is a health care entity under the Florida Act.[29]

When a medical provider authorized to purchase and possess prescription drugs in Florida acquires prescription drugs that have not been dispensed to a patient, the transaction is a wholesale distribution. The medical provider must obtain the prescription drug from an authorized source,[30] i.e., a wholesale distributor permitted under the Florida Act to distribute prescription drugs to that type of medical provider. In addition, a pharmacy that distributes prescription drugs in a wholesale distribution is required to provide a pedigree paper[31] to the recipient medical provider.[32]

Practitioner Need for Compounded Medications for Office Use

Senate professional staff surveyed associations representing pharmacies and pharmacists, hospitals, health-system pharmacists, medical and osteopathic physicians, and hospices to determine whether compounding for office use is needed in various health-care settings. Senate professional staff also requested input on strategies that might be

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[24] 21 C.F.R. 203.3(cc) and s. 499.003(53), F.S.
[25] The Florida Pharmacy Act in s. 465.003(6), F.S. (2007).
[26] Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures, Final Rule, December 3, 1999, Comments on the Proposed Rule on Page 67748, found at: <http://www.fda.gov/OHRMS/DOCKETS/98fr/120399a.txt> (Last visited on September 23, 2008).
[27] s. 499.01(2)(f), F.S.
[28] A pharmacy registered to dispense controlled substances may distribute such substances (without being registered with the DEA as a distributor) to another pharmacy or to a practitioner to dispense, provided that several conditions are met, including, the total number of dosage units of controlled substances distributed by the pharmacy does not exceed five percent of all controlled substances dispensed by that pharmacy during a calendar year. Source: 21 C.F.R. §1307.11(a)(1).
[29] See the definitions of "closed pharmacy," "health care entity," and "retail pharmacy" in s. 499.003, F.S.
[30] s. 499.005(14), and s. 499.0051(4), F.S.
[31] A pedigree paper is a document containing information regarding the sales and distributions of a prescription drug. See s. 499.003(36), F.S.
[32] s. 499.005(28) and (29) and s. 499.0051, F.S.

available to minimize or reduce the risk to the ultimate patient related to non-patient specific compounding. In addition, Senate professional staff received input from individual pharmacists and practitioners in the state.

Without exception, all parties communicated the medical necessity for patient-specific compounding. However, Senate professional staff was unable to document an immediate medical need for a non-patient specific compounded drug where the timeframe precluded ordering the medication for the specified patient.[33] Some parties cited convenience to both the practitioner and patient as justifying compounding for office use. For example, a compounding pharmacist explained that if a practitioner has compounded anesthetic gels in the office, then the practitioner might be able to perform certain tests or procedures during an initial office examination without scheduling a follow-up appointment. Although commercially available anesthetic gels exist for these types of routine procedures, the compounding pharmacist explained that some practitioners may prefer to use combination products that act more quickly or have additional substances in them. Practitioners in Florida may be obtaining these compounded medications from pharmacies located in other states.

Hospices provided conflicting comments on the need for Ativan, Benadryl, Haldol, and Reglan (ABHR) suppositories immediately upon admission of patients. Some suggested that this very common compounded medication, or something similar, should be made available as floor stock for inpatient hospices to expedite care and eliminate wastage that frequently occurs despite the hospice filling the prescription on a 3-day supply basis.

Compounding for Office Use in Other States

At least 15 states specifically authorize pharmacies to compound medication for physician office use. These states have varying levels of authorizations and requirements. Some states authorize a compounded medication that is not patient specific to be provided to other pharmacies, clinics, or institutional pharmacies for administration while some states restrict this practice to providing the medication to practitioners. Some states require a pharmacy to adhere to detailed standards that are similar to good manufacturing practices that a manufacturer must follow, while other states specify less detail in regulating the compounding process.

In May 2005, the FDA responded to the Texas Department of State Health Services' request to clarify the FDA's regulatory approach to pharmacy compounding of human drugs and to comment generally on proposed Senate Bill 492 (2005), which addresses pharmacy compounding under Texas state law.[34] The FDA stated that it believes that the legislation would disserve Texans because it would purport to legalize conduct that is illegal under federal law. The FDA further stated that although the FDA generally defers to state authorities regarding the regulation of pharmacy compounding, the agency remains prepared to enforce the FDCA as appropriate to protect the public health and vindicate the integrity of the new drug approval process.

Notwithstanding the FDA's concerns that the specific bill purports to authorize conduct that would run afoul of federal law and the FDA's regulatory approach, the FDA discussed provisions that should be included in any bill that would be consistent with the FDA's regulatory approach. Some of this discussion includes:

> The FDA recognizes that it may be appropriate in some circumstances for pharmacists to compound limited supplies of drugs solely for administration in a practitioner's office, but the FDA is concerned that this proposed bill fails to include sufficient limitations and safeguards. The FDA believes that any bill should [not] become a back door for the sale of compounded drugs to other pharmacies, health facilities and wholesalers … The FDA believes that any bill that would be consistent with the FDA's regulatory approach should … provide that pharmacies may compound and deliver only a "limited" quantity of drugs to a practitioner "solely" for administration in a practitioner's office … The FDA would also suggest that the bill require that any drug compounded and delivered pursuant to these provisions be labeled "for Office Use Only" and "Not for Resale."

[33] The Florida Hospital Association was not aware of any regulatory obstacles that make it difficult or impossible for hospitals to obtain needed drugs. Cardioplegia solutions used in emergency heart surgeries, other admixtures used by hospitals, and certain radiopharmaceuticals have unique state and federal regulatory provisions to address availability of these products.

[34] Correspondence to Karen Tannert, R.Ph., Drug and Medical Devices Group, Texas Department of State Health Services from Steven D. Silverman, Director, Division of New Drugs and Labeling Compliance CDER, Office of Compliance, dated May 4, 2005.

Florida's Compounding Rule

On October 7, 2008, the Florida Board of Pharmacy amended a rule to authorize compounding for office use.[35] This rule may not comport with FDA's guidance related to its exercise of enforcement discretion regarding compounding for office use by:

- Authorizing a pharmacist to dispense and deliver a compounded drug to a practitioner to administer in a health care facility or treatment setting, including a hospital, ambulatory surgical center, or pharmacy;
- Authorizing a pharmacy to compound a "reasonable quantity" as defined in the rule[36] versus a "limited quantity;" and
- Omitting the suggested labeling of compounded products for office use.

Another concern with this rule is that it purports to legalize conduct related to the wholesale distribution of certain compounded drugs that may not be lawful under the Florida Act.

Risks Associated with Compounded Drugs[37]

Compounded drugs can pose both direct and indirect health risks. Compounded drugs may be unsafe and pose direct health risks because of the use of poor quality compounding practices. They may be sub- or super-potent, contaminated, or otherwise adulterated. Indirect health risks include the possibility that patients will use ineffective compounded drugs instead of FDA-approved drugs that have been shown to be safe and effective.

Some pharmacists are well-trained and well-equipped to compound certain medications safely. But not all pharmacists have the same level of skills[38] and equipment, and some drugs may be inappropriate for compounding. In some cases, compounders may lack sufficient controls (e.g., equipment, training, testing, or facilities) to ensure product quality or to compound complex drugs like sterile or extended-release drugs. The quality of the drugs that these pharmacists compound is unknown and these drugs pose potential risks to the patients who take them.

When pharmacy compounders both operate like drug manufacturers and engage in high-volume distribution, the risk of patient harm increases. Over the past several years, the FDA has become aware of serious adverse events, including deaths, associated with compounded drugs. For example, the FDA:

- Issued a warning letter[39] to a pharmacy in Alabama related to its compounding activities for producing large volumes of injectable and non-injectable products which may be copies, or essentially copies, of FDA-approved, commercially available products. A consumer complaint of an adverse incident related to a compounded injectable suspension prompted an FDA inspection, which revealed that the compounding firm had received at least 70 complaints associated with that injectable suspension. The day following the FDA inspection, the firm issued a voluntary recall on two lots of the product.
- Issued warning letters to five firms about their standardized compounded, high-strength topical anesthetic creams. Two deaths were connected to the topical anesthetics compounded by two of the pharmacies.

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[35] Rule 64B16-27.700, F.A.C.

[36] The rule states that the quantity of compounded drug for any practitioner and all practitioners as a whole, is not greater than an amount the pharmacy is capable of compounding in compliance with pharmaceutical standards for identity, strength, quality, and purity of compounded drug that are consistent with USP guidelines and accreditation practices.

[37] FDA's Compounded Menopausal Hormone Therapy Questions and Answers, found at <http://www.fda.gov/cder/pharmcomp/BHRT_qa.htm> (Last visited on September 23, 2008).

[38] A survey sent to 82 deans of pharmacy schools throughout the country in 2005 revealed that instruction provided to pharmacy students in preparing compounded sterile preparations varied widely. Only 7 of the 53 respondents (13 percent) believed that their students had adequate training in the compounding of sterile preparations via didactic and laboratory courses before graduation ... and 88.7 percent of the respondents believed that students could only become fully competent in such compounding over time in practice. *Instruction on compounded sterile preparations at U.S. schools of pharmacy* by Mac Hellums, Susan P. Alverson, and Mary R. Monk-Tutor, American Journal of Health-System Pharmacy, Vol. 64, Issue 21, 2267-2274 (2007).

[39] A copy of the warning letter is available at: <http://www.fda.gov/foi/warning_letters/s6529c.pdf> (Last visited on September 23, 2008).

- Warned three firms to stop manufacturing and distributing thousands of doses of unapproved inhalation drugs under the guise of compounding. Warning letters to these firms identify a range of serious concerns including inadequate quality control, concerns about potency, and compounding copies of FDA-approved drugs.

The FDA receives adverse drug reaction reports[40] from manufacturers as required by regulation. Health care professionals and consumers send reports voluntarily through the MedWatch program. These reports support the FDA's post-marketing safety surveillance program for all approved drugs and therapeutic biologic products. The FDA may take regulatory actions to improve product safety and protect the public health, such as updating a product's labeling information, sending out a "Dear Health Care Professional" letter, or re-evaluating an approval decision, based on analysis of these reports.[41] Compounded drugs are not similarly tracked.[42]

USP Standards and Compounding Accreditation

USP Standards

The United States Pharmacopeia (USP) is an official public standards-setting authority for all prescription and over-the-counter medicines and other health care products manufactured or sold in the United States.[43] The FDCA designates the USP/NF (National Formulary) as the official compendia for drugs marketed in the United States. A drug product in the U.S. market must conform to the USP/NF standards for strength, quality, purity, packaging, and labeling of medicines to avoid possible charges of adulteration and misbranding. The Florida Act also refers to and requires compliance with this official compendium.[44]

The USP has two chapters related to pharmaceutical compounding. USP Chapter 795 addresses pharmaceutical compounding for nonsterile preparations. The newest version of USP Chapter 797 Pharmaceutical Compounding-Sterile Preparations (USP Chapter 797) became effective on June 1, 2008. Both USP Chapters are enforceable by the FDA; however since the FDA defers to the states to regulate the practice of pharmacy and to perform inspections, individual states are adopting some or all of the standards, especially with respect to compounding sterile preparations. The Florida Board of Pharmacy recently adopted by rule Standards of Practice for Compounding Sterile Preparations[45] that a pharmacist in Florida must follow when compounding low, medium, and high-risk sterile preparations. This rule closely tracks USP Chapter 797.[46]

Compounding Accreditation

The Pharmacy Compounding Accreditation Board (PCAB) was created in 2004 as a voluntary accreditation body to establish high quality standards for compounding pharmacies. The PCAB was formed by eight national pharmacy organizations, including the USP and the National Association of Boards of Pharmacy. Pharmacies that successfully meet the PCAB's requirements, including documented compliance with USP Chapter 797, receive the designation "PCAB Accredited™ compounding pharmacy" and are able to display the PCAB Seal of Accreditation. Three pharmacies in Florida are accredited and four applications for accreditation of pharmacies located in Florida are pending.[47]

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[40] Adverse event reporting is required on prescription and non-prescription drugs and, as of December, 2007, on dietary supplements as required by Public Law 109–462.

[41] Additional information on the FDA Adverse Event Reporting System may be obtained at <http://www.fda.gov/cder/aers/default.htm> (Last visited on September 23, 2008).

[42] *Ibid at 38.*

[43] U.S. Pharmacopeia, About USP – an Overview found at: <http://www.usp.org/aboutUSP/index.html?USP> (Last visited on September 23, 2008).

[44] See for example, s. 499.003(35) and s. 499.006, F.S.

[45] Rule 64B16-27.797, effective June 18, 2008.

[46] Hospital pharmacies may still be assessing their ability to fully comply with the applicable practice standards for compounding sterile preparations. Source: Response for the Senate staff survey from the Florida Society of Health-System Pharmacists, Inc., dated September 12, 2008.

[47] See <http://www.pcab.org/find-a-pharmacy.shtml#fl> (Last visited on September 23, 2008).

Conclusion

Although contrary to the FDCA, and whether or not the compounding provisions in the FDAMA are determined by the courts to be valid, the FDA appears to have opened the door through the exercise of enforcement discretion for state law to authorize, in a limited manner with adequate safeguards, pharmacies to compound medications for a practitioner's office use. If the Legislature determines that the need for and benefits from this activity outweigh the associated risks,[48] in addition to providing parameters consistent with the factors the FDA considers in determining whether to exercise enforcement discretion, several key statutory provisions would need to be addressed and possibly amended, including but not limited to providing for:

- Compounding practice standards and accreditation to help ensure patient safety;
- Modification of the definition of an adulterated drug so that the compounded preparation does not run afoul of the adulteration provisions;
- Labeling conventions so that the compounded preparation is not misbranded;
- A new permit to authorize the compounding pharmacy to engage in the wholesale distribution of compounded preparations to a practitioner for office use; and
- Exempting the wholesale distribution of compounded preparations to a practitioner for office use from certain recordkeeping requirements or providing for specific recordkeeping provisions related to the wholesale distribution of prescription drugs.

[48] In addition to risk of direct or indirect physical harm to the patient, there may also be financial risk to third party payers related to inappropriate billing for a compounded medication, such as using a "similar" commercially available product's billing code to effectuate payment.

Florida Healthy Kids Corporation

Assuring access to quality health care services for Florida's children

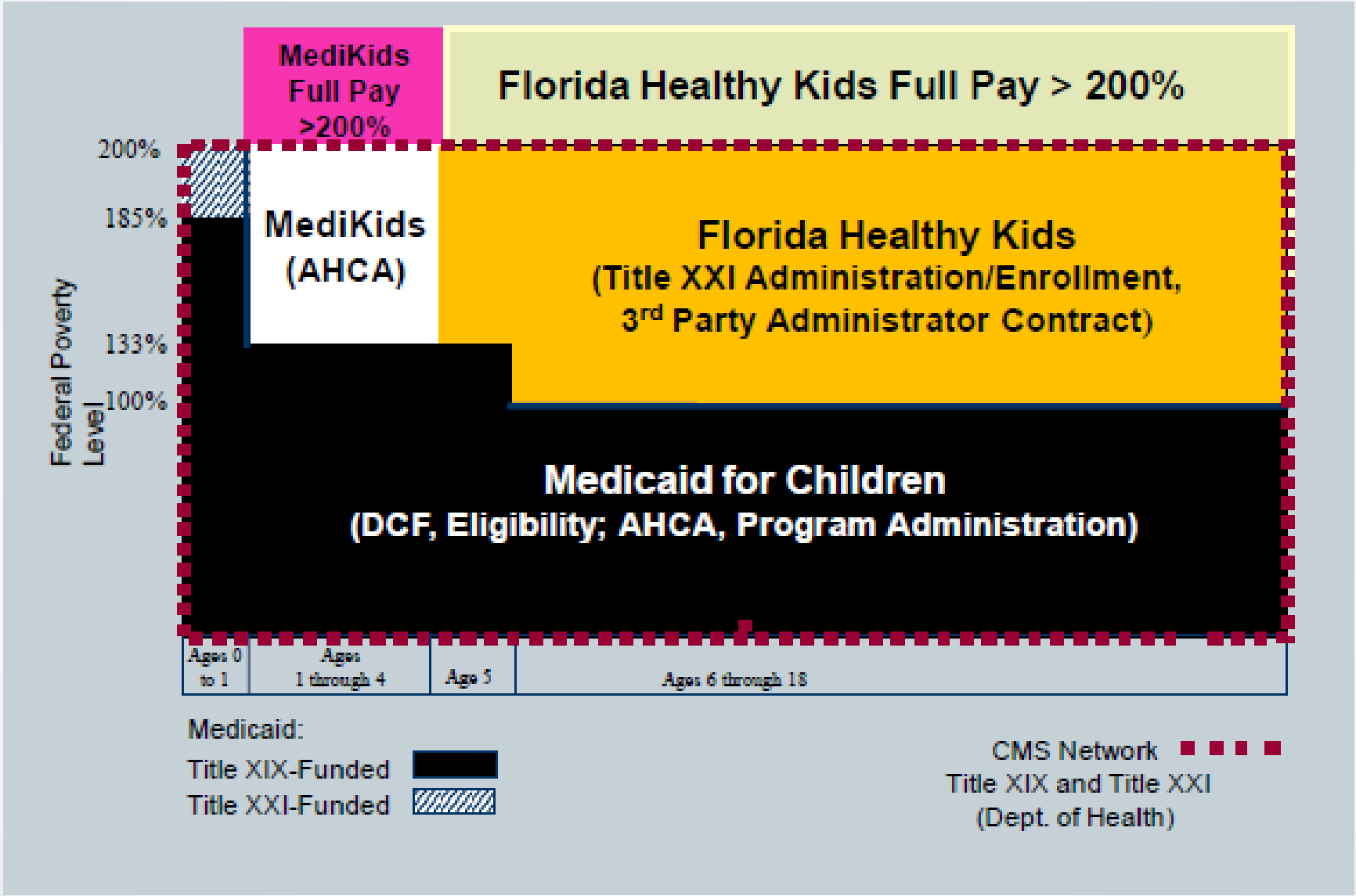
Florida KidCare

Through Florida KidCare, the state of Florida offers comprehensive health insurance for children from birth through age 18, even if one or both parents are working.

Families qualify for Florida KidCare based on age and family income through one of the following programs:

- **MediKids**: 1-4 years
- **Florida Healthy Kids**: 5-18 years
- **Children's Medical Services Network:** Birth-18 years, with special health care needs
- **Medicaid**: Age-based eligibility tied to federal poverty level

Florida KidCare Eligibility



Third Party Administrator (TPA) Transition

- Transitioned from Xerox to Maximus as new third party administrator in October 2013
- Operations handled out of Fort Pierce, Florida
- More than 300 staff members
- TPA transition yielding **savings of $15 million** to the state of Florida

CHIP Administration

- KidCare application intake
- Eligibility determination and verification
- Enrollment
- Subsidy determination
- Premium collection
- Customer service call center operations

New System Capabilities

- System architecture allows flexibility for modifications made necessary by Affordable Care Act (ACA)
- Families will experience more automated service and reduced processing time
- Simplification of notices to families reviewed by Maximus' Center for Health Literacy
- System's capabilities will enhance retention

Transition to Date

Call Volume

- **384,206 calls** to customer service reps *(equal to 4.5 months' typical volume)*
- **182,481 calls** answered within 60 seconds

Workload

- **296,799 total individual work items**
- **1,949 items** currently in queue to be processed
- **Less than 3 days**: oldest work item

Mail Volume

- **45,910 faxes**
- **14,491 emails**
- **98,356 envelopes**

ACA Modifications

Specific requirements for CHIP programs include:

- Accept new ACA data fields
- Medicaid eligibility check
- Account transfer functionality
- Verification service call through DCF to federal (hub) and state Partners
- Eligibility service call to DCF MAGI Rule Engine

ACA Transition Children

- Children currently in CHIP under 138% FPL will move to Medicaid
- Number of children moved estimated at 50,000+
- Transition is optional until August 1, 2014
- Transition completed by December 31, 2014, as families renew coverage
- New enrollees will be enrolled in Medicaid

Thank You!

Rich Robleto, Executive Director,
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HealthyKids™

To assure access to quality health care services for Florida's children.

WHO WE ARE

The Florida Healthy Kids Corporation (FHKC) is Florida's low-cost, high-quality health insurance marketplace for children ages 5-18.

Healthy Kids is a public-private partnership created to improve access to comprehensive health insurance for Florida's children. It has a 20-plus-year history of success.

Along with MediKids (1-4 years), Children's Medical Services Network/ CMSN (birth through 18 with special health care needs) and Children's Medicaid (age-based eligibility tied to Federal Poverty Level), Healthy Kids is one of the four programs that make up Florida KidCare.

Healthy Kids enrollees have comprehensive benefits, a choice between at least two different health and dental plans, and a regular commercial insurance ID card.

WHAT WE DO

Florida Healthy Kids oversees the administration of health care for FHK, MediKids and Children's Medical Services Network enrollees.

Florida Healthy Kids is responsible for all application intake, eligibility (non-Medicaid only), enrollment, subsidy determinations, premium collection and customer service call center operations.

Florida Healthy Kids prioritizes customer satisfaction and efficiency by continuously monitoring quality of health and dental plan performance.

WHAT STILL NEEDS TO BE DONE

Florida continues to make strides in getting kids covered, and ranked in the **top 3 states** for reducing the number of uninsured children and 6th in reducing the percentage of uninsured from 2010-2012.* However, there is still much work that needs to be done.

According to a national study, almost **70% of U.S. children** are actually eligible for coverage through Medicaid or the Children's Health Insurance Program (CHIP)*, but haven't been enrolled.

Florida currently has approximately **436,000 uninsured children***. Applying the national rate here, that means in Florida today there are approximately **more than 300,000 uninsured children** currently eligible for Medicaid or CHIP.

**Georgetown University Health Policy Institute's Center for Children and Families*

FLORIDA HEALTHY KIDS BY THE NUMBERS

- **$30,000,000** is paid out to health and dental plans monthly by Florida Healthy Kids
- **$26,000,000** in Federal and State funds are managed monthly by Florida Healthy Kids
- **$7,500,000** in premium funds are collected per month
- **300,000** children are covered through Florida Healthy Kids
- **90,000** phone calls are handled through the call center monthly
- **17,000** new applications are processed monthly
- **13,000** renewal applications are processed monthly
- **200%** of the Federal Poverty Level allows premiums to be $15 or $20 per family
- **$149** is the full-pay price for non-subsidized Florida Healthy Kids coverage
- **87%** of Florida Healthy Kids families receive subsidized coverage
- **85%** medical loss ratio requirement ensures that premiums go toward family services
- **67** Florida counties are receiving comprehensive coverage from Florida Healthy Kids
- **12%** of Florida Healthy Kids families receive full-pay coverage
- **7** health plans are managed through Florida Healthy Kids, all competitively bid
- **3** statewide dental plans are managed through Florida Healthy Kids, all competitively bid

HealthyKids™

HOW FLORIDA KIDCARE WORKS

Florida Healthy Kids is one of four programs that make up Florida KidCare. Through Florida KidCare, the state of Florida offers health insurance for children from birth through age 18, even if one or both parents are working.

When families apply for the insurance, they will be assigned to one of the following Florida KidCare programs based on age and family income:

- MediKids: 1-4 years
- Florida Healthy Kids: 5-18 years
- Children's Medical Services Network (CMSN): Birth-18 years, with special health care needs
- Medicaid: age-based eligibility tied to Federal Poverty Level

All Florida KidCare programs, including Florida Healthy Kids, cover doctor visits, checkups, immunizations, surgeries, prescriptions, emergencies, dental care and more.

Many Florida Healthy Kids and Florida KidCare families pay as little as $15 or $20 a month, but most families pay nothing at all. Families that don't qualify for subsidized coverage can utilize the full-pay option.

Florida KidCare continues to bring tangible cost savings and an affordable peace of mind to parents across Florida.

HIGHLIGHTS:

- Combined, the four Florida KidCare programs administered by Florida Healthy Kids provided coverage in 2013 for more than 2.1 million children who otherwise would not have insurance – a 3% gain from the previous year.
- Compared to the previous year, the programs received more than 7,900 additional applications in 2013, a 4.3% increase.
- The Florida Healthy Kids program grew by more than 2.3% in the last year, and now serves 300,000 children in our great state.
- 97% of Florida KidCare families say they agree that the small monthly premium is worth the peace of mind they receive from knowing their children have access to needed health insurance coverage and services.
- 95% of Florida KidCare families say they feel good about paying for part of their children's health insurance coverage.

THE VALUE OF HEALTH INSURANCE

Many families pay only **$15 or $20 a month** for Florida KidCare coverage, and most pay nothing at all. Full-pay options are also available for those who don't qualify for subsidized coverage.

Some Examples	With FKC Insurance*	Without Insurance**
Antibiotic Prescription Doxycycline hyclate er 30-day supply	$5	$410
Arm Cast	$5	$163
Ambulance Ride	$10	$2,000
Removal of Tonsils or Appendix 2 days in hospital	$5	$1,087
Chest X-Ray	Free	$44

*MediKids, Medicaid and CMSN do not charge copays **Source: Healthcare Blue Book

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CourtSmart Tag Report

Room: KN 412 **Case:** **Type:**
Caption: Senate Health Policy Committee **Judge:**

Started: 1/8/2014 4:03:26 PM
Ends: 1/8/2014 6:00:45 PM Length: 01:57:20

4:03:37 PM Opening Remarks by Chair
4:04:29 PM Roll Call
4:04:54 PM Tab #2 - SB 268 by Senator Grimsley
4:07:52 PM AM 756214 - Strike all
4:08:19 PM AM 391926 Tech Amendment to AM 756214
4:08:35 PM AM 391926 Adopted
4:08:59 PM AM 667212 Tech Amendment to AM 756214
4:09:12 PM AM 667212 Adopted
4:09:22 PM AM 756214 Strike All as Amended
4:09:50 PM Chair asks if objection to the strike all?
4:10:03 PM No objection and strike all is adopted
4:10:16 PM Sen. Joyner has question
4:10:20 PM Chair Responds
4:10:42 PM Public Testimony - Carol A. Berkowitz, Esq., Sr. Dir., Legal & Regulatory Affairs, LeadingAge, FL
4:11:01 PM Carol Berkowitz waives testimony in support
4:11:06 PM Tony Marshall, Sr. Dir., of Reimbursement, FL Health Care Assoc. - waives in support
4:11:11 PM Jack McRay, AARP, waives testimony in support
4:11:13 PM Chris Hudson, Foundation for Gov't Accountability, waives testimony in support
4:11:22 PM Chair taking questions, comments or thoughts
4:11:27 PM Sen. Joyner has a question
4:11:55 PM Sen. Grimsley responds
4:12:52 PM Chair
4:13:52 PM Sen. Garcia has question
4:13:59 PM Sen. Grimsley responds
4:14:22 PM Sen. Garcia continues
4:14:26 PM Sen. Grimsley responds and waives close
4:14:44 PM Motion for a Committee Substitute
4:15:00 PM Roll Call on CS/SB 268 Favorable
4:16:03 PM Tab #1 - Sen. Sobel presents SB 248 re Assisted Living Facilities
4:19:13 PM Sub AM #730014
4:19:30 PM Sen. Sobel explains 730014
4:20:35 PM AM 730014 Adopted
4:20:44 PM AM 877366 - strike all
4:20:56 PM AM 877366 adopted as amended
4:21:20 PM Public Testimony - Carol A. Berkowitz, Esq., Sr. Dir., Legal & Regulatory Affairs, LeadingAge, FL
4:22:04 PM Jack McRay, AARP, waives testimony in support
4:22:28 PM Testimony: Brian Jogerst, FL Health Care Assoc.
4:22:37 PM Testimony: Bobby Brantley, FL Lifecare Resident Assoc. (FLICRA)
4:23:18 PM Testimony: Brian Pitts, Justice-2-Jesus
4:26:03 PM Chair asks for debate or comment
4:26:12 PM Sen. Sobel closes
4:27:28 PM Sen. Joyner moves CS - no objection
4:27:44 PM Chair directs Admin. Asst. to Call Roll on CS/SB 248
4:27:57 PM Roll Call on CS/SB 248 - Favorable
4:27:58 PM Chair
4:28:08 PM TAB #3 - SB 344 by Sen. Flores - Dentists; Estab. Dental Student Loan Repayment Prog.
4:28:47 PM Chair
4:28:56 PM Public Testimony - Brian Pitts, Justice 2 Jesus
4:31:10 PM Casey Stoutamire, Lobbyist, FL Dental Assoc. - waives testimony in support
4:31:47 PM Sen. Flores waives close
4:31:53 PM Roll Call on SB 344 - Favorable
4:32:13 PM Tab #4 - SB 340 by Sen. Flores - Prepaid Dental Plans

4:38:04 PM Chair asks for questions from Senators
4:38:08 PM Sen. Joyner has question
4:38:52 PM Sen. Flores responds
4:39:06 PM Sen. Joyner - money in terms of dental care for children
4:39:32 PM Sen. Flores responds
4:40:31 PM Sen. Joyner
4:40:42 PM Sen. Flores responds
4:42:03 PM Sen. Garcia makes comment about dental program
4:42:35 PM Sen. Joyner asks question about implementation
4:43:09 PM Sen. Flores
4:43:47 PM Sen. Joyner follow-up
4:44:26 PM Sen. Flores responds
4:45:02 PM Sen. Joyner
4:45:27 PM Chair asks for further questions
4:45:37 PM Sen. Grimsley has question
4:46:08 PM Testimony by Michael Garner, VP Gov't Relations, Amerigroup
4:50:17 PM Sen. Garcia has question
4:50:41 PM Mr. Garner responds
4:50:53 PM Sen. Garcia
4:51:10 PM Mr. Garner responds
4:51:47 PM Sen. Grimsley has question re Medicaid Reform
4:52:22 PM Mr. Garner responds
4:53:12 PM Sen. Flores
4:53:25 PM Mr. Garner responds
4:53:53 PM Sen. Flores
4:54:08 PM Mr. Garner responds
4:54:24 PM Testimony by John Carvelli, Ex, VP Liberty Dental Plan of FL
4:57:35 PM Sen. Flores has question
4:57:46 PM Mr. Carvelli responds
4:58:01 PM Sen. Flores asks questions about other states
4:58:17 PM Mr. Carvelli responds
4:58:32 PM Sen. Flores comments
4:58:57 PM Mr. Carvelli responds
4:59:11 PM Sen. Joyner asks about date
5:00:44 PM Chair makes comments
5:00:44 PM Chair continues
5:00:57 PM Sen. Joyner
5:01:05 PM Mr. Carvelli responds
5:01:10 PM Beth Nunnally, VP External Relations, Sunshine Health
5:04:50 PM Sen. Flores has question re $10 co-pay
5:05:13 PM Ms. Nunnally responds
5:05:52 PM Sen. Flores has a follow-up re Medicaid benefit
5:06:43 PM Sen. Flores
5:07:08 PM Ms. Nunnally responds
5:07:48 PM Sen. Flores has a question about network
5:08:04 PM Ms. Nunnally responds
5:08:46 PM Brian Pitts, Justice 2 Jesus
5:11:58 PM Casey Stoutamire, FL Dental Assoc.
5:13:18 PM Audrey Brwn, Pres./CEO FL Assoc. of Health Plans
5:15:54 PM Sen. Joyner has question
5:16:50 PM Sen. Flores has question
5:17:43 PM Ms. Brown responds
5:17:58 PM Sen. Flores comments
5:18:24 PM House Chair with comments
5:21:44 PM House Chair with comments
5:22:44 PM Debate
5:22:49 PM Sen. Joyner
5:22:58 PM Chair recognizes Sen. Dudeck
5:23:34 PM Sec. Dudeck
5:23:59 PM Sec. Dudeck
5:24:20 PM Sen. Joyner has question
5:24:31 PM Sec. Dudeck responds

5:25:49 PM Sen. Joyner
5:26:11 PM Sec. Dudeck responds
5:26:42 PM Sec. Dudeck responds
5:26:49 PM Sen. Joyner
5:27:11 PM Sec. Dudeck responds to Sen. Joyner
5:27:59 PM Sen. Sobel has question about Managed Care Plan
5:29:06 PM Sen. Flores responds
5:29:23 PM Chair asks for debate or questions
5:29:32 PM Sen. Brandes asks to be recorded fav on missed bills
5:29:53 PM Sen. Galvano has comments
5:31:41 PM Sen. Brandes has comments
5:31:53 PM Sen. Joyner comments
5:35:11 PM Sen. Sobel comments
5:36:15 PM Sen. Flores closes on SB 340
5:38:25 PM Roll Call on SB 340
5:38:38 PM Chair - SB 340 Favorable
5:38:58 PM Tab #5 SB 380 by Sen. Bean
5:39:11 PM Sen. Bean presents SB 380
5:40:15 PM AM 441014
5:40:43 PM Testimony by Marc Inglese, FMA waives in support
5:40:59 PM Brian Pitts, Just 2 Jesus
5:42:24 PM Amy Young, waives in support
5:42:42 PM Sub AM 604616 adopted
5:43:06 PM Sen. Garcia has question re 120 days
5:43:38 PM Sen. Bean responds
5:44:04 PM Sen. Garcia
5:44:18 PM Sen. Bean responds
5:44:55 PM Sen. Garcia
5:45:39 PM Sen. Sobel comments
5:46:41 PM Sen. closes on SB 380
5:47:19 PM Motion for CS
5:47:27 PM Roll Call on CS/SB 380
5:47:45 PM Favorable - SB 380
5:47:53 PM Chair Bean has comments
5:48:40 PM Rich Robleto, Executive Director, Florida Healthy Kids-presentation on CHIP
6:00:02 PM Comments by Chair Bean
6:00:07 PM Meeting adjourned