The Florida Senate

COMMITTEE MEETING EXPANDED AGENDA

HEALTH REGULATION
Senator Garcia, Chair
Senator Sobel, Vice Chair

MEETING DATE: Thursday, February 9, 2012
TIME: 1:15 —3:15 p.m.
PLACE: *Pat Thomas Committee Room,* 412 Knott Building

MEMBERS: Senator Garcia, Chair; Senator Sobel, Vice Chair; Senators Diaz de la Portilla, Fasano, Gaetz, Jones, and Norman; EX OFFICIO: Senator Bennett

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
1	**SB 1316** Gaetz (Compare CS/H 653, CS/CS/H 943, H 1091, CS/CS/S 208, CS/S 320, CS/S 1884)	Health Care; Revising the fine that may be imposed against a home health agency for failing to timely submit certain information to the Agency for Health Care Administration; authorizing the agency to review and analyze information from sources other than Medicaid-enrolled providers for purposes of determining fraud, abuse, overpayment, or neglect; authorizing the agency and the Medicaid Fraud Control Unit to review certain records; requiring the agency to submit a report to the Legislature on adverse incident reports from assisted living facilities; revising the federal offenses for which the Department of Health must issue an emergency order suspending the license of certain health care professionals; requiring the agency to prepare a report for public comment and submission to the Legislature following the expansion of services to new populations or of new services, etc. HR 01/31/2012 Temporarily Postponed HR 02/09/2012 Fav/CS BC	Fav/CS Yeas 5 Nays 3
2	**SB 1506** Thrasher (Similar CS/CS/H 385, Compare S 614)	Medical Malpractice; Providing that the claimant has the burden of proving by clear and convincing evidence that the actions of a health care provider represented a breach of the prevailing professional standard of care in an action for damages based on death or personal injury which alleges that the death or injury resulted from the failure of a health care provider to order, perform, or administer supplemental diagnostic tests; requiring that the Department of Health issue an emergency order suspending the license of any licensee under the department's jurisdiction who fails to indemnify the state or enter into a repayment agreement; providing for disciplinary action for licensees in the Division of Medical Quality Assurance of the department, etc. HR 02/09/2012 Fav/CS JU BC	Fav/CS Yeas 4 Nays 3

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
3	**CS/SB 1516** Children, Families, and Elder Affairs / Negron (Compare H 991, S 460)	Agency for Persons with Disabilities; Clarifying provisions relating to eligibility requirements based on citizenship and state residency; requiring the agency to promote partnerships and collaborative efforts to enhance the availability of nonwaiver services; revising provisions relating to eligibility under the Medicaid waiver redesign; providing criteria for calculating a client's initial iBudget; providing that facilities that are accredited by certain organizations must be inspected and reviewed by the agency every 2 years; providing limitations on the amount of cost sharing which may be required of parents for home and community-based services provided to their minor children, etc. CF 01/25/2012 Fav/CS HR 01/31/2012 Temporarily Postponed HR 02/09/2012 Fav/CS BC	Fav/CS Yeas 7 Nays 0
4	**SB 1350** Sobel (Identical H 1073)	Cancer Control; Revising legislative intent to delete provisions relating to research activities for cancer control; changing the name of the cancer control and research advisory council to the Florida Cancer Control and Resource Advisory Council; providing for the appointment and terms of council members and duties of the council; providing duties of the council for the development, review, and approval of the Florida Cancer Plan; deleting responsibilities of the council and the Board of Governors of the State University System relating to cancer research, etc. HR 02/09/2012 Fav/CS BC	Fav/CS Yeas 7 Nays 0

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
5	**SB 1808** Storms (Similar H 1405)	Provision of Psychotropic Medication to Children in Out-of-home Placements; Requiring that children placed in out-of-home care receive a comprehensive behavioral health assessment; specifying eligibility; prescribing duties for the Department of Children and Family Services; requiring that a guardian ad litem be appointed by the court to represent a child in the custody of the Department of Children and Family Services who is prescribed a psychotropic medication; requiring that a court authorize the administration of psychotropic medication to a child who is in shelter care or in foster care and for whom informed consent from the parents or a legal guardian has not been obtained; specifying circumstances under which the department may provide psychotropic medication to a child before court authorization is obtained; requiring that the department inform the court of a child's medical and behavioral status at each judicial hearing, etc. CF 01/25/2012 Favorable HR 02/09/2012 Favorable BC	Favorable Yeas 7 Nays 0
6	**SB 282** Wise (Identical H 279)	Health Care Transition/Adolescents and Young Adults/Special Health Care Needs; Establishing a program within the Division of Children's Medical Services Network in the Department of Health to implement health care transition programs for adolescents and young adults who have special health care needs; requiring the Department of Health, in partnership with the Agency for Health Care Administration, to identify options for addressing the compensation of health care providers and improving access to adult and specialty health care for adolescents and young adults who have special health care needs; requiring the Department of Health to work with community-based pediatric and adult health care providers to explore and recommend the development of local health and transition services programs in each of the regions of the Children's Medical Services Network, etc. HR 02/09/2012 Fav/CS CF BC	Fav/CS Yeas 7 Nays 0

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
7	**SB 1474** Gibson (Similar H 167)	Public Health; Creating the expedited partner therapy pilot project in Duval and Gadsden Counties; providing an exemption from specified rules and statutory requirements for the pilot program; providing for training of physicians and patient education; requiring the pilot project to be funded by the existing budget of the pilot project area or by developing partnerships; providing for the use of funds, etc. HR 02/09/2012 Favorable BC	Favorable Yeas 7 Nays 0
8	**SB 1378** Altman (Identical H 983)	Payment for Services Provided by Licensed Psychologists; Adding licensed psychologists to the list of health care providers who are protected by a limitations period from claims for overpayment being sought by health insurers or health maintenance organizations; adding licensed psychologists to the list of health care providers who are subject to a limitations period for submitting claims to health insurers or health maintenance organizations for underpayment; adding licensed psychologists to the list of health care providers who are eligible for direct payment for medical services by a health insurer under certain circumstances, etc. HR 02/09/2012 Not Considered BI BC	Not Considered
9	**SB 1228** Montford (Similar CS/CS/H 799)	Practice of Physical Therapy; Requiring the Board of Physical Therapy Practice within the Department of Health to issue a temporary permit authorizing a person to practice as a physical therapist or physical therapist assistant under certain conditions; prohibiting the board from renewing a temporary permit to practice as a physical therapist or physical therapist assistant; requiring that a person who has a current temporary permit to practice as a physical therapist or physical therapist assistant receive direct supervision at all times from a physical therapist; prohibiting the supervising physical therapist from supervising more than one physical therapist or physical therapist assistant, etc. HR 02/09/2012 Fav/CS BC	Fav/CS Yeas 7 Nays 0
10	**SB 1750** Siplin (Identical H 1195)	Advanced Registered Nurse Practitioners; Authorizing advanced registered nurse practitioners to initiate involuntary examinations under the Baker Act of persons believed to have mental illness, etc. HR 02/09/2012 Not Considered BC	Not Considered

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
11	**SB 1294** Garcia	Florida Kidcare Program; Deleting a provision preventing children who do not meet the definition of a qualified alien from participating in the program, etc. HR 02/09/2012 Not Considered BC	Not Considered
12	**SB 1006** Latvala	Prescription Drug Wholesale Regulations; Requiring the Department of Health to issue a permit by endorsement to an out-of-state prescription drug wholesale distributor that meets certain requirements; authorizing out-of-state wholesale distributors holding a valid permit to continue to operate under that permit until its expiration, etc. HR 02/09/2012 Not Considered CM BC	Not Considered
13	**SB 1594** Garcia (Identical H 1311)	Surgical First Assistants; Providing requirements for the performance of supervising physicians; providing the duties and scope and location of practice for certified surgical first assistants; providing contracting and employment guidelines for physicians, hospitals, clinics, or ambulatory surgical centers employing certified surgical first assistants; providing that an unlicensed person who holds himself or herself out as, or indicates or implies that he or she is, licensed commits a third-degree felony and is subject to applicable penalties; providing for payments to a physician assistant under contracts providing for payment for surgical first assisting benefits or services, etc. HR 02/09/2012 Not Considered BC	Not Considered
	Other Related Meeting Materials		

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 Health Regulation Committee

BILL: CS/SB 1316

INTRODUCER: Health Regulation Committee and Senator Gaetz

SUBJECT: Health Care

DATE: February 11, 2012 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Wilson	Stovall	HR	**Fav/CS**
2.			BC	
3.				
4.				
5.				
6.				

Please see Section VIII. for Additional Information:

A. COMMITTEE SUBSTITUTE.....	X	Statement of Substantial Changes
B. AMENDMENTS.....		Technical amendments were recommended
		Amendments were recommended
		Significant amendments were recommended

I. Summary:

This bill modifies existing statutory provisions relating to health care fraud, particularly in the Florida Medicaid program. These modifications include the following:

- Reducing the penalty for home health agencies that fail to timely file certain reports;
- Adding specified offenses for which persons rendering care under the Medicaid consumer-directed care program must be screened and rescreened;
- Requiring Medicaid providers to retain all medical and Medicaid-related records for 6 years rather than the current 5-year retention period;
- Requiring Medicaid providers to report a change in any principal of the provider to the Agency for Health Care Administration (AHCA) in writing no later than 30 days after the change occurs;
- Defining the term "administrative fines" for purposes of liability of parties for payment of such fines in the event of a change of ownership;
- Authorizing the AHCA to conduct onsite inspections of the service location of a provider applying for a provider agreement, before entering into a provider agreement with that provider, to determine the provider's ability to provide services in compliance with the Medicaid program and professional regulations;

- Amending the surety bond requirements for certain Medicaid providers to clarify that the additional bond required by the Agency, if a provider's billing during the first year exceeds the bond amount, need not exceed $50,000 for certain providers;
- Removing certain exceptions to background screening requirements for Medicaid providers;
- Including participants in a Medicaid managed care provider network in the definition of "Medicaid provider" for purposes of oversight of the integrity of the Medicaid program;
- Authorizing the AHCA to review and analyze information from sources other than enrolled Medicaid providers in conducting investigations of potential fraud, abuse, overpayment or recipient neglect;
- Expanding the list of offenses for which the AHCA must terminate the participation of a Medicaid provider in the Medicaid program;
- Requiring the AHCA to impose the sanction of termination for cause against a provider that voluntarily relinquishes its Medicaid provider number under certain circumstances;
- Requiring the AHCA, when it is making a determination that an overpayment has occurred, to base its determination solely upon information available to it before issuance of the audit report and upon contemporaneous records;
- Removing a requirement that the AHCA pay interest at the rate of 10 percent a year on provider payments that have been withheld under suspicion of fraud or abuse, if it is determined that there was no fraud or abuse;
- Requiring overpayments and fines to be paid within 30 days after a final order;
- Clarifying the scope of the immunity from civil liability for persons who provide the state with information about fraud or suspected fraudulent acts by a Medicaid provider; and
- Modifying the grounds under which a professional board or the Department of Health (DOH) must refuse to admit a candidate to an examination and refuse to issue or renew a license, certificate, or registration of a health care practitioner.

The bill reinstates certain statutory provisions that previously were repealed. The reinstated provisions include:

- The submission by the AHCA of an annual report on adverse incidents reported by assisted living facilities; and
- Medical examinations and mental health evaluations of residents of assisted living facilities who appear to need care beyond that which the facility is licensed to provide.

The bill includes the following new provisions:

- Changes the definition of "accrediting organizations" for purposes of the regulation of hospitals and ambulatory surgical centers;
- Provides additional exemptions from licensure and regulation as a health care clinic for the following:
  - Pediatric cardiology or perinatology clinic facilities or anesthesia clinical facilities; and
  - Certain publicly traded entities;
- Imposes restrictions on the techniques used by Medicaid managed care plans to manage the use of prescribed drugs by enrollees;
- Requires allopathic and osteopathic physicians who perform certain liposuction procedures to register their offices with the DOH and be subject to inspection by the DOH;
- Authorizes a virtual inventory for certain prescription drugs that were purchased under the 340B program;

- Expands the types of ocular pharmaceutical agents that certified optometrist may administer and prescribe, including some controlled substances;
- Requires optometrists to report adverse incidents to the DOH;
- Authorizes optometrists to operate clinical laboratories;
- Requires clinical laboratories to accept specimens for examination from optometrists;
- Requires a medical negligence claimant to prove by clear and convincing evidence that the actions of a health care provider represented a breach of the prevailing professional standard of care in an action for damages based on death or personal injury which alleges that the death or injury resulted from the failure of a health care provider to order, perform, or administer supplemental diagnostic tests;
- Authorizes informal discovery to be used in ex parte interviews;
- Authorizes certain health care providers and their patients to enter into voluntary binding arbitration agreements and limit damages; and
- Requires the AHCA to report on the impact of the implementation of an expansion of managed care to new populations or the provision of new items and services.

This bill substantially amends the following sections of the Florida Statutes: 395.002, 400.474, 400.9905, 409.221, 409.907, 409.913, 409.920, 409.967, 429.23, 429.26, 456.036, 456.0635, 456.074, 458.309, 459.005, 463.002, 463.005, 463.0055, 463.0057, 463.006, 463.0135, 463.014, 483.035, 483.041, 483.181, 499.003, 766.102, 766.106, 893.02, and 893.05.

The bill also creates ss. 463.0141 and 766.1091, F.S., and one undesignated section of law.

II. Present Situation:

Regulation of Hospitals, Ambulatory Surgical Centers, and Mobile Surgical Facilities

Part I of ch. 395, F.S., provides for the licensure and regulation of hospitals, ambulatory surgical centers, and mobile surgical facilities by the AHCA. Section 395.0161, F.S., specifies the types of inspections and investigations of these facilities that the AHCA may conduct. The law requires the AHCA to accept, in lieu of its own periodic inspections for licensure, the survey or inspection of an accrediting organization, provided the accreditation of the licensed facility is not provisional and provided the licensed facility authorizes release of, and the AHCA receives, the report of the accrediting organization. The law recognizes the following accrediting organizations for ch. 395, F.S.:

- Joint Commission on Accreditation of Healthcare Organizations;
- American Osteopathic Association;
- Commission on Accreditation of Rehabilitation Facilities; and
- Accreditation Association for Ambulatory Health Care, Inc.[1]

Section 1865(b)(1) of the Social Security Act permits Medicare providers and suppliers "accredited" by an approved national accreditation organization to be exempt from routine surveys by State survey agencies to determine compliance with Medicare conditions. As of April 2011, the Centers for Medicare and Medicaid Services had approved the following accreditation organizations for hospitals and ambulatory surgical centers:

[1] *See* s. 395.002(1), F.S.

- Joint Commission;
- DNV Healthcare;
- American Osteopathic Association/Healthcare Facilities Accreditation Program;
- American Association for Accreditation of Ambulatory Surgery Facilities; and
- Accreditation Association for Ambulatory Health Care.[2]

Health Care Fraud

In 2009, the Legislature passed CS/CS/CS/SB 1986, a comprehensive bill designed to address systemic health care fraud in Florida. That bill increased the Medicaid program's authority to address fraud, particularly as it relates to home health services; increased health care facility and health care practitioner licensing standards to keep fraudulent actors from obtaining a health care license in Florida; and created disincentives to commit Medicaid fraud by increasing the administrative penalties for committing Medicaid fraud, posting sanctioned and terminated Medicaid providers on the AHCA website, and creating additional criminal felonies for committing health care fraud; among other anti-fraud provisions.[3]

With over 2 years of experience with the implementation of CS/CS/CS/SB 1986, some changes have been identified that would enhance Florida's efforts to prevent health care fraud and abuse and to effectively counter fraud and abuse that does occur. This bill addresses some of the practical effects of CS/CS/CS/SB 1986: provisions that appear to be too onerous, gaps in enforcement authority, and consumer protections that were repealed that maybe should have been retained.

Home Health Agency Regulation

Home health agencies are licensed and regulated by the AHCA under the authority of part III of ch. 400, F.S. Section 400.474, F.S., authorizes the AHCA to deny, revoke, or suspend the license of a home health agency and requires the AHCA to impose a $5,000 fine against a home health agency that commits certain acts. One of these acts is the failure of the home health agency to submit a report, within 15 days after the end of each calendar quarter, which includes the following information:

- The number of insulin dependent diabetic patients receiving insulin-injection services from the home health agency;
- The number of patients receiving both home health services from the home health agency and hospice services;
- The number of patients receiving home health services from that home health agency; and
- The names and license numbers of nurses whose primary job responsibility is to provide home health services to patients and who received remuneration from the home health agency in excess of $25,000 during the calendar quarter.

[2] Centers for Medicare and Medicaid Services, *CMS-Approved Accreditation Organization Contact Information*, April 2011. Found at: <https://www.cms.gov/SurveyCertificationGenInfo/Downloads/AOContactInformation.pdf> (Last visited on February 7, 2012).
[3] *See* ch. 2009-223, Laws of Florida.

These data items help identify possible fraud, such as billing for a high number of injection visits for insulin-dependent patients who could self-inject insulin, fraudulent billing for patients who did not receive the visits, possible duplicate payment for patients receiving both hospice and home health services, and nurses earning well above the average salary that could indicate false billing. The results of each quarter's reporting are shared with the U.S. Department of Health and Human Services Centers for Medicare and Medicaid Services' Medicare Program Integrity Miami Satellite Division, the AHCA's Medicaid Program Integrity Office, and the Medicare Fraud Investigations Manager at SafeGuard Services, LLC.

Regulation of Health Care Clinics

Health care clinics are regulated under part X of ch. 400, F.S. A clinic is defined as an entity at which health care services are provided to individuals and which tenders charges for reimbursement for such services, including a mobile clinic and a portable equipment provider. Subsection 400.9905(4), F.S., creates a number of exemptions from the clinic licensure requirements.

Medicaid

Medicaid is the medical assistance program that provides access to health care for low-income families and individuals. Medicaid also assists aged and disabled people with the costs of nursing facility care and other medical expenses. The AHCA is responsible for Medicaid. Medicaid serves approximately 3.19 million people in Florida. Estimated Medicaid expenditures for fiscal year 2011-2012 are approximately $20.3 billion. The statutory authority for the Medicaid program is contained in part III of ch. 409, F.S.

Medicaid reimburses health care providers that have a provider agreement with the AHCA only for goods and services that are covered by the Medicaid program and only for individuals who are eligible for medical assistance from Medicaid. Section 409.907, F.S., establishes requirements for Medicaid provider agreements, which include, among other things, background screening requirements, notification requirements for change of ownership of a Medicaid provider, records retention requirements, authority for AHCA site-visits of provider service locations, and surety bond requirements.

Under s. 409.912(37), F.S., the AHCA is required to implement a Medicaid prescribed-drug spending-control program that includes a preferred drug list (PDL), which is a listing of cost-effective therapeutic options recommended by the Medicaid Pharmaceutical and Therapeutics Committee established pursuant to s. 409.91195, F.S. The PDL is used to inform clinicians of effective products that provide favorable net costs to Medicaid. The PDL educates clinicians about cost effective choices in prescribing for Medicaid recipients, but clinicians always retain the option of selecting the drug product they feel is most appropriate for their patient by calling the Therapeutic Consultation Program. If the prescriber cannot readily obtain authorization the pharmacist may dispense a 72-hour supply. The pharmacist may also use his or her professional judgment if other situations arise that would necessitate a 72-hour emergency supply.[4]

[4] Medicaid Pharmaceutical and Therapeutics Committee, Agency for Health Care Administration. Found at: <http://ahca.myflorida.com/medicaid/Prescribed_Drug/pharm_thera/index.shtml> (Last visited on February 11, 2012).

Section 409.913, F.S., outlines provisions relating to the AHCA's responsibilities for oversight of the integrity of the Medicaid program, to ensure that fraudulent and abusive behavior and neglect of recipients occur to the minimum extent possible, and to recover overpayments and impose sanctions as appropriate.

Sections 409.920, 409.9201, 409.9203, and 409.9205, F.S., contain provisions relating specifically to Medicaid fraud. One of these is a provision that provides immunity from civil liability for a person who provides the State with information about fraud or suspected fraud by a Medicaid provider, including a managed care organization.[5]

Part IV of ch. 409, F.S., requires all Medicaid recipients to enroll in a managed care plan unless they are specifically exempted. The statewide Medicaid managed care program includes the long-term care managed care program and the managed medical assistance program. The law directs the AHCA to begin implementation of the long-term care managed care program by July 1, 2012, with full implementation in all regions of the State by October 1, 2013. By January 1, 2013, the AHCA must begin implementation of the managed medical assistance program, with full implementation in all regions of the State by October 1, 2014.

Section 409.967, F.S., establishes requirements for the accountability of managed care plans in the new statewide Medicaid managed care program, including requirements regarding coverage of prescription drugs. The AHCA is required to establish standards relating to access to care, which include the following statements regarding prescription drugs:

- The exclusive use of mail-order pharmacies may not be sufficient to meet network access standards.
- Each managed care plan must publish any prescribed drug formulary or preferred drug list on the plan's website in a manner that is accessible to and searchable by enrollees and providers.
- The plan must update the list within 24 hours after making a change.
- Each plan must ensure that the prior authorization process for prescribed drugs is readily accessible to health care providers, including posting appropriate contact information on its website and providing timely responses to providers.

These requirements will apply to all plans by October 1, 2014. Currently, operating Medicaid managed care plans may develop their own utilization and clinical protocols to manage drug costs, so long as they are ultimately no more restrictive than the Medicaid fee-for-service drug benefit. The contracts between the managed care plans and the AHCA specify requirements concerning access to the drug benefit.

Background Screening

Chapter 435, F.S., establishes standards for background screening for employment. Section 435.03, F.S., sets standards for Level 1 background screening. Level 1 background screening includes, but is not limited to, employment history checks and statewide criminal correspondence checks through the Department of Law Enforcement, and a check of the Dru

[5] *See* s. 409.920(8), F.S.

Sjodin National Sex Offender Public Website, and may include local criminal records checks through local law enforcement agencies.

Level 2 background screening includes, but is not limited to, fingerprinting for statewide criminal history records checks through the Department of Law Enforcement and national criminal history records checks through the Federal Bureau of Investigation. They may also include local criminal records checks through local law enforcement agencies. Section 435.04(2), F.S., lists the offenses that will disqualify an applicant from employment.

Section 409.809, F.S., establishes background screening requirements and procedures for entities licensed by the AHCA. The AHCA must conduct Level 2 background screening for specified individuals. Each person subject to this section is subject to Level 2 background screening every 5 years. This section of law also specifies additional disqualifying offenses beyond those included in s. 435.04(2), F.S.

Florida Consumer-Directed Care Act

The Florida Consumer-Directed Care Act[6] requires the AHCA to establish the consumer-directed care program for persons with disabilities who need long-term care services and who are enrolled in one of the Medicaid home and community-based waiver programs. These types of waiver programs offer services that allow frail elders and people with disabilities to receive long-term-care services in their homes or in the community to keep them from needing care in a nursing facility or intermediate care facility for the developmentally disabled. The purpose of the consumer-directed care program is to allow enrolled persons to choose the providers of services and to direct the delivery of services, to best meet their long-term care needs.

All persons who render care in the program are required to undergo Level 2 background screening pursuant to ch. 435, F.S. The Florida Consumer-Directed Care Act does not currently require re-screening and authorizes persons who have been subject to background screening and who have not been unemployed for more than 90 days following such screening to not be required to be rescreened. They must attest to not having been convicted of a disqualifying offense since completing screening.

Regulation of Assisted Living Facilities

Assisted living facilities are regulated under part I of ch. 429, F.S. Section 429.23, F.S., requires assisted living facilities to submit to the AHCA, within 1 day after the occurrence of an adverse incident, a preliminary report concerning the incident. The assisted living facility is also required to provide a more detailed report to the AHCA within 15 days after the incident. The AHCA collects and stores the data received from the adverse incident reports. The information is currently confidential and is not discoverable or admissible in any civil or administrative action, except in disciplinary proceedings by the AHCA or appropriate regulatory board. However, the AHCA does fill public record's requests for statistical information, but detailed information on an adverse incident is not provided.

[6] *See* s. 409.221, F.S.

Section 429.26, F.S., establishes requirements relating to the appropriateness of placements of individuals in assisted living facilities and examinations of residents in an assisted living facility. The AHCA requires that residents be examined only at admission, every 3 years, and after a "significant change." A significant change is defined in Rule 58A-35.0131(33), F.A.C.,[7] to mean a sudden or major shift in behavior or mood, or deterioration in health status such as unplanned weight change, stroke, heart condition, or stage 2, 3, or 4 pressure sores. The facility administrator is responsible for determining the appropriateness of placement. If the AHCA determines a resident is not appropriate based on observations and facility documentation, a facility is cited for the violation and required to take appropriate action to discharge the resident to a facility that can meet the resident's needs.

Health Care Practitioner Licensure Authority of the Department of Health

The DOH is responsible for the licensure of most health care practitioners in the state. Chapter 456, F.S., provides general provisions for the regulation of health care professions in addition to the regulatory authority in specific practice acts for each profession or occupation. Section 456.001, F.S., defines "health care practitioner" as any person licensed under:

- Chapter 457 (acupuncture),
- Chapter 458 (medical practice),
- Chapter 459 (osteopathic medicine),
- Chapter 460 (chiropractic medicine),
- Chapter 461 (podiatric medicine),
- Chapter 462 (naturopathy),
- Chapter 463 (optometry),
- Chapter 464 (nursing),
- Chapter 465 (pharmacy),
- Chapter 466 (dentistry),
- Chapter 467 (midwifery),
- Part I, part II, part III, part V, part X, part XIII, or part XIV of chapter 468 (speech-language pathology and audiology; nursing home administration; occupational therapy; respiratory therapy; dietetics and nutrition practice; athletic trainers; and orthotics, prosthetics, and pedorthics),
- Chapter 478 (electrolysis),
- Chapter 480 (massage practice),
- Part III or part IV of chapter 483 (clinical laboratory personnel and medical physicists),
- Chapter 484 (dispensing of optical devices and hearing aids),
- Chapter 486 (physical therapy practice),
- Chapter 490 (psychological services), and
- Chapter 491 (clinical, counseling, and psychotherapy services)

Current law[8] prohibits the DOH and the medical boards within the DOH from allowing any person to sit for an examination who has been:

[7] Found at: <https://www.flrules.org/gateway/RuleNo.asp?title=ASSISTED%20LIVING%20FACILITIES&ID=58A-5.0131> (Last visited on February 11, 2012).
[8] *See* s. 456.0635, F.S.

- Convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under ch. 409, F.S.,[9] ch. 817, F.S.,[10] ch. 893, F.S.,[11] 21 U.S.C. ss. 801-970,[12] or 42 U.S.C. ss. 1395-1396,[13] unless the sentence and any subsequent period of probation for such conviction or pleas ended more than 15 years prior to the date of the application;
- Terminated for cause from the Florida Medicaid program, unless the applicant has been in good standing with the Florida Medicaid program for the most recent 5 years; or
- Terminated for cause, pursuant to the appeals procedures established by the state or Federal Government, from any other state Medicaid program or the federal Medicare program, unless the applicant has been in good standing with a state Medicaid program or the federal Medicare program for the most recent 5 years and the termination occurred at least 20 years prior to the date of application.

The DOH and the medical boards must refuse to issue or renew a license, certificate, or registration if an applicant or person affiliated with that applicant has violated any of the provisions listed above. The DOH applies the denial of licensure renewals to offenses occurring after July 1, 2009, when the new provisions requiring denial of renewals went into effect. Neither the boards nor the DOH currently deny initial licensure or licensure renewal based upon termination for cause from the Medicare program, because no such termination exists in federal law. Federal law references mandatory and permissive exclusions.

Any individual who is seeking licensure must apply for licensure and meet the current requirements regardless of whether the applicant previously held a Florida license. If an applicant is required to have passed a licensure examination within a certain number of years prior to licensure, then an applicant whose test scores have "expired" would be required to re-test and pass the licensure examination. Between July 1, 2009, and November 22, 2011, 91 licensees have been denied renewal under s. 456.0635, F.S.

Optometrists and Ophthalmologists

Optometrists are the primary health care professionals for the eye. Optometrists examine, diagnose, treat, and manage diseases and injuries of the visual system as well as identify systemic conditions which affect visual health. Optometrists may prescribe certain medications, vision therapy, and corrective lenses but may not perform surgical procedures in Florida.[14]

Optometrist training involves an undergraduate degree and completion of a 4-year program at a college of optometry. Some optometrists complete residencies to gain more specialized knowledge, but residency training is not required for licensure or practice.[15]

[9] *See* ch. 409, F.S., "Social and Economic Assistance," is in Title XXX, "Social Welfare," and includes the Florida Medicaid and Kidcare programs, among other programs.
[10] *See* ch. 817, F.S., "Fraudulent Practices," is in Title XLVI, "Crimes."
[11] *See* ch. 893, F.S., "Drug Abuse Prevention and Control," is in Title XLVI, "Crimes."
[12] 21 U.S.C. ss. 801-970 create the Controlled Substances Act, which regulates the registration of manufacturers, distributors, and dispensers of controlled substances at the federal level.
[13] 42 U.S.C. ss. 1395-1396 create the federal Medicare, Medicaid, and Children's Health Insurance programs.
[14] *See* s. 463.014(4), F.S.
[15] American Optometric Association, *What is a Doctor of Optometry?* Found at: <http://www.aoa.org/x4891.xml> (Last visited on February 11, 2102).

Ophthalmologists are medical physicians who specialize in diseases of the eye. Ophthalmologists provide a full spectrum of eye care, from prescribing corrective lenses and medications to performing eye surgery. Ophthalmologists also care for patients with more advanced and complicated diseases than do optometrists. Ophthalmologist training involves an undergraduate degree, 4 years of medical school, and completion of at least 4 years of residency training in ophthalmology.[16]

Florida law requires optometrists who diagnose patients with certain diseases to refer such patients to ophthalmologists for further treatment.[17] Optometrists are also required to maintain the names of at least three physicians, clinics, or hospitals to which they may refer patients who experience adverse drug reactions.[18]

Administration of Medications by Optometrists

Licensed optometrists may administer and prescribe topical ocular pharmaceutical agents if they are appropriately certified by the Board of Optometry (the board). Such pharmaceuticals must be related to the diagnosis and treatment of ocular conditions and must not require surgery or other invasive techniques for administration. Medications approved for prescription by certified optometrists are listed in a formulary maintained by the board.[19,20]

To be certified for prescribing privileges, an optometrist must:[21]

- Complete at least 100 hours of board-approved coursework and clinical training in general and ocular pharmacology at an accredited institution. Such training may have been part of an optometry training program;
- Complete at least 1 year of supervised experience in differential diagnosis of eye disorders, which may occur during training or clinical practice;
- Pass part II of the National Board of Examiners in Optometry examination;[22] and
- Pay a $500 fee.[23]

Certification for prescribing privileges is a required component of the general licensure process for optometrists and has been so for the last 25 years.[24,25] Optometrists who are not certified may use topical anesthetics for glaucoma examinations.[26]

[16] American Academy of Ophthalmology, *About Ophthalmology and Eye M.D.s*. Found at: <http://www.aao.org/about/eyemds.cfm> (Last visited on February 11, 2012).
[17] Diagnoses which mandate a referral to an ophthalmologist include acute angle glaucoma, congenital or infantile glaucoma, infectious corneal diseases refractory to standard treatment, and retinal detachment.
[18] *See* s. 463.0135, F.S.
[19] *See* s. 463.0055, F.S.
[20] The formulary is listed in Rule 64B13-18.002, F.A.C., and includes agents to dilate and constrict pupils, local anesthetics, antibiotics, anti-inflammatory agents, antihistamines, antivirals, and anti-glaucoma medications. All medications are for topical ocular use only.
[21] Rule 64B13-10.001, F.A.C.
[22] This examination consists of 60 simulated patient cases to assess the examinee's performance in clinical practice situations. See <http://www.optometry.org/part_2_pam.cfm> (Last visited on February 11, 2012).
[23] Rule 64B13-6.001(9), F.A.C.
[24] *See* s. 463.006, F.S.

Prescribing Controlled Substances

The Drug Enforcement Administration (DEA) within the U.S. Department of Justice is tasked with monitoring controlled substances and preventing their abuse. Controlled substances fall into five categories, or schedules, depending on their addictive potential. Drug schedules are specified by the United States Department of Justice Drug Enforcement Administration (DEA) in 21 C.F.R. ss. 1308.11-15 and in s. 893.03, F.S.

Schedule I controlled substances currently have no accepted medical use in treatment in the United States and therefore may not be prescribed, administered, or dispensed for medical use. These substances have a high potential for abuse and include heroin, lysergic acid diethylamide (LSD), and marijuana. Schedule II controlled substances have a high potential for abuse which may lead to severe psychological or physical dependence, including morphine and its derivatives, amphetamines, cocaine, and pentobarbital. Schedule III controlled substances have lower abuse potential than Schedule II substances but may still cause psychological or physical dependence. Schedule III substances include products containing less than 15 milligrams (mg) of hydrocodone (such as Vicodin) or less than 90 mg of codeine per dose (such as Tylenol #3), ketamine, and anabolic steroids. Schedule IV substances have a low potential for abuse and include propoxyphene (Darvocet), alprazolam (Xanax), and lorazepam (Ativan). Schedule V controlled substances have an extremely low potential for abuse and primarily consist of preparations containing limited quantities of certain narcotics, such as cough syrup.[27]

Any health care professional wishing to prescribe controlled substances must apply for a prescribing number from the DEA. Prescribing numbers are linked to state licenses and may be suspended or revoked upon any disciplinary action taken against a licensee. The DEA will grant prescribing numbers to a wide range of health care professionals, including physicians, nurse practitioners, physician assistants, optometrists, dentists, and veterinarians, but such professionals may only prescribe controlled substances that have been authorized to them under state law. Prescribing numbers must be renewed every 3 years.[28]

In Florida, only licensed physicians, dentists, veterinarians, naturopaths, and podiatrists are currently permitted to prescribe controlled substances, and they may only prescribe medications within the scope of their own practices.[29]

Clinical Laboratories

A clinical laboratory is a location in which body fluids or tissues are analyzed for purposes of the diagnosis, assessment, or prevention of a medical condition. Clinical laboratories may be free-

[25] Department of Health, *2012 Bill Analysis, Economic Statement, and Fiscal Note for SB 788*. A copy is on file with the Senate Health Regulation Committee.
[26] *See* s. 463.0055(1), F.S.
[27] DEA, Office of Diversion Control, *Controlled Substance Schedules.* Found at: <http://www.deadiversion.usdoj.gov/schedules/#define> (Last visited on February 9, 2012).
[28] DEA, *Questions and Answers*. Found at: <http://www.deadiversion.usdoj.gov/drugreg/faq.htm> (Last visited on February 11, 2012).
[29] *See* ss. 893.02 and 893.05, F.S.

standing facilities, may be part of a hospital, or may be part of a private practitioner's office.[30] Practitioners authorized to operate their own clinical laboratories exclusively to diagnose and treat their own patients are physicians, chiropractors, podiatrists, naturopaths, and dentists. Laboratories must be biennially licensed and inspected by the AHCA to ensure quality standards in examination of specimens, equipment, sanitation, staffing, and other measures.[31]

A clinical laboratory may examine human specimens at the request of the following licensed practitioners:[32]

- Physicians
- Physician assistants
- Medical assistants
- Chiropractors
- Chiropractic assistants
- Chiropractic physician's assistants
- Podiatrists
- Naturopaths
- Dentists
- Nurse practitioners

Results of laboratory tests must be reported directly to the requesting practitioner. The same price must be charged regardless of what type of practitioner requests the testing.

Florida Drug and Cosmetic Act

Part I of ch. 499, F.S., the Florida Drug and Cosmetic Act, is administered by the Department of Business and Professional Regulation to safeguard the health, safety, and welfare of Floridians from injury due to the use of adulterated, contaminated, misbranded drugs, drug ingredients and cosmetics. Section 499.003, F.S., provides definitions for part I of ch. 499, F.S. Subsection (54) of that section defines "wholesale distribution" as distribution of prescription drugs to persons other than a consumer or patient.

The law provides certain exceptions. One of the exceptions is for the sale, purchase, trade, or other transfer of a prescription drug from or for any federal, state, or local government agency or any entity eligible to purchase prescription drugs at public health services prices (known as 340B) to a contract provider or its subcontractor under certain conditions. One of these conditions is that a contract provider or subcontractor must maintain separate and apart from other prescription drug inventory any prescription drugs of the agency or entity in its possession.

Standard of Proof in Medical Malpractice Actions

In any action for recovery of damages based on the death or personal injury of any person in which it is alleged that the death or injury resulted from the negligence of a health care provider, the claimant has the burden of proving by the greater weight of evidence that the alleged action

[30] *See* s. 483.041, F.S.
[31] *See* s 483.051, F.S.
[32] *See* s. 483.181, F.S.

of the health care provider represented a breach of the prevailing professional standard of care for that health care provider. The prevailing professional standard of care is that level of care, skill, and treatment which, in light of all relevant surrounding circumstances, is recognized as acceptable and appropriate by reasonably prudent similar health care providers.[33] Nevertheless, s. 766.102(4), F.S., provides that the "failure of a health care provider to order, perform, or administer supplemental diagnostic tests shall not be actionable if the health care provider acted in good faith and with due regard for the prevailing professional standard of care."

Greater weight of the evidence means the "more persuasive and convincing force and effect of the entire evidence in the case."[34] Other statutes, such as license disciplinary statutes involving the revocation or suspension of a license, require a heightened standard of proof called "clear and convincing evidence."[35] Clear and convincing evidence has been described as follows:

> [C]lear and convincing evidence requires that the evidence must be found to be credible; the facts to which the witnesses testify must be distinctly remembered; the testimony must be precise and explicit and the witnesses must be lacking in confusion as to the facts in issue. The evidence must be of such weight that it produces in the mind of the trier of fact a firm belief or conviction, without hesitancy, as to the truth of the allegations sought to be established.[36]

Medical Malpractice Presuit Investigation

Prior to the filing of a lawsuit, the person allegedly injured by medical negligence or a party bringing a wrongful death action arising from an alleged incidence of medical malpractice (the claimant) and the defendant (the health care professional or health care facility) are required to conduct presuit investigations to determine whether medical negligence occurred and what damages, if any, are appropriate.

The claimant is required to conduct an investigation[37] to ascertain that there are reasonable grounds to believe that:

- A named defendant in the litigation was negligent in the care or treatment of the claimant; and
- That negligence resulted in injury to the claimant.

After completion of the presuit investigation and prior to filing a complaint for medical negligence, a claimant shall notify each prospective defendant of intent to initiate litigation for medical negligence.[38] Notice to each prospective defendant must include, if available, a list of all known health care providers seen by the claimant for the injuries complained of subsequent to the alleged act of negligence, all known health care providers during the 2-year period prior to the alleged act of negligence who treated or evaluated the claimant, copies of all of the medical

[33] *See* s. 766.102, F.S.
[34] *Castillo v. E.I. Du Pont De Nemours & Co., Inc.*, 854 So. 2d 1264, 1277 (Fla. 2003).
[35] *See e.g.*, ss. 458.331(3), and 459.015(3), F.S.
[36] *Inquiry Concerning Davey*, 645 So. 2d 398, 404 (Fla. 1994)(quoting *Slomowitz v. Walker*, 429 So. 2d 797, 800 (Fla. 4th DCA 1983).
[37] *See* s. 766.203, F.S.
[38] *See* s. 766.106, F.S.

records relied upon by the expert in signing the affidavit, and an executed authorization for release of protected health information. The presuit notice is void if this authorization does not accompany the presuit notice.[39]

A suit may not be filed for a period of 90 days after notice is mailed to any prospective defendant. The statue of limitations is tolled during the 90-day period. During the 90-day period, the prospective defendant or the defendant's insurer or self-insurer shall conduct a presuit investigation to determine the liability of the defendant.

Before the defendant issues his or her response, the defendant or his or her insurer or self-insurer is required to ascertain whether there are reasonable grounds to believe that:

- The defendant was negligent in the care or treatment of the claimant; and
- That negligence resulted in injury to the claimant.

Corroboration of the lack of reasonable grounds for medical negligence litigation must be provided by submission of a verified written medical expert opinion which corroborates reasonable grounds for lack of negligent injury sufficient to support the response denying negligent injury.

At or before the end of the 90 days, the prospective defendant or the prospective defendant's insurer or self-insurer shall provide the claimant with a response:

- Rejecting the claim;
- Making a settlement offer; or
- Making an offer to arbitrate in which liability is deemed admitted and arbitration will be held only on the issue of damages. This offer may be made contingent upon a limit of general damages.

Failure of the prospective defendant or insurer or self-insurer to reply to the notice within 90 days after receipt is deemed a final rejection of the claim for purposes of this provision.

Discovery and Admissibility of Evidence

Statements, discussions, written documents, reports, or other work product generated by the presuit screening process are not discoverable or admissible in any civil action for any purpose by the opposing party.[40] All participants, including, but not limited to, physicians, investigators, witnesses, and employees or associates of the defendant, are immune from civil liability arising from participation in the presuit screening process.[41]

Upon receipt by a prospective defendant of a notice of claim, the parties are required to make discoverable information available without undertaking formal discovery. Informal discovery

[39] *See* s. 766.1065(1), F.S. If the authorization is revoked, the presuit notice is deemed retroactively void from the date of issuance, and any tolling effect that the presuit notice may have had on any applicable statute-of-limitations period is retroactively rendered void.
[40] However, the presuit expert witness opinions are subject to discovery under s. 766.203(4), F.S.
[41] *See* s. 766.106(5), F.S.

may be used to obtain unsworn statements, the production of documents or things, and physical and mental examinations as follows:[42]

- Unsworn statements – Any party may require other parties to appear for the taking of an unsworn statement. Unsworn statements may be used only for the purpose of presuit screening and are not discoverable or admissible in any civil action for any purpose by any party.
- Documents or things – Any party may request discovery of documents or things. This includes medical records.
- Physical and mental examination – A prospective defendant may require an injured claimant to be examined by an appropriate health care provider. Unless otherwise impractical, a claimant is required to submit to only one examination of behalf of all potential defendants. The examination report is available to the parties and their attorney and may be used only for the purpose of presuit screening. Otherwise the examination is confidential.
- Written questions – Any party may request answers to written questions.
- Unsworn statements of treating health care providers – The statements must be limited to those areas that are potentially relevant to the claim. Reasonable notice and an opportunity to be heard must be given to the claimant before taking unsworn statements. The claimant, or claimant's legal representative, has the right to attend the taking of these unsworn statements.

The failure to cooperate on the part of any party during the presuit investigation may be grounds to strike any claim made, or defense raised in the suit.[43]

Arbitration Generally

For many years, courts and legislatures have utilized arbitration as an alternative method to resolve disputes between parties in an expedient, efficient, and inexpensive manner.[44] However, when parties agree to participate in arbitration, they concede some of the safeguards that are traditionally afforded to those who proceed to court, one of which is the right to have the evidence weighed in accordance with established legal principles.[45] Arbitration may be defined as "a process that allows parties voluntarily to refer their disputes to an impartial third person, an arbitrator, selected by them to determine the parties' rights and liabilities."[46] Typically, a decision rendered by arbitrators is as binding and conclusive as the judgment of a court.[47] Because of the federal policy favoring and encouraging the use of arbitration to resolve disputes, the use of pre-dispute arbitration agreements has expanded beyond use in commercial contexts between large businesses and those with equal bargaining power, to use in many noncommercial consumer contracts.[48]

[42] *See* s. 766.106(6), F.S.
[43] *See* s. 766.106(7), F.S.
[44] Elizabeth K. Stanley, *Parties' Defenses to Binding Arbitration Agreements in the Health Care Field & the Operation of the McCarran-Ferguson Act*, 38 ST. MARY'S L.J. 591, 591-92 (2007).
[45] *Affiliated Marketing, Inc. v. Dyco Chemicals & Coatings, Inc*., 340 So. 2d 1240 (Fla. 2d DCA 1976).
[46] Stanley, *supra* note 44, at 592 (internal citations omitted).
[47] *Capital Factors, Inc. v. Alba Rent-A-Car, Inc*., 965 So. 2d 1178, 1182 (Fla. 4th DCA 2007).
[48] Stanley, *supra* note 44, at 592.

Florida Arbitration Code

Florida traditionally has favored arbitration. In 1957, the Legislature enacted the Florida Arbitration Code (FAC),[49] which prescribes a framework governing the rights and procedures under arbitration agreements, including the enforceability of arbitration agreements. The FAC governs arbitration clauses where interstate commerce is not implicated.[50] The FAC governs the arbitration process in its entirety, including, but not limited to the scope and enforceability of arbitration agreements, the appointment of arbitrators, the arbitration hearing process and procedure, the entry and enforcement of arbitration awards, and appeals.

Under the FAC, Florida courts have held that the determination of whether any dispute is subject to arbitration should be resolved in favor of arbitration.[51] A court's role in deciding whether to compel arbitration is limited to three gateway issues to determine the enforceability of an arbitration agreement: (1) whether a valid written agreement to arbitrate exists; (2) whether an arbitrable issue exists; and (3) whether the right to arbitration has been waived.[52] The FAC applies in arbitration cases only to the extent that it is not in conflict with federal law.[53]

Voluntary Binding Arbitration

Section 766.207, F.S., related to medical malpractice, establishes a procedure for voluntary binding arbitration of damages upon the completion of presuit investigation with preliminary reasonable grounds for a medical negligence claim. A proceeding for voluntary binding arbitration is an alternative to jury trial and does not supersede the right of any party to a jury trial.[54] Either party may initiate the election for voluntary binding arbitration of damages. A claimant's offer to arbitrate must be made to each defendant and each defendant's offer to arbitrate must be made to each claimant.[55] The arbitration panel's decision is subject to the limitations on damages that are provided in s. 766.207, F.S.

If the defendant refuses a claimant's offer of voluntary binding arbitration and the claimant proves medical negligence, the claimant is entitled to recover damages subject to the limitations in s. 766.118, F.S., prejudgment interest, and reasonable attorney's fees up to 25 percent of the award reduced to present value. If a claimant rejects a defendant's offer of voluntary binding arbitration, the damages awardable at trial are limited to net economic damages, plus noneconomic damages not to exceed $350,000 per incident.56

[49] *See* ch. 682. F.S.
[50] *O'Keefe Architects, Inc. v. CED Construction Partners, Ltd.*, 944 So. 2d 181, 184 (Fla. 2006).
[51] Michael Cavendish, *The Concept of Arbitrability Under the Florida Arbitration Code*, 82 FLA. B.J. 18, 19 (Nov. 2008) (citing *O'Keefe Architects, Inc. v. CED Construction Partners, Ltd.*, 944 So. 2d 181, 184 (Fla. 2006)).
[52] *Seifert v. U.S. Home Corp*., 750 So. 2d 633, 636 (Fla. 1999).
[53] *Powertel, Inc. v. Bexley*, 743 So. 2d 570, 573 (Fla. 1st DCA 1999), *review denied*, 763 So. 2d 1044 (Fla. 2000), and *Florida Power Corp. v. Casselberry*, 793 So. 2d 1174, 1179 (Fla. 5th DCA 2001)
[54] *See* s. 766.209, F.S.
[55] *See* s. 766.207(7)(k), F.S.
[56] *See* s. 766.209, F.S.

Arbitration Agreements in Contracts for Medical Services

Insurance companies and physicians are more frequently requiring patients to enter into arbitration agreements regarding any potential medical malpractice claims resulting from the medical treatment or care.[57] Therefore, some patients may face a choice when seeking medical treatment or care: sign an arbitration agreement or forego treatment with a particular physician or other health care provider.[58] These arbitration agreements may apply to all medical negligence and professional malpractice claims arising out of the physician-patient relationship, and bind the patient, as well as the spouse and heirs of the patient.[59]

Some patients have challenged the enforceability of arbitration agreements in this context by asserting that the agreements are void as against public policy, are too broad, are essentially contracts of adhesion, and are unconscionable.[60] Generally, courts will closely scrutinize physician-patient arbitration agreements under general contract principles to determine if the agreements are unenforceable contracts of adhesion.[61] In *Jonathan M. Frantz, M.D., P.A. v. Shedden*, a Florida eye patient brought a medical malpractice action against an eye clinic after complication arose from elective eye surgery.[62] The eye clinic moved to stay litigation and enforce arbitration. During a preoperative visit, the plaintiff had signed an arbitration agreement that was separate from other documents, was afforded the opportunity to review the agreement, and was advised that he could ask staff questions regarding the agreement. The court concluded that, because the agreement was neither procedurally nor substantively unconscionable, the litigation should be stayed in favor of arbitration.[63]

III. Effect of Proposed Changes:

Section 1 amends s. 395.002, F.S., which provides definitions for the regulation of hospitals and ambulatory surgical centers, to define "accrediting organizations" to mean national accreditation organizations that are approved by the Centers for Medicare and Medicaid Services and whose standards incorporate comparable licensure regulations required by Florida. The bill deletes the names of four organizations that are currently included in the definition.

Section 2 amends s. 400.474, F.S., to reduce the fine that the AHCA currently must impose on a home health agency that fails to submit, within 15 days after the end of each calendar quarter, a

[57] Jennifer Gillespie, *Physician-Patient Arbitration Agreements: Procedural Safeguards May Not Be Enough*, 1997 J. DISP. RESOL. 119, 119 (1997).
[58] *Id.*
[59] *Id*. at 120.
[60] *See Buraczynski v. Eyring*, 919 S.W.2d 314 (Tenn. 1996). In *Buraczynski*, a patient signed an arbitration agreement in the context of medical services prior to a knee-replacement operation. The agreement covered all medical negligence and malpractice claims arising out of the surgery, and provided that the patient would have 30 days to revoke the agreement by providing written notice to the physician. After a challenge by the patient's heirs to avoid participation in arbitration, the Tennessee Supreme Court found that the agreement was consistent with public policy, was not overly broad, and was an enforceable adhesion contract because it was supported by consideration and was not oppressive or unconscionable. *Id.* at 321.
[61] *See Broemmer v. Abortion Services of Phoenix Ltd.*, 840 P.2d 1013 (Ariz. 1992); *Leong by Leong v. Kaiser Foundation Hosp.*, 788 P.2d 164 (Haw. 1990); and *Obstetrics and Gynecologists William G. Wixted, M.D., Patrick M. Flanagan, M.D., William F. Robinson, M.D. Ltd. v. Pepper*, 693 P.2d 1259 (Nev. 1985).
[62] *Jonathan M. Frantz, M.D., P.A. v. Shedden*, 974 So. 2d 1193 (Fla. 2d DCA 2008).
[63] *Id*. at 1198.

report that includes certain fraud detection information. The bill changes the penalty to a mandatory $50 per day fine, with no maximum, instead of the current permissive denial, revocation, or suspension of the home health agency's license and a mandatory fine of $5,000. Thus, the amount of the fine will be substantially less for those agencies that are only a few days late submitting the report. However, reports more than 100 days late will exceed the existing fine of $5,000.

Section 3 amends s. 400.9905, F.S., to exempt pediatric cardiology or perinatology clinical facilities and anesthesia clinical facilities that are a publicly traded corporation or are wholly owned, directly or indirectly, by a publicly traded corporation from the definition of health care clinic and the clinic licensure requirements. The bill also creates a new exemption from the definition of clinic and the clinic licensure requirements for entities that are owned or controlled, directly or indirectly, by a publicly traded entity that has $100 million or more, in the aggregate, in total annual revenues derived from providing health care services by licensed health care practitioners who are employed or contracted by such an entity.

Section 4 amends s. 409.221, F.S., to require persons who render care under the Medicaid consumer-directed care program to undergo Level 2 background screening pursuant to the provisions of s. 408.809, F.S., in addition to the provisions of ch. 435, F.S. The effect is to require persons rendering care under the consumer-directed care program to be screened for additional disqualifying offenses and to be re-screened every 5 years.

Section 5 amends s. 409.907, F.S., relating to Medicaid provider agreements, to require Medicaid providers to retain all medical and Medicaid-related records for 6 years, rather than the current statutory retention period of 5 years, consistent with Health Insurance Portability and Accountability Act (HIPAA) of 1996 administrative simplification rules.[64]

The bill requires a Medicaid provider to report in writing any change of any principal of the provider to the AHCA no later than 30 days after the change occurs. The bill specifies who is included in the term "principal."

The bill amends the statutory provisions relating to the liability of Medicaid providers in a change of ownership for outstanding overpayments, administrative fines, and any other moneys owed to the AHCA. The bill defines "administrative fines" to include any amount identified in any notice of a monetary penalty or fine that has been issued by the AHCA or any other regulatory or licensing agency that governs the provider.

The requirement for the AHCA to conduct random onsite inspections of Medicaid providers' service locations within 60 days after receipt of a fully complete new provider's application and prior to making the first payment to the provider for Medicaid services is amended to authorize, rather than require, the AHCA to perform onsite inspections. The inspection would be conducted prior to the AHCA entering into a Medicaid provider agreement with the provider and would be used to determine the applicant's ability to provide services in compliance with the Medicaid

[64] *See* 45 CFR 164.316(b)(2). Found at: <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=be9877c2440a17a8ebe3b02b0948a06a&rgn=div8&view=text&node=45:1.0.1.3.79.3.27.8&idno=45> (Last visited on February 9, 2012).

program and professional regulations. The law currently only requires the AHCA to determine the applicant's ability to provide the services for which they will seek Medicaid payment. The bill also removes an exception to the current onsite-inspection requirement for a provider or program that is licensed by the AHCA, that provides services under waiver programs for home and community-based services, or that is licensed as a medical foster home by the Department of Children and Family Services, since the selection of providers for onsite inspections is no longer a random selection, but is left up to the discretion of the AHCA under the bill.

The bill amends existing surety bond requirements for certain Medicaid providers to clarify that the additional bond required by the AHCA, if a provider's billing during the first year exceeds the bond amount, need not exceed $50,000 for certain providers.

The bill amends the requirements for a criminal history record check of each Medicaid provider, or each principal of the provider, to remove an exemption from such checks for hospitals, nursing homes, hospices, and assisted living facilities. The bill specifies that for hospitals and nursing homes the principals of the provider are those who meet the definition of a controlling interest in s. 408.803, F.S.

The bill removes the provision that proof of compliance with Level 2 background screening under ch. 435, F.S., conducted within 12 months before the date the Medicaid provider application is submitted to the AHCA satisfies the requirements for a criminal history background check. This conforms to screening provisions in ch. 435, F.S., and ch. 408, F.S.

Section 6 amends s. 409.913, F.S., which relates to oversight of the integrity of the Medicaid program. The bill defines "Medicaid provider" or "provider" to include not only persons or entities that have a Medicaid provider agreement in effect with the AHCA and that are in good standing with the AHCA, but also, for purposes of oversight of the integrity of the Medicaid program, participants in a Medicaid managed care provider network.

The bill authorizes the AHCA, as part of its fraud and abuse detection efforts, to review and analyze information from sources other than enrolled Medicaid providers. Medicaid providers are required to retain medical, professional, financial, and business records pertaining to services and goods furnished to a Medicaid recipient and billed to Medicaid for 6 years, rather than the current statutory retention period of 5 years.

The bill amends subsection (13) of s. 409.913, F.S., to remove a requirement that the AHCA *immediately* terminate participation of a Medicaid provider that has been convicted of certain offenses. In order to immediately terminate a provider, the AHCA must show an immediate harm to the public health, which is not always possible. The AHCA still must terminate a Medicaid provider from participation in the Medicaid program, unless the AHCA determines that the provider did not participate or acquiesce in the offense.

The AHCA may seek civil remedies or impose administrative sanctions if a provider *has been convicted* of any of the following offenses.

- A criminal offense under federal law or the law of any state relating to the practice of the provider's profession.

- An offense listed in s. 409.907(10), F.S., relating to factors the AHCA may consider when reviewing an application for a Medicaid provider agreement, which includes:
  - Making a false representation or omission of any material fact in making an application for a provider agreement;
  - Exclusion, suspension, termination, or involuntary withdrawal from participation in any Medicaid program or other governmental or private health care or health insurance program;
  - Being convicted of a criminal offense relating to the delivery of any goods or services under Medicaid or Medicare or any other public or private health care or health insurance program including the performance of management or administrative services relating to the delivery of goods or services under any such program;
  - Being convicted of a criminal offense under federal or state law related to the neglect or abuse of a patient in connection with the delivery of any health care goods or services;
  - Being convicted of a criminal offense under federal or state law related to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance;
  - Being convicted of any criminal offense relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct;
  - Being convicted of a criminal offense under federal or state law punishable by imprisonment of 1 year or more which involves moral turpitude;
  - Being convicted in connection with the interference or obstruction of any investigation into any criminal offense listed above;
  - Violation of federal or state laws, rules, or regulations governing any Medicaid program, the Medicare program, or any other publicly funded federal or state health care or health insurance program, if they have been sanctioned accordingly;
  - Violation of the standards or conditions relating to professional licensure or certification or the quality of services provided; or
  - Failure to pay fines and overpayments under the Medicaid program.
- An offense listed in s. 408.809(4), F.S., relating to background screening of licensees, which includes the following offenses or any similar offense of another jurisdiction:
  - Any authorizing statutes, if the offense was a felony;
  - Chapter 408, F.S., if the offense was a felony;
  - Section 409.920, F.S., relating to Medicaid provider fraud;
  - Section 409.9201, F.S., relating to Medicaid fraud;
  - Section 741.28, F.S., relating to domestic violence;
  - Section 817.034, F.S., relating to fraudulent acts through mail, wire, radio, electromagnetic, photoelectronic, or photooptical systems;
  - Section 817.234, F.S., relating to false and fraudulent insurance claims;
  - Section 817.505, F.S., relating to patient brokering;
  - Section 817.568, F.S., relating to criminal use of personal identification information;
  - Section 817.60, F.S., relating to obtaining a credit card through fraudulent means;
  - Section 817.61, F.S., relating to fraudulent use of credit cards, if the offense was a felony;
  - Section 831.01, F.S., relating to forgery;
  - Section 831.02, F.S., relating to uttering forged instruments;
  - Section 831.07, F.S., relating to forging bank bills, checks, drafts, or promissory notes;
  - Section 831.09, F.S., relating to uttering forged bank bills, checks, drafts, or promissory notes;
  - Section 831.30, F.S., relating to fraud in obtaining medicinal drugs; or

- Section 831.31, F.S., relating to the sale, manufacture, delivery, or possession with the intent to sell, manufacture, or deliver any counterfeit controlled substance, if the offense was a felony.

- An offense listed in s. 435.04(2), F.S., relating to employee background screening, which includes the following offenses or any similar offense of another jurisdiction:
  - Section 393.135, F.S., relating to sexual misconduct with certain developmentally disabled clients and reporting of such sexual misconduct;
  - Section 394.4593, F.S., relating to sexual misconduct with certain mental health patients and reporting of such sexual misconduct;
  - Section 415.111, F.S., relating to adult abuse, neglect, or exploitation of aged persons or disabled adults;
  - Section 782.04, F.S., relating to murder;
  - Section 782.07, F.S., relating to manslaughter, aggravated manslaughter of an elderly person or disabled adult, or aggravated manslaughter of a child;
  - Section 782.071, F.S., relating to vehicular homicide;
  - Section 782.09, F.S., relating to killing of an unborn quick child by injury to the mother;
  - Chapter 784, F.S., relating to assault, battery, and culpable negligence, if the offense was a felony;
  - Section 784.011, F.S., relating to assault, if the victim of the offense was a minor;
  - Section 784.03, F.S., relating to battery, if the victim of the offense was a minor;
  - Section 787.01, F.S., relating to kidnapping;
  - Section 787.02, F.S., relating to false imprisonment;
  - Section 787.025, F.S., relating to luring or enticing a child;
  - Section 787.04(2), F.S., relating to taking, enticing, or removing a child beyond the state limits with criminal intent pending custody proceedings;
  - Section 787.04(3), F.S., relating to carrying a child beyond the state lines with criminal intent to avoid producing a child at a custody hearing or delivering the child to the designated person;
  - Section 790.115(1), F.S., relating to exhibiting firearms or weapons within 1,000 feet of a school;
  - Section 790.115(2)(b), F.S., relating to possessing an electric weapon or device, destructive device, or other weapon on school property;
  - Section 794.011, F.S., relating to sexual battery;
  - Former s. 794.041, F.S., relating to prohibited acts of persons in familial or custodial authority;
  - Section 794.05, F.S., relating to unlawful sexual activity with certain minors;
  - Chapter 796, F.S., relating to prostitution;
  - Section 798.02, F.S., relating to lewd and lascivious behavior;
  - Chapter 800, F.S., relating to lewdness and indecent exposure;
  - Section 806.01, F.S., relating to arson;
  - Section 810.02, F.S., relating to burglary;
  - Section 810.14, F.S., relating to voyeurism, if the offense is a felony;
  - Section 810.145, F.S., relating to video voyeurism, if the offense is a felony;
  - Chapter 812, F.S., relating to theft, robbery, and related crimes, if the offense is a felony;
  - Section 817.563, F.S., relating to fraudulent sale of controlled substances, only if the offense was a felony;

  - Section 825.102, F.S., relating to abuse, aggravated abuse, or neglect of an elderly person or disabled adult;
  - Section 825.1025, F.S., relating to lewd or lascivious offenses committed upon or in the presence of an elderly person or disabled adult;
  - Section 825.103, F.S., relating to exploitation of an elderly person or disabled adult, if the offense was a felony;
  - Section 826.04, F.S., relating to incest;
  - Section 827.03, F.S., relating to child abuse, aggravated child abuse, or neglect of a child;
  - Section 827.04, F.S., relating to contributing to the delinquency or dependency of a child;
  - Former s. 827.05, F.S., relating to negligent treatment of children;
  - Section 827.071, F.S., relating to sexual performance by a child;
  - Section 843.01, F.S., relating to resisting arrest with violence;
  - Section 843.025, F.S., relating to depriving a law enforcement, correctional, or correctional probation officer means of protection or communication;
  - Section 843.12, F.S., relating to aiding in an escape;
  - Section 843.13, F.S., relating to aiding in the escape of juvenile inmates in correctional institutions;
  - Chapter 847, F.S., relating to obscene literature;
  - Section 874.05(1), F.S., relating to encouraging or recruiting another to join a criminal gang;
  - Chapter 893, F.S., relating to drug abuse prevention and control, only if the offense was a felony or if any other person involved in the offense was a minor;
  - Section 916.1075, F.S., relating to sexual misconduct with certain forensic clients and reporting of such sexual misconduct;
  - Section 944.35(3), F.S., relating to inflicting cruel or inhuman treatment on an inmate resulting in great bodily harm;
  - Section 944.40, F.S., relating to escape;
  - Section 944.46, F.S., relating to harboring, concealing, or aiding an escaped prisoner;
  - Section 944.47, F.S., relating to introduction of contraband into a correctional facility;
  - Section 985.701, F.S., relating to sexual misconduct in juvenile justice programs; or
  - Section 985.711, F.S., relating to contraband introduced into detention facilities.

The bill amends subsection (15) of s. 409.913, F.S., relating to noncriminal actions of Medicaid providers for which the AHCA may impose sanctions, to include the act of *authorizing* certain services that are inappropriate, unnecessary, excessive, or harmful to the recipient or are of inferior quality, or *authorizing* certain requests and reports that contain materially false or incorrect information. The bill also adds that the AHCA may sanction a provider if the provider is charged by information or indictment with any offense referenced in subsection (13). (See above for a listing of the offenses.) The AHCA may impose sanctions under this subsection if the provider or certain persons affiliated with the provider participated or acquiesced in the proscribed activity.

Subsection (16) of s. 409.913, F.S., relating to sanctions the AHCA may impose for the acts listed in subsection (15), is amended to state that, if a Medicaid provider voluntarily relinquishes its Medicaid provider number after receiving notice of an audit or investigation for which the sanction of suspension or termination will be imposed, the AHCA must impose the sanction of termination for cause against the provider. Currently, if a Medicaid provider receives notification

that it is going to be suspended or terminated, the provider is able to voluntarily terminate their contract. By doing this, a provider has the ability to avoid sanctions of suspension or termination, which would affect the ability of the provider to reenter the program in the future. Existing language in this subsection gives the Secretary of the AHCA the authority to make a determination that imposition of a sanction is not in the best interest of the Medicaid program, in which case a sanction may not be imposed.

The bill amends subsection (21) of s. 409.913, F.S., to specify that when the AHCA is making a determination that an overpayment has occurred, the determination must be based solely upon information available to it before it issues the audit report and, in the case of documentation obtained to substantiate claims for Medicaid reimbursement, based solely upon contemporaneous records. Subsection (22) is amended to specify that testimony or evidence that is not based upon contemporaneous records or that was not furnished to the AHCA within 21 days after the issuance of the audit report is inadmissible in an administrative hearing on a Medicaid overpayment or an administrative sanction. Also, all documentation to be offered as evidence in an administrative hearing on an administrative sanction (in addition to Medicaid overpayments) must be exchanged by all parties at least 14 days before the administrative hearing or excluded from consideration.

Subsection (25) of s. 409.913, F.S., is amended to remove the requirement that the AHCA pay, interest at the rate of 10 percent a year on Medicaid payments that have been withheld from a provider based on suspected fraud or criminal activity, if it is determined that there was no fraud or that a crime did not occur. Also, payment arrangements for overpayments and fines owed to the AHCA must be made within 30 days after the date of the final order and are not subject to further appeal.

The bill amends subsection (28) of s. 409.913, F.S., to make Leon County the venue for all Medicaid program integrity cases, not just overpayment cases. However, the AHCA has discretion concerning venue. Subsection (29) is amended to authorize the AHCA and the Medicaid Fraud Control Unit of the Department of Legal Affairs to review a *person's*, in addition to a provider's, Medicaid-related and non-Medicaid-related records in order to determine the total output of a provider's practice to reconcile quantities of goods or services billed to Medicaid with quantities of goods or services used in the provider's total practice.

Subsection (30) of s. 409.913, F.S., is amended to require the AHCA to terminate a provider's participation in the Medicaid program if the provider fails to pay a fine within 30 days after the date of the final order imposing the fine. The time within which a provider must reimburse an overpayment is reduced from 35 to 30 days after the date of the final order. Subsection (31) is amended to include fines, as well as overpayments, that are due upon the issuance of a final order at the conclusion of a requested administrative hearing.

Section 7 amends s. 409.920, F.S., relating to Medicaid provider fraud, to clarify that the existing immunity from civil liability extended to persons who provide information about fraud or suspected fraudulent acts is for civil liability for libel, slander, or any other relevant tort. The bill defines "fraudulent acts" for purposes of the immunity from civil liability to include actual or suspected fraud, abuse, or overpayment, including any fraud-related matters that a provider or health plan is required to report to the AHCA or a law enforcement agency. The immunity from

civil liability extends to reports conveyed to the AHCA in any manner and includes all discussions subsequent to the report and subsequent inquiries from the AHCA, unless the person reporting acted with knowledge that the information was false or with reckless disregard for the truth or falsity of the information.

Section 8 amends s. 409.967, F.S., relating to Medicaid managed care plan accountability, to establish requirements for managed care plans relating to coverage of prescribed drugs, which do not currently exist for the Medicaid fee-for-service drug program or Medicaid managed care plans. With regard to standards for managed care plan networks, the bill states that exclusive use of mail-order pharmacies *is not sufficient* to meet network access standards. Current law states that exclusive use of mail-order pharmacies *may not be sufficient*. The effect is that managed care plans will be required to use some pharmacies that are not mail-order pharmacies.

The bill establishes the following requirements for managed care plans that use a prescribed drug formulary or preferred drug list. The plan must:

- Provide a broad range of therapeutic options for the treatment of disease states consistent with the general needs of an outpatient population, including at least two products in a therapeutic class whenever feasible;
- Include coverage via prior authorization for each new drug approved by the federal Food and Drug Administration until the plan's Pharmaceutical and Therapeutics Committee reviews the drug for inclusion on its formulary. The new drug must be reviewed by the committee for inclusion on the formulary at the next regularly scheduled meeting of the committee following 3 months of distribution of the drug to the general public; and
- Provide a response within 24 hours after receipt of all necessary information for a request for prior authorization and provide a procedure for escalating a delayed prior authorization request to the pharmacy management team for resolution or override of other medical management tools.

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

The bill establishes requirements for the use of step-therapy or fail-first protocols by managed care plans. Plans that impose step-therapy or a fail-first protocol must:

- Provide the prescriber with access to a clear and convenient process to expeditiously request a prior authorization that includes a procedure for escalation to the pharmacy management team if the request is not resolved in a timely manner;
- Expeditiously grant an escalation to the pharmacy management team if the prescriber can submit appropriate and complete medical documentation to the plan that the preferred treatment required under the step-therapy or fail-first protocol:
  - Has been ineffective in the treatment of the enrollee's disease or medical condition;
  - Is reasonably expected to be ineffective based on the known relevant physical or mental characteristics and medical history of the enrollee and known characteristics of the drug regimen; or
  - Will cause or will likely cause an adverse reaction or other physical harm to the enrollee.

- Require the pharmacy management team to work directly with the medical provider to bring the prior authorization request to a clinically appropriate, cost effective, and timely resolution.

The bill establishes prior authorization requirements relating to prescribed drugs.

- Each managed care plan must ensure that the prior authorization process is readily accessible to health care providers, including posting appropriate contact information on its website and providing timely responses to providers. (This is an existing statutory requirement that is being relocated.)
- If a drug is approved via prior authorization, the managed care plan must provide for sufficient refills to complete the duration of the prescription. If the medication is still clinically appropriate for ongoing therapy after the initial prior authorization expires, the plan must provide a process of expedited review to evaluate ongoing therapy.
- If a prescribed drug requires prior authorization, the managed care plan must reimburse the pharmacist for dispensing a 72-hour supply of oral maintenance medications to the enrollee and process the prior authorization request. Dispensing a 72-hour supply must be consistent with pharmacy practice laws and controlled substance laws. The managed care plan must process all prior authorization requests in as timely a manner as possible.

Section 9 amends s. 429.23, F.S., relating to adverse incident reporting requirements for assisted living facilities, to reestablish a requirement for the AHCA to annually submit a report on adverse incident reports by assisted living facilities. The requirement for an annual report was repealed July 1, 2009 (s. 63 of ch. 2009-223, L.O.F.). The AHCA will once again be required to submit an annual report to the Legislature containing certain information, by county, about reported adverse incidents in assisted living facilities.

Section 10 amends s. 429.26, F.S., relating to appropriateness of placement of residents of assisted living facilities, to reestablish a requirement for physical examination or mental health evaluation of residents who appear to need care beyond that which the assisted living facility is licensed to provide. The requirement for such examinations or evaluations was repealed July 1, 2009 (s. 64 of ch. 2009-223, L.O.F.).

If personnel of the AHCA question whether a resident needs care beyond that which the facility is licensed to provide, the AHCA may require the resident to be physically examined by a licensed physician, licensed physician assistant, or certified nurse practitioner. To the extent possible, the examination must be performed by a health care provider who is preferred by the resident. The cost of the examination must be paid for by the resident with personal funds, except for certain low-income residents. The requirement for the AHCA to have such an examination conducted does not preclude the AHCA from imposing sanctions against an assisted living facility for violating its duty to determine the continuing appropriateness of placement of its residents.

Following the physical examination and based on a completed medical form submitted to the AHCA by the examining health care provider, a medical team designated by the AHCA must determine if the resident is appropriately residing in the facility. The AHCA may consult with the examining provider if necessary. A determination by the medical team that the resident's placement is not appropriate is final and binding upon the facility and the resident. A resident

who is determined to be inappropriately residing in a facility must be given 30 days' written notice to relocate, unless the resident's continued residence in the facility presents an imminent danger to the health, safety, or welfare of the resident or a substantial probability exists that death or serious physical harm to the resident would result if the resident is allowed to remain in the facility.

If a mental health resident appears to have needs in addition to those identified in the community living support plan, the AHCA may require an evaluation by a mental health professional, as determined by the Department of Children and Family Services.

A facility may not be required to retain a resident who requires more services or care than the facility is able to provide in accordance with its policies and criteria for admission and continued residency.

Section 11 amends s. 456.0635, F.S., effective July 1, 2012, relating to disqualification for licensure, certification, or registration of health care practitioners for Medicaid fraud. The catch line is changed from "Medicaid fraud; disqualification for license, certificate, or registration," to "Health care fraud; disqualification for license, certificate, or registration." Other references in the statute to the general subject of "Medicaid fraud" are changed to "health care fraud." References to "candidate" vs. "candidate or applicant" are also standardized.

The bill separates the disqualifications for initial licensure, certification, or registration from those relating to licensure renewal into two different statutory subsections.

The bill requires a board or the DOH to refuse to admit a candidate to any examination and to refuse to issue a license to any applicant who has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under ch. 409, F.S., ch. 817, F.S., ch. 893, F.S., *or similar felony offenses committed in another state or jurisdiction*. The bill deletes the provision in current law that nullifies the prohibition if the sentence and probation period ended more than 15 years prior to the date of application, and replaces it with the following provisions:

- For felonies of the first or second degree, the prohibition expires when the sentence and probation period have ended more than 15 years before the date of application.
- For felonies of the third degree, the prohibition expires when the sentence and probation period have ended more than 10 years before the date of application, except for felonies of the third degree under s. 893.13(6)(a), F.S.[65]
- For felonies of the third degree under s. 893.13(6)(a), F.S., the prohibition expires when the sentence and probation period have ended more than 5 years before the date of application.

An applicant or candidate who has been convicted of or pled guilty or nolo contendere to any state felony listed above is eligible for initial licensure without any prohibition if he or she

[65] Section 893.13(6)(a), F.S., makes it unlawful for any person to be in actual or constructive possession of a controlled substance unless such controlled substance was lawfully obtained from a practitioner or pursuant to a valid prescription or order of a practitioner while acting in the course of his or her professional practice, or to be in actual or constructive possession of a controlled substance except as otherwise authorized by ch. 893, F.S.

successfully completes a drug court program for that felony and provides proof that the plea has been withdrawn or the charges have been dismissed.

The bill moves into a new paragraph the requirement for a board or the DOH to refuse to admit a candidate to any examination and to refuse to issue a license to any applicant who has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970[66] or 42 U.S.C. ss. 1395-1396,[67] unless the sentence and any probation period for such conviction or plea ended more than 15 years before the date of the application.

The bill deletes reference to "terminated for cause" from the federal Medicare program as grounds for which a board or the DOH is required to deny a license and creates a new standard to exclude applicants currently listed on the U.S. Department of Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities.

The bill specifies that the prohibitions above relating to examination, licensure, certification, or registration do not apply to applicants for initial licensure or certification who were enrolled in a DOH- or board-recognized educational or training program on or before July 1, 2009, and who applied for licensure after July 1, 2012.

The bill creates a new statutory subsection relating to license *renewal* that requires a board or the DOH to deny renewal to applicants who, after July 1, 2009, have been convicted of or pled guilty or nolo contendere to the same felony offenses listed under the subsection on initial licensure. The same 5, 10, and 15-year prohibition periods apply concerning eligibility for relicensure after a felony as for initial licensure after a felony. Applicants who have been convicted of or pled guilty or nolo contendere to specified state felonies are eligible for license renewal without any prohibition period if they are currently enrolled in a drug court program that allows the withdrawal of the plea for that felony upon successful completion of the program.

The bill also includes the same provisions for denying licensure renewal as those described above for initial examination, licensure, certification, and registration, relative to exclusion from the Medicare program and termination from Medicaid programs in Florida or in other states.

Section 12 amends s. 456.036, F.S., effective July 1, 2012, to authorize any person who has been denied renewal of licensure, certification, or registration under s. 456.0635(3), F.S., to regain licensure, certification, or registration by undergoing the procedure for initial licensure as defined by a board or the department. However, a person who was denied renewal between July 1, 2009 and June 30, 2012, is not required to retake any examinations which would otherwise be necessary for initial licensure.

Section 13 amends s. 456.074, F.S., relating to the immediate suspension of the license of certain health care practitioners who plead guilty to, are convicted or found guilty of, or who enter a plea of nolo contendere to, regardless of adjudication, certain offenses. The bill removes the limiting

[66] 21 U.S.C. ss. 801-970 relate to drug abuse prevention and control. It regulates the registration of manufacturers, distributors, and dispensers of controlled substances; provides for offenses and penalties; and regulates the import and export of controlled substances.
[67] 42 U.S.C. ss. 1395-1396 contain provisions relating to Medicare, Medicaid, and the Children's Health Insurance Program.

clause "relating to the Medicaid program" as it modifies a list of federal misdemeanor or felony offenses. The effect would be that the listed health care practitioners would be subject to immediate suspension of their license for the misdemeanor or felony offenses, whether or not the offense related to the Medicaid program.

Section 14 amends s. 458.309, F.S., to require an allopathic physician who performs liposuction procedures in which more than 1,000 cubic centimeters of supernatant fat is removed to register his or her office with the DOH and be subject to inspection by the DOH.

Section 15 amends s. 459.005, F.S., to require an osteopathic physician who performs liposuction procedures in which more than 1,000 cubic centimeters of supernatant fat is removed to register his or her office with the DOH and be subject to inspection by the DOH.

Section 16 amends s. 463.002, F.S., to allow certified optometrists to administer and prescribe any medications related to the diagnosis and treatment of ocular conditions, not just those which are topically applied to the eye.

Section 17 amends s. 463.005, F.S., to allow the Board of Optometry to promulgate rules related to administration and prescription of all ocular pharmaceutical agents, not only topical agents.

Section 18 amends s. 463.0055, F.S., to require a certified optometrist, before he or she prescribes oral pharmaceutical agents, to complete a course and subsequent examination on general and ocular pharmacology with particular emphasis on the ingestion and side effects of oral pharmaceuticals. The bill provides specifics concerning the format of the courses and examinations and requires the Florida Medical Association and the Florida Optometric Association to jointly develop and administer the course and examination.

The bill also alters the composition of the committee that maintains the formulary of topical drugs certified optometrists are permitted to prescribe to specify that the two optometrists on the committee must be certified optometrists. The bill specifies that the formulary of topical ocular pharmaceutical agents will consist of those topical agents that are appropriate to treat and diagnose ocular diseases and disorders. The bill also establishes a statutory formulary of oral pharmaceutical agents that certified optometrists are permitted to prescribe.

Section 19 amends s. 463.0057, F.S., to prohibit holders of faculty certificates from prescribing ocular pharmaceutical agents unless they take a course on general and ocular pharmacology, pass an examination, and are licensed and certified optometrists.

Section 20 amends s. 463.006, F.S., to require that the licensure examination for optometrists include questions on the use and side effects of all ocular pharmaceutical agents, not just topical agents. Anyone who passes this examination and fulfills other licensure and certification requirements will be permitted to administer and prescribe pharmaceutical agents in the diagnosis and treatment of ocular conditions.

Section 21 amends s. 463.0135, F.S., to state that a certified optometrist shall administer and prescribe oral ocular pharmaceutical agents in a manner consistent with applicable preferred practice patterns of the American Academy of Ophthalmology. The bill also provides that

optometrists who diagnose neovascular glaucoma, in addition to other types of glaucoma currently listed in statute, must promptly and without unreasonable delay refer the patient to a licensed physician skilled in diseases of the eye. In addition, an optometrist must timely refer to such a physician any patient who experiences progressive glaucoma due to failed pharmaceutical management by the optometrist.

The bill also requires co-management of post-operative care to be conducted pursuant to an established protocol that governs the relationship between the operating surgeon and the optometrist. The patient must be informed that either physician will be available for emergency care throughout the post-operative period, and the patient must consent to the co-management relationship in writing.

Section 22 amends s. 463.014, F.S., to prohibit optometrists from prescribing or otherwise distributing any drug for the purpose of treating a systemic disease, except that optometrists may use commonly-accepted methods to immediately treat anaphylaxis. The bill also further clarifies the definition of surgery in ch. 463, F.S., which prohibits optometrists from conducting surgery.

Section 23 creates s. 463.0141, F.S., to require and provide specifications for reporting of adverse incidents in the practice of optometry.

Section 24 amends s. 483.035, F.S., to include optometrists in the list of licensed practitioners who are permitted to operate clinical laboratories exclusively in connection with the diagnosis and treatment of their own patients.

Section 25 amends s. 483.041, F.S., to include optometrists in the definition of licensed practitioner with respect to clinical laboratories.

Section 26 amends s. 483.181, F.S., to require clinical laboratories to accept specimens for examination submitted by optometrists.

Section 27 amends s. 499.003, F.S., to delete the requirement that contractors and subcontractors that receive prescription drugs from an entity that purchased the drugs under the 340B program (federal Public Health Services Act) maintain these drugs separate from any other prescription drugs in their possession.

Section 28 amends s. 766.102, F.S., to change the burden of proof for a claimant in an action alleging a breach of the prevailing professional standard of care in an action for damages based on death or personal injury that allegedly resulted from the failure of a health care provider to order, perform, or administer supplemental diagnostic tests. The burden of proof is increased from greater weight of the evidence to clear and convincing evidence.

Section 29 amends s. 766.106, F.S., to authorize a prospective defendant, or his or her legal representative, to conduct ex parte interviews of the claimant's treating health care providers without the presence of the claimant or the claimant's legal representative. Notice of any intended interviews must be provided to the claimant at least 10 days before the date of the interview.

Section 30 creates s. 766.1091, F.S., to authorize certain health care providers and a patient or prospective patient to agree in writing to submit to arbitration any claim for medical negligence that may currently exist or that may accrue in the future that would otherwise be brought under ch. 766, F.S., relating to medical malpractice. The health care providers include:

- Allopathic physicians;
- Osteopathic physicians;
- Certified optometrists;
- Dentists;
- Any entity owned in whole or in part by an allopathic physician, osteopathic physician, certified optometrist, or dentist; or
- A health care clinic licensed under part X of ch. 400, F.S.

An arbitration agreement entered into under this section would be governed by the FAC. Such an arbitration agreement may contain a provision that would limit the available damages in any arbitration award.

Section 31 amends s. 893.02, F.S., to include certified optometrists as authorized prescribers of controlled substances in Florida, if they hold valid federal controlled substance registry numbers.

Section 32 amends s. 893.05, F.S., to prohibit certified optometrists from prescribing any Schedule I or II controlled substances listed in the Florida Comprehensive Drug Abuse Prevention and Control Act.

Section 33 creates a new undesignated section of law to require the AHCA to prepare a report within 18 months after the implementation of an expansion of managed care to new populations or the provision of new items and services. The AHCA must post a draft of the report on its website and provide an opportunity for public comment. The final report must be submitted to the Legislature, along with a description of the process for public input. The report must include an assessment of:

- The impact of managed care on patient access to care, including any new barriers to the use of services or prescription drugs created by the use of medical management or cost-containment tools.
- The impact of managed care expansion on the utilization of services, quality of care, and patient outcomes.
- The use of prior authorization and other utilization management tools, including whether these tools pose an undue administrative burden for health care providers or create barriers to needed care.

Section 34 provides that the bill will take effect upon becoming a law, except as otherwise expressly provided in this act.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of the bill have no impact on public records or open meetings issues under the requirements of Article I, Section 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

The change in the fine imposed on home health agencies will result in a reduction in the amount of the fines assessed, but the fiscal impact is indeterminate.

A resident in an assisted living facility may incur the cost of a medical examination if the AHCA questions whether a resident needs care beyond that which the facility is licensed to provide.

C. Government Sector Impact:

Department of Health
The Department of Health should experience little fiscal impact as certification procedures for optometrists are already in effect. There will be an increase in workload relating to updating the formulary of drugs which certified optometrists may prescribe as well as non-recurring rulemaking costs which may be adequately absorbed with current resources.

The DOH will experience recurring and non-recurring increases in workload to implement the provisions of this bill, but current resources and budget authority are adequate to absorb the costs of these increases.

Agency for Health Care Administration
The Agency for Health Care Administration may experience an increase in applications for clinical laboratory licenses from optometrists, although this number is estimated to be small. There will also be a slightly increased workload related to additional inspections of such laboratories, which should be offset by an increase in revenues from licensure and renewal fees.[68]

[68] Department of Health, *2012 Bill Analysis, Economic Statement, and Fiscal Note for SB 788*. A copy is on file with the Senate Health Regulation Committee.

VI. Technical Deficiencies:

None.

VII. Related Issues:

It is not clear whether the intent of lines 676 through 680 is to terminate a Medicaid provider's participation in the Medicaid program only if the provider has been convicted of criminal offenses in the enumerated sections of statute or whether noncriminal actions in those sections of statute would also be grounds for termination from the Medicaid program.

The informal discovery options include taking unsworn statements of treating health care providers. In Section 29, lines 1802 and 1803 provide in existing law that the claimant or claimant's legal representative has the right to attend the taking of such unsworn statements. Lines 1806 – 1807 provide for ex parte interviews of treating health care providers without the presence of the claimant or the claimant's legal representative. Neither "unsworn statements" nor "ex parte interviews" are defined. To avoid inconsistency and potential litigation, it might be prudent to define or distinguish an unsworn statement and an ex parte interview.

According to the AHCA, the requirement in Section 33 for the AHCA to prepare a report within 18 months after implementation of an expansion of managed care is a duplication of federal requirements for the Section 1915(b) Long Term Care Managed Care Waiver and Section 1115 Research and Demonstration Waiver. The AHCA suggests that Section 33 is not necessary and should either be removed or revised to accurately reflect the federal requirements for waivers.[69]

VIII. 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 Regulation on February 9, 2012:
The committee substitute:

- Changes the definition of "accrediting organizations" for purposes of the regulation of hospitals and ambulatory surgical centers;
- Provides additional exemptions from licensure and regulation as a health care clinic;
- Modifies the surety bond requirements for certain Medicaid providers;
- Modifies the requirements for managed care plans' management of prescribed drugs;
- Modifies the grounds under which a professional board or the DOH must refuse to admit a candidate to an examination and refuse to issue or renew a license, certificate, or registration of a health care practitioner;
- Expands the types of drugs that certified optometrists may administer and prescribe;
- Requires optometrists to report adverse incidents;
- Authorizes optometrists to operate a clinical laboratory exclusively in connection with the diagnosis and treatment of their own patients;

[69] *See* Agency for Health Care Administration 2012 Bill Analysis and Economic Impact Statement for SB 1316 – on file with the Senate Health Regulation Committee.

- Requires clinical laboratories to accept for examination specimens submitted by optometrists;
- Requires physicians who perform liposuction procedures in which more than 1,000 cubic centimeters of fat is removed to register with the DOH and be inspected by the DOH;
- Authorizes a virtual inventory for certain prescription drugs that were purchased under the 340B program;
- Requires a medical negligence claimant to prove by clear and convincing evidence that the actions of a health care provider represented a breach of the prevailing professional standard of care in an action for damages based on death or personal injury which alleges that the death or injury resulted from the failure of a health care provider to order, perform, or administer supplemental diagnostic tests;
- Authorizes ex parte interviews to be used in informal discovery; and
- Authorizes certain health care providers and their patients to enter into voluntary binding arbitration agreements and limit damages.

B. Amendments:

None.

815246

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
02/09/2012	.	
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The Committee on Health Regulation (Gaetz) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause and insert:

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

395.002 Definitions.—As used in this chapter:

(1) "Accrediting organizations" means national accreditation organizations that are approved by the Centers for Medicare and Medicaid Services and whose standards incorporate comparable licensure regulations required by the state ~~the Joint Commission on Accreditation of Healthcare Organizations, the~~

815246

~~American Osteopathic Association, the Commission on Accreditation of Rehabilitation Facilities, and the Accreditation Association for Ambulatory Health Care, Inc~~.

Section 2. Subsection (6) of section 400.474, Florida Statutes, is amended, present subsection (7) of that section is renumbered as subsection (8), and a new subsection (7) is added to that section, to read:

400.474 Administrative penalties.—

(6) The agency may deny, revoke, or suspend the license of a home health agency and shall impose a fine of $5,000 against a home health agency that:

(a) Gives remuneration for staffing services to:

1. Another home health agency with which it has formal or informal patient-referral transactions or arrangements; or

2. A health services pool with which it has formal or informal patient-referral transactions or arrangements,

unless the home health agency has activated its comprehensive emergency management plan in accordance with s. 400.492. This paragraph does not apply to a Medicare-certified home health agency that provides fair market value remuneration for staffing services to a non-Medicare-certified home health agency that is part of a continuing care facility licensed under chapter 651 for providing services to its own residents if each resident receiving home health services pursuant to this arrangement attests in writing that he or she made a decision without influence from staff of the facility to select, from a list of Medicare-certified home health agencies provided by the facility, that Medicare-certified home health agency to provide

815246

the services.

(b) Provides services to residents in an assisted living facility for which the home health agency does not receive fair market value remuneration.

(c) Provides staffing to an assisted living facility for which the home health agency does not receive fair market value remuneration.

(d) Fails to provide the agency, upon request, with copies of all contracts with assisted living facilities which were executed within 5 years before the request.

(e) Gives remuneration to a case manager, discharge planner, facility-based staff member, or third-party vendor who is involved in the discharge planning process of a facility licensed under chapter 395, chapter 429, or this chapter from whom the home health agency receives referrals.

~~(f) Fails to submit to the agency, within 15 days after the end of each calendar quarter, a written report that includes the following data based on data as it existed on the last day of the quarter:~~

~~1. The number of insulin-dependent diabetic patients receiving insulin-injection services from the home health agency;~~

~~2. The number of patients receiving both home health services from the home health agency and hospice services;~~

~~3. The number of patients receiving home health services from that home health agency; and~~

~~4. The names and license numbers of nurses whose primary job responsibility is to provide home health services to patients and who received remuneration from the home health~~

815246

~~agency in excess of $25,000 during the calendar quarter.~~

(f) ~~(g)~~ Gives cash, or its equivalent, to a Medicare or Medicaid beneficiary.

(g) ~~(h)~~ Has more than one medical director contract in effect at one time or more than one medical director contract and one contract with a physician-specialist whose services are mandated for the home health agency in order to qualify to participate in a federal or state health care program at one time.

(h) ~~(i)~~ Gives remuneration to a physician without a medical director contract being in effect. The contract must:

1. Be in writing and signed by both parties;

2. Provide for remuneration that is at fair market value for an hourly rate, which must be supported by invoices submitted by the medical director describing the work performed, the dates on which that work was performed, and the duration of that work; and

3. Be for a term of at least 1 year.

The hourly rate specified in the contract may not be increased during the term of the contract. The home health agency may not execute a subsequent contract with that physician which has an increased hourly rate and covers any portion of the term that was in the original contract.

(i) ~~(j)~~ Gives remuneration to:

1. A physician, and the home health agency is in violation of paragraph (g) ~~(h)~~ or paragraph (h) ~~(i)~~;

2. A member of the physician's office staff; or

3. An immediate family member of the physician,

if the home health agency has received a patient referral in the preceding 12 months from that physician or physician's office staff.

(j) ~~(k)~~ Fails to provide to the agency, upon request, copies of all contracts with a medical director which were executed within 5 years before the request.

(k) ~~(l)~~ Demonstrates a pattern of billing the Medicaid program for services to Medicaid recipients which are medically unnecessary as determined by a final order. A pattern may be demonstrated by a showing of at least two such medically unnecessary services within one Medicaid program integrity audit period.

Paragraphs (e) and (i) do not apply to or preclude ~~Nothing in paragraph (c) or paragraph (j) shall be interpreted as applying to or precluding~~ any discount, compensation, waiver of payment, or payment practice permitted by 42 U.S.C. s. 1320a-7(b) or regulations adopted thereunder, including 42 C.F.R. s. 1001.952 or s. 1395nn or regulations adopted thereunder.

(7) The agency shall impose a fine of $50 per day against a home health agency that fails to submit to the agency, within 15 days after the end of each calendar quarter, a written report that includes the following data based on data as it existed on the last day of the quarter:

(a) The number of patients receiving both home health services from the home health agency and hospice services;

(b) The number of patients receiving home health services from the home health agency;

(c) The number of insulin-dependent diabetic patients receiving insulin-injection services from the home health agency; and

(d) The names and license numbers of nurses whose primary job responsibility is to provide home health services to patients and who received remuneration from the home health agency in excess of $25,000 during the calendar quarter.

Section 3. Paragraph (l) of subsection (4) of section 400.9905, Florida Statutes, is amended, and paragraph (m) is added to that subsection, to read:

400.9905 Definitions.—

(4) "Clinic" means an entity at which health care services are provided to individuals and which tenders charges for reimbursement for such services, including a mobile clinic and a portable equipment provider. For purposes of this part, the term does not include and the licensure requirements of this part do not apply to:

(l) Orthotic, ~~or~~ prosthetic, pediatric cardiology, or perinatology clinical facilities or anesthesia clinical facilities that are not otherwise exempt under paragraph (a) or paragraph (k) and that are a publicly traded corporation or ~~that~~ are wholly owned, directly or indirectly, by a publicly traded corporation. As used in this paragraph, a publicly traded corporation is a corporation that issues securities traded on an exchange registered with the United States Securities and Exchange Commission as a national securities exchange.

(m) Entities that are owned or controlled, directly or indirectly, by a publicly traded entity that has $100 million or more, in the aggregate, in total annual revenues derived from

providing health care services by licensed health care practitioners who are employed or contracted by an entity described in this paragraph.

Section 4. Paragraph (i) of subsection (4) of section 409.221, Florida Statutes, is amended to read:

409.221 Consumer-directed care program.—

(4) CONSUMER-DIRECTED CARE.—

(i) *Background screening requirements.*—All persons who render care under this section must undergo level 2 background screening pursuant to chapter 435 and s. 408.809. The agency shall, as allowable, reimburse consumer-employed caregivers for the cost of conducting such ~~background~~ screening ~~as required by this section~~. For purposes of this section, a person who has undergone screening, who is qualified for employment under this section and applicable rule, and who has not been unemployed for more than 90 days following such screening is not required to be rescreened. Such person must attest under penalty of perjury to not having been convicted of a disqualifying offense since completing such screening.

Section 5. Paragraph (c) of subsection (3) of section 409.907, Florida Statutes, is amended, paragraph (k) is added to that subsection, and subsections (6), (7), and (8) of that section are amended, to read:

409.907 Medicaid provider agreements.—The agency may make payments for medical assistance and related services rendered to Medicaid recipients only to an individual or entity who has a provider agreement in effect with the agency, who is performing services or supplying goods in accordance with federal, state, and local law, and who agrees that no person shall, on the

grounds of handicap, race, color, or national origin, or for any other reason, be subjected to discrimination under any program or activity for which the provider receives payment from the agency.

(3) The provider agreement developed by the agency, in addition to the requirements specified in subsections (1) and (2), shall require the provider to:

(c) Retain all medical and Medicaid-related records for 6 ~~a period of 5~~ years to satisfy all necessary inquiries by the agency.

(k) Report a change in any principal of the provider, including any officer, director, agent, managing employee, or affiliated person, or any partner or shareholder who has an ownership interest equal to 5 percent or more in the provider, to the agency in writing no later than 30 days after the change occurs.

(6) A Medicaid provider agreement may be revoked, at the option of the agency, due to ~~as the result of~~ a change of ownership of any facility, association, partnership, or other entity named as the provider in the provider agreement.

(a) In the event of a change of ownership, the transferor remains liable for all outstanding overpayments, administrative fines, and any other moneys owed to the agency before the effective date of the change of ownership. ~~In addition to the continuing liability of the transferor,~~ The transferee is also liable to the agency for all outstanding overpayments identified by the agency on or before the effective date of the change of ownership. ~~For purposes of this subsection, the term "outstanding overpayment" includes any amount identified in a~~


815246

~~preliminary audit report issued to the transferor by the agency on or before the effective date of the change of ownership.~~ In the event of a change of ownership for a skilled nursing facility or intermediate care facility, the Medicaid provider agreement shall be assigned to the transferee if the transferee meets all other Medicaid provider qualifications. In the event of a change of ownership involving a skilled nursing facility licensed under part II of chapter 400, liability for all outstanding overpayments, administrative fines, and any moneys owed to the agency before the effective date of the change of ownership shall be determined in accordance with s. 400.179.

(b) At least 60 days before the anticipated date of the change of ownership, the transferor must ~~shall~~ notify the agency of the intended change of ownership and the transferee must ~~shall~~ submit to the agency a Medicaid provider enrollment application. If a change of ownership occurs without compliance with the notice requirements of this subsection, the transferor and transferee are ~~shall be~~ jointly and severally liable for all overpayments, administrative fines, and other moneys due to the agency, regardless of whether the agency identified the overpayments, administrative fines, or other moneys before or after the effective date of the change of ownership. The agency may not approve a transferee's Medicaid provider enrollment application if the transferee or transferor has not paid or agreed in writing to a payment plan for all outstanding overpayments, administrative fines, and other moneys due to the agency. This subsection does not preclude the agency from seeking any other legal or equitable remedies available to the agency for the recovery of moneys owed to the Medicaid program.


815246

In the event of a change of ownership involving a skilled nursing facility licensed under part II of chapter 400, liability for all outstanding overpayments, administrative fines, and any moneys owed to the agency before the effective date of the change of ownership shall be determined in accordance with s. 400.179 if the Medicaid provider enrollment application for change of ownership is submitted before the change of ownership.

(c) As used in this subsection, the term:

1. "Administrative fines" includes any amount identified in a notice of a monetary penalty or fine which has been issued by the agency or other regulatory or licensing agency that governs the provider.

2. "Outstanding overpayment" includes any amount identified in a preliminary audit report issued to the transferor by the agency on or before the effective date of a change of ownership.

(7) ~~The agency may require,~~ As a condition of participating in the Medicaid program and before entering into the provider agreement, the agency may require ~~that~~ the provider to submit information, in an initial and any required renewal applications, concerning the professional, business, and personal background of the provider and permit an onsite inspection of the provider's service location by agency staff or other personnel designated by the agency to perform this function. Before entering into a provider agreement, the agency may ~~shall~~ perform an ~~a random~~ onsite inspection~~, within 60 days after receipt of a fully complete new provider's application,~~ of the provider's service location ~~prior to making its first payment to the provider for Medicaid services~~ to determine the

815246

applicant's ability to provide ~~the~~ services in compliance with the Medicaid program and professional regulations ~~that the applicant is proposing to provide for Medicaid reimbursement~~. ~~The agency is not required to perform an onsite inspection of a provider or program that is licensed by the agency, that provides services under waiver programs for home and community-based services, or that is licensed as a medical foster home by the Department of Children and Family Services.~~ As a continuing condition of participation in the Medicaid program, a provider must ~~shall~~ immediately notify the agency of any current or pending bankruptcy filing. Before entering into the provider agreement, or as a condition of continuing participation in the Medicaid program, the agency may also require that Medicaid providers reimbursed on a fee-for-services basis or fee schedule basis that ~~which~~ is not cost-based, post a surety bond not to exceed $50,000 or the total amount billed by the provider to the program during the current or most recent calendar year, whichever is greater. For new providers, the amount of the surety bond shall be determined by the agency based on the provider's estimate of its first year's billing. If the provider's billing during the first year exceeds the bond amount, the agency may require the provider to acquire an additional bond equal to the actual billing level of the provider. A provider's bond need ~~shall~~ not exceed $50,000 if a physician or group of physicians licensed under chapter 458, chapter 459, or chapter 460 has a 50 percent or greater ownership interest in the provider or if the provider is an assisted living facility licensed under chapter 429. The bonds permitted by this section are in addition to the bonds

815246

referenced in s. 400.179(2)(d). If the provider is a corporation, partnership, association, or other entity, the agency may require the provider to submit information concerning the background of that entity and of any principal of the entity, including any partner or shareholder having an ownership interest in the entity equal to 5 percent or greater, and any treating provider who participates in or intends to participate in Medicaid through the entity. The information must include:

(a) Proof of holding a valid license or operating certificate, as applicable, if required by the state or local jurisdiction in which the provider is located or if required by the Federal Government.

(b) Information concerning any prior violation, fine, suspension, termination, or other administrative action taken under the Medicaid laws, rules, or regulations of this state or of any other state or the Federal Government; any prior violation of the laws, rules, or regulations relating to the Medicare program; any prior violation of the rules or regulations of any other public or private insurer; and any prior violation of the laws, rules, or regulations of any regulatory body of this or any other state.

(c) Full and accurate disclosure of any financial or ownership interest that the provider, or any principal, partner, or major shareholder thereof, may hold in any other Medicaid provider or health care related entity or any other entity that is licensed by the state to provide health or residential care and treatment to persons.

(d) If a group provider, identification of all members of the group and attestation that all members of the group are


815246

enrolled in or have applied to enroll in the Medicaid program.

(8)~~(a)~~ Each provider, or each principal of the provider if the provider is a corporation, partnership, association, or other entity, seeking to participate in the Medicaid program must submit a complete set of his or her fingerprints to the agency for the purpose of conducting a criminal history record check. Principals of the provider include any officer, director, billing agent, managing employee, or affiliated person, or any partner or shareholder who has an ownership interest equal to 5 percent or more in the provider. However, for a hospital licensed under chapter 395 or a nursing home licensed under chapter 400, principals of the provider are those who meet the definition of a controlling interest under s. 408.803. A director of a not-for-profit corporation or organization is not a principal for purposes of a background investigation as required by this section if the director: serves solely in a voluntary capacity for the corporation or organization, does not regularly take part in the day-to-day operational decisions of the corporation or organization, receives no remuneration from the not-for-profit corporation or organization for his or her service on the board of directors, has no financial interest in the not-for-profit corporation or organization, and has no family members with a financial interest in the not-for-profit corporation or organization; and if the director submits an affidavit, under penalty of perjury, to this effect to the agency and the not-for-profit corporation or organization submits an affidavit, under penalty of perjury, to this effect to the agency as part of the corporation's or organization's Medicaid provider agreement application.


815246

(a) Notwithstanding the above, the agency may require a background check for any person reasonably suspected by the agency to have been convicted of a crime. This subsection does not apply to:

~~1. A hospital licensed under chapter 395;~~

~~2. A nursing home licensed under chapter 400;~~

~~3. A hospice licensed under chapter 400;~~

~~4. An assisted living facility licensed under chapter 429;~~

1.~~5.~~ A unit of local government, except that requirements of this subsection apply to nongovernmental providers and entities contracting with the local government to provide Medicaid services. The actual cost of the state and national criminal history record checks must be borne by the nongovernmental provider or entity; or

2.~~6.~~ Any business that derives more than 50 percent of its revenue from the sale of goods to the final consumer, and the business or its controlling parent is required to file a form 10-K or other similar statement with the Securities and Exchange Commission or has a net worth of $50 million or more.

(b) Background screening shall be conducted in accordance with chapter 435 and s. 408.809. The cost of the state and national criminal record check shall be borne by the provider.

~~(c) Proof of compliance with the requirements of level 2 screening under chapter 435 conducted within 12 months before the date the Medicaid provider application is submitted to the agency fulfills the requirements of this subsection.~~

Section 6. Present paragraphs (e) and (f) of subsection (1) of section 409.913, Florida Statutes, are redesignated as paragraphs (f) and (g), respectively, a new paragraph (e) is

added to that subsection, and subsections (2), (9), (13), (15), (16), (21), (22), (25), (28), (29), (30), and (31) of that section are amended, to read:

409.913 Oversight of the integrity of the Medicaid program.—The agency shall operate a program to oversee the activities of Florida Medicaid recipients, and providers and their representatives, to ensure that fraudulent and abusive behavior and neglect of recipients occur to the minimum extent possible, and to recover overpayments and impose sanctions as appropriate. Beginning January 1, 2003, and each year thereafter, the agency and the Medicaid Fraud Control Unit of the Department of Legal Affairs shall submit a joint report to the Legislature documenting the effectiveness of the state's efforts to control Medicaid fraud and abuse and to recover Medicaid overpayments during the previous fiscal year. The report must describe the number of cases opened and investigated each year; the sources of the cases opened; the disposition of the cases closed each year; the amount of overpayments alleged in preliminary and final audit letters; the number and amount of fines or penalties imposed; any reductions in overpayment amounts negotiated in settlement agreements or by other means; the amount of final agency determinations of overpayments; the amount deducted from federal claiming as a result of overpayments; the amount of overpayments recovered each year; the amount of cost of investigation recovered each year; the average length of time to collect from the time the case was opened until the overpayment is paid in full; the amount determined as uncollectible and the portion of the uncollectible amount subsequently reclaimed from the Federal Government; the

number of providers, by type, that are terminated from participation in the Medicaid program as a result of fraud and abuse; and all costs associated with discovering and prosecuting cases of Medicaid overpayments and making recoveries in such cases. The report must also document actions taken to prevent overpayments and the number of providers prevented from enrolling in or reenrolling in the Medicaid program as a result of documented Medicaid fraud and abuse and must include policy recommendations necessary to prevent or recover overpayments and changes necessary to prevent and detect Medicaid fraud. All policy recommendations in the report must include a detailed fiscal analysis, including, but not limited to, implementation costs, estimated savings to the Medicaid program, and the return on investment. The agency must submit the policy recommendations and fiscal analyses in the report to the appropriate estimating conference, pursuant to s. 216.137, by February 15 of each year. The agency and the Medicaid Fraud Control Unit of the Department of Legal Affairs each must include detailed unit-specific performance standards, benchmarks, and metrics in the report, including projected cost savings to the state Medicaid program during the following fiscal year.

(1) For the purposes of this section, the term:

(e) "Medicaid provider" or "provider" has the same meaning as provided in s. 409.901 and, for purposes of oversight of the integrity of the Medicaid program, also includes a participant in a Medicaid managed care provider network.

(2) The agency shall conduct, or cause to be conducted by contract or otherwise, reviews, investigations, analyses, audits, or any combination thereof, to determine possible fraud,


815246

abuse, overpayment, or recipient neglect in the Medicaid program and ~~shall~~ report the findings of any overpayments in audit reports as appropriate. At least 5 percent of all audits must ~~shall~~ be conducted on a random basis. As part of its ongoing fraud detection activities, the agency shall identify and monitor, by contract or otherwise, patterns of overutilization of Medicaid services based on state averages. The agency shall track Medicaid provider prescription and billing patterns and evaluate them against Medicaid medical necessity criteria and coverage and limitation guidelines adopted by rule. Medical necessity determination requires that service be consistent with symptoms or confirmed diagnosis of illness or injury under treatment and not in excess of the patient's needs. The agency shall conduct reviews of provider exceptions to peer group norms and ~~shall~~, using statistical methodologies, provider profiling, and analysis of billing patterns, detect and investigate abnormal or unusual increases in billing or payment of claims for Medicaid services and medically unnecessary provision of services. The agency may review and analyze information from sources other than enrolled Medicaid providers in conducting its activities under this subsection.

(9) A Medicaid provider shall retain medical, professional, financial, and business records pertaining to services and goods furnished to a Medicaid recipient and billed to Medicaid for 6 ~~a period of 5~~ years after the date of furnishing such services or goods. The agency may investigate, review, or analyze such records, which must be made available during normal business hours. However, 24-hour notice must be provided if patient treatment would be disrupted. The provider is responsible for


815246

furnishing to the agency, and keeping the agency informed of the location of, the provider's Medicaid-related records. The authority of the agency to obtain Medicaid-related records from a provider is neither curtailed nor limited during a period of litigation between the agency and the provider.

(13) The agency shall ~~immediately~~ terminate participation of a Medicaid provider in the Medicaid program and may seek civil remedies or impose other administrative sanctions against a Medicaid provider, if the provider or any principal, officer, director, agent, managing employee, or affiliated person of the provider, or any partner or shareholder having an ownership interest in the provider equal to 5 percent or greater, has been convicted of a criminal offense under federal law or the law of any state relating to the practice of the provider's profession, or an offense listed under s. 409.907(10), s. 408.809(4), or s. 435.04(2) ~~has been:~~

~~(a) Convicted of a criminal offense related to the delivery of any health care goods or services, including the performance of management or administrative functions relating to the delivery of health care goods or services;~~

~~(b) Convicted of a criminal offense under federal law or the law of any state relating to the practice of the provider's profession; or~~

~~(c) Found by a court of competent jurisdiction to have neglected or physically abused a patient in connection with the delivery of health care goods or services~~. If the agency determines that the ~~a~~ provider did not participate or acquiesce in the ~~an~~ offense ~~specified in paragraph (a), paragraph (b), or paragraph (c)~~, termination will not be imposed. If the agency

effects a termination under this subsection, the agency shall issue an immediate final order pursuant to s. 120.569(2)(n).

(15) The agency shall seek a remedy provided by law, including, but not limited to, any remedy provided in subsections (13) and (16) and s. 812.035, if:

(a) The provider's license has not been renewed, or has been revoked, suspended, or terminated, for cause, by the licensing agency of any state;

(b) The provider has failed to make available or has refused access to Medicaid-related records to an auditor, investigator, or other authorized employee or agent of the agency, the Attorney General, a state attorney, or the Federal Government;

(c) The provider has not furnished or has failed to make available such Medicaid-related records as the agency has found necessary to determine whether Medicaid payments are or were due and the amounts thereof;

(d) The provider has failed to maintain medical records made at the time of service, or prior to service if prior authorization is required, demonstrating the necessity and appropriateness of the goods or services rendered;

(e) The provider is not in compliance with provisions of Medicaid provider publications that have been adopted by reference as rules in the Florida Administrative Code; with provisions of state or federal laws, rules, or regulations; with provisions of the provider agreement between the agency and the provider; or with certifications found on claim forms or on transmittal forms for electronically submitted claims that are submitted by the provider or authorized representative, as such

provisions apply to the Medicaid program;

(f) The provider or person who ordered, authorized, or prescribed the care, services, or supplies has furnished, ~~or~~ ordered, or authorized the furnishing of~~,~~ goods or services to a recipient which are inappropriate, unnecessary, excessive, or harmful to the recipient or are of inferior quality;

(g) The provider has demonstrated a pattern of failure to provide goods or services that are medically necessary;

(h) The provider or an authorized representative of the provider, or a person who ordered, authorized, or prescribed the goods or services, has submitted or caused to be submitted false or a pattern of erroneous Medicaid claims;

(i) The provider or an authorized representative of the provider, or a person who has ordered, authorized, or prescribed the goods or services, has submitted or caused to be submitted a Medicaid provider enrollment application, a request for prior authorization for Medicaid services, a drug exception request, or a Medicaid cost report that contains materially false or incorrect information;

(j) The provider or an authorized representative of the provider has collected from or billed a recipient or a recipient's responsible party improperly for amounts that should not have been so collected or billed by reason of the provider's billing the Medicaid program for the same service;

(k) The provider or an authorized representative of the provider has included in a cost report costs that are not allowable under a Florida Title XIX reimbursement plan~~,~~ after the provider or authorized representative had been advised in an audit exit conference or audit report that the costs were not


815246

allowable;

(l) The provider is charged by information or indictment with fraudulent billing practices or any offense referenced in subsection (13). The sanction applied for this reason is limited to suspension of the provider's participation in the Medicaid program for the duration of the indictment unless the provider is found guilty pursuant to the information or indictment;

(m) The provider or a person who has ordered, authorized, or prescribed the goods or services is found liable for negligent practice resulting in death or injury to the provider's patient;

(n) The provider fails to demonstrate that it had available during a specific audit or review period sufficient quantities of goods, or sufficient time in the case of services, to support the provider's billings to the Medicaid program;

(o) The provider has failed to comply with the notice and reporting requirements of s. 409.907;

(p) The agency has received reliable information of patient abuse or neglect or of any act prohibited by s. 409.920; or

(q) The provider has failed to comply with an agreed-upon repayment schedule.

A provider is subject to sanctions for violations of this subsection as the result of actions or inactions of the provider, or actions or inactions of any principal, officer, director, agent, managing employee, or affiliated person of the provider, or any partner or shareholder having an ownership interest in the provider equal to 5 percent or greater, in which the provider participated or acquiesced.


815246

(16) The agency shall impose any of the following sanctions or disincentives on a provider or a person for any of the acts described in subsection (15):

(a) Suspension for a specific period of time of not more than 1 year. Suspension precludes ~~shall preclude~~ participation in the Medicaid program, which includes any action that results in a claim for payment to the Medicaid program as a result of furnishing, supervising a person who is furnishing, or causing a person to furnish goods or services.

(b) Termination for a specific period of time of from more than 1 year to 20 years. Termination precludes ~~shall preclude~~ participation in the Medicaid program, which includes any action that results in a claim for payment to the Medicaid program as a result of furnishing, supervising a person who is furnishing, or causing a person to furnish goods or services.

(c) Imposition of a fine of up to $5,000 for each violation. Each day that an ongoing violation continues, such as refusing to furnish Medicaid-related records or refusing access to records, is considered, for the purposes of this section, to be a separate violation. Each instance of improper billing of a Medicaid recipient; each instance of including an unallowable cost on a hospital or nursing home Medicaid cost report after the provider or authorized representative has been advised in an audit exit conference or previous audit report of the cost unallowability; each instance of furnishing a Medicaid recipient goods or professional services that are inappropriate or of inferior quality as determined by competent peer judgment; each instance of knowingly submitting a materially false or erroneous Medicaid provider enrollment application, request for prior


815246

authorization for Medicaid services, drug exception request, or cost report; each instance of inappropriate prescribing of drugs for a Medicaid recipient as determined by competent peer judgment; and each false or erroneous Medicaid claim leading to an overpayment to a provider is considered, for the purposes of this section, to be a separate violation.

(d) Immediate suspension, if the agency has received information of patient abuse or neglect or of any act prohibited by s. 409.920. Upon suspension, the agency must issue an immediate final order under s. 120.569(2)(n).

(e) A fine, not to exceed $10,000, for a violation of paragraph (15)(i).

(f) Imposition of liens against provider assets, including, but not limited to, financial assets and real property, not to exceed the amount of fines or recoveries sought, upon entry of an order determining that such moneys are due or recoverable.

(g) Prepayment reviews of claims for a specified period of time.

(h) Comprehensive followup reviews of providers every 6 months to ensure that they are billing Medicaid correctly.

(i) Corrective-action plans that ~~would~~ remain in effect ~~for providers~~ for up to 3 years and that are ~~would be~~ monitored by the agency every 6 months while in effect.

(j) Other remedies as permitted by law to effect the recovery of a fine or overpayment.

If a provider voluntarily relinquishes its Medicaid provider number after receiving written notice that the agency is conducting, or has conducted, an audit or investigation and the


815246

sanction of suspension or termination will be imposed for noncompliance discovered as a result of the audit or investigation, the agency shall impose the sanction of termination for cause against the provider. The Secretary of Health Care Administration may make a determination that imposition of a sanction or disincentive is not in the best interest of the Medicaid program, in which case a sanction or disincentive may ~~shall~~ not be imposed.

(21) When making a determination that an overpayment has occurred, the agency shall prepare and issue an audit report to the provider showing the calculation of overpayments. The agency's determination shall be based solely upon information available to it before issuance of the audit report and, in the case of documentation obtained to substantiate claims for Medicaid reimbursement, based solely upon contemporaneous records.

(22) The audit report, supported by agency work papers, showing an overpayment to a provider constitutes evidence of the overpayment. A provider may not present or elicit testimony, ~~either~~ on direct examination or cross-examination in any court or administrative proceeding, regarding the purchase or acquisition by any means of drugs, goods, or supplies; sales or divestment by any means of drugs, goods, or supplies; or inventory of drugs, goods, or supplies, unless such acquisition, sales, divestment, or inventory is documented by written invoices, written inventory records, or other competent written documentary evidence maintained in the normal course of the provider's business. Testimony or evidence that is not based upon contemporaneous records or that was not furnished to the


815246

agency within 21 days after the issuance of the audit report is inadmissible in an administrative hearing on a Medicaid overpayment or an administrative sanction. Notwithstanding the applicable rules of discovery, all documentation to ~~that will~~ be offered as evidence at an administrative hearing on a Medicaid overpayment or an administrative sanction must be exchanged by all parties at least 14 days before the administrative hearing or ~~must be~~ excluded from consideration.

(25)(a) The agency shall withhold Medicaid payments, in whole or in part, to a provider upon receipt of reliable evidence that the circumstances giving rise to the need for a withholding of payments involve fraud, willful misrepresentation, or abuse under the Medicaid program, or a crime committed while rendering goods or services to Medicaid recipients. If it is determined that fraud, willful misrepresentation, abuse, or a crime did not occur, the payments withheld must be paid to the provider within 14 days after such determination ~~with interest at the rate of 10 percent a year~~. ~~Any money withheld in accordance with this paragraph shall be placed in a suspended account, readily accessible to the agency, so that any payment ultimately due the provider shall be made within 14 days.~~

(b) The agency shall deny payment, or require repayment, if the goods or services were furnished, supervised, or caused to be furnished by a person who has been suspended or terminated from the Medicaid program or Medicare program by the Federal Government or any state.

(c) Overpayments owed to the agency bear interest at the rate of 10 percent per year from the date of determination of


815246

the overpayment by the agency, and payment arrangements regarding overpayments and fines must be made within 30 days after the date of the final order and are not subject to further appeal ~~at the conclusion of legal proceedings~~. ~~A provider who does not enter into or adhere to an agreed-upon repayment schedule may be terminated by the agency for nonpayment or partial payment.~~

(d) The agency, upon entry of a final agency order, a judgment or order of a court of competent jurisdiction, or a stipulation or settlement, may collect the moneys owed by all means allowable by law, including, but not limited to, notifying any fiscal intermediary of Medicare benefits that the state has a superior right of payment. Upon receipt of such written notification, the Medicare fiscal intermediary shall remit to the state the sum claimed.

(e) The agency may institute amnesty programs to allow Medicaid providers the opportunity to voluntarily repay overpayments. The agency may adopt rules to administer such programs.

(28) Venue for all Medicaid program integrity ~~overpayment~~ cases lies ~~shall lie~~ in Leon County, at the discretion of the agency.

(29) Notwithstanding other provisions of law, the agency and the Medicaid Fraud Control Unit of the Department of Legal Affairs may review a person's or provider's Medicaid-related and non-Medicaid-related records in order to determine the total output of a provider's practice to reconcile quantities of goods or services billed to Medicaid with quantities of goods or services used in the provider's total practice.


815246

(30) The agency shall terminate a provider's participation in the Medicaid program if the provider fails to reimburse an overpayment or pay a fine that has been determined by final order, not subject to further appeal, within 30 ~~35~~ days after the date of the final order, unless the provider and the agency have entered into a repayment agreement.

(31) If a provider requests an administrative hearing pursuant to chapter 120, such hearing must be conducted within 90 days following assignment of an administrative law judge, absent exceptionally good cause shown as determined by the administrative law judge or hearing officer. Upon issuance of a final order, the outstanding balance of the amount determined to constitute the overpayment and fines is ~~shall become~~ due. If a provider fails to make payments in full, fails to enter into a satisfactory repayment plan, or fails to comply with the terms of a repayment plan or settlement agreement, the agency shall withhold ~~medical assistance~~ reimbursement payments for Medicaid services until the amount due is paid in full.

Section 7. Subsection (8) of section 409.920, Florida Statutes, is amended to read:

409.920 Medicaid provider fraud.—

(8) A person who provides the state, any state agency, any of the state's political subdivisions, or any agency of the state's political subdivisions with information about fraud or suspected fraudulent acts ~~fraud~~ by a Medicaid provider, including a managed care organization, is immune from civil liability for libel, slander, or any other relevant tort for providing any ~~the~~ information about fraud or suspected fraudulent acts, unless the person acted with knowledge that the


815246

information was false or with reckless disregard for the truth or falsity of the information. For purposes of this subsection, the term "fraudulent acts" includes actual or suspected fraud, abuse, or overpayment, including any fraud-related matters that a provider or health plan is required to report to the agency or a law enforcement agency. The immunity from civil liability extends to reports of fraudulent acts conveyed to the agency in any manner, including any forum and with any audience as directed by the agency, and includes all discussions subsequent to the report and subsequent inquiries from the agency, unless the person acted with knowledge that the information was false or with reckless disregard for the truth or falsity of the information.

Section 8. Paragraph (c) of subsection (2) of section 409.967, Florida Statutes, is amended to read:

409.967 Managed care plan accountability.—

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

(c) *Access.*—

1. Providers.—The agency shall establish specific standards for the number, type, and regional distribution of providers in managed care plan networks to ensure access to care for both adults and children. Each plan must maintain a regionwide network of providers in sufficient numbers to meet the access standards for specific medical services for all recipients enrolled in the plan. The exclusive use of mail-order pharmacies is ~~may~~ not ~~be~~ sufficient to meet network access standards.

Consistent with the standards established by the agency, provider networks may include providers located outside the region. A plan may contract with a new hospital facility before the date the hospital becomes operational if the hospital has commenced construction, will be licensed and operational by January 1, 2013, and a final order has issued in any civil or administrative challenge. Each plan shall establish and maintain an accurate and complete electronic database of contracted providers, including information about licensure or registration, locations and hours of operation, specialty credentials and other certifications, specific performance indicators, and such other information as the agency deems necessary. The database must be available online to both the agency and the public and have the capability to compare the availability of providers to network adequacy standards and to accept and display feedback from each provider's patients. Each plan shall submit quarterly reports to the agency identifying the number of enrollees assigned to each primary care provider.

2. Prescribed drugs.—

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

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

(II) Include coverage via prior authorization for each drug newly approved by the federal Food and Drug Administration until the plan's Pharmaceutical and Therapeutics Committee reviews

such drug for inclusion on the formulary. The timing of the formulary review must comply with s. 409.91195; and

(III) Provide a response within 24 hours after receipt of all necessary information from the medical provider for a request for prior authorization and provide a procedure for escalating a delayed prior authorization request to the pharmacy management team for resolution or to override other medical management tools.

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

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

d. A managed care plan that imposes a step-therapy or a fail-first protocol must do so in accordance with the following:

(I) If prescribed drugs for the treatment of a medical condition are restricted for use by the plan through a step-therapy or fail-first protocol, the plan must provide the prescriber with access to a clear and convenient process to

expeditiously request a prior authorization that includes a procedure for escalation to the pharmacy management team if not resolved in a timely manner.

(II) Escalation to the pharmacy management team must be expeditiously granted by the plan if the prescriber can submit appropriate and complete medical documentation to the plan that the preferred treatment required under the step-therapy or fail-first protocol:

(A) Has been ineffective in the treatment of the enrollee's disease or medical condition;

(B) Is reasonably expected to be ineffective based on the known relevant physical or mental characteristics and medical history of the enrollee and known characteristics of the drug regimen; or

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

(III) The pharmacy management team shall work directly with the medical provider to bring the prior-authorization request to a clinically appropriate, cost-effective, and timely resolution.

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

3. Prior authorization.—

a. Each managed care plan must ensure that the prior authorization process for prescribed drugs is readily accessible to health care providers, including posting appropriate contact information on its website and providing timely responses to

providers.

b. If a drug, determined to be medically necessary and prescribed for an enrollee by a physician using sound clinical judgment, is subject to prior authorization and approved, the managed care plan must provide for sufficient refills to complete the duration of the prescription. If the medication is still clinically appropriate for ongoing therapy after the initial prior authorization expires, the plan must provide a process of expedited review to evaluate ongoing therapy.

c. If a prescribed drug requires prior authorization, the managed care plan shall reimburse the pharmacist for dispensing a 72-hour supply of oral maintenance medications to the enrollee and process the prior authorization request. Dispensing a 72-hour supply must be consistent with laws that govern pharmacy practice and controlled substances. The managed care plan shall process all prior authorization requests in as timely a manner as possible.

d.~~3.~~ Managed care plans, and their fiscal agents or intermediaries, must accept prior authorization requests for prescribed drugs ~~any service~~ electronically.

Section 9. Subsection (11) is added to section 429.23, Florida Statutes, to read:

429.23 Internal risk management and quality assurance program; adverse incidents and reporting requirements.—

(11) The agency shall annually submit a report to the Legislature on adverse incident reports by assisted living facilities. The report must include the following information arranged by county:

(a) A total number of adverse incidents;


815246

(b) A listing, by category, of the type of adverse incidents occurring within each category and the type of staff involved;

(c) A listing, by category, of the types of injuries, if any, and the number of injuries occurring within each category;

(d) Types of liability claims filed based on an adverse incident report or reportable injury; and

(e) Disciplinary action taken against staff, categorized by the type of staff involved.

Section 10. Present subsections (9), (10), and (11) of section 429.26, Florida Statutes, are renumbered as subsections (12), (13), and (14), respectively, and new subsections (9), (10), and (11) are added to that section, to read:

429.26 Appropriateness of placements; examinations of residents.—

(9) If, at any time after admission to a facility, agency personnel question whether a resident needs care beyond that which the facility is licensed to provide, the agency may require the resident to be physically examined by a licensed physician, licensed physician assistant, or certified nurse practitioner. To the extent possible, the examination must be performed by the resident's preferred physician, physician assistant, or nurse practitioner and paid for by the resident with personal funds, except as provided in s. 429.18(2). This subsection does not preclude the agency from imposing sanctions for violations of subsection (1).

(a) Following examination, the examining physician, physician assistant, or nurse practitioner shall complete and sign a medical form provided by the agency. The completed


815246

medical form must be submitted to the agency within 30 days after the date the facility owner or administrator was notified by the agency that a physical examination is required.

(b) A medical review team designated by the agency shall determine whether the resident is appropriately residing in the facility based on the completed medical form and, if necessary, consultation with the physician, physician assistant, or nurse practitioner who performed the examination. Members of the medical review team making the determination may not include the agency personnel who initially questioned the appropriateness of the resident's placement. The medical review team shall base its decision on a comprehensive review of the resident's physical and functional status. A determination that the resident's placement is not appropriate is final and binding upon the facility and the resident.

(c) A resident who is determined by the medical review team to be inappropriately residing in a facility shall be given 30 days' written notice to relocate by the owner or administrator, unless the resident's continued residence in the facility presents an imminent danger to the health, safety, or welfare of the resident or a substantial probability exists that death or serious physical harm to the resident would result if the resident is allowed to remain in the facility.

(10) If a mental health resident appears to have needs in addition to those identified in the community living support plan, the agency may require an evaluation by a mental health professional, as determined by the Department of Children and Family Services.

(11) A facility may not be required to retain a resident

who requires more services or care than the facility is able to provide in accordance with its policies and criteria for admission and continued residency.

Section 11. Effective July 1, 2012, section 456.0635, Florida Statutes, is amended to read:

456.0635 Health care ~~Medicaid~~ fraud; disqualification for license, certificate, or registration.—

(1) Health care ~~Medicaid~~ fraud in the practice of a health care profession is prohibited.

(2) Each board under ~~within~~ the jurisdiction of the department, or the department if there is no board, shall refuse to admit a candidate to an ~~any~~ examination and refuse to issue ~~or renew~~ a license, certificate, or registration to an ~~any~~ applicant if the candidate or applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant~~, has been~~:

(a) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under chapter 409, chapter 817, or chapter 893, or a similar felony offense committed in another state or jurisdiction, unless the candidate or applicant has successfully completed a drug court program for that felony and provides proof that the plea has been withdrawn or the charges have been dismissed. Any such conviction or plea shall exclude the applicant or candidate from licensure, examination, certification, or registration ~~21 U.S.C. ss. 801-970, or 42 U.S.C. ss. 1395-1396,~~ unless the sentence and any subsequent period of probation for such conviction or plea ~~pleas~~ ended: ~~more than 15 years prior to the date of the application;~~

1. For felonies of the first or second degree, more than 15 years before the date of application.

2. For felonies of the third degree, more than 10 years before the date of application, except for felonies of the third degree under s. 893.13(6)(a).

3. For felonies of the third degree under s. 893.13(6)(a), more than 5 years before the date of application.

(b) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970 or 42 U.S.C. ss. 1395-1396, unless the sentence and any subsequent period of probation for such conviction or plea ended more than 15 years before the date of the application.

(c) ~~(b)~~ Has been terminated for cause from the Florida Medicaid program pursuant to s. 409.913, unless the candidate or applicant has been in good standing with the Florida Medicaid program for the most recent 5 years.~~;~~

(d) ~~(c)~~ Has been terminated for cause, pursuant to the appeals procedures established by the state ~~or Federal Government~~, from any other state Medicaid program ~~or the federal Medicare program~~, unless the candidate or applicant has been in good standing with that ~~a~~ state Medicaid program ~~or the federal Medicare program~~ for the most recent 5 years and the termination occurred at least 20 years before ~~prior to~~ the date of the application.

(e) Is currently listed on the United States Department of Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities.


815246

This subsection does not apply to candidates or applicants for initial licensure or certification who were enrolled in an educational or training program on or before July 1, 2009, which was recognized by a board or, if there is no board, recognized by the department, and who applied for licensure after July 1, 2012.

(3) The department shall refuse to renew a license, certificate, or registration of any applicant if the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant:

(a) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under chapter 409, chapter 817, or chapter 893, or a similar felony offense committed in another state or jurisdiction, unless the applicant is currently enrolled in a drug court program that allows the withdrawal of the plea for that felony upon successful completion of that program. Any such conviction or plea excludes the applicant or candidate from licensure, examination, certification, or registration unless the sentence and any subsequent period of probation for such conviction or plea ended:

1. For felonies of the first or second degree, more than 15 years before the date of application.

2. For felonies of the third degree, more than 10 years before the date of application, except for felonies of the third degree under s. 893.13(6)(a).

3. For felonies of the third degree under s. 893.13(6)(a), more than 5 years before the date of application.

(b) Has been convicted of, or entered a plea of guilty or


815246

nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970 or 42 U.S.C. ss. 1395-1396 since July 1, 2009, unless the sentence and any subsequent period of probation for such conviction or plea ended more than 15 years before the date of the application.

(c) Has been terminated for cause from the Florida Medicaid program pursuant to s. 409.913, unless the applicant has been in good standing with the Florida Medicaid program for the most recent 5 years.

(d) Has been terminated for cause, pursuant to the appeals procedures established by the state, from any other state Medicaid program, unless the applicant has been in good standing with that state Medicaid program for the most recent 5 years and the termination occurred at least 20 years before the date of the application.

(e) Is currently listed on the United States Department of Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities.

(4) ~~(3)~~ Licensed health care practitioners shall report allegations of health care ~~Medicaid~~ fraud to the department, regardless of the practice setting in which the alleged health care ~~Medicaid~~ fraud occurred.

(5) ~~(4)~~ The acceptance by a licensing authority of a licensee's ~~candidate's~~ relinquishment of a license which is offered in response to or anticipation of the filing of administrative charges alleging health care ~~Medicaid~~ fraud or similar charges constitutes the permanent revocation of the license.

Section 12. Effective July 1, 2012, present subsections


815246

(14) and (15) of section 456.036, Florida Statutes, are renumbered as subsections (15) and (16), respectively, and a new subsection (14) is added to that section, to read:

456.036 Licenses; active and inactive status; delinquency.—

(14) A person who has been denied license renewal, certification, or registration under s. 456.0635(3) may regain licensure, certification, or registration only by meeting the qualifications and completing the application process for initial licensure as defined by the board, or the department if there is no board. However, a person who was denied renewal of licensure, certification, or registration under s. 24 of chapter 2009-223, Laws of Florida, between July 1, 2009, and June 30, 2012, is not required to retake and pass examinations applicable for initial licensure, certification, or registration.

Section 13. Subsection (1) of section 456.074, Florida Statutes, is amended to read:

456.074 Certain health care practitioners; immediate suspension of license.—

(1) The department shall issue an emergency order suspending the license of any person licensed under chapter 458, chapter 459, chapter 460, chapter 461, chapter 462, chapter 463, chapter 464, chapter 465, chapter 466, or chapter 484 who pleads guilty to, is convicted or found guilty of, or who enters a plea of nolo contendere to, regardless of adjudication~~, to~~:

(a) A felony under chapter 409, chapter 817, or chapter 893 or under 21 U.S.C. ss. 801-970 or ~~under~~ 42 U.S.C. ss. 1395-1396; or

(b) A misdemeanor or felony under 18 U.S.C. s. 669, ss. 285-287, s. 371, s. 1001, s. 1035, s. 1341, s. 1343, s. 1347, s.


815246

1349, or s. 1518 or 42 U.S.C. ss. 1320a-7b~~, relating to the Medicaid program~~.

Section 14. Subsections (3), (4), and (5) of section 463.002, Florida Statutes, are amended to read:

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

(3)(a) "Licensed practitioner" means a person who is a primary health care provider licensed to engage in the practice of optometry under the authority of this chapter.

(b) A licensed practitioner who is not a certified optometrist shall be required to display at her or his place of practice a sign which states, "I am a Licensed Practitioner, not a Certified Optometrist, and I am not able to prescribe ~~topical~~ ocular pharmaceutical agents."

(c) All practitioners initially licensed after July 1, 1993, must be certified optometrists.

(4) "Certified optometrist" means a licensed practitioner authorized by the board to administer and prescribe ~~topical~~ ocular pharmaceutical agents.

(5) "Optometry" means the diagnosis of conditions of the human eye and its appendages; the employment of any objective or subjective means or methods, including the administration of ~~topical ocular~~ pharmaceutical agents, for the purpose of determining the refractive powers of the human eyes, or any visual, muscular, neurological, or anatomic anomalies of the human eyes and their appendages; and the prescribing and employment of lenses, prisms, frames, mountings, contact lenses, orthoptic exercises, light frequencies, and any other means or methods, including ~~topical ocular~~ pharmaceutical agents, for the correction, remedy, or relief of any insufficiencies or abnormal


815246

conditions of the human eyes and their appendages.

Section 15. Paragraph (g) of subsection (1) of section 463.005, Florida Statutes, is amended to read:

463.005 Authority of the board.—

(1) The Board of Optometry has authority to adopt rules pursuant to ss. 120.536(1) and 120.54 to implement the provisions of this chapter conferring duties upon it. Such rules shall include, but not be limited to, rules relating to:

(g) Administration and prescription of ~~topical~~ ocular pharmaceutical agents.

Section 16. Section 463.0055, Florida Statutes, is amended to read:

463.0055 Administration and prescription of ~~topical~~ ocular pharmaceutical agents; committee.—

(1)(a) Certified optometrists may administer and prescribe ~~topical ocular~~ pharmaceutical agents as provided in this section for the diagnosis and treatment of ocular conditions of the human eye and its appendages without the use of surgery or other invasive techniques. However, a licensed practitioner who is not certified may use topically applied anesthetics solely for the purpose of glaucoma examinations~~,~~ but is otherwise prohibited from administering or prescribing ~~topical ocular~~ pharmaceutical agents.

(b) Before a certified optometrist may administer or prescribe oral ocular pharmaceutical agents, the certified optometrist must complete a course and subsequent examination on general and ocular pharmacology which have a particular emphasis on the ingestion of oral pharmaceutical agents and the side effects of those agents. For certified optometrists licensed


815246

before January 1, 1990, the course shall consist of 50 contact hours and 25 of those hours shall be Internet-based. For certified optometrists licensed on or after January 1, 1990, the course shall consist of 20 contact hours and 10 of those hours shall be Internet-based. The first course and examination shall be presented by January 1, 2013, and shall thereafter be administered at least annually. The Florida Medical Association and the Florida Optometric Association shall jointly develop and administer a course and examination for such purpose and jointly determine the site or sites for the course and examination.

(2)(a) There is ~~hereby~~ created a committee composed of two certified optometrists licensed pursuant to this chapter, appointed by the Board of Optometry, two board-certified ophthalmologists licensed pursuant to chapter 458 or chapter 459, appointed by the Board of Medicine, and one additional person with a doctorate degree in pharmacology who is not licensed pursuant to chapter 458, chapter 459, or this chapter, appointed by the State Surgeon General. The committee shall review requests for additions to, deletions from, or modifications of a formulary of topical ocular pharmaceutical agents for administration and prescription by certified optometrists and shall provide to the board advisory opinions and recommendations on such requests. The formulary of topical ocular pharmaceutical agents shall consist of those topical ~~ocular pharmaceutical~~ agents that are appropriate to treat and diagnose ocular diseases and disorders and that ~~which~~ the certified optometrist is qualified to use in the practice of optometry. The board shall establish, add to, delete from, or modify the formulary by rule. Notwithstanding any provision of


815246

chapter 120 to the contrary, the formulary rule shall become effective 60 days from the date it is filed with the Secretary of State.

(b) The topical formulary may be added to, deleted from, or modified according to the procedure described in paragraph (a). Any person who requests an addition, deletion, or modification of an authorized topical ~~ocular pharmaceutical~~ agent shall have the burden of proof to show cause why such addition, deletion, or modification should be made.

(c) The State Surgeon General shall have standing to challenge any rule or proposed rule of the board pursuant to s. 120.56. In addition to challenges for any invalid exercise of delegated legislative authority, the administrative law judge, upon such a challenge by the State Surgeon General, may declare all or part of a rule or proposed rule invalid if it:

1. Does not protect the public from any significant and discernible harm or damages;

2. Unreasonably restricts competition or the availability of professional services in the state or in a significant part of the state; or

3. Unnecessarily increases the cost of professional services without a corresponding or equivalent public benefit.

However, there shall not be created a presumption of the existence of any of the conditions cited in this subsection in the event that the rule or proposed rule is challenged.

(d) Upon adoption of the topical formulary required by this section, and upon each addition, deletion, or modification to the topical formulary, the board shall mail a copy of the


815246

amended topical formulary to each certified optometrist and to each pharmacy licensed by the state.

(3) In addition to the formulary of topical ocular pharmaceutical agents in subsection (2), there is created a statutory formulary of oral pharmaceutical agents, which include the following agents:

(a) The following analgesics, or their generic or therapeutic equivalents, which may not be administered or prescribed for more than 72 hours without consultation with a physician licensed under chapter 458 or chapter 459 who is skilled in diseases of the eye:

1. Tramadol hydrochloride.

2. Acetaminophen 300 mg with No. 3 codeine phosphate 30 mg.

(b) The following antibiotics, or their generic or therapeutic equivalents:

1. Amoxicillin.

2. Azithromycin.

3. Ciprofloxacin.

4. Dicloxacillin.

5. Doxycycline.

6. Keflex.

7. Minocycline.

(c) The following antivirals, or their generic or therapeutic equivalents:

1. Acyclovir.

2. Famciclovir.

3. Valacyclovir.

(d) The following oral anti-glaucoma agents, or their generic or therapeutic equivalents, which may not be

815246

administered or prescribed for more than 72 hours without consultation with a physician licensed under chapter 458 or chapter 459 who is skilled in diseases of the eye:

1. Acetazolamide.

2. Methazolamide.

Any oral pharmaceutical agent listed in the statutory formulary set forth in this subsection which is subsequently determined by the United States Food and Drug Administration to be unsafe for administration or prescription shall be considered to have been deleted from the formulary of oral pharmaceutical agents. The oral pharmaceutical agents on the statutory formulary set forth in this subsection may not otherwise be deleted by the board, the department, or the State Surgeon General.

(4) ~~(3)~~ A certified optometrist shall be issued a prescriber number by the board. Any prescription written by a certified optometrist for a ~~topical ocular~~ pharmaceutical agent pursuant to this section shall have the prescriber number printed thereon.

Section 17. Subsection (3) of section 463.0057, Florida Statutes, is amended to read:

463.0057 Optometric faculty certificate.—

(3) The holder of a faculty certificate may engage in the practice of optometry as permitted by this section~~,~~ but may not administer or prescribe ~~topical~~ ocular pharmaceutical agents unless the certificateholder has satisfied the requirements of ss. 463.0055(1)(b) and ~~s.~~ 463.006(1)(b)4. and 5.

Section 18. Subsections (2) and (3) of section 463.006, Florida Statutes, are amended to read:

815246

463.006 Licensure and certification by examination.—

(2) The examination shall consist of the appropriate subjects, including applicable state laws and rules and general and ocular pharmacology with emphasis on the use ~~topical application~~ and side effects of ocular pharmaceutical agents. The board may by rule substitute a national examination as part or all of the examination and may by rule offer a practical examination in addition to the written examination.

(3) Each applicant who successfully passes the examination and otherwise meets the requirements of this chapter is entitled to be licensed as a practitioner and to be certified to administer and prescribe ~~topical ocular~~ pharmaceutical agents in the diagnosis and treatment of ocular conditions.

Section 19. Subsections (1) and (2) of section 463.0135, Florida Statutes, are amended, and subsection (10) is added to that section, to read:

463.0135 Standards of practice.—

(1) A licensed practitioner shall provide that degree of care which conforms to that level of care provided by medical practitioners in the same or similar communities. A certified optometrist shall administer and prescribe oral ocular pharmaceutical agents in a manner consistent with applicable preferred practice patterns of the American Academy of Ophthalmology. A licensed practitioner shall advise or assist her or his patient in obtaining further care when the service of another health care practitioner is required.

(2) A licensed practitioner diagnosing angle closure, neovascular, infantile, or congenital forms of glaucoma shall promptly and without unreasonable delay refer the patient to a

physician skilled in diseases of the eye and licensed under chapter 458 or chapter 459. In addition, a licensed practitioner shall timely refer any patient who experiences progressive glaucoma due to failed pharmaceutical intervention to a physician who is skilled in diseases of the eye and licensed under chapter 458 or chapter 459.

(10) Comanagement of postoperative care shall be conducted pursuant to an established protocol that governs the relationship between the operating surgeon and the optometrist. The patient shall be informed that either physician will be available for emergency care throughout the postoperative period, and the patient shall consent in writing to the comanagement relationship.

Section 20. Subsections (3) and (4) of section 463.014, Florida Statutes, are amended to read:

463.014 Certain acts prohibited.—

(3) Prescribing, ordering, dispensing, administering, supplying, selling, or giving any ~~systemic~~ drugs for the purpose of treating a systemic disease by a licensed practitioner is prohibited. However, a certified optometrist is permitted to use commonly accepted means or methods to immediately address incidents of anaphylaxis.

(4) Surgery of any kind, including the use of lasers, is expressly prohibited. For purposes of this subsection, the term "surgery" means a procedure using an instrument, including lasers, scalpels, or needles, in which human tissue is cut, burned, or vaporized by incision, injection, ultrasound, laser, or radiation. The term includes procedures using instruments that require closing by suturing, clamping, or another such

device. Certified optometrists may remove superficial foreign bodies. For the purposes of this subsection, the term "superficial foreign bodies" means any foreign matter that is embedded in the conjunctiva or cornea but which has not penetrated the globe.

Section 21. Section 463.0141, Florida Statutes, is created to read:

463.0141 Reports of adverse incidents in the practice of optometry.—

(1) Any adverse incident that occurs on or after January 1, 2013, in the practice of optometry must be reported to the department in the accordance with this section.

(2) The required notification to the department must be submitted in writing by certified mail and postmarked within 15 days after the occurrence of the adverse incident.

(3) For purposes of notification to the department, the term "adverse incident," as used in this section, means an event that is associated in whole or in part with the prescribing of an oral ocular pharmaceutical agent and that results in one of the following:

(a) Any condition that requires the transfer of a patient to a hospital licensed under chapter 395;

(b) Any condition that requires the patient to obtain care from a physician licensed under chapter 458 or chapter 459, other than a referral or a consultation required under this chapter;

(c) Permanent physical injury to the patient;

(d) Partial or complete permanent loss of sight by the patient; or

(e) Death of the patient.

(4) The department shall review each incident and determine whether it potentially involved conduct by the licensed practitioner which may be subject to disciplinary action, in which case s. 456.073 applies. Disciplinary action, if any, shall be taken by the board.

Section 22. Subsection (1) of section 483.035, Florida Statutes, is amended to read:

483.035 Clinical laboratories operated by practitioners for exclusive use; licensure and regulation.—

(1) A clinical laboratory operated by one or more practitioners licensed under chapter 458, chapter 459, chapter 460, chapter 461, chapter 462, chapter 463, or chapter 466, exclusively in connection with the diagnosis and treatment of their own patients, must be licensed under this part and must comply with the provisions of this part, except that the agency shall adopt rules for staffing, for personnel, including education and training of personnel, for proficiency testing, and for construction standards relating to the licensure and operation of the laboratory based upon and not exceeding the same standards contained in the federal Clinical Laboratory Improvement Amendments of 1988 and the federal regulations adopted thereunder.

Section 23. Subsection (7) of section 483.041, Florida Statutes, is amended to read:

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

(7) "Licensed practitioner" means a physician licensed under chapter 458, chapter 459, chapter 460, ~~or~~ chapter 461, or chapter 463; a dentist licensed under chapter 466; a person

licensed under chapter 462; or an advanced registered nurse practitioner licensed under part I of chapter 464; or a duly licensed practitioner from another state licensed under similar statutes who orders examinations on materials or specimens for nonresidents of the State of Florida, but who reside in the same state as the requesting licensed practitioner.

Section 24. Subsection (5) of section 483.181, Florida Statutes, is amended to read:

483.181 Acceptance, collection, identification, and examination of specimens.—

(5) A clinical laboratory licensed under this part must accept a human specimen submitted for examination by a practitioner licensed under chapter 458, chapter 459, chapter 460, chapter 461, chapter 462, chapter 463, s. 464.012, or chapter 466, if the specimen and test are the type performed by the clinical laboratory. A clinical laboratory may only refuse a specimen based upon a history of nonpayment for services by the practitioner. A clinical laboratory shall not charge different prices for tests based upon the chapter under which a practitioner submitting a specimen for testing is licensed.

Section 25. Paragraph (a) of subsection (54) of section 499.003, Florida Statutes, is amended to read:

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

(54) "Wholesale distribution" means distribution of prescription drugs to persons other than a consumer or patient, but does not include:

(a) Any of the following activities, which is not a violation of s. 499.005(21) if such activity is conducted in

accordance with s. 499.01(2)(g):

1. The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a prescription drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of that organization.

2. The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug by a charitable organization described in s. 501(c)(3) of the Internal Revenue Code of 1986, as amended and revised, to a nonprofit affiliate of the organization to the extent otherwise permitted by law.

3. The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug among hospitals or other health care entities that are under common control. For purposes of this subparagraph, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, by voting rights, by contract, or otherwise.

4. The sale, purchase, trade, or other transfer of a prescription drug from or for any federal, state, or local government agency or any entity eligible to purchase prescription drugs at public health services prices pursuant to Pub. L. No. 102-585, s. 602 to a contract provider or its subcontractor for eligible patients of the agency or entity under the following conditions:

a. The agency or entity must obtain written authorization for the sale, purchase, trade, or other transfer of a

prescription drug under this subparagraph from the State Surgeon General or his or her designee.

b. The contract provider or subcontractor must be authorized by law to administer or dispense prescription drugs.

c. In the case of a subcontractor, the agency or entity must be a party to and execute the subcontract.

~~d. A contract provider or subcontractor must maintain separate and apart from other prescription drug inventory any prescription drugs of the agency or entity in its possession.~~

d.~~e.~~ The contract provider and subcontractor must maintain and produce immediately for inspection all records of movement or transfer of all the prescription drugs belonging to the agency or entity, including, but not limited to, the records of receipt and disposition of prescription drugs. Each contractor and subcontractor dispensing or administering these drugs must maintain and produce records documenting the dispensing or administration. Records that are required to be maintained include, but are not limited to, a perpetual inventory itemizing drugs received and drugs dispensed by prescription number or administered by patient identifier, which must be submitted to the agency or entity quarterly.

e.~~f.~~ The contract provider or subcontractor may administer or dispense the prescription drugs only to the eligible patients of the agency or entity or must return the prescription drugs for or to the agency or entity. The contract provider or subcontractor must require proof from each person seeking to fill a prescription or obtain treatment that the person is an eligible patient of the agency or entity and must, at a minimum, maintain a copy of this proof as part of the records of the

contractor or subcontractor required under sub-subparagraph e.

f.~~g.~~ In addition to the departmental inspection authority set forth in s. 499.051, the establishment of the contract provider and subcontractor and all records pertaining to prescription drugs subject to this subparagraph shall be subject to inspection by the agency or entity. All records relating to prescription drugs of a manufacturer under this subparagraph shall be subject to audit by the manufacturer of those drugs, without identifying individual patient information.

Section 26. Subsection (4) of section 766.102, Florida Statutes, is amended to read:

766.102 Medical negligence; standards of recovery; expert witness.—

(4)(a) The Legislature is cognizant of the changing trends and techniques for the delivery of health care in this state and the discretion that is inherent in the diagnosis, care, and treatment of patients by different health care providers. The failure of a health care provider to order, perform, or administer supplemental diagnostic tests is ~~shall~~ not ~~be~~ actionable if the health care provider acted in good faith and with due regard for the prevailing professional standard of care.

(b) The claimant has the burden of proving by clear and convincing evidence that the alleged actions of the health care provider represent a breach of the prevailing professional standard of care in an action for damages based on death or personal injury which alleges that the death or injury resulted from the failure of a health care provider to order, perform, or administer supplemental diagnostic tests.

Section 27. Paragraph (b) of subsection (6) of section 766.106, Florida Statutes, is amended to read:

766.106 Notice before filing action for medical negligence; presuit screening period; offers for admission of liability and for arbitration; informal discovery; review.—

(6) INFORMAL DISCOVERY.—

(b) Informal discovery may be used by a party to obtain unsworn statements, the production of documents or things, ~~and~~ physical and mental examinations, and ex parte interviews, as follows:

1. Unsworn statements.—Any party may require other parties to appear for the taking of an unsworn statement. Such statements may be used only for the purpose of presuit screening and are not discoverable or admissible in any civil action for any purpose by any party. A party desiring to take the unsworn statement of any party must give reasonable notice in writing to all parties. The notice must state the time and place for taking the statement and the name and address of the party to be examined. Unless otherwise impractical, the examination of any party must be done at the same time by all other parties. Any party may be represented by counsel at the taking of an unsworn statement. An unsworn statement may be recorded electronically, stenographically, or on videotape. The taking of unsworn statements is subject to the provisions of the Florida Rules of Civil Procedure and may be terminated for abuses.

2. Documents or things.—Any party may request discovery of documents or things. The documents or things must be produced, at the expense of the requesting party, within 20 days after the date of receipt of the request. A party is required to produce

discoverable documents or things within that party's possession or control. Medical records shall be produced as provided in s. 766.204.

3. Physical and mental examinations.—A prospective defendant may require an injured claimant to appear for examination by an appropriate health care provider. The prospective defendant shall give reasonable notice in writing to all parties as to the time and place for examination. Unless otherwise impractical, a claimant is required to submit to only one examination on behalf of all potential defendants. The practicality of a single examination must be determined by the nature of the claimant's condition, as it relates to the liability of each prospective defendant. Such examination report is available to the parties and their attorneys upon payment of the reasonable cost of reproduction and may be used only for the purpose of presuit screening. Otherwise, such examination report is confidential and exempt from the provisions of s. 119.07(1) and s. 24(a), Art. I of the State Constitution.

4. Written questions.—Any party may request answers to written questions, the number of which may not exceed 30, including subparts. A response must be made within 20 days after receipt of the questions.

5. Unsworn statements of treating health care providers.—A prospective defendant or his or her legal representative may also take unsworn statements of the claimant's treating health care providers. The statements must be limited to those areas that are potentially relevant to the claim of personal injury or wrongful death. Subject to the procedural requirements of subparagraph 1., a prospective defendant may take unsworn

statements from a claimant's treating physicians. Reasonable notice and opportunity to be heard must be given to the claimant or the claimant's legal representative before taking unsworn statements. The claimant or claimant's legal representative has the right to attend the taking of such unsworn statements.

6. Ex parte interviews of treating health care providers.—A prospective defendant or his or her legal representative may interview the claimant's treating health care providers without the presence of the claimant or the claimant's legal representative. If a prospective defendant or his or her legal representative intends to interview a claimant's health care providers, the prospective defendant must provide the claimant with notice of such interview at least 10 days before the date of the interview.

Section 28. Section 766.1091, Florida Statutes, is created to read:

766.1091 Voluntary binding arbitration; damages.—

(1) A health care provider licensed under chapter 458, chapter 459, chapter 463, or chapter 466; any entity owned in whole or in part by a health care provider licensed under chapter 458, chapter 459, chapter 463, or chapter 466; or any health care clinic licensed under part X of chapter 400, and a patient or prospective patient, may agree in writing to submit to arbitration any claim for medical negligence which may currently exist or may accrue in the future and would otherwise be brought pursuant to this chapter. Any arbitration agreement entered into pursuant to this section shall be governed by chapter 682.

(2) Any arbitration agreement entered into pursuant to

subsection (1) may contain a provision that limits the available damages in an arbitration award.

Section 29. Subsection (21) of section 893.02, Florida Statutes, is amended to read:

893.02 Definitions.—The following words and phrases as used in this chapter shall have the following meanings, unless the context otherwise requires:

(21) "Practitioner" means a physician licensed pursuant to chapter 458, a dentist licensed pursuant to chapter 466, a veterinarian licensed pursuant to chapter 474, an osteopathic physician licensed pursuant to chapter 459, a naturopath licensed pursuant to chapter 462, a certified optometrist licensed under chapter 463, or a podiatric physician licensed pursuant to chapter 461, provided such practitioner holds a valid federal controlled substance registry number.

Section 30. Subsection (1) of section 893.05, Florida Statutes, is amended to read:

893.05 Practitioners and persons administering controlled substances in their absence.—

(1) A practitioner, in good faith and in the course of his or her professional practice only, may prescribe, administer, dispense, mix, or otherwise prepare a controlled substance, or the practitioner may cause the same to be administered by a licensed nurse or an intern practitioner under his or her direction and supervision only. A veterinarian may so prescribe, administer, dispense, mix, or prepare a controlled substance for use on animals only~~,~~ and may cause it to be administered by an assistant or orderly under the veterinarian's direction and supervision only. A certified optometrist licensed under chapter

463 may not administer or prescribe pharmaceutical agents in Schedule I or Schedule II of the Florida Comprehensive Drug Abuse Prevention and Control Act.

Section 31. The Agency for Health Care Administration shall prepare a report within 18 months after the implementation of an expansion of managed care to new populations or the provision of new items and services. The agency shall post a draft of the report on its website and provide an opportunity for public comment. The final report shall be submitted to the Legislature, along with a description of the process for public input. The report must include an assessment of:

(1) The impact of managed care on patient access to care, including an evaluation of any new barriers to the use of services and prescription drugs, created by the use of medical management or cost-containment tools.

(2) The impact of the increased managed care expansion on the utilization of services, quality of care, and patient outcomes.

(3) The use of prior authorization and other utilization management tools, including an assessment of whether these tools pose an undue administrative burden for health care providers or create barriers to needed care.

Section 32. Except as otherwise expressly provided in this act, this act shall take effect upon becoming a law.

================ 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:


815246

A bill to be entitled

An act relating to health care; amending s. 395.002, F.S.; redefining the term "accrediting organizations" as it applies to the regulation of hospitals and other licensed facilities; amending s. 400.474, F.S.; revising the fine that may be imposed against a home health agency for failing to timely submit certain information to the Agency for Health Care Administration; amending s. 400.9905, F.S.; revising the definition of the term "clinic" as it relates to the Health Care Clinic Act; amending s. 409.221, F.S.; revising the background screening requirements for persons rendering care in the consumer-directed care program administered by the Agency for Health Care Administration; amending s. 409.907, F.S.; extending the records-retention period for certain Medicaid provider records; revising the provider agreement to require Medicaid providers to report changes in any principal of the provider to the agency; defining the term "administrative fines" for purposes of revoking a Medicaid provider agreement due to changes of ownership; authorizing, rather than requiring, an onsite inspection of a Medicaid provider's service location before entering into a provider agreement; specifying the principals of a hospital or nursing home provider for the purposes of submitting fingerprints for background screening; removing certain providers from being subject to agency background checks; amending s. 409.913, F.S.; defining


815246

the term "Medicaid provider" or "provider" for purposes of oversight of the integrity of the Medicaid program; authorizing the agency to review and analyze information from sources other than Medicaid-enrolled providers for purposes of determining fraud, abuse, overpayment, or neglect; extending the records-retention period for certain Medicaid provider records; revising the grounds for terminating a provider from the Medicaid program; requiring the agency to base its overpayment audit reports on certain information; deleting a requirement that the agency pay interest on certain withheld Medicaid payments; requiring payment arrangements for overpayments and fines to be made within a certain time; specifying that the venue for all Medicaid program integrity cases lies in Leon County; authorizing the agency and the Medicaid Fraud Control Unit to review certain records; amending s. 409.920, F.S.; clarifying the applicability of immunity from civil liability extended to persons who provide information about fraud or suspected fraudulent acts by a Medicaid provider; amending s. 409.967, F.S.; specifying required components of a Medicaid managed care plan relating to the provisions of medications; amending s. 429.23, F.S.; requiring the agency to submit a report to the Legislature on adverse incident reports from assisted living facilities; amending s. 429.26, F.S.; authorizing the agency to require a resident of an assisted living facility to undergo a

physical examination if the agency questions the appropriateness of the resident's placement in that facility; authorizing release of the results of the examination to a medical review team to be used along with additional information to determine whether the resident's placement in the assisted living facility is appropriate; providing for resident notification and relocation if the resident's continued placement in the facility is not appropriate; authorizing the agency to require the evaluation of a mental health resident by a mental health professional; authorizing an assisted living facility to discharge a resident who requires more services or care than the facility is able to provide; amending s. 456.0635, F.S.; revising the grounds under which the Department of Health or corresponding board is required to refuse to admit a candidate to an examination and refuse to issue or renew a license, certificate, or registration of a health care practitioner; providing an exception; amending s. 456.036, F.S.; providing that all persons who were denied renewal of licensure, certification, or registration under s. 456.0635(3), F.S., may regain licensure, certification, or registration only by completing the application process for initial licensure; providing an exception; amending s. 456.074, F.S.; revising the federal offenses for which the Department of Health must issue an emergency order suspending the license of certain health care professionals; amending s. 463.002, F.S.; conforming

provisions to changes made by the act; amending s. 463.005, F.S.; authorizing the Board of Optometry to adopt rules for the administration and prescription of ocular pharmaceutical agents; amending s. 463.0055, F.S.; authorizing certified optometrists to administer and prescribe pharmaceutical agents under certain circumstances; requiring that a certified optometrist complete a course and subsequent examination on general and ocular pharmacology; providing requirements for the course; requiring that the Florida Medical Association and the Florida Optometric Association jointly develop and administer the course and examination; revising qualifications of certain members of the formulary committee; providing for a formulary of topical ocular pharmaceutical agents which the committee may modify; specifying the agents that make up the statutory formulary of oral pharmaceutical agents; authorizing the deletion of an oral pharmaceutical agent listed in the statutory formulary under certain circumstances; prohibiting the board, the Department of Health, or the State Surgeon General from deleting an oral pharmaceutical agent listed in the statutory formulary; amending ss. 463.0057 and 463.006, F.S.; conforming provisions to changes made by the act; amending s. 463.0135, F.S.; requiring that a certified optometrist administer and prescribe oral ocular pharmaceutical agents in a certain manner; requiring that a licensed practitioner who diagnoses a patient who has a neovascular form of

815246

glaucoma or progressive glaucoma immediately refer the patient to a physician who is skilled in the diseases of the eye; requiring that comanagement of postoperative care be conducted pursuant to an established protocol; requiring that the patient be informed that a physician will be available for emergency care throughout the postoperative period; requiring that the patient consent in writing to the comanagement relationship; amending s. 463.014, F.S.; revising certain prohibited acts regarding an optometrist conducting surgery and dispensing, administering, ordering, supplying, or selling certain drugs; creating s. 463.0141, F.S.; requiring that adverse incidents in the practice of optometry be reported to the Department of Health; providing requirements for notifying the department of an adverse incident; providing a definition; requiring that the department review each incident and determine whether it involved conduct that is subject to disciplinary action; requiring that the Board of Optometry take disciplinary action if necessary; amending s. 483.035, F.S., relating to licensure and regulation of clinical laboratories operated by practitioners for exclusive use; providing applicability to clinical laboratories operated by practitioners licensed to practice optometry; amending s. 483.041, F.S.; revising the definition of the term "licensed practitioner" to include a practitioner licensed under ch. 463, F.S.; amending s. 483.181,

815246

F.S.; requiring clinical laboratories to accept human specimens submitted by practitioners licensed to practice under ch. 463, F.S.; amending s. 499.003, F.S.; removing a requirement that a contract provider or subcontractor maintain prescription drugs of the agency or entity in its possession separate and apart from other prescription drugs; amending s. 766.102, F.S.; providing that the claimant has the burden of proving by clear and convincing evidence that the actions of a health care provider represented a breach of the prevailing professional standard of care in an action for damages based on death or personal injury which alleges that the death or injury resulted from the failure of a health care provider to order, perform, or administer supplemental diagnostic tests; amending s. 766.106, F.S.; authorizing a prospective defendant to obtain informal discovery by conducting ex parte interviews of treating health care providers; requiring advance notice to the claimant of an ex parte interview; creating s. 766.1091, F.S.; authorizing a health care provider or health care clinic and a patient to agree to submit a claim of medical negligence to arbitration; requiring that the arbitration agreement be governed by ch. 682, F.S.; authorizing the arbitration agreement to contain a provision that limits an award of damages; amending s. 893.02, F.S.; revising the definition of the term "practitioner" to include certified optometrists for purposes of the Florida Comprehensive Drug Abuse

815246

Prevention and Control Act; amending s. 893.05, F.S.; prohibiting certified optometrists from administering and prescribing certain controlled substances; requiring the Agency for Health Care Administration to prepare a report for public comment and submission to the Legislature following the expansion of services to new populations or of new services; providing effective dates.

702404

LEGISLATIVE ACTION

Senate	.	House
Comm: FAV	.	
02/09/2012	.	
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The Committee on Health Regulation (Sobel) recommended the following:

Senate Amendment to Amendment (815246) (with title amendment)

Between lines 1116 and 1117
insert:

Section 14. Subsection (3) of section 458.309, Florida Statutes, is amended to read:

458.309 Rulemaking authority.—

(3) A physician ~~All physicians~~ who performs liposuction procedures in which more than 1,000 cubic centimeters of supernatant fat is removed, ~~perform~~ level 2 procedures lasting more than 5 minutes, and all level 3 surgical procedures in an

office setting must register the office with the department unless that office is licensed as a facility under ~~pursuant to~~ chapter 395. The department shall inspect the physician's office annually unless the office is accredited by a nationally recognized accrediting agency or an accrediting organization subsequently approved by the Board of Medicine. The actual costs for registration and inspection or accreditation shall be paid by the person seeking to register and operate the office setting in which office surgery is performed.

Section 15. Subsection (2) of section 459.005, Florida Statutes, is amended to read:

459.005 Rulemaking authority.—

(2) A physician ~~All physicians~~ who performs liposuction procedures in which more than 1,000 cubic centimeters of supernatant fat is removed, ~~perform~~ level 2 procedures lasting more than 5 minutes, and all level 3 surgical procedures in an office setting must register the office with the department unless that office is licensed as a facility under ~~pursuant to~~ chapter 395. The department shall inspect the physician's office annually unless the office is accredited by a nationally recognized accrediting agency or an accrediting organization subsequently approved by the Board of Osteopathic Medicine. The actual costs for registration and inspection or accreditation shall be paid by the person seeking to register and operate the office setting in which office surgery is performed.

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

And the title is amended as follows:

Delete line 1752

and insert:

professionals; amending ss. 458.309 and 459.005, F.S.; requiring a physician or osteopathic physician who performs certain medical procedures relating to liposuction in an office setting to register the office with the Department of Health unless that office is licensed as a facility under ch. 395, F.S., relating to hospital licensing and regulation; amending s. 463.002, F.S.; conforming

291568

LEGISLATIVE ACTION

Senate	.	House
Comm: UNFAV	.	
02/09/2012	.	
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The Committee on Health Regulation (Diaz de la Portilla) recommended the following:

Senate Amendment to Amendment (815246) (with title amendment)

Delete lines 1593 - 1609.

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

And the title is amended as follows:

Delete lines 1830 - 1836

and insert:

parte interview; amending s.

810774

LEGISLATIVE ACTION

Senate	.	House
Comm: UNFAV	.	
02/09/2012	.	
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The Committee on Health Regulation (Garcia) recommended the following:

Senate Substitute for Amendment (815246) (with title amendment)

Delete everything after the enacting clause

and insert:

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

395.002 Definitions.—As used in this chapter:

(1) "Accrediting organizations" means national accreditation organizations that are approved by the Centers for Medicare and Medicaid Services and whose standards incorporate

comparable licensure regulations required by the state ~~the Joint Commission on Accreditation of Healthcare Organizations, the American Osteopathic Association, the Commission on Accreditation of Rehabilitation Facilities, and the Accreditation Association for Ambulatory Health Care, Inc~~.

Section 2. Subsection (6) of section 400.474, Florida Statutes, is amended, present subsection (7) of that section is renumbered as subsection (8), and a new subsection (7) is added to that section, to read:

400.474 Administrative penalties.—

(6) The agency may deny, revoke, or suspend the license of a home health agency and shall impose a fine of $5,000 against a home health agency that:

(a) Gives remuneration for staffing services to:

1. Another home health agency with which it has formal or informal patient-referral transactions or arrangements; or

2. A health services pool with which it has formal or informal patient-referral transactions or arrangements,

unless the home health agency has activated its comprehensive emergency management plan in accordance with s. 400.492. This paragraph does not apply to a Medicare-certified home health agency that provides fair market value remuneration for staffing services to a non-Medicare-certified home health agency that is part of a continuing care facility licensed under chapter 651 for providing services to its own residents if each resident receiving home health services pursuant to this arrangement attests in writing that he or she made a decision without influence from staff of the facility to select, from a

list of Medicare-certified home health agencies provided by the facility, that Medicare-certified home health agency to provide the services.

(b) Provides services to residents in an assisted living facility for which the home health agency does not receive fair market value remuneration.

(c) Provides staffing to an assisted living facility for which the home health agency does not receive fair market value remuneration.

(d) Fails to provide the agency, upon request, with copies of all contracts with assisted living facilities which were executed within 5 years before the request.

(e) Gives remuneration to a case manager, discharge planner, facility-based staff member, or third-party vendor who is involved in the discharge planning process of a facility licensed under chapter 395, chapter 429, or this chapter from whom the home health agency receives referrals.

~~(f) Fails to submit to the agency, within 15 days after the end of each calendar quarter, a written report that includes the following data based on data as it existed on the last day of the quarter:~~

~~1. The number of insulin-dependent diabetic patients receiving insulin-injection services from the home health agency;~~

~~2. The number of patients receiving both home health services from the home health agency and hospice services;~~

~~3. The number of patients receiving home health services from that home health agency; and~~

~~4. The names and license numbers of nurses whose primary~~

~~job responsibility is to provide home health services to patients and who received remuneration from the home health agency in excess of $25,000 during the calendar quarter.~~

(f) ~~(g)~~ Gives cash, or its equivalent, to a Medicare or Medicaid beneficiary.

(g) ~~(h)~~ Has more than one medical director contract in effect at one time or more than one medical director contract and one contract with a physician-specialist whose services are mandated for the home health agency in order to qualify to participate in a federal or state health care program at one time.

(h) ~~(i)~~ Gives remuneration to a physician without a medical director contract being in effect. The contract must:

1. Be in writing and signed by both parties;

2. Provide for remuneration that is at fair market value for an hourly rate, which must be supported by invoices submitted by the medical director describing the work performed, the dates on which that work was performed, and the duration of that work; and

3. Be for a term of at least 1 year.

The hourly rate specified in the contract may not be increased during the term of the contract. The home health agency may not execute a subsequent contract with that physician which has an increased hourly rate and covers any portion of the term that was in the original contract.

(i) ~~(j)~~ Gives remuneration to:

1. A physician, and the home health agency is in violation of paragraph (g) ~~(h)~~ or paragraph (h) ~~(i)~~;

2. A member of the physician's office staff; or

3. An immediate family member of the physician,

if the home health agency has received a patient referral in the preceding 12 months from that physician or physician's office staff.

(j) ~~(k)~~ Fails to provide to the agency, upon request, copies of all contracts with a medical director which were executed within 5 years before the request.

(k) ~~(l)~~ Demonstrates a pattern of billing the Medicaid program for services to Medicaid recipients which are medically unnecessary as determined by a final order. A pattern may be demonstrated by a showing of at least two such medically unnecessary services within one Medicaid program integrity audit period.

Paragraphs (e) and (i) do not apply to or preclude ~~Nothing in paragraph (e) or paragraph (j) shall be interpreted as applying to or precluding~~ any discount, compensation, waiver of payment, or payment practice permitted by 42 U.S.C. s. 1320a-7(b) or regulations adopted thereunder, including 42 C.F.R. s. 1001.952 or s. 1395nn or regulations adopted thereunder.

(7) The agency shall impose a fine of $50 per day against a home health agency that fails to submit to the agency, within 15 days after the end of each calendar quarter, a written report that includes the following data based on data as it existed on the last day of the quarter:

(a) The number of patients receiving both home health services from the home health agency and hospice services;

(b) The number of patients receiving home health services from the home health agency;

(c) The number of insulin-dependent diabetic patients receiving insulin-injection services from the home health agency; and

(d) The names and license numbers of nurses whose primary job responsibility is to provide home health services to patients and who received remuneration from the home health agency in excess of $25,000 during the calendar quarter.

Section 3. Paragraph (l) of subsection (4) of section 400.9905, Florida Statutes, is amended, and paragraph (m) is added to that subsection, to read:

400.9905 Definitions.—

(4) "Clinic" means an entity at which health care services are provided to individuals and which tenders charges for reimbursement for such services, including a mobile clinic and a portable equipment provider. For purposes of this part, the term does not include and the licensure requirements of this part do not apply to:

(l) Orthotic, ~~or~~ prosthetic, pediatric cardiology, or perinatology clinical facilities or anesthesia clinical facilities that are not otherwise exempt under paragraph (a) or paragraph (k) and that are a publicly traded corporation or ~~that~~ are wholly owned, directly or indirectly, by a publicly traded corporation. As used in this paragraph, a publicly traded corporation is a corporation that issues securities traded on an exchange registered with the United States Securities and Exchange Commission as a national securities exchange.

(m) Entities that are owned or controlled, directly or

indirectly, by a publicly traded entity that has $100 million or more, in the aggregate, in total annual revenues derived from providing health care services by licensed health care practitioners who are employed or contracted by an entity described in this paragraph.

Section 4. Paragraph (i) of subsection (4) of section 409.221, Florida Statutes, is amended to read:

409.221 Consumer-directed care program.—

(4) CONSUMER-DIRECTED CARE.—

(i) *Background screening requirements.*—All persons who render care under this section must undergo level 2 background screening pursuant to chapter 435 and s. 408.809. The agency shall, as allowable, reimburse consumer-employed caregivers for the cost of conducting such ~~background~~ screening ~~as required by this section~~. For purposes of this section, a person who has undergone screening, who is qualified for employment under this section and applicable rule, and who has not been unemployed for more than 90 days following such screening is not required to be rescreened. Such person must attest under penalty of perjury to not having been convicted of a disqualifying offense since completing such screening.

Section 5. Paragraph (c) of subsection (3) of section 409.907, Florida Statutes, is amended, paragraph (k) is added to that subsection, and subsections (6), (7), and (8) of that section are amended, to read:

409.907 Medicaid provider agreements.—The agency may make payments for medical assistance and related services rendered to Medicaid recipients only to an individual or entity who has a provider agreement in effect with the agency, who is performing

services or supplying goods in accordance with federal, state, and local law, and who agrees that no person shall, on the grounds of handicap, race, color, or national origin, or for any other reason, be subjected to discrimination under any program or activity for which the provider receives payment from the agency.

(3) The provider agreement developed by the agency, in addition to the requirements specified in subsections (1) and (2), shall require the provider to:

(c) Retain all medical and Medicaid-related records for 6 ~~a period of 5~~ years to satisfy all necessary inquiries by the agency.

(k) Report a change in any principal of the provider, including any officer, director, agent, managing employee, or affiliated person, or any partner or shareholder who has an ownership interest equal to 5 percent or more in the provider, to the agency in writing no later than 30 days after the change occurs.

(6) A Medicaid provider agreement may be revoked, at the option of the agency, due to ~~as the result of~~ a change of ownership of any facility, association, partnership, or other entity named as the provider in the provider agreement.

(a) In the event of a change of ownership, the transferor remains liable for all outstanding overpayments, administrative fines, and any other moneys owed to the agency before the effective date of the change of ownership. ~~In addition to the continuing liability of the transferor,~~ The transferee is also liable to the agency for all outstanding overpayments identified by the agency on or before the effective date of the change of

ownership. ~~For purposes of this subsection, the term "outstanding overpayment" includes any amount identified in a preliminary audit report issued to the transferor by the agency on or before the effective date of the change of ownership.~~ In the event of a change of ownership for a skilled nursing facility or intermediate care facility, the Medicaid provider agreement shall be assigned to the transferee if the transferee meets all other Medicaid provider qualifications. In the event of a change of ownership involving a skilled nursing facility licensed under part II of chapter 400, liability for all outstanding overpayments, administrative fines, and any moneys owed to the agency before the effective date of the change of ownership shall be determined in accordance with s. 400.179.

(b) At least 60 days before the anticipated date of the change of ownership, the transferor must ~~shall~~ notify the agency of the intended change of ownership and the transferee must ~~shall~~ submit to the agency a Medicaid provider enrollment application. If a change of ownership occurs without compliance with the notice requirements of this subsection, the transferor and transferee are ~~shall be~~ jointly and severally liable for all overpayments, administrative fines, and other moneys due to the agency, regardless of whether the agency identified the overpayments, administrative fines, or other moneys before or after the effective date of the change of ownership. The agency may not approve a transferee's Medicaid provider enrollment application if the transferee or transferor has not paid or agreed in writing to a payment plan for all outstanding overpayments, administrative fines, and other moneys due to the agency. This subsection does not preclude the agency from


810774

seeking any other legal or equitable remedies available to the agency for the recovery of moneys owed to the Medicaid program. In the event of a change of ownership involving a skilled nursing facility licensed under part II of chapter 400, liability for all outstanding overpayments, administrative fines, and any moneys owed to the agency before the effective date of the change of ownership shall be determined in accordance with s. 400.179 if the Medicaid provider enrollment application for change of ownership is submitted before the change of ownership.

(c) As used in this subsection, the term:

1. "Administrative fines" includes any amount identified in a notice of a monetary penalty or fine which has been issued by the agency or other regulatory or licensing agency that governs the provider.

2. "Outstanding overpayment" includes any amount identified in a preliminary audit report issued to the transferor by the agency on or before the effective date of a change of ownership.

(7) ~~The agency may require,~~ As a condition of participating in the Medicaid program and before entering into the provider agreement, the agency may require ~~that~~ the provider to submit information, in an initial and any required renewal applications, concerning the professional, business, and personal background of the provider and permit an onsite inspection of the provider's service location by agency staff or other personnel designated by the agency to perform this function. Before entering into a provider agreement, the agency may ~~shall~~ perform an ~~a random~~ onsite inspection~~, within 60 days after receipt of a fully complete new provider's application,~~ of


810774

the provider's service location ~~prior to making its first payment to the provider for Medicaid services~~ to determine the applicant's ability to provide ~~the~~ services in compliance with the Medicaid program and professional regulations ~~that the applicant is proposing to provide for Medicaid reimbursement~~. ~~The agency is not required to perform an onsite inspection of a provider or program that is licensed by the agency, that provides services under waiver programs for home and community-based services, or that is licensed as a medical foster home by the Department of Children and Family Services.~~ As a continuing condition of participation in the Medicaid program, a provider must ~~shall~~ immediately notify the agency of any current or pending bankruptcy filing. Before entering into the provider agreement, or as a condition of continuing participation in the Medicaid program, the agency may also require that Medicaid providers reimbursed on a fee-for-services basis or fee schedule basis that ~~which~~ is not cost-based, post a surety bond not to exceed $50,000 or the total amount billed by the provider to the program during the current or most recent calendar year, whichever is greater. For new providers, the amount of the surety bond shall be determined by the agency based on the provider's estimate of its first year's billing. If the provider's billing during the first year exceeds the bond amount, the agency may require the provider to acquire an additional bond equal to the actual billing level of the provider. A provider's bond need ~~shall~~ not exceed $50,000 if a physician or group of physicians licensed under chapter 458, chapter 459, or chapter 460 has a 50 percent or greater ownership interest in the provider or if the provider is an

assisted living facility licensed under chapter 429. The bonds permitted by this section are in addition to the bonds referenced in s. 400.179(2)(d). If the provider is a corporation, partnership, association, or other entity, the agency may require the provider to submit information concerning the background of that entity and of any principal of the entity, including any partner or shareholder having an ownership interest in the entity equal to 5 percent or greater, and any treating provider who participates in or intends to participate in Medicaid through the entity. The information must include:

(a) Proof of holding a valid license or operating certificate, as applicable, if required by the state or local jurisdiction in which the provider is located or if required by the Federal Government.

(b) Information concerning any prior violation, fine, suspension, termination, or other administrative action taken under the Medicaid laws, rules, or regulations of this state or of any other state or the Federal Government; any prior violation of the laws, rules, or regulations relating to the Medicare program; any prior violation of the rules or regulations of any other public or private insurer; and any prior violation of the laws, rules, or regulations of any regulatory body of this or any other state.

(c) Full and accurate disclosure of any financial or ownership interest that the provider, or any principal, partner, or major shareholder thereof, may hold in any other Medicaid provider or health care related entity or any other entity that is licensed by the state to provide health or residential care and treatment to persons.

(d) If a group provider, identification of all members of the group and attestation that all members of the group are enrolled in or have applied to enroll in the Medicaid program.

(8)~~(a)~~ Each provider, or each principal of the provider if the provider is a corporation, partnership, association, or other entity, seeking to participate in the Medicaid program must submit a complete set of his or her fingerprints to the agency for the purpose of conducting a criminal history record check. Principals of the provider include any officer, director, billing agent, managing employee, or affiliated person, or any partner or shareholder who has an ownership interest equal to 5 percent or more in the provider. However, for a hospital licensed under chapter 395 or a nursing home licensed under chapter 400, principals of the provider are those who meet the definition of a controlling interest under s. 408.803. A director of a not-for-profit corporation or organization is not a principal for purposes of a background investigation as required by this section if the director: serves solely in a voluntary capacity for the corporation or organization, does not regularly take part in the day-to-day operational decisions of the corporation or organization, receives no remuneration from the not-for-profit corporation or organization for his or her service on the board of directors, has no financial interest in the not-for-profit corporation or organization, and has no family members with a financial interest in the not-for-profit corporation or organization; and if the director submits an affidavit, under penalty of perjury, to this effect to the agency and the not-for-profit corporation or organization submits an affidavit, under penalty of perjury, to this effect

to the agency as part of the corporation's or organization's Medicaid provider agreement application.

(a) Notwithstanding the above, the agency may require a background check for any person reasonably suspected by the agency to have been convicted of a crime. This subsection does not apply to:

~~1. A hospital licensed under chapter 395;~~

~~2. A nursing home licensed under chapter 400;~~

~~3. A hospice licensed under chapter 400;~~

~~4. An assisted living facility licensed under chapter 429;~~

1.~~5.~~ A unit of local government, except that requirements of this subsection apply to nongovernmental providers and entities contracting with the local government to provide Medicaid services. The actual cost of the state and national criminal history record checks must be borne by the nongovernmental provider or entity; or

2.~~6.~~ Any business that derives more than 50 percent of its revenue from the sale of goods to the final consumer, and the business or its controlling parent is required to file a form 10-K or other similar statement with the Securities and Exchange Commission or has a net worth of $50 million or more.

(b) Background screening shall be conducted in accordance with chapter 435 and s. 408.809. The cost of the state and national criminal record check shall be borne by the provider.

~~(c) Proof of compliance with the requirements of level 2 screening under chapter 435 conducted within 12 months before the date the Medicaid provider application is submitted to the agency fulfills the requirements of this subsection.~~

Section 6. Present paragraphs (e) and (f) of subsection (1)

of section 409.913, Florida Statutes, are redesignated as paragraphs (f) and (g), respectively, a new paragraph (e) is added to that subsection, and subsections (2), (9), (13), (15), (16), (21), (22), (25), (28), (29), (30), and (31) of that section are amended, to read:

409.913 Oversight of the integrity of the Medicaid program.—The agency shall operate a program to oversee the activities of Florida Medicaid recipients, and providers and their representatives, to ensure that fraudulent and abusive behavior and neglect of recipients occur to the minimum extent possible, and to recover overpayments and impose sanctions as appropriate. Beginning January 1, 2003, and each year thereafter, the agency and the Medicaid Fraud Control Unit of the Department of Legal Affairs shall submit a joint report to the Legislature documenting the effectiveness of the state's efforts to control Medicaid fraud and abuse and to recover Medicaid overpayments during the previous fiscal year. The report must describe the number of cases opened and investigated each year; the sources of the cases opened; the disposition of the cases closed each year; the amount of overpayments alleged in preliminary and final audit letters; the number and amount of fines or penalties imposed; any reductions in overpayment amounts negotiated in settlement agreements or by other means; the amount of final agency determinations of overpayments; the amount deducted from federal claiming as a result of overpayments; the amount of overpayments recovered each year; the amount of cost of investigation recovered each year; the average length of time to collect from the time the case was opened until the overpayment is paid in full; the amount

determined as uncollectible and the portion of the uncollectible amount subsequently reclaimed from the Federal Government; the number of providers, by type, that are terminated from participation in the Medicaid program as a result of fraud and abuse; and all costs associated with discovering and prosecuting cases of Medicaid overpayments and making recoveries in such cases. The report must also document actions taken to prevent overpayments and the number of providers prevented from enrolling in or reenrolling in the Medicaid program as a result of documented Medicaid fraud and abuse and must include policy recommendations necessary to prevent or recover overpayments and changes necessary to prevent and detect Medicaid fraud. All policy recommendations in the report must include a detailed fiscal analysis, including, but not limited to, implementation costs, estimated savings to the Medicaid program, and the return on investment. The agency must submit the policy recommendations and fiscal analyses in the report to the appropriate estimating conference, pursuant to s. 216.137, by February 15 of each year. The agency and the Medicaid Fraud Control Unit of the Department of Legal Affairs each must include detailed unit-specific performance standards, benchmarks, and metrics in the report, including projected cost savings to the state Medicaid program during the following fiscal year.

(1) For the purposes of this section, the term:

(e) "Medicaid provider" or "provider" has the same meaning as provided in s. 409.901 and, for purposes of oversight of the integrity of the Medicaid program, also includes a participant in a Medicaid managed care provider network.

(2) The agency shall conduct, or cause to be conducted by

contract or otherwise, reviews, investigations, analyses, audits, or any combination thereof, to determine possible fraud, abuse, overpayment, or recipient neglect in the Medicaid program and ~~shall~~ report the findings of any overpayments in audit reports as appropriate. At least 5 percent of all audits must ~~shall~~ be conducted on a random basis. As part of its ongoing fraud detection activities, the agency shall identify and monitor, by contract or otherwise, patterns of overutilization of Medicaid services based on state averages. The agency shall track Medicaid provider prescription and billing patterns and evaluate them against Medicaid medical necessity criteria and coverage and limitation guidelines adopted by rule. Medical necessity determination requires that service be consistent with symptoms or confirmed diagnosis of illness or injury under treatment and not in excess of the patient's needs. The agency shall conduct reviews of provider exceptions to peer group norms and ~~shall~~, using statistical methodologies, provider profiling, and analysis of billing patterns, detect and investigate abnormal or unusual increases in billing or payment of claims for Medicaid services and medically unnecessary provision of services. The agency may review and analyze information from sources other than enrolled Medicaid providers in conducting its activities under this subsection.

(9) A Medicaid provider shall retain medical, professional, financial, and business records pertaining to services and goods furnished to a Medicaid recipient and billed to Medicaid for 6 ~~a period of 5~~ years after the date of furnishing such services or goods. The agency may investigate, review, or analyze such records, which must be made available during normal business

hours. However, 24-hour notice must be provided if patient treatment would be disrupted. The provider is responsible for furnishing to the agency, and keeping the agency informed of the location of, the provider's Medicaid-related records. The authority of the agency to obtain Medicaid-related records from a provider is neither curtailed nor limited during a period of litigation between the agency and the provider.

(13) The agency shall ~~immediately~~ terminate participation of a Medicaid provider in the Medicaid program and may seek civil remedies or impose other administrative sanctions against a Medicaid provider, if the provider or any principal, officer, director, agent, managing employee, or affiliated person of the provider, or any partner or shareholder having an ownership interest in the provider equal to 5 percent or greater, has been convicted of a criminal offense under federal law or the law of any state relating to the practice of the provider's profession, or an offense listed under s. 409.907(10), s. 408.809(4), or s. 435.04(2) ~~has been:~~

~~(a) Convicted of a criminal offense related to the delivery of any health care goods or services, including the performance of management or administrative functions relating to the delivery of health care goods or services;~~

~~(b) Convicted of a criminal offense under federal law or the law of any state relating to the practice of the provider's profession; or~~

~~(c) Found by a court of competent jurisdiction to have neglected or physically abused a patient in connection with the delivery of health care goods or services~~. If the agency determines that the ~~a~~ provider did not participate or acquiesce

in the ~~an~~ offense ~~specified in paragraph (a), paragraph (b), or paragraph (c)~~, termination will not be imposed. If the agency effects a termination under this subsection, the agency shall issue an immediate final order pursuant to s. 120.569(2)(n).

(15) The agency shall seek a remedy provided by law, including, but not limited to, any remedy provided in subsections (13) and (16) and s. 812.035, if:

(a) The provider's license has not been renewed, or has been revoked, suspended, or terminated, for cause, by the licensing agency of any state;

(b) The provider has failed to make available or has refused access to Medicaid-related records to an auditor, investigator, or other authorized employee or agent of the agency, the Attorney General, a state attorney, or the Federal Government;

(c) The provider has not furnished or has failed to make available such Medicaid-related records as the agency has found necessary to determine whether Medicaid payments are or were due and the amounts thereof;

(d) The provider has failed to maintain medical records made at the time of service, or prior to service if prior authorization is required, demonstrating the necessity and appropriateness of the goods or services rendered;

(e) The provider is not in compliance with provisions of Medicaid provider publications that have been adopted by reference as rules in the Florida Administrative Code; with provisions of state or federal laws, rules, or regulations; with provisions of the provider agreement between the agency and the provider; or with certifications found on claim forms or on

transmittal forms for electronically submitted claims that are submitted by the provider or authorized representative, as such provisions apply to the Medicaid program;

(f) The provider or person who ordered, authorized, or prescribed the care, services, or supplies has furnished, ~~or~~ ordered, or authorized the furnishing of, ~~,~~ goods or services to a recipient which are inappropriate, unnecessary, excessive, or harmful to the recipient or are of inferior quality;

(g) The provider has demonstrated a pattern of failure to provide goods or services that are medically necessary;

(h) The provider or an authorized representative of the provider, or a person who ordered, authorized, or prescribed the goods or services, has submitted or caused to be submitted false or a pattern of erroneous Medicaid claims;

(i) The provider or an authorized representative of the provider, or a person who has ordered, authorized, or prescribed the goods or services, has submitted or caused to be submitted a Medicaid provider enrollment application, a request for prior authorization for Medicaid services, a drug exception request, or a Medicaid cost report that contains materially false or incorrect information;

(j) The provider or an authorized representative of the provider has collected from or billed a recipient or a recipient's responsible party improperly for amounts that should not have been so collected or billed by reason of the provider's billing the Medicaid program for the same service;

(k) The provider or an authorized representative of the provider has included in a cost report costs that are not allowable under a Florida Title XIX reimbursement plan, ~~,~~ after

the provider or authorized representative had been advised in an audit exit conference or audit report that the costs were not allowable;

(l) The provider is charged by information or indictment with fraudulent billing practices or any offense referenced in subsection (13). The sanction applied for this reason is limited to suspension of the provider's participation in the Medicaid program for the duration of the indictment unless the provider is found guilty pursuant to the information or indictment;

(m) The provider or a person who has ordered, authorized, or prescribed the goods or services is found liable for negligent practice resulting in death or injury to the provider's patient;

(n) The provider fails to demonstrate that it had available during a specific audit or review period sufficient quantities of goods, or sufficient time in the case of services, to support the provider's billings to the Medicaid program;

(o) The provider has failed to comply with the notice and reporting requirements of s. 409.907;

(p) The agency has received reliable information of patient abuse or neglect or of any act prohibited by s. 409.920; or

(q) The provider has failed to comply with an agreed-upon repayment schedule.

A provider is subject to sanctions for violations of this subsection as the result of actions or inactions of the provider, or actions or inactions of any principal, officer, director, agent, managing employee, or affiliated person of the provider, or any partner or shareholder having an ownership


810774

interest in the provider equal to 5 percent or greater, in which the provider participated or acquiesced.

(16) The agency shall impose any of the following sanctions or disincentives on a provider or a person for any of the acts described in subsection (15):

(a) Suspension for a specific period of time of not more than 1 year. Suspension precludes ~~shall preclude~~ participation in the Medicaid program, which includes any action that results in a claim for payment to the Medicaid program as a result of furnishing, supervising a person who is furnishing, or causing a person to furnish goods or services.

(b) Termination for a specific period of time of from more than 1 year to 20 years. Termination precludes ~~shall preclude~~ participation in the Medicaid program, which includes any action that results in a claim for payment to the Medicaid program as a result of furnishing, supervising a person who is furnishing, or causing a person to furnish goods or services.

(c) Imposition of a fine of up to $5,000 for each violation. Each day that an ongoing violation continues, such as refusing to furnish Medicaid-related records or refusing access to records, is considered, for the purposes of this section, to be a separate violation. Each instance of improper billing of a Medicaid recipient; each instance of including an unallowable cost on a hospital or nursing home Medicaid cost report after the provider or authorized representative has been advised in an audit exit conference or previous audit report of the cost unallowability; each instance of furnishing a Medicaid recipient goods or professional services that are inappropriate or of inferior quality as determined by competent peer judgment; each


810774

instance of knowingly submitting a materially false or erroneous Medicaid provider enrollment application, request for prior authorization for Medicaid services, drug exception request, or cost report; each instance of inappropriate prescribing of drugs for a Medicaid recipient as determined by competent peer judgment; and each false or erroneous Medicaid claim leading to an overpayment to a provider is considered, for the purposes of this section, to be a separate violation.

(d) Immediate suspension, if the agency has received information of patient abuse or neglect or of any act prohibited by s. 409.920. Upon suspension, the agency must issue an immediate final order under s. 120.569(2)(n).

(e) A fine, not to exceed $10,000, for a violation of paragraph (15)(i).

(f) Imposition of liens against provider assets, including, but not limited to, financial assets and real property, not to exceed the amount of fines or recoveries sought, upon entry of an order determining that such moneys are due or recoverable.

(g) Prepayment reviews of claims for a specified period of time.

(h) Comprehensive followup reviews of providers every 6 months to ensure that they are billing Medicaid correctly.

(i) Corrective-action plans that ~~would~~ remain in effect ~~for providers~~ for up to 3 years and that are ~~would be~~ monitored by the agency every 6 months while in effect.

(j) Other remedies as permitted by law to effect the recovery of a fine or overpayment.

If a provider voluntarily relinquishes its Medicaid provider

number after receiving written notice that the agency is conducting, or has conducted, an audit or investigation and the sanction of suspension or termination will be imposed for noncompliance discovered as a result of the audit or investigation, the agency shall impose the sanction of termination for cause against the provider. The Secretary of Health Care Administration may make a determination that imposition of a sanction or disincentive is not in the best interest of the Medicaid program, in which case a sanction or disincentive may ~~shall~~ not be imposed.

(21) When making a determination that an overpayment has occurred, the agency shall prepare and issue an audit report to the provider showing the calculation of overpayments. The agency's determination shall be based solely upon information available to it before issuance of the audit report and, in the case of documentation obtained to substantiate claims for Medicaid reimbursement, based solely upon contemporaneous records.

(22) The audit report, supported by agency work papers, showing an overpayment to a provider constitutes evidence of the overpayment. A provider may not present or elicit testimony, ~~either~~ on direct examination or cross-examination in any court or administrative proceeding, regarding the purchase or acquisition by any means of drugs, goods, or supplies; sales or divestment by any means of drugs, goods, or supplies; or inventory of drugs, goods, or supplies, unless such acquisition, sales, divestment, or inventory is documented by written invoices, written inventory records, or other competent written documentary evidence maintained in the normal course of the

provider's business. Testimony or evidence that is not based upon contemporaneous records or that was not furnished to the agency within 21 days after the issuance of the audit report is inadmissible in an administrative hearing on a Medicaid overpayment or an administrative sanction. Notwithstanding the applicable rules of discovery, all documentation to ~~that will~~ be offered as evidence at an administrative hearing on a Medicaid overpayment or an administrative sanction must be exchanged by all parties at least 14 days before the administrative hearing or ~~must be~~ excluded from consideration.

(25)(a) The agency shall withhold Medicaid payments, in whole or in part, to a provider upon receipt of reliable evidence that the circumstances giving rise to the need for a withholding of payments involve fraud, willful misrepresentation, or abuse under the Medicaid program, or a crime committed while rendering goods or services to Medicaid recipients. If it is determined that fraud, willful misrepresentation, abuse, or a crime did not occur, the payments withheld must be paid to the provider within 14 days after such determination ~~with interest at the rate of 10 percent a year~~. ~~Any money withheld in accordance with this paragraph shall be placed in a suspended account, readily accessible to the agency, so that any payment ultimately due the provider shall be made within 14 days.~~

(b) The agency shall deny payment, or require repayment, if the goods or services were furnished, supervised, or caused to be furnished by a person who has been suspended or terminated from the Medicaid program or Medicare program by the Federal Government or any state.

(c) Overpayments owed to the agency bear interest at the rate of 10 percent per year from the date of determination of the overpayment by the agency, and payment arrangements regarding overpayments and fines must be made within 30 days after the date of the final order and are not subject to further appeal ~~at the conclusion of legal proceedings~~. ~~A provider who does not enter into or adhere to an agreed-upon repayment schedule may be terminated by the agency for nonpayment or partial payment.~~

(d) The agency, upon entry of a final agency order, a judgment or order of a court of competent jurisdiction, or a stipulation or settlement, may collect the moneys owed by all means allowable by law, including, but not limited to, notifying any fiscal intermediary of Medicare benefits that the state has a superior right of payment. Upon receipt of such written notification, the Medicare fiscal intermediary shall remit to the state the sum claimed.

(e) The agency may institute amnesty programs to allow Medicaid providers the opportunity to voluntarily repay overpayments. The agency may adopt rules to administer such programs.

(28) Venue for all Medicaid program integrity ~~overpayment~~ cases lies ~~shall lie~~ in Leon County, at the discretion of the agency.

(29) Notwithstanding other provisions of law, the agency and the Medicaid Fraud Control Unit of the Department of Legal Affairs may review a person's or provider's Medicaid-related and non-Medicaid-related records in order to determine the total output of a provider's practice to reconcile quantities of goods

or services billed to Medicaid with quantities of goods or services used in the provider's total practice.

(30) The agency shall terminate a provider's participation in the Medicaid program if the provider fails to reimburse an overpayment or pay a fine that has been determined by final order, not subject to further appeal, within 30 ~~35~~ days after the date of the final order, unless the provider and the agency have entered into a repayment agreement.

(31) If a provider requests an administrative hearing pursuant to chapter 120, such hearing must be conducted within 90 days following assignment of an administrative law judge, absent exceptionally good cause shown as determined by the administrative law judge or hearing officer. Upon issuance of a final order, the outstanding balance of the amount determined to constitute the overpayment and fines is ~~shall become~~ due. If a provider fails to make payments in full, fails to enter into a satisfactory repayment plan, or fails to comply with the terms of a repayment plan or settlement agreement, the agency shall withhold ~~medical assistance~~ reimbursement payments for Medicaid services until the amount due is paid in full.

Section 7. Subsection (8) of section 409.920, Florida Statutes, is amended to read:

409.920 Medicaid provider fraud.—

(8) A person who provides the state, any state agency, any of the state's political subdivisions, or any agency of the state's political subdivisions with information about fraud or suspected fraudulent acts ~~fraud~~ by a Medicaid provider, including a managed care organization, is immune from civil liability for libel, slander, or any other relevant tort for

providing any ~~the~~ information about fraud or suspected fraudulent acts, unless the person acted with knowledge that the information was false or with reckless disregard for the truth or falsity of the information. For purposes of this subsection, the term "fraudulent acts" includes actual or suspected fraud, abuse, or overpayment, including any fraud-related matters that a provider or health plan is required to report to the agency or a law enforcement agency. The immunity from civil liability extends to reports of fraudulent acts conveyed to the agency in any manner, including any forum and with any audience as directed by the agency, and includes all discussions subsequent to the report and subsequent inquiries from the agency, unless the person acted with knowledge that the information was false or with reckless disregard for the truth or falsity of the information.

Section 8. Paragraph (c) of subsection (2) of section 409.967, Florida Statutes, is amended to read:

409.967 Managed care plan accountability.—

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

(c) *Access.*—

1. Providers.—The agency shall establish specific standards for the number, type, and regional distribution of providers in managed care plan networks to ensure access to care for both adults and children. Each plan must maintain a regionwide network of providers in sufficient numbers to meet the access standards for specific medical services for all recipients

enrolled in the plan. The exclusive use of mail-order pharmacies is ~~may~~ not ~~be~~ sufficient to meet network access standards. Consistent with the standards established by the agency, provider networks may include providers located outside the region. A plan may contract with a new hospital facility before the date the hospital becomes operational if the hospital has commenced construction, will be licensed and operational by January 1, 2013, and a final order has issued in any civil or administrative challenge. Each plan shall establish and maintain an accurate and complete electronic database of contracted providers, including information about licensure or registration, locations and hours of operation, specialty credentials and other certifications, specific performance indicators, and such other information as the agency deems necessary. The database must be available online to both the agency and the public and have the capability to compare the availability of providers to network adequacy standards and to accept and display feedback from each provider's patients. Each plan shall submit quarterly reports to the agency identifying the number of enrollees assigned to each primary care provider.

2. Prescribed drugs.—

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

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

(II) Include coverage via prior authorization for each drug

newly approved by the federal Food and Drug Administration until the plan's Pharmaceutical and Therapeutics Committee reviews such drug for inclusion on the formulary. The timing of the formulary review must comply with s. 409.91195; and

(III) Provide a response within 24 hours after receipt of all necessary information from the medical provider for a request for prior authorization and provide a procedure for escalating a delayed prior authorization request to the pharmacy management team for resolution or to override other medical management tools.

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

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

d. A managed care plan that imposes a step-therapy or a fail-first protocol must do so in accordance with the following:

(I) If prescribed drugs for the treatment of a medical condition are restricted for use by the plan through a step-

therapy or fail-first protocol, the plan must provide the prescriber with access to a clear and convenient process to expeditiously request a prior authorization that includes a procedure for escalation to the pharmacy management team if not resolved in a timely manner.

(II) Escalation to the pharmacy management team must be expeditiously granted by the plan if the prescriber can submit appropriate and complete medical documentation to the plan that the preferred treatment required under the step-therapy or fail-first protocol:

(A) Has been ineffective in the treatment of the enrollee's disease or medical condition;

(B) Is reasonably expected to be ineffective based on the known relevant physical or mental characteristics and medical history of the enrollee and known characteristics of the drug regimen; or

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

(III) The pharmacy management team shall work directly with the medical provider to bring the prior-authorization request to a clinically appropriate, cost-effective, and timely resolution.

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

3. Prior authorization.—

a. Each managed care plan must ensure that the prior authorization process for prescribed drugs is readily accessible

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

b. If a drug, determined to be medically necessary and prescribed for an enrollee by a physician using sound clinical judgment, is subject to prior authorization and approved, the managed care plan must provide for sufficient refills to complete the duration of the prescription. If the medication is still clinically appropriate for ongoing therapy after the initial prior authorization expires, the plan must provide a process of expedited review to evaluate ongoing therapy.

c. If a prescribed drug requires prior authorization, the managed care plan shall reimburse the pharmacist for dispensing a 72-hour supply of oral maintenance medications to the enrollee and process the prior authorization request. Dispensing a 72-hour supply must be consistent with laws that govern pharmacy practice and controlled substances. The managed care plan shall process all prior authorization requests in as timely a manner as possible.

d.~~3.~~ Managed care plans, and their fiscal agents or intermediaries, must accept prior authorization requests for prescribed drugs ~~any service~~ electronically.

Section 9. Subsection (11) is added to section 429.23, Florida Statutes, to read:

429.23 Internal risk management and quality assurance program; adverse incidents and reporting requirements.—

(11) The agency shall annually submit a report to the Legislature on adverse incident reports by assisted living facilities. The report must include the following information

arranged by county:

(a) A total number of adverse incidents;

(b) A listing, by category, of the type of adverse incidents occurring within each category and the type of staff involved;

(c) A listing, by category, of the types of injuries, if any, and the number of injuries occurring within each category;

(d) Types of liability claims filed based on an adverse incident report or reportable injury; and

(e) Disciplinary action taken against staff, categorized by the type of staff involved.

Section 10. Present subsections (9), (10), and (11) of section 429.26, Florida Statutes, are renumbered as subsections (12), (13), and (14), respectively, and new subsections (9), (10), and (11) are added to that section, to read:

429.26 Appropriateness of placements; examinations of residents.—

(9) If, at any time after admission to a facility, agency personnel question whether a resident needs care beyond that which the facility is licensed to provide, the agency may require the resident to be physically examined by a licensed physician, licensed physician assistant, or certified nurse practitioner. To the extent possible, the examination must be performed by the resident’s preferred physician, physician assistant, or nurse practitioner and paid for by the resident with personal funds, except as provided in s. 429.18(2). This subsection does not preclude the agency from imposing sanctions for violations of subsection (1).

(a) Following examination, the examining physician,

physician assistant, or nurse practitioner shall complete and sign a medical form provided by the agency. The completed medical form must be submitted to the agency within 30 days after the date the facility owner or administrator was notified by the agency that a physical examination is required.

(b) A medical review team designated by the agency shall determine whether the resident is appropriately residing in the facility based on the completed medical form and, if necessary, consultation with the physician, physician assistant, or nurse practitioner who performed the examination. Members of the medical review team making the determination may not include the agency personnel who initially questioned the appropriateness of the resident's placement. The medical review team shall base its decision on a comprehensive review of the resident's physical and functional status. A determination that the resident's placement is not appropriate is final and binding upon the facility and the resident.

(c) A resident who is determined by the medical review team to be inappropriately residing in a facility shall be given 30 days' written notice to relocate by the owner or administrator, unless the resident's continued residence in the facility presents an imminent danger to the health, safety, or welfare of the resident or a substantial probability exists that death or serious physical harm to the resident would result if the resident is allowed to remain in the facility.

(10) If a mental health resident appears to have needs in addition to those identified in the community living support plan, the agency may require an evaluation by a mental health professional, as determined by the Department of Children and

Family Services.

(11) A facility may not be required to retain a resident who requires more services or care than the facility is able to provide in accordance with its policies and criteria for admission and continued residency.

Section 11. Effective July 1, 2012, section 456.0635, Florida Statutes, is amended to read:

456.0635 Health care ~~Medicaid~~ fraud; disqualification for license, certificate, or registration.—

(1) Health care ~~Medicaid~~ fraud in the practice of a health care profession is prohibited.

(2) Each board under ~~within~~ the jurisdiction of the department, or the department if there is no board, shall refuse to admit a candidate to an ~~any~~ examination and refuse to issue ~~or renew~~ a license, certificate, or registration to an ~~any~~ applicant if the candidate or applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant~~, has been~~:

(a) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under chapter 409, chapter 817, or chapter 893, or a similar felony offense committed in another state or jurisdiction, unless the candidate or applicant has successfully completed a drug court program for that felony and provides proof that the plea has been withdrawn or the charges have been dismissed. Any such conviction or plea shall exclude the applicant or candidate from licensure, examination, certification, or registration ~~21 U.S.C. ss. 801-970, or 42 U.S.C. ss. 1395-1396,~~ unless the sentence and any subsequent period of probation for such conviction or plea

~~pleas~~ ended: ~~more than 15 years prior to the date of the application;~~

1. For felonies of the first or second degree, more than 15 years before the date of application.

2. For felonies of the third degree, more than 10 years before the date of application, except for felonies of the third degree under s. 893.13(6)(a).

3. For felonies of the third degree under s. 893.13(6)(a), more than 5 years before the date of application.

(b) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970 or 42 U.S.C. ss. 1395-1396, unless the sentence and any subsequent period of probation for such conviction or plea ended more than 15 years before the date of the application.

(c) ~~(b)~~ Has been terminated for cause from the Florida Medicaid program pursuant to s. 409.913, unless the candidate or applicant has been in good standing with the Florida Medicaid program for the most recent 5 years.~~,~~

(d) ~~(c)~~ Has been terminated for cause, pursuant to the appeals procedures established by the state ~~or Federal Government~~, from any other state Medicaid program ~~or the federal Medicare program~~, unless the candidate or applicant has been in good standing with that ~~a~~ state Medicaid program ~~or the federal Medicare program~~ for the most recent 5 years and the termination occurred at least 20 years before ~~prior to~~ the date of the application.

(e) Is currently listed on the United States Department of Health and Human Services Office of Inspector General's List of

Excluded Individuals and Entities.

This subsection does not apply to candidates or applicants for initial licensure or certification who were enrolled in an educational or training program on or before July 1, 2009, which was recognized by a board or, if there is no board, recognized by the department, and who applied for licensure after July 1, 2012.

(3) The department shall refuse to renew a license, certificate, or registration of any applicant if the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant:

(a) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under chapter 409, chapter 817, or chapter 893, or a similar felony offense committed in another state or jurisdiction, unless the applicant is currently enrolled in a drug court program that allows the withdrawal of the plea for that felony upon successful completion of that program. Any such conviction or plea excludes the applicant or candidate from licensure, examination, certification, or registration unless the sentence and any subsequent period of probation for such conviction or plea ended:

1. For felonies of the first or second degree, more than 15 years before the date of application.

2. For felonies of the third degree, more than 10 years before the date of application, except for felonies of the third degree under s. 893.13(6)(a).

3. For felonies of the third degree under s. 893.13(6)(a),

more than 5 years before the date of application.

(b) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970 or 42 U.S.C. ss. 1395-1396 since July 1, 2009, unless the sentence and any subsequent period of probation for such conviction or plea ended more than 15 years before the date of the application.

(c) Has been terminated for cause from the Florida Medicaid program pursuant to s. 409.913, unless the applicant has been in good standing with the Florida Medicaid program for the most recent 5 years.

(d) Has been terminated for cause, pursuant to the appeals procedures established by the state, from any other state Medicaid program, unless the applicant has been in good standing with that state Medicaid program for the most recent 5 years and the termination occurred at least 20 years before the date of the application.

(e) Is currently listed on the United States Department of Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities.

(4) ~~(3)~~ Licensed health care practitioners shall report allegations of health care ~~Medicaid~~ fraud to the department, regardless of the practice setting in which the alleged health care ~~Medicaid~~ fraud occurred.

(5) ~~(4)~~ The acceptance by a licensing authority of a licensee's ~~candidate's~~ relinquishment of a license which is offered in response to or anticipation of the filing of administrative charges alleging health care ~~Medicaid~~ fraud or similar charges constitutes the permanent revocation of the

license.

Section 12. Effective July 1, 2012, present subsections (14) and (15) of section 456.036, Florida Statutes, are renumbered as subsections (15) and (16), respectively, and a new subsection (14) is added to that section, to read:

456.036 Licenses; active and inactive status; delinquency.—

(14) A person who has been denied license renewal, certification, or registration under s. 456.0635(3) may regain licensure, certification, or registration only by meeting the qualifications and completing the application process for initial licensure as defined by the board, or the department if there is no board. However, a person who was denied renewal of licensure, certification, or registration under s. 24 of chapter 2009-223, Laws of Florida, between July 1, 2009, and June 30, 2012, is not required to retake and pass examinations applicable for initial licensure, certification, or registration.

Section 13. Subsection (1) of section 456.074, Florida Statutes, is amended to read:

456.074 Certain health care practitioners; immediate suspension of license.—

(1) The department shall issue an emergency order suspending the license of any person licensed under chapter 458, chapter 459, chapter 460, chapter 461, chapter 462, chapter 463, chapter 464, chapter 465, chapter 466, or chapter 484 who pleads guilty to, is convicted or found guilty of, or who enters a plea of nolo contendere to, regardless of adjudication~~, to~~:

(a) A felony under chapter 409, chapter 817, or chapter 893 or under 21 U.S.C. ss. 801-970 or ~~under~~ 42 U.S.C. ss. 1395-1396; or

(b) A misdemeanor or felony under 18 U.S.C. s. 669, ss. 285-287, s. 371, s. 1001, s. 1035, s. 1341, s. 1343, s. 1347, s. 1349, or s. 1518 or 42 U.S.C. ss. 1320a-7b~~, relating to the Medicaid program~~.

Section 14. Subsections (3), (4), and (5) of section 463.002, Florida Statutes, are amended to read:

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

(3)(a) "Licensed practitioner" means a person who is a primary health care provider licensed to engage in the practice of optometry under the authority of this chapter.

(b) A licensed practitioner who is not a certified optometrist shall be required to display at her or his place of practice a sign which states, "I am a Licensed Practitioner, not a Certified Optometrist, and I am not able to prescribe ~~topical~~ ocular pharmaceutical agents."

(c) All practitioners initially licensed after July 1, 1993, must be certified optometrists.

(4) "Certified optometrist" means a licensed practitioner authorized by the board to administer and prescribe ~~topical~~ ocular pharmaceutical agents.

(5) "Optometry" means the diagnosis of conditions of the human eye and its appendages; the employment of any objective or subjective means or methods, including the administration of ~~topical ocular~~ pharmaceutical agents, for the purpose of determining the refractive powers of the human eyes, or any visual, muscular, neurological, or anatomic anomalies of the human eyes and their appendages; and the prescribing and employment of lenses, prisms, frames, mountings, contact lenses, orthoptic exercises, light frequencies, and any other means or

methods, including ~~topical ocular~~ pharmaceutical agents, for the correction, remedy, or relief of any insufficiencies or abnormal conditions of the human eyes and their appendages.

Section 15. Paragraph (g) of subsection (1) of section 463.005, Florida Statutes, is amended to read:

463.005 Authority of the board.—

(1) The Board of Optometry has authority to adopt rules pursuant to ss. 120.536(1) and 120.54 to implement the provisions of this chapter conferring duties upon it. Such rules shall include, but not be limited to, rules relating to:

(g) Administration and prescription of ~~topical~~ ocular pharmaceutical agents.

Section 16. Section 463.0055, Florida Statutes, is amended to read:

463.0055 Administration and prescription of ~~topical~~ ocular pharmaceutical agents; committee.—

(1)(a) Certified optometrists may administer and prescribe ~~topical ocular~~ pharmaceutical agents as provided in this section for the diagnosis and treatment of ocular conditions of the human eye and its appendages without the use of surgery or other invasive techniques. However, a licensed practitioner who is not certified may use topically applied anesthetics solely for the purpose of glaucoma examinations~~,~~ but is otherwise prohibited from administering or prescribing ~~topical ocular~~ pharmaceutical agents.

(b) Before a certified optometrist may administer or prescribe oral ocular pharmaceutical agents, the certified optometrist must complete a course and subsequent examination on general and ocular pharmacology which have a particular emphasis

on the ingestion of oral pharmaceutical agents and the side effects of those agents. For certified optometrists licensed before January 1, 1990, the course shall consist of 50 contact hours and 25 of those hours shall be Internet-based. For certified optometrists licensed on or after January 1, 1990, the course shall consist of 20 contact hours and 10 of those hours shall be Internet-based. The first course and examination shall be presented by January 1, 2013, and shall thereafter be administered at least annually. The Florida Medical Association and the Florida Optometric Association shall jointly develop and administer a course and examination for such purpose and jointly determine the site or sites for the course and examination.

(2)(a) There is ~~hereby~~ created a committee composed of two certified optometrists licensed pursuant to this chapter, appointed by the Board of Optometry, two board-certified ophthalmologists licensed pursuant to chapter 458 or chapter 459, appointed by the Board of Medicine, and one additional person with a doctorate degree in pharmacology who is not licensed pursuant to chapter 458, chapter 459, or this chapter, appointed by the State Surgeon General. The committee shall review requests for additions to, deletions from, or modifications of a formulary of topical ocular pharmaceutical agents for administration and prescription by certified optometrists and shall provide to the board advisory opinions and recommendations on such requests. The formulary of topical ocular pharmaceutical agents shall consist of those topical ~~ocular pharmaceutical~~ agents that are appropriate to treat and diagnose ocular diseases and disorders and that ~~which~~ the certified optometrist is qualified to use in the practice of

optometry. The board shall establish, add to, delete from, or modify the formulary by rule. Notwithstanding any provision of chapter 120 to the contrary, the formulary rule shall become effective 60 days from the date it is filed with the Secretary of State.

(b) The topical formulary may be added to, deleted from, or modified according to the procedure described in paragraph (a). Any person who requests an addition, deletion, or modification of an authorized topical ~~ocular pharmaceutical~~ agent shall have the burden of proof to show cause why such addition, deletion, or modification should be made.

(c) The State Surgeon General shall have standing to challenge any rule or proposed rule of the board pursuant to s. 120.56. In addition to challenges for any invalid exercise of delegated legislative authority, the administrative law judge, upon such a challenge by the State Surgeon General, may declare all or part of a rule or proposed rule invalid if it:

1. Does not protect the public from any significant and discernible harm or damages;

2. Unreasonably restricts competition or the availability of professional services in the state or in a significant part of the state; or

3. Unnecessarily increases the cost of professional services without a corresponding or equivalent public benefit.

However, there shall not be created a presumption of the existence of any of the conditions cited in this subsection in the event that the rule or proposed rule is challenged.

(d) Upon adoption of the topical formulary required by this

section, and upon each addition, deletion, or modification to the topical formulary, the board shall mail a copy of the amended topical formulary to each certified optometrist and to each pharmacy licensed by the state.

(3) In addition to the formulary of topical ocular pharmaceutical agents in subsection (2), there is created a statutory formulary of oral pharmaceutical agents, which include the following agents:

(a) The following analgesics, or their generic or therapeutic equivalents, which may not be administered or prescribed for more than 72 hours without consultation with a physician licensed under chapter 458 or chapter 459 who is skilled in diseases of the eye:

1. Tramadol hydrochloride.

2. Acetaminophen 300 mg with No. 3 codeine phosphate 30 mg.

(b) The following antibiotics, or their generic or therapeutic equivalents:

1. Amoxicillin.

2. Azithromycin.

3. Ciprofloxacin.

4. Dicloxacillin.

5. Doxycycline.

6. Keflex.

7. Minocycline.

(c) The following antivirals, or their generic or therapeutic equivalents:

1. Acyclovir.

2. Famciclovir.

3. Valacyclovir.

(d) The following oral anti-glaucoma agents, or their generic or therapeutic equivalents, which may not be administered or prescribed for more than 72 hours without consultation with a physician licensed under chapter 458 or chapter 459 who is skilled in diseases of the eye:

1. Acetazolamide.

2. Methazolamide.

Any oral pharmaceutical agent listed in the statutory formulary set forth in this subsection which is subsequently determined by the United States Food and Drug Administration to be unsafe for administration or prescription shall be considered to have been deleted from the formulary of oral pharmaceutical agents. The oral pharmaceutical agents on the statutory formulary set forth in this subsection may not otherwise be deleted by the board, the department, or the State Surgeon General.

(4) ~~(3)~~ A certified optometrist shall be issued a prescriber number by the board. Any prescription written by a certified optometrist for a ~~topical ocular~~ pharmaceutical agent pursuant to this section shall have the prescriber number printed thereon.

Section 17. Subsection (3) of section 463.0057, Florida Statutes, is amended to read:

463.0057 Optometric faculty certificate.—

(3) The holder of a faculty certificate may engage in the practice of optometry as permitted by this section~~,~~ but may not administer or prescribe ~~topical~~ ocular pharmaceutical agents unless the certificateholder has satisfied the requirements of ss. 463.0055(1)(b) and ~~s.~~ 463.006(1)(b)4. and 5.

Section 18. Subsections (2) and (3) of section 463.006, Florida Statutes, are amended to read:

463.006 Licensure and certification by examination.—

(2) The examination shall consist of the appropriate subjects, including applicable state laws and rules and general and ocular pharmacology with emphasis on the use ~~topical application~~ and side effects of ocular pharmaceutical agents. The board may by rule substitute a national examination as part or all of the examination and may by rule offer a practical examination in addition to the written examination.

(3) Each applicant who successfully passes the examination and otherwise meets the requirements of this chapter is entitled to be licensed as a practitioner and to be certified to administer and prescribe ~~topical ocular~~ pharmaceutical agents in the diagnosis and treatment of ocular conditions.

Section 19. Subsections (1) and (2) of section 463.0135, Florida Statutes, are amended, and subsection (10) is added to that section, to read:

463.0135 Standards of practice.—

(1) A licensed practitioner shall provide that degree of care which conforms to that level of care provided by medical practitioners in the same or similar communities. A certified optometrist shall administer and prescribe oral ocular pharmaceutical agents in a manner consistent with applicable preferred practice patterns of the American Academy of Ophthalmology. A licensed practitioner shall advise or assist her or his patient in obtaining further care when the service of another health care practitioner is required.

(2) A licensed practitioner diagnosing angle closure,

neovascular, infantile, or congenital forms of glaucoma shall promptly and without unreasonable delay refer the patient to a physician skilled in diseases of the eye and licensed under chapter 458 or chapter 459. In addition, a licensed practitioner shall timely refer any patient who experiences progressive glaucoma due to failed pharmaceutical intervention to a physician who is skilled in diseases of the eye and licensed under chapter 458 or chapter 459.

(10) Comanagement of postoperative care shall be conducted pursuant to an established protocol that governs the relationship between the operating surgeon and the optometrist. The patient shall be informed that either physician will be available for emergency care throughout the postoperative period, and the patient shall consent in writing to the comanagement relationship.

Section 20. Subsections (3) and (4) of section 463.014, Florida Statutes, are amended to read:

463.014 Certain acts prohibited.—

(3) Prescribing, ordering, dispensing, administering, supplying, selling, or giving any ~~systemic~~ drugs for the purpose of treating a systemic disease by a licensed practitioner is prohibited. However, a certified optometrist is permitted to use commonly accepted means or methods to immediately address incidents of anaphylaxis.

(4) Surgery of any kind, including the use of lasers, is expressly prohibited. For purposes of this subsection, the term "surgery" means a procedure using an instrument, including lasers, scalpels, or needles, in which human tissue is cut, burned, or vaporized by incision, injection, ultrasound, laser,

or radiation. The term includes procedures using instruments that require closing by suturing, clamping, or another such device. Certified optometrists may remove superficial foreign bodies. For the purposes of this subsection, the term "superficial foreign bodies" means any foreign matter that is embedded in the conjunctiva or cornea but which has not penetrated the globe.

Section 21. Section 463.0141, Florida Statutes, is created to read:

463.0141 Reports of adverse incidents in the practice of optometry.—

(1) Any adverse incident that occurs on or after January 1, 2013, in the practice of optometry must be reported to the department in the accordance with this section.

(2) The required notification to the department must be submitted in writing by certified mail and postmarked within 15 days after the occurrence of the adverse incident.

(3) For purposes of notification to the department, the term "adverse incident," as used in this section, means an event that is associated in whole or in part with the prescribing of an oral ocular pharmaceutical agent and that results in one of the following:

(a) Any condition that requires the transfer of a patient to a hospital licensed under chapter 395;

(b) Any condition that requires the patient to obtain care from a physician licensed under chapter 458 or chapter 459, other than a referral or a consultation required under this chapter;

(c) Permanent physical injury to the patient;

(d) Partial or complete permanent loss of sight by the patient; or

(e) Death of the patient.

(4) The department shall review each incident and determine whether it potentially involved conduct by the licensed practitioner which may be subject to disciplinary action, in which case s. 456.073 applies. Disciplinary action, if any, shall be taken by the board.

Section 22. Subsection (1) of section 483.035, Florida Statutes, is amended to read:

483.035 Clinical laboratories operated by practitioners for exclusive use; licensure and regulation.—

(1) A clinical laboratory operated by one or more practitioners licensed under chapter 458, chapter 459, chapter 460, chapter 461, chapter 462, chapter 463, or chapter 466, exclusively in connection with the diagnosis and treatment of their own patients, must be licensed under this part and must comply with the provisions of this part, except that the agency shall adopt rules for staffing, for personnel, including education and training of personnel, for proficiency testing, and for construction standards relating to the licensure and operation of the laboratory based upon and not exceeding the same standards contained in the federal Clinical Laboratory Improvement Amendments of 1988 and the federal regulations adopted thereunder.

Section 23. Subsection (7) of section 483.041, Florida Statutes, is amended to read:

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

(7) "Licensed practitioner" means a physician licensed

under chapter 458, chapter 459, chapter 460, ~~or~~ chapter 461, or chapter 463; a dentist licensed under chapter 466; a person licensed under chapter 462; or an advanced registered nurse practitioner licensed under part I of chapter 464; or a duly licensed practitioner from another state licensed under similar statutes who orders examinations on materials or specimens for nonresidents of the State of Florida, but who reside in the same state as the requesting licensed practitioner.

Section 24. Subsection (5) of section 483.181, Florida Statutes, is amended to read:

483.181 Acceptance, collection, identification, and examination of specimens.—

(5) A clinical laboratory licensed under this part must accept a human specimen submitted for examination by a practitioner licensed under chapter 458, chapter 459, chapter 460, chapter 461, chapter 462, chapter 463, s. 464.012, or chapter 466, if the specimen and test are the type performed by the clinical laboratory. A clinical laboratory may only refuse a specimen based upon a history of nonpayment for services by the practitioner. A clinical laboratory shall not charge different prices for tests based upon the chapter under which a practitioner submitting a specimen for testing is licensed.

Section 25. Paragraph (a) of subsection (54) of section 499.003, Florida Statutes, is amended to read:

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

(54) "Wholesale distribution" means distribution of prescription drugs to persons other than a consumer or patient, but does not include:

(a) Any of the following activities, which is not a violation of s. 499.005(21) if such activity is conducted in accordance with s. 499.01(2)(g):

1. The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a prescription drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of that organization.

2. The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug by a charitable organization described in s. 501(c)(3) of the Internal Revenue Code of 1986, as amended and revised, to a nonprofit affiliate of the organization to the extent otherwise permitted by law.

3. The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug among hospitals or other health care entities that are under common control. For purposes of this subparagraph, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, by voting rights, by contract, or otherwise.

4. The sale, purchase, trade, or other transfer of a prescription drug from or for any federal, state, or local government agency or any entity eligible to purchase prescription drugs at public health services prices pursuant to Pub. L. No. 102-585, s. 602 to a contract provider or its subcontractor for eligible patients of the agency or entity under the following conditions:

a. The agency or entity must obtain written authorization for the sale, purchase, trade, or other transfer of a prescription drug under this subparagraph from the State Surgeon General or his or her designee.

b. The contract provider or subcontractor must be authorized by law to administer or dispense prescription drugs.

c. In the case of a subcontractor, the agency or entity must be a party to and execute the subcontract.

~~d. A contract provider or subcontractor must maintain separate and apart from other prescription drug inventory any prescription drugs of the agency or entity in its possession.~~

d.~~e.~~ The contract provider and subcontractor must maintain and produce immediately for inspection all records of movement or transfer of all the prescription drugs belonging to the agency or entity, including, but not limited to, the records of receipt and disposition of prescription drugs. Each contractor and subcontractor dispensing or administering these drugs must maintain and produce records documenting the dispensing or administration. Records that are required to be maintained include, but are not limited to, a perpetual inventory itemizing drugs received and drugs dispensed by prescription number or administered by patient identifier, which must be submitted to the agency or entity quarterly.

e.~~f.~~ The contract provider or subcontractor may administer or dispense the prescription drugs only to the eligible patients of the agency or entity or must return the prescription drugs for or to the agency or entity. The contract provider or subcontractor must require proof from each person seeking to fill a prescription or obtain treatment that the person is an

eligible patient of the agency or entity and must, at a minimum, maintain a copy of this proof as part of the records of the contractor or subcontractor required under sub-subparagraph e.

f.~~g.~~ In addition to the departmental inspection authority set forth in s. 499.051, the establishment of the contract provider and subcontractor and all records pertaining to prescription drugs subject to this subparagraph shall be subject to inspection by the agency or entity. All records relating to prescription drugs of a manufacturer under this subparagraph shall be subject to audit by the manufacturer of those drugs, without identifying individual patient information.

Section 26. Paragraph (b) of subsection (6) of section 766.106, Florida Statutes, is amended to read:

766.106 Notice before filing action for medical negligence; presuit screening period; offers for admission of liability and for arbitration; informal discovery; review.—

(6) INFORMAL DISCOVERY.—

(b) Informal discovery may be used by a party to obtain unsworn statements, the production of documents or things, ~~and~~ physical and mental examinations, and ex parte interviews, as follows:

1. Unsworn statements.—Any party may require other parties to appear for the taking of an unsworn statement. Such statements may be used only for the purpose of presuit screening and are not discoverable or admissible in any civil action for any purpose by any party. A party desiring to take the unsworn statement of any party must give reasonable notice in writing to all parties. The notice must state the time and place for taking the statement and the name and address of the party to be

examined. Unless otherwise impractical, the examination of any party must be done at the same time by all other parties. Any party may be represented by counsel at the taking of an unsworn statement. An unsworn statement may be recorded electronically, stenographically, or on videotape. The taking of unsworn statements is subject to the provisions of the Florida Rules of Civil Procedure and may be terminated for abuses.

2. Documents or things.—Any party may request discovery of documents or things. The documents or things must be produced, at the expense of the requesting party, within 20 days after the date of receipt of the request. A party is required to produce discoverable documents or things within that party's possession or control. Medical records shall be produced as provided in s. 766.204.

3. Physical and mental examinations.—A prospective defendant may require an injured claimant to appear for examination by an appropriate health care provider. The prospective defendant shall give reasonable notice in writing to all parties as to the time and place for examination. Unless otherwise impractical, a claimant is required to submit to only one examination on behalf of all potential defendants. The practicality of a single examination must be determined by the nature of the claimant's condition, as it relates to the liability of each prospective defendant. Such examination report is available to the parties and their attorneys upon payment of the reasonable cost of reproduction and may be used only for the purpose of presuit screening. Otherwise, such examination report is confidential and exempt from the provisions of s. 119.07(1) and s. 24(a), Art. I of the State Constitution.

4. Written questions.—Any party may request answers to written questions, the number of which may not exceed 30, including subparts. A response must be made within 20 days after receipt of the questions.

5. Unsworn statements of treating health care providers.—A prospective defendant or his or her legal representative may also take unsworn statements of the claimant's treating health care providers. The statements must be limited to those areas that are potentially relevant to the claim of personal injury or wrongful death. Subject to the procedural requirements of subparagraph 1., a prospective defendant may take unsworn statements from a claimant's treating physicians. Reasonable notice and opportunity to be heard must be given to the claimant or the claimant's legal representative before taking unsworn statements. The claimant or claimant's legal representative has the right to attend the taking of such unsworn statements.

6. Ex parte interviews of treating health care providers.—A prospective defendant or his or her legal representative may interview the claimant's treating health care providers without the presence of the claimant or the claimant's legal representative. If a prospective defendant or his or her legal representative intends to interview a claimant's health care providers, the prospective defendant must provide the claimant with notice of such interview at least 10 days before the date of the interview.

Section 27. Section 766.1091, Florida Statutes, is created to read:

766.1091 Voluntary binding arbitration; damages.—

(1) A health care provider licensed under chapter 458,

chapter 459, chapter 463, or chapter 466; any entity owned in whole or in part by a health care provider licensed under chapter 458, chapter 459, chapter 463, or chapter 466; or any health care clinic licensed under part X of chapter 400, and a patient or prospective patient, may agree in writing to submit to arbitration any claim for medical negligence which may currently exist or may accrue in the future and would otherwise be brought pursuant to this chapter. Any arbitration agreement entered into pursuant to this section shall be governed by chapter 682.

(2) Any arbitration agreement entered into pursuant to subsection (1) may contain a provision that limits the available damages in an arbitration award.

Section 28. Subsection (21) of section 893.02, Florida Statutes, is amended to read:

893.02 Definitions.—The following words and phrases as used in this chapter shall have the following meanings, unless the context otherwise requires:

(21) "Practitioner" means a physician licensed pursuant to chapter 458, a dentist licensed pursuant to chapter 466, a veterinarian licensed pursuant to chapter 474, an osteopathic physician licensed pursuant to chapter 459, a naturopath licensed pursuant to chapter 462, a certified optometrist licensed under chapter 463, or a podiatric physician licensed pursuant to chapter 461, provided such practitioner holds a valid federal controlled substance registry number.

Section 29. Subsection (1) of section 893.05, Florida Statutes, is amended to read:

893.05 Practitioners and persons administering controlled

substances in their absence.—

(1) A practitioner, in good faith and in the course of his or her professional practice only, may prescribe, administer, dispense, mix, or otherwise prepare a controlled substance, or the practitioner may cause the same to be administered by a licensed nurse or an intern practitioner under his or her direction and supervision only. A veterinarian may so prescribe, administer, dispense, mix, or prepare a controlled substance for use on animals only, and may cause it to be administered by an assistant or orderly under the veterinarian's direction and supervision only. A certified optometrist licensed under chapter 463 may not administer or prescribe pharmaceutical agents in Schedule I or Schedule II of the Florida Comprehensive Drug Abuse Prevention and Control Act.

Section 30. The Agency for Health Care Administration shall prepare a report within 18 months after the implementation of an expansion of managed care to new populations or the provision of new items and services. The agency shall post a draft of the report on its website and provide an opportunity for public comment. The final report shall be submitted to the Legislature, along with a description of the process for public input. The report must include an assessment of:

(1) The impact of managed care on patient access to care, including an evaluation of any new barriers to the use of services and prescription drugs, created by the use of medical management or cost-containment tools.

(2) The impact of the increased managed care expansion on the utilization of services, quality of care, and patient outcomes.

(3) The use of prior authorization and other utilization management tools, including an assessment of whether these tools pose an undue administrative burden for health care providers or create barriers to needed care.

Section 31. Except as otherwise expressly provided in this act, this act shall take effect upon becoming a law.

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

And the title is amended as follows:

Delete everything before the enacting clause and insert:

A bill to be entitled

An act relating to health care; amending s. 395.002, F.S.; redefining the term "accrediting organizations" as it applies to the regulation of hospitals and other licensed facilities; amending s. 400.474, F.S.; revising the fine that may be imposed against a home health agency for failing to timely submit certain information to the Agency for Health Care Administration; amending s. 400.9905, F.S.; revising the definition of the term "clinic" as it relates to the Health Care Clinic Act; amending s. 409.221, F.S.; revising the background screening requirements for persons rendering care in the consumer-directed care program administered by the Agency for Health Care Administration; amending s. 409.907, F.S.; extending the records-retention period for certain Medicaid provider records; revising the provider agreement to

require Medicaid providers to report changes in any principal of the provider to the agency; defining the term "administrative fines" for purposes of revoking a Medicaid provider agreement due to changes of ownership; authorizing, rather than requiring, an onsite inspection of a Medicaid provider's service location before entering into a provider agreement; specifying the principals of a hospital or nursing home provider for the purposes of submitting fingerprints for background screening; removing certain providers from being subject to agency background checks; amending s. 409.913, F.S.; defining the term "Medicaid provider" or "provider" for purposes of oversight of the integrity of the Medicaid program; authorizing the agency to review and analyze information from sources other than Medicaid-enrolled providers for purposes of determining fraud, abuse, overpayment, or neglect; extending the records-retention period for certain Medicaid provider records; revising the grounds for terminating a provider from the Medicaid program; requiring the agency to base its overpayment audit reports on certain information; deleting a requirement that the agency pay interest on certain withheld Medicaid payments; requiring payment arrangements for overpayments and fines to be made within a certain time; specifying that the venue for all Medicaid program integrity cases lies in Leon County; authorizing the agency and the Medicaid Fraud Control

Unit to review certain records; amending s. 409.920, F.S.; clarifying the applicability of immunity from civil liability extended to persons who provide information about fraud or suspected fraudulent acts by a Medicaid provider; amending s. 409.967, F.S.; specifying required components of a Medicaid managed care plan relating to the provisions of medications; amending s. 429.23, F.S.; requiring the agency to submit a report to the Legislature on adverse incident reports from assisted living facilities; amending s. 429.26, F.S.; authorizing the agency to require a resident of an assisted living facility to undergo a physical examination if the agency questions the appropriateness of the resident's placement in that facility; authorizing release of the results of the examination to a medical review team to be used along with additional information to determine whether the resident's placement in the assisted living facility is appropriate; providing for resident notification and relocation if the resident's continued placement in the facility is not appropriate; authorizing the agency to require the evaluation of a mental health resident by a mental health professional; authorizing an assisted living facility to discharge a resident who requires more services or care than the facility is able to provide; amending s. 456.0635, F.S.; revising the grounds under which the Department of Health or corresponding board is required to refuse to admit a candidate to an examination and refuse to

issue or renew a license, certificate, or registration of a health care practitioner; providing an exception; amending s. 456.036, F.S.; providing that all persons who were denied renewal of licensure, certification, or registration under s. 456.0635(3), F.S., may regain licensure, certification, or registration only by completing the application process for initial licensure; providing an exception; amending s. 456.074, F.S.; revising the federal offenses for which the Department of Health must issue an emergency order suspending the license of certain health care professionals; amending s. 463.002, F.S.; conforming provisions to changes made by the act; amending s. 463.005, F.S.; authorizing the Board of Optometry to adopt rules for the administration and prescription of ocular pharmaceutical agents; amending s. 463.0055, F.S.; authorizing certified optometrists to administer and prescribe pharmaceutical agents under certain circumstances; requiring that a certified optometrist complete a course and subsequent examination on general and ocular pharmacology; providing requirements for the course; requiring that the Florida Medical Association and the Florida Optometric Association jointly develop and administer the course and examination; revising qualifications of certain members of the formulary committee; providing for a formulary of topical ocular pharmaceutical agents which the committee may modify; specifying the agents that make up the statutory formulary of oral

pharmaceutical agents; authorizing the deletion of an oral pharmaceutical agent listed in the statutory formulary under certain circumstances; prohibiting the board, the Department of Health, or the State Surgeon General from deleting an oral pharmaceutical agent listed in the statutory formulary; amending ss. 463.0057 and 463.006, F.S.; conforming provisions to changes made by the act; amending s. 463.0135, F.S.; requiring that a certified optometrist administer and prescribe oral ocular pharmaceutical agents in a certain manner; requiring that a licensed practitioner who diagnoses a patient who has a neovascular form of glaucoma or progressive glaucoma immediately refer the patient to a physician who is skilled in the diseases of the eye; requiring that comanagement of postoperative care be conducted pursuant to an established protocol; requiring that the patient be informed that a physician will be available for emergency care throughout the postoperative period; requiring that the patient consent in writing to the comanagement relationship; amending s. 463.014, F.S.; revising certain prohibited acts regarding an optometrist conducting surgery and dispensing, administering, ordering, supplying, or selling certain drugs; creating s. 463.0141, F.S.; requiring that adverse incidents in the practice of optometry be reported to the Department of Health; providing requirements for notifying the department of an adverse incident; providing a definition; requiring

that the department review each incident and determine whether it involved conduct that is subject to disciplinary action; requiring that the Board of Optometry take disciplinary action if necessary; amending s. 483.035, F.S., relating to licensure and regulation of clinical laboratories operated by practitioners for exclusive use; providing applicability to clinical laboratories operated by practitioners licensed to practice optometry; amending s. 483.041, F.S.; revising the definition of the term "licensed practitioner" to include a practitioner licensed under ch. 463, F.S.; amending s. 483.181, F.S.; requiring clinical laboratories to accept human specimens submitted by practitioners licensed to practice under ch. 463, F.S.; amending s. 499.003, F.S.; removing a requirement that a contract provider or subcontractor maintain prescription drugs of the agency or entity in its possession separate and apart from other prescription drugs; amending s. 766.106, F.S.; authorizing a prospective defendant to obtain informal discovery by conducting ex parte interviews of treating health care providers; requiring advance notice to the claimant of an ex parte interview; creating s. 766.1091, F.S.; authorizing a health care provider or health care clinic and a patient to agree to submit a claim of medical negligence to arbitration; requiring that the arbitration agreement be governed by ch. 682, F.S.; authorizing the arbitration agreement to contain a provision that

810774

limits an award of damages; amending s. 893.02, F.S.; revising the definition of the term "practitioner" to include certified optometrists for purposes of the Florida Comprehensive Drug Abuse Prevention and Control Act; amending s. 893.05, F.S.; prohibiting certified optometrists from administering and prescribing certain controlled substances; requiring the Agency for Health Care Administration to prepare a report for public comment and submission to the Legislature following the expansion of services to new populations or of new services; providing an effective date.

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LEGISLATIVE ACTION

Senate	.	House
Comm: UNFAV	.	
02/09/2012	.	
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The Committee on Health Regulation (Diaz de la Portilla) recommended the following:

Senate Amendment to Substitute Amendment (810774) (with title amendment)

Delete lines 1574 - 1590.

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

And the title is amended as follows:

Delete lines 1804 - 1810

and insert:

amending s. 893.02, F.S.

830922

LEGISLATIVE ACTION

Senate . House

. . . . . .

The Committee on Health Regulation (Gaetz) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause and insert:

Section 1. Subsection (6) of section 400.474, Florida Statutes, is amended, present subsection (7) of that section is renumbered as subsection (8), and a new subsection (7) is added to that section, to read:

400.474 Administrative penalties.—

(6) The agency may deny, revoke, or suspend the license of a home health agency and shall impose a fine of $5,000 against a home health agency that:

830922

(a) Gives remuneration for staffing services to:

1. Another home health agency with which it has formal or informal patient-referral transactions or arrangements; or

2. A health services pool with which it has formal or informal patient-referral transactions or arrangements,

unless the home health agency has activated its comprehensive emergency management plan in accordance with s. 400.492. This paragraph does not apply to a Medicare-certified home health agency that provides fair market value remuneration for staffing services to a non-Medicare-certified home health agency that is part of a continuing care facility licensed under chapter 651 for providing services to its own residents if each resident receiving home health services pursuant to this arrangement attests in writing that he or she made a decision without influence from staff of the facility to select, from a list of Medicare-certified home health agencies provided by the facility, that Medicare-certified home health agency to provide the services.

(b) Provides services to residents in an assisted living facility for which the home health agency does not receive fair market value remuneration.

(c) Provides staffing to an assisted living facility for which the home health agency does not receive fair market value remuneration.

(d) Fails to provide the agency, upon request, with copies of all contracts with assisted living facilities which were executed within 5 years before the request.

(e) Gives remuneration to a case manager, discharge

830922

planner, facility-based staff member, or third-party vendor who is involved in the discharge planning process of a facility licensed under chapter 395, chapter 429, or this chapter from whom the home health agency receives referrals.

~~(f) Fails to submit to the agency, within 15 days after the end of each calendar quarter, a written report that includes the following data based on data as it existed on the last day of the quarter:~~

~~1. The number of insulin-dependent diabetic patients receiving insulin-injection services from the home health agency;~~

~~2. The number of patients receiving both home health services from the home health agency and hospice services;~~

~~3. The number of patients receiving home health services from that home health agency; and~~

~~4. The names and license numbers of nurses whose primary job responsibility is to provide home health services to patients and who received remuneration from the home health agency in excess of $25,000 during the calendar quarter.~~

(f) ~~(g)~~ Gives cash, or its equivalent, to a Medicare or Medicaid beneficiary.

(g) ~~(h)~~ Has more than one medical director contract in effect at one time or more than one medical director contract and one contract with a physician-specialist whose services are mandated for the home health agency in order to qualify to participate in a federal or state health care program at one time.

(h) ~~(i)~~ Gives remuneration to a physician without a medical director contract being in effect. The contract must:

830922

1. Be in writing and signed by both parties;

2. Provide for remuneration that is at fair market value for an hourly rate, which must be supported by invoices submitted by the medical director describing the work performed, the dates on which that work was performed, and the duration of that work; and

3. Be for a term of at least 1 year.

The hourly rate specified in the contract may not be increased during the term of the contract. The home health agency may not execute a subsequent contract with that physician which has an increased hourly rate and covers any portion of the term that was in the original contract.

(i) ~~(j)~~ Gives remuneration to:

1. A physician, and the home health agency is in violation of paragraph (g) ~~(h)~~ or paragraph (h) ~~(i)~~;

2. A member of the physician's office staff; or

3. An immediate family member of the physician,

if the home health agency has received a patient referral in the preceding 12 months from that physician or physician's office staff.

(j) ~~(k)~~ Fails to provide to the agency, upon request, copies of all contracts with a medical director which were executed within 5 years before the request.

(k) ~~(l)~~ Demonstrates a pattern of billing the Medicaid program for services to Medicaid recipients which are medically unnecessary as determined by a final order. A pattern may be demonstrated by a showing of at least two such medically

unnecessary services within one Medicaid program integrity audit period.

Paragraphs (e) and (i) do not apply to or preclude ~~Nothing in paragraph (c) or paragraph (j) shall be interpreted as applying to or precluding~~ any discount, compensation, waiver of payment, or payment practice permitted by 42 U.S.C. s. 1320a-7(b) or regulations adopted thereunder, including 42 C.F.R. s. 1001.952 or s. 1395nn or regulations adopted thereunder.

(7) The agency shall impose a fine of $50 per day against a home health agency that fails to submit to the agency, within 15 days after the end of each calendar quarter, a written report that includes the following data based on data as it existed on the last day of the quarter:

(a) The number of patients receiving both home health services from the home health agency and hospice services;

(b) The number of patients receiving home health services from the home health agency;

(c) The number of insulin-dependent diabetic patients receiving insulin-injection services from the home health agency; and

(d) The names and license numbers of nurses whose primary job responsibility is to provide home health services to patients and who received remuneration from the home health agency in excess of $25,000 during the calendar quarter.

Section 2. Paragraph (l) of subsection (4) of section 400.9905, Florida Statutes, is amended, and paragraph (m) is added to that subsection, to read:

400.9905 Definitions.—

(4) "Clinic" means an entity at which health care services are provided to individuals and which tenders charges for reimbursement for such services, including a mobile clinic and a portable equipment provider. For purposes of this part, the term does not include and the licensure requirements of this part do not apply to:

(l) Orthotic, ~~or~~ prosthetic, pediatric cardiology, or perinatology clinical facilities or anesthesia clinical facilities that are not otherwise exempt under paragraph (a) or paragraph (k) and that are a publicly traded corporation or ~~that~~ are wholly owned, directly or indirectly, by a publicly traded corporation. As used in this paragraph, a publicly traded corporation is a corporation that issues securities traded on an exchange registered with the United States Securities and Exchange Commission as a national securities exchange.

(m) Entities that are owned or controlled, directly or indirectly, by a publicly traded entity that has $100 million or more, in the aggregate, in total annual revenues derived from providing health care services by licensed health care practitioners who are employed or contracted by an entity described in this paragraph.

Section 3. Paragraph (i) of subsection (4) of section 409.221, Florida Statutes, is amended to read:

409.221 Consumer-directed care program.—

(4) CONSUMER-DIRECTED CARE.—

(i) *Background screening requirements.*—All persons who render care under this section must undergo level 2 background screening pursuant to chapter 435 and s. 408.809. The agency shall, as allowable, reimburse consumer-employed caregivers for

the cost of conducting such ~~background~~ screening ~~as required by this section~~. For purposes of this section, a person who has undergone screening, who is qualified for employment under this section and applicable rule, and who has not been unemployed for more than 90 days following such screening is not required to be rescreened. Such person must attest under penalty of perjury to not having been convicted of a disqualifying offense since completing such screening.

Section 4. Paragraph (c) of subsection (3) of section 409.907, Florida Statutes, is amended, paragraph (k) is added to that subsection, and subsections (6), (7), and (8) of that section are amended, to read:

409.907 Medicaid provider agreements.—The agency may make payments for medical assistance and related services rendered to Medicaid recipients only to an individual or entity who has a provider agreement in effect with the agency, who is performing services or supplying goods in accordance with federal, state, and local law, and who agrees that no person shall, on the grounds of handicap, race, color, or national origin, or for any other reason, be subjected to discrimination under any program or activity for which the provider receives payment from the agency.

(3) The provider agreement developed by the agency, in addition to the requirements specified in subsections (1) and (2), shall require the provider to:

(c) Retain all medical and Medicaid-related records for 6 ~~a period of 5~~ years to satisfy all necessary inquiries by the agency.

(k) Report a change in any principal of the provider,

including any officer, director, agent, managing employee, or affiliated person, or any partner or shareholder who has an ownership interest equal to 5 percent or more in the provider, to the agency in writing no later than 30 days after the change occurs.

(6) A Medicaid provider agreement may be revoked, at the option of the agency, due to ~~as the result of~~ a change of ownership of any facility, association, partnership, or other entity named as the provider in the provider agreement.

(a) In the event of a change of ownership, the transferor remains liable for all outstanding overpayments, administrative fines, and any other moneys owed to the agency before the effective date of the change of ownership. ~~In addition to the continuing liability of the transferor,~~ The transferee is also liable to the agency for all outstanding overpayments identified by the agency on or before the effective date of the change of ownership. ~~For purposes of this subsection, the term "outstanding overpayment" includes any amount identified in a preliminary audit report issued to the transferor by the agency on or before the effective date of the change of ownership.~~ In the event of a change of ownership for a skilled nursing facility or intermediate care facility, the Medicaid provider agreement shall be assigned to the transferee if the transferee meets all other Medicaid provider qualifications. In the event of a change of ownership involving a skilled nursing facility licensed under part II of chapter 400, liability for all outstanding overpayments, administrative fines, and any moneys owed to the agency before the effective date of the change of ownership shall be determined in accordance with s. 400.179.

(b) At least 60 days before the anticipated date of the change of ownership, the transferor must ~~shall~~ notify the agency of the intended change of ownership and the transferee must ~~shall~~ submit to the agency a Medicaid provider enrollment application. If a change of ownership occurs without compliance with the notice requirements of this subsection, the transferor and transferee are ~~shall be~~ jointly and severally liable for all overpayments, administrative fines, and other moneys due to the agency, regardless of whether the agency identified the overpayments, administrative fines, or other moneys before or after the effective date of the change of ownership. The agency may not approve a transferee's Medicaid provider enrollment application if the transferee or transferor has not paid or agreed in writing to a payment plan for all outstanding overpayments, administrative fines, and other moneys due to the agency. This subsection does not preclude the agency from seeking any other legal or equitable remedies available to the agency for the recovery of moneys owed to the Medicaid program. In the event of a change of ownership involving a skilled nursing facility licensed under part II of chapter 400, liability for all outstanding overpayments, administrative fines, and any moneys owed to the agency before the effective date of the change of ownership shall be determined in accordance with s. 400.179 if the Medicaid provider enrollment application for change of ownership is submitted before the change of ownership.

(c) As used in this subsection, the term:

1. "Administrative fines" includes any amount identified in a notice of a monetary penalty or fine which has been issued by

the agency or other regulatory or licensing agency that governs the provider.

2. "Outstanding overpayment" includes any amount identified in a preliminary audit report issued to the transferor by the agency on or before the effective date of a change of ownership.

(7) ~~The agency may require,~~ As a condition of participating in the Medicaid program and before entering into the provider agreement, the agency may require ~~that~~ the provider to submit information, in an initial and any required renewal applications, concerning the professional, business, and personal background of the provider and permit an onsite inspection of the provider's service location by agency staff or other personnel designated by the agency to perform this function. Before entering into a provider agreement, the agency may ~~shall~~ perform an ~~a random~~ onsite inspection~~, within 60 days after receipt of a fully complete new provider's application,~~ of the provider's service location ~~prior to making its first payment to the provider for Medicaid services~~ to determine the applicant's ability to provide ~~the~~ services in compliance with the Medicaid program and professional regulations ~~that the applicant is proposing to provide for Medicaid reimbursement~~. ~~The agency is not required to perform an onsite inspection of a provider or program that is licensed by the agency, that provides services under waiver programs for home and community-based services, or that is licensed as a medical foster home by the Department of Children and Family Services.~~ As a continuing condition of participation in the Medicaid program, a provider must ~~shall~~ immediately notify the agency of any current or pending bankruptcy filing. Before entering into the provider

agreement, or as a condition of continuing participation in the Medicaid program, the agency may also require that Medicaid providers reimbursed on a fee-for-services basis or fee schedule basis that ~~which~~ is not cost-based, post a surety bond not to exceed $50,000 or the total amount billed by the provider to the program during the current or most recent calendar year, whichever is greater. For new providers, the amount of the surety bond shall be determined by the agency based on the provider's estimate of its first year's billing. If the provider's billing during the first year exceeds the bond amount, the agency may require the provider to acquire an additional bond equal to the actual billing level of the provider. A provider's bond need ~~shall~~ not exceed $50,000 if a physician or group of physicians licensed under chapter 458, chapter 459, or chapter 460 has a 50 percent or greater ownership interest in the provider or if the provider is an assisted living facility licensed under chapter 429. The bonds permitted by this section are in addition to the bonds referenced in s. 400.179(2)(d). If the provider is a corporation, partnership, association, or other entity, the agency may require the provider to submit information concerning the background of that entity and of any principal of the entity, including any partner or shareholder having an ownership interest in the entity equal to 5 percent or greater, and any treating provider who participates in or intends to participate in Medicaid through the entity. The information must include:

(a) Proof of holding a valid license or operating certificate, as applicable, if required by the state or local jurisdiction in which the provider is located or if required by

the Federal Government.

(b) Information concerning any prior violation, fine, suspension, termination, or other administrative action taken under the Medicaid laws, rules, or regulations of this state or of any other state or the Federal Government; any prior violation of the laws, rules, or regulations relating to the Medicare program; any prior violation of the rules or regulations of any other public or private insurer; and any prior violation of the laws, rules, or regulations of any regulatory body of this or any other state.

(c) Full and accurate disclosure of any financial or ownership interest that the provider, or any principal, partner, or major shareholder thereof, may hold in any other Medicaid provider or health care related entity or any other entity that is licensed by the state to provide health or residential care and treatment to persons.

(d) If a group provider, identification of all members of the group and attestation that all members of the group are enrolled in or have applied to enroll in the Medicaid program.

(8) ~~(a)~~ Each provider, or each principal of the provider if the provider is a corporation, partnership, association, or other entity, seeking to participate in the Medicaid program must submit a complete set of his or her fingerprints to the agency for the purpose of conducting a criminal history record check. Principals of the provider include any officer, director, billing agent, managing employee, or affiliated person, or any partner or shareholder who has an ownership interest equal to 5 percent or more in the provider. However, for a hospital licensed under chapter 395 or a nursing home licensed under

830922

chapter 400, principals of the provider are those who meet the definition of a controlling interest under s. 408.803. A director of a not-for-profit corporation or organization is not a principal for purposes of a background investigation as required by this section if the director: serves solely in a voluntary capacity for the corporation or organization, does not regularly take part in the day-to-day operational decisions of the corporation or organization, receives no remuneration from the not-for-profit corporation or organization for his or her service on the board of directors, has no financial interest in the not-for-profit corporation or organization, and has no family members with a financial interest in the not-for-profit corporation or organization; and if the director submits an affidavit, under penalty of perjury, to this effect to the agency and the not-for-profit corporation or organization submits an affidavit, under penalty of perjury, to this effect to the agency as part of the corporation's or organization's Medicaid provider agreement application.

(a) Notwithstanding the above, the agency may require a background check for any person reasonably suspected by the agency to have been convicted of a crime. This subsection does not apply to:

~~1. A hospital licensed under chapter 395;~~

~~2. A nursing home licensed under chapter 400;~~

~~3. A hospice licensed under chapter 400;~~

~~4. An assisted living facility licensed under chapter 429;~~

1.~~5.~~ A unit of local government, except that requirements of this subsection apply to nongovernmental providers and entities contracting with the local government to provide

830922

Medicaid services. The actual cost of the state and national criminal history record checks must be borne by the nongovernmental provider or entity; or

2.~~6.~~ Any business that derives more than 50 percent of its revenue from the sale of goods to the final consumer, and the business or its controlling parent is required to file a form 10-K or other similar statement with the Securities and Exchange Commission or has a net worth of $50 million or more.

(b) Background screening shall be conducted in accordance with chapter 435 and s. 408.809. The cost of the state and national criminal record check shall be borne by the provider.

~~(c) Proof of compliance with the requirements of level 2 screening under chapter 435 conducted within 12 months before the date the Medicaid provider application is submitted to the agency fulfills the requirements of this subsection.~~

Section 5. Present paragraphs (e) and (f) of subsection (1) of section 409.913, Florida Statutes, are redesignated as paragraphs (f) and (g), respectively, a new paragraph (e) is added to that subsection, and subsections (2), (9), (13), (15), (16), (21), (22), (25), (28), (29), (30), and (31) of that section are amended, to read:

409.913 Oversight of the integrity of the Medicaid program.—The agency shall operate a program to oversee the activities of Florida Medicaid recipients, and providers and their representatives, to ensure that fraudulent and abusive behavior and neglect of recipients occur to the minimum extent possible, and to recover overpayments and impose sanctions as appropriate. Beginning January 1, 2003, and each year thereafter, the agency and the Medicaid Fraud Control Unit of

the Department of Legal Affairs shall submit a joint report to the Legislature documenting the effectiveness of the state's efforts to control Medicaid fraud and abuse and to recover Medicaid overpayments during the previous fiscal year. The report must describe the number of cases opened and investigated each year; the sources of the cases opened; the disposition of the cases closed each year; the amount of overpayments alleged in preliminary and final audit letters; the number and amount of fines or penalties imposed; any reductions in overpayment amounts negotiated in settlement agreements or by other means; the amount of final agency determinations of overpayments; the amount deducted from federal claiming as a result of overpayments; the amount of overpayments recovered each year; the amount of cost of investigation recovered each year; the average length of time to collect from the time the case was opened until the overpayment is paid in full; the amount determined as uncollectible and the portion of the uncollectible amount subsequently reclaimed from the Federal Government; the number of providers, by type, that are terminated from participation in the Medicaid program as a result of fraud and abuse; and all costs associated with discovering and prosecuting cases of Medicaid overpayments and making recoveries in such cases. The report must also document actions taken to prevent overpayments and the number of providers prevented from enrolling in or reenrolling in the Medicaid program as a result of documented Medicaid fraud and abuse and must include policy recommendations necessary to prevent or recover overpayments and changes necessary to prevent and detect Medicaid fraud. All policy recommendations in the report must include a detailed

fiscal analysis, including, but not limited to, implementation costs, estimated savings to the Medicaid program, and the return on investment. The agency must submit the policy recommendations and fiscal analyses in the report to the appropriate estimating conference, pursuant to s. 216.137, by February 15 of each year. The agency and the Medicaid Fraud Control Unit of the Department of Legal Affairs each must include detailed unit-specific performance standards, benchmarks, and metrics in the report, including projected cost savings to the state Medicaid program during the following fiscal year.

(1) For the purposes of this section, the term:

(e) "Medicaid provider" or "provider" has the same meaning as provided in s. 409.901 and, for purposes of oversight of the integrity of the Medicaid program, also includes a participant in a Medicaid managed care provider network.

(2) The agency shall conduct, or cause to be conducted by contract or otherwise, reviews, investigations, analyses, audits, or any combination thereof, to determine possible fraud, abuse, overpayment, or recipient neglect in the Medicaid program and ~~shall~~ report the findings of any overpayments in audit reports as appropriate. At least 5 percent of all audits must ~~shall~~ be conducted on a random basis. As part of its ongoing fraud detection activities, the agency shall identify and monitor, by contract or otherwise, patterns of overutilization of Medicaid services based on state averages. The agency shall track Medicaid provider prescription and billing patterns and evaluate them against Medicaid medical necessity criteria and coverage and limitation guidelines adopted by rule. Medical necessity determination requires that service be consistent with

830922

symptoms or confirmed diagnosis of illness or injury under treatment and not in excess of the patient's needs. The agency shall conduct reviews of provider exceptions to peer group norms and ~~shall~~, using statistical methodologies, provider profiling, and analysis of billing patterns, detect and investigate abnormal or unusual increases in billing or payment of claims for Medicaid services and medically unnecessary provision of services. The agency may review and analyze information from sources other than enrolled Medicaid providers in conducting its activities under this subsection.

(9) A Medicaid provider shall retain medical, professional, financial, and business records pertaining to services and goods furnished to a Medicaid recipient and billed to Medicaid for 6 ~~a period of 5~~ years after the date of furnishing such services or goods. The agency may investigate, review, or analyze such records, which must be made available during normal business hours. However, 24-hour notice must be provided if patient treatment would be disrupted. The provider is responsible for furnishing to the agency, and keeping the agency informed of the location of, the provider's Medicaid-related records. The authority of the agency to obtain Medicaid-related records from a provider is neither curtailed nor limited during a period of litigation between the agency and the provider.

(13) The agency shall ~~immediately~~ terminate participation of a Medicaid provider in the Medicaid program and may seek civil remedies or impose other administrative sanctions against a Medicaid provider, if the provider or any principal, officer, director, agent, managing employee, or affiliated person of the provider, or any partner or shareholder having an ownership

830922

interest in the provider equal to 5 percent or greater, has been convicted of a criminal offense under federal law or the law of any state relating to the practice of the provider's profession, or an offense listed under s. 409.907(10), s. 408.809(4), or s. 435.04(2) ~~has been:~~

~~(a) Convicted of a criminal offense related to the delivery of any health care goods or services, including the performance of management or administrative functions relating to the delivery of health care goods or services;~~

~~(b) Convicted of a criminal offense under federal law or the law of any state relating to the practice of the provider's profession; or~~

~~(c) Found by a court of competent jurisdiction to have neglected or physically abused a patient in connection with the delivery of health care goods or services~~. If the agency determines that the ~~a~~ provider did not participate or acquiesce in the ~~an~~ offense ~~specified in paragraph (a), paragraph (b), or paragraph (c)~~, termination will not be imposed. If the agency effects a termination under this subsection, the agency shall issue an immediate final order pursuant to s. 120.569(2)(n).

(15) The agency shall seek a remedy provided by law, including, but not limited to, any remedy provided in subsections (13) and (16) and s. 812.035, if:

(a) The provider's license has not been renewed, or has been revoked, suspended, or terminated, for cause, by the licensing agency of any state;

(b) The provider has failed to make available or has refused access to Medicaid-related records to an auditor, investigator, or other authorized employee or agent of the

agency, the Attorney General, a state attorney, or the Federal Government;

(c) The provider has not furnished or has failed to make available such Medicaid-related records as the agency has found necessary to determine whether Medicaid payments are or were due and the amounts thereof;

(d) The provider has failed to maintain medical records made at the time of service, or prior to service if prior authorization is required, demonstrating the necessity and appropriateness of the goods or services rendered;

(e) The provider is not in compliance with provisions of Medicaid provider publications that have been adopted by reference as rules in the Florida Administrative Code; with provisions of state or federal laws, rules, or regulations; with provisions of the provider agreement between the agency and the provider; or with certifications found on claim forms or on transmittal forms for electronically submitted claims that are submitted by the provider or authorized representative, as such provisions apply to the Medicaid program;

(f) The provider or person who ordered, authorized, or prescribed the care, services, or supplies has furnished, ~~or~~ ordered, or authorized the furnishing of~~,~~ goods or services to a recipient which are inappropriate, unnecessary, excessive, or harmful to the recipient or are of inferior quality;

(g) The provider has demonstrated a pattern of failure to provide goods or services that are medically necessary;

(h) The provider or an authorized representative of the provider, or a person who ordered, authorized, or prescribed the goods or services, has submitted or caused to be submitted false

or a pattern of erroneous Medicaid claims;

(i) The provider or an authorized representative of the provider, or a person who has ordered, authorized, or prescribed the goods or services, has submitted or caused to be submitted a Medicaid provider enrollment application, a request for prior authorization for Medicaid services, a drug exception request, or a Medicaid cost report that contains materially false or incorrect information;

(j) The provider or an authorized representative of the provider has collected from or billed a recipient or a recipient's responsible party improperly for amounts that should not have been so collected or billed by reason of the provider's billing the Medicaid program for the same service;

(k) The provider or an authorized representative of the provider has included in a cost report costs that are not allowable under a Florida Title XIX reimbursement plan~~,~~ after the provider or authorized representative had been advised in an audit exit conference or audit report that the costs were not allowable;

(l) The provider is charged by information or indictment with fraudulent billing practices or any offense referenced in subsection (13). The sanction applied for this reason is limited to suspension of the provider's participation in the Medicaid program for the duration of the indictment unless the provider is found guilty pursuant to the information or indictment;

(m) The provider or a person who has ordered, authorized, or prescribed the goods or services is found liable for negligent practice resulting in death or injury to the provider's patient;

(n) The provider fails to demonstrate that it had available during a specific audit or review period sufficient quantities of goods, or sufficient time in the case of services, to support the provider's billings to the Medicaid program;

(o) The provider has failed to comply with the notice and reporting requirements of s. 409.907;

(p) The agency has received reliable information of patient abuse or neglect or of any act prohibited by s. 409.920; or

(q) The provider has failed to comply with an agreed-upon repayment schedule.

A provider is subject to sanctions for violations of this subsection as the result of actions or inactions of the provider, or actions or inactions of any principal, officer, director, agent, managing employee, or affiliated person of the provider, or any partner or shareholder having an ownership interest in the provider equal to 5 percent or greater, in which the provider participated or acquiesced.

(16) The agency shall impose any of the following sanctions or disincentives on a provider or a person for any of the acts described in subsection (15):

(a) Suspension for a specific period of time of not more than 1 year. Suspension precludes ~~shall preclude~~ participation in the Medicaid program, which includes any action that results in a claim for payment to the Medicaid program as a result of furnishing, supervising a person who is furnishing, or causing a person to furnish goods or services.

(b) Termination for a specific period of time of from more than 1 year to 20 years. Termination precludes ~~shall preclude~~

participation in the Medicaid program, which includes any action that results in a claim for payment to the Medicaid program as a result of furnishing, supervising a person who is furnishing, or causing a person to furnish goods or services.

(c) Imposition of a fine of up to $5,000 for each violation. Each day that an ongoing violation continues, such as refusing to furnish Medicaid-related records or refusing access to records, is considered, for the purposes of this section, to be a separate violation. Each instance of improper billing of a Medicaid recipient; each instance of including an unallowable cost on a hospital or nursing home Medicaid cost report after the provider or authorized representative has been advised in an audit exit conference or previous audit report of the cost unallowability; each instance of furnishing a Medicaid recipient goods or professional services that are inappropriate or of inferior quality as determined by competent peer judgment; each instance of knowingly submitting a materially false or erroneous Medicaid provider enrollment application, request for prior authorization for Medicaid services, drug exception request, or cost report; each instance of inappropriate prescribing of drugs for a Medicaid recipient as determined by competent peer judgment; and each false or erroneous Medicaid claim leading to an overpayment to a provider is considered, for the purposes of this section, to be a separate violation.

(d) Immediate suspension, if the agency has received information of patient abuse or neglect or of any act prohibited by s. 409.920. Upon suspension, the agency must issue an immediate final order under s. 120.569(2)(n).

(e) A fine, not to exceed $10,000, for a violation of

paragraph (15)(i).

(f) Imposition of liens against provider assets, including, but not limited to, financial assets and real property, not to exceed the amount of fines or recoveries sought, upon entry of an order determining that such moneys are due or recoverable.

(g) Prepayment reviews of claims for a specified period of time.

(h) Comprehensive followup reviews of providers every 6 months to ensure that they are billing Medicaid correctly.

(i) Corrective-action plans that ~~would~~ remain in effect ~~for providers~~ for up to 3 years and that are ~~would be~~ monitored by the agency every 6 months while in effect.

(j) Other remedies as permitted by law to effect the recovery of a fine or overpayment.

If a provider voluntarily relinquishes its Medicaid provider number after receiving written notice that the agency is conducting, or has conducted, an audit or investigation and the sanction of suspension or termination will be imposed for noncompliance discovered as a result of the audit or investigation, the agency shall impose the sanction of termination for cause against the provider. The Secretary of Health Care Administration may make a determination that imposition of a sanction or disincentive is not in the best interest of the Medicaid program, in which case a sanction or disincentive may ~~shall~~ not be imposed.

(21) When making a determination that an overpayment has occurred, the agency shall prepare and issue an audit report to the provider showing the calculation of overpayments. The

agency's determination shall be based solely upon information available to it before issuance of the audit report and, in the case of documentation obtained to substantiate claims for Medicaid reimbursement, based solely upon contemporaneous records.

(22) The audit report, supported by agency work papers, showing an overpayment to a provider constitutes evidence of the overpayment. A provider may not present or elicit testimony, ~~either~~ on direct examination or cross-examination in any court or administrative proceeding, regarding the purchase or acquisition by any means of drugs, goods, or supplies; sales or divestment by any means of drugs, goods, or supplies; or inventory of drugs, goods, or supplies, unless such acquisition, sales, divestment, or inventory is documented by written invoices, written inventory records, or other competent written documentary evidence maintained in the normal course of the provider's business. Testimony or evidence that is not based upon contemporaneous records or that was not furnished to the agency within 21 days after the issuance of the audit report is inadmissible in an administrative hearing on a Medicaid overpayment or an administrative sanction. Notwithstanding the applicable rules of discovery, all documentation to ~~that will~~ be offered as evidence at an administrative hearing on a Medicaid overpayment or an administrative sanction must be exchanged by all parties at least 14 days before the administrative hearing or ~~must be~~ excluded from consideration.

(25)(a) The agency shall withhold Medicaid payments, in whole or in part, to a provider upon receipt of reliable evidence that the circumstances giving rise to the need for a

withholding of payments involve fraud, willful misrepresentation, or abuse under the Medicaid program, or a crime committed while rendering goods or services to Medicaid recipients. If it is determined that fraud, willful misrepresentation, abuse, or a crime did not occur, the payments withheld must be paid to the provider within 14 days after such determination ~~with interest at the rate of 10 percent a year~~. ~~Any money withheld in accordance with this paragraph shall be placed in a suspended account, readily accessible to the agency, so that any payment ultimately due the provider shall be made within 14 days.~~

(b) The agency shall deny payment, or require repayment, if the goods or services were furnished, supervised, or caused to be furnished by a person who has been suspended or terminated from the Medicaid program or Medicare program by the Federal Government or any state.

(c) Overpayments owed to the agency bear interest at the rate of 10 percent per year from the date of determination of the overpayment by the agency, and payment arrangements regarding overpayments and fines must be made within 30 days after the date of the final order and are not subject to further appeal ~~at the conclusion of legal proceedings~~. ~~A provider who does not enter into or adhere to an agreed-upon repayment schedule may be terminated by the agency for nonpayment or partial payment.~~

(d) The agency, upon entry of a final agency order, a judgment or order of a court of competent jurisdiction, or a stipulation or settlement, may collect the moneys owed by all means allowable by law, including, but not limited to, notifying

any fiscal intermediary of Medicare benefits that the state has a superior right of payment. Upon receipt of such written notification, the Medicare fiscal intermediary shall remit to the state the sum claimed.

(e) The agency may institute amnesty programs to allow Medicaid providers the opportunity to voluntarily repay overpayments. The agency may adopt rules to administer such programs.

(28) Venue for all Medicaid program integrity ~~overpayment~~ cases lies ~~shall lie~~ in Leon County, at the discretion of the agency.

(29) Notwithstanding other provisions of law, the agency and the Medicaid Fraud Control Unit of the Department of Legal Affairs may review a person's or provider's Medicaid-related and non-Medicaid-related records in order to determine the total output of a provider's practice to reconcile quantities of goods or services billed to Medicaid with quantities of goods or services used in the provider's total practice.

(30) The agency shall terminate a provider's participation in the Medicaid program if the provider fails to reimburse an overpayment or pay a fine that has been determined by final order, not subject to further appeal, within 30 ~~35~~ days after the date of the final order, unless the provider and the agency have entered into a repayment agreement.

(31) If a provider requests an administrative hearing pursuant to chapter 120, such hearing must be conducted within 90 days following assignment of an administrative law judge, absent exceptionally good cause shown as determined by the administrative law judge or hearing officer. Upon issuance of a

final order, the outstanding balance of the amount determined to constitute the overpayment and fines is ~~shall become~~ due. If a provider fails to make payments in full, fails to enter into a satisfactory repayment plan, or fails to comply with the terms of a repayment plan or settlement agreement, the agency shall withhold ~~medical assistance~~ reimbursement payments for Medicaid services until the amount due is paid in full.

Section 6. Subsection (8) of section 409.920, Florida Statutes, is amended to read:

409.920 Medicaid provider fraud.—

(8) A person who provides the state, any state agency, any of the state's political subdivisions, or any agency of the state's political subdivisions with information about fraud or suspected fraudulent acts ~~fraud~~ by a Medicaid provider, including a managed care organization, is immune from civil liability for libel, slander, or any other relevant tort for providing any ~~the~~ information about fraud or suspected fraudulent acts, unless the person acted with knowledge that the information was false or with reckless disregard for the truth or falsity of the information. For purposes of this subsection, the term "fraudulent acts" includes actual or suspected fraud, abuse, or overpayment, including any fraud-related matters that a provider or health plan is required to report to the agency or a law enforcement agency. The immunity from civil liability extends to reports of fraudulent acts conveyed to the agency in any manner, including any forum and with any audience as directed by the agency, and includes all discussions subsequent to the report and subsequent inquiries from the agency, unless the person acted with knowledge that the information was false

or with reckless disregard for the truth or falsity of the information.

Section 7. Paragraph (c) of subsection (2) of section 409.967, Florida Statutes, is amended to read:

409.967 Managed care plan accountability.—

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

(c) *Access.*—

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

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

2. Prescribed drugs.—

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

(I) Provide coverage for drugs in categories and classes for all disease states and provide a broad range of therapeutic options for all therapeutic categories;

(II) Include coverage for each drug newly approved by the federal Food and Drug Administration until the plan's Pharmaceutical and Therapeutics Committee reviews such drug for inclusion on the formulary;

(III) Provide a response within 24 hours after receipt of all necessary information for a request for prior authorization or override of other medical management tools; and

(IV) Report all denials to the agency on a quarterly basis. For each nonformulary drug, the plan must report the total number of requests and the total number of denials.

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

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

c. The managed care plan must continue to permit an enrollee who was receiving a prescription drug that was on the plan's formulary and subsequently removed or changed to continue to receive that drug if requested by the enrollee and prescriber for as long as the enrollee is a member of the plan.

d. A managed care plan that imposes a step-therapy or a fail-first protocol must do so in accordance with the following:

(I) If prescribed drugs for the treatment of a medical condition are restricted for use by the plan through a step-therapy or fail-first protocol, the plan must provide the prescriber with access to a clear and convenient process to expeditiously request an override of such restriction from the plan.

(II) An override of the restriction must be expeditiously granted by the plan if the prescriber can demonstrate to the plan that the preferred treatment required under the step-therapy or fail-first protocol:

(A) Has been ineffective in the treatment of the enrollee's disease or medical condition;

(B) Is reasonably expected to be ineffective based on the known relevant physical or mental characteristics and medical history of the enrollee and known characteristics of the drug regimen; or

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

(III) The maximum duration of a step-therapy or fail-first

protocol requirement may not be longer than the customary period for the prescribed drug if such treatment is demonstrated by the prescriber to be clinically ineffective. If the plan can demonstrate, through sound clinical evidence, that the originally prescribed drug is likely to require more than the customary period for such drug to provide any relief or amelioration to the enrollee, the step-therapy or fail-first protocol may be extended, but no longer than the original customary period for the drug, after which time the prescriber may deem such treatment as clinically ineffective for the enrollee. Once the prescriber deems the treatment to be clinically ineffective, the plan must dispense and cover the originally prescribed drug recommended by the prescriber.

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

3. Prior authorization.—

a. Each managed care plan must ensure that the prior authorization process for prescribed drugs is readily accessible to health care providers, including posting appropriate contact information on its website and providing timely responses to providers.

b. If a drug, determined to be medically necessary and prescribed for an enrollee by a physician using sound clinical judgment, is subject to prior authorization, the managed care plan must provide payment to the pharmacist for dispensing such drug without seeking prior authorization if the pharmacist

confirms that:

(I) The prescription is a refill or renewal of the same drug for the same enrollee written by the same prescriber; or

(II) If the drug is generally prescribed for an indication that is treated on an ongoing basis by continuous medication or as-needed, the enrollee for whom the drug is prescribed has filled a prescription for the same drug within the preceding 30 to 90 days.

c. If a prescribed drug requires prior authorization, the managed care plan shall reimburse the pharmacist for dispensing a 72-hour supply to the enrollee and process the prior authorization request and send a response to the requesting pharmacist within 24 hours after receiving the pharmacist's request for prior authorization.

d.~~3.~~ Managed care plans, and their fiscal agents or intermediaries, must accept prior authorization requests for any service electronically.

Section 8. Subsection (11) is added to section 429.23, Florida Statutes, to read:

429.23 Internal risk management and quality assurance program; adverse incidents and reporting requirements.—

(11) The agency shall annually submit a report to the Legislature on adverse incident reports by assisted living facilities. The report must include the following information arranged by county:

(a) A total number of adverse incidents;

(b) A listing, by category, of the type of adverse incidents occurring within each category and the type of staff involved;

(c) A listing, by category, of the types of injuries, if any, and the number of injuries occurring within each category;

(d) Types of liability claims filed based on an adverse incident report or reportable injury; and

(e) Disciplinary action taken against staff, categorized by the type of staff involved.

Section 9. Present subsections (9), (10), and (11) of section 429.26, Florida Statutes, are renumbered as subsections (12), (13), and (14), respectively, and new subsections (9), (10), and (11) are added to that section, to read:

429.26 Appropriateness of placements; examinations of residents.—

(9) If, at any time after admission to a facility, agency personnel question whether a resident needs care beyond that which the facility is licensed to provide, the agency may require the resident to be physically examined by a licensed physician, licensed physician assistant, or certified nurse practitioner. To the extent possible, the examination must be performed by the resident's preferred physician, physician assistant, or nurse practitioner and paid for by the resident with personal funds, except as provided in s. 429.18(2). This subsection does not preclude the agency from imposing sanctions for violations of subsection (1).

(a) Following examination, the examining physician, physician assistant, or nurse practitioner shall complete and sign a medical form provided by the agency. The completed medical form must be submitted to the agency within 30 days after the date the facility owner or administrator was notified by the agency that a physical examination is required.

(b) A medical review team designated by the agency shall determine whether the resident is appropriately residing in the facility based on the completed medical form and, if necessary, consultation with the physician, physician assistant, or nurse practitioner who performed the examination. Members of the medical review team making the determination may not include the agency personnel who initially questioned the appropriateness of the resident's placement. The medical review team shall base its decision on a comprehensive review of the resident's physical and functional status. A determination that the resident's placement is not appropriate is final and binding upon the facility and the resident.

(c) A resident who is determined by the medical review team to be inappropriately residing in a facility shall be given 30 days' written notice to relocate by the owner or administrator, unless the resident's continued residence in the facility presents an imminent danger to the health, safety, or welfare of the resident or a substantial probability exists that death or serious physical harm to the resident would result if the resident is allowed to remain in the facility.

(10) If a mental health resident appears to have needs in addition to those identified in the community living support plan, the agency may require an evaluation by a mental health professional, as determined by the Department of Children and Family Services.

(11) A facility may not be required to retain a resident who requires more services or care than the facility is able to provide in accordance with its policies and criteria for admission and continued residency.

Section 10. Effective July 1, 2012, section 456.0635, Florida Statutes, is amended to read:

456.0635 Health care ~~Medicaid~~ fraud; disqualification for license, certificate, or registration.—

(1) Health care ~~Medicaid~~ fraud in the practice of a health care profession is prohibited.

(2) Each board under ~~within~~ the jurisdiction of the department, or the department if there is no board, shall refuse to admit a candidate to an ~~any~~ examination and refuse to issue ~~or renew~~ a license, certificate, or registration to an ~~any~~ applicant if the candidate or applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant~~, has been~~:

(a) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under chapter 409, chapter 817, or chapter 893, or a similar felony offense committed in another state or jurisdiction, unless the candidate or applicant has successfully completed a drug court program for that felony and provides proof that the plea has been withdrawn or the charges have been dismissed. Any such conviction or plea shall exclude the applicant or candidate from licensure, examination, certification, or registration ~~21 U.S.C. ss. 801-970, or 42 U.S.C. ss. 1395-1396,~~ unless the sentence and any subsequent period of probation for such conviction or plea ~~pleas~~ ended: ~~more than 15 years prior to the date of the application;~~

1. For felonies of the first or second degree, more than 15 years before the date of application.

2. For felonies of the third degree, more than 10 years

before the date of application, except for felonies of the third degree under s. 893.13(6)(a).

3. For felonies of the third degree under s. 893.13(6)(a), more than 5 years before the date of application.

(b) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970 or 42 U.S.C. ss. 1395-1396, unless the sentence and any subsequent period of probation for such conviction or plea ended more than 15 years before the date of the application.

(c) ~~(b)~~ Has been terminated for cause from the Florida Medicaid program pursuant to s. 409.913, unless the candidate or applicant has been in good standing with the Florida Medicaid program for the most recent 5 years.~~;~~

(d) ~~(c)~~ Has been terminated for cause, pursuant to the appeals procedures established by the state ~~or Federal Government~~, from any other state Medicaid program ~~or the federal Medicare program~~, unless the candidate or applicant has been in good standing with that ~~a~~ state Medicaid program ~~or the federal Medicare program~~ for the most recent 5 years and the termination occurred at least 20 years before ~~prior to~~ the date of the application.

(e) Is currently listed on the United States Department of Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities.

This subsection does not apply to candidates or applicants for initial licensure or certification who were enrolled in an educational or training program on or before July 1, 2009, which

was recognized by a board or, if there is no board, recognized by the department, and who applied for licensure after July 1, 2012.

(3) The department shall refuse to renew a license, certificate, or registration of any applicant if the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant:

(a) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under chapter 409, chapter 817, or chapter 893, or a similar felony offense committed in another state or jurisdiction, unless the applicant is currently enrolled in a drug court program that allows the withdrawal of the plea for that felony upon successful completion of that program. Any such conviction or plea excludes the applicant or candidate from licensure, examination, certification, or registration unless the sentence and any subsequent period of probation for such conviction or plea ended:

1. For felonies of the first or second degree, more than 15 years before the date of application.

2. For felonies of the third degree, more than 10 years before the date of application, except for felonies of the third degree under s. 893.13(6)(a).

3. For felonies of the third degree under s. 893.13(6)(a), more than 5 years before the date of application.

(b) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970 or 42 U.S.C. ss. 1395-1396 since July 1, 2009, unless the sentence and any subsequent period of probation

for such conviction or plea ended more than 15 years before the date of the application.

(c) Has been terminated for cause from the Florida Medicaid program pursuant to s. 409.913, unless the applicant has been in good standing with the Florida Medicaid program for the most recent 5 years.

(d) Has been terminated for cause, pursuant to the appeals procedures established by the state, from any other state Medicaid program, unless the applicant has been in good standing with that state Medicaid program for the most recent 5 years and the termination occurred at least 20 years before the date of the application.

(e) Is currently listed on the United States Department of Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities.

(4) ~~(3)~~ Licensed health care practitioners shall report allegations of health care ~~Medicaid~~ fraud to the department, regardless of the practice setting in which the alleged health care ~~Medicaid~~ fraud occurred.

(5) ~~(4)~~ The acceptance by a licensing authority of a licensee's ~~candidate's~~ relinquishment of a license which is offered in response to or anticipation of the filing of administrative charges alleging health care ~~Medicaid~~ fraud or similar charges constitutes the permanent revocation of the license.

Section 11. Effective July 1, 2012, present subsections (14) and (15) of section 456.036, Florida Statutes, are renumbered as subsections (15) and (16), respectively, and a new subsection (14) is added to that section, to read:

830922

456.036 Licenses; active and inactive status; delinquency.—

(14) A person who has been denied license renewal, certification, or registration under s. 456.0635(3) may regain licensure, certification, or registration only by meeting the qualifications and completing the application process for initial licensure as defined by the board, or the department if there is no board. However, a person who was denied renewal of licensure, certification, or registration under s. 24 of chapter 2009-223, Laws of Florida, between July 1, 2009, and June 30, 2012, is not required to retake and pass examinations applicable for initial licensure, certification, or registration.

Section 12. Subsection (1) of section 456.074, Florida Statutes, is amended to read:

456.074 Certain health care practitioners; immediate suspension of license.—

(1) The department shall issue an emergency order suspending the license of any person licensed under chapter 458, chapter 459, chapter 460, chapter 461, chapter 462, chapter 463, chapter 464, chapter 465, chapter 466, or chapter 484 who pleads guilty to, is convicted or found guilty of, or who enters a plea of nolo contendere to, regardless of adjudication~~, to~~:

(a) A felony under chapter 409, chapter 817, or chapter 893 or under 21 U.S.C. ss. 801-970 or ~~under~~ 42 U.S.C. ss. 1395-1396; or

(b) A misdemeanor or felony under 18 U.S.C. s. 669, ss. 285-287, s. 371, s. 1001, s. 1035, s. 1341, s. 1343, s. 1347, s. 1349, or s. 1518 or 42 U.S.C. ss. 1320a-7b~~, relating to the Medicaid program~~.

Section 13. Paragraph (a) of subsection (54) of section

830922

499.003, Florida Statutes, is amended to read:

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

(54) "Wholesale distribution" means distribution of prescription drugs to persons other than a consumer or patient, but does not include:

(a) Any of the following activities, which is not a violation of s. 499.005(21) if such activity is conducted in accordance with s. 499.01(2)(g):

1. The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a prescription drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of that organization.

2. The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug by a charitable organization described in s. 501(c)(3) of the Internal Revenue Code of 1986, as amended and revised, to a nonprofit affiliate of the organization to the extent otherwise permitted by law.

3. The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug among hospitals or other health care entities that are under common control. For purposes of this subparagraph, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, by voting rights, by contract, or otherwise.

4. The sale, purchase, trade, or other transfer of a


830922

prescription drug from or for any federal, state, or local government agency or any entity eligible to purchase prescription drugs at public health services prices pursuant to Pub. L. No. 102-585, s. 602 to a contract provider or its subcontractor for eligible patients of the agency or entity under the following conditions:

a. The agency or entity must obtain written authorization for the sale, purchase, trade, or other transfer of a prescription drug under this subparagraph from the State Surgeon General or his or her designee.

b. The contract provider or subcontractor must be authorized by law to administer or dispense prescription drugs.

c. In the case of a subcontractor, the agency or entity must be a party to and execute the subcontract.

~~d. A contract provider or subcontractor must maintain separate and apart from other prescription drug inventory any prescription drugs of the agency or entity in its possession.~~

d.~~e.~~ The contract provider and subcontractor must maintain and produce immediately for inspection all records of movement or transfer of all the prescription drugs belonging to the agency or entity, including, but not limited to, the records of receipt and disposition of prescription drugs. Each contractor and subcontractor dispensing or administering these drugs must maintain and produce records documenting the dispensing or administration. Records that are required to be maintained include, but are not limited to, a perpetual inventory itemizing drugs received and drugs dispensed by prescription number or administered by patient identifier, which must be submitted to the agency or entity quarterly.


830922

e.~~f.~~ The contract provider or subcontractor may administer or dispense the prescription drugs only to the eligible patients of the agency or entity or must return the prescription drugs for or to the agency or entity. The contract provider or subcontractor must require proof from each person seeking to fill a prescription or obtain treatment that the person is an eligible patient of the agency or entity and must, at a minimum, maintain a copy of this proof as part of the records of the contractor or subcontractor required under sub-subparagraph e.

f.~~g.~~ In addition to the departmental inspection authority set forth in s. 499.051, the establishment of the contract provider and subcontractor and all records pertaining to prescription drugs subject to this subparagraph shall be subject to inspection by the agency or entity. All records relating to prescription drugs of a manufacturer under this subparagraph shall be subject to audit by the manufacturer of those drugs, without identifying individual patient information.

Section 14. The Agency for Health Care Administration shall prepare a report within 18 months after the implementation of an expansion of managed care to new populations or the provision of new items and services. The agency shall post a draft of the report on its website and provide an opportunity for public comment. The final report shall be submitted to the Legislature, along with a description of the process for public input. The report must include an assessment of:

(1) The impact of managed care on patient access to care, including an evaluation of any new barriers to the use of services and prescription drugs, created by the use of medical management or cost-containment tools.

(2) The impact of the increased managed care expansion on the utilization of services, quality of care, and patient outcomes.

(3) The use of prior authorization and other utilization management tools, including an assessment of whether these tools pose an undue administrative burden for health care providers or create barriers to needed care.

Section 15. Except as otherwise expressly provided in this act, this act shall take effect upon becoming a law.

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

And the title is amended as follows:

Delete everything before the enacting clause and insert:

A bill to be entitled

An act relating to health care; amending s. 400.474, F.S.; revising the fine that may be imposed against a home health agency for failing to timely submit certain information to the Agency for Health Care Administration; amending s. 400.9905, F.S.; revising the definition of the term "clinic" as it relates to the Health Care Clinic Act; amending s. 409.221, F.S.; revising the background screening requirements for persons rendering care in the consumer-directed care program administered by the Agency for Health Care Administration; amending s. 409.907, F.S.; extending the records-retention period for certain Medicaid provider records; revising the provider agreement to require Medicaid providers to report changes in any

principal of the provider to the agency; defining the term "administrative fines" for purposes of revoking a Medicaid provider agreement due to changes of ownership; authorizing, rather than requiring, an onsite inspection of a Medicaid provider's service location before entering into a provider agreement; specifying the principals of a hospital or nursing home provider for the purposes of submitting fingerprints for background screening; removing certain providers from being subject to agency background checks; amending s. 409.913, F.S.; defining the term "Medicaid provider" or "provider" for purposes of oversight of the integrity of the Medicaid program; authorizing the agency to review and analyze information from sources other than Medicaid-enrolled providers for purposes of determining fraud, abuse, overpayment, or neglect; extending the records-retention period for certain Medicaid provider records; revising the grounds for terminating a provider from the Medicaid program; requiring the agency to base its overpayment audit reports on certain information; deleting a requirement that the agency pay interest on certain withheld Medicaid payments; requiring payment arrangements for overpayments and fines to be made within a certain time; specifying that the venue for all Medicaid program integrity cases lies in Leon County; authorizing the agency and the Medicaid Fraud Control Unit to review certain records; amending s. 409.920,

F.S.; clarifying the applicability of immunity from civil liability extended to persons who provide information about fraud or suspected fraudulent acts by a Medicaid provider; amending s. 409.967, F.S.; specifying required components of a Medicaid managed care plan relating to the provisions of medications; amending s. 429.23, F.S.; requiring the agency to submit a report to the Legislature on adverse incident reports from assisted living facilities; amending s. 429.26, F.S.; authorizing the agency to require a resident of an assisted living facility to undergo a physical examination if the agency questions the appropriateness of the resident's placement in that facility; authorizing release of the results of the examination to a medical review team to be used along with additional information to determine whether the resident's placement in the assisted living facility is appropriate; providing for resident notification and relocation if the resident's continued placement in the facility is not appropriate; authorizing the agency to require the evaluation of a mental health resident by a mental health professional; authorizing an assisted living facility to discharge a resident who requires more services or care than the facility is able to provide; amending s. 456.0635, F.S.; revising the grounds under which the Department of Health or corresponding board is required to refuse to admit a candidate to an examination and refuse to issue or renew a license, certificate, or registration

of a health care practitioner; providing an exception; amending s. 456.036, F.S.; providing that all persons who were denied renewal of licensure, certification, or registration under s. 456.0635(3), F.S., may regain licensure, certification, or registration only by completing the application process for initial licensure; providing an exception; amending s. 456.074, F.S.; revising the federal offenses for which the Department of Health must issue an emergency order suspending the license of certain health care professionals; amending s. 499.003, F.S.; removing a requirement that a contract provider or subcontractor maintain prescription drugs of the agency or entity in its possession separate and apart from other prescription drugs; requiring the Agency for Health Care Administration to prepare a report for public comment and submission to the Legislature following the expansion of services to new populations or of new services; providing effective dates.

THE FLORIDA SENATE

APPEARANCE RECORD

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

2-8-12
Meeting Date

Topic Med Mal

Bill Number 1316

Name Rebecca O'Hara

Amendment Barcode 810774 *(if applicable)*

464150 *(if applicable)*

Job Title VP Govt Affairs

Address 113 E College Ave
Street

Phone 339 6211

Tallahassee FL 32301
City *State* *Zip*

E-mail rohara@flmedical.org

Speaking: ☐ For ☒ Against ☐ Information

Against 2 Amendments

Representing Fla Medical Assn

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.

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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)

2/9/11
Meeting Date

Topic _____ Bill Number ~~810774~~ 1316 *(if applicable)*

Name Chris Nuland Amendment Barcode 810774 *(if applicable)*

Job Title _____

Address 1000 Riverside Ave Phone 904-355-1555
Street

Jax, FL 32204 E-mail NUlandlaw@aol.com
City *State* *Zip*

Speaking: ☐ For ☑ Against ☐ Information

Representing Florida Chapter, American College of Surgeons

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.

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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)

2/9/2012
Meeting Date

Topic Garcia Amendment

Bill Number 1316 *(if applicable)*

Name Stephen Cain

Amendment Barcode 810744 *(if applicable)*

Job Title

Address 1 SE 3rd Ave, Suite 3000
Street

Phone 305-358-6644

Miami, FL 33131
City *State* *Zip*

E-mail scain@stfblaw.com

Speaking: ☒ For ☐ Against ☐ Information

Representing

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.

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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)

2-9-12
Meeting Date

Topic Patient protections in section 8 Bill Number SB 1316 *(if applicable)*

Name Jacklyn J. Burkett, BSW Amendment Barcode *(if applicable)*

Job Title Case Manager

Address 1215 Lee Avenue Suite M4 Phone (850) 222-1777
Street

Tallahassee FL 32303 E-mail eabbcm@embarqmail.com
City *State* *Zip*

Speaking: ☑ For ☐ Against ☐ Information

Representing Epilepsy Association of the Big Bend

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.

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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)

2-9-12
Meeting Date

Topic Patient protections in Section 8

Bill Number SB 1316 *(if applicable)*

Name Dr. John Seay

Amendment Barcode _____ *(if applicable)*

Job Title Secretary

Address 1030 E Lafayette St
Street
Tallahassee FL 32301
City *State* *Zip*

Phone 850-510-5741

E-mail ragstr@embarqmail.com

Speaking: ☑ For ☐ Against ☐ Information

Representing NAMI Florida

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☐ Yes ☑ No

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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)

2-8-12
Meeting Date

Topic Med Mal + Optometry

Bill Number 1316 *(if applicable)*

Name Neal Dunn, M.D.

Amendment Barcode *(if applicable)*

Job Title

Address 80 Doctors Dr. *Street*

Phone 850 785 8557

Panama City FL 32405 *City* *State* *Zip*

E-mail

Speaking: ☒ For ☐ Against ☐ Information

Representing Fla Medical Association

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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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)

2-9-12
Meeting Date

Topic Health Care

Bill Number SB 1316 *(if applicable)*

Name Anne Swerlick

Amendment Barcode *(if applicable)*

Job Title Attorney

Address 2425 Torreya Dr.
Street
Tallahassee, Fl.
City *State* *Zip*

Phone 850-385-7900

E-mail anne@floridalegal.org

Speaking: ☑ For ☐ Against ☐ Information

Representing Florida Legal Services

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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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)

2-9-12
Meeting Date

Topic Health Care Bill Number 1316 *(if applicable)*

Name Steven Grigas Amendment Barcode *(if applicable)*

Job Title Attorney

Address ~~3042~~ 106 East College Ave Phone (850) 224-9634
Street

Ste 1200, Tallahassee, FL 32301 E-mail STEVEN.GRIGAS@AKERMAN.COM
City *State* *Zip*

Speaking: ☐ For ☑ Against ☐ Information

IN PART

Representing FLORIDA BAR, HEALTH LAW EXECUTIVE COUNCIL

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

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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 Med Mal - Ex Parte provision

Bill Number 1316 (if applicable)

Name Dana Brooks

Amendment Barcode The Bill (if applicable)

Job Title Attorney

Address 3360 Capital Circle NE, Ste B (Street)

Tallahassee FL 32308 (City / State / Zip)

Phone 850-224-3310

E-mail dana@tallahasseepersonalinjury.com

Speaking: ☐ For ☑ Against ☐ Information

Representing my firm, Eubanks Barrett Fasig & Brooks & FJA

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☐

Spoke

THE FLORIDA SENATE

APPEARANCE RECORD

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

02.09.12
Meeting Date

Topic Health Care

Bill Number 1316

Name William Large

Amendment Barcode 815246 *(if applicable)*

Job Title President

Address 210 S. Monroe Street
Street
Tallahassee FL 32301
City *State* *Zip*

Phone 850.222.0170

E-mail williame@justice.org

Speaking: ☑ For ☐ Against ☐ Information

Representing Florida Justice Reform Institute

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.

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S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

02.09.12
Meeting Date

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

Topic Health Care

Bill Number 1316 *(if applicable)*

Name William Large

Amendment Barcode 810774 *(if applicable)*

Job Title President

Address 210 S. Monroe Street
Street
Tallahassee FL 32301
City *State* *Zip*

Phone 850.222.0170

E-mail William@fljustice.org

Speaking: ☒ For ☐ Against ☐ Information

Representing Florida Justice Reform Institute

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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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)

Feb 9 2012
Meeting Date

Topic Healthcare

Bill Number 1316 *(if applicable)*

Name Dr. Scott Hopes

Amendment Barcode 815246 *(if applicable)*

Job Title CEO

Address 13955 SW 127th St
Street

Phone 305-776-0049

Miami FL 33186
City *State* *Zip*

E-mail scott.hopes@hmd-healthcare.com

Speaking: ☑ For ☐ Against ☐ Information

Representing Florida Optometric Association

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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S-001 (10/20/11)

Spoke

THE FLORIDA SENATE

APPEARANCE RECORD

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

02.09.12
Meeting Date

Topic Health Regulation

Bill Number 1316 *(if applicable)*

Name William Large

Amendment Barcode 291568 *(if applicable)*

Job Title President

Address 210 South Monroe Street
Street
Tallahassee, FL 32301
City *State* *Zip*

Phone 850-222-0170

E-mail William@fljustice.org

Speaking: ☐ For ☑ Against ☐ Information

Representing Florida Justice Reform Institute

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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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)

2/9/12
Meeting Date

Topic HEALTH CARE

Bill Number 1316 *(if applicable)*

Name DR. KEN LAWSON

Amendment Barcode 815246 *(if applicable)*

Job Title LEGISLATIVE CHAIRMAN

Address 120 S. MONROE ST
Street

TALLAHASSEE, FL 32301
City *State* *Zip*

Phone 850-727 7087

E-mail

Speaking: ☑ For ☐ Against ☐ Information

Representing FLORIDA OPTOMETRIC ASSOCIATION

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☐ Yes ☑ No

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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)

Spoke

02/09/12
Meeting Date

Topic Health Care

Bill Number Section 8 of strike all for SB 1316 *(if applicable)*

Name Michael W. Garner, Ph.D.

Amendment Barcode 815246 *(if applicable)*

Job Title President & CEO

Address 200 W. College Ave., Suite 104
Street

Phone (850) 386-2904

Tallahassee FL 32301
City *State* *Zip*

E-mail michael@fahp.net

Speaking: ☐ For ☑ Against ☐ Information

Representing Florida Association of Health Plans

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

Spoke

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

Meeting Date

Topic _____ Bill Number 1316 *(if applicable)*

Name Charles Slonim MD Amendment Barcode 815246 *(if applicable)*

Job Title ophthalmologist

Address 10770 N. 46th St. Phone 8139742064

Street

Tampa, FL 33617 E-mail cslonim@health.usf.edu

City *State* *Zip*

Speaking: ☐ For ☒ Against ☐ Information

Representing FL Society of Ophthalmology & Amer. Academy of Ophthalmology

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.

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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)

2/8/2012
Meeting Date

Topic _____ Bill Number 1316

Name Mark Delegal *(if applicable)*

Amendment Barcode 291568 *(if applicable)*

Job Title Retained Counsel

Address 215 S. Monroe St. #200 Phone 850-222-3533
Street

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

Speaking: ☐ For ☑ Against ☐ Information

Representing Safety Net Hospital Alliance

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

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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)

2-9-12
Meeting Date

Topic Patient protections in section 8 Bill Number SB 1316 *(if applicable)*

Name Velma Penermon Stevens, MSW Amendment Barcode *(if applicable)*

Job Title Executive Director

Address 1336 Vickers Road Phone 850-212-3796
Street

Tallahassee FL 32303 E-mail velma@sicklecellfoundation.org
City *State* *Zip*

Speaking: ☑ For ☐ Against ☐ Information

Representing Sickle Cell Foundation of the Big Bend

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.

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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)

2/9/12
Meeting Date

Topic _____ Bill Number 1316 *(if applicable)*

Name Jim Gustafson Amendment Barcode 810744 *(if applicable)*

Job Title _____

Address 517 N. Calhoun St. Phone 850-251-4011
Street

Tallahassee FL 32301 E-mail jawgustafson@gmail.com
City *State* *Zip*

Speaking: ☒ For ☐ Against ☐ Information

Amendment

Representing _____

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.

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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)

2/9/12
Meeting Date

Topic Senator DCP Amendment / Arbitration

Bill Number 1316 *(if applicable)*

Name Debra Henley

Amendment Barcode 291568 *(if applicable)*

Job Title Executive Director

Address 218. S. Monroe St.
Street
Tallahassee, FL 32301
City *State* *Zip*

Phone 224-9403

E-mail DHenley@FloridaJustice Association.org

Speaking: [X] For [ ] Against [ ] Information

Representing Florida Justice Association

Appearing at request of Chair: [ ] Yes [X] No

Lobbyist registered with Legislature: [X] 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.

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S-001 (10/20/11)

Spoke

THE FLORIDA SENATE

APPEARANCE RECORD

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

2/9/12
Meeting Date

Topic _____ Bill Number SB 1316

Name Jeff Scott Amendment Barcode 291568 *(if applicable)*

Job Title _____

Address 113 E. College Ave. Phone 224-6496
Street

Tallahassee FL 32309 E-mail jscott@medmac.org
City *State* *Zip*

Speaking: ☐ For ☑ Against (Amendment) ☐ Information

Representing Florida Medical 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.

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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)

2/9/12
Meeting Date

Topic Senate DLP Amendment to Substitute Amnt Arbitration

Bill Number 1316 *(if applicable)*

Name Debra Henley

Amendment Barcode 464150 *(if applicable)*

Job Title Executive Director

Address 218 S. Monroe St
Street
Tallahassee, FL 32301
City *State* *Zip*

Phone 224-9403

E-mail DHenley@FloridaJusticeAssociation.org

Speaking: ☒ For ☐ Against ☐ Information

Representing Florida Justice 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.

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S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

Spoke

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

2/9/12
Meeting Date

Topic Medical Malpractice

Bill Number 1310 / 1506 (291568) *(if applicable)*

Name ALEXANDER CLEM

Amendment Barcode 784708 *(if applicable)*

Job Title Attorney

Address 20 North Orange Ave. *Street*

Phone 407-420-1414

Orlando FL 32801 *City State Zip*

E-mail a clem@forthepeople.com

Amendment

Speaking: ☑ For ☐ Against ☐ Information

Representing FJA

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☐ Yes ☑ No

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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)

2/9/12
Meeting Date

Topic Lipesuction

Bill Number 1316

Name Chris Nuland

Amendment Barcode 702404 *(if applicable)*

Job Title

Address 1000 Riverside Ave #115
Street
Jacksonville, FL 32204
City *State* *Zip*

Phone 904-355-1555

E-mail nulandlaw@aol.com

Speaking: ☑ For ☐ Against ☐ Information

Representing Florida Society of Plastic Surgeons

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)

POSITION STATEMENT

The Executive Council of the Health Law Section of The Florida Bar is committed to working with our legislators and the Governor to insure the continued viability and integrity of the State's health care system and the many professionals that serve within it.

The Executive Council is concerned, however, with the restrictions that SB 1316 places upon the licensure status of certain health care providers practicing in the State. Specifically, we believe that the expanded mandate to mandatorily revoke or otherwise refuse to renew the licenses of practitioners on the basis of certain categories of crimes or the decisions of the Centers for Medicare and Medicaid Services in Washington, D.C. in matters unrelated to licensure does not serve the best interests of the State. By removing the discretion of each licensing authority to review the facts and circumstances of a situation and determine how best to discipline the license, the legislature is removing the right of a licensed health care professional to work in Florida, and perhaps nationwide, without regard for the particulars of each situation.

The proposed bill penalizes individuals who have never been adjudicated guilty by treating persons who entered a no contest plea the same as those who have been convicted. The bill then denies individuals a hearing and the opportunity to explain the factors that influenced their decision to enter the no contest plea. Consequently, many people will not understand the ramification of not contesting certain arrests or decisions by CMS and have no recourse once they grasp that the plea ended their professional career.

The Council contends that the proposed bill likely will have a disproportionate impact on those licensees who were unfamiliar with the impact of certain pleas on their ability to earn a living in Florida (including those practicing in other states who may relocate here) or those who do not have the financial ability to contest criminal charges. As the legislature has seen, the earlier version of this law has affected primarily nurses and nurses aides who cannot escape for decades the ramifications of an earlier poor decision or an economic decision to file a no contest plea. Additionally, the legislature may not be aware that the loss of a professional license in one state generally leads to the revocation of all similar licenses in other state. Thus, the bill creates the situation where those who cannot afford to hire knowledgeable criminal counsel will have unknowingly terminated their

ability to practice their profession in Florida and elsewhere.

The proposed addition of Medicare exclusion to the grounds for automatic license revocation is also troubling because the bill does not differentiate between mandatory and permissive exclusions. While we understand the legislature's concern about licensing those mandatorily excluded from Medicare for certain crimes, the permissive reasons for exclusion are much broader and include failing to supply information timely, or failure to grant timely access to a facility. These infractions may not merit professional licensure revocation. Therefore, we question their inclusion in the bill.

In summary, the proposed bill eliminates the ability of the licensing authority (agency head or professional board) to impose a penalty appropriate to the circumstances and results in a professional "death sentence" to the licensee who will not be able to qualify for re-licensure after such a lengthy period away from professional practice. We believe the ability to determine which licenses should be revoked is best left with the licensing authorities.

As such, the Health Law Section Executive Council respectfully opposes the bill before you today.

Steven A. Grigas

Akerman

Akerman Senterfitt
106 East College Avenue
12th Floor
Tallahassee, FL 32301

Tel: 850.224.9634
Fax: 850.222.0103
steven.grigas@akerman.com

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 Health Regulation Committee

BILL: CS/SB 1506

INTRODUCER: Health Regulation Committee and Senator Thrasher

SUBJECT: Health Care

DATE: February 10, 2012 REVISED: _____ _____ _____ _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Wilson	Stovall	HR	**Fav/CS**
2.			JU	
3.			BC	
4.				
5.				
6.				

Please see Section VIII. for Additional Information:

A. COMMITTEE SUBSTITUTE.....	X	Statement of Substantial Changes
B. AMENDMENTS.....		Technical amendments were recommended
		Amendments were recommended
		Significant amendments were recommended

I. Summary:

The bill authorizes certified optometrists to administer and prescribe oral, in addition to topical, ocular medications related to the diagnosis and treatment of ocular conditions. Certified optometrists are authorized to prescribe controlled substances other than Schedule I or II substances, if they hold a valid federal controlled substance registry number. Before a certified optometrist may administer or prescribe oral ocular medications, he or she must complete a course and subsequent examination on general and ocular pharmacology.

The bill alters the composition of the committee that maintains the formulary of topical drugs certified optometrists are permitted to prescribe to specify that the two optometrists on the committee must be certified optometrists. The bill creates a statutory formulary of oral ocular medications that certified optometrists may prescribe. The standards of practice of optometry are amended to include requirements related to the administration and prescription of oral ocular medications, co-management of post-operative care, and referral of patients to physicians in certain situations. The bill also requires optometrists to report adverse incidents to the Department of Health.

With respect to clinical laboratories, the bill includes optometrists in the list of licensed practitioners who are permitted to operate such laboratories, adds optometrists to the definition of licensed practitioner, and requires laboratories to accept specimens for examination from optometrists.

The bill changes the burden of proof for a claimant in an action alleging a breach of the prevailing professional standard of care in an action for damages based on death or personal injury that allegedly resulted from the failure of a health care provider to order, perform, or administer supplemental diagnostic tests. The burden of proof is increased from a greater weight of the evidence to clear and convincing evidence.

The bill also authorizes a prospective defendant, or his or her legal representative, to conduct ex parte interviews of the claimant's treating health care providers without the presence of the claimant or the claimant's legal representative. Notice of any intended interviews must be provided to the claimant at least 10 days before the date of the interview.

The bill authorizes certain health care providers and a patient or prospective patient to agree in writing to submit to arbitration any claim for medical negligence that may currently exist or that may accrue in the future that would otherwise be brought under ch. 766, F.S., relating to medical malpractice. An arbitration agreement entered into under this section would be governed by the Florida Arbitration Code. Such an arbitration agreement may contain a provision that would limit the available damages in any arbitration award.

This bill substantially amends the following sections of the Florida Statutes: 463.002, 463.005, 463.0055, 463.0057, 463.006, 463.0135, 463.014, 483.035, 483.041, 483.181, 766.102, 766.106, 893.02, and 893.05. The bill creates ss. 463.0141 and 766.1091, F.S.

II. Present Situation:

Optometrists and Ophthalmologists

Optometrists are the primary health care professionals for the eye. Optometrists examine, diagnose, treat, and manage diseases and injuries of the visual system as well as identify systemic conditions that affect visual health. Optometrists may prescribe certain medications, vision therapy, and corrective lenses but may not perform surgical procedures in Florida.[1]

Optometrist training involves an undergraduate degree and completion of a 4-year program at a college of optometry. Some optometrists complete residencies to gain more specialized knowledge, but residency training is not required for licensure or practice.[2]

Ophthalmologists are medical physicians who specialize in diseases of the eye. Ophthalmologists provide a full spectrum of eye care, from prescribing corrective lenses and other medications to performing eye surgery. Ophthalmologists also care for patients with more advanced and complicated diseases than do optometrists. Ophthalmologist training involves an undergraduate

[1] s. 463.014(4), F.S.
[2] American Optometric Association, *What is a Doctor of Optometry?* Found at: <http://www.aoa.org/x4891.xml> (Last visited on February 10, 2102).

degree, 4 years of medical school, and completion of at least 4 years of residency training in ophthalmology.[3]

Florida law requires optometrists who diagnose patients with certain diseases to refer such patients to ophthalmologists for further treatment.[4] Optometrists are also required to maintain the names of at least three physicians, clinics, or hospitals to which they may refer patients who experience adverse drug reactions.[5]

Administration of Medications by Optometrists

Licensed optometrists may administer and prescribe topical ocular pharmaceutical agents if they are appropriately certified by the Board of Optometry (the board). Such pharmaceuticals must be related to the diagnosis and treatment of ocular conditions and must not require surgery or other invasive techniques for administration. Medications approved for prescription by certified optometrists are listed in a formulary maintained by the board.[6,7]

To be certified for prescribing privileges, an optometrist must:[8]

- Complete at least 100 hours of board-approved coursework and clinical training in general and ocular pharmacology at an accredited institution. Such training may have been part of an optometry training program;
- Complete at least 1 year of supervised experience in differential diagnosis of eye disorders, which may occur during training or clinical practice;
- Pass part II of the National Board of Examiners in Optometry examination;[9] and
- Pay a $500 fee.[10]

Certification for prescribing privileges is a required component of the general licensure process for optometrists and has been so for the last 25 years.[11,12] Optometrists who are not certified may use topical anesthetics for glaucoma examinations.[13]

[3] American Academy of Ophthalmology, *About Ophthalmology and Eye M.D.s.* Found at: <http://www.aao.org/about/eyemds.cfm> (Last visited on February 10, 2012).
[4] Diagnoses which mandate a referral to an ophthalmologist include acute angle glaucoma, congenital or infantile glaucoma, infectious corneal diseases refractory to standard treatment, and retinal detachment.
[5] s. 463.0135, F.S.
[6] s. 463.0055, F.S.
[7] The formulary is listed in Rule 64B13-18.002, F.A.C., and includes agents to dilate and constrict pupils, local anesthetics, antibiotics, anti-inflammatory agents, antihistamines, antivirals, and anti-glaucoma medications. All medications are for topical ocular use only.
[8] Rule 64B13-10.001, F.A.C.
[9] This examination consists of 60 simulated patient cases to assess the examinee's performance in clinical practice situations. Found at: <http://www.optometry.org/part_2_pam.cfm> (Last visited on February 10, 2012).
[10] Rule 64B13-6.001(9), F.A.C.
[11] s. 463.006, F.S.
[12] Department of Health, *2012 Bill Analysis, Economic Statement, and Fiscal Note for SB 788.* A copy is on file with the Senate Health Regulation Committee.
[13] s. 463.0055(1), F.S.

Prescribing Controlled Substances

The Drug Enforcement Administration (DEA) within the U.S. Department of Justice is tasked with monitoring controlled substances and preventing their abuse. Controlled substances fall into five categories, or schedules, depending on their addictive potential. Drug schedules are specified by the United States Department of Justice Drug Enforcement Administration in 21 C.F.R. ss. 1308.11-15 and in s. 893.03, F.S.

Schedule I controlled substances currently have no accepted medical use in treatment in the United States and therefore may not be prescribed, administered, or dispensed for medical use. These substances have a high potential for abuse and include heroin, lysergic acid diethylamide (LSD), and marijuana. Schedule II controlled substances have a high potential for abuse which may lead to severe psychological or physical dependence, including morphine and its derivatives, amphetamines, cocaine, and pentobarbital. Schedule III controlled substances have lower abuse potential than Schedule II substances but may still cause psychological or physical dependence. Schedule III substances include products containing less than 15 milligrams (mg) of hydrocodone (such as Vicodin) or less than 90 mg of codeine per dose (such as Tylenol #3), ketamine, and anabolic steroids. Schedule IV substances have a low potential for abuse and include propoxyphene (Darvocet), alprazolam (Xanax), and lorazepam (Ativan). Schedule V controlled substances have an extremely low potential for abuse and primarily consist of preparations containing limited quantities of certain narcotics, such as cough syrup.[14]

Any health care professional wishing to prescribe controlled substances must apply for a prescribing number from the DEA. Prescribing numbers are linked to state licenses and may be suspended or revoked upon any disciplinary action taken against a licensee. The DEA will grant prescribing numbers to a wide range of health care professionals, including physicians, nurse practitioners, physician assistants, optometrists, dentists, and veterinarians, but such professionals may only prescribe controlled substances that have been authorized to them under state law. Prescribing numbers must be renewed every 3 years.[15]

In Florida, only licensed physicians, dentists, veterinarians, naturopaths, and podiatrists are currently permitted to prescribe controlled substances, and they may only prescribe medications within the scope of their own practices.[16]

Clinical Laboratories

A clinical laboratory is a location in which body fluids or tissues are analyzed for purposes of the diagnosis, assessment, or prevention of a medical condition. Clinical laboratories may be free-standing facilities, may be part of a hospital, or may be part of a private practitioner's office.[17] Practitioners authorized to operate their own clinical laboratories exclusively to diagnose and treat their own patients are physicians, chiropractors, podiatrists, naturopaths, and dentists.

[14] DEA, Office of Diversion Control, *Controlled Substance Schedules.* Found at: <http://www.deadiversion.usdoj.gov/schedules/#define> (Last visited on February 10, 2012).
[15] DEA, *Questions and Answers.* Found at: <http://www.deadiversion.usdoj.gov/drugreg/faq.htm> (Last visited on February 10, 2012).
[16] ss. 893.02 and 893.05, F.S.
[17] s. 483.041, F.S.

Laboratories must be biennially licensed and inspected by the Agency for Health Care Administration to ensure quality standards in examination of specimens, equipment, sanitation, staffing, and other measures.[18]

A clinical laboratory may examine human specimens at the request of the following licensed practitioners:[19]

- Physicians
- Physician assistants
- Medical assistants
- Chiropractors
- Chiropractic assistants
- Chiropractic physician's assistants
- Podiatrists
- Naturopaths
- Dentists
- Nurse practitioners

Results of laboratory tests must be reported directly to the requesting practitioner. The same price must be charged regardless of what type of practitioner requests the testing.

Standard of Proof in Medical Malpractice Actions

In any action for recovery of damages based on the death or personal injury of any person in which it is alleged that the death or injury resulted from the negligence of a health care provider, the claimant has the burden of proving by the greater weight of evidence that the alleged action of the health care provider represented a breach of the prevailing professional standard of care for that health care provider. The prevailing professional standard of care is that level of care, skill, and treatment which, in light of all relevant surrounding circumstances, is recognized as acceptable and appropriate by reasonably prudent similar health care providers.[20] Nevertheless, s. 766.102(4), F.S., provides that the "failure of a health care provider to order, perform, or administer supplemental diagnostic tests shall not be actionable if the health care provider acted in good faith and with due regard for the prevailing professional standard of care."

Greater weight of the evidence means the "more persuasive and convincing force and effect of the entire evidence in the case."[21] Other statutes, such as license disciplinary statutes involving the revocation or suspension of a license, require a heightened standard of proof called "clear and convincing evidence."[22] Clear and convincing evidence has been described as follows:

> [C]lear and convincing evidence requires that the evidence must be found to be credible; the facts to which the witnesses testify must be distinctly remembered; the testimony must be precise and explicit and the witnesses must be lacking in confusion as to the facts in issue. The evidence must be of such weight that it produces in the mind of the trier of fact a firm belief or conviction, without hesitancy, as to the truth of the allegations sought to be established.[23]

[18] s. 483.051, F.S.
[19] s. 483.181, F.S.
[20] s. 766.102, F.S.
[21] *Castillo v. E.I. Du Pont De Nemours & Co., Inc.*, 854 So. 2d 1264, 1277 (Fla. 2003).
[22] *See e.g.*, ss. 458.331(3), and 459.015(3), F.S.

Medical Malpractice Presuit Investigation

Prior to the filing of a lawsuit, the person allegedly injured by medical negligence or a party bringing a wrongful death action arising from an alleged incidence of medical malpractice (the claimant) and the defendant (the health care professional or health care facility) are required to conduct presuit investigations to determine whether medical negligence occurred and what damages, if any, are appropriate.

The claimant is required to conduct an investigation[24] to ascertain that there are reasonable grounds to believe that:

- A named defendant in the litigation was negligent in the care or treatment of the claimant; and
- That negligence resulted in injury to the claimant.

After completion of the presuit investigation and prior to filing a complaint for medical negligence, a claimant shall notify each prospective defendant of intent to initiate litigation for medical negligence.[25] Notice to each prospective defendant must include, if available, a list of all known health care providers seen by the claimant for the injuries complained of subsequent to the alleged act of negligence, all known health care providers during the 2-year period prior to the alleged act of negligence who treated or evaluated the claimant, copies of all of the medical records relied upon by the expert in signing the affidavit, and an executed authorization for release of protected health information. The presuit notice is void if this authorization does not accompany the presuit notice.[26]

A suit may not be filed for a period of 90 days after notice is mailed to any prospective defendant. The statue of limitations is tolled during the 90-day period. During the 90-day period, the prospective defendant or the defendant's insurer or self-insurer shall conduct a presuit investigation to determine the liability of the defendant.

Before the defendant issues his or her response, the defendant or his or her insurer or self-insurer is required to ascertain whether there are reasonable grounds to believe that:

- The defendant was negligent in the care or treatment of the claimant; and
- That negligence resulted in injury to the claimant.

Corroboration of the lack of reasonable grounds for medical negligence litigation must be provided by submission of a verified written medical expert opinion which corroborates

[23] *Inquiry Concerning Davey*, 645 So. 2d 398, 404 (Fla. 1994)(quoting *Slomowitz v. Walker*, 429 So. 2d 797, 800 (Fla. 4th DCA 1983).
[24] s. 766.203, F.S.
[25] s. 766.106, F.S.
[26] s. 766.1065(1), F.S. If the authorization is revoked, the presuit notice is deemed retroactively void from the date of issuance, and any tolling effect that the presuit notice may have had on any applicable statute-of-limitations period is retroactively rendered void.

reasonable grounds for lack of negligent injury sufficient to support the response denying negligent injury.

At or before the end of the 90 days, the prospective defendant or the prospective defendant's insurer or self-insurer shall provide the claimant with a response:

- Rejecting the claim;
- Making a settlement offer; or
- Making an offer to arbitrate in which liability is deemed admitted and arbitration will be held only on the issue of damages. This offer may be made contingent upon a limit of general damages.

Failure of the prospective defendant or insurer or self-insurer to reply to the notice within 90 days after receipt is deemed a final rejection of the claim for purposes of this provision.

Discovery and Admissibility of Evidence

Statements, discussions, written documents, reports, or other work product generated by the presuit screening process are not discoverable or admissible in any civil action for any purpose by the opposing party.[27] All participants, including, but not limited to, physicians, investigators, witnesses, and employees or associates of the defendant, are immune from civil liability arising from participation in the presuit screening process.[28]

Upon receipt by a prospective defendant of a notice of claim, the parties are required to make discoverable information available without undertaking formal discovery. Informal discovery may be used to obtain unsworn statements, the production of documents or things, and physical and mental examinations as follows:[29]

- Unsworn statements – Any party may require other parties to appear for the taking of an unsworn statement. Unsworn statements may be used only for the purpose of presuit screening and are not discoverable or admissible in any civil action for any purpose by any party.
- Documents or things – Any party may request discovery of documents or things. This includes medical records.
- Physical and mental examination – A prospective defendant may require an injured claimant to be examined by an appropriate health care provider. Unless otherwise impractical, a claimant is required to submit to only one examination of behalf of all potential defendants. The examination report is available to the parties and their attorney and may be used only for the purpose of presuit screening. Otherwise the examination is confidential.
- Written questions – Any party may request answers to written questions.
- Unsworn statements of treating health care providers – The statements must be limited to those areas that are potentially relevant to the claim. Reasonable notice and an opportunity to be heard must be given to the claimant before taking unsworn statements. The claimant, or claimant's legal representative, has the right to attend the taking of these unsworn statements.

[27] However, the presuit expert witness opinions are subject to discovery under s. 766.203(4), F.S.
[28] s. 766.106(5), F.S.
[29] s. 766.106(6), F.S.

The failure to cooperate on the part of any party during the presuit investigation may be grounds to strike any claim made, or defense raised in the suit.[30]

Arbitration Generally

For many years, courts and legislatures have utilized arbitration as an alternative method to resolve disputes between parties in an expedient, efficient, and inexpensive manner.[31] However, when parties agree to participate in arbitration, they concede some of the safeguards that are traditionally afforded to those who proceed to court, one of which is the right to have the evidence weighed in accordance with established legal principles.[32] Arbitration may be defined as "a process that allows parties voluntarily to refer their disputes to an impartial third person, an arbitrator, selected by them to determine the parties' rights and liabilities."[33] Typically, a decision rendered by arbitrators is as binding and conclusive as the judgment of a court.[34] Because of the federal policy favoring and encouraging the use of arbitration to resolve disputes, the use of pre-dispute arbitration agreements has expanded beyond use in commercial contexts between large businesses and those with equal bargaining power, to use in many noncommercial consumer contracts.[35]

Florida Arbitration Code

Florida traditionally has favored arbitration. In 1957, the Legislature enacted the Florida Arbitration Code (FAC),[36] which prescribes a framework governing the rights and procedures under arbitration agreements, including the enforceability of arbitration agreements. The FAC governs arbitration clauses where interstate commerce is not implicated.[37] The FAC governs the arbitration process in its entirety, including, but not limited to the scope and enforceability of arbitration agreements, the appointment of arbitrators, the arbitration hearing process and procedure, the entry and enforcement of arbitration awards, and appeals.

Under the FAC, Florida courts have held that the determination of whether any dispute is subject to arbitration should be resolved in favor of arbitration.[38] A court's role in deciding whether to compel arbitration is limited to three gateway issues to determine the enforceability of an arbitration agreement: (1) whether a valid written agreement to arbitrate exists; (2) whether an arbitrable issue exists; and (3) whether the right to arbitration has been waived.[39] The FAC applies in arbitration cases only to the extent that it is not in conflict with federal law.[40]

[30] s. 766.106(7), F.S.
[31] Elizabeth K. Stanley, *Parties' Defenses to Binding Arbitration Agreements in the Health Care Field & the Operation of the McCarran-Ferguson Act*, 38 ST. MARY'S L.J. 591, 591-92 (2007).
[32] *Affiliated Marketing, Inc. v. Dyco Chemicals & Coatings, Inc*., 340 So. 2d 1240 (Fla. 2d DCA 1976).
[33] Stanley, *supra* note 33, at 592 (internal citations omitted).
[34] *Capital Factors, Inc. v. Alba Rent-A-Car, Inc*., 965 So. 2d 1178, 1182 (Fla. 4th DCA 2007).
[35] Stanley, *supra* note 33, at 592.
[36] *See* ch. 682. F.S.
[37] *O'Keefe Architects, Inc. v. CED Construction Partners, Ltd.*, 944 So. 2d 181, 184 (Fla. 2006).
[38] Michael Cavendish, *The Concept of Arbitrability Under the Florida Arbitration Code*, 82 FLA. B.J. 18, 19 (Nov. 2008) (citing *O'Keefe Architects, Inc. v. CED Construction Partners, Ltd.*, 944 So. 2d 181, 184 (Fla. 2006)).
[39] *Seifert v. U.S. Home Corp*., 750 So. 2d 633, 636 (Fla. 1999).
[40] *Powertel, Inc. v. Bexley*, 743 So. 2d 570, 573 (Fla. 1st DCA 1999), *review denied*, 763 So. 2d 1044 (Fla. 2000), and *Florida Power Corp. v. Casselberry*, 793 So. 2d 1174, 1179 (Fla. 5th DCA 2001).

Voluntary Binding Arbitration

Section 766.207, F.S., related to medical malpractice, establishes a procedure for voluntary binding arbitration of damages upon the completion of presuit investigation with preliminary reasonable grounds for a medical negligence claim. A proceeding for voluntary binding arbitration is an alternative to jury trial and does not supersede the right of any party to a jury trial.41 Either party may initiate the election for voluntary binding arbitration of damages. A claimant's offer to arbitrate must be made to each defendant and each defendant's offer to arbitrate must be made to each claimant.[42] The arbitration panel's decision is subject to the limitations on damages that are provided in s. 766.207, F.S.

If the defendant refuses a claimant's offer of voluntary binding arbitration and the claimant proves medical negligence, the claimant is entitled to recover damages subject to the limitations in s. 766.118, F.S., prejudgment interest, and reasonable attorney's fees up to 25 percent of the award reduced to present value. If a claimant rejects a defendant's offer of voluntary binding arbitration, the damages awardable at trial are limited to net economic damages, plus noneconomic damages not to exceed $350,000 per incident.[43]

Arbitration Agreements in Contracts for Medical Services

Insurance companies and physicians are more frequently requiring patients to enter into arbitration agreements regarding any potential medical malpractice claims resulting from the medical treatment or care.[44] Therefore, some patients may face a choice when seeking medical treatment or care: sign an arbitration agreement or forego treatment with a particular physician or other health care provider.[45] These arbitration agreements may apply to all medical negligence and professional malpractice claims arising out of the physician-patient relationship, and bind the patient, as well as the spouse and heirs of the patient.[46]

Some patients have challenged the enforceability of arbitration agreements in this context by asserting that the agreements are void as against public policy, are too broad, are essentially contracts of adhesion, and are unconscionable.[47] Generally, courts will closely scrutinize physician-patient arbitration agreements under general contract principles to determine if the

[41] s. 766.209, F.S.
[42] s. 766.207(7)(k), F.S.
[43] s. 766.209, F.S.
[44] Jennifer Gillespie, *Physician-Patient Arbitration Agreements: Procedural Safeguards May Not Be Enough*, 1997 J. DISP. RESOL. 119, 119 (1997).
[45] *Id.*
[46] *Id*. at 120.
[47] *See Buraczynski v. Eyring*, 919 S.W.2d 314 (Tenn. 1996). In *Buraczynski*, a patient signed an arbitration agreement in the context of medical services prior to a knee-replacement operation. The agreement covered all medical negligence and malpractice claims arising out of the surgery, and provided that the patient would have 30 days to revoke the agreement by providing written notice to the physician. After a challenge by the patient's heirs to avoid participation in arbitration, the Tennessee Supreme Court found that the agreement was consistent with public policy, was not overly broad, and was an enforceable adhesion contract because it was supported by consideration and was not oppressive or unconscionable. *Id.* at 321.

agreements are unenforceable contracts of adhesion.[48] In *Jonathan M. Frantz, M.D., P.A. v. Shedden*, a Florida eye patient brought a medical malpractice action against an eye clinic after complication arose from elective eye surgery.[49] The eye clinic moved to stay litigation and enforce arbitration. During a preoperative visit, the plaintiff had signed an arbitration agreement that was separate from other documents, was afforded the opportunity to review the agreement, and was advised that he could ask staff questions regarding the agreement. The court concluded that, because the agreement was neither procedurally nor substantively unconscionable, the litigation should be stayed in favor of arbitration.[50]

Medical Malpractice Insurance & Claims

The Office of Insurance Regulation (OIR) publishes a report annually on medical malpractice insurance and claims.[51] According to the most recent report of 2010 data that was published on October 1, 2011:

- In 2010, the Florida medical malpractice insurance companies reported 2,520 closed claims in Florida. This continues the annual decline in the number of closed claims reported by Florida medical malpractice insurance companies. For 2009, 2087 closed claims were reported, for 2008, 3,336 were reported, for 2007, 3,553 were reported, and for 2006, 3,811 closed claims were reported. [52]
- As in previous reports, the most commonly reported claims location was hospital inpatient facilities with 1,204 claims closed. The emergency room ranked third in the injury location with 318 closed claims (see page 44).

III. Effect of Proposed Changes:

Section 1 amends s. 463.002, F.S., to allow certified optometrists to administer and prescribe oral medications related to the diagnosis and treatment of ocular conditions, not just those which are topically applied to the eye.

Section 2 amends s. 463.005, F.S., to allow the Board of Optometry to promulgate rules related to administration of all ocular pharmaceutical agents, not only topical agents.

Section 3 amends s. 463.0055, F.S., to require a certified optometrist, before he or she prescribes oral pharmaceutical agents, to complete a course and subsequent examination on general and ocular pharmacology with particular emphasis on the ingestion and side effects of oral

[48] *See Broemmer v. Abortion Services of Phoenix Ltd.*, 840 P.2d 1013 (Ariz. 1992); *Leong by Leong v. Kaiser Foundation Hosp.*, 788 P.2d 164 (Haw. 1990); and *Obstetrics and Gynecologists William G. Wixted, M.D., Patrick M. Flanagan, M.D., William F. Robinson, M.D. Ltd. v. Pepper*, 693 P.2d 1259 (Nev. 1985).
[49] *Jonathan M. Frantz, M.D., P.A. v. Shedden*, 974 So. 2d 1193 (Fla. 2d DCA 2008).
[50] *Id*. at 1198.
[51] Florida OIR 2011 Annual Report – October 1, 2011 *Medical Malpractice Financial Information Closed Claim Database and Rate Filings*, available at: <http://www.floir.com/siteDocuments/MedicalMalReport10012011.pdf > (Last visited on February 8, 2012).
[52] Florida OIR 2010 Annual Report – October 1, 2010 *Medical Malpractice Financial Information Closed Claim Database and Rate Filings*, available at: < http://www.floir.com/siteDocuments/MedicalMalReport10012010.pdf> (Last visited on February 10, 2012). *See also* Senate Bill *Analysis and Fiscal Impact Statement for SB 1474* (2010), available at: <http://archive.flsenate.gov/session/index.cfm?BI_Mode=ViewBillInfo&Mode=Bills&ElementID=JumpToBox&SubMenu=1&Year=2010&billnum=1474> (Last visited on February 10, 2012).

pharmaceuticals. The bill provides specifics concerning the format of the courses and examinations and requires the Florida Medical Association and the Florida Optometric Association to jointly develop and administer the course and examination.

The bill also alters the composition of the committee that maintains the formulary of topical drugs such optometrists are permitted to prescribe to specify that the two optometrists on the committee must be certified optometrists. The bill specifies that the formulary of topical ocular pharmaceutical agents will consist of those topical agents that are appropriate to treat and diagnose ocular diseases and disorders. The bill also establishes a statutory formulary of oral pharmaceutical agents that certified optometrists are permitted to prescribe.

Section 4 amends s. 463.0057, F.S., to prohibit holders of faculty certificates from prescribing ocular pharmaceutical agents unless they take a course on general and ocular pharmacology, pass an examination, and are licensed and certified optometrists.

Section 5 amends s. 463.006, F.S., to require that the licensure examination for optometrists include questions on the use and side effects of all ocular pharmaceutical agents, not just topical agents. Anyone who passes this examination and fulfills other licensure and certification provisions will be permitted to administer and prescribe pharmaceutical agents in the diagnosis and treatment of ocular conditions.

Section 6 amends s. 463.0135, F.S., to state that a certified optometrist shall administer and prescribe oral ocular pharmaceutical agents in a manner consistent with applicable preferred practice patterns of the American Academy of Ophthalmology. The bill also provides that optometrists who diagnose neovascular glaucoma, in addition to other types of glaucoma currently listed in statute, must promptly and without unreasonable delay refer the patient to a licensed physician skilled in diseases of the eye. In addition, an optometrist must timely refer to such a physician any patient who experiences progressive glaucoma due to failed pharmaceutical management by the optometrist.

The bill also requires co-management of post-operative care to be conducted pursuant to an established protocol which governs the relationship between the operating surgeon and the optometrist. The patient must be informed that either physician will be available for emergency care throughout the post-operative period, and the patient must consent to the co-management relationship in writing.

Section 7 amends s. 463.014, F.S., to prohibit optometrists from prescribing or otherwise distributing any drug for the purpose of treating a systemic disease, except that optometrists may use commonly-accepted methods to immediately treat anaphylaxis. The bill also further clarifies the definition of surgery in ch. 463, F.S., which prohibits optometrists from conducting surgery.

Section 8 creates s. 463.0141, F.S., to require and provide specifications for reporting of adverse incidents in the practice of optometry.

Section 9 amends s. 483.035, F.S., to include optometrists in the list of licensed practitioners who are permitted to operate clinical laboratories exclusively in connection with the diagnosis and treatment of their own patients.

Section 10 amends s. 483.041, F.S., to include optometrists in the definition of licensed practitioner with respect to clinical laboratories.

Section 11 amends s. 483.181, F.S., to require clinical laboratories to accept specimens for examination submitted by optometrists.

Section 12 amends s. 766.102, F.S., to change the burden of proof for a claimant in an action alleging a breach of the prevailing professional standard of care in an action for damages based on death or personal injury that allegedly resulted from the failure of a health care provider to order, perform, or administer supplemental diagnostic tests. The burden of proof is increased from greater weight of the evidence to clear and convincing evidence.

Section 13 amends s. 766.106, F.S., to authorize a prospective defendant, or his or her legal representative, to conduct ex parte interviews of the claimant's treating health care providers without the presence of the claimant or the claimant's legal representative. Notice of any intended interviews must be provided to the claimant at least 10 days before the date of the interview.

Section 14 creates s. 766.1091, F.S., to authorize certain health care providers and a patient or prospective patient to agree in writing to submit to arbitration any claim for medical negligence that may currently exist or that may accrue in the future that would otherwise be brought under ch. 766, F.S., relating to medical malpractice. The health care providers include:

- Allopathic physicians;
- Osteopathic physicians;
- Certified optometrists;
- Dentists;
- Any entity owned in whole or in part by an allopathic physician, osteopathic physician, certified optometrist, or dentist; or
- A health care clinic licensed under part X of ch. 400, F.S.

An arbitration agreement entered into under this section would be governed by the FAC. Such an arbitration agreement may contain a provision that would limit the available damages in any arbitration award.

Section 15 amends s. 893.02, F.S., to include certified optometrists as authorized prescribers of controlled substances in the state, provided that they hold valid federal controlled substance registry numbers.

Section 16 amends s. 893.05, F.S., to prohibit certified optometrists from prescribing any Schedule I or II controlled substances listed in the Florida Comprehensive Drug Abuse Prevention and Control Act.

Section 17 provides an effective date of July 1, 2012.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of this bill have no impact on public records or open meetings issues under the requirements of Article I, Section 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Certified optometrists will be able to prescribe additional types of medication related to the diagnosis and treatment of ocular conditions.

C. Government Sector Impact:

The Department of Health should experience little fiscal impact as certification procedures for optometrists are already in effect. There will be an increase in workload relating to updating the formulary of drugs which certified optometrists may prescribe as well as non-recurring rulemaking costs which may be adequately absorbed with current resources.

The Agency for Health Care Administration may experience an increase in applications for clinical laboratory licenses from optometrists, although this number is estimated to be small. There will also be a slightly increased workload related to additional inspections of such laboratories, which should be offset by an increase in revenues from licensure and renewal fees.[53]

VI. Technical Deficiencies:

None.

[53] Department of Health, *2012 Bill Analysis, Economic Statement, and Fiscal Note for SB 788*. A copy is on file with the Senate Health Regulation Committee.

VII. Related Issues:

The informal discovery options include taking unsworn statements of treating health care providers. Lines 484 and 485 provide in existing law that the claimant or claimant's legal representative has the right to attend the taking of such unsworn statements. Lines 486 – 494 provide for ex parte interviews of treating health care providers without the presence of the claimant or the claimant's legal representative. Neither "unsworn statements" nor "ex parte interviews" are defined. To avoid inconsistency and potential litigation, it might be prudent to define or distinguish an unsworn statement and an ex parte interview.

VIII. 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 Regulation on February 9, 2012:
The committee substitute:

- Expands the types of ocular pharmaceutical agents that certified optometrist may administer and prescribe, including some controlled substances;
- Requires optometrists to report adverse incidents to the Department of Health;
- Authorizes optometrists to operate clinical laboratories;
- Requires clinical laboratories to accept specimens for examination from optometrists;
- Authorizes certain health care providers and their patients to enter into voluntary binding arbitration agreements and limit damages; and
- Removes the part of the bill extending sovereign immunity to emergency health care providers.

B. Amendments:

None.

227268

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
02/09/2012	.	
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The Committee on Health Regulation (Gaetz) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause and insert:

Section 1. Subsections (3), (4), and (5) of section 463.002, Florida Statutes, are amended to read:

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

(3)(a) "Licensed practitioner" means a person who is a primary health care provider licensed to engage in the practice of optometry under the authority of this chapter.

(b) A licensed practitioner who is not a certified optometrist shall be required to display at her or his place of

227268

practice a sign which states, "I am a Licensed Practitioner, not a Certified Optometrist, and I am not able to prescribe ~~topical~~ ocular pharmaceutical agents."

(c) All practitioners initially licensed after July 1, 1993, must be certified optometrists.

(4) "Certified optometrist" means a licensed practitioner authorized by the board to administer and prescribe ~~topical~~ ocular pharmaceutical agents.

(5) "Optometry" means the diagnosis of conditions of the human eye and its appendages; the employment of any objective or subjective means or methods, including the administration of ~~topical ocular~~ pharmaceutical agents, for the purpose of determining the refractive powers of the human eyes, or any visual, muscular, neurological, or anatomic anomalies of the human eyes and their appendages; and the prescribing and employment of lenses, prisms, frames, mountings, contact lenses, orthoptic exercises, light frequencies, and any other means or methods, including ~~topical ocular~~ pharmaceutical agents, for the correction, remedy, or relief of any insufficiencies or abnormal conditions of the human eyes and their appendages.

Section 2. Paragraph (g) of subsection (1) of section 463.005, Florida Statutes, is amended to read:

463.005 Authority of the board.—

(1) The Board of Optometry has authority to adopt rules pursuant to ss. 120.536(1) and 120.54 to implement the provisions of this chapter conferring duties upon it. Such rules shall include, but not be limited to, rules relating to:

(g) Administration and prescription of ~~topical~~ ocular pharmaceutical agents.

227268

Section 3. Section 463.0055, Florida Statutes, is amended to read:

463.0055 Administration and prescription of ~~topical~~ ocular pharmaceutical agents; committee.—

(1)(a) Certified optometrists may administer and prescribe ~~topical ocular~~ pharmaceutical agents as provided in this section for the diagnosis and treatment of ocular conditions of the human eye and its appendages without the use of surgery or other invasive techniques. However, a licensed practitioner who is not certified may use topically applied anesthetics solely for the purpose of glaucoma examinations~~,~~ but is otherwise prohibited from administering or prescribing ~~topical ocular~~ pharmaceutical agents.

(b) Before a certified optometrist may administer or prescribe oral ocular pharmaceutical agents, the certified optometrist must complete a course and subsequent examination on general and ocular pharmacology which have a particular emphasis on the ingestion of oral pharmaceutical agents and the side effects of those agents. For certified optometrists licensed before January 1, 1990, the course shall consist of 50 contact hours and 25 of those hours shall be Internet-based. For certified optometrists licensed on or after January 1, 1990, the course shall consist of 20 contact hours and 10 of those hours shall be Internet-based. The first course and examination shall be presented by January 1, 2013, and shall thereafter be administered at least annually. The Florida Medical Association and the Florida Optometric Association shall jointly develop and administer a course and examination for such purpose and jointly determine the site or sites for the course and examination.

227268

(2)(a) There is ~~hereby~~ created a committee composed of two certified optometrists licensed pursuant to this chapter, appointed by the Board of Optometry, two board-certified ophthalmologists licensed pursuant to chapter 458 or chapter 459, appointed by the Board of Medicine, and one additional person with a doctorate degree in pharmacology who is not licensed pursuant to chapter 458, chapter 459, or this chapter, appointed by the State Surgeon General. The committee shall review requests for additions to, deletions from, or modifications of a formulary of topical ocular pharmaceutical agents for administration and prescription by certified optometrists and shall provide to the board advisory opinions and recommendations on such requests. The formulary of topical ocular pharmaceutical agents shall consist of those topical ~~ocular pharmaceutical~~ agents that are appropriate to treat and diagnose ocular diseases and disorders and that ~~which~~ the certified optometrist is qualified to use in the practice of optometry. The board shall establish, add to, delete from, or modify the formulary by rule. Notwithstanding any provision of chapter 120 to the contrary, the formulary rule shall become effective 60 days from the date it is filed with the Secretary of State.

(b) The topical formulary may be added to, deleted from, or modified according to the procedure described in paragraph (a). Any person who requests an addition, deletion, or modification of an authorized topical ~~ocular pharmaceutical~~ agent shall have the burden of proof to show cause why such addition, deletion, or modification should be made.

(c) The State Surgeon General shall have standing to

challenge any rule or proposed rule of the board pursuant to s. 120.56. In addition to challenges for any invalid exercise of delegated legislative authority, the administrative law judge, upon such a challenge by the State Surgeon General, may declare all or part of a rule or proposed rule invalid if it:

1. Does not protect the public from any significant and discernible harm or damages;

2. Unreasonably restricts competition or the availability of professional services in the state or in a significant part of the state; or

3. Unnecessarily increases the cost of professional services without a corresponding or equivalent public benefit.

However, there shall not be created a presumption of the existence of any of the conditions cited in this subsection in the event that the rule or proposed rule is challenged.

(d) Upon adoption of the topical formulary required by this section, and upon each addition, deletion, or modification to the topical formulary, the board shall mail a copy of the amended topical formulary to each certified optometrist and to each pharmacy licensed by the state.

(3) In addition to the formulary of topical ocular pharmaceutical agents in subsection (2), there is created a statutory formulary of oral pharmaceutical agents, which include the following agents:

(a) The following analgesics, or their generic or therapeutic equivalents, which may not be administered or prescribed for more than 72 hours without consultation with a physician licensed under chapter 458 or chapter 459 who is

skilled in diseases of the eye:

1. Tramadol hydrochloride.

2. Acetaminophen 300 mg with No. 3 codeine phosphate 30 mg.

(b) The following antibiotics, or their generic or therapeutic equivalents:

1. Amoxicillin.

2. Azithromycin.

3. Ciproflaxacin.

4. Dicloxacillin.

5. Doxycycline.

6. Keflex.

7. Minocycline.

(c) The following antivirals, or their generic or therapeutic equivalents:

1. Acyclovir.

2. Famciclovir.

3. Valacyclovir.

(d) The following oral anti-glaucoma agents, or their generic or therapeutic equivalents, which may not be administered or prescribed for more than 72 hours without consultation with a physician licensed under chapter 458 or chapter 459 who is skilled in diseases of the eye:

1. Acetazolamide.

2. Methazolamide.

Any oral pharmaceutical agent that is listed in the statutory formulary set forth in this subsection and that is subsequently determined by the United States Food and Drug Administration to be unsafe for administration or prescription shall be considered

227268

to have been deleted from the formulary of oral pharmaceutical agents. The oral pharmaceutical agents on the statutory formulary set forth in this subsection may not otherwise be deleted by the board, the department, or the State Surgeon General.

(4) ~~(3)~~ A certified optometrist shall be issued a prescriber number by the board. Any prescription written by a certified optometrist for a ~~topical ocular~~ pharmaceutical agent pursuant to this section shall have the prescriber number printed thereon.

Section 4. Subsection (3) of section 463.0057, Florida Statutes, is amended to read:

463.0057 Optometric faculty certificate.—

(3) The holder of a faculty certificate may engage in the practice of optometry as permitted by this section~~,~~ but may not administer or prescribe ~~topical~~ ocular pharmaceutical agents unless the certificateholder has satisfied the requirements of ss. 463.0055(1)(b) and ~~s.~~ 463.006(1)(b)4. and 5.

Section 5. Subsections (2) and (3) of section 463.006, Florida Statutes, are amended to read:

463.006 Licensure and certification by examination.—

(2) The examination shall consist of the appropriate subjects, including applicable state laws and rules and general and ocular pharmacology with emphasis on the use ~~topical application~~ and side effects of ocular pharmaceutical agents. The board may by rule substitute a national examination as part or all of the examination and may by rule offer a practical examination in addition to the written examination.

(3) Each applicant who successfully passes the examination

227268

and otherwise meets the requirements of this chapter is entitled to be licensed as a practitioner and to be certified to administer and prescribe ~~topical ocular~~ pharmaceutical agents in the diagnosis and treatment of ocular conditions.

Section 6. Subsections (1) and (2) of section 463.0135, Florida Statutes, are amended, and subsection (10) is added to that section, to read:

463.0135 Standards of practice.—

(1) A licensed practitioner shall provide that degree of care which conforms to that level of care provided by medical practitioners in the same or similar communities. A certified optometrist shall administer and prescribe oral ocular pharmaceutical agents in a manner consistent with applicable preferred practice patterns of the American Academy of Ophthalmology. A licensed practitioner shall advise or assist her or his patient in obtaining further care when the service of another health care practitioner is required.

(2) A licensed practitioner diagnosing angle closure, neovascular, infantile, or congenital forms of glaucoma shall promptly and without unreasonable delay refer the patient to a physician skilled in diseases of the eye and licensed under chapter 458 or chapter 459. In addition, a licensed practitioner shall timely refer any patient who experiences progressive glaucoma due to failed pharmaceutical intervention to a physician who is skilled in diseases of the eye and licensed under chapter 458 or chapter 459.

(10) Comanagement of postoperative care shall be conducted pursuant to an established protocol that governs the relationship between the operating surgeon and the optometrist.

227268

The patient shall be informed that either physician will be available for emergency care throughout the postoperative period, and the patient shall consent in writing to the comanagement relationship.

Section 7. Subsections (3) and (4) of section 463.014, Florida Statutes, are amended to read:

463.014 Certain acts prohibited.—

(3) Prescribing, ordering, dispensing, administering, supplying, selling, or giving any ~~systemic~~ drugs for the purpose of treating a systemic disease by a licensed practitioner is prohibited. However, a certified optometrist is permitted to use commonly accepted means or methods to immediately address incidents of anaphylaxis.

(4) Surgery of any kind, including the use of lasers, is expressly prohibited. For purposes of this subsection, the term "surgery" means a procedure using an instrument, including lasers, scalpels, or needles, in which human tissue is cut, burned, or vaporized by incision, injection, ultrasound, laser, or radiation. The term includes procedures using instruments that require closing by suturing, clamping, or another such device. Certified optometrists may remove superficial foreign bodies. For the purposes of this subsection, the term "superficial foreign bodies" means any foreign matter that is embedded in the conjunctiva or cornea but which has not penetrated the globe.

Section 8. Section 463.0141, Florida Statutes, is created to read:

463.0141 Reports of adverse incidents in the practice of optometry.—

227268

(1) Any adverse incident that occurs on or after January 1, 2013, in the practice of optometry must be reported to the department in accordance with this section.

(2) The required notification to the department must be submitted in writing by certified mail and postmarked within 15 days after the occurrence of the adverse incident.

(3) For purposes of notification to the department, the term "adverse incident," as used in this section, means an event that is associated in whole or in part with the prescribing of an oral ocular pharmaceutical agent and that results in one of the following:

(a) Any condition that requires the transfer of a patient to a hospital licensed under chapter 395;

(b) Any condition that requires the patient to obtain care from a physician licensed under chapter 458 or chapter 459, other than a referral or a consultation required under this chapter;

(c) Permanent physical injury to the patient;

(d) Partial or complete permanent loss of sight by the patient; or

(e) Death of the patient.

(4) The department shall review each incident and determine whether it potentially involved conduct by the licensed practitioner which may be subject to disciplinary action, in which case s. 456.073 applies. Disciplinary action, if any, shall be taken by the board.

Section 9. Subsection (1) of section 483.035, Florida Statutes, is amended to read:

483.035 Clinical laboratories operated by practitioners for

227268

exclusive use; licensure and regulation.—

(1) A clinical laboratory operated by one or more practitioners licensed under chapter 458, chapter 459, chapter 460, chapter 461, chapter 462, chapter 463, or chapter 466, exclusively in connection with the diagnosis and treatment of their own patients, must be licensed under this part and must comply with the provisions of this part, except that the agency shall adopt rules for staffing, for personnel, including education and training of personnel, for proficiency testing, and for construction standards relating to the licensure and operation of the laboratory based upon and not exceeding the same standards contained in the federal Clinical Laboratory Improvement Amendments of 1988 and the federal regulations adopted thereunder.

Section 10. Subsection (7) of section 483.041, Florida Statutes, is amended to read:

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

(7) "Licensed practitioner" means a physician licensed under chapter 458, chapter 459, chapter 460, ~~or~~ chapter 461, or chapter 463; a dentist licensed under chapter 466; a person licensed under chapter 462; or an advanced registered nurse practitioner licensed under part I of chapter 464; or a duly licensed practitioner from another state licensed under similar statutes who orders examinations on materials or specimens for nonresidents of the State of Florida, but who reside in the same state as the requesting licensed practitioner.

Section 11. Subsection (5) of section 483.181, Florida Statutes, is amended to read:

483.181 Acceptance, collection, identification, and

227268

examination of specimens.—

(5) A clinical laboratory licensed under this part must accept a human specimen submitted for examination by a practitioner licensed under chapter 458, chapter 459, chapter 460, chapter 461, chapter 462, chapter 463, s. 464.012, or chapter 466, if the specimen and test are the type performed by the clinical laboratory. A clinical laboratory may only refuse a specimen based upon a history of nonpayment for services by the practitioner. A clinical laboratory shall not charge different prices for tests based upon the chapter under which a practitioner submitting a specimen for testing is licensed.

Section 12. Subsection (4) of section 766.102, Florida Statutes, is amended to read:

766.102 Medical negligence; standards of recovery; expert witness.—

(4)(a) The Legislature is cognizant of the changing trends and techniques for the delivery of health care in this state and the discretion that is inherent in the diagnosis, care, and treatment of patients by different health care providers. The failure of a health care provider to order, perform, or administer supplemental diagnostic tests is ~~shall~~ not ~~be~~ actionable if the health care provider acted in good faith and with due regard for the prevailing professional standard of care.

(b) The claimant has the burden of proving by clear and convincing evidence that the alleged actions of the health care provider represent a breach of the prevailing professional standard of care in an action for damages based on death or personal injury which alleges that the death or injury resulted

227268

from the failure of a health care provider to order, perform, or administer supplemental diagnostic tests.

Section 13. Paragraph (b) of subsection (6) of section 766.106, Florida Statutes, is amended to read:

766.106 Notice before filing action for medical negligence; presuit screening period; offers for admission of liability and for arbitration; informal discovery; review.—

(6) INFORMAL DISCOVERY.—

(b) Informal discovery may be used by a party to obtain unsworn statements, the production of documents or things, ~~and~~ physical and mental examinations, and ex parte interviews, as follows:

1. Unsworn statements.—Any party may require other parties to appear for the taking of an unsworn statement. Such statements may be used only for the purpose of presuit screening and are not discoverable or admissible in any civil action for any purpose by any party. A party desiring to take the unsworn statement of any party must give reasonable notice in writing to all parties. The notice must state the time and place for taking the statement and the name and address of the party to be examined. Unless otherwise impractical, the examination of any party must be done at the same time by all other parties. Any party may be represented by counsel at the taking of an unsworn statement. An unsworn statement may be recorded electronically, stenographically, or on videotape. The taking of unsworn statements is subject to the provisions of the Florida Rules of Civil Procedure and may be terminated for abuses.

2. Documents or things.—Any party may request discovery of documents or things. The documents or things must be produced,

227268

at the expense of the requesting party, within 20 days after the date of receipt of the request. A party is required to produce discoverable documents or things within that party's possession or control. Medical records shall be produced as provided in s. 766.204.

3. Physical and mental examinations.—A prospective defendant may require an injured claimant to appear for examination by an appropriate health care provider. The prospective defendant shall give reasonable notice in writing to all parties as to the time and place for examination. Unless otherwise impractical, a claimant is required to submit to only one examination on behalf of all potential defendants. The practicality of a single examination must be determined by the nature of the claimant's condition, as it relates to the liability of each prospective defendant. Such examination report is available to the parties and their attorneys upon payment of the reasonable cost of reproduction and may be used only for the purpose of presuit screening. Otherwise, such examination report is confidential and exempt from the provisions of s. 119.07(1) and s. 24(a), Art. I of the State Constitution.

4. Written questions.—Any party may request answers to written questions, the number of which may not exceed 30, including subparts. A response must be made within 20 days after receipt of the questions.

5. Unsworn statements of treating health care providers.—A prospective defendant or his or her legal representative may also take unsworn statements of the claimant's treating health care providers. The statements must be limited to those areas that are potentially relevant to the claim of personal injury or

wrongful death. Subject to the procedural requirements of subparagraph 1., a prospective defendant may take unsworn statements from a claimant's treating physicians. Reasonable notice and opportunity to be heard must be given to the claimant or the claimant's legal representative before taking unsworn statements. The claimant or claimant's legal representative has the right to attend the taking of such unsworn statements.

6. Ex parte interviews of treating health care providers.—A prospective defendant or his or her legal representative may interview the claimant's treating health care providers without the presence of the claimant or the claimant's legal representative. If a prospective defendant or his or her legal representative intends to interview a claimant's health care providers, the prospective defendant must provide the claimant with notice of such interview at least 10 days before the date of the interview.

Section 14. Section 766.1091, Florida Statutes, is created to read:

766.1091 Voluntary binding arbitration; damages.—

(1) A health care provider licensed under chapter 458, chapter 459, chapter 463, or chapter 466; any entity owned in whole or in part by a health care provider licensed under chapter 458, chapter 459, chapter 463, or chapter 466; or any health care clinic licensed under part X of chapter 400, and a patient or prospective patient, may agree in writing to submit to arbitration any claim for medical negligence which may currently exist or may accrue in the future and would otherwise be brought pursuant to this chapter. Any arbitration agreement entered into pursuant to this section shall be governed by

chapter 682.

(2) Any arbitration agreement entered into pursuant to subsection (1) may contain a provision that limits the available damages in an arbitration award.

Section 15. Subsection (21) of section 893.02, Florida Statutes, is amended to read:

893.02 Definitions.—The following words and phrases as used in this chapter shall have the following meanings, unless the context otherwise requires:

(21) "Practitioner" means a physician licensed pursuant to chapter 458, a dentist licensed pursuant to chapter 466, a veterinarian licensed pursuant to chapter 474, an osteopathic physician licensed pursuant to chapter 459, a naturopath licensed pursuant to chapter 462, a certified optometrist licensed under chapter 463, or a podiatric physician licensed pursuant to chapter 461, provided such practitioner holds a valid federal controlled substance registry number.

Section 16. Subsection (1) of section 893.05, Florida Statutes, is amended to read:

893.05 Practitioners and persons administering controlled substances in their absence.—

(1) A practitioner, in good faith and in the course of his or her professional practice only, may prescribe, administer, dispense, mix, or otherwise prepare a controlled substance, or the practitioner may cause the same to be administered by a licensed nurse or an intern practitioner under his or her direction and supervision only. A veterinarian may so prescribe, administer, dispense, mix, or prepare a controlled substance for use on animals only~~,~~ and may cause it to be administered by an

assistant or orderly under the veterinarian's direction and supervision only. A certified optometrist licensed under chapter 463 may not administer or prescribe pharmaceutical agents in Schedule I or Schedule II of the Florida Comprehensive Drug Abuse Prevention and Control Act.

Section 17. This act shall take effect July 1, 2012.

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

And the title is amended as follows:

Delete everything before the enacting clause

and insert:

A bill to be entitled

An act relating to health care; amending s. 463.002, F.S.; conforming provisions to changes made by the act; amending s. 463.005, F.S.; authorizing the Board of Optometry to adopt rules for the administration and prescription of ocular pharmaceutical agents; amending s. 463.0055, F.S.; authorizing certified optometrists to administer and prescribe pharmaceutical agents under certain circumstances; requiring that a certified optometrist complete a course and subsequent examination on general and ocular pharmacology; providing requirements for the course; requiring that the Florida Medical Association and the Florida Optometric Association jointly develop and administer the course and examination; revising qualifications of certain members of the formulary committee; providing for a formulary of topical ocular pharmaceutical agents which the committee may modify; specifying the

agents that make up the statutory formulary of oral pharmaceutical agents; authorizing the deletion of an oral pharmaceutical agent listed in the statutory formulary under certain circumstances; prohibiting the board, the Department of Health, or the State Surgeon General from deleting an oral pharmaceutical agent listed in the statutory formulary; amending ss. 463.0057 and 463.006, F.S.; conforming provisions to changes made by the act; amending s. 463.0135, F.S.; requiring that a certified optometrist administer and prescribe oral ocular pharmaceutical agents in a certain manner; requiring that a licensed practitioner who diagnoses a patient who has a neovascular form of glaucoma or progressive glaucoma immediately refer the patient to a physician who is skilled in the diseases of the eye; requiring that comanagement of postoperative care be conducted pursuant to an established protocol; requiring that the patient be informed that a physician will be available for emergency care throughout the postoperative period; requiring that the patient consent in writing to the comanagement relationship; amending s. 463.014, F.S.; revising certain prohibited acts regarding an optometrist conducting surgery and dispensing, administering, ordering, supplying, or selling certain drugs; creating s. 463.0141, F.S.; requiring that adverse incidents in the practice of optometry be reported to the Department of Health; providing requirements for notifying the department of an


227268

adverse incident; providing a definition; requiring that the department review each incident and determine whether it involved conduct that is subject to disciplinary action; requiring that the Board of Optometry take disciplinary action if necessary; amending s. 483.035, F.S., relating to licensure and regulation of clinical laboratories operated by practitioners for exclusive use; providing applicability to clinical laboratories operated by practitioners licensed to practice optometry; amending s. 483.041, F.S.; revising the definition of the term "licensed practitioner" to include a practitioner licensed under ch. 463, F.S.; amending s. 483.181, F.S.; requiring clinical laboratories to accept human specimens submitted by practitioners licensed to practice under ch. 463, F.S.; amending s. 766.102, F.S.; providing that the claimant has the burden of proving by clear and convincing evidence that the actions of a health care provider represented a breach of the prevailing professional standard of care in an action for damages based on death or personal injury which alleges that the death or injury resulted from the failure of a health care provider to order, perform, or administer supplemental diagnostic tests; amending s. 766.106, F.S.; authorizing a prospective defendant to obtain informal discovery by conducting ex parte interviews of treating health care providers; requiring advance notice to the claimant of an ex parte interview; creating s. 766.1091, F.S.;


227268

authorizing a health care provider or health care clinic and a patient or prospective patient to agree to submit a current or future claim of medical negligence to arbitration; requiring that the arbitration agreement be governed by ch. 682, F.S.; authorizing the arbitration agreement to contain a provision that limits an award of damages; amending s. 893.02, F.S.; revising the definition of the term "practitioner" to include certified optometrists for purposes of the Florida Comprehensive Drug Abuse Prevention and Control Act; amending s. 893.05, F.S.; prohibiting certified optometrists from administering and prescribing certain controlled substances; providing an effective date.

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LEGISLATIVE ACTION

Senate	.	House
Comm: WD	.	
02/09/2012	.	
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The Committee on Health Regulation (Diaz de la Portilla) recommended the following:

Senate Amendment to Amendment (227268) (with title amendment)

Delete lines 406 - 422.

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

And the title is amended as follows:

Delete lines 534 - 541

and insert:

parte interview; amending s.

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LEGISLATIVE ACTION

Senate	.	House
Comm: WD	.	
02/09/2012	.	
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The Committee on Health Regulation (Garcia) recommended the following:

Senate Substitute for Amendment (227268) (with title amendment)

Delete everything after the enacting clause

and insert:

Section 1. Subsections (3), (4), and (5) of section 463.002, Florida Statutes, are amended to read:

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

(3)(a) "Licensed practitioner" means a person who is a primary health care provider licensed to engage in the practice of optometry under the authority of this chapter.

(b) A licensed practitioner who is not a certified

358292

optometrist shall be required to display at her or his place of practice a sign which states, "I am a Licensed Practitioner, not a Certified Optometrist, and I am not able to prescribe ~~topical~~ ocular pharmaceutical agents."

(c) All practitioners initially licensed after July 1, 1993, must be certified optometrists.

(4) "Certified optometrist" means a licensed practitioner authorized by the board to administer and prescribe ~~topical~~ ocular pharmaceutical agents.

(5) "Optometry" means the diagnosis of conditions of the human eye and its appendages; the employment of any objective or subjective means or methods, including the administration of ~~topical ocular~~ pharmaceutical agents, for the purpose of determining the refractive powers of the human eyes, or any visual, muscular, neurological, or anatomic anomalies of the human eyes and their appendages; and the prescribing and employment of lenses, prisms, frames, mountings, contact lenses, orthoptic exercises, light frequencies, and any other means or methods, including ~~topical ocular~~ pharmaceutical agents, for the correction, remedy, or relief of any insufficiencies or abnormal conditions of the human eyes and their appendages.

Section 2. Paragraph (g) of subsection (1) of section 463.005, Florida Statutes, is amended to read:

463.005 Authority of the board.—

(1) The Board of Optometry has authority to adopt rules pursuant to ss. 120.536(1) and 120.54 to implement the provisions of this chapter conferring duties upon it. Such rules shall include, but not be limited to, rules relating to:

(g) Administration and prescription of ~~topical~~ ocular

358292

pharmaceutical agents.

Section 3. Section 463.0055, Florida Statutes, is amended to read:

463.0055 Administration and prescription of ~~topical~~ ocular pharmaceutical agents; committee.—

(1)(a) Certified optometrists may administer and prescribe ~~topical ocular~~ pharmaceutical agents as provided in this section for the diagnosis and treatment of ocular conditions of the human eye and its appendages without the use of surgery or other invasive techniques. However, a licensed practitioner who is not certified may use topically applied anesthetics solely for the purpose of glaucoma examinations~~,~~ but is otherwise prohibited from administering or prescribing ~~topical ocular~~ pharmaceutical agents.

(b) Before a certified optometrist may administer or prescribe oral ocular pharmaceutical agents, the certified optometrist must complete a course and subsequent examination on general and ocular pharmacology which have a particular emphasis on the ingestion of oral pharmaceutical agents and the side effects of those agents. For certified optometrists licensed before January 1, 1990, the course shall consist of 50 contact hours and 25 of those hours shall be Internet-based. For certified optometrists licensed on or after January 1, 1990, the course shall consist of 20 contact hours and 10 of those hours shall be Internet-based. The first course and examination shall be presented by January 1, 2013, and shall thereafter be administered at least annually. The Florida Medical Association and the Florida Optometric Association shall jointly develop and administer a course and examination for such purpose and jointly

358292

determine the site or sites for the course and examination.

(2)(a) There is ~~hereby~~ created a committee composed of two certified optometrists licensed pursuant to this chapter, appointed by the Board of Optometry, two board-certified ophthalmologists licensed pursuant to chapter 458 or chapter 459, appointed by the Board of Medicine, and one additional person with a doctorate degree in pharmacology who is not licensed pursuant to chapter 458, chapter 459, or this chapter, appointed by the State Surgeon General. The committee shall review requests for additions to, deletions from, or modifications of a formulary of topical ocular pharmaceutical agents for administration and prescription by certified optometrists and shall provide to the board advisory opinions and recommendations on such requests. The formulary of topical ocular pharmaceutical agents shall consist of those topical ~~ocular pharmaceutical~~ agents that are appropriate to treat and diagnose ocular diseases and disorders and that ~~which~~ the certified optometrist is qualified to use in the practice of optometry. The board shall establish, add to, delete from, or modify the formulary by rule. Notwithstanding any provision of chapter 120 to the contrary, the formulary rule shall become effective 60 days from the date it is filed with the Secretary of State.

(b) The topical formulary may be added to, deleted from, or modified according to the procedure described in paragraph (a). Any person who requests an addition, deletion, or modification of an authorized topical ~~ocular pharmaceutical~~ agent shall have the burden of proof to show cause why such addition, deletion, or modification should be made.

358292

(c) The State Surgeon General shall have standing to challenge any rule or proposed rule of the board pursuant to s. 120.56. In addition to challenges for any invalid exercise of delegated legislative authority, the administrative law judge, upon such a challenge by the State Surgeon General, may declare all or part of a rule or proposed rule invalid if it:

1. Does not protect the public from any significant and discernible harm or damages;

2. Unreasonably restricts competition or the availability of professional services in the state or in a significant part of the state; or

3. Unnecessarily increases the cost of professional services without a corresponding or equivalent public benefit.

However, there shall not be created a presumption of the existence of any of the conditions cited in this subsection in the event that the rule or proposed rule is challenged.

(d) Upon adoption of the topical formulary required by this section, and upon each addition, deletion, or modification to the topical formulary, the board shall mail a copy of the amended topical formulary to each certified optometrist and to each pharmacy licensed by the state.

(3) In addition to the formulary of topical ocular pharmaceutical agents in subsection (2), there is created a statutory formulary of oral pharmaceutical agents, which include the following agents:

(a) The following analgesics, or their generic or therapeutic equivalents, which may not be administered or prescribed for more than 72 hours without consultation with a

358292

physician licensed under chapter 458 or chapter 459 who is skilled in diseases of the eye:

1. Tramadol hydrochloride.

2. Acetaminophen 300 mg with No. 3 codeine phosphate 30 mg.

(b) The following antibiotics, or their generic or therapeutic equivalents:

1. Amoxicillin.

2. Azithromycin.

3. Ciproflaxacin.

4. Dicloxacillin.

5. Doxycycline.

6. Keflex.

7. Minocycline.

(c) The following antivirals, or their generic or therapeutic equivalents:

1. Acyclovir.

2. Famciclovir.

3. Valacyclovir.

(d) The following oral anti-glaucoma agents, or their generic or therapeutic equivalents, which may not be administered or prescribed for more than 72 hours without consultation with a physician licensed under chapter 458 or chapter 459 who is skilled in diseases of the eye:

1. Acetazolamide.

2. Methazolamide.

Any oral pharmaceutical agent that is listed in the statutory formulary set forth in this subsection and that is subsequently determined by the United States Food and Drug Administration to

358292

be unsafe for administration or prescription shall be considered to have been deleted from the formulary of oral pharmaceutical agents. The oral pharmaceutical agents on the statutory formulary set forth in this subsection may not otherwise be deleted by the board, the department, or the State Surgeon General.

(4) ~~(3)~~ A certified optometrist shall be issued a prescriber number by the board. Any prescription written by a certified optometrist for a ~~topical ocular~~ pharmaceutical agent pursuant to this section shall have the prescriber number printed thereon.

Section 4. Subsection (3) of section 463.0057, Florida Statutes, is amended to read:

463.0057 Optometric faculty certificate.—

(3) The holder of a faculty certificate may engage in the practice of optometry as permitted by this section~~,~~ but may not administer or prescribe ~~topical~~ ocular pharmaceutical agents unless the certificateholder has satisfied the requirements of ss. 463.0055(1)(b) and ~~s.~~ 463.006(1)(b)4. and 5.

Section 5. Subsections (2) and (3) of section 463.006, Florida Statutes, are amended to read:

463.006 Licensure and certification by examination.—

(2) The examination shall consist of the appropriate subjects, including applicable state laws and rules and general and ocular pharmacology with emphasis on the use ~~topical application~~ and side effects of ocular pharmaceutical agents. The board may by rule substitute a national examination as part or all of the examination and may by rule offer a practical examination in addition to the written examination.

358292

(3) Each applicant who successfully passes the examination and otherwise meets the requirements of this chapter is entitled to be licensed as a practitioner and to be certified to administer and prescribe ~~topical ocular~~ pharmaceutical agents in the diagnosis and treatment of ocular conditions.

Section 6. Subsections (1) and (2) of section 463.0135, Florida Statutes, are amended, and subsection (10) is added to that section, to read:

463.0135 Standards of practice.—

(1) A licensed practitioner shall provide that degree of care which conforms to that level of care provided by medical practitioners in the same or similar communities. A certified optometrist shall administer and prescribe oral ocular pharmaceutical agents in a manner consistent with applicable preferred practice patterns of the American Academy of Ophthalmology. A licensed practitioner shall advise or assist her or his patient in obtaining further care when the service of another health care practitioner is required.

(2) A licensed practitioner diagnosing angle closure, neovascular, infantile, or congenital forms of glaucoma shall promptly and without unreasonable delay refer the patient to a physician skilled in diseases of the eye and licensed under chapter 458 or chapter 459. In addition, a licensed practitioner shall timely refer any patient who experiences progressive glaucoma due to failed pharmaceutical intervention to a physician who is skilled in diseases of the eye and licensed under chapter 458 or chapter 459.

(10) Comanagement of postoperative care shall be conducted pursuant to an established protocol that governs the

358292

relationship between the operating surgeon and the optometrist. The patient shall be informed that either physician will be available for emergency care throughout the postoperative period, and the patient shall consent in writing to the comanagement relationship.

Section 7. Subsections (3) and (4) of section 463.014, Florida Statutes, are amended to read:

463.014 Certain acts prohibited.—

(3) Prescribing, ordering, dispensing, administering, supplying, selling, or giving any ~~systemic~~ drugs for the purpose of treating a systemic disease by a licensed practitioner is prohibited. However, a certified optometrist is permitted to use commonly accepted means or methods to immediately address incidents of anaphylaxis.

(4) Surgery of any kind, including the use of lasers, is expressly prohibited. For purposes of this subsection, the term "surgery" means a procedure using an instrument, including lasers, scalpels, or needles, in which human tissue is cut, burned, or vaporized by incision, injection, ultrasound, laser, or radiation. The term includes procedures using instruments that require closing by suturing, clamping, or another such device. Certified optometrists may remove superficial foreign bodies. For the purposes of this subsection, the term "superficial foreign bodies" means any foreign matter that is embedded in the conjunctiva or cornea but which has not penetrated the globe.

Section 8. Section 463.0141, Florida Statutes, is created to read:

463.0141 Reports of adverse incidents in the practice of

optometry.—

(1) Any adverse incident that occurs on or after January 1, 2013, in the practice of optometry must be reported to the department in accordance with this section.

(2) The required notification to the department must be submitted in writing by certified mail and postmarked within 15 days after the occurrence of the adverse incident.

(3) For purposes of notification to the department, the term "adverse incident," as used in this section, means an event that is associated in whole or in part with the prescribing of an oral ocular pharmaceutical agent and that results in one of the following:

(a) Any condition that requires the transfer of a patient to a hospital licensed under chapter 395;

(b) Any condition that requires the patient to obtain care from a physician licensed under chapter 458 or chapter 459, other than a referral or a consultation required under this chapter;

(c) Permanent physical injury to the patient;

(d) Partial or complete permanent loss of sight by the patient; or

(e) Death of the patient.

(4) The department shall review each incident and determine whether it potentially involved conduct by the licensed practitioner which may be subject to disciplinary action, in which case s. 456.073 applies. Disciplinary action, if any, shall be taken by the board.

Section 9. Subsection (1) of section 483.035, Florida Statutes, is amended to read:

483.035 Clinical laboratories operated by practitioners for exclusive use; licensure and regulation.—

(1) A clinical laboratory operated by one or more practitioners licensed under chapter 458, chapter 459, chapter 460, chapter 461, chapter 462, chapter 463, or chapter 466, exclusively in connection with the diagnosis and treatment of their own patients, must be licensed under this part and must comply with the provisions of this part, except that the agency shall adopt rules for staffing, for personnel, including education and training of personnel, for proficiency testing, and for construction standards relating to the licensure and operation of the laboratory based upon and not exceeding the same standards contained in the federal Clinical Laboratory Improvement Amendments of 1988 and the federal regulations adopted thereunder.

Section 10. Subsection (7) of section 483.041, Florida Statutes, is amended to read:

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

(7) "Licensed practitioner" means a physician licensed under chapter 458, chapter 459, chapter 460, ~~or~~ chapter 461, or chapter 463; a dentist licensed under chapter 466; a person licensed under chapter 462; or an advanced registered nurse practitioner licensed under part I of chapter 464; or a duly licensed practitioner from another state licensed under similar statutes who orders examinations on materials or specimens for nonresidents of the State of Florida, but who reside in the same state as the requesting licensed practitioner.

Section 11. Subsection (5) of section 483.181, Florida Statutes, is amended to read:

358292

483.181 Acceptance, collection, identification, and examination of specimens.—

(5) A clinical laboratory licensed under this part must accept a human specimen submitted for examination by a practitioner licensed under chapter 458, chapter 459, chapter 460, chapter 461, chapter 462, chapter 463, s. 464.012, or chapter 466, if the specimen and test are the type performed by the clinical laboratory. A clinical laboratory may only refuse a specimen based upon a history of nonpayment for services by the practitioner. A clinical laboratory shall not charge different prices for tests based upon the chapter under which a practitioner submitting a specimen for testing is licensed.

Section 12. Paragraph (b) of subsection (6) of section 766.106, Florida Statutes, is amended to read:

766.106 Notice before filing action for medical negligence; presuit screening period; offers for admission of liability and for arbitration; informal discovery; review.—

(6) INFORMAL DISCOVERY.—

(b) Informal discovery may be used by a party to obtain unsworn statements, the production of documents or things, ~~and~~ physical and mental examinations, and ex parte interviews, as follows:

1. Unsworn statements.—Any party may require other parties to appear for the taking of an unsworn statement. Such statements may be used only for the purpose of presuit screening and are not discoverable or admissible in any civil action for any purpose by any party. A party desiring to take the unsworn statement of any party must give reasonable notice in writing to all parties. The notice must state the time and place for taking

358292

the statement and the name and address of the party to be examined. Unless otherwise impractical, the examination of any party must be done at the same time by all other parties. Any party may be represented by counsel at the taking of an unsworn statement. An unsworn statement may be recorded electronically, stenographically, or on videotape. The taking of unsworn statements is subject to the provisions of the Florida Rules of Civil Procedure and may be terminated for abuses.

2. Documents or things.—Any party may request discovery of documents or things. The documents or things must be produced, at the expense of the requesting party, within 20 days after the date of receipt of the request. A party is required to produce discoverable documents or things within that party's possession or control. Medical records shall be produced as provided in s. 766.204.

3. Physical and mental examinations.—A prospective defendant may require an injured claimant to appear for examination by an appropriate health care provider. The prospective defendant shall give reasonable notice in writing to all parties as to the time and place for examination. Unless otherwise impractical, a claimant is required to submit to only one examination on behalf of all potential defendants. The practicality of a single examination must be determined by the nature of the claimant's condition, as it relates to the liability of each prospective defendant. Such examination report is available to the parties and their attorneys upon payment of the reasonable cost of reproduction and may be used only for the purpose of presuit screening. Otherwise, such examination report is confidential and exempt from the provisions of s. 119.07(1)

and s. 24(a), Art. I of the State Constitution.

4. Written questions.—Any party may request answers to written questions, the number of which may not exceed 30, including subparts. A response must be made within 20 days after receipt of the questions.

5. Unsworn statements of treating health care providers.—A prospective defendant or his or her legal representative may also take unsworn statements of the claimant's treating health care providers. The statements must be limited to those areas that are potentially relevant to the claim of personal injury or wrongful death. Subject to the procedural requirements of subparagraph 1., a prospective defendant may take unsworn statements from a claimant's treating physicians. Reasonable notice and opportunity to be heard must be given to the claimant or the claimant's legal representative before taking unsworn statements. The claimant or claimant's legal representative has the right to attend the taking of such unsworn statements.

6. Ex parte interviews of treating health care providers.—A prospective defendant or his or her legal representative may interview the claimant's treating health care providers without the presence of the claimant or the claimant's legal representative. If a prospective defendant or his or her legal representative intends to interview a claimant's health care providers, the prospective defendant must provide the claimant with notice of such interview at least 10 days before the date of the interview.

Section 13. Section 766.1091, Florida Statutes, is created to read:

766.1091 Voluntary binding arbitration; damages.—

(1) A health care provider licensed under chapter 458, chapter 459, chapter 463, or chapter 466; any entity owned in whole or in part by a health care provider licensed under chapter 458, chapter 459, chapter 463, or chapter 466; or any health care clinic licensed under part X of chapter 400, and a patient or prospective patient, may agree in writing to submit to arbitration any claim for medical negligence which may currently exist or may accrue in the future and would otherwise be brought pursuant to this chapter. Any arbitration agreement entered into pursuant to this section shall be governed by chapter 682.

(2) Any arbitration agreement entered into pursuant to subsection (1) may contain a provision that limits the available damages in an arbitration award.

Section 14. Subsection (21) of section 893.02, Florida Statutes, is amended to read:

893.02 Definitions.—The following words and phrases as used in this chapter shall have the following meanings, unless the context otherwise requires:

(21) "Practitioner" means a physician licensed pursuant to chapter 458, a dentist licensed pursuant to chapter 466, a veterinarian licensed pursuant to chapter 474, an osteopathic physician licensed pursuant to chapter 459, a naturopath licensed pursuant to chapter 462, a certified optometrist licensed under chapter 463, or a podiatric physician licensed pursuant to chapter 461, provided such practitioner holds a valid federal controlled substance registry number.

Section 15. Subsection (1) of section 893.05, Florida Statutes, is amended to read:

358292

893.05 Practitioners and persons administering controlled substances in their absence.—

(1) A practitioner, in good faith and in the course of his or her professional practice only, may prescribe, administer, dispense, mix, or otherwise prepare a controlled substance, or the practitioner may cause the same to be administered by a licensed nurse or an intern practitioner under his or her direction and supervision only. A veterinarian may so prescribe, administer, dispense, mix, or prepare a controlled substance for use on animals only~~,~~ and may cause it to be administered by an assistant or orderly under the veterinarian's direction and supervision only. A certified optometrist licensed under chapter 463 may not administer or prescribe pharmaceutical agents in Schedule I or Schedule II of the Florida Comprehensive Drug Abuse Prevention and Control Act.

Section 16. This act shall take effect July 1, 2012.

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

And the title is amended as follows:

Delete everything before the enacting clause and insert:

A bill to be entitled

An act relating to health care; amending s. 463.002, F.S.; conforming provisions to changes made by the act; amending s. 463.005, F.S.; authorizing the Board of Optometry to adopt rules for the administration and prescription of ocular pharmaceutical agents; amending s. 463.0055, F.S.; authorizing certified optometrists

358292

to administer and prescribe pharmaceutical agents under certain circumstances; requiring that a certified optometrist complete a course and subsequent examination on general and ocular pharmacology; providing requirements for the course; requiring that the Florida Medical Association and the Florida Optometric Association jointly develop and administer the course and examination; revising qualifications of certain members of the formulary committee; providing for a formulary of topical ocular pharmaceutical agents which the committee may modify; specifying the agents that make up the statutory formulary of oral pharmaceutical agents; authorizing the deletion of an oral pharmaceutical agent listed in the statutory formulary under certain circumstances; prohibiting the board, the Department of Health, or the State Surgeon General from deleting an oral pharmaceutical agent listed in the statutory formulary; amending ss. 463.0057 and 463.006, F.S.; conforming provisions to changes made by the act; amending s. 463.0135, F.S.; requiring that a certified optometrist administer and prescribe oral ocular pharmaceutical agents in a certain manner; requiring that a licensed practitioner who diagnoses a patient who has a neovascular form of glaucoma or progressive glaucoma immediately refer the patient to a physician who is skilled in the diseases of the eye; requiring that comanagement of postoperative care be conducted pursuant to an established protocol; requiring that the patient be

358292

informed that a physician will be available for emergency care throughout the postoperative period; requiring that the patient consent in writing to the comanagement relationship; amending s. 463.014, F.S.; revising certain prohibited acts regarding an optometrist conducting surgery and dispensing, administering, ordering, supplying, or selling certain drugs; creating s. 463.0141, F.S.; requiring that adverse incidents in the practice of optometry be reported to the Department of Health; providing requirements for notifying the department of an adverse incident; providing a definition; requiring that the department review each incident and determine whether it involved conduct that is subject to disciplinary action; requiring that the Board of Optometry take disciplinary action if necessary; amending s. 483.035, F.S., relating to licensure and regulation of clinical laboratories operated by practitioners for exclusive use; providing applicability to clinical laboratories operated by practitioners licensed to practice optometry; amending s. 483.041, F.S.; revising the definition of the term "licensed practitioner" to include a practitioner licensed under ch. 463, F.S.; amending s. 483.181, F.S.; requiring clinical laboratories to accept human specimens submitted by practitioners licensed to practice under ch. 463, F.S.; amending s. 766.106, F.S.; authorizing a prospective defendant to obtain informal discovery by conducting ex parte interviews

358292

of treating health care providers; requiring advance notice to the claimant of an ex parte interview; creating s. 766.1091, F.S.; authorizing a health care provider or health care clinic and a patient or prospective patient to agree to submit a current or future claim of medical negligence to arbitration; requiring that the arbitration agreement be governed by ch. 682, F.S.; authorizing the arbitration agreement to contain a provision that limits an award of damages; amending s. 893.02, F.S.; revising the definition of the term "practitioner" to include certified optometrists for purposes of the Florida Comprehensive Drug Abuse Prevention and Control Act; amending s. 893.05, F.S.; prohibiting certified optometrists from administering and prescribing certain controlled substances; providing an effective date.

800732

LEGISLATIVE ACTION

Senate	.	House
Comm: WD	.	
02/09/2012	.	
	.	
	.	
	.	

The Committee on Health Regulation (Diaz de la Portilla) recommended the following:

Senate Amendment to Substitute Amendment (358292) (with title amendment)

Delete lines 387 - 403.

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

And the title is amended as follows:

Delete lines 508 - 515

and insert:

amending s. 893.02, F.S.; revising the

THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

SENATOR JOHN THRASHER
8th District

COMMITTEES:
Rules, *Chair*
Budget - Subcommittee on Higher Education Appropriations, *Vice Chair*
Budget
Budget - Subcommittee on Criminal and Civil Justice Appropriations
Community Affairs
Judiciary
Reapportionment
Regulated Industries
Rules - Subcommittee on Ethics and Elections

January 23, 2012

MEMORANDUM

To: Senator Rene Garcia, Chairman
Senate Committee on Health Regulation

Fm: Senator John Thrasher

Re: Senate Bill 1506; Medical Malpractice

It will be appreciated if you will agenda my Senate Bill 1506 for a hearing by the Senate Committee on Health Regulation at the earliest practicable time.

Thank you for your consideration of this request.

ENTERED

REPLY TO:
❒ 9485 Regency Square Boulevard, Suite 108, Jacksonville, Florida 32225-8145 (904) 727-3600
❒ 400 Senate Office Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5030
1-888-861-9761

Senate's Website: *www.flsenate.gov*

MIKE HARIDOPOLOS
President of the Senate

MICHAEL S. "MIKE" BENNETT
President Pro Tempore

THE FLORIDA SENATE

APPEARANCE RECORD

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

02.09.12
Meeting Date

Topic Medical Malpractice

Bill Number 1506 *(if applicable)*

Name William Large

Amendment Barcode 358292 *(if applicable)*

Job Title President

Address 210 South Monroe Street
Street
Tallahsasee FL 32301
City *State* *Zip*

Phone 850-222-0170

E-mail William@fljustice.org

Speaking: ☑ For ☐ Against ☐ Information

Representing Florida Justice Reform Institute

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

2/9/2012
Meeting Date

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

Topic Garcia Amendment Bill Number 1506 *(if applicable)*

Name Stephen Cain Amendment Barcode 358292 *(if applicable)*

Job Title

Address 1SE 3rd Ave., Suite 3000 Phone 305-358-6644
Street

Miami, FL 33131 E-mail scain@stfblaw.com
City *State* *Zip*

Speaking: ☒ For ☐ Against ☐ Information

Representing Florida Justice Assoc.

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.

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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)

2/9/12
Meeting Date

Topic _____ Bill Number 1506 *(if applicable)*

Name Jim Gustafson Amendment Barcode 355292 *(if applicable)*

Job Title _____

Address 517 N. Calhoun St. *Street* Phone 850-251-4011

Tallahassee Fl 32301 *City* *State* *Zip* E-mail jwgustafson@gmail.com

Speaking: ☒ For ☐ Against ☐ Information
Amendment

Representing _____

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.

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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)

2-9-12
Meeting Date

Topic Medical Malpractice

Bill Number 1506

Name Rebecca O'Hara *2 Amendments: 358292 (Garcia) (if applicable)

Amendment Barcode 800732 (DLP) (if applicable)

Job Title VP & Governmental Affairs

Address PO BOX 10269
Street

Phone 224-6496

Tallahassee
City *State* *Zip*

E-mail

Speaking: ☐ For ☒ Against ☐ Information AGAINST 2 Amendments

Representing FL Medical 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)

2/8/2012
Meeting Date

Topic _____ Bill Number 1506 *(if applicable)*

Name Mark Delegal Amendment Barcode 800732 *(if applicable)*

Job Title Retained Counsel

Address 215 S. Monroe Street #200 Phone 850-222-3533
Street

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

Speaking: ☐ For ☑ Against ☐ Information

Representing Safety Net Hospital Alliance

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)

02.09.12
Meeting Date

Topic Medical Malpractice

Bill Number 1506 *(if applicable)*

Name William Large

Amendment Barcode 227268 *(if applicable)*

Job Title President

Address 210 South Monroe Street
Street

Tallahsasee FL 32301
City *State* *Zip*

Phone 850-222-0170

E-mail William@fljustice.org

Speaking: ☑ For ☐ Against ☐ Information

Representing Florida Justice Reform Institute

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)

2/9/12
Meeting Date

Topic _____ Bill Number SB 1506 *(if applicable)*

Name Charles Slonim MD Amendment Barcode 227268 *(if applicable)*

Job Title ophthalmologist

Address 1077 N. 46th St. Phone 813 974 2064
Street

Tampa, FL 33617 E-mail cslonim@health.usf.edu
City *State* *Zip*

Speaking: ☐ For ☒ Against ☐ Information

Representing Florida Society of Ophthalmology & American Academy of Ophthalmology

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)

2/9/12
Meeting Date

Topic Medical Malpractice

Bill Number 1506

Name ~~A Horney~~ ALEXANDER CLEM

Amendment Barcode 784708 *(if applicable)*

(if applicable)

Job Title A Horney

Address 20 No. Orange Ave
Street

Orlando FL 32801
City *State* *Zip*

Phone 407-420-1414

E-mail aclem@forthepeople.com

Speaking: ☑ For ☐ Against ☐ Information

amendment

Representing FJA

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)

2/9/12
Meeting Date

Topic _____ Bill Number SB 1506 *(if applicable)*

Name Jeff Scott Amendment Barcode 784708 *(if applicable)*

Job Title _____

Address 113 E. College Ave. Phone 224-6496
Street

Tallahassee FL 32309 E-mail jscott@medone.org
City *State* *Zip*

Speaking: ☐ For ☑ Against ☐ Information

Representing Amendment Florida Medical Association

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

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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)

02.09.12
Meeting Date

Topic Medical Malpractice

Bill Number 1506 *(if applicable)*

Name William Large

Amendment Barcode 784708 *(if applicable)*

Job Title President

Address 210 South Monroe Street
Street

Phone 850-222-0170

Tallahassee, FL 32301
City *State* *Zip*

E-mail William@fljustice.org

Speaking: ☐ For ☑ Against ☐ Information

Representing Florida Justice Reform Institute

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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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)

2/9/12
Meeting Date

Topic MED MAL

Bill Number 1506 *(if applicable)*

Name DR. KEN LAWSON

Amendment Barcode *(if applicable)*

Job Title LEGISLATIVE CHAIRMAN

Address 120 S. MONROE ST.
Street

Phone 850.727-7087

TALLAHASSEE, FL 32301
City *State* *Zip*

E-mail

Speaking: ☑ For ☐ Against ☐ Information

Representing FLORIDA OPTOMETRIC ASSOCIATION

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☐ Yes ☑ No

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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)

Feb 9 2012
Meeting Date

Topic Healthcare

Bill Number 1506 *(if applicable)*

Name Dr. Scott Hopes

Amendment Barcode *(if applicable)*

Job Title CEO

Address 13955 SW 127 ST
Street
Miami, FL 33186
City *State* *Zip*

Phone 305-776-0049

E-mail scott.hopes@hnd-healthcare.com

Speaking: ☒ For ☐ Against ☐ Information

Representing Florida Optometric Association

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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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)

2-8-12
Meeting Date

Topic Med Mal + Optometry Bill Number 1506 *(if applicable)*

Name Neal Dunn, M.D. Amendment Barcode *(if applicable)*

Job Title

Address 80 Doctors Dr Phone 850 785 8557
Street

Panama City FL 32405 E-mail
City *State* *Zip*

Speaking: ☒ For ☐ Against ☐ Information

Representing Fla Medical Assn

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

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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)

02.09.12
Meeting Date

Topic Medical Malpractice

Bill Number 1506 *(if applicable)*

Name William Large

Amendment Barcode _____ *(if applicable)*

Job Title President

Address 210 South Monroe Street
Street
Tallahsasee FL 32301
City *State* *Zip*

Phone 850-222-0170

E-mail William@fljustice.org

Speaking: ☑ For ☐ Against ☐ Information

Representing Florida Justice Reform Institute

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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S-001 (10/20/11)

Waive in support

THE FLORIDA SENATE

APPEARANCE RECORD

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

2/9/12
Meeting Date

Topic Tort Reform

Bill Number SB 1506 *(if applicable)*

Name Ron Watson

Amendment Barcode *(if applicable)*

Job Title Lobbyist

Address 118 E Jefferson
Street
Tallahassee FL 32301
City *State* *Zip*

Phone 224-1089

E-mail rwatson@floridadental.org

Speaking: ☐ For ☐ Against ☐ Information

Representing FDA - Florida Dental Association

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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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)

2/9/12
Meeting Date

Topic _____ Bill Number 1506 *(if applicable)*

Name Teye Reeves Amendment Barcode _____ *(if applicable)*

Job Title Policy Director

Address 136 S. Bronough ST Phone 850 521 1235

Street

Tallahassee FL 32301 E-mail teye@flchamber.com

City *State* *Zip*

Speaking: ☒ For ☐ Against ☐ Information

Representing FL Chamber of Commerce

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

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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 Health Regulation Committee

BILL: CS/SB 1516

INTRODUCER: Children, Families, and Elder Affairs Committee, Senator Negron, and others

SUBJECT: Agency for Persons with Disabilities

DATE: January 28, 2012 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Daniell	Farmer	CF	**Fav/CS**
2.	Wilson	Stovall	HR	**Pre-meeting**
3.			BC	
4.				
5.				
6.				

Please see Section VIII. for Additional Information:

A. COMMITTEE SUBSTITUTE.....	X	Statement of Substantial Changes
B. AMENDMENTS.....		Technical amendments were recommended
		Amendments were recommended
		Significant amendments were recommended

I. Summary:

This bill makes significant changes to Florida law relating to the Agency for Persons with Disabilities (APD or agency). Specifically, the bill:

- Provides that it is the intent of the Legislature to prioritize state funds for those services needed to ensure the health and safety of individuals with disabilities, and that other services should be supported through natural supports and community resources, with the Medicaid waivers being the payor of last resort for home and community-based programs;
- Defines "adult day services," "nonwaiver resources," and "waiver"; amends the definition of "adult day training," "personal care services," and "support coordinator"; and deletes the definition of "domicile";
- Requires an individual to be a U.S. citizen or qualified noncitizen in order to receive services;
- Makes the authorization of certain services contingent on available funding;
- Provides that tier eligibility under the four-tiered waiver system may not be made until a waiver slot and funding become available, and that assignment to a higher tier must be based on crisis criteria;
- Prohibits the APD from authorizing a waiver service if that service can be covered by the Medicaid state plan;

- Removes the $150,000 per-client cap for total annual tier one expenditures per year;
- Changes the definitions of tier two and tier three to include clients whose need for services meets the criteria of the tier above but which can be met within the expenditure of either tier two or tier three;
- Authorizes the APD to collect fees, in addition to premiums or other cost sharing methods, from the parents of children being served by a waiver;
- Establishes a framework to evaluate waiver support coordinators;
- Provides flexibility to a client in determining the type, amount, frequency, duration, and scope of services if the agency determines such services meet the individual's health and safety needs;
- Provides a methodology for the determination of a client's iBudget allocation;
- Provides for an abbreviated inspection and review process if a facility has certain accreditation;
- Authorizes the APD to execute a petition for involuntary admission to residential services;
- Authorizes the APD to issue a final order at the conclusion of a Medicaid hearing conducted by the Department of Children and Family Services (DCF or department);
- Provides that the welfare of clients includes the establishment, maintenance, and operation of sheltered workshops that include client wages;
- Prohibits the premium, fee, or other cost sharing paid by a parent on behalf of a child under the age of 18 from exceeding the cost of waiver services to the client;
- Provides that a client may not be denied waiver services due to nonpayment by a parent, however, adoptive and foster parents are exempt from payment of any premiums, fees, or other cost-sharing; and
- Makes technical and conforming changes.

This bill substantially amends the following sections of the Florida Statutes: 393.062, 393.063, 393.065, 393.066, 393.0661, 393.0662, 393.067, 393.068, 393.11, 393.125, 393.23, 409.906, and 514.072.

II. Present Situation:

Agency for Persons with Disabilities

In October 2004, the Developmental Disabilities Program separated from the DCF and became the APD.[1] The agency was tasked with serving the needs of Floridians with developmental disabilities.[2] The primary purpose of the APD is to work in partnership with local communities to ensure the safety, well-being, and self-sufficiency of the people served by the agency, and provide assistance in identifying needs and funding to purchase supports and services.[3]

[1] Agency for Persons with Disabilities, *About Us.* Found at: <http://apdcares.org/about/> (Last visited on January 27, 2012).
[2] *Id.*
[3] Office of Program Policy Analysis & Government Accountability, The Florida Legislature, *Agency for Persons with Disabilities.* Found at: <http://www.oppaga.state.fl.us/profiles/5060/> (Last visited on January 27, 2012).

The agency provides services to individuals with developmental disabilities[4] in home and community-based settings, private intermediate care facilities, or state-run developmental services institutions. Individuals who need minimal or limited support may live in their own home, a family home, or a group home, all of which are considered "home and community-based settings." During fiscal year 2009-2010, the APD served over 53,000 individuals in the community.[5]

One of the primary goals of the APD is to improve the quality of life of persons with disabilities by helping them live and work in the community, rather than being placed in an institution. Toward that end, the APD administers the Home and Community-based Services waivers (HCBS waivers) system. This system offers 28 supports and services to assist individuals with developmental disabilities live in their community.[6] The system has four tiers, described below:

- Tier one is limited to individuals with intensive medical or adaptive needs and for whom services are essential to avoid institutionalization, or who possess exceptional behavioral problems. Tier one has a $150,000 per-client annual expenditure cap, unless the individual can show a documented medical necessity requiring intensive behavioral residential habilitation services, intensive behavioral residential habilitation services with medical needs, or special medical home care. Tier one is limited to persons with service needs that can't be met in any of the other tiers.
- Tier two is for individuals who have high-cost residential facility and residential habilitation service needs or supported living needs that are greater than six hours per day. Tier two has a $53,625 per-client annual expenditure cap.
- Tier three has a $34,125 per-client annual expenditure cap and is for individuals who require lower residential placements, independent or supported living situations, and persons who live in their family home.
- Tier four has a $14,422 per-client annual expenditure cap and is for individuals who were formerly enrolled in the Family and Supported Living Waiver. This tier funds 12 services.[7]

For Fiscal Year 2011-2012, the APD was appropriated $1,009,499,581 by the Florida Legislature to operate the agency.[8] Out of that, $810 million – or approximately 80 percent – is budgeted for clients on the Medicaid HCBS waivers.[9] In October 2011, 29,641 individuals were served by the HCBS waivers.[10]

Historically, the agency has had problems keeping waiver spending in line with its appropriation. In Fiscal Year 2005-2006, the APD was required to provide quarterly reports to the Executive Office of the Governor, the chair of the Senate Ways and Means Committee, and the chair of the

[4] Section 393.063(9), F.S., defines the term "developmental disability" as a disorder or syndrome that is attributable to retardation, cerebral palsy, autism, spina bifida, or Prader-Willi syndrome; that manifests before the age of 18; and that constitutes a substantial handicap that can reasonably be expected to continue indefinitely.
[5] Office of Program Policy Analysis & Government Accountability, *supra* note 3.
[6] Agency for Persons with Disabilities, *HCBS Waiver Services*. Found at: <http://apd.myflorida.com/brochures/supports-and-services-brochure.pdf> (Last visited on January 28, 2012).
[7] Office of Program Policy Analysis & Government Accountability, *supra* note 3.
[8] *Id*.
[9] Agency for Persons with Disabilities, *2012 Bill Analysis, SB 1516* (January 20, 2012) (on file with the Senate Committee on Children, Families, and Elder Affairs).
[10] *Id*.

House Fiscal Council regarding the financial status of the HCBS waivers.[11] In a presentation on its Fiscal Year 2009-2010 Legislative Budget Request, the agency reported "significant progress" in managing the waivers.[12] However, in March 2009, the agency requested $26 million to cover the remaining HCBS waivers deficit, and by February 2010, the APD's budget recommendation included a request for $100 million to eliminate the projected deficit in the HCBS waivers.[13] The deficit reached nearly $169 million during the 2011 Regular Session,[14] and the agency is facing the same challenges in Fiscal Year 2011-2012, as the agency is projecting $930 million in community-based expenditures which is to be covered with an $810 million legislative appropriation.[15]

A number of strategies have been employed to achieve the goal of containing costs, including: a standardized rate structure; ongoing utilization reviews; a prior authorization process for services; pre-payment billing review; support coordination; and capping costs through use of a tiered rate structure based on an assessment of needs.[16]

In 2010, the Legislature directed the APD to pursue development and implementation of a comprehensive redesign of the HCBS waivers delivery system to combat deficit spending. Individual Budgeting, known as iBudget Florida, involves giving each waiver service recipient an annual budget that is based on the legislative appropriation and factors that include an individual's abilities, disability, needs, and living situation.[17] The iBudget system will replace the tier structure. The state received federal approval to implement the iBudget system in March 2011, and implementation has begun in North Florida.[18]

Medicaid

Medicaid is the medical assistance program that provides access to health care for low-income families and individuals. Medicaid also assists aged and disabled people with the costs of nursing facility care and other medical expenses. Medicaid reimburses health care providers that have a provider agreement with the Agency for Health Care Administration only for goods and services that are covered by the Medicaid program and only for individuals who are eligible for medical assistance from Medicaid.

The Agency for Health Care Administration is responsible for Medicaid. Medicaid serves approximately 3.19 million people in Florida. Estimated Medicaid expenditures for FY 2011-2012 are approximately $20.3 billion. The statutory authority for the Medicaid program is contained in part III of ch. 409, F.S.

[11] Chapter 2005-70 and Chapter 2005-71, L.O.F. This requirement is now codified in s. 393.0661(9), F.S.
[12] Budget Committee, The Florida Senate, *Bill Analysis and Fiscal Impact Statement SB 2148*, (April 1, 2011). Found at: <http://www.flsenate.gov/Session/Bill/2011/2148/Analyses/YX4Y4hiD5jfSJG5bH97TJYAiHoA=%7C7/Public/Bills/2100-2199/2148/Analysis/2011s2148.bc.PDF> (Last visited on January 27, 2012).
[13] *Id*.
[14] *Id*.
[15] Agency for Persons with Disabilities, *supra* note 9.
[16] *Id*.
[17] *Id*.
[18] *Id*.

Medicaid HCBS waiver programs are authorized under s. 1915(c) of the Social Security Act and governed by Title 42, Code of Federal Regulations (C.F.R.), Parts 440 and 441. Section 409.906, F.S., and Chapter 59G, Florida Administrative Code (F.A.C.), authorize the Florida Medicaid developmental disabilities waivers. There are five Medicaid HCBS waivers; the Developmental Disabilities waivers Tiers 1-4 and the Individual Budgeting waiver. The Developmental Disabilities Waivers Tiers One, Two, Three, and Four are Medicaid programs that provide home and community-based supports and services to eligible persons with developmental disabilities living at home or in a home-like setting. The waivers are funded by the federal Centers for Medicare and Medicaid Services and matching state dollars.

III. Effect of Proposed Changes:

This bill makes significant changes to Florida law relating to the APD. According to the agency, the changes proposed in this bill will:

> [A]ssist the agency in improving accountability, predicting cost and allocating [scarce] resources. . . The bill continues the evolvement of the basic waiver program structure, and emphasizes a more robust utilization of natural supports and community resources to augment waiver resources. The bill's strategic approach is to make the Medicaid waivers only one of the many strategies employed to address the needs of individuals with disabilities and the waiver as the funding of last resort.[19]

Section 1 amends s. 393.062, F.S., to state that priority *should*, rather than *shall*, be given to the development and implementation of community-based services that will enable individuals to achieve their greatest potential for independent and productive living in noninstitutional settings. The bill provides that it is the intent of the Legislature to prioritize state funds for those services needed to ensure the health and safety of individuals with disabilities, and that other services be supported through natural supports and community resources. To accomplish this goal, the bill provides that the Medicaid waiver will be the payor of last resort for home and community-based programs.

Section 2 amends s. 393.063, F.S., to define:

- "Adult day services" as services that are provided in a nonresidential setting, separate from the home or facility in which the client resides, unless the client resides in a planned residential community as defined in s. 419.001(1), F.S.; that are intended to support the participation of clients in daily, meaningful, and valued routines of the community; and that may provide social activities.
- "Nonwaiver resources" as supports or services obtainable through private insurance, the Medicaid state plan, nonprofit organizations, charitable donations from private businesses, other government programs, family, natural supports, community resources, and any other source other than a waiver.
- "Waiver" as a federally approved Medicaid waiver program, including, but not limited to, the Developmental Disabilities Home and Community-Based Services Waivers Tiers 1-4, the Developmental Disabilities Individual Budget Waiver, and the Consumer-Directed Care Plus

[19] *Id*.

Program, authorized pursuant to s. 409.906, F.S., and administered by the agency to provide home and community-based services to clients.

The bill also amends the definitions of "adult day training," "developmental disability," "personal care services," and "support coordinator." The definition of "developmental disability" is amended to include Down syndrome. The bill deletes the definition of "domicile."

Section 3 amends s. 393.065, F.S., to limit eligibility for APD services to U.S. citizens and qualified noncitizens who meet the criteria provided in s. 414.095(3), F.S.,[20] and who have established domicile in Florida or are otherwise determined to be legal residents of this state.

Section 4 amends s. 393.066, F.S., to clearly delineate the agency's goal of providing community services in the most cost-effective manner, to the extent resources are specified in the General Appropriations Act, to avoid institutionalization. The bill narrows the scope of the purpose of APD services, removes a requirement that all elements of community-based services must be made available, and removes a requirement that eligibility for services must be consistent across the state.

The bill revises the list of services allowed by adding adult day services, residential habilitation services, and support coordination. The bill removes from the list of services parent training, recreation, and social services. The bill requires the APD to identify and engage in efforts to develop, increase, or enhance the availability of nonwaiver resources to individuals and to promote collaborative efforts with families and organizations. Subsection 393.066(5), F.S., relating to the development of day habilitation services is deleted.[21]

Section 5 amends s. 393.0661, F.S., to specify that a final determination of tier eligibility may not be made until a waiver slot and funding becomes available. A client who is eligible for a higher tier may only move based on crisis criteria as adopted by rule. The bill authorizes the agency to move a client to a lower tier if the client's service needs change and can be met by services provided in a lower tier. Also, the bill provides that the APD may not authorize services that are duplicated by, or above the coverage limits of, the Medicaid state plan.

The bill amends the current tier structure. First, the bill removes the $150,000 per-client expenditure cap in tier one. The bill amends tier two to provide that it also includes clients whose need for services meets the criteria for tier one but which can be met within the expenditure limit of tier two. Tier three is also amended to provide that the tier includes clients whose need for services meets the criteria for tier two but which can be met within the expenditure limit of tier three.

The bill removes language concerning adjusting a client's cost plan that is supported by certain waivers to conform with other sections of the bill.

[20] Section 414.095(3), F.S., defines which noncitizens are eligible for cash assistance through the Temporary Assistance for Needy Families (TANF) program.
[21] According to the APD, deleting the language in subsection (5) of s. 393.066, F.S., is technical and conforming in nature. Agency for Persons with Disabilities, *supra* note 9.

The bill authorizes the APD to collect fees, in addition to premiums or other cost sharing, from the parents of children younger than 18 years of age being served by the agency through a waiver. Refer to section 12 of the bill for limits on the fees.

The bill makes a support coordinator responsible for assisting the client in meeting his or her service needs through nonwaiver resources, as well as through the client's budget allocation or cost plan under the waiver. The bill requires the APD to review waiver support coordination performance to ensure that the support coordinator meets or exceeds the criteria established by the agency. Criteria for evaluating support coordinator performance include:

- The protection of the health and safety of clients.
- Assisting clients to obtain employment and pursue other meaningful activities.
- Assisting clients to access services that allow them to live in their community.
- The use of family resources.
- The use of private resources.
- The use of community resources.
- The use of charitable resources.
- The use of volunteer resources.
- The use of services from other governmental entities.
- The overall outcome in securing nonwaiver resources.
- The cost-effective use of waiver resources.
- Coordinating all available resources to ensure that clients' outcomes are met.

The agency is authorized to exempt a waiver support coordinator from annual quality assurance reviews if the coordinator consistently has superior performance, and the agency may sanction poor performance.

Section 6 amends s. 393.0662, F.S., relating to the iBudget. The bill provides that a client shall have the flexibility to determine the type, amount, frequency, duration, and scope of the services on his or her cost plan if the agency determines that such services meet his or her health and safety needs, meet the requirements contained in the Coverage and Limitations Handbook, and comply with the other requirements of s. 393.0662, F.S.

Further, the bill provides that during the 2011-2012 and 2012-2013 fiscal years, the APD shall determine a client's iBudget by comparing the client's algorithm allocation to the client's existing annual cost plan and the amount for the client's extraordinary needs. A client's allocation is the amount determined by the algorithm, adjusted to the APD's appropriation, and any necessary set-asides, such as funding for extraordinary needs. A client's extraordinary needs shall be the annualized sum of any of the following services authorized on the client's cost plan in the amount, duration, frequency, intensity, and scope determined by the agency to be necessary for the client's health and safety:

- Behavior assessment, behavior analysis services, and behavior assistant services.
- Consumable medical supplies.
- Durable medical equipment.
- In-home support services.
- Nursing services.
- Occupational therapy assessment and occupational therapy.

- Personal care assistance.
- Physical therapy assessment and physical therapy.
- Residential habilitation.
- Respiratory therapy assessment and respiratory therapy.
- Special medical home care.
- Support coordination.
- Supported employment.
- Supported living coaching.

The bill does not reference a client's "significant needs" when determining a client's iBudget allocation, although current law provides that the APD may approve an increase in the amount of money allocated based on a client having significant needs (see lines 905-965 of the bill). However, according to the APD, both a client's significant needs and extraordinary needs will be considered when calculating a client's iBudget allocation.[22]

The way the APD determines a client's initial iBudget allocation is if the client's algorithm allocation is:

- Greater than the client's cost plan, the client's iBudget is equal to the cost plan.
- Less than the client's cost plan but greater than the amount for the client's extraordinary needs, the client's iBudget is equal to the algorithm allocation.
- Less than the amount for the client's extraordinary needs, the client's iBudget is equal to the amount for the client's extraordinary needs.

The bill provides that a client's initial iBudget amount may not be less than 50 percent of that client's existing annualized cost plan. Increases to the client's initial iBudget amount may only be granted if his or her situation meets the crisis criteria.

Section 7 amends s. 393.067, F.S., to authorize the APD to inspect and review facilities or programs that have certain accreditation once every two years, rather than annually. Notwithstanding accreditation, the APD may continue to monitor the facility or program with respect to:

- Ensuring that services for which the agency is paying are being provided;
- Investigating complaints, identifying problems that would affect the safety or viability of the facility or program, and monitoring the facility or program's compliance with any resulting negotiated terms and conditions;
- Ensuring compliance with federal and state laws, federal regulations, or state rules if such monitoring does not duplicate the accrediting organization's review; and
- Ensuring Medicaid compliance with federal certification and precertification review requirements.

Section 8 amends s. 393.068, F.S., to make technical and conforming changes.

[22] E-mail from Chris Coker, Legislative Affairs Director, Agency for Persons with Disabilities, to Senate professional staff of the Committee on Children, Families, and Elder Affairs (January 24, 2012) (on file with the Senate Committee on Children, Families, and Elder Affairs).

Section 9 amends s. 393.11, F.S., to authorize the APD to execute a petition for involuntary admission to residential services. In cases of involuntary admission, the individual ("defendant" as changed by this bill) has a right to notice and a hearing. At the hearing, if the defendant's attorney or any other interested party believes that the person's presence at the hearing is not in the person's best interest, or good cause is otherwise shown, the court may order that the defendant be excluded from the hearing.

Section 10 amends s. 393.125, F.S., to provide that at the conclusion of the hearing related to Medicaid programs, the DCF shall submit its recommended order to the APD and the agency shall issue the final order. This is current practice.

Section 11 amends s. 393.23, F.S., to provide that the welfare of clients includes the establishment, maintenance, and operation of sheltered workshops that include client wages.

Section 12 amends s. 409.906, F.S., to provide that premiums, fees, or other cost sharing for home and community-based services may not exceed the cost of the services to the client, and for parents who have more than one child, the parent may not be required to pay more than the amount required for the child with the highest expenditures. The bill provides that a client may not be denied services due to nonpayment by a parent. Adoptive and foster parents are exempt from payment of any premiums, fees, or other cost sharing. The bill authorizes the Agency for Health Care Administration, the APD, and the DCF to adopt rules to administer this paragraph.

Section 13 amends s. 514.072, F.S., to correct a cross-reference, delete obsolete language, and make conforming changes.

Section 14 provides an effective date of July 1, 2012.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of the bill have no impact on public records or open meetings issues under the requirements of Article I, Section 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

This bill spells out the APD methodology for determining a client's iBudget allocation. The way the APD determines a client's initial iBudget allocation is if the client's algorithm allocation is:

- Greater than the client's cost plan, the client's iBudget is equal to the cost plan.
- Less than the client's cost plan but greater than the amount for the client's extraordinary needs, the client's iBudget is equal to the algorithm allocation.
- Less than the amount for the client's extraordinary needs, the client's iBudget is equal to the amount for the client's extraordinary needs.

It appears that in certain situations, a client's iBudget allocation may be less than what he or she is receiving with their current cost plan.

C. Government Sector Impact:

According to the APD and the Agency for Health Care Administration, this bill is not expected to have a fiscal impact on either agency.

The bill amends s. 393.125, F.S., specifying that at the conclusion of a Medicaid hearing, the DCF shall submit a recommended order to the APD, and the agency shall issue the final order. According to the DCF, its Office of Appeals Hearings currently issues recommended orders in Medicaid waiver benefits cases. Accordingly, the bill does not appear to have a fiscal impact on the DCF.[23]

VI. Technical Deficiencies:

On lines 202-203, the definition of "down syndrome" is changed. Down syndrome occurs when some or all of a person's cells have an extra full or partial copy of chromosome 21.[24] The words "full or partial" should be inserted after the word "extra."

Section 5 of the bill (starting on line 522) removes intent language that APD develop and implement a comprehensive redesign of the home and community-based services delivery system. Reference to the "redesign" is also deleted on line 533. These references are being deleted because the system redesign has already occurred. Accordingly, the Legislature may wish to amend the bill to remove "comprehensive redesign" from the catch-line of the statute on line 525.

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[23] Department of Children and Families, *Staff Analysis and Economic Impact, SB 1516* (January 10, 2012) (on file with the Senate Committee on Children, Families, and Elder Affairs).
[24] *Down Syndrome Fact Sheet*, National Down Syndrome Society. Found at: <http://www.ndss.org/index.php?option=com_content&view=article&id=54:down-syndrome-fact-sheet&catid=35:about-down-syndrome&Itemid=74> (Last visited on January 28, 2012).

On line 821, the bill refers to "Medicaid" waiver programs. The word "Medicaid" is removed in the rest of the bill when referring to waivers or waiver programs.

On lines 977 and 980, the bill refers to a cost plan. The term is not defined in statute. The Legislature may wish to include a definition of "cost plan" in s. 393.063, F.S. The cost plan is the document used by the waiver support coordinator that lists all waiver services requested by the recipient on the support plan and the anticipated cost of each waiver service.[25]

On lines 1170-1172, the bill authorizes the APD to execute a petition for involuntary admission to residential services. In current law only a petitioning commission can execute the petition and the "name, age, and present address of the commissioners and their relationship to the person" must be listed in the petition (see lines 1177-1179). The bill does not require similar identifying information to be provided if the agency is the one executing the petition. According to the APD, the agency and any agency witnesses are easily identified and contacted.[26] However, it may still be beneficial to provide a requirement for the agency to list some contact information in the petition.

VII. Related Issues:

Under the bill, the APD would be the agency that issues final orders in Medicaid fair hearings. This creates a conflict with existing state law and federal law and rules that require the Agency for Health Care Administration to be the single state Medicaid agency designated to administer or supervise the administration of the State Medicaid Plan, including providing for Medicaid Fair Hearings. The DCF conducts fair hearings pursuant to an agreement with the Agency for Health Care Administration.[27]

VIII. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by the Children, Families, and Elder Affairs Committee on January 25, 2012
The committee substitute:

- Adds the phrase "unless the client resides in a planned residential community as defined in s. 419.001(1)" to both the newly created definition of "adult day services" and to the current definition of "adult day training";
- Removes the prohibition of a client or support coordinator from applying for additional waiver funding unless the client is determined to be in crisis;

[25] Agency for Health Care Administration, Florida Medicaid, *Developmental Disabilities Waiver Services Coverage and Limitations Handbook*, page 2-9, May 2010. Found at: http://portal.flmmis.com/FLPublic/Portals/0/StaticContent/Public/HANDBOOKS/CL_10_100501_DD_Waiver_ver1.0.pdf (Last visited on January 27, 2012).
[26] E-mail from Chris Coker, Legislative Affairs Director, Agency for Persons with Disabilities, to Senate professional staff of the Committee on Children, Families, and Elder Affairs (January 24, 2012) (on file with the Senate Committee on Children, Families, and Elder Affairs).
[27] Agency for Health Care Administration, *2012 Bill Analysis and Economic Impact Statement for SB 1516*, (on file with the Senate Committee on Health Regulation).

- Revises the list of available community services allowed as long as the APD has the resources specified in the General Appropriations Act; and
- Reinstates current law relating to the rate structure for reimbursing a provider of services rendered to a persons with developmental disabilities pursuant to a waiver.

B. Amendments:

None.

636972

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
02/09/2012	.	
	.	
	.	
	.	

The Committee on Health Regulation (Gaetz) recommended the following:

Senate Amendment

Delete line 438
and insert:
their own homes or communities, to support them in maximizing their independence using innovative, effective, efficient, and sustainable solutions, and to avoid institutionalization

311224

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
02/09/2012	.	
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The Committee on Health Regulation (Gaetz) recommended the following:

Senate Amendment

Delete lines 997 - 1042
and insert:
(a) During the transition, the agency shall determine an individual's initial iBudget by comparing the individual's algorithm allocation to the individual's current annual cost plan and the individual's extraordinary needs. The individual's algorithm allocation shall be the amount determined by the algorithm, adjusted to the agency's appropriation and any set-asides determined necessary by the agency, including, but not limited to, funding for individuals who have extraordinary needs

311224

as delineated in paragraph (2)(b). The amount of funding needed to address the individual's extraordinary needs shall be reviewed for each individual by the area office in order to determine medical necessity for each service in the amount, duration, frequency, intensity, and scope that meets the individual's needs. The agency shall consider the individual's characteristics based on a needs assessment as well as the individual's living setting, availability of natural supports, family circumstances, and other factors that may affect the level of service needed.

(b) The individual's medical-necessity review must include a comparison of the following:

1. If the individual's algorithm allocation is greater than the individual cost plan, the individual's initial iBudget shall be equal to the total cost plan amount.

2. If the individual's algorithm allocation is less than the individual's cost plan but is greater than the amount for the individual's extraordinary needs, the individual's initial iBudget shall be equal to the algorithm allocation.

3. If the individual's algorithm allocation is less than the amount for the individual's extraordinary needs, the individual's initial iBudget shall be equal to the amount for the individual's extraordinary needs.

The individual's initial annualized iBudget amount may not be less than 50 percent of that individual's existing annualized cost plan. If the individual's initial iBudget is less than the individual's current cost plan, and is within $1,000 of the current cost plan, the agency may adjust the iBudget to equal

311224

the cost plan amount.

(c) During the 2011-2012 and 2012-2013 fiscal years, increases to an individual's initial iBudget amount may be granted only if a significant change in circumstances has occurred and if the criteria for extraordinary needs as described above are met.

565228

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
02/09/2012	.	
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	.	
	.	

The Committee on Health Regulation (Gaetz) recommended the following:

Senate Amendment (with title amendment)

Between lines 1322 and 1323
insert:
Section 12. Paragraph (b) of subsection (2) of section 393.502, Florida Statutes, is amended to read:
393.502 Family care councils.—
(2) MEMBERSHIP.—
(b) At least three of the members of the council must be individuals receiving or waiting to receive services from the agency ~~consumers~~. One such member shall be an individual ~~a consumer~~ who has been receiving ~~received~~ services within the 4

565228

years before ~~prior to~~ the date of recommendation~~, or the legal guardian of such a consumer~~. The remainder of the council members shall be parents, grandparents, nonpaid full-time caregivers, nonpaid legal guardians, or siblings of individual's who have ~~persons with~~ developmental disabilities and who qualify for services pursuant to this chapter. A nonpaid full-time caregiver or nonpaid legal guardian may not serve at the same time as the individual who is receiving care from the caregiver or who is the ward of the guardian.

========== T I T L E A M E N D M E N T ==========
And the title is amended as follows:
Delete line 46
and insert:
client wages at sheltered workshops; amending s. 393.502, F.S.; revising the membership of family care councils; amending s.

THE FLORIDA SENATE

APPEARANCE RECORD

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

2/9/12
Meeting Date

Topic APD

Bill Number 1516 *(if applicable)*

Name Carl Galloway

Amendment Barcode *(if applicable)*

Job Title Father

Address 1950 King Authur Circle
Street
Maitland FL 32751
City *State* *Zip*

Phone 407-376-9339

E-mail chgalloway@cfl.rr.com

Speaking: ☐ For ☐ Against ☐ Information

Representing Maitland Academy + ALL Therapy

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)

4-9-12
Meeting Date

Topic APD

Bill Number CS/SB 1516 *(if applicable)*

Name Lou Ogburn

Amendment Barcode *(if applicable)*

Job Title Chairman, AREA 2 FCC

Address 3263 Robinhood Rd
Street

Phone 850 385-7400

City Tallahassee, FL 32312
City *State* *Zip*

E-mail lou0@comcast.net

Speaking: ☑ For ☐ Against ☐ Information

Representing Family Care Council 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)

Spoke

2-9-12
Meeting Date

Topic Agency for Persons w/ Disabilities

Bill Number SB 1516 *(if applicable)*

Name Margaret J. Hooper

Amendment Barcode *(if applicable)*

Job Title Public Policy Coordinator

Address 124 Marriott Dr. #203
Street
Tallahassee, FL 32301
City *State* *Zip*

Phone 850-921-7263

E-mail MargaretH@FDDC.org

Speaking: ☐ For ☐ Against ☑ Information

Representing Florida Developmental Disabilities Council

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

Spoke

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

2/9/12
Meeting Date

Topic SB 1516 Concerns

Bill Number SB1516 *(if applicable)*

Name Pamela Andrews S.

Amendment Barcode *(if applicable)*

Job Title Parent

Address 1239 Spring Oaks lane *Street*

Phone

TLH FL 32305
City *State* *Zip*

E-mail Pamela Andrews 40@yahoo.com

Speaking: ☐ For ☒ Against ☐ Information

Representing Child w/ DD

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

spoke

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

2/9/2012
Meeting Date

Topic SB 1516 concerns

Bill Number SB 1516 *(if applicable)*

Name Katie Porta

Amendment Barcode *(if applicable)*

Job Title President

Address 500 E Colonial Drive
Street

Phone 407 218-4371

Orlando FL 32803
City *State* *Zip*

E-mail kporta@questinc.org

Speaking: ☐ For ☒ Against ☐ Information

Representing Quest, Inc

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

Spoke

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

09 February
Meeting Date

Topic Senate Bill 1516 Bill Number 1516 *(if applicable)*

Name Phillip Hall Amendment Barcode — *(if applicable)*

Job Title Executive Director

Address 1949 Commonwealth Lane Phone
Street

Tallahassee FL 32303 E-mail
City *State* *Zip*

Speaking: ☐ For ☑ Against ☐ Information

Representing Leon Advocacy and Resource Center

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 Health Regulation Committee

BILL: CS/SB 1350

INTRODUCER: Health Regulation Committee and Senator Sobel

SUBJECT: Cancer Control

DATE: February 10, 2012 REVISED: _____ _____ _____ _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	O'Callaghan	Stovall	HR	**Fav/CS**
2.			BC	
3.				
4.				
5.				
6.				

Please see Section VIII. for Additional Information:

A. COMMITTEE SUBSTITUTE.....	X	Statement of Substantial Changes
B. AMENDMENTS.....		Technical amendments were recommended
		Amendments were recommended
		Significant amendments were recommended

I. Summary:

This committee substitute (CS) renames the Cancer Control and Research Act as the "Florida Cancer Control Act" (Act). The CS also replaces the Florida Cancer Control and Research Advisory Council (C-CRAB) with the "Florida Cancer Control and Resource Advisory Council" (Resource Advisory Council). The Resource Advisory Council is different from the existing C-CRAB in that it:

- Continues to recommend solutions and policy alternatives to the State Surgeon General, but not to the Board of Governors;
- Is made up of 38 members, instead of 35 members;
- Consists of members who have been nominated by a nominating committee prior to being appointed by the Governor, instead of being selected and appointed by the Governor;
- Consists of a delineated number of types of cancer stakeholders in Florida, instead of consisting of representatives from stakeholders as specified in law;
- Contains an executive committee of nine members, four of whom are selected by the chairperson, instead of three or more members who are all appointed by the chairperson;
- May invite additional state cancer stakeholder organizations, groups, or individuals with expertise, experience, or resources to serve as consultants to assist the Resource Advisory Council, without voting rights;

- Must advise the State Surgeon General, the Legislature, and the Governor, but not the Board of Governors, with respect to cancer control and resources, but not specifically research, in Florida;
- Must review and approve the Florida Cancer Plan every 4 years, instead of annually;
- Must formulate and recommend to the State Surgeon General, as well as the Governor, the President of the Senate, and the Speaker of the House of Representatives, an evidence-based plan for the prevention and early detection of cancer;
- Is responsible for providing expertise and input in the content and development of the Florida Cancer Plan, not just making recommendations;
- Is authorized, not required, to form committees to develop strategies for taking action regarding certain cancer-related topics;
- Is authorized, instead of required, to recommend to the State Surgeon General the awarding of grants and contracts to qualified entities to perform activities related to cancer control, prevention, and education or training;
- Has input as to the prioritization and implementation of statewide programs and the allocation of resources in the Department of Health's (DOH) comprehensive cancer control program, consistent with the Florida Cancer Plan;
- Must develop or purchase, if funded by the Legislature, written summaries to inform citizens and professionals on the general prevention, detection, treatment, and survivorship of cancer, instead of written summaries about specified types of cancers;
- Must develop position statements, as well as educational programs, to inform not only citizen groups, associations, and voluntary organizations, but also government officials, about cancer-related matters;
- May recommend to the State Surgeon General, the Governor, the President of the Senate, and the Speaker of the House of Representatives, but not the Board of Governors, methods of enforcing and implementing laws already enacted concerning cancer control and education; and
- Must report by December 1, instead of by February 15 each year, findings and recommendations to the State Surgeon General, the Governor, the President of the Senate, and the Speaker of the House of Representatives.

This CS also removes several references to cancer research, removes cancer research as a focus of the Act, and makes the provisions of the Act broader in scope as they relate to cancer control, prevention, and education or training.

In addition, the CS staggers the terms of certain members of the Resource Advisory Council; provides that 20 members constitute a quorum; and requires the H. Lee Moffitt Cancer Center and Research Institute, Inc., (Moffitt) to provide a full-time executive director to coordinate, facilitate, and communicate the mission of the council, and provide additional administrative support.

The CS removes the Board of Governor's authorization to award grants under the Act and authorizes, but does not require the State Surgeon General to award such grants. The CS also authorizes the DOH, instead of the Board of Governors or the State Surgeon General to adopt rules to implement the Act.

The CS provides that the Florida Cancer Plan is established within the DOH, which must utilize the Resource Advisory Council in developing the plan, prioritizing goals, allocating resources, and approving the Florida Cancer Plan in its final form.

The CS removes the provision for awarding financial aid to cancer patients under the Act.

Under the CS, the Florida Cancer Control and Research Fund is renamed the "Florida Cancer Control Fund."

The CS also makes several cross-reference corrections to conform to changes made by the CS.

This CS substantially amends the following sections of the Florida Statutes: 1004.435, 458.324, and 459.0125.

II. Present Situation:

Cancer Control and Research Act

The Cancer Control and Research Act is created in s. 1004.435, F.S. The C-CRAB is established within the Cancer Control and Research Act to advise the Board of Governors, the State Surgeon General, and the Legislature with respect to cancer control and research in Florida.

The C-CRAB consists of 34 members and the chair of C-CRAB appoints members to an executive committee. The C-CRAB is divided into 4 sub-committees which focus on the following four goals and strategies:

- Goal 1. Develop System Capacity Strategy: Reconfigure the cancer councils into one united network.
- Goal 2. Prevention Strategy: Strengthen links to partner organizations to reduce the burden of tobacco and obesity.
- Goal 3. Treatment and Access to Care: Strategy: Improve cancer resource awareness and access for minority and disparate populations.
- Goal 4. Survivorship Strategy: Improve record keeping systems, and expand services and resources for cancer survivors.[1]

Staff and administrative support are provided to C-CRAB by Moffitt in Tampa, Florida.[2]

Annually the C-CRAB approves the Florida Cancer Plan,[3] which is a program for cancer control and research that must be consistent with the State Health Plan and integrated and coordinated with existing programs in Florida.[4] Additional responsibilities of the C-CRAB include:

[1] Florida Cancer Control & Research Advisory Council, *What is the Cancer Control and Research Advisory Council?*, available at: http://ccrab.org/ (Last visited on February 3, 2012).
[2] *Id.*
[3] The 2010 Florida Cancer Plan is available at: http://www.doh.state.fl.us/Family/cancer/ccc/plan/NewFlorida_Cancer_Plan_2010.pdf (Last visited on February 6, 2012).
[4] The Florida Cancer Plan (2010) provides an overview of the cancer burden in Florida, health disparities by population, specific behavioral and preventive measures that may reduce one's risk of cancer, and early detection techniques by 10 specific cancer sites or classifications. These cancer sites and classifications include breast, cervical, childhood, colorectal, lung, lymphoma, oral and pharyngeal, ovarian, prostate, and melanoma of the skin. These specific cancer sites have been included because they are either the most common cancer sites or are some of the most receptive to prevention and early etection. More importantly, when addressed through public health and policy, decreasing the incidence and mortality of these cancers can reduce the burden of cancer in Florida and nationwide.

- Recommending to the State Surgeon General a plan for the care and treatment of persons suffering from cancer and standard requirements for cancer units in hospitals and clinics in Florida;
- Recommending grant and contract awards for the planning, establishment, or implementation of programs in cancer control or prevention, cancer education and training, and cancer research;
- Pursuant to legislative appropriations, providing written summaries that are easily understood by the average adult patient, informing actual and high-risk breast cancer patients, prostate cancer patients, and men who are considering prostate cancer screening of the medically viable treatment alternatives available to them and explaining the relative advantages, disadvantages, and risks associated therewith;
- Implementing an educational program for the prevention of cancer and its early detection and treatment;
- Advising the Board of Governors and the State Surgeon General on methods of enforcing and implementing laws concerning cancer control, research, and education; and
- Recommending to the Board of Governors or the State Surgeon General rulemaking needed to enable the C-CRAB to perform its duties.

H. Lee Moffitt Cancer Center and Research Institute, Inc.

Moffitt opened its doors on October 26, 1986, on the Tampa campus of the University of South Florida. Moffitt's main priority is fighting cancer through patient care, education and research.[5]

Funding for construction of Moffitt's initial $70 million facility came primarily from the state's cigarette tax, while the momentum to create Moffitt's Cancer Center came from a cadre of legislators, physicians, educators and business leaders who envisioned a new dimension of cancer care and research in Florida.[6]

The Moffitt Cancer Center is a not-for-profit institution. It includes private patient rooms, the southeast's largest blood and marrow transplant program, outpatient treatment programs that record more than 320,500 visits a year, the Moffitt Research Center, Moffitt Cancer Center at International Plaza, and the Lifetime Cancer Screening & Prevention Center.[7]

In 1999, Moffitt developed the Affiliate Network Program, a professional partnership involving strategic affiliations with community physicians and health care facilities throughout Florida and beyond. Moffitt works with its partners to offer clinical expertise and research trials found only at a National Cancer Institute Comprehensive Cancer Center. Moffitt reaches about 20 percent of the cancer patient population in Florida through these relationships.[8]

[5] H. Lee Moffitt Cancer Center and Research Institute, *About Moffitt: Background*, available at: http://www.moffitt.org/Site.aspx?spid=104F906D53A4406796FB87126C8301EA (Last visited on February 3, 2012).
[6] *Id.*
[7] H. Lee Moffitt Cancer Center and Research Institute, *About Moffitt: Overview of Moffitt*, available at: http://www.moffitt.org/about (Last visited on February 3, 2012).
[8] *Supra* fn. 1.

Florida's Cancer-Related Programs

The James and Esther King Biomedical Research Program (King Program) provides an annual and perpetual source of funding to support research initiatives that address the health care problems of Floridians in the areas of tobacco-related cancer, cardiovascular disease, stroke, and pulmonary disease.[9] The King Program offers competitive grants to researchers throughout Florida. Grant applications from any university or established research institute[10] in Florida will be considered for biomedical research funding. All qualified investigators in the state, regardless of institutional affiliation, have equal access and opportunity to compete for the research funding.[11]

The William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program's (Bankhead-Coley Program) purpose is to advance progress toward cures for cancer through grants awarded for cancer research. Applications for funding cancer research from any university or established research institute in Florida are considered under the Bankhead-Coley Program. All qualified investigators in the state, regardless of institutional affiliation, have equal access and opportunity to compete for the research funding.[12]

The DOH administers the Comprehensive Cancer Control Program (CCCP) that is funded by the Centers for Disease Control and Prevention. The CCCP coordinates closely with the C-CRAB and contracts with Moffitt to develop the Florida Cancer Plan and conduct CCCP activities as provided for in law.[13]

The DOH contracts with the University of Miami to oversee the operations of the state's cancer registry, the Florida Cancer Data System, established under ch. 385, F.S. Information collected

[9] Section 215.5602, F.S.

[10] An "established research institute" is any Florida non-profit or foreign non-profit corporation covered under ch. 617, F.S., with a physical location in Florida, whose stated purpose and power is scientific, biomedical or biotechnological research or development and is legally registered with the Florida Department of State, Division of Corporations. This includes the federal government and non-profit medical and surgical hospitals, including veterans' administration hospitals. *See* James & Esther King Biomedical Research Program, *Call for Grant Applications: Biomedical, Biotechnological, and Social Scientific Research and Development, Fiscal Year 2009-2010*, page 7, available at: http://forms.floridabiomed.com/jek_call/King%20Call%2009-10.pdf (Last visited on March 16, 2011).

[11] Grant award recipients for FY 2010-11 include the following institutions or investigators associated with these institutions: Bay Pines VA Healthcare System, Florida International University (FIU), Florida State University, M.D. Anderson Cancer Center, Mayo Clinic, Miami VA Healthcare System, H. Lee Moffitt Cancer Center & Research Institute (Moffitt Cancer Center), Sanford-Burnham Institute, Scripps Research Institute, Torrey Pines Institute, University of Central Florida, University of Florida, University of Miami, and University of South Florida. *See* James & Esther King Biomedical Research Program, *Florida Biomedical Research Programs Grants Awarded by Institution*, available at: http://forms.floridabiomed.com/Forms/GrantsAwardedbyInstitution.pdf (Last visited on March 16, 2011).

[12] Grant award recipients for FY 2010-11 include the following institutions or investigators associated with these institutions: Florida A&M University, Florida State University, M.D. Anderson Cancer Center, Mayo Clinic, Moffitt Cancer Center, Sanford-Burnham Institute, Scripps Research Institute, University of Central Florida, University of Florida, University of Miami, and the University of South Florida. *See* James & Esther King Biomedical Research Program, *Florida Biomedical Research Programs Grants Awarded by Institution*, available at: http://forms.floridabiomed.com/Forms/GrantsAwardedbyInstitution.pdf (Last visited on March 16, 2011).

[13] Department of Health, *Bill Analysis, Economic Statement, and Fiscal Note for SB 1350*, January 24, 2012, on file with the Senate Health Regulation Committee.

from the data system is used to inform the C-CRAB and used by C-CRAB to make recommendations.[14]

III. Effect of Proposed Changes:

This CS renames the Cancer Control and Research Act as the "Florida Cancer Control Act" (Act); replaces the Florida Cancer Control and Research Advisory Council (C-CRAB) with the "Florida Cancer Control and Resource Advisory Council" (Resource Advisory Council); and renames the Florida Cancer Control and Research Fund as the "Florida Cancer Control Fund."

This CS also removes several references to cancer research, removes cancer research as a focus of the Act, and makes the provisions of the Act broader in scope as they relate to cancer control, prevention, and education or training. In addition, the Board of Governor's role in awarding grants, and receiving input from the council concerning such grants, cancer control, research, and education, is eliminated.

The CS requires the Resource Advisory Council to serve as a resource and clearinghouse for comprehensive cancer control in Florida and facilitate effective communication, shared resources, and synergism between and among the cancer stakeholder organizations and groups within Florida.

The CS outlines the membership of the Resource Advisory Council, which is to consist of members representing the various cancer constituencies in the state. There is to be a total of 38 voting members and all members must be residents of Florida. Of those members, three represent the general public and are appointed by the Governor, one is appointed by the President of the Senate, one is appointed by the Speaker of the House of Representatives, one is appointed by the State Surgeon General, and 32 represent cancer stakeholders and are appointed by the Governor. At least 10 of the 32 stakeholder members must be a minority person, defined under s. 288.703, F.S., to include a lawful, permanent resident of Florida who is:

- An African American, a person having origins in any of the black racial groups of the African Diaspora, regardless of cultural origin.
- An Hispanic American, a person of Spanish or Portuguese culture with origins in Spain, Portugal, Mexico, South America, Central America, or the Caribbean, regardless of race.
- An Asian American, a person having origins in any of the original peoples of the Far East, Southeast Asia, the Indian Subcontinent, or the Pacific Islands, including the Hawaiian Islands before 1778.
- A Native American, a person who has origins in any of the Indian Tribes of North America before 1835, upon presentation of proper documentation thereof as established by rule of the Department of Management Services.
- An American woman.

The CS staggers the terms of the three members of the Resource Advisory Council who represent the general public. All members serve 4-year terms and a chair and vice-chair are to be elected by the council membership for 2-year terms.

[14] *Id.*

The CS changes current law to remove the requirement that at least one of the members appointed by the Governor be 60 years of age or older and the CS deletes the prescribed representation of the membership of the C-CRAB. Instead, the CS establishes a nominating committee, which consists of at least one member from seven membership categories outlined in the CS (see below), including the vice chair of the Resource Advisory Council. The nominating committee must review applicants for the Resource Advisory Council on an annual basis and make recommendations for gubernatorial appointments to the council. Each nominated member is eligible for reappointment one time, meaning a member may not serve more than two 4-year terms.

The 32 members appointed by the Governor who represent cancer stakeholders in Florida must be recommended by cancer stakeholder organizations or groups, by council nomination, or through self-referrals. The membership categories and the maximum number of members in each category include:

- Five members from university-based health care delivery systems with major cancer programs, including the H. Lee Moffitt Cancer Center and Research Institute, Inc., the University of Florida Shands Cancer Center, and the University of Miami Sylvester Comprehensive Cancer Center.
- Five members from community-based health care delivery systems or practices with American College of Surgeons accredited cancer programs.
- Four members from nonprofit or voluntary organizations, including a representative from the American Cancer Society.
- Three members from health and health care disparities research and outreach cancer programs.
- Five members from state governmental agencies, including the DOH, the Department of Education, and the Biomedical Research Advisory Council.
- Five members from cancer-related professional organizations, including the Florida Society of Clinical Oncology, the Florida Society of Oncology Social Workers, the Florida Society of Pathologists, the Florida Dental Association, and the Florida Medical Association.
- Five members each representing one of the state regional cancer collaboratives.

The Resource Advisory Council is to establish an executive committee, which is responsible for coordinating the activities and planning the direction of the council. The executive committee consists of the council's chair, vice chair, the appointee of the Speaker of the House of Representatives, the appointee of the President of the Senate, the appointee of the State Surgeon General, and four members selected by the chair. Each member of the executive committee serves a 2-year term, which must correspond to the chair's term in office. The executive committee must also consist of at least one member of each stakeholder membership group (see above). Additional members may serve on the committee at the discretion of the chair.

The Resource Advisory Council may, by majority vote, invite additional state cancer stakeholder organizations, groups, or individuals with expertise, experience, or resources to serve as consultants to assist the council in accomplishing its mission. The consultants do not have voting rights.

The CS provides that 20 members of the Resource Advisory Council constitute a quorum for the purpose of exercising all of the powers of the council. A majority vote is required for all actions of the council.

Just as with the C-CRAB, the Resource Advisory Council members may not be paid for their service, but are entitled to reimbursement for per diem and travel expenses; may not participate in discussions or decisions which are a conflict of interest; and may prescribe, amend, and repeal bylaws governing the manner in which the business of the council is conducted.

The Resource Advisory Council is responsible for:

- Advising the State Surgeon General, the Governor, and the Legislature, about cancer control and resources in Florida.
- Reviewing and approving at least every 4 years the Florida Cancer Plan, which is generated through the DOH.
- Formulating and recommending to the State Surgeon General, the Governor, the President of the Senate, and the Speaker of the House of Representatives an evidence-based plan that is consistent with standards of practice and supported by evidence-based medicine and is for the prevention and early detection of cancer.
- Providing expertise and input in the content and development of the Florida Cancer Plan, including recommendations for the coordination and integration of other state efforts concerned with cancer control.
- Developing or purchasing, if funding is provided, standardized written summaries, written in layperson's terms and in language easily understood by the average adult patient, which are to inform citizens and professionals on cancer prevention, detection, treatment, and survivorship. In addition, the council must develop and implement educational programs and position statements to inform citizen groups, associations, government officials, and voluntary organizations about cancer-related matters.
- Formulating and implementing a continuing education program for the prevention of cancer and its early diagnosis and disseminating to hospitals, cancer patients, and the public, information concerning the proper treatment of cancer.
- Reporting its findings and recommendations to the State Surgeon General, the Governor, the President of the Senate, and the Speaker of the House of Representatives by December 1 of each year.

The Resource Advisory Council may form committees to develop strategies for taking action regarding:

- Cancer plan evaluation, including the creation of a tumor registry, data retrieval systems, and epidemiology of cancer in Florida.
- Cancer prevention.
- Cancer detection.
- Cancer treatments.
- Support services for cancer patients and caregivers.
- Cancer education for laypersons and professionals.
- Other cancer-control-related topics.

The CS authorizes the Resource Advisory Council to recommend to the State Surgeon General the awarding of grants and contracts to qualified profit or nonprofit associations or governmental agencies to plan, establish, or conduct programs in cancer control, prevention, and education or training. The council must have input into the prioritization and implementation of statewide programs and the allocation of resources in the DOH's comprehensive cancer control program, consistent with the Florida Cancer Plan.

The Resource Advisory Council may also recommend to the State Surgeon General, the Governor, the President of the Senate, and the Speaker of the House of Representatives methods of enforcing and implementing laws already enacted and concerned with cancer control and education and may recommend to the State Surgeon General rules that are not inconsistent with law that are deemed necessary for the performance if its duties and proper administration of the Act.

The CS also provides for the responsibilities of Moffitt, the State Surgeon General, and the DOH. The CS authorizes the State Surgeon General, after consultation with the Resource Advocacy Council, to award grants and contracts to qualified nonprofit associations and governmental agencies in order to plan, establish, or conduct programs in cancer control or prevention and cancer education or training.

Moffitt is required to provide a full-time executive director to coordinate, facilitate, and communicate the mission and responsibilities of the Resource Advisory Council and provide additional administrative support, information, and other assistance as reasonably necessary for the completion of the responsibilities of the council.

The DOH, after consultation with the Resource Advisory Council, may adopt rules necessary for implementation of the Act. The Florida Cancer Plan is established within the DOH, and the DOH must utilize the Resource Advisory Council in developing the Florida Cancer Plan, prioritizing goals, allocating resources, and approving the plan in its final form.

The CS removes the provision for awarding financial aid to cancer patients under the Act.

The CS changes the name of the Florida Cancer Control and Research Fund to the Florida Cancer Control Fund (the Fund). The Fund may no longer be used for related activities authorized by the State Board of Education.

The CS also corrects several cross-references to conform to changes made by the CS.

The CS provides that it will take effect on July 1, 2012.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this CS have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of the CS have no impact on public records or open meetings issues under the requirements of Article I, Section 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this CS have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

Moffitt is required to provide a full-time executive director to coordinate, facilitate, and communicate the mission and responsibilities of the Resource Advisory Council and provide additional administrative support, information, and other assistance as reasonably necessary for the completion of the responsibilities of the council. Therefore, Moffitt is likely to incur an indeterminate amount of costs associated with such responsibilities.

Resource Advisory Council members must serve on the council without pay, but may be reimbursed for per diem and travel. The CS does not specify the entity responsible for paying the reimbursement for per diem and travel.

The Resource Advisory Council must, if funded by the Legislature, develop or purchase standardized written summaries informing citizens and professionals on cancer prevention, detection, treatment, and survivorship. In addition the council must develop and implement educational programs and position statements regarding cancer-related matters.

VI. Technical Deficiencies:

Lines 298-304 of the CS refers to the State Surgeon General awarding contracts and grants to qualified *profit* or nonprofit associations or governmental agencies in order to plan, establish, or conduct programs in cancer control or prevention and cancer education or training. However, lines 398-405 of the CS provide that the Fund may only be used for grants and contracts to qualified nonprofit associations or governmental agencies for the purpose of cancer control or prevention; cancer education or training; all expenses incurred in connection with the administration of the Act; and programs funded through the grants and contracts authorized by the State Surgeon General.

VII. Related Issues:

Although "plan" is defined in the CS to mean the Florida Cancer Plan, it is unclear whether the intent is for the word "plan" in lines 262 and 273 to mean the Florida Cancer Plan. This is unclear because lines 260-274 require the Resource Advisory Council to formulate and recommend an evidence-based "plan" and requires the State Surgeon General to consider the "plan" in developing DOH priorities, while lines 275-281 require the Resource Advisory Council to provide expertise and input in the content and development of the "Florida Cancer Plan" and make recommendations that include the coordination and integration of other state efforts concerned with cancer control.

VIII. 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 Regulation on February 9, 2012:
The CS revises the membership of the Resource Advisory Council to require, of the 32 members appointed by the Governor, one member to be from the Florida Society of Pathologists and one member to be from the Florida Dental Association.

B. Amendments:

None.

730784

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
02/09/2012	.	
	.	
	.	
	.	

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

Senate Amendment

Delete line 198
and insert:
Oncology, the Florida Society of Oncology Social Workers, the Florida Society of Pathologists, the Florida Dental Association, and

The Florida Senate

Committee Agenda Request

To: Senator Rene Garcia, Chair
Committee on Health Regulation

Subject: Committee Agenda Request

Date: January 11, 2012

I respectfully request that **Senate Bill #1350**, relating to Cancer Control, be placed on the:

☐ committee agenda at your earliest possible convenience.

☒ next committee agenda.

Eleanor Sobel

Senator Eleanor Sobel
Florida Senate, District 31

ENTERED

File signed original with committee office

S-020 (03/2004)

THE FLORIDA SENATE

APPEARANCE RECORD

Waive in support

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

2/9/12
Meeting Date

Topic C-CRAB

Bill Number SB 1350

Name Ron Watson

Amendment Barcode 730784 *(if applicable)*

Job Title Lobbyist

Address 118 E Jefferson St

Phone 224-1084

Street

Tallahassee FL 32301

E-mail

City *State* *Zip*

Speaking: ☐ For ☐ Against ☐ Information

Representing FDA

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 Health Regulation Committee

BILL: SB 1808

INTRODUCER: Senator Storms and others

SUBJECT: Psychotropic Medication

DATE: February 7, 2012 REVISED: 2/9/2012

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Preston	Farmer	CF	**Favorable**
2.	Davlantes	Stovall	HR	**Favorable**
3.			BC	
4.				
5.				
6.				

I. Summary:

The bill makes a number of changes to current law relating to psychotropic medication and children in out-of-home placements, including:

- Providing that every child placed in out-of-home care be provided a comprehensive behavioral health assessment;
- Providing for legislative findings and intent;
- Providing definitions for terms used in a newly created section of law;
- Providing for the appointment of a guardian ad litem (GAL) for every child who is being prescribed a psychotropic medication and providing duties and responsibilities of the GAL;
- Prescribing procedures for obtaining express and informed consent and assent;
- Requiring the development of a mental health treatment plan for children in out-of-home care who need mental health services;
- Providing procedures to be followed for the administration of psychotropic medication to a child in out-of-home care when parental consent has not been obtained and for the administration of psychotropic medication to a child in out-of-home care before court authorization has been obtained;
- Requiring a court finding of a compelling government interest before administering psychotropic medication to certain children; and
- Prohibiting a child in the custody of the Department of Children and Family Services (DCF or department) from participating in clinical trials involving psychotropic medication.

This bill amends sections 39.407 and 743.0645 and creates section 39.4071, of the Florida Statutes.

II. Present Situation:

Psychotropic Medications[1]

Psychotropic medications are one of many treatment interventions that may be used to address mental health problems. Medication may be recommended and prescribed for children with mental, behavioral, or emotional symptoms when the potential benefits of treatment outweigh the risks. This is particularly true when the problems experienced by the child are so severe that there would be serious negative consequences for the child if the child is left untreated and when other treatment interventions have not been effective. However, public concern is growing over reports that very young children are being prescribed psychotropic medications, which is not generally the first option of treatment for a child, that some children are on multiple medications, and that these medications are sometimes used inappropriately to control a child's behavior.

Major categories of psychotropic medications include stimulants, antidepressants, anti-anxiety agents, anti-psychotics, and mood stabilizers. However, effective treatment with psychotropic medication depends on the appropriate diagnosis of the problem. These medications may be used to treat a variety of symptoms, which include:

- **Stimulant medications** that are frequently used to treat Attention Deficit Hyperactivity Disorder (ADHD), the most common behavioral disorder of childhood;
- **Anti-depressants and anti-anxiety medications** which follow the stimulant medications in prevalence among children and adolescents. These medications are commonly used for depression, anxiety, and obsessive compulsive disorders;
- **Anti-psychotic medications**, which are used to treat children with schizophrenia, bipolar disorders, autism, and severe conduct disorders; and
- **Mood stabilizing medications**, which are used to treat bipolar disorders.

Some of the concerns regarding the use of psychotropic medications with children stem from the limited information that is available regarding the efficacy and the potential side effects of these drugs with children. Most clinical trials for these drugs were conducted on an adult population. The same results are not always obtained when these drugs are used with children, and the side effects for children are frequently different than those experienced by adults. The Food and Drug Administration has expressed concern regarding the use of antidepressants in children and established an advisory committee to further study and evaluate the use of such medications.

Use of Psychotropic Medications by Children: Background

Many children in the United States receive psychotropic medications, and this number has increased over time. The use of multiple psychotropic medications has also been reported to have

[1] 1 The information in this portion of this bill analysis is from the analysis for CS/CS/SB 1090 by the Senate Committee on Health and Human Services Appropriations (April 14, 2005). Retrieved January 21, 2012, from http://www.flsenate.gov/data/session/2005/Senate/bills/analysis/pdf/2005s1090.ha.pdf.

increased among children. The efficacy and short-and long-term safety knowledge base for pediatric psychopharmacology has increased in recent years but remains limited.[2]

An issue that has increasingly received national attention over the past decade has been the concern for the overuse of psychotropic medications among our nation's youth in general, with a potentially disproportionate increase among children in foster care.[3] Among community-based populations, children in foster care tend to receive psychotropic medication as much as, or more than, disabled youth and three to four times the rate among children with Medicaid coverage based on family income.[4] Children in foster care and disabled youth have the greatest likelihood of receiving complex, poorly evidenced, high cost medication regimens.[5]

The few research studies available show rates of psychotropic medication use ranging from 13-50 percent among children in foster care, compared with approximately 4 percent in youth in the general population.[6] A 2006 report prepared by the Government Accountability Office found that 15 states identified the overuse of psychotropic medications as one of the leading issues facing their child welfare systems.[7] In her testimony to Congress, Dr. Laurel Leslie, on behalf of the American Academy of Pediatrics, stated:

> It is difficult to know from these preliminary analyses or the multitude of reports that are emerging in the media whether the use of these medications by children in foster care is appropriate, although at the very least the use of combinations of three or more medications remains controversial. Clearly, medication can be helpful to some children, but with the increasing use of these medications among children in general, there comes the added responsibility to ensure that children have access to an array of treatment strategies, from medication to community-based services that may augment or replace the need for medications in many circumstances. Furthermore, the failure to coordinate and provide continuity in services and the absence of clear guidelines and accountability to ensure that treatment decisions are in the child's best interest, create a greater risk that medications will be prescribed to control children's behaviors in the absence of individualized service plans that might offer the best chance for success.[8]

[2] Alfiee M. Breland-Nobel et al., *Use of Psychotropic Medications by Youths in Therapeutic Foster Care and Group Homes*, PSYCHIATRIC SERVICES, Vol. 55, No. 6., 706 (June 2004), Retrieved January 21, 2012, from http://ps.psychiatryonline.org/cgi/reprint/55/6/706 .
[3] Laurel K. Leslie, MD MPH FAAP, Am. Acad. of Pediatrics, *Hearing on the Utilization of Psychotropic Medication for Children in Foster Care*, 6 (May 8, 2008). Retrieved January 21, 2012, from http://www.aap.org/en-us/advocacy-and-policy/federal-advocacy/Documents/HearingontheUtilizationofPsychotropicMedicationforChildreninFosterCare.pdf.
[4] Julie M. Zito, PhD, Professor of Pharmacy and Psychiatry, U. of Maryland, *Prescription Psychotropic Drug Use Among Children in Foster Care*, 2-3 (May 8, 2008). Retrieved January 21, 2012, from http://www.hunter.cuny.edu/socwork/nrcfcpp/teleconferences/2-10-10/Zito%20Medication%20handout.doc.
[5] *Id*. at 2.
[6] Leslie, supra note 3, at 6.
[7] *Id*. (citing U.S. Government Accountability Office, *Child Welfare: Improving Social Service Program, Training, and Technical Assistance Information Would Help Address Long-standing Service-Level and Workforce Challenges*, Report GAO-07-75 (Oct. 2006). Retrieved January 21, 2012, from http://www.gao.gov/new.items/d0775.pdf.
[8] Leslie, supra note 3, at 7.

Use of Psychotropic Medications by Children: Florida

In Florida, prescribing psychotropic medications for children in out-of-home placements has been an issue for at least a decade. The Statewide Advocacy Council (SAC)[9] conducted an investigation in 2001 of the use of psychotropic drugs in foster children, with an emphasis on children under the age of 5.[10] When an internal investigation by the department was conducted, it concluded that the use of psychotropic drugs in children in the department's care was not a problem. However, information received from the Agency for Health Care Administration (AHCA) revealed that more than 9,500 children in Florida on Medicaid had received psychotropic drugs in the year 2000.

The SAC published its final report to the Governor in 2003, which found that out of the 1,180 children reviewed, 652 were on one or more psychotropic medications, and that the average age of the children on medication was 12. The final recommendation of the SAC was: "Until there is more information regarding the safety and efficiency of these drugs, Florida's foster care children should be monitored closely. The information in this report should be immediately incorporated into an agenda in order to preserve and protect the health, safety, welfare and rights of children in foster care."[11]

In 2004, the DCF studied the use of psychotropic medications with children in care over a specified period of time. The department determined that 13 percent of all children in state custody were receiving at least one psychotropic medication. Of this group, 8 percent were being treated with three or more medications concurrently. Findings also indicated that 3.5 percent of the children in state custody age 5 and under received at least one psychotropic medication. An additional finding was that 25 percent of the children living in a foster care setting were being treated with psychotropic medications, a rate five times higher than the general population of Medicaid eligible children. Despite initiatives by DCF to identify children in its care who were on psychotropic medications and to determine the appropriateness of this treatment, limited information existed.[12]

In 2005, the Florida Legislature enacted Senate Bill 1090,[13] which provided a comprehensive statutory framework relating to the use of psychotropic medications with children who are in out-of-home placements. As of June 2011, 1.50 percent of children in care ages 0-5, 19.57 percent of children in care ages 6-12 and 29.61 percent of children in care ages 13-17 are receiving

[9] Statewide and local advocacy councils began in 1972 as a consumer protection mechanism for people receiving services from state agencies in Florida. The councils were codified in 1975. The councils investigate complaints about abuse and deprivations of human and constitutional rights; monitor and investigate reports of abuse; monitor programs and facilities that are operated, funded, or contracted by state agencies; review research projects involving human subjects; and generally advocate for the welfare of individuals who are in the care and custody of state agencies in the social service area or private vendors under contract to the state. Senate Staff Analysis and Economic Impact Statement, CS/CS/SB 2718, April 14, 2010.
[10] Senate Staff Analysis and Economic Impact Statement, CS/CS/SB 2718, April 14, 2010.
[11] Florida Statewide Advocacy Council, Red Item Report: Psychotropic Drug Use in Foster Care, 4, 23 (July 2003) . Senate Staff Analysis and Economic Impact Statement, CS/CS/SB 2718, April 14, 2010.
[12] Senate Staff Analysis and Economic Impact Statement, CS/CS/SB 1090, supra note 1.
[13] Chapter 2005-65, L.O.F.

psychotropic medication. The total number of children in care receiving psychotropic medication is 13.34 percent. This appears to reflect little, if any, change since the 2004 estimates.[14]

Gabriel Myers

Seven-year old Gabriel Myers was adjudicated dependent on September 2, 2008, following the arrest of his mother and the filing of the abuse report that brought him into the care of DCF on June 29, 2008. During the following 10 months, Gabriel was initially sheltered in a licensed foster home until being placed with relatives. When the relative placement failed, he was returned to the licensed home where he was initially placed. When that placement also failed, he was sent to the licensed home in which he resided until he died. This particular home had previously served as a respite for Gabriel, and he was familiar with the surroundings.[15]

In February and March 2009, Gabriel experienced a number of significant life events, including changes in foster homes, therapists, and after-school programs. He lost privileges at home and visitation time with his mother, all of which more than likely contributed to his mental status at the time of his death.[16]

While in care, he received numerous mental health and behavioral assessments and underwent regular treatment from a psychiatrist and two therapists, one of whom documented that "it is clear that this child is overwhelmed with change and possibly re-experiencing trauma."[17] Gabriel demonstrated a number of incidents of destructive behavior and conduct problems and was treated with counseling and several psychotropic medications. On April 16, 2009, Gabriel Myers hanged himself in the residence of his foster parents.[18]

A review of Gabriel's medical records by the Broward County Medical Examiner's office indicates that Gabriel was prescribed Vyvanse and Symbax by Dr. Sohail Punjwani, M.D.[19]

A report issued by DCF on May 20, 2009, stated that the Child Resource Record for Gabriel that contained medical information, including medications, was secured by law enforcement. A timeline of medications that were prescribed to Gabriel, based on the information obtained from the documentation available for review, is provided below:

[14] Department of Children and Family Services, DCF Quick Facts. December 2011. Retrieved January 22, 2012, from http://www.dcf.state.fl.us/newsroom/docs/quickfacts.pdf.
[15] Department of Children and Family Services., Report of the Gabriel Myers Work Group, 3 (Nov. 19. 2009), Retrieved January 21, 2012, from http://www.dcf.state.fl.us/initiatives/GMWorkgroup/docs/GabrielMyersWorkGroupReport082009Final.pdf.
[16] *Id*. at 3-4.
[17] *Id*. at 3.
[18] *Id.*
[19] Broward County Medical Examiner, Autopsy No. 09-0557 (Apr. 17, 2009). Retrieved January 21, 2012, from http://www.dcf.state.fl.us/initiatives/GMWorkgroup/docs/GM_ME_Report.pdf. Dr. Punjwani was the psychiatrist treating Gabriel at the time of his death. A warning letter from the United States Food and Drug Administration stated that Dr. Punjwani overmedicated children who were enrolled in clinical trials for undisclosed drugs and that her "failure to conduct the requisite safety measures contributed to the unnecessary exposure of pediatric subjects to significant overdoses, which jeopardized the subjects right, safety, and welfare." U.S. Food and Drug Admin., Warning Letter (Feb. 4, 2010). Retrieved January 21, 2012, from http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm202862.htm.

- June 29, 2008, Adderall;
- July 31, 2008, Adderall discontinued;
- August 21, 2008, Dr. Punjwani noted medication was not indicated at that time;
- December 09, 2008, Vyvanse[20] for ADHD prescribed;
- February 03, 2009, Vyvanse continued and Lexapro prescribed;
- March 18, 2009, Vyvanse continued, Lexapro discontinued, Symbyax[21] prescribed.[22]

Gabriel Myers Work Group[23]

The Gabriel Myers Work Group was appointed in April 2009 to analyze and make recommendations relating to Gabriel Myers and the use of psychotropic medication for children in out-of-home care. The work group identified 147 findings in 10 areas, resulting in 90 recommendations for action.[24]

The work group determined that a detailed framework of safeguards for Florida's foster children exists and is articulated in statute, administrative rule, and operating procedures. The core failures in the system, however, stem from lack of compliance with this framework and with failures in communication, advocacy, supervision, monitoring, and oversight.

Of the 90 recommendations contained in the final report (with the exception of five that are related to funding requests), there were 10 recommendations directed to the Legislature:

- The Legislature should amend the requirement for a pre-consent consultation for all children in out-of-home care under age six. The consultation should be expanded to include all children age 11 and younger who are prescribed two or more psychotropic medications.
- The Legislature should review current statutes to ensure that procedural safeguards employed for the use of psychotropic medications are applied to all medications that alter brain function, regardless of the purpose of the prescription, to ensure they are adequate.
- The Legislature should amend s. 39.407, F.S., to change the term "medical report" to "medical treatment plan" so that interventions focus on treatment and the holistic needs of the child.

[20] Vyvanse is lisdexamfetamine, an amphetamine used for treating attention deficit hyperactivity disorder (ADHD) in certain patients. It is used as a part of a total treatment program that may include psychological, educational, and social therapy. *Lisdexamfetamine* . Retrieved January 21, 2012, from http://www.drugs.com/cdi/lisdexamfetamine.html.
[21] Symbyax contains a combination of fluoxetine and olanzapine. Fluoxetine is an antidepressant in a group of drugs called selective serotonin reuptake inhibitors (SSRIs). Olanzapine is an antipsychotic medication. Symbyax is used to treat depression caused by bipolar disorder (manic depression). Symbyax is also used to treat depression after at least two other medications have been tried without successful treatment of symptoms. It is not known if Symbyax is safe and works in children under 18 years of age. *Symbyax*. Retrieved January 21, 2012, from http://www.drugs.com/symbyax.html.
[22] Department of Children and Family Services., Issue Summary Update, 4 (May 20, 2009). Retrieved January 21, 2012, from http://www.dcf.state.fl.us/initiatives/GMWorkgroup/docs/FinalMyers.pdf.
[23] The information in this portion of this bill analysis is from the Report of the Gabriel Myers Work Group by the Department of Children and Family Services., supra note 14.
[24] In August 2009, a Miami Herald article reporting on the Gabriel Myers Work Group stated that one of the work group's findings was that "[t]he state has failed to implement recommendations from prior task forces that studied the deaths of foster children or the use of psychotropic drugs. Indeed, DCF has failed to even assign "responsibility" or "accountability" for implementing such reports." Carol Marbin Miller, Child-welfare panel: Drugs misused on foster kids, MIAMI HERALD, Aug. 13, 2009, at A-7.

- The Legislature should authorize DCF to develop a single medical treatment plan form with standardized information that can be utilized in all judicial circuits across the state.
- The Legislature should ensure that statutes and department policies, procedures, and practices recognize that children should be fully involved and allowed to participate in court hearings and treatment decisions. As part of this, prescribers should be required to confer with and seek assent from each child and to document the child's position. The department should be required to inform the Court of the child's position.
- The Legislature should review Florida statutes to ensure requirements are practical and clearly defined for:
  - Prescribing psychotropic medications;
  - Obtaining informed consent;
  - Obtaining the child's assent;
  - Requiring a parent, case worker, or other adult responsible for the child's care to attend each medical appointment with the child;
  - Administering and monitoring psychotropic medications;
  - Discontinuing, when appropriate, psychotropic medications. To include a formal plan for discontinuation;
  - Notifying involved parties; and
  - Reporting adverse incidents.
- The Legislature should require all prescribing physicians to report adverse consequences of psychotropic medications; all adverse effects should become a record in the medical file of a child in the care of the state.
- The Legislature should allow Advanced Registered Nurse Practitioners and Physician Assistants to provide information to parents and legal guardians in order to obtain express and informed consent for treatment.
- The Legislature should preclude any participation by children in state care in clinical trials relating to the development of new psychotropic medications.
- In any legislation arising from this report, the Legislature should utilize these guiding principles articulated by the work group as the statement of legislative intent and expected standards of care for children in the care of the state.

III. Effect of Proposed Changes:

This bill addresses many of the recommendations raised by the department's Gabriel Myers Work Group, as well as additional issues that were raised by others. The bill makes a number of changes related to the provision of psychotropic medication to children who are in an out-of-home placement. Specifically, the bill creates s. 39.4071, F.S., which is titled "Use of psychotropic medication for children in out-of-home placement."

The bill provides legislative findings and intent that, due to multiple risk factors, children in out-of-home care are more likely to have behavioral and emotional disorders, receive mental health services, and be provided psychotropic medications at higher rates than other children. The bill states that it is the intent of the Legislature that children in out-of-home care who need psychotropic medications receive them as part of a comprehensive treatment plan monitored by a court-appointed guardian ad litem (GAL).

The bill creates definitions for the following terms:

- "Behavior analysis" means "services rendered by a provider who is certified by the Behavior Analysis Certification Board in accordance with chapter 393."
- "Obtaining assent" means "a process by which a provider of medical services helps a child achieve a developmentally appropriate awareness of the nature of his or her condition, informs the child of what can be expected through tests and treatment, makes a clinical assessment of the child's understanding of the situation and the factors influencing how he or she is responding, and solicits an expression of the child's willingness to adhere to the proposed care. The mere absence of an objection by the child may not be construed as assent."
- "Comprehensive behavior health assessment" means "an in-depth and detailed assessment of the child's emotional, social, behavioral, and developmental functioning within the family home, school, and community. A comprehensive behavioral health assessment must include direct observation of the child in the home, school, and community, as well as in the clinical setting, and must adhere to the requirements contained in the Florida Medicaid Community Behavioral Health Services Coverage and Limitations Handbook."
- "Express and informed consent" means "a process by which a provider of medical services obtains voluntary consent from a parent whose rights have not been terminated or a legal guardian of the child who has received full, accurate, and sufficient information and an explanation about the child's medical condition, medication, and treatment to enable the parent or guardian to make a knowledgeable decision without any element of fraud, deceit, duress, or other form of coercion."
- "Mental health treatment plan" means "a plan which lists the particular mental health needs of the child and the services that will be provided to address those needs." If the plan includes prescribing psychotropic medication to a child in out-of-home placement, the plan must also include certain specified information.
- "Psychotropic medication" means "a prescription medication that is used for the treatment of mental disorders and includes, without limitation, hypnotics, antipsychotics, antidepressants, antianxiety agents, sedatives, stimulants, and mood stabilizers."[25]

The bill provides for the appointment of a GAL at the earliest possible time to represent the best interest of a child in DCF custody who is prescribed a psychotropic medication. The bill provides duties and responsibilities of the GAL and requires the department and its community-based care lead agencies to notify the GAL within 24 hours after any change in the status of the child.

When DCF believes that a child in its custody may need psychiatric treatment, an evaluation must be conducted by a physician licensed under chs. 458 or 459, F.S. If, at the time of removal from his or her home, a child is already being provided prescribed medication, the prescribing physician shall try to obtain express and informed consent of the parent or legal guardian and assent of the child. The bill provides that the prescribing physician must consider the capacity of the child to make an independent decision based on his or her age, maturity, and psychological and emotional state when determining whether or not it is appropriate to obtain assent from the child. The bill provides different instructions for the physician in obtaining assent, depending on

[25] The Florida Rules of Criminal Procedure provide a slightly different definition of psychotropic medication. Specifically, rule 3.215 provides that psychotropic medication is "any drug or compound affecting the mind, behavior, intellectual functions, perception, moods, or emotion and includes anti-psychotic, anti-depressant, anti-manic, and anti-anxiety drugs."

the age of the child. Whether the child assents or refuses to give assent, the physician must document it and place it in the child's mental health treatment plan.

The physician must also attempt to get express and informed consent for the administration of psychotropic medication from the child's parent or legal guardian. Consent may only be given by a parent whose rights have not been terminated or a legal guardian who has received full, accurate, and sufficient information about the child's medical condition, medication, and treatment. A copy of the parent's or legal guardian's consent (or lack thereof) must be documented and placed in the child's mental health treatment plan. The bill requires that when assent or informed consent is obtained, a copy of the assent or consent documents must be placed in the child's mental health treatment plan and filed with the court. Oral assent or informed consent must be documented by the prescribing physician.

Consent may become invalid under certain circumstances and if that happens, DCF must immediately notify all parties and try to obtain consent from the other parent or another legal guardian. If DCF cannot obtain valid consent, then the department must file a motion for administration of psychotropic medication. The child must continue on his or her medication until the court rules on the motion.

The bill provides procedures to be followed by the department and the court in cases where a child is in an out-of-home placement and may need a psychotropic medication, but parental consent has not been obtained. In any case where consent is invalid, the department must file a motion with the court within 3 working days to authorize the administration of the psychotropic medication before the administration of the medication.

The motion must include:

- A written report by DCF describing the efforts made to obtain express and informed consent, and describing other treatments attempted, considered, and recommended for the child; and
- The prescribing physician's completed and signed mental health treatment plan.

The department must notify all parties within 48 hours of filing the motion with the court. An objection to the motion must be made within 2 working days after a party is notified of the motion. If an objection is not filed and the motion is legally sufficient, the court may enter an order without a hearing. If an objection is timely filed, the court shall hold a hearing as soon as possible. The court must find a compelling governmental interest that the proposed psychotropic medication is in the child's best interest when issuing its order. The bill provides certain factors for a court to consider when determining if the medication is in the child's best interest. The bill also outlines procedures to be followed when administering psychotropic medication before a court order has been obtained, including cases when a child receives a one-time dose of medication. Specifically:

- If a child is removed from his or her home and taken into custody, the department may continue to administer a current prescription of psychotropic medication until the shelter hearing, where the department must request court authorization for the continued administration of the medication.

- If it approves, the court may only authorize continued use of the medication until the arraignment hearing on the petition for adjudication. If DCF believes that it needs to continue the medication beyond the time authorized by the court, the department must file a motion at the same time that it files the dependency petition.
- The department must administer the medication to the child immediately if the prescribing physician certifies that a delay in providing the medication would cause significant harm. The bill provides certain requirements if the department immediately administers the medication to the child.
- The department may authorize, in advance of a court order, the administration of psychotropic medication to a child in its custody in a hospital, crisis stabilization unit or receiving facility, therapeutic group home, or in a statewide inpatient psychiatric program. Upon administering the medication, the department must file a motion to seek court authorization for the continued administration of the medication within 3 working days.
- If a child receives a one-time dose of a psychotropic medication during a crisis, the department must immediately notify all parties and the court of the emergency use.

The bill provides procedures for discontinuing or altering the provision of psychotropic medication to a child and requires the department to ensure destruction of unused medication that is no longer being taken by a child.

The bill requires that any child who needs mental health services must have a mental health treatment plan. This plan must include:

- The name of the child, a statement indicating that there is a need to prescribe psychotropic medication to the child based upon a diagnosed condition for which there is an evidence base for the medication that is being prescribed, a statement indicating the compelling governmental interest in prescribing the psychotropic medication, and the name and range of the dosage of the psychotropic medication.
- A statement indicating that the physician has reviewed all medical information concerning the child which has been provided by the department or community-based care lead agency and briefly listing all such information received.
- A medication profile, including all medications the child is prescribed or will be prescribed, any previously prescribed medications where known, and whether those medications are being added, continued, or discontinued upon implementation of the mental health treatment plan.
- A statement indicating that the psychotropic medication, at its prescribed dosage, is appropriate for treating the child's diagnosed medical condition, as well as the behaviors and symptoms that the medication, at its prescribed dosage, is expected to address.
- An explanation of the nature and purpose of the treatment; the recognized side effects, risks, and contraindications of the medication, including procedures for reporting adverse effects; drug-interaction precautions; the possible effects of stopping or not initiating the medication; and how the treatment will be monitored, followed by a statement indicating that this explanation was provided to the child if developmentally appropriate and to the child's caregiver.
- Documentation addressing whether the psychotropic medication will replace or supplement any other currently prescribed medications or treatments; the length of time the child is

expected to be taking the medication; a plan for the discontinuation of any medication when medically appropriate; and any additional medical, mental health, behavioral, counseling, or other services that the prescribing physician recommends as part of a comprehensive treatment plan.

- A document describing those observable behaviors warranting psychotropic treatment, the means for obtaining reliable frequency data on these same observable behaviors, and the reporting of this data with sufficient frequency to support medication decisions.

The bill provides that no child under 11 years of age may be prescribed psychotropic medication absent a finding of a compelling governmental interest.[26] The current age requirement for pre-consent review is any child 6 years old or younger. It is unclear whether the court must find a compelling governmental interest in order for psychotropic medication to be prescribed to a child under the age of 11 if the parent or legal guardian has given consent.

Before psychotropic medication is authorized, a review of the administration must be obtained from a child psychiatrist licensed under chs. 458 or 459, F.S. It is unclear if a child is already being seen by a psychiatrist if that child would need to get a second opinion under this provision, or if the child's current psychiatrist could review the administration.

The department may authorize, in advance of a court order, the administration of psychotropic medications to a child from birth through 10 years of age in its custody in the following levels of residential care:

- Hospital;
- Crisis stabilization unit or receiving facility;
- Therapeutic group home; or
- Statewide inpatient psychiatric program.

If the child is in one of these levels of residential care, the compelling governmental interest requirement is satisfied. The department must still file a motion with the court to seek authorization or continued administration of the medication. If the department authorizes a one-time dose of psychotropic medication during a crisis, the department must immediately notify all parties and the court.

The bill prohibits a child in the custody of the department from participating in clinical trials relating to the development of new psychotropic medications. The bill also provides for additional information relating to psychotropic medication to be added to judicial review hearings.

Finally, the bill provides rulemaking authority to the department to ensure that children receive timely access to mental health services, including, but not limited to, clinically appropriate psychotropic medications.

[26] A compelling governmental interest is a very high burden and is often reserved for situations where a fundamental right is involved. See *A.W. v. Dep't of Children and Families*, 969 So. 2d 496, 504 (Fla. 1st DCA 2007) (citing *North Fla. Women's Health and Counseling Services., Inc. v. State*, 866 So. 2d 612, 625 n. 16 (Fla. 2003).

The bill deletes provisions in s. 39.407, F.S., relating to the provisions of psychotropic medications to children in out-of-home care (similar provisions were included in the newly created s. 39.4071, F.S.). Additionally, the bill amends s. 39.407, F.S., to require that every child placed in out-of-home care receive a comprehensive behavioral health assessment, specify who is eligible for the assessment, and require that the assessment be provided to the physician involved in developing the mental health treatment plan for any child in need of mental health services.

The bill amends s. 743.0645, F.S., to conform to other changes made by the bill.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of the bill have no impact on public records or open meetings issues under the requirements of Article I, Section 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Physicians prescribing psychotropic medicine to foster care children will have to increase the amount of time spent with each child in order to complete the additional examination and medical documentation requirements in this bill.

This bill creates a potential liability for guardian volunteers who fail to provide medical records, behavioral observations, or other requirements necessary for the prescription of psychotropic medications to children. This could subject the GAL and the GAL program to claims resulting from children who are injured as a result of such failure.

C. Government Sector Impact:

At the time of this analysis, there were no available analyses from state agencies or other entities. However, an analysis from the department for an identical bill from the 2010 Legislative Session stated the fiscal impact of the bill on DCF was anticipated to be

covered within existing resources. The fiscal impact would have resulted from the increase in the number of pre-consent authorizations. Specifically:

> This cost is based on $160 per authorization, at an average of 3 pre-consent reviews (as medications change) per child for 917 children aged 10 and under and who are on psychotropic medication: $480 x 917 = $440,160. An additional $4,000 to establish an online submission capacity for pre-consent reviews is added into this recommendation for a total of $444,160.[27]

The Guardian ad Litem Program also anticipated no additional costs as a result of the 2010 bill.[28]

VI. Technical Deficiencies:

The bill's language describes court proceedings in terms that are not consistent with existing law or procedure, including requiring the court to treat certain behavior of the child as a "motion" and that the court must schedule a hearing on that "motion." In addition, there is no "motion" for a final judgment of termination of parental rights (lines 543-545). The correct language should simply be "along with a copy of the final judgment of termination of parental rights."

Lines 424-431 state that the GAL is the "representative of" the child. This may cause unnecessary confusion as several entities may represent a child, including the child himself or herself, a parent or guardian, or an attorney or attorney ad litem. Perhaps these lines could be rewritten to conform to the role of the GAL as the representative of the child's best interests.

On line 497, the bill provides that consent forms for parents and older children must be written at a sixth- to eighth-grade reading level. The portion regarding consent forms for parents may need to be included in paragraph (b) instead (starting at line 503), which deals specifically with obtaining express and informed consent from a child's parent or legal guardian. Currently, it is in the paragraph relating to obtaining assent from the child.

Given the definition of "parental consent" in this bill, it might be inappropriate to authorize the department to obtain parental consent (lines 525-528). By definition, this can only be obtained by the child's physician or staff.

It is unclear to what "revokes assent" refers in line 537. "Assent" in this bill is otherwise mentioned only when referring to assuring the cooperation of the child before prescribing psychotropic medication. Perhaps this should be changed to "consent" to maintain consistency with the remainder of the bill's language.

[27] Department of Children and Family Services, Staff Analysis and Economic Impact HB 1567 (SB 2718), (Mar. 5, 2010) (on file with the Senate Committee on Children, Families and Elder Affairs).
[28] E-mail from Nathan Ray, Guardian ad Litem Program, to professional staff of the Senate Committee on Children, Families and Elder Affairs (Apr. 8, 2010) (on file with the Senate Committee on Children, Families, and Elder Affairs).

VII. Related Issues:

"No other parent or legal guardian gives informed consent" in lines 542-543 could be construed in two ways. It could be that another parent or legal guardian is available and does not give consent to treatment with psychotropic medications, or it could mean that no other parent or legal guardian could be found to ask for consent. If another parent or legal guardian is found, is deemed competent, and declines further treatment of the child with psychotropic medications, that decision should be respected like any other healthcare decision a parent makes for a child, unless the lack of intervention can be proven to result in the child suffering or potentially suffering unnecessarily. Similar reasoning applies to the language in lines 546-549, 558-567, and 703-706.

The child's act of refusing medication (lines 712-716) cannot be treated as a motion in court. Although the concept makes sense, there must be a process in place for filing a written motion. Therefore, the caregiver must be required to notify the case manager or the GAL, who would be required to file and serve a written motion on all parties. They would then set the motion for a hearing no later than 7 days after service to all parties. Additionally, defining "repeated" refusal could avoid confusion on the part of the child's caregiver.

In lines 785-816, the bill provides that no child under 11 years of age may be prescribed psychotropic medication absent a finding of a compelling governmental interest. The current age requirement for pre-consent review is any child 6 years old or younger. It is unclear whether the court must find a compelling governmental interest in order for psychotropic medication to be prescribed to a child under the age of 11 if the parent or legal guardian has given consent.

VIII. 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.

THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

COMMITTEES:
Children, Families, and Elder Affairs, *Chair*
Budget - Subcommittee on Criminal and Civil Justice
Appropriations
Community Affairs
Military Affairs, Space, and Domestic Security
Reapportionment
Transportation

SENATOR RONDA STORMS
10th District

January 26, 2012

Senator Rene Garcia, Chair
Senate Committee on Health Regulation
310 Senate Office Building
404 S. Monroe Street
Tallahassee, FL 32399-1100

Dear Chairman Garcia:

Senate Bill 1808, relating to *Psychotropic Medications,* has been referred to your committee for its second committee of reference.

I would greatly appreciate you placing SB 1808 on the Health Regulation committee's agenda at your earliest convenience. Please do not hesitate to contact me should you have any questions.

Thank you for your consideration of this request.

Sincerely,

Senator Ronda Storms
Florida State Senate
10th District

Cc: Ms. Sandra R. Stovall, Staff Director
510 Knott Building

ENTERED

REPLY TO:
❒ Lithia Oaks Business Center, 421 Lithia Pinecrest Road, Brandon, Florida 33511 (813) 651-2189 FAX: (813) 651-2188
❒ 413 Senate Office Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5072
Internet Address: storms.ronda.web@flsenate.gov

Senate's Website: *www.flsenate.gov*

MIKE HARIDOPOLOS
President of the Senate

MICHAEL S. "MIKE" BENNETT
President Pro Tempore

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 Health Regulation Committee

BILL: CS/SB 282

INTRODUCER: Health Regulation Committee and Senators Wise and Storms

SUBJECT: Health Care Transition Programs

DATE: February 9, 2012 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Wilson	Stovall	HR	**Fav/CS**
2.			CF	
3.			BC	
4.				
5.				
6.				

Please see Section VIII. for Additional Information:

A. COMMITTEE SUBSTITUTE.....	X	Statement of Substantial Changes
B. AMENDMENTS.....		Technical amendments were recommended
		Amendments were recommended
		Significant amendments were recommended

I. Summary:

The bill creates a program called the Florida Health And Transition Services (FloridaHATS) in the Department of Health (DOH) Division of Children's Medical Services (CMS) Network to oversee health care transitional services in Florida for adolescents and young adults (individuals who are 12 through 26 years of age) with special health care needs. The bill assigns certain responsibilities to the program.

This bill creates one undesignated section of law.

II. Present Situation:

Health Care Transition

It is only recently that children and youth with disabilities and complex health conditions have survived to adulthood in relatively large numbers. There has been growing recognition that health care transition is a critical aspect of successful entry of these youth to adulthood. Taking responsibility for one's own health care is part of growing up and becoming independent. Health care transition is the purposeful planned movement of adolescents and young adults with chronic physical and medical conditions from child-centered to adult-oriented health care systems.[1] Successful health care transition supports economic self-sufficiency, independence, and prevents school dropout and delinquency.[2] Proactive transition to the adult health care system encourages young people to be successfully integrated into a comprehensive care system to meet their complex needs.

The 2006 Legislature provided a non-recurring appropriation of $300,000[3] to support a pilot program to develop transition services for adolescents and young adults with disabilities residing in Duval (Jacksonville), Baker, Clay, Nassau and St. Johns Counties. The Jacksonville Health And Transition Services (JaxHATS) program serves teens and young adults, ages 16-26 with chronic medical or developmental problems.[4] In FY 2010-2011, JaxHATS recorded a total of 1,014 visits by 909 patients. The patients ranged in age from 14 through 25 years, although 67 percent were in the age group 20-25 years old.[5]

Services provided by JaxHATS include primary care and care coordination up to age 26, as well as, referrals to adult medical homes, specialty physicians, and other transition-related services (e.g., education, employment, and independent living).[6] JaxHATS data indicate that patients who are well established within their program have significant decreases in reported emergency room visits and inpatient hospitalizations. The CMS continues to contract with the University of Florida for a total of $100,000 per year to pay for a portion of the JaxHATS staffing and clinic expenses.

Florida Health Care Transition Services Task Force for Youth and Young Adults with Disabilities

The 2008 Legislature passed CS/SB 988 (ch. 2008-211, L.O.F.) requiring the DOH to create a statewide Health Care Transition Services Task Force for Youth and Young Adults with Disabilities. The charge to the task force was to "assess the need for health care transition services for youth with disabilities, develop strategies to ensure successful transition from the pediatric to the adult health care system, and identify existing and potential funding sources." The task force submitted its final report on December 30, 2008.[7] The report contained 16 recommendations, including a recommendation to "leverage CMS's infrastructure and federally mandated responsibility for health care transition planning to establish a state Office of Health Care Transition within CMS that guides, monitors, and supports local public/private transition coalitions . . ."

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[1] Blum, RW; Garell, D; Hodgman, CH; Jorissen, TW; Okinow, NA; Orr, DP; and Slap, GB. *Transition from Child-Centered to Adult Health-Care Systems for Adolescents with Chronic Conditions, A Position Paper of the Society for Adolescent Medicine*. Journal of Adolescent Health, 1993, Vol. 14, No. 7, p. 570-576.
[2] Florida Health Care Transition Services Task Force for Youth and Young Adults with Disabilities, *Report and Recommendations, Ensuring Successful Transition from Pediatric to Adult Health Care*, January 1, 2009. Found at: <http://www.floridahats.org/?page_id=587> (Last visited on February 9, 2012).
[3] *See* proviso language in line item 623 of the General Appropriations Act for FY 2006-2007, Chapter 2006-25, L.O.F.
[4] JaxHATS, *Welcome to JaxHATS*. Found at: <http://jaxhats.ufl.edu/index.php> (Last visited on February 9, 2012).
[5] *See* Department of Health Bill Analysis, Economic Statement and Fiscal Note for SB 282, on file with the Senate Health Regulation Committee.
[6] *Id.*
[7] *Supra* footnote 2.

While the legislatively mandated task force dissolved on December 30, 2008, workgroup members continued with strategic plan development[8] based on findings and recommendations in the legislative report. In 2009, the program was officially named Florida Health And Transition Services, or FloridaHATS. Implementation activities outlined in the strategic plan have included the development of an insurance guide for young adults in Florida, an online training program for professionals, and regional health care transition coalitions (HillsboroughHATS and PanhandleHATS, in addition to JaxHATS). A strategic planning guide for regional coalitions was created to help communities in building local systems of care. All of these products are available on the FloridaHATS website.[9]

Children's Medical Services

The CMS program in the DOH provides children with special health care needs a family-centered, comprehensive, and coordinated statewide managed system of care that links community-based health care with multidisciplinary, regional, and tertiary pediatric care. Children with special health care needs are those children under age 21 whose serious or chronic physical or developmental conditions require extensive preventive and maintenance care beyond that required by typically healthy children.

The program provides services through two divisions, the Division of CMS Network and Related Programs and the Division of CMS Prevention and Intervention. The Division of CMS Network and Related Programs provides a continuum of early identification, screening, medical, developmental, and supporting services for eligible children with special health care needs. The CMS Division of Prevention and Intervention promotes the safety and well being of Florida's children by providing specialized services to children with special health care needs associated with child abuse and neglect.

Services are provided through 22 CMS area offices, 15 Early Steps offices, and contracted programs located throughout the state. A team of trained nursing and social work professionals and support staff at each CMS area office coordinate primary and specialty care services with the family through their local medical community.

The CMS currently provides transition education and assistance through its existing care coordination and provider systems. However, once a young adult reaches age 21, these services are no longer available.

Title V of the Social Security Act

Since its inception in 1935, the Maternal and Child Health Services Block Grant (Title V of the Social Security Act) has provided a foundation for ensuring the health of America's mothers and children. Title V provides funding to state maternal and child health programs, which serve 35 million women and children in the United States. Every state and the District of Columbia have a Title V Program for Children with Special Health Care Needs that is funded, in part,

[8] Florida Strategic Plan for Health Care Transition, 11/1/2010. Found at: <http://www.floridahats.org/wp-content/uploads/2010/03/OnePageVisual_11-1-10.pdf> (Last visited on February 9, 2012).
[9] FloridaHATS, *About FloridaHATS, Background*. Found at: <http://www.floridahats.org/?page_id=587> (Last visited on February 9, 2012).

through the Maternal and Child Health block grants. The CMS administers Florida's Title V Program for Children with Special Health Care Needs.

Title V block grants are provided to states to enable them, among other things, to provide and to promote family-centered, community-based, coordinated care (including care coordination services) for children with special health care needs and to facilitate the development of community-based systems of services for these children and their families. Care coordination means services to promote the effective and efficient organization and utilization of resources to assure access to necessary comprehensive services for children with special health care needs and their families.[10]

III. Effect of Proposed Changes:

The bill creates an undesignated section of law relating to health care transition programs and services for adolescents and young adults who have special health care needs.

The bill states that it is the intent of the Legislature to provide a strategic and comprehensive approach to the development and implementation of effective health care transition programs and services for adolescents and young adults who have special health care needs. The bill gives recognition to the plan developed by the Health Care Transition Services Task Force for Youth and Young Adults with Disabilities pursuant to chapter 2008-211, Laws of Florida.

The bill establishes a program called the Florida Health And Transition Services (FloridaHATS) in the Division of CMS Network of the DOH to oversee transitional services in Florida. This program will be responsible for:

- Developing and overseeing a planning and implementation process and the necessary guides for use by community providers and organizations in developing coordinated systems of services for adolescents and young adults who have special health care needs.
- Developing and disseminating resource guides that outline the various public and private health care financing options, including commercial insurance, and the respective health care benefits.
- Coordinating with educational institutions, including medical centers, to identify and make available for health care providers existing training programs regarding the principles, objectives, and methods for the successful transition of adolescents and young adults who have special health care needs to adult health care providers.
- Maintaining and updating the FloridaHATS's website with web-based materials related to health care transition services.
- Collecting and disseminating information in specific clinical areas concerning evidence-based practices and best practices for providing health care transition services.
- Providing technical assistance to entities that are involved in the development and implementation of systems of services for adolescents and young adults who have special health care needs.
- Developing and disseminating quality improvement and evaluation components to other health care providers, which components must include a common or comparable set of performance measures for all entities that provide health care transition services.

[10] *See* 42 U.S.C. §701

- Establishing a network of experts in the fields of pediatric and adolescent medicine, adult medicine, and allied health to provide technical assistance and recommendations regarding best practices and policy guidance in health care transition.

The bill defines the term "adolescents and young adults who have special health care needs" as individuals who are 12 through 26 years of age; who have chronic physical, developmental, behavioral, or emotional conditions; and who require health care or related services of a type or amount beyond that which is generally required by adolescents or young adults. The effect of this provision is that CMS would be authorized to extend care coordination support for young adults who have special health care needs from the age of 21 through 26 years of age.

The effective date of the bill is July 1, 2012.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of the bill have no impact on public records or open meetings issues under the requirements of Article I, Section 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

Some of the activities assigned to the FloridaHATS program in the bill would appear to require funding, however, some of these activities have already been completed, or partially completed, with existing funding. The Department of Health proposes to use existing funds to establish the oversight of FloridaHATS and does not expect any impact on state revenue. The bill authorizes oversight of transition services only, not the provision of medical services to young adults from age 21 through age 26.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. 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 Regulation on February 9, 2010:
The CS limits the activities of the Department of Health with regard to health care transition programs and services for adolescents and young adults who have special health care needs to overseeing transitional services, not providing clinical services. The CS also removes several activities assigned to the Department of Health in the original bill that had a fiscal impact.

B. Amendments:

None.

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
02/09/2012	.	
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	.	
	.	

The Committee on Health Regulation (Fasano) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause and insert:

Section 1. Legislative intent; health care transition programs and services for adolescents and young adults who have special health care needs.—

(1) It is the intent of the Legislature to provide a strategic and comprehensive approach to the development and implementation of effective health care transition programs and services for adolescents and young adults who have special health care needs. The Health Care Transition Services Task

Force for Youth and Young Adults with Disabilities developed a statewide plan to promote the development of such health care transition services, in accordance with chapter 2008-211, Laws of Florida, and outlined the plan in its subsequent report.

(2) A program called the Florida Health And Transition Services (FloridaHATS) is established within the Division of Children's Medical Services Network to oversee transitional services in this state using existing state plans in order to implement effective transition services for adolescents and young adults who have special health care needs. As used in this section, the term "adolescents and young adults who have special health care needs" means individuals who are 12 through 26 years of age; who have chronic physical, developmental, behavioral, or emotional conditions; and who require health care or related services of a type or amount beyond that which is generally required by adolescents or young adults. FloridaHATS shall be responsible for:

(a) Developing and overseeing a planning and implementation process and the necessary guides for use by community providers and organizations in developing coordinated systems of services for adolescents and young adults who have special health care needs.

(b) Developing and disseminating resource guides that outline the various public and private health care financing options, including commercial insurance, and the respective health care benefits.

(c) Coordinating with educational institutions, including medical centers, to identify and make available for health care providers existing training programs regarding the principles,

objectives, and methods for the successful transition of adolescents and young adults who have special health care needs to adult health care providers.

(d) Maintaining and updating the FloridaHATS's website with web-based materials related to health care transition services which can be used by adolescents and young adults who have special health care needs and their families, providers, and others involved in health care transition.

(e) Collecting and disseminating information in specific clinical areas concerning evidence-based practices and best practices for providing health care transition services for adolescents and young adults who have special health care needs.

(f) Providing technical assistance to communities, providers, and organizations that are involved in the development and implementation of systems of services for adolescents and young adults who have special health care needs.

(g) Developing and disseminating quality improvement and evaluation components to other health care providers. The quality improvement and evaluation components must include a common or comparable set of performance measures for all entities that provide health care transition services for adolescents and young adults who have special health care needs.

(h) Establishing a network of experts in the fields of pediatric and adolescent medicine, adult medicine, and allied health to provide technical assistance and recommendations regarding best practices and policy guidance in health care transition.

Section 2. This act shall take effect July 1, 2012.

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

And the title is amended as follows:

Delete everything before the enacting clause and insert:

A bill to be entitled

An act relating to health care transition programs and services for adolescents and young adults who have special health care needs; providing legislative intent; establishing a program within the Division of Children's Medical Services Network in the Department of Health to oversee transitional services in this state using existing state plans in order to implement health care transition programs for adolescents and young adults who have special health care needs; specifying responsibilities of the program with respect to the oversight, implementation, and coordination of the program; providing an effective date.

The Florida Senate

Committee Agenda Request

To: Senator Rene Garcia, Chair
Committee on Health Regulation

Subject: Committee Agenda Request

Date: November 22, 2011

I respectfully request that **Senate Bill # 282**, relating to Health Care Transition/Adolescents & Young Adults, be placed on the:

☒ committee agenda at your earliest possible convenience.

☐ next committee agenda.

Senator Stephen R. Wise
Florida Senate, District 5

ENTERED

File signed original with committee office

S-020 (03/2004)

THE FLORIDA SENATE

APPEARANCE RECORD

2-9-12
Meeting Date

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

Topic Health Care Transition

Bill Number SB 282 *(if applicable)*

Name Margaret S. Hooper

Amendment Barcode *(if applicable)*

Job Title Public Policy Coordinator

Address 124 Marriott Dr. #203
Street
Tallahassee FL 32301
City *State* *Zip*

Phone 850-921-7263

E-mail MargaretH@FDDC.org

Speaking: ☑ For ☐ Against ☐ Information

Representing Florida Developmental Disabilities Council

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)

2/9/12
Meeting Date

Topic _____ Bill Number SB 282 *(if applicable)*

Name Phil Williams Amendment Barcode _____ *(if applicable)*

Job Title Asst. Sec. Medicaid Finance

Address 2727 Mahan Drive Phone 412-3600
Street

Tallahassee FL 32308 E-mail _____
City *State* *Zip*

Speaking: ☐ For ☐ Against ☒ Information

Representing AHCA

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 Health Regulation Committee

BILL: SB 1474

INTRODUCER: Senator Gibson

SUBJECT: Public Health

DATE: February 8, 2012 REVISED: _____ _____ _____ _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Davlantes	Stovall	HR	**Favorable**
2.			BC	
3.				
4.				
5.				
6.				

I. Summary:

The bill requires the Department of Health (the department) to create a pilot project in Duval and Gadsden Counties to use expedited partner therapy (EPT) to treat sexually-transmitted diseases (STDs). The cost of the pilot project will be covered by identifying resources within the existing budget of the pilot project area or by developing partnerships.

This bill creates one undesignated section of law.

II. Present Situation:

Sexually-Transmitted Diseases

STDs are infections which spread from person to person during sexual activity. Such infections include gonorrhea, Chlamydia, herpes, HIV, trichomoniasis, human papillomavirus (HPV), and syphilis. STDs infect both men and women, but they are more likely to cause symptoms in women. STDs in women who are pregnant can lead to birth defects, high-risk pregnancies, congenital infections, and other serious health risks for the unborn child.[1]

Chlamydia, gonorrhea, and trichomoniasis can be treated with single doses of certain oral antibiotics. Syphilis can be treated with a single intramuscular dose of penicillin. HIV and HPV are unable to be cured once they are contracted.[2]

[1] Medline Plus, *Sexually Transmitted Diseases*, available at: http://www.nlm.nih.gov/medlineplus/sexuallytransmitteddiseases.html (last visited on February 2, 2012).
[2] Epocrates, *Epocrates Essentials*. A copy is on file with the Senate Health Regulation Committee.

In Florida in 2011, Leon and Gadsden Counties had the highest rates of STDs as reported to the department. These two counties consistently have the highest rates of STDs in the state. The next-highest ranking counties for 2011 were Union, Hamilton, Alachua, and Duval. In 2010 department data showed similar trends.[3]

Expedited Partner Therapy

People who get STDs once are likely to get them again, often from the same sexual partner. Since STDs are often asymptomatic in men, they may be unaware that they have a disease. Upon treating a patient with a STD, it is common medical practice to advise that the patient's partner be tested and treated as well; however, partner management based on patient referral or provider referral has had only moderate success in assuring partner treatment.

EPT is the practice of treating the sex partners of persons with STDs without an intervening medical evaluation or professional prevention counseling. The usual implementation of EPT is through patient-delivered partner therapy (PDPT), meaning that health care providers give patients antibiotics to deliver to their partners, although other methods may be employed. Clinical studies comparing rates of recurrent STDs after patient referral and after EPT has shown a slight decrease in STD rates among patients treated with EPT, although further studies are needed to confirm any trends.

However, the practice of treating partners without a preliminary medical examination can have serious health ramifications. Partners treated with EPT may have more serious forms of the STD which require stronger treatment or even hospitalization, be allergic to the antibiotics they are given, or have co-existing STDs which the original patient was not tested for and are therefore not treated with EPT. All of these conditions will go unnoticed unless the person being treated has had his or her own medical evaluation. The patient treated with EPT will also lose the benefit of prevention counseling, an important part of an STD medical evaluation. Furthermore, it is unclear where the liability lies when a health care professional treats a patient he or she did not see and adverse outcomes occur.

The Centers for Disease Control and Prevention (CDC) recommends that EPT be considered by clinicians as an option for partner management, but not replace classic strategies such as patient referral or provider-assisted referral, and that EPT should be accompanied by information that advises recipients to seek personal health care.[4]

Expedited Partner Therapy in Other States

In 2009, the Texas Medical Board amended the Texas Administrative Code to permit EPT for the management of STDs. A professional relationship with a patient is not required for a physician to prescribe medications for sexually-transmitted diseases for partners of the physician's established patient, if the physician determines that the patient may have been infected with a sexually-transmitted disease.[5] Similar rules also apply to advanced registered

[3] Telephone conversation with staff from the Department of Health, Bureau of STD Prevention and Control.
[4] Centers for Disease Control and Prevention, *Expedited partner therapy in the management of sexually transmitted diseases*, available at: http://www.cdc.gov/std/treatment/EPTFinalReport2006.pdf (last visited on February 2, 2012).
[5] 22 Tex. Admin. Code s. 190.8(1)(L)(iii).

nurse practitioners.[6] The Texas Department of State Health Services website provides many resources for EPT, including fact sheets for patients in English and Spanish and practice guidelines for health practitioners.[7]

Staff from the Texas Department of State Health Services report that STD rates have not changed since EPT became legal in the state. This is mainly due to the reluctance of health practitioners to prescribe EPT. Despite endorsements from leaders from state government, medical organizations, and nursing organizations, it is estimated that less than 40 percent of physicians who treat STD patients in Texas utilize EPT.[8]

EPT is currently prohibited in seven states, including Florida. It is potentially allowable in 13 states, meaning that no statutes or rules specifically permit or prohibit the practice, and is legally permissible in 30 states.[9]

III. Effect of Proposed Changes:

Section 1 requires the department to develop and implement an EPT pilot program in Duval and Gadsden Counties. The pilot project will exempt providers in those counties from the requirements of ss. 384.27 and 465.023(1)(h), F.S., and Rule 64B8-9.014, F.A.C.[10] Under the proposed pilot project, a physician is authorized to provide a single dose of medication provided by the county health department (CHD) to infected patients for use by their partners. EPT is not mandated under the pilot project; rather, it is offered as a treatment option. The pilot project will also provide provider and patient education material concerning EPT developed by the CDC and by the state of Texas.

The cost of the pilot project may be covered by identifying resources within the existing budget of the pilot project area or by developing partnerships. The funds will be used to purchase medication, provide additional material for physicians and patients, and evaluate the progress of the project.

Section 2 provides an effective date of July 1, 2012.

[6] 22 Tex. Admin. Code s. 222.4(e).
[7] Texas Department of State Health Services, *Expedited Partner Therapy (EPT)*, available at: http://www.dshs.state.tx.us/hivstd/ept/default.shtm (last visited on February 2, 2012).
[8] Telephone conversation with staff from the Texas Department of State Health Services.
[9] Centers for Disease Control and Prevention, *Legal Status of EPT*, available at: http://www.cdc.gov/std/ept/legal/default.htm (last visited on February 2, 2012).
[10] Section 384.27, F.S., relates to physical examination and treatment of patients with STDs. Section 465.023(1)(h), F.S., prohibits a pharmacist from dispensing any drug when the pharmacist knows or has reason to believe that the prescription offered for that drug is not based upon a valid practitioner-patient relationship that includes a documented patient evaluation. Rule 64B8-9.014, F.A.C., prohibits allopathic physicians and physician assistants from issuing prescriptions unless a documented patient evaluation has taken place and treatment options have been discussed with the patient.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of the bill have no impact on public records or open meetings issues under the requirements of Article I, Section 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Partners of patients with STDs in Duval and Gadsden Counties will have easier access to antibiotic treatment. Transmission of STDs may be reduced, thereby reducing health care costs.

C. Government Sector Impact:

CHDs will experience a negative fiscal impact as they will be asked to provide additional dosages of antibiotics for patients participating in the EPT program. However, CHD leadership in both Gadsden and Duval Counties support implementation of an EPT pilot program.[11] State and local government may also experience increased costs related to other aspects of the pilot project, depending on the success of developing partnerships with private organizations.

The department estimates that it will experience $127,535 of recurring costs related to hiring an epidemiologist to evaluate the project, purchasing antibiotics and laboratory tests for use in the pilot project, and printing of educational and instructional materials for providers and patients. Estimates are based on treatment of 4,000 patients and their partners each year for Chlamydia and gonorrhea, although it is possible that many more individuals will participate in the pilot project and that other STDs might be identified and need treatment in such individuals.[12]

[11] Telephone conversation with Department of Health staff.
[12] Department of Health, *2012 Bill Analysis, Economic Impact, and Fiscal Note for SB 1474*. A copy is on file with the Senate Health Regulation Committee.

VI. Technical Deficiencies:

None.

VII. Related Issues:

The bill provides that the department develop and implement an EPT pilot project in Duval and Gadsden Counties. However, it does not specify in which institutions the pilot project will occur. CHDs must provide the extra doses of medication needed for the EPT pilot project, but it is unclear if the project is limited only to CHDs.

Further, the bill requires CHDs to provide a dose of medication to a physician, who then provides the dose to an infected patient. If such a physician is in private practice, providing a dose of medication would violate s. 499.003(54), F.S., the wholesale distribution law.

The bill exempts providers from the requirements of Rule 64B8-9.014, F.A.C., which prohibits an allopathic physician from issuing a prescription without performing a physical exam on a patient. However, the bill does not provide an exemption from Rule 64B15-14.008, F.A.C., a similar rule which governs osteopathic physicians.

Lines 43-46 allow physicians to provide a single dose of medication to infected patients for use by their partners. Not only does this language fail to specify the types of physicians permitted to provide such medications (assumedly the intention is physicians licensed or registered under chs. 458 or 459, F.S.), but there is no language in the bill to permit nurse practitioners and physician assistants to participate in the project. Nurse practitioners and physician assistants also have prescribing authority under state law and constitute a significant proportion of the primary care providers in Florida.

The bill does not specify the length of time for which the pilot project should be enacted. Pilot projects generally do not continue indefinitely.

Lines 56-59 state that funding for the pilot project may be appropriated for various uses, including evaluating the progress of the project. However, no provision is made to report such progress or findings to any government entity. Customarily, progress reports for projects, task forces, and other agencies are submitted by a certain date to the Governor, the President of the Senate, and the Speaker of the House of Representatives.

It is unclear if physicians will be liable for any adverse reactions occurring to a partner as a result of EPT treatment.

The bill exempts pharmacy permitholders from professional discipline for dispensing to a person known not to have a prescriber-patient relationship with the prescriber, notwithstanding s. 465.023(1)(h), F.S. Section 465.016(1)(s), F.S., addresses pharmacists and could cover dispensing practitioners under s. 465.0276, F.S. This protects dispensing pharmacy personnel in the Duval CHD Pharmacy. However, the Gadsden CHD has no pharmacy. In the Gadsden CHD, partner medication would be dispensed under the Nurse Issue program in s. 154.04(1)(c), F.S., or by order of a CHD physician. Neither the CHD physicians nor CHD nurses are pharmacy

permittees under ch. 465, F.S., and therefore remain subject to professional discipline. Neither are such CHD physicians and nurses registered as dispensing practitioners under s. 465.0276, F.S., so compliance with the bill could expose them to the risk of professional discipline.

Similarly, all private sector physicians in both Duval and Gadsden Counties may be subject to professional discipline for the above-described dispensing activity and possibly could be at risk for related prescribing activity.

The bill does not provide specific authority sufficient to support adoption of rules to implement the pilot project.

VIII. 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.

2nd Request

THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

COMMITTEES:
Budget - Subcommittee on General Government Appropriations
Budget - Subcommittee on Transportation, Tourism, and Economic Development
Children, Families, and Elder Affairs
Community Affairs
Military Affairs, Space, and Domestic Security
Reapportionment
Transportation

JOINT COMMITTEE:
Public Counsel Oversight

SENATOR AUDREY GIBSON
1st District

January 23, 2012

Senator Rene Garcia, Chair
Committee on Health Regulation
530 Knott Building
404 South Monroe Street
Tallahassee, Florida 32399-1100

Chairman Garcia

I respectfully request that SB 1474, relating to Public Health, be placed on the next committee agenda.

SB 1474 is a pilot program specific to Duval & Gadsden Counties and uses existing funds.

Thank you for your time and consideration.

Sincerely,

Audrey Gibson
State Senator
District 1

REPLY TO:
- 101 E. Union Street, Suite 104, Jacksonville, Florida 32202 (904) 359-2553 FAX: (904) 359-2532
- 226 Senate Office Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5024
- Daytona State College, Building 110, Room 222, 1200 W. Int'l Speedway Blvd., Daytona Beach, FL 32114 (386) 506-3494
- St. John's County Complex, 75 King Street, St. Augustine, Florida 32084

Senate's Website: *www.flsenate.gov*

MIKE HARIDOPOLOS
President of the Senate

MICHAEL S. "MIKE" BENNETT
President Pro Tempore

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 Health Regulation Committee

BILL: SB 1378

INTRODUCER: Senator Altman

SUBJECT: Payment For Services Provided By Licensed Psychologists

DATE: February 2, 2012 REVISED: _____ _____ _____ _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Steele	Stovall	HR	**Pre-meeting**
2.			BI	
3.			BC	
4.				
5.				
6.				

I. Summary:

This bill:

- Amends provisions relating to health insurance policies and health maintenance organizations (HMOs) to add psychologists to the list of health care providers protected by a 12-month limitations period from claims by health insurers or health maintenance organizations for *overpayment*, and adding psychologists to the list of health care providers subject to a 12-month limitations period for submitting claims to health insurers or health maintenance organizations for a claim for *underpayment*;
- Adds psychologists to the list of health care providers eligible for direct payment for medical services by a health insurer in accordance with the provisions of each policy; and
- Provides an effective date of July 1, 2012.

This bill substantially amends the following sections of the Florida Statutes: 627.6131, 641.3155, and 627.638.

II. Present Situation:

Chapter 490, F.S., the "Psychological Services Act," governs the practice of psychology and school psychology in Florida. A person desiring to practice psychology or school psychology in Florida must be licensed by the Department of Health. "Practice of psychology" means the observations, description, evaluation, interpretation, and modification of human behavior, by the use of scientific and applied psychological principles, methods, and procedures, for the purpose of describing, preventing, alleviating, or eliminating symptomatic, maladaptive, or undesired behavior and of enhancing interpersonal behavioral health and mental or psychological health.[1]

[1] S. 490.003(4), F.S.

"Practice of school psychology" means the rendering or offering to render to an individual, a group, an organization, a government agency, or the public any of the following services:[2] assessment, counseling, consultation, and development of programs.

Psychologists who contract as preferred providers[3] (also network providers) with an insurer receive payment directly from the insurer, instead of the insured, for services rendered.[4] In contrast, non-network psychologists are generally paid by the insured. After paying the psychologist, the insured then files a claim for reimbursement with the insurer. In comparison, non-network recognized hospitals, licensed ambulance providers, physicians, dentists, and other persons who provided services to the insured, in accordance with the provisions of the policy between the insured and the insurer, are directly reimbursed by the insurer if the insured specifically authorizes payment of benefits to the provider of services.[5]

After payment is made to a psychologist for services rendered to an insured, health insurers and HMOs are time-limited to making a claim for overpayment within 30 months (2-½ years) from the date of that payment.[6] If a claim for overpayment is made, the psychologist has 40 days to pay it.[7] If the psychologist denies or contests the claim, he/she must do so in writing within 35 days of receiving the claim.[8] In comparison, claims of overpayment by health insurers and HMOs for service rendered by allopathic physicians, osteopathic physicians, chiropractic physicians, and dentists, must be submitted to the provider within 12 months after the health insurer's payment of the claim.[9]

Assignment of Benefits to Health Care Providers

Prior to the 2009 Legislative Session, s. 627.638(2), F.S., required direct payment by health insurers to certain health care providers if the patient authorized assignment of benefits, unless otherwise provided in the insurance contract.[10]

Statutory amendments by the 2009 Legislature in ch. 2009-124, L.O.F., to s. 627.638(2), F.S., require health insurers and HMOs to directly pay non-network hospitals, licensed ambulance providers, physicians, dentists, and other persons who provide services to an insured, in accordance with the provisions of the policy between the insured and the insurer, if the insured specifically authorizes payment of benefits to the provider of services.

Due to concerns that this would lead to increased costs to the state's group health plan as a result of providers leaving the network, language was included in ch. 2009-124, L.O.F., providing for the amendments to be automatically repealed on July 1, 2012, and the language in s. 627.638(2),

[2] S. 490.003(5), F.S.
[3] S. 627.6471(1)(b), F.S. defines preferred provider as, "any licensed health care provider with which the insurer has directly or indirectly contracted for an alternative or a reduced rate of payment…"
[4] S. 627.638(3), F.S.
[5] S. 627.638(2), F.S.
[6] SS. 627.6131(6)(a)(1), F.S. and 641.3155, F.S.
[7] S. 627.6131(6)(a)(1), F.S.
[8] S. 627.6131(6)(a)(2), F.S.
[9] SS. 627.6131(18), F.S. and 641.3155(14), F.S.
[10] An exception existed that the insurance contract could not prohibit the assignment of benefits and direct payment for emergency services and care.

F.S., to revert to the language that existed on June 30, 2009, if the Office of Program Policy Analysis and Government Accountability (OPPAGA) made certain findings in a study to be published on or before March 1, 2012. The amendments would repeal if the OPPAGA found that: 1) the amendments have caused the third-party administrator of the state's group health plan to suffer a net loss of physicians from its preferred provider plan network and 2) as a direct result, the state's group health plan incurred an increase in costs.[11]

In January 2012, the OPPAGA issued Report No. 12-01 as required by s. 2 of ch. 2009-124, L.O.F.[12] The OPPAGA's report found that the statutory changes made in 2009: 1) did not result in a loss of network physicians in the state's group health plan and 2) that no cost increase in the state's group health plan could be directly attributed to the 2009 changes.

III. Effect of Proposed Changes:

Section 1 amends s. 627.6131, F.S., relating to overpayment or underpayment of claims by health insurers to a provider, to include psychologists and school psychologists in the list of providers:

- To whom an insurer must submit a claim for overpayment within 12 months after the health insurer's payment of the claim; and
- Who must submit a claim for underpayment to an insurer within 12 months after the health insurer's payment of the claim.

Section 2 amends s. 641.3155, F.S., relating to overpayment or underpayment of claims by an HMO to a provider, to include psychologists and school psychologists in the list of providers:

- To whom an insurer must submit a claim for overpayment within 12 months after the health insurer's payment of the claim; and
- Who must submit a claim for underpayment to an insurer within 12 months after the health insurer's payment of the claim.

Section 3 amends s. 627.638(2), F.S. to include non-network psychologists in the list of providers:

- To whom an insurer must make direct payment, if the insured specifically authorizes the payment of benefits directly to the psychologist;
- For which an insurance contract may not prohibit the direct payment of benefits; and
- For which an insurer must provide a claim form with an option for direct payment of benefits.

This section is contingent upon the language in s. 627.638(2), F.S. *not* reverting to that in existence on June 30, 2009. Since the condition for reversion was not met, this section would take effect.

[11] Ch. 2009-124, L.O.F.
[12] *Negative Effects on the State's Third Party Provider Network from 2009 Law Not Apparent*, Report No. 12-01, January 2012, Office of Program Policy Analysis and Government Accountability. Available at: <http://www.oppaga.state.fl.us/MonitorDocs/Reports/pdf/1201rpt.pdf> (Last visited on Jan. 30, 2012).

Section 4 amends s. 627.638(2), F.S. to include psychologists in the list of providers:

- To whom an insurer must make direct payment to, if the insured specifically authorizes payment of benefits directly to the psychologist, unless otherwise provided in the insurance contract;
- For which an insurance contract may not prohibit the direct payment of benefits for emergencies services and care; and
- For which an insurer must provide a claim form with an option for direct payment of benefits for emergency services and care.

This section is contingent upon the text of s. 627.638(2), F.S. reverting to that in existence on June 30, 2009. Since the text would not revert, this section has no effect.

Section 5 provides an effective date of July 1, 2012.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of the bill have no impact on public records or open meetings issues under the requirements of Article I, Section 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Psychologists will have a shorter time frame for bringing insurance claims for services to conclusion.

Non-network psychologists will benefit by being entitled to direct payment of benefits from insurers, assuming that the insured executes an assignment of benefits.

The insured will be able to assign benefits to non-network psychologists, instead of paying the psychologist first and then seeking reimbursement from the insurer.

Health insurers and HMOs may have to update their claim forms to reflect psychologists as an option for assignment of benefits.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

Sections 3 and 4 assume in conditional language that the OPPAGA report has not been released yet. As it has been released, and as it has shown that the test for automatic reversion has not been met, section 4 is not needed and the conditional provision in the directory clause in section 3 is unnecessary.

VIII. 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.

249756

LEGISLATIVE ACTION

Senate . House

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The Committee on Health Regulation (Gaetz) recommended the following:

Senate Amendment

Delete lines 60 - 102
and insert:
Section 3. Subsection (2) of section 627.638, Florida Statutes, is amended to read:
627.638 Direct payment for hospital, medical services.—
(2) Whenever, in any health insurance claim form, an insured specifically authorizes payment of benefits directly to any recognized hospital, licensed ambulance provider, physician, dentist, psychologist, or other person who provided the services in accordance with the provisions of the policy, the insurer shall make such payment to the designated provider of such services. The insurance contract may not prohibit, and claims forms must provide an option for, the payment of benefits directly to a licensed hospital, licensed ambulance provider, physician, dentist, psychologist, or other person who provided the services in accordance with the provisions of the policy for care provided. The insurer may require written attestation of assignment of benefits. Payment to the provider from the insurer may not be more than the amount that the insurer would otherwise have paid without the assignment.

Florida Senate - 2012 COMMITTEE AMENDMENT
Bill No. SB 1378

249756

THE FLORIDA LEGISLATURE
OPPAGA
OFFICE OF PROGRAM POLICY ANALYSIS & GOVERNMENT ACCOUNTABILITY

January 2012 **Report No. 12-01**

Negative Effects on the State's Third Party Provider Network from 2009 Law Not Apparent

at a glance

Statutory changes made by the 2009 Legislature that require the state group health plan's third party administrator to directly pay non-network providers for services did not result in a loss of network physicians. Since December 2009, the number of physicians participating in Blue Cross and Blue Shield of Florida's (BCBS) preferred provider network for the state group has increased by 12.5%. In addition, while the number and amount of non-network physician and other profession claims has increased slightly since 2009, the proportion of these claims to overall physician and other profession claims for the state group has remained at about 2%. Moreover, the discount rate BCBS negotiates with network providers for the state group has remained relatively unchanged.

Overall costs for state group health participants have increased; per enrollee per month costs increased from $479 in Fiscal Year 2008-09 to $541 in Fiscal Year 2010-11. However, these increased costs cannot be directly linked to the 2009 law because many factors contribute to rising health care costs.

Scope

Chapter 2009-124, *Laws of Florida*, directs OPPAGA to examine whether the state's third party insurance preferred provider network experienced a net loss of physicians due to statutory changes requiring the third party administrator to directly pay non-network providers for services.[1] The law also directs OPPAGA to determine if, as a direct result of these statutory changes, costs increased for the state group health plan.

Background

The Department of Management Services, Division of State Group Insurance offers and manages a comprehensive package of pre- and post-tax health and welfare insurance benefits for active and retired state employees and their families, including health insurance; flexible spending and health savings accounts; life, vision, and dental insurance; and other supplemental insurance products. Employees have several health insurance options for which they share the cost of coverage with the state.[2]

- Membership in a self-insured ***preferred provider organization*** (PPO)[3]
- Membership in a fully-insured ***health maintenance organization*** (HMO)[4]

[1] The 2009 law requires insurers to pay directly all non-network providers, including hospitals, surgery centers, physical therapy centers, etc. However, the law directs OPPAGA to examine the effect of the law on physicians in the preferred provider network.

[2] PPO plans are available on a statewide basis, while HMO plans are available only in certain areas. All options provide enrollees access to a variety of services such as physician care, inpatient hospitalization, outpatient services, and prescription drugs. Employees elect to enroll in any of the options and may select individual or family coverage.

[3] Monthly premiums: Single—$549.80 ($50 for enrollee and $499.80 for state); Family—$1,243.34 ($180 for enrollee and $1,063.34 for state).

[4] Monthly premiums: Single—$549.80 ($50 for enrollee and $499.80 for state); Family—$1,243.34 ($180 for enrollee and $1,063.34 for state).

- Access to a ***health savings account*** (HSA) through a PPO or HMO[5]

The state's PPO plan uses funds from the State Employees' Group Health Self-Insurance Trust Fund to pay claims and plan administrative costs. Contributions made by state agencies and enrollees are deposited into the trust fund. The state contracts with a third-party administrator, Blue Cross and Blue Shield of Florida, Inc. (BCBS), for access to its provider network, to process medical claims for the PPO plan, and to provide cost control services such as case management review and coordination of benefits with other insurance plans.

In Fiscal Year 2010-11, the PPO plan included 92,763 enrollees. During this period, the state's costs for PPO medical claims totaled $602.5 million.

Preferred provider organizations rely on a network of physicians, medical facilities, and other health care providers. PPOs contract with various types of health care providers, including physicians, hospitals, and healthcare clinics. Network providers agree to provide health care services at discounted rates in return for certain benefits, such as access to a large patient group, direct prompt payment from the insurer, and other benefits as negotiated by Blue Cross and Blue Shield of Florida.

BCBS benefits from having providers participate in the network, because it can negotiate provider discounts and manage patient costs for the numerous plans that it manages. According to company officials, the self-insured state PPO plan, together with various entities, access a single, statewide provider network.

Recent changes to Florida law affected preferred provider organization payments for non-network services. PPO participants typically receive services from network providers but can choose to obtain services from providers who do not to participate in the PPO's network. Choosing non-network providers may increase a participant's out-of-pocket costs. In the absence of a negotiated discount, the participant may have to pay the difference between the insurer's reimbursement and the amount charged by the non-network provider.

Prior to 2009, when BCBS approved a claim for services from a non-network provider, the payment was made to the plan participant. The participant would then be responsible for paying the provider. Non-network providers argued that this payment policy made it difficult for them to be reimbursed, because sometimes plan participants would spend reimbursement monies for other expenses and fail to pay for services received. However, BCBS argued that the policy helped to attract providers, thus enabling the company to maintain a strong network and contain costs.

In 2009, the Legislature amended s. 627.638(2), *Florida Statutes*, to require the state's third party administrator to directly pay non-network providers for services. Patients must sign a form to transfer their insurance benefit to the non-network provider, allowing these providers to receive direct payment for services (i.e., assignment of benefits).[6] Network providers continue to receive payment in the same manner as they did prior to the legislation.

Findings

BCBS's preferred provider network has not suffered a net loss of physicians since 2009

Physicians may join preferred provider networks for many reasons. By participating in the network, physicians gain access to patients and receive direct prompt payment for services from the insurer. Depending on the insurer's market share, network physicians may also be more or less able to negotiate a favorable reimbursement.

[5] Monthly premiums: Single—$514.80 ($15.00 for enrollee and $499.80 for state); if the employee enrolls in a health savings account, the state contributes up to $500 annually to the account. Family plan—$1,127.64 ($64.30 for enrollee and $1,063.34 for state); if the employee chooses to enroll in a health savings account, the state contributes up to $1,000 annually to the account.

[6] Patients that are members of a health plan, such as state group health insurance, receive coverage for their health costs as a benefit from their employer. Thus, the patient must transfer a portion of their benefit in order for non-network providers to receive payment for services. This is referred to as "assignment of benefits".

Physicians may also leave provider networks for many reasons, including moving out-of-state, ceasing to practice, retirement, or dissatisfaction with network reimbursements. At the time of the 2009 law change, BCBS expressed concern that the amendment would result in a loss of network physicians, because one of the advantages the company uses to attract providers to the network, prompt direct payment, would be available to non-network providers as well.

As shown in Exhibit 1, the overall number of physicians in BCBS's preferred provider network has increased since 2009. Just prior to the enactment of the 2009 law, the number of participating medical doctors (MDs) and doctors of osteopathic medicine (DOs) decreased slightly, from 35,793 to 35,301 (1.4%); the number of other participating professionals (chiropractors, dentists, optometrists, oral surgeons, podiatrists, and psychologists) also decreased from 4,999 to 4,899 (2%). Participation decreased again slightly just after the law was passed, from July to December 2009. However, since December 2009, the number of participating MDs and DOs has increased by 12.5%, and the number of other participating professionals has increased by 14%.

Exhibit 1
The Number of Medical Doctors and Others Participating in the PPO Network has Increased[1]

Date	Participating MDs and DOs	Other Participating Providers	Total
July – Dec 2008	35,793	4,999	**40,792**
Jan – June 2009	35,301	4,899	**40,200**
July – Dec 2009	34,757	4,862	**39,619**
Jan – June 2010	35,707	5,142	**40,849**
July – Dec 2010	38,316	5,860	**44,176**
Jan – June 2011	39,112	6,057	**45,169**

[1] Other participating providers include chiropractors, dentists, optometrists, oral surgeons, podiatrists, and psychologists.

Source: Blue Cross and Blue Shield of Florida.

BCBS formed several workgroups to address changes from the 2009 law, including a group to make the technical changes necessary to provide for the direct payment of non-network providers, a team to address customer satisfaction issues that could arise related to non-network provider billing practices, and a group focused on increasing provider recruitment.

While the network has not experienced a net loss of physicians, we could not determine how many physicians may have left the network due to the law change or what effect BCBS recruitment efforts had on the network. As a result, we cannot assess the full impact of the law on provider participation.

BCBS's non-network state group claims have increased slightly since the law change

In 2009, Blue Cross and Blue Shield of Florida officials suggested that state group health plan costs would increase due to an increase in non-network claims. Officials also suggested that the company might need to adjust its discount rate to encourage participating providers to remain in the network.

According to BCBS data, non-network claims for the state group for physicians and other professionals have increased slightly since 2009. As shown in Exhibit 2, the number of such non-network claims increased from 88,078 in Fiscal Year 2008-09 to 89,246 in Fiscal Year 2010-11, a 1.3% increase. Despite the increase in non-network physician claims, the percentage of non-network claims remains very low. For the three fiscal years from Fiscal Year 2008-09 through Fiscal Year 2010-11, non-network physician claims for the state group represent only about 2% of the cost of total physician and other profession claims, suggesting no appreciable change in non-network claims following the 2009 law.

In order to encourage providers to continue participating in the BCBS network, company officials also anticipated altering the discount rate the company negotiates with certain network providers. Physicians and other providers agree to discount the fees they charge to BCBS from their normal and customary rates in return for the benefits provided by network participation. BCBS officials anticipated renegotiating these discount rates with certain physicians in order to maintain the network and discourage physicians from leaving the network after passage of the 2009 law.

Exhibit 2
Non-Network State Group Claims for Physician and Other Professional Services Have Increased, but Such Claims as a Percentage of Total Costs has Remained Stable

	State PPO Plan (State Group Health Plan)					
Fiscal Year	Number of Plan Enrollees and Dependents	Total Number of Claims[1]	Total Claims Costs[1,2]	Total Number of Non-Network Claims	Total Non-Network Claims Costs	Non-Network Claims Costs as a Percent of Total Claims Costs
2008-09	194,463	2,104,900	$207,438,193	88,078	$4,568,427	2.20%
2009-10	187,239	2,083,259	$215,974,790	83,104	$4,726,247	2.19%
2010-11	182,948	2,033,679	$222,408,839	89,246	$4,763,969	2.14%

[1] Claims for MDs, DOs, and other professions as reported in Exhibit 1.
[2] Figures for claim amounts reflect what BCBS paid in physician and other profession claims; an amount equal to the difference between the amounts allowed less member responsibility. Medical claims for the State Group Health Plan for all providers including physicians totaled $602.5 million for Fiscal Year 2010-11 according to the Office of Economic and Demographic Research.

Source: Blue Cross and Blue Shield of Florida.

BCBS officials reported that since the legislation, the discount rate has remained relatively unchanged, but they declined to provide specific information about rate changes. The officials consider such information confidential, proprietary business information and a trade secret. While they reported that the discount rate remains generally unchanged, officials noted that even small changes in the discount rate could affect the cost of claims for specific providers, depending on utilization of services.

Preferred provider network costs have increased, but many factors likely contributed to these increases

Evidence shows that costs for the state group health plan have increased in recent years. As shown in Exhibit 3, from Fiscal Year 2008-09 through Fiscal Year 2010-11, the number of PPO participants has declined, while per enrollee per month costs have increased. Specifically, PPO enrollment declined from 98,589 to 92,763, while per enrollee per month costs increased from $479 in Fiscal Year 2008-09 to $541 in Fiscal Year 2010-11. Enrollment figures in Exhibit 3 include state plan enrollees only and do not include dependents.

According to Blue Cross and Blue Shield of Florida officials, it would be very difficult to attribute these cost increases to the 2009 law, because many factors influence rising health care costs. For example, health care inflation—a product of health care prices, utilization, and population size—has contributed to rising health care costs nationwide. For the month of October 2011, the health care inflation rate was 3.1%. While the Consumer Price Index measures inflation for all consumer spending, health care inflation focuses on health care services and measures the increased consumer spending needed to purchase the same services at new prices.[7] Since 2001, the annual health care inflation rate has been as high as 4.7% (2002) and as low as 3.2% (2009).

BCBS officials also mentioned the effect of federal health care reform on insurance and healthcare costs.[8] These national reforms include a wide range of measures to modify the nation's health insurance system. The changes introduced by the federal law will affect numerous entities and programs, including insurance companies, Medicare, and Medicaid.

Exhibit 3
PPO Enrollment has Declined but per Enrollee per Month Costs Have Increased[1]

Fiscal Year	PPO Enrollment	Per Enrollee Per Month Costs For Medical Services[1]
2008-09	98,589	$479.26
2009-10	95,843	$512.64
2010-11	92,763	$541.25

[1] Does not include costs for prescription drug services.

Source: Florida Office of Economic and Demographic Research.

[7] The goal of the Consumer Price Index is to measure the percentage by which consumers would have to increase their spending to be as well off with the new prices as they were with the old prices.

[8] In March 2010, the federal government enacted the Patient Protection and Affordable Care Act (referred to as the Affordable Care Act).

Agency Response

In accordance with the provisions of s. 11.51(5), *Florida Statutes*, a draft of our report was submitted to the Secretary of the Department of Management Services for review and response. The written response has been reproduced in Appendix A.

Appendix A

RICK SCOTT
Governor

DEPARTMENT OF MANAGEMENT SERVICES

JOHN P. MILES
Secretary

4050 Esplanade Way | Tallahassee, Florida 32399-0950 | Tel: 850.488.2786 | Fax: 850.922.6149

January 9, 2012

Mr. R. Phillip Twogood, Coordinator
Office of Program Policy Analysis and
Government Accountability
Claude Pepper Building Room 312
111 West Madison Street
Tallahassee, FL 32399-1450

Dear Mr. Twogood:

Pursuant to Section 11.51(2), Florida Statutes, this is our response to your preliminary and tentative report, ***Negative Effects on the State's Third Party Provider Network from 2009 Law Not Apparent.***

While the report did not include recommendations for the Department of Management Services, the department agrees with the findings and conclusions contained in the report. The department recognizes the importance of any issue that affects health care for active and retired state employees.

We appreciate your staff's efforts and cordial working relationship over the past few months. If you need additional information, please contact Steve Rumph, Inspector General, at 488-5285.

Sincerely,

John P. Miles
Secretary

cc: Brett Rayman, Chief of Staff
Barbara Crosier, Director, State Group Insurance
Stephanie Leeds, Legislative Affairs Director
Kris Purcell, Communications Director

The Florida Legislature

Office of Program Policy Analysis and Government Accountability

OPPAGA provides performance and accountability information about Florida government in several ways.

- Reports deliver program evaluation and policy analysis to assist the Legislature in overseeing government operations, developing policy choices, and making Florida government better, faster, and cheaper.
- PolicyCasts, short narrated slide presentations, provide bottom-line briefings of findings and recommendations for select reports.
- Government Program Summaries (GPS), an online encyclopedia, www.oppaga.state.fl.us/government, provides descriptive, evaluative, and performance information on more than 200 Florida state government programs.
- The Florida Monitor Weekly, an electronic newsletter, delivers brief announcements of research reports, conferences, and other resources of interest for Florida's policy research and program evaluation community.
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OPPAGA website: www.oppaga.state.fl.us

Project supervised by Kara Collins-Gomez (850/487-4257)
Project conducted by Mary Alice Nye and Jeanine Brown
R. Philip Twogood, Coordinator

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 Health Regulation Committee

BILL: CS/SB 1228

INTRODUCER: Health Regulation Committee and Senator Montford

SUBJECT: Practice of Physical Therapy

DATE: February 9, 2012 REVISED: _____ _____ _____ _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Davlantes	Stovall	HR	**Fav/CS**
2.			BC	
3.				
4.				
5.				
6.				

Please see Section VIII. for Additional Information:

A. COMMITTEE SUBSTITUTE.....	X	Statement of Substantial Changes
B. AMENDMENTS.....		Technical amendments were recommended
		Amendments were recommended
		Significant amendments were recommended

I. Summary:

The bill authorizes the Board of Physical Therapy Practice (the board) to issue temporary permits to practice as physical therapists (PT) or physical therapist assistants (PTA) under the direct supervision of licensed PTs to applicants who meet certain conditions, not including passage of a national examination approved by the board. The bill provides that a temporary permit will be valid until a license is granted and will be void if the permittee does not pass or sit for such an examination within 6 months of graduation from a PT or PTA training program. The bill provides standards that supervising PTs must meet and prohibits certain fraudulent acts concerning temporary permits.

The effective date of this bill is June 1, 2012.

This bill creates ss. 486.0715 and 486.1065, F.S., and amends s. 486.151, F.S.

II. Present Situation:

Licensure of Physical Therapists and Physical Therapist Assistants

To be licensed as a PT, an applicant must:

- Be at least 18 years old;
- Be of good moral character;
- Meet one of the following requirements:
  - Have graduated from a PT training program in the United States accredited by the Commission on Accreditation for Physical Therapy Education (CAPTE)[1] and have passed the NPTE for PTs offered by the Federation of State Boards of Physical Therapy (FSBPT) within 5 years before the date of application for licensure;
  - Have graduated from a PT training program in a foreign country, have had his or her credentials deemed by the Foreign Credentialing Commission on Physical Therapy or other board-approved credentialing agency to be equivalent to those of U.S.-educated PTs, have successfully completed a board-approved English proficiency examination if English was not the language of instruction in the PT training program, and have passed the NPTE for PTs within 5 years before the date of application for licensure;
  - Have passed a board-approved examination and hold an active license to practice physical therapy in another state or jurisdiction if the board determines that the standards for licensure in that state or jurisdiction are as high as those of this state;
- Pass the Laws and Rules Examination offered by the FSBPT (a $25 fee is required[2]) within 5 years before the date of application for licensure;[3]
- Meet the general requirements for licensure of all health care practitioners in ch. 456, F.S., including those in s. 456.0635, F.S., relating to past felony convictions; and
- Pay a $180 fee.[4]

Licenses must be renewed biennially for an $80 fee.[5] Continuing education of 24 hours per biennium is also required. At least 1 hour of education must be on HIV/AIDS, and 2 hours must be on medical error prevention. Certain exceptions to continuing education requirements may be made for licensees experiencing emergencies or hardship.[6]

Licensure requirements for PTAs are the same as those for PTs except that applicants must have graduated from an approved PTA training program, passed the NPTE for PTAs, or hold an active PTA license in another state or jurisdiction. Licensure fees and continuing education requirements are also the same.[7]

[1] CAPTE primarily accredits U.S.-based schools, although it also provides accreditation to two programs in Canada and one in Scotland. Source: CAPTE, *Directory of Programs*, available at: http://www.capteonline.org/Programs/ (last visited on January 19, 2012).
[2] Rule 64B-1.016(1)(a), F.A.C.
[3] Rules 64B17-3.001, 64B17-3.002, and 64B17-3.003, F.A.C.
[4] Rule 64B17-2.001, F.A.C.
[5] Rule 64B17-2.005(1), F.A.C.
[6] Rules 64B17-8.001, 64B17-8.002, and 64B17-8.003. F.A.C.
[7] Rules 64B17-4.001, 64B17-4.002, and 64B17-4.003, F.A.C.

Currently, no statute or rule authorizes issuance of temporary permits for PTs or PTAs; statutory provisions concerning such permits were deleted in 1999.[8]

Only PTs licensed in good standing by the board are authorized to use the words "physical therapist," "physical therapy," or "physiotherapist" or the abbreviations "PT," "PhT," "RPT," or "LPT" in connection with their names and places of business. Only PTAs licensed in good standing by the board are authorized to use the words "physical therapist assistant" or "physical therapy technician" or the abbreviations "PTA," "LPTA," "RPTA," or "PTT" in connection with their names and places of business.[9]

Testing Schedules

The NPTE is a multiple-choice, computerized exam which is only administered at Prometric testing centers. Until recently, the NBTE was offered on a continuous basis; examinees could take the exam at any Prometric center on any business day of their choosing. Since July 2011 for the NPTE for PTs, and starting in March 2012 for the NPTE for PTAs, the examinations will only be administered on certain days of the year. In 2012, the NPTE for PTs will be offered five times: January 30, March 29, July 2, July 31, and October 23; the NPTE for PTAs will be offered on April 26, July 17, and October 20. The examinations will thereafter be scheduled four times per year.

This change is intended to address security concerns and to protect the integrity of the exam and its questions, but it has also created accessibility problems for PT and PTA students, especially those in populous areas.[10] Many PT students must wait months for the opportunity to take the NBCE at a nearby Prometric center, compromising their ability to find jobs and become licensed. There are 12 Prometric locations which administer the NBCE in Florida; only one is in Miami, and only one is in the Orlando metro area.[11]

Exam scores are released to state physical therapy boards within 5 business days of each examination.[12]

The Florida Laws and Rules Examination is a multiple-choice exam offered on a continuous basis at any Prometric center.[13]

Delegation of Duties to Unlicensed Personnel

Unlicensed personnel may assist in the delivery of patient care treatment under the direct supervision of a PT. Except in a case of emergency, direct supervision requires the physical presence of the licensed PT for consultation and direction of the actions of a PT or PTA who is

[8] Department of Health, *2012 Bill Analysis, Economic Impact, and Fiscal Note for SB 1228*. A copy is on file with the Senate Health Regulation Committee.
[9] Section 486.135, F.S.
[10] FSBPT, *Fixed-date testing information for the PT and PTA NPTE*, available at: https://www.fsbpt.org/ForCandidatesAndLicensees/FixedDateTesting/index.asp (Last visited on December 15, 2011).
[11] Prometric, *Test Center Selection*, available at: https://securereg3.prometric.com/siteselection.aspx (Last visited on December 15, 2011).
[12] Phone conversation with FSBT staff.
[13] Email correspondence with board staff. Copies are on file with the Senate Health Regulation Committee.

practicing under a temporary permit and who is a candidate for licensure by examination.[14] A PT may only delegate tasks which he or she is qualified to perform, and it is the responsibility of the PT to ensure that tasks are completed adequately by appropriately-trained personnel. The PT remains liable for anything performed under his or her supervision.

PTs are not allowed to delegate tasks to unlicensed personnel which require the special knowledge, judgment, and skills of a PT or PTA, including:

- Initial evaluation or any subsequent evaluation of the patient;
- Interpretation of the initial evaluation or any subsequent evaluation;
- Establishment or revision of physical therapy goals;
- Development or alteration of the plan of care;
- Assessment of the progress of the patient in relation to the plan of care; and
- Final completion of patient progress notes.[15]

III. Effect of Proposed Changes:

Section 1 creates s. 486.0715, F.S., to allow the board to issue a temporary PT permit to an applicant who:

- Completes an application on a form approved by the department;
- Meets all eligibility requirements for licensure under ch. 456, F.S., s. 486.031, F.S., and related rules, except that passage of a national examination approved by the board is not required;
- Submits an application for licensure under s. 486.041, F.S.;
- Demonstrates proof of malpractice insurance; and
- Submits documentation, under rules adopted by the board, verifying that he or she will practice under the direct supervision of a licensed PT meeting certain conditions.

A temporary permit is nonrenewable and is valid until a license is granted by the board. A temporary permit becomes void if a permittee does not pass or sit for such an examination within 6 months of graduation from a department-approved training program.

Supervising PTs must have been licensed in this state for at least 6 months before the supervision period begins, may only supervise one permittee at a time, and must cosign all patient records produced by a permittee.

Section 2 creates s. 486.1065, F.S., to provide identical provisions for issuance of temporary PTA permits. Applicants must meet eligibility requirements for licensure under s. 486.102, F.S., rather than s. 486.031, F.S., and must submit an application for licensure under s. 486.103, F.S., rather than s. 486.041, F.S.

Section 3 amends s. 486.151, F.S., to prevent permittees from being prosecuted for unlicensed practice and prohibit certain acts related to fraudulent obtainment or use of temporary permits.

[14] Section 486.021(9), F.S. This language remained in statute after provisions for issuing temporary permits were repealed in 1999.
[15] Rule 64B17-6.007, F.A.C.

Section 4 provides an effective date of June 1, 2012.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of the bill have no impact on public records or open meetings issues under the requirements of Article I, Section 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Recent PT and PTA graduates will be able to practice in their chosen fields while waiting to take the NPTE.

C. Government Sector Impact:

The Department of Health (department) might experience an increase in workload related to issuing temporary permits for PTs and PTAs. However, each application for a temporary permit must be accompanied by an application for licensure; fees related to licensure applications should help offset the fiscal impact of issuing temporary permits. An exact fiscal impact cannot be calculated at this time because the number of potential applicants for temporary permits is unknown.

The department will also incur non-recurring costs for rulemaking and updating its practitioner licensure database, both of which current resources are adequate to absorb.

VI. Technical Deficiencies:

"Such an examination" in lines 33 and 66 should be replaced with "a national examination approved by the board" to increase clarity.

VII. Related Issues:

Lines 26 and 59 require applicants for temporary PT or PTA licenses to submit proof of malpractice insurance to the board. However, the bill does not specify what level of coverage is required. Furthermore, fully-licensed PTs and PTAs are not required to hold malpractice insurance.[16]

VIII. 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 Regulation on February 9, 2012:
The CS clarifies that applicants for temporary permits must fulfill all the requirements for general licensure, including general licensure requirements in ch. 456, F.S., except passage of a department-approved examination. It removes language from the bill which is currently specified in rule rather than in statute. The CS requires that applications for temporary permits must be submitted concomitantly with applications for general licensure, clarifies conditions upon which permits become void, and states that licensed PTs may only supervise one permitee at a time. Prevents permitees from being prosecuted for unlicensed practice and prohibits other acts related to fraudulent obtainment or use of temporary permits and changes the effective date of the bill to June 1, 2012.

B. Amendments:

None.

[16] Email correspondence with board staff. Copies are on file with the Senate Health Regulation Committee.

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LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
02/09/2012	.	
	.	
	.	
	.	

The Committee on Health Regulation (Jones) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause and insert:

Section 1. Section 486.0715, Florida Statutes, is created to read:

486.0715 Physical therapist; issuance of temporary permit.—

(1) The board shall issue a temporary physical therapist permit to an applicant who meets the following requirements:

(a) Completes an application for a temporary permit on a form approved by the department.

(b) Meets all the eligibility requirements for licensure

402778

under ch. 456, s. 486.031, and related rules, except passage of a national examination approved by the board is not required.

(c) Submits an application for licensure under s. 486.041.

(d) Demonstrates proof of possessing malpractice insurance.

(e) Submits documentation, under rules adopted by the board, verifying that the applicant will practice under the direct supervision of a licensed physical therapist as provided in subsection (3).

(2) A temporary permit is not renewable and is valid until a license is granted by the board. A temporary permit is void if the permittee does not pass or sit for such an examination within 6 months after the date of graduation from a physical therapy training program.

(3) An applicant for a temporary permit shall not work as a physical therapist until a temporary permit is issued by the board. A physical therapist who is practicing under a temporary permit must do so under the direct supervision of a licensed physical therapist. A supervising physical therapist shall only supervise one permittee at any given time. The supervising physical therapist must be licensed for a minimum of 6 months before the supervision period begins and must cosign all patient records produced by the physical therapist who is practicing under a temporary permit.

Section 2. Section 486.1065, Florida Statutes, is created to read:

486.1065 Physical therapist assistant; issuance of temporary permit.—

(1) The board shall issue a temporary physical therapist assistant permit to an applicant who meets the following

402778

requirements:

(a) Completes an application for a temporary permit on a form approved by the department.

(b) Meets all the eligibility requirements for licensure under ch. 456, s. 486.102, and related rules, except passage of a national examination approved by the board is not required.

(c) Submits an application for licensure under s. 486.103.

(d) Demonstrates proof of possessing malpractice insurance.

(e) Submits documentation, under rules adopted by the board, verifying that the applicant will practice under the direct supervision of a licensed physical therapist as provided in subsection (3).

(2) A temporary permit is not renewable and is valid until a license is granted by the board. A temporary permit is void if the permittee does not pass or sit for such an examination within 6 months after the date of graduation from a physical therapy assistant training program.

(3) An applicant for a temporary permit shall not work as a physical therapist assistant until a temporary permit is issued by the board. A physical therapist assistant who is practicing under a temporary permit must do so under the direct supervision of a licensed physical therapist. A supervising physical therapist shall only supervise one permittee at any given time. The supervising physical therapist must be licensed for a minimum of 6 months before the supervision period begins and must cosign all patient records produced by the physical therapist assistant who is practicing under a temporary permit.

Section 3. Subsection (1) of section 486.151, Florida Statutes, is amended to read:

402778

486.151 Prohibited acts; penalty.—

(1) It is unlawful for any person to:

(a) Practice physical therapy or attempt to practice physical therapy without an active license or temporary permit.

(b) Use or attempt to use a license or temporary permit to practice physical therapy which is suspended, ~~or~~ revoked, or void.

(c) Obtain or attempt to obtain a license or temporary permit to practice physical therapy by fraudulent misrepresentation.

(d) Use the name or title "Physical Therapist" or "Physical Therapist Assistant" or any other name or title which would lead the public to believe that the person using the name or title is licensed to practice physical therapy, unless such person holds a valid license.

(e) Make any willfully false oath or affirmation whenever an oath or affirmation is required by this chapter.

(f) Knowingly conceal information relating to violations of this chapter.

Section 4. This act shall take effect June 1, 2012.

================ 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 physical therapy; creating ss. 486.0715 and 486.1065, F.S.; authorizing issuance of a temporary permit to practice as a physical therapist

402778

or physical therapist assistant; providing requirements for issuing a temporary permit; providing for voiding of a temporary permit; providing requirements for the supervision of temporary permittees; amending s. 486.151, F.S.; prohibiting certain acts concerning temporary permits; providing an effective date.

The Florida Senate

Committee Agenda Request

To: Senator Rene Garcia, Chair
Committee on Health Regulation

Subject: Committee Agenda Request

Date: January 19, 2012

I respectfully request that **Senate Bill #1228**, relating to Practice of Physical Therapy, be placed on the:

☐ committee agenda at your earliest possible convenience.

☒ next committee agenda.

Senator Bill Montford
Florida Senate, District 6

ENTERED

File signed original with committee office

S-020 (03/2004)

THE FLORIDA SENATE

APPEARANCE RECORD

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

2/9/2012
Meeting Date

Topic Physical Therapy

Bill Number SB 1228 *(if applicable)*

Name Dr. Scott Harp, PT, PhD

Amendment Barcode *(if applicable)*

Job Title Vice President, Florida Physical Therapy Assoc.

Address *Street*

Phone 407-865-2712

Tallahassee FL
City *State* *Zip*

E-mail

Speaking: ☑ For ☐ Against ☐ Information

Representing Self

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)

2/9/12
Meeting Date

Topic Physical Therapists

Bill Number 1228 *(if applicable)*

Name Bob Harris

Amendment Barcode *(if applicable)*

Job Title

Address 2618 Centennial Place
Street
Tallahassee FL 32308
City *State* *Zip*

Phone 222-0720

E-mail bharris@lawfla.com

Speaking: ☑ For ☐ Against ☐ Information

Representing

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)

2/9/12
Meeting Date

Topic Practice of Physical Therapy Bill Number 1228 *(if applicable)*

Name Natalie Hair Amendment Barcode *(if applicable)*

Job Title Doctor of Physical Therapy Student (UCF)

Address 5024 Fiske Cir Phone (407) 493-0009
Street

Orlando, FL 32826 E-mail natalie.hair@knights.ucf.edu
City *State* *Zip*

Speaking: ☑ For ☐ Against ☐ Information

Representing Florida PT + PTA students

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)

02/09/2012
Meeting Date

Topic PHYSICAL THERAPY

Bill Number SB 1228 *(if applicable)*

Name HOWARD F. "GENE" ADAMS

Amendment Barcode _____ *(if applicable)*

Job Title ATTORNEY

Address 215 SOUTH MONROE ST., 2ND FLOOR *Street*
TALLAHASSEE FLA. 32301-1839 *City State Zip*

Phone 850-222-3533

E-mail GENE@PENNINGTONLAW.COM

Speaking: [X] For [ ] Against [ ] Information

Representing FLORIDA PHYSICAL THERAPY ASSOC.

Appearing at request of Chair: [ ] Yes [X] No

Lobbyist registered with Legislature: [X] 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 Health Regulation Committee

BILL: SB 1750

INTRODUCER: Senators Siplin and Montford

SUBJECT: Advanced Registered Nurse Practitioners

DATE: February 7, 2012 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Davlantes	Stovall	HR	**Pre-meeting**
2.			BC	
3.				
4.				
5.				
6.				

I. Summary:

This bill authorizes Advanced Registered Nurse Practitioners (ARNPs) to execute a certificate for involuntary examination of a person for mental illness at a receiving facility designated by the Department of Children and Families. Current law provides that physicians, clinical psychologists, psychiatric nurses, mental health counselors, marriage and family therapists, and clinical social workers may execute certificates for involuntary examination.

This bill substantially amends s. 394.463, F.S.

II. Present Situation:

Involuntary Examination

In 1971, the Legislature passed the Florida Mental Health Act (also known as The Baker Act) to address mental health needs in the state. Part I of ch. 394, F.S., provides authority and process for the voluntary and involuntary examination of persons with evidence of a mental illness and the subsequent inpatient or outpatient placement of individuals for treatment. The Department of Children and Families (DCF) administers this law through receiving facilities, which provide for the examination of persons with evidence of a mental illness. Receiving facilities are designated by DCF and may be public or private facilities which provide for the involuntary examination and short-term treatment of persons who meet criteria under this act.[1] Subsequent to examination at a receiving facility, a person who requires further treatment may be transported to a treatment facility. Treatment facilities designated by DCF are state hospitals (e.g., Florida State Hospital)

[1] Section 394.455(26), F.S.

which provide extended treatment and hospitalization beyond what is provided in a receiving facility.[2]

Current law provides that an involuntary examination may be initiated for a person if there is reason to believe the person has a mental illness, and, because of the illness, the person has refused a voluntary examination after explanation of the purpose of the exam or the person is unable to determine for themselves that an examination is needed and is likely to suffer from self-neglect, cause substantial harm to themselves, or be a danger to themselves or others.[3] An involuntary examination may be initiated by any of the following:[4]

- A court may enter an *ex parte* order stating a person meets the criteria for involuntary examination. This order is based on the sworn testimony by the petitioner, either written or oral;
- A law enforcement officer may take a person into custody who appears to meet the criteria for involuntary examination and transport him or her to a receiving facility for examination; or
- Physicians, clinical psychologists, psychiatric nurses, mental health counselors, marriage and family therapists or clinical social workers may issue a certificate stating that a person they examined within the preceding 48 hours meets the criteria for involuntary examination.

Current law provides that physicians, clinical psychologists, and psychiatric nurses who issue certificates for involuntary examinations must have additional experience or education requirements related to mental disorders.[5] Clinical social workers are required by law to have experience in providing psychotherapy and counseling.[6] Marriage and Family Therapist practice includes using psychological methods to evaluate, assess, diagnose, treat, and prevent emotional and mental disorders or dysfunctions.[7]

In 2009, there were 136,120 involuntary examinations initiated in the state. Law enforcement initiated almost half of the involuntary examinations (48.89 percent), followed by mental health professionals (48.74 percent), and then *ex parte* orders by judges (2.37 percent).[8]

Advanced Registered Nurse Practitioners

Part I of ch. 464, F.S., governs the licensure and regulation of nurses in Florida. Nurses are licensed by the Department of Health (DOH) and are regulated by the Board of Nursing (BON). Licensure requirements to practice professional nursing include completion of education requirements,[9] demonstration of passage of a department-approved examination, a clean criminal

[2] Section 394.455(32), F.S.
[3] Section 394.463(1), F.S.
[4] Section 394.463, F.S.
[5] Sections 394.455(2)(21)(23), F.S.
[6] Section 491.003(3), F.S.
[7] Section 491.003(8), F.S.
[8] Report of Baker Act Data, Summary of Data from 2009. USF, de la Parte Florida Mental Health Institute. http://bakeract.fmhi.usf.edu. (last visited on January 12, 2012).
[9] Rule 64B9-4.003, F.A.C., provides that an Advanced Nursing Program shall be at least one year long and shall include theory in the biological, behavioral, nursing and medical sciences relevant to the area of advanced practice in addition to clinical expertise with a qualified preceptor.

background screening, and payment of applicable fees.[10] Renewal is biennial and is contingent upon completion of certain continuing medical education requirements.

A nurse who holds a license to practice professional nursing may be certified as an ARNP under s. 464.012, F.S., if the nurse meets one or more of the following requirements:

- Completion of a post-basic education program of at least one academic year that prepares nurses for advanced or specialized practice;
- Certification by a specialty board, including boards for registered nurse anesthetists or nurse midwives; or
- Possession of a master's degree in a nursing clinical specialty area.

Current law defines three categories of ARNPs: certified registered nurse anesthetists, certified nurse midwives, and nurse practitioners.[11] All ARNPs, regardless of practice category, may only practice within the framework of an established protocol and under the supervision of an allopathic or osteopathic physician or a dentist. ARNPs may carry out treatments as specified in statute, including:[12]

- Monitoring and altering drug therapies;
- Initiating appropriate therapies for certain conditions;
- Performing additional functions as may be determined by rule in accordance with s. 464.003(2), F.S.;[13] and
- Ordering diagnostic tests and physical and occupational therapy.

In addition to the above permitted acts, ARNPs may perform other acts as permitted in statute within the specialty.[14] If it is within an established protocol, an ARNP may also diagnose behavioral problems and make treatment recommendations.[15]

There are 13,519 active, licensed ARNPs in Florida.[16]

III. Effect of Proposed Changes:

Section 1 amends s. 394.463, F.S., to permit an ARNP to execute a certificate stating that a person, who the ARNP has examined within the preceding 48 hours, appears to meet criteria for involuntary examination for mental illness. Current law provides that physicians, clinical psychologists, psychiatric nurses, mental health counselors, marriage and family therapists and clinical social workers may execute certificates for involuntary examination. These professions are required by statute to have experience and education in mental health treatment. ARNP training programs require students to have education in behavioral sciences.[17]

[10] Section 464.009, F.S., provides an alternative to licensure by examination for nurses through licensure by endorsement.
[11] Section 464.012(2), F.S.
[12] Section 464.012(3), F.S.
[13] Section 464.003(2), F.S., defines "Advanced or Specialized Nursing Practice" to include additional activities that an ARNP may perform as approved by the Board of Nursing.
[14] Section 464.012(4), F.S.
[15] Section 464.012(4)(c)5., F.S.
[16] Florida Department of Health, Medical Quality Assurance Annual Report 2010-2011.
[17] Rule 64B9-4.003, F.A.C., provides that an Advanced Nursing Program shall be at least one year long and shall include theory in the biological, behavioral, nursing and medical sciences relevant to the area of advanced practice in addition to clinical expertise with a qualified preceptor.

Section 2 provides an effective date of July 1, 2012.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of the bill have no impact on public records or open meetings issues under the requirements of Article I, Section 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

ARNPs will be able to initiate involuntary patient examinations under the Baker Act.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

Although ARNPs practice within an established protocol, it is unclear in the bill whether the authority to execute a certificate for involuntary examination is restricted to a protocol that authorizes the diagnosis of behavioral problems and treatment recommendations or whether any licensed ARNP may execute a certificate for involuntary examination.

VIII. 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.

The Florida Senate

Committee Agenda Request

To: Senator Rene Garcia, Chair
Committee on Health Regulation

Subject: Committee Agenda Request

Date: January 18, 2012

I respectfully request that **Senate Bill #1750**, relating to Advanced Registered Nurse Practitioners, be placed on the:

☐ committee agenda at your earliest possible convenience.

☒ next committee agenda.

Senator Gary Siplin
Florida Senate, District 19

cc: Sandra R. Stovall, Staff Director

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 Health Regulation Committee

BILL: SB 1294

INTRODUCER: Senator Garcia

SUBJECT: Florida Kidcare Program

DATE: February 7, 2012 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Wilson	Stovall	HR	**Pre-meeting**
2.			BC	
3.				
4.				
5.				
6.				

I. Summary:

The bill removes the exclusion from eligibility for the Florida Kidcare program of children who are aliens (not a citizen or national of the United States). Currently, only children who are "qualified aliens" are eligible for Kidcare. Under the bill, any child who is an alien, regardless of his or her alien status, would be eligible for Kidcare, as long as he or she meets the other eligibility requirements (primarily age and income) for the program.

This bill substantially amends section 409.814 of the Florida Statutes.

II. Present Situation:

Florida Kidcare Program

The Kidcare program was created by the Florida Legislature in 1998 in response to the federal enactment of the State Children's Health Insurance Program in 1997, later known more simply as the Children's Health Insurance Program (CHIP). The federal authority for the CHIP is located in Title XXI of the Social Security Act.[1] Initially authorized for 10 years and then recently re-authorized[2] through 2019 with federal funding through 2015, the CHIP provides subsidized health insurance coverage to uninsured children who do not qualify for Medicaid but

[1] Title XXI – State Children's Health Insurance Program. Found at: <http://www.ssa.gov/OP_Home/ssact/title21/2100.htm> (Last visited on February 7, 2012).
[2] Children's Health Insurance Program Reauthorization Act of 2009, Public Law 111-3. Found at: <http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_public_laws&docid=f:publ003.111.pdf%20> (Last visited on February 7, 2012).

who meet other eligibility requirements. Florida's statutory authority for Kidcare is found in part II of ch. 409, F.S.

Kidcare encompasses four programs: Medicaid for children, the Medikids program, the Children's Medical Services Network, and the Florida Healthy Kids program. Kidcare coverage is funded by state and federal funds through Title XIX (Medicaid) and Title XXI (CHIP) of the federal Social Security Act. Families also contribute to the cost of the coverage under the Title XXI-funded components of Kidcare based on their household size, income, and other eligibility factors. For families with incomes above the income limits for premium assistance or who do not otherwise qualify for assistance, Kidcare also offers an option under the Healthy Kids component and the Medikids component for the family to obtain coverage for their children by paying the full premium.

Eligibility for the Kidcare components that are funded by Title XXI is determined in part by age and household income as follows:[3]

- Medicaid for Children: Title XXI funding is available from birth until age 1 for family incomes between 185 percent and 200 percent of the Federal Poverty Level (FPL).
- Medikids: Title XXI funding is available from age 1 until age 5 for family incomes between 133 percent and 200 percent of the FPL.
- Healthy Kids: Title XXI funding is available from age 5 until age 6 for family incomes between 133 percent and 200 percent of the FPL. For age 6 until age 19, Title XXI funding is available for family incomes between 100 percent and 200 percent of the FPL.
- Children's Medical Services Network: Title XXI and Title XIX funds are available from birth until age 19 for family incomes up to 200 percent of the FPL for children with special health care needs. The Department of Health assesses whether children meet the program's clinical requirements.

Kidcare is administered jointly by the Agency for Health Care Administration, the Department of Children and Families, the Department of Health, and the Florida Healthy Kids Corporation. Each entity has specific duties and responsibilities under Kidcare as detailed in part II of ch. 409, F.S. The Department of Children and Families determines eligibility for Medicaid, and the Florida Healthy Kids Corporation processes all Kidcare applications and determines eligibility for the CHIP, which include a Medicaid screening and referral process to the Department of Children and Families, as appropriate.

To enroll in Kidcare, families utilize a form that is both a Medicaid and CHIP application. Families may apply using the paper application or an online application. Both formats are available in English, Spanish, and Creole. Income eligibility is determined through electronic data matches with available databases or, in cases where income cannot be verified electronically, through submission of current pay stubs, tax returns, or W-2 forms.

The 2011-2012 General Appropriations Act appropriated $520,962,322 for Kidcare, including $61,436,037 in General Revenue.[4] The Social Services Estimating Conference convened on

[3] Florida Kidcare Eligibility. Found at: <http://www.doh.state.fl.us/alternatesites/kidcare/images/data/FKC-eligibilityflag-accessible.pdf> (Last visited on February 7, 2012).
[4] *See* ch. 2011-69, L.O.F., line item 151.

December 12, 2011, to adopt a caseload and expenditure forecast for Kidcare through June 2015. For the current fiscal year the program is projected to end the year with a surplus of $39.4 million with $12.8 million of the surplus being General Revenue.[5] For FY 2012-2013, the projected expenditures for General Revenue are $6.2 million below the current year appropriation.

Eligibility of Alien Children for CHIP

The Immigration and Nationality Act (INA) was created in 1952 to consolidate a variety of statutes governing immigration law. The INA has been amended numerous times since 1952. The INA defines the term "alien" as "any person not a citizen or national of the United States."[6] Nationals of the United States are citizens of the United States, or persons who, though not a citizen of the United States, owe permanent allegiance to the United States. Nationals who are not citizens include persons born in American Samoa or Swain's Island after December 24, 1952, and residents of the Northern Mariana Islands who did not elect to become U.S. citizens.

Generally, under the INA, an alien is not eligible for any State or local public benefit, including health benefits, unless the alien is:[7]

- A qualified alien[8],
- A nonimmigrant alien[9] under the INA, or
- An alien who is paroled into the United States under the INA.[10]

There are limited exceptions to the ineligibility for public benefits for treatment of emergency medical conditions, emergency disaster relief, immunizations, and services such as soup kitchens, crisis counseling and intervention, and short-term shelter.[11]

The INA gives states the authority to provide that an alien who is not lawfully present in the United States is eligible for any state or local public benefit for which the alien would otherwise be ineligible, but only through the enactment of a state law which affirmatively provides for such eligibility. The term "lawfully present" includes immigrants or noncitizens who have been inspected and admitted into the United States and not overstayed the period for which they were admitted, or have current permission from the U.S. Citizenship and Immigrant Services to stay or live in the U.S.

The enactment of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (Public Law 104-193) placed limitations on Federal funding for health coverage of immigrant families. The law imposed a 5-year waiting period on certain groups of qualified aliens, including most children and pregnant women who were otherwise eligible for Medicaid. Medicaid coverage for individuals subject to the 5-year waiting period and for those who do not

[5] Social Services Estimating Conference – Kidcare Program, December 12, 2011. Found at: <http://edr.state.fl.us/Content/conferences/kidcare/index.cfm> (Last visited on February 7, 2012).
[6] *See* 8 U.S.C. §1101(a)(3).
[7] *See* 8 U.S.C. §1621(a).
[8] *See* 8 U.S.C. §1641(b) There are nine classes of qualified aliens.
[9] *See* 8 U.S.C. §1101(a)(15) There are 22 classes of nonimmigrant aliens identified in this section.
[10] *See* 8 U.S.C. §1182(d)(5).
[11] *See* 8 U.S.C. §1621(b).

meet the definition of qualified alien was limited to treatment of an emergency medical condition. The 5-year waiting period also applied to children and pregnant women under the CHIP.

When Florida enacted Kidcare in 1998, s. 409.814, F.S., excluded children who are aliens, except for children who are qualified aliens, from eligibility for Kidcare.

The Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA), Public Law 111-3, permits states to cover certain children and pregnant women who are "lawfully residing in the United States" in both Medicaid and the CHIP, notwithstanding certain provisions in the Personal Responsibility and Work Opportunity Reconciliation Act of 1996. States may elect to cover these groups under Medicaid only or under both Medicaid and the CHIP. The law does not permit states to cover these new groups only in the CHIP, without also extending the option to Medicaid.[12]

On July 1, 2010, the Centers for Medicare and Medicaid Services sent a letter to state health officials regarding Medicaid and CHIP coverage for lawfully residing children and pregnant women.[13] The letter states that children and pregnant women who fall into one of the following categories will be considered lawfully present. These individuals are eligible for Medicaid and CHIP coverage, if the state elects the new option under CHIPRA, and the child or pregnant woman meets the state residency requirements and other Medicaid or CHIP eligibility requirements.

- A qualified alien as defined in section 431 of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (8 U.S.C. §1641).
- An alien in nonimmigrant status who has not violated the terms of the status under which he or she was admitted or to which he or she has changed after admission.
- An alien who has been paroled into the U.S. pursuant to section 212(d)(5) of the INA (8 U.S.C. §1182(d)(5)) for less than 1 year, except for an alien paroled for prosecution, for deferred inspection or pending removal proceedings.
- An alien who belongs to one of the following classes:
  - Aliens currently in temporary resident status pursuant to section 210 or 245A of the INA (8 U.S.C. §§1160 or 1255a, respectively);
  - Aliens currently under Temporary Protected Status (TPS) pursuant to section 244 of the INA (8 U.S.C. §1254a), and pending applicants for TPS who have been granted employment authorization;
  - Aliens who have been granted employment authorization under 8 CFR 274a.12(c)(9), (10), (16), (18), (20), (22), or (24);
  - Family Unity beneficiaries pursuant to section 301 of Pub. L. 101-649, as amended;
  - Aliens currently under Deferred Enforced Departure (DED) pursuant to a decision made by the President;
  - Aliens currently in deferred action status; or

[12] *See* 42 U.S.C. §1397gg(e).
[13] Letter to State Health Officials dated July 1, 2010, from the Center for Medicaid, CHIP and Survey and Certification, U.S. Department of Health and Human Services, regarding Medicaid and CHIP Coverage of "Lawfully Residing" Children and Pregnant Women, SHO #10-006, CHIPRA #17. Found at: <https://www.cms.gov/smdl/downloads/SHO10006.pdf> (Last visited on February 7, 2012).

  - Aliens whose visa petition has been approved and who have a pending application for adjustment of status.
- A pending applicant for asylum under section 208(a) of the INA (8 U.S.C. §1158) or for withholding of removal under section 241(b)(3) of the INA (8 U.S.C. §1231) or under the Convention Against Torture who has been granted employment authorization, and such an applicant under the age of 14 who has had an application pending for at least 180 days.
- An alien who has been granted withholding of removal under the Convention Against Torture.
- A child who has a pending application for Special Immigrant Juvenile status as described in section 101(a)(27)(J) of the INA (8 U.S.C. §1101(a)(27)(J)).
- An alien who is lawfully present in the Commonwealth of the Northern Mariana Islands under 48 U.S.C. §1806(e).
- An alien who is lawfully present in American Samoa under the immigration laws of American Samoa.

Because "children who are lawfully residing in the U.S." is a new eligibility group, claims paid on their behalf may be matched at the enhanced Title XXI match rate, regardless of whether the child is covered through Medicaid or a separate CHIP program. Medicaid eligible children for whom a state receives the enhanced Title XXI match rate and who would be subject to the 5-year waiting period must be claimed at the regular Medicaid match rate once these children have met the 5-year waiting period. For children ages 19 to 21, who are not eligible for CHIP, the regular Medicaid match rate is available. There would be no federal match for services provided through Medicaid or CHIP for alien children who are not lawfully residing in the U.S.

Historical Overview of Coverage of Non-Citizens in Florida Kidcare/Healthy Kids

Currently, the Kidcare program does not subsidize coverage of a child who is not a citizen or does not meet the definition of a qualified alien. The Kidcare application asks whether or not each child on the application who is seeking coverage is a citizen and citizenship status is verified through external sources such as the Department of Health's Vital Statistics birth registry, and if not confirmed through other sources, then applicants are asked for proof of citizenship, such as birth certificates or passports. If citizenship is not confirmed or the child does not meet the eligibility criteria, the family may be offered non-subsidized coverage through Medikids or Healthy Kids.

In addition to this option, a few children in the Healthy Kids program who are non-citizens receive subsidized coverage through a local match program. Since the 2000-2001 state fiscal year, Healthy Kids has been authorized to collect local funds and in some fiscal years, state funds, to subsidize coverage for non-qualified, non-citizens. These enrollees are not eligible for any federal matching funds under the Medicaid program or the CHIP.

In FY 2000-2001, when the Florida Healthy Kids Corporation Act was amended to incorporate this change, the non-Title XXI enrollment, which included non-citizens and a small number of dependants of state employees supported with state and local funds, was over 21,000 children. The state funding was capped each year through budget proviso language with the maximum amount at $13.5 million in the first year of the match program with the funds then pulled from cash reserves of the Florida Healthy Kids Corporation. In the latter years the state funding was

reduced until the current situation where local organizations contribute 100 percent of the funds after the family contributions.

Currently, less than 30 enrollees remain in the non-subsidized, non-citizen component of the program. They are subsidized by nine counties at a cost of less than $40,000. Enrolled families pay the same subsidized costs as the CHIP enrollees and receive the same benefits and plans. No new enrollees have been accepted in this component since January 31, 2004.[14]

Local match has always been voluntary on the part of the counties and the other entities that contribute the funds each fiscal year. If a local entity decides it no longer wants to participate, the subsidized enrollees in that county are notified that their subsidized coverage is increasing to the full-pay rate. The local match and local funding components with subsidized coverage for the non-Title XXI eligible population were unique features of the Healthy Kids program only.

III. Effect of Proposed Changes:

The bill removes the exclusion from eligibility for the Florida Kidcare program of children who are nonqualified aliens. Children who are qualified aliens are currently eligible for Kidcare.

Aliens who are not currently eligible for Kidcare, but who would be made eligible by this bill, include:

- Undocumented or illegal aliens.
- Nonqualified aliens (noncitizens who are lawfully present in the U.S. and are not included in the definition of qualified aliens).
  - Citizens of Marshall Islands, Micronesia or Palau.
  - Immigrants paroled into the U.S. for less than one year.
  - Immigrants granted temporary protected status.
  - Nonimmigrants who are allowed entry into the U.S. for a specific purpose and usually for a limited time.

By making children who are lawfully residing in the U.S. eligible for the CHIP, the state would have to make them an eligibility category for Medicaid also.

The bill also has the effect of removing the 5-year waiting period, which currently makes immigrant children under Medicaid and the CHIP, who are lawfully residing in the U.S., eligible only for emergency care during those 5 years. The bill would allow these children to receive Medicaid and Title XXI subsidized coverage regardless of the child's date of entry into the U.S., provided they meet all of the other eligibility requirements.

The effective date of the bill is July 1, 2012.

[14] *See* s. 6 of ch.2004-1, L.O.F.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of the bill have no impact on public records or open meetings issues under the requirements of Article I, Section 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Additional families will benefit from the subsidized health insurance made available for their children by the bill.

C. Government Sector Impact:

If the intent is to make undocumented or illegal aliens eligible for Title XXI subsidized coverage and Medicaid coverage, federal matching funds will not be available. Such an eligibility expansion would have to be fully state funded. The following fiscal impact estimates included in the bill analyses from the Agency for Health Care Administration and the bill analysis from the Department of Children and Families do not contemplate making undocumented or illegal aliens eligible.

Agency for Health Care Administration
The Agency for Health Care Administration estimates that 5,430 additional children will be covered by Title XXI subsidized Kidcare coverage at a total additional cost of $10,874,555. Of that amount, $3,028,687 would be from State General Revenue funds.

The Agency for Health Care Administration estimates that 15,120 additional children will be covered by Medicaid at a total additional cost of $47,399,386. Of that amount, $20,035,720 would be from State General Revenue funds.

The total fiscal impact on the Agency for Health Care Administration for both Title XXI and Title XIX in state FY 2012-2013 will be $58,273,941, with $23,064,407 being the General Revenue impact.

Department of Children and Families
The Department of Children and Families estimates that the bill will have a $44,279 fiscal impact on the department for personnel to process the applications that will be generated as a result of this bill.

Florida Healthy Kids Corporation
The Florida Healthy Kids Corporation will incur programming costs for its third party administrator to accommodate the changes in eligibility for premium subsidy. The estimated one-time programming costs for these changes would be $1.5 million. The state share of those costs would be $461,550 and the federal share would be $1,038,450.

VI. Technical Deficiencies:

Section 409.903(1), F.S., will need to be amended to make children lawfully residing in the U.S. eligible for Medicaid, as well as the CHIP, in order to comply with federal law.

VII. Related Issues:

It is not clear whether the bill, by removing the exclusion from eligibility of children who are aliens, meets the INA requirement that a state that wants to make illegal aliens eligible must enact legislation that affirmatively provides for eligibility of aliens who are not lawfully present in the U.S.

VIII. 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.

440118

LEGISLATIVE ACTION

Senate . House

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The Committee on Health Regulation (Garcia) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause and insert:

Section 1. Subsection (4) of section 409.814, Florida Statutes, is amended to read:

409.814 Eligibility.—A child who has not reached 19 years of age whose family income is equal to or below 200 percent of the federal poverty level is eligible for the Florida Kidcare program as provided in this section. For enrollment in the Children's Medical Services Network, a complete application includes the medical or behavioral health screening. If,

440118

subsequently, an individual is determined to be ineligible for coverage, he or she must immediately be disenrolled from the respective Florida Kidcare program component.

(4) The following children are not eligible to receive Title XXI-funded premium assistance for health benefits coverage under the Florida Kidcare program, except under Medicaid if the child would have been eligible for Medicaid under s. 409.903 or s. 409.904 as of June 1, 1997:

(a) A child who is eligible for coverage under a state health benefit plan on the basis of a family member's employment with a public agency in the state.

(b) A child who is covered under a family member's group health benefit plan or under other private or employer health insurance coverage, if the cost of the child's participation is not greater than 5 percent of the family's income. If a child is otherwise eligible for a subsidy under the Florida Kidcare program and the cost of the child's participation in the family member's health insurance benefit plan is greater than 5 percent of the family's income, the child may enroll in the appropriate subsidized Kidcare program.

(c) A child who is seeking premium assistance for the Florida Kidcare program through employer-sponsored group coverage, if the child has been covered by the same employer's group coverage during the 60 days before the family submitted ~~prior to the family's submitting~~ an application for determination of eligibility under the program.

(d) A child who is an alien~~,~~ and is not lawfully present ~~but who does not meet the definition of qualified alien,~~ in the United States. For purposes of eligibility for the Florida

Kidcare program, the term "lawfully present" means that the child is an immigrant or noncitizen who has been inspected and admitted into the United States and not overstayed the period for which the child was admitted, or has current permission from the United States Citizenship and Immigrant Services to stay or live in the United States.

(e) A child who is an inmate of a public institution or a patient in an institution for mental diseases.

(f) A child who is otherwise eligible for premium assistance for the Florida Kidcare program and has had his or her coverage in an employer-sponsored or private health benefit plan voluntarily canceled in the last 60 days, except those children whose coverage was voluntarily canceled for good cause, including, but not limited to, the following circumstances:

1. The cost of participation in an employer-sponsored health benefit plan is greater than 5 percent of the family's income;

2. The parent lost a job that provided an employer-sponsored health benefit plan for children;

3. The parent who had health benefits coverage for the child is deceased;

4. The child has a medical condition that, without medical care, would cause serious disability, loss of function, or death;

5. The employer of the parent canceled health benefits coverage for children;

6. The child's health benefits coverage ended because the child reached the maximum lifetime coverage amount;

7. The child has exhausted coverage under a COBRA

continuation provision;

8. The health benefits coverage does not cover the child's health care needs; or

9. Domestic violence led to loss of coverage.

Section 2. Subsection (1) of section 409.903, Florida Statutes, is amended to read:

409.903 Mandatory payments for eligible persons.—The agency shall make payments for medical assistance and related services on behalf of the following persons who the department, or the Social Security Administration by contract with the Department of Children and Family Services, determines to be eligible, subject to the income, assets, and categorical eligibility tests set forth in federal and state law. Payment on behalf of these Medicaid eligible persons is subject to the availability of moneys and any limitations established by the General Appropriations Act or chapter 216.

(1) Low-income families with children are eligible for Medicaid provided they meet the following requirements:

(a) The family includes a dependent child who is living with a caretaker relative.

(b) The family's income does not exceed the gross income test limit.

(c) The family's countable income and resources do not exceed the applicable Aid to Families with Dependent Children (AFDC) income and resource standards under the AFDC state plan in effect in July 1996, except as amended in the Medicaid state plan to conform as closely as possible to the requirements of the welfare transition program, to the extent permitted by federal law.

440118

(d) A child, 18 years of age or less, who is an immigrant or noncitizen who has been inspected and admitted into the United States and not overstayed the period for which the child was admitted, or has current permission from the United States Citizenship and Immigrant Services to stay or live in the United States and who meets the Medicaid eligibility requirements, may enroll in Medicaid, regardless of the child's date of entry.

Section 3. This act shall take effect July 1, 2012.

========== 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 the Florida Kidcare program; amending s. 409.814, F.S.; making certain immigrant or noncitizen children who are lawfully residing in the United States eligible for the Florida Kidcare program; amending s. 409.903, F.S.; making certain immigrant or noncitizen children who are lawfully residing in the United States eligible for Medicaid; providing an effective date.

743490

LEGISLATIVE ACTION

Senate . House

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

Senate Amendment to Amendment (440118) (with title amendment)

Between lines 106 and 107
insert:

Section 3. Paragraph (a) of subsection (6) of section 624.91, Florida Statutes, is amended to read:

624.91 The Florida Healthy Kids Corporation Act.—

(6) BOARD OF DIRECTORS.—

(a) The Florida Healthy Kids Corporation shall operate subject to the supervision and approval of a board of directors chaired by the Chief Financial Officer or her or his designee,

743490

and composed of 12 ~~11~~ other members selected for 3-year terms of office as follows:

1. The Secretary of Health Care Administration, or his or her designee.

2. One member appointed by the Commissioner of Education from the Office of School Health Programs of the Florida Department of Education.

3. One member appointed by the Chief Financial Officer from among three members nominated by the Florida Pediatric Society.

4. One member, appointed by the Governor, who represents the Children's Medical Services Program.

5. One member appointed by the Chief Financial Officer from among three members nominated by the Florida Hospital Association.

6. One member, appointed by the Governor, who is an expert on child health policy.

7. One member, appointed by the Chief Financial Officer, from among three members nominated by the Florida Academy of Family Physicians.

8. One member, appointed by the Governor, who represents the state Medicaid program.

9. One member, appointed by the Chief Financial Officer, from among three members nominated by the Florida Association of Counties.

10. The State Health Officer or her or his designee.

11. The Secretary of Children and Family Services, or his or her designee.

12. One member, appointed by the Governor, from among three members nominated by the Florida Dental Association.

743490

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

And the title is amended as follows:

Delete line 119

and insert:

residing in the United States eligible for Medicaid; amending s. 624.91, F.S.; revising the membership of the board of directors of the Florida Healthy Kids Corporation to include a member nominated by the Florida Dental Association and appointed by the Governor; providing

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 Health Regulation Committee

BILL:	SB 1006
INTRODUCER:	Senator Latvala
SUBJECT:	Prescription Drug Wholesale Regulations
DATE:	February 3, 2012 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Wilson	Stovall	HR	**Pre-meeting**
2.			CM	
3.			BC	
4.				
5.				
6.				

I. Summary:

The bill establishes a permit by endorsement for out-of-state prescription drug wholesale distributors that satisfy the requirements of chapter 499, Florida Statutes, and hold a valid drug wholesale distributor license or permit from another state.

This bill substantially amends section 499.01 of the Florida Statutes.

II. Present Situation:

Florida Drug and Cosmetic ActPart I of ch. 499, F.S., is the Florida Drug and Cosmetic Act (the Act). One purpose of the Act is to safeguard the public health and promote the public welfare by protecting the public from injury by product use and by merchandising deceit involving drugs, devices, and cosmetics. Another purpose of the Act is to promote uniformity between state and federal laws and their administration and enforcement, throughout the United States.

Section 499.01, F.S., requires a variety of manufacturers, distributors, and other business entities involved in the preparation, manufacture, repackaging, or distribution of drugs, devices, and cosmetics to obtain a permit prior to operating. One of the permits is for out-of-state prescription drug wholesale distributors which engage in the wholesale distribution of prescription drugs into Florida. An out-of-state prescription drug wholesale distributor must be permitted by the Department of Business and Professional Regulation (department or DBPR) and comply with all the provisions required of a wholesale distributor by the Act. An out-of-state prescription drug wholesale distributor must submit a bond of $100,000 or other equivalent means of security.

Section 499.012(8), F.S., sets forth the application requirements for an out-of-state prescription drug wholesale distributor. Generally, the applicant must identify the business (name and trade names, address, and telephone number); and provide information about the ownership, operations and affiliated groups,[1] including the name and address of each shareholder of a corporation that owns 5 percent or more of the corporation; a background statement and fingerprint card for affiliated persons;[2] the estimated or actual annual dollar volume of certain activities pertaining to prescription drugs by the applicant; a copy of the deed or lease for the business property; a list of all licenses and permits issued to the applicant by any other state which authorize the applicant to purchase or posses prescription drugs; and documentation of the credentialing policies and procedures for customers if the applicant intends to sell Schedule II or Schedule III controlled substances to physicians in Florida.[3]

In 2003, the Legislature enacted the Prescription Drug Protection Act.[4] This legislation was predicated on the findings and recommendations of the report of the Seventeenth Statewide Grand Jury in its First Interim Report to the Legislature.[5] That grand jury was called to examine, among other matters, the safety of prescription drugs in Florida. In particular, they examined the situation concerning the sale and re-sale of prescription drugs in the wholesale market. Prior to enactment of this legislation, the Act included a provision for licensure by reciprocity. However, the following language was removed in the Prescription Drug Protection Act:[6]

> The department may adopt rules that allow out-of-state drug wholesalers to obtain a drug wholesale permit on the basis of reciprocity to the extent that an out-of-state drug wholesaler:
> a. Possesses a valid permit granted by another state that has requirements comparable to those that a drug wholesaler in this state must meet as prerequisites to obtaining a permit under the laws of this state.
> b. Can show that the other state from which the wholesaler holds a permit would extend reciprocal treatment under its own laws to a drug wholesaler of this state.

Effective October 1, 2011, all of the statutory powers, duties, and functions, records, personnel, property, and unexpended balances of appropriations, allocations, or other funds for the administration of ch. 499, F.S., relating to drugs, devices, cosmetics, and household products were transferred from the Department of Health to the DBPR.[7]

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[1] "Affiliated group" is defined in s. 499.003(2), F.S., to mean an affiliated group as defined by s. 1504 of the Internal Revenue Code of 1986, as amended, which is composed of chain drug entities, including at least 50 retail pharmacies, warehouses, or repackagers, which are members of the same affiliated group. The affiliated group must disclose the names of all its members to the department.

[2] "Affiliated party" is defined in s. 499.003(3), F.S. In summary, it means a director, officer, trustee, partner, or committee member or a subsidiary or service corporation of the permittee or applicant; a person who, directly or indirectly, manages, controls, or oversees the operation of a permittee or applicant; and the five largest natural shareholders that own at least five percent of the permittee or applicant.

[3] The specific application requirement is for documentation of the credentialing policies and procedures requirements by s. 499.0121(14), F.S., However, that subsection addresses reporting requirements. Subsection (15) addresses credentialing requirements for physician-customers for certain controlled substances.

[4] *See* ch. 2003-155, L.O.F.

[5] The report is available at: <http://myfloridalegal.com/pages.nsf/Main/09558F82389E020785256CDA006DB01A> (Last visited on February 6, 2012).

[6] *See* s. 13, ch. 2003-155, L.O.F.

[7] *See* s. 27, ch. 2010-161, L.O.F.

Licensure by Endorsement

Licensure by endorsement is usually a streamlined application process that is available to individuals or organizations that are licensed in another state that has significantly comparable licensing requirements to the state in which the licensure applicant wishes to be licensed. Typically, licensure by endorsement means that a licensure applicant is eligible for a license without any additional schooling or examination.

III. Effect of Proposed Changes:

The bill amends s. 499.01, F.S., to require the DBPR to issue an out-of-state permit by endorsement to an applicant who, upon applying to the department and remitting a filing fee, set by the board, demonstrates to the board that the applicant satisfies the requirements of the Act and holds a valid drug wholesale distributor license or permit from another state. The bill authorizes an out-of-state prescription drug wholesale distributor that holds a valid permit under the Act on July 1, 2012, to continue to operate under that permit until its expiration, at which time the distributor may apply for a permit by endorsement.

Currently, prescription drug wholesaler distributors that are located outside of the State of Florida, but that are distributing prescription drugs into Florida, have to be permitted as an out-of-state prescription drug wholesale distributor. In order to be permitted, the applicant must demonstrate that the applicant:

- Has a license or permit to engage in wholesale distribution in the applicant's state of residence; and
- Complies with all the provisions required of a wholesale distributor under the Act.

The bill does not change any of the current permitting requirements for an out-of-state prescription drug wholesale distributor.

The effective date of the bill is July 1, 2012.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of the bill have no impact on public records or open meetings issues under the requirements of Article I, Section 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

The DBPR indicates that some modifications to information systems will be required, but the modifications can be made with existing resources.

VI. Technical Deficiencies:

On line 4, the bill refers to the Department of Health. Responsibility for ch. 499, F.S., has been transferred from the Department of Health to the DBPR.

On line 47, the bill refers to "the board" as the entity responsible for setting the filing fee and ultimately approving the application for a permit. There is no board with any authority over ch. 499, F.S. The DBPR, not a board, has the regulatory authority over these permits.

VII. Related Issues:

The bill does not address whether the DBPR is to inspect out-of-state prescription drug wholesale distributor permittees by endorsement.

VIII. 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.

416374

LEGISLATIVE ACTION

Senate . House

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The Committee on Health Regulation (Norman) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause and insert:

Section 1. Subsections (17), (19), (20), and (43) of section 499.003, Florida Statutes, are amended to read:

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

(17) "Distribute" or "distribution" means to sell; offer to sell; give away; transfer, whether by passage of title, physical movement, or both; deliver; or offer to deliver. The term does not mean to administer or dispense and does not include the

416374

billing and invoicing activities that commonly follow a wholesale distribution transaction.

(19) "Drug" means an article that is:

(a) Recognized in the current edition of the United States Pharmacopoeia and National Formulary, official Homeopathic Pharmacopoeia of the United States, or any supplement to any of those publications;

(b) Intended for use in the diagnosis, cure, mitigation, treatment, therapy, or prevention of disease in humans or other animals;

(c) Intended to affect the structure or any function of the body of humans or other animals; or

(d) Intended for use as a component of any article specified in paragraph (a), paragraph (b), or paragraph (c), and includes active pharmaceutical ingredients, but does not include devices or their components, parts, or accessories. For purposes of this paragraph, an "active pharmaceutical ingredient" includes any substance or mixture of substances intended, represented, or labeled for use in drug manufacturing that furnishes or is intended to furnish, in a finished dosage form, any pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, therapy, or prevention of disease in humans or other animals, or to affect the structure or any function of the body of humans or other animals.

(20) "Establishment" means a place of business which is at one general physical location and may extend to one or more contiguous suites, units, floors, or buildings operated and controlled exclusively by entities under common operation and

control. Where multiple buildings are under common exclusive ownership, operation, and control, an intervening thoroughfare does not affect the contiguous nature of the buildings. For purposes of permitting, each suite, unit, floor, or building must be identified in the most recent permit application.

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

Section 2. Paragraphs (c) and (e) of subsection (2) of section 499.01, Florida Statutes, are amended, and subsection (3) is added to that section, to read:

499.01 Permits.—

(2) The following permits are established:

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

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

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

~~3. A nonresident prescription drug manufacturer permit is not required for a manufacturer to distribute a prescription drug active pharmaceutical ingredient that it manufactures to a prescription drug manufacturer permitted in this state in limited quantities intended for research and development and not for resale, or human use other than lawful clinical trials and biostudies authorized and regulated by federal law. A manufacturer claiming to be exempt from the permit requirements of this subparagraph and the prescription drug manufacturer purchasing and receiving the active pharmaceutical ingredient shall comply with the recordkeeping requirements of s. 499.0121(6), but not the requirements of s. 499.01212. The~~

~~prescription drug manufacturer purchasing and receiving the active pharmaceutical ingredient shall maintain on file a record of the FDA registration number; the out-of-state license, permit, or registration number; and, if available, a copy of the most current FDA inspection report, for all manufacturers from whom they purchase active pharmaceutical ingredients under this section. The department shall specify by rule the allowable number of transactions within a given period of time and the amount of active pharmaceutical ingredients that qualify as limited quantities for purposes of this exemption. The failure to comply with the requirements of this subparagraph, or rules adopted by the department to administer this subparagraph, for the purchase of prescription drug active pharmaceutical ingredients is a violation of s. 499.005(14).~~

(e) *Out-of-state prescription drug wholesale distributor permit.*—An out-of-state prescription drug wholesale distributor is a wholesale distributor located outside this state which engages in the wholesale distribution of prescription drugs into this state and which must be permitted by the department and comply with all the provisions required of a wholesale distributor under this part. An out-of-state prescription drug wholesale distributor that applies to the department for a new permit or the renewal of a permit must submit a bond of $100,000, or other equivalent means of security acceptable to the department, such as an irrevocable letter of credit or a deposit in a trust account or financial institution, payable to the Florida Drug, Device, and Cosmetic Trust Fund. The purpose of the bond is to secure payment of any administrative penalties imposed by the department and any fees and costs incurred by the

department regarding that permit which are authorized under state law and which the permittee fails to pay 30 days after the fine or costs become final. The department may make a claim against such bond or security until 1 year after the permittee's license ceases to be valid or until 60 days after any administrative or legal proceeding authorized in this part which involves the permittee is concluded, including any appeal, whichever occurs later.

~~1.~~ The out-of-state prescription drug wholesale distributor must maintain at all times a license or permit to engage in the wholesale distribution of prescription drugs in compliance with laws of the state in which it is a resident.

~~2. An out-of-state prescription drug wholesale distributor permit is not required for an intracompany sale or transfer of a prescription drug from an out-of-state establishment that is duly licensed as a prescription drug wholesale distributor, in its state of residence, to a licensed prescription drug wholesale distributor in this state, if both wholesale distributors conduct wholesale distributions of prescription drugs under the same business name. The recordkeeping requirements of ss. 499.0121(6) and 499.01212 must be followed for this transaction.~~

(3)(a) A permit issued under this part is not required to distribute a prescription drug active pharmaceutical ingredient from an establishment located in the United States to an establishment located in this state permitted as a prescription drug manufacturer under this part for use by the recipient in preparing, deriving, processing, producing, or fabricating a prescription drug finished dosage form at the establishment in

this state where the product is received under an approved and otherwise valid New Drug Approval Application, Abbreviated New Drug Application, New Animal Drug Application, or Therapeutic Biologic Application, provided that the application, active pharmaceutical ingredient, or finished dosage form has not been withdrawn or removed from the market in this country for public health reasons.

1. Any distributor claiming exemption from permitting requirements pursuant to this paragraph shall maintain a license, permit, or registration to engage in the wholesale distribution of prescription drugs under the laws of the state from which the product is distributed.

2. Any distributor claiming exemption from permitting requirements pursuant to this paragraph and the prescription drug manufacturer purchasing and receiving the active pharmaceutical ingredient shall comply with the recordkeeping requirements of s. 499.0121(6), but not the requirements of s. 499.01212.

(b) A permit issued under this part is not required to distribute limited quantities of a prescription drug that has not been repackaged from an establishment located in the United States to an establishment located in this state permitted as a prescription drug manufacturer under this part for research and development or to a holder of a letter of exemption issued by the department under s. 499.03(4) for research, teaching, or testing. The department shall define "limited quantities" by rule and may include the allowable number of transactions within a given period of time and the amounts of prescription drugs distributed into the state for purposes of this exemption.

1. Any distributor claiming exemption from permitting requirements pursuant to this paragraph shall maintain a license, permit, or registration to engage in the wholesale distribution of prescription drugs under the laws of the state from which the product is distributed.

2. All purchasers and recipients of any prescription drugs distributed pursuant to this paragraph shall ensure that the products are not resold or used, directly or indirectly, on humans except in lawful clinical trials and biostudies authorized and regulated by federal law.

3. Any distributor claiming exemption from permitting requirements pursuant to this paragraph, and the purchaser and recipient of the prescription drug, shall comply with the recordkeeping requirements of s. 499.0121(6), but not the requirements of s. 499.01212.

4. The immediate package or container of any active pharmaceutical ingredient distributed into the state that is intended for teaching, testing, research, and development shall bear a label prominently displaying the statement: "Caution: Research, Teaching, or Testing Only – Not for Manufacturing, Compounding, or Resale."

(c) An out-of-state prescription drug wholesale distributor permit is not required for an intracompany sale or transfer of a prescription drug from an out-of-state establishment that is duly licensed as a prescription drug wholesale distributor in its state of residence to a licensed prescription drug wholesale distributor in this state, if both wholesale distributors conduct wholesale distributions of prescription drugs under the same business name. The recordkeeping requirements of ss.

499.0121(6) and 499.01212 must be followed for such transactions.

(d) Persons receiving prescription drugs from a source claimed to be exempt from permitting requirements under this subsection shall maintain on file:

1. A record of the FDA establishment registration number, if any;

2. The resident state prescription drug wholesale distribution license, permit, or registration number; and

3. A copy of the most recent resident state or FDA inspection report, for all distributors and establishments whom they purchase or receive prescription drugs under this subsection.

(e) All persons claiming exemption from permitting requirements pursuant to this subsection who engage in the distribution of prescription drugs within or into the state are subject to this part, including ss. 499.005 and 499.0051, and shall make available, within 48 hours, to the department on request all records related to any prescription drugs distributed under this subsection, including those records described in s. 499.051(4), regardless of the location where the records are stored.

(f) A person purchasing and receiving a prescription drug from a person claimed to be exempt from licensing requirements pursuant to this subsection shall report to the department in writing within 14 days after receiving any product that is misbranded or adulterated or that fails to meet minimum standards set forth in the official compendium or state or federal good manufacturing practices for identity, purity,

potency, or sterility, regardless of whether the product is thereafter rehabilitated, quarantined, returned, or destroyed.

(g) The department may adopt rules to administer this subsection which are necessary for the protection of the public health, safety, and welfare. Failure to comply with the requirements of this subsection, or rules adopted by the department to administer this subsection, is a violation of s. 499.005(14), and a knowing failure is a violation of s. 499.0051(4).

(h) This subsection does not relieve any person from any requirement prescribed by law with respect to controlled substances as defined in the applicable federal and state laws.

Section 3. This act shall take effect July 1, 2012.

================ 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 prescription drug wholesale regulations; amending s. 499.003, F.S.; revising the definitions of the terms “distribute” or “distribution,” “drug,” “establishment,” and “prescription drug”; amending s. 499.01, F.S.; deleting provisions relating to an exemption from nonresident prescription drug manufacturer permit requirements; deleting provisions relating to an exemption from out-of-state prescription drug wholesale distributor permit requirements for

intracompany sale or transfer of prescription drugs; providing an exemption from permit requirements for the distribution into this state of prescription drug active pharmaceutical ingredients for incorporation into prescription drugs in finished dosage form; requiring a distributor claiming such exemption to maintain a valid license, permit, or registration in the state from which the prescription drug was distributed; requiring compliance with certain recordkeeping requirements; exempting compliance with pedigree paper requirements; providing an exemption from permit requirements for distribution into this state of limited quantities of a prescription drug that has not been repackaged, for research and development or to a holder of a letter of exemption issued by the Department of Business and Professional Regulation for research, teaching, or testing; granting the department authority to define "limited quantities" by rule and limit therein the number of transactions and amount of prescription drugs distributed into the state; requiring a distributor claiming such exemption to maintain a valid license, permit, or registration in the state from which the prescription drug was distributed; requiring all purchasers and recipients of such prescription drugs to ensure the products are not resold or used on humans except in lawful clinical trials and biostudies; requiring compliance with certain recordkeeping requirements; exempting compliance from

pedigree paper requirements; providing labeling requirements for active pharmaceutical ingredients distributed within the state for teaching, testing, research, and development; exempting from out-of-state prescription drug wholesale distributor permit requirements intracompany transactions or the sale of prescription drugs from an out-of-state distributor to a distributor in this state if both distributors conduct wholesale distributions under the same business name; requiring compliance with recordkeeping and pedigree paper requirements; allowing distributors and recipients of prescription drugs claiming exemption from certain permitting requirements to maintain on file their FDA registration number, resident state distributor license or permit number, and most recent resident state or FDA inspection report; providing that persons claiming such exemptions are subject to part I of chapter 499, F.S., the Florida Drug and Cosmetic Act; requiring persons claiming such exemptions to make all records regarding prescription drug distribution available to the department, upon request, within 48 hours; requiring submission of a report of mishandled or adulterated prescription drugs within 14 days after receipt of such drugs; authorizing the department to adopt rules; providing that failure to comply with requirements or rules governing such exemptions constitutes unlawful purchase or receipt of a prescription drug from a person not authorized to distribute prescription drugs

416374

to that purchaser or recipient; providing that knowing failure to comply with such requirements constitutes unlawful sale, distribution, purchase, trade, holding, or offering of a drug; providing penalties; providing construction with respect to federal and state laws relating to controlled substances; providing an effective date.

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LEGISLATIVE ACTION

Senate . House

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

Senate Amendment to Amendment (416374) (with title amendment)

Between lines 4 and 5
insert:

Section 1. Section 383.146, Florida Statutes, is created to read:

383.146 Newborn screening for critical congenital heart disease.—

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

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

(b) "Newborn" means an age range from birth through 29

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days.

(c) "Screening" means measuring blood oxygen saturation using pulse oximetry to determine whether a newborn needs additional diagnostic evaluation for critical congenital heart disease.

(2) REQUIREMENTS FOR SCREENING OF NEWBORNS; REFERRAL FOR ONGOING SERVICES.—

(a) Each licensed hospital that provides maternity and newborn care services shall ensure that, prior to discharge, all newborns are screened for the detection of critical congenital heart disease.

(b) Each licensed birth center that provides maternity and newborn care services shall ensure that, prior to discharge, all newborns are screened for the detection of critical congenital heart disease.

(c) If the parent or legal guardian of the newborn objects to the screening, the screening must not be completed, notwithstanding any other provision of this section. In such case, the physician, midwife, or other person who is attending the newborn shall maintain a record that the screening has not been performed and attach a written objection that must be signed by the parent or guardian.

(d) For home births, the health care provider in attendance is responsible for the screening.

(e) Appropriate documentation of the screening completion, results, interpretation, and recommendations must be placed in the medical record within 24 hours after completion of the screening procedure.

(f) Each hospital shall formally designate a lead physician

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who is responsible for programmatic oversight of newborn congenital heart disease screening. Each licensed birth center shall designate a licensed health care provider to provide such programmatic oversight. Such physician or health care provider shall ensure that the appropriate referrals are completed following a positive screening test result.

(g) By October 1, 2012, screening for critical congenital heart disease must be conducted on all newborns in hospitals and birth centers in this state following birth admission.

(3) RULES.—After consultation with the Genetics and Newborn Screening Advisory Council, the department shall adopt and enforce rules requiring that every newborn in this state be screened for critical congenital heart disease. The department shall adopt such additional rules as are necessary for the administration of this section, including rules providing definitions of terms, rules relating to the methods used and time or times for testing as accepted medical practice indicates, rules relating to charging and collecting fees for the administration of the newborn screening program required by this section, rules for processing requests and releasing test and screening results, and rules requiring mandatory reporting of the results of tests and screenings for this condition to the department.

(4) POWERS AND DUTIES OF THE DEPARTMENT.—The department shall administer and provide services required pursuant to this section and shall:

(a) Furnish to all physicians, county health departments, perinatal centers, birth centers, and hospitals forms on which the results of tests for critical congenital heart disease shall

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be reported to the department.

(b) Have the authority to charge and collect fees sufficient to administer the newborn screening program required under this section.

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

And the title is amended as follows:

Delete lines 264 - 265

and insert:

An act relating to health care; creating s. 383.146, F.S.; providing definitions; providing requirements for screening newborns for critical congenital heart disease; providing an exception; requiring that the physician, midwife, or other person attending the newborn maintain a record if the screening has not been performed and attach a written objection signed by the parent or guardian; requiring appropriate documentation of the screening completion in the medical record; requiring that each hospital and each licensed birth center designate a lead physician and a licensed health care provider, respectively, to provide programmatic oversight for the screening; requiring that the screening for critical congenital heart disease be conducted on all newborns in hospitals and birth centers in this state; authorizing the Department of Health to adopt rules to administer the screening program; providing powers and duties of the department; amending s. 499.003, F.S.; revising the

942294

LEGISLATIVE ACTION

Senate . House

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The Committee on Health Regulation (Norman) recommended the following:

Senate Amendment to Amendment (416374) (with directory and title amendments)

Between lines 56 and 57

insert:

(54) "Wholesale distribution" means distribution of prescription drugs to persons other than a consumer or patient, but does not include:

(a) Any of the following activities, which is not a violation of s. 499.005(21) if such activity is conducted in accordance with s. 499.01(2)(g):

1. The purchase or other acquisition by a hospital or other

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health care entity that is a member of a group purchasing organization of a prescription drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of that organization.

2. The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug by a charitable organization described in s. 501(c)(3) of the Internal Revenue Code of 1986, as amended and revised, to a nonprofit affiliate of the organization to the extent otherwise permitted by law.

3. The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug among hospitals or other health care entities that are under common control. For purposes of this subparagraph, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, by voting rights, by contract, or otherwise.

4. The sale, purchase, trade, or other transfer of a prescription drug from or for any federal, state, or local government agency or any entity eligible to purchase prescription drugs at public health services prices pursuant to Pub. L. No. 102-585, s. 602 to a contract provider or its subcontractor for eligible patients of the agency or entity under the following conditions:

a. The agency or entity must obtain written authorization for the sale, purchase, trade, or other transfer of a prescription drug under this subparagraph from the State Surgeon General or his or her designee.

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b. The contract provider or subcontractor must be authorized by law to administer or dispense prescription drugs.

c. In the case of a subcontractor, the agency or entity must be a party to and execute the subcontract.

~~d. A contract provider or subcontractor must maintain separate and apart from other prescription drug inventory any prescription drugs of the agency or entity in its possession.~~

d.~~c.~~ The contract provider and subcontractor must maintain and produce immediately for inspection all records of movement or transfer of all the prescription drugs belonging to the agency or entity, including, but not limited to, the records of receipt and disposition of prescription drugs. Each contractor and subcontractor dispensing or administering these drugs must maintain and produce records documenting the dispensing or administration. Records that are required to be maintained include, but are not limited to, a perpetual inventory itemizing drugs received and drugs dispensed by prescription number or administered by patient identifier, which must be submitted to the agency or entity quarterly.

e.~~f.~~ The contract provider or subcontractor may administer or dispense the prescription drugs only to the eligible patients of the agency or entity or must return the prescription drugs for or to the agency or entity. The contract provider or subcontractor must require proof from each person seeking to fill a prescription or obtain treatment that the person is an eligible patient of the agency or entity and must, at a minimum, maintain a copy of this proof as part of the records of the contractor or subcontractor required under sub-subparagraph d ~~sub-subparagraph c~~.

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f.g. In addition to the departmental inspection authority set forth in s. 499.051, the establishment of the contract provider and subcontractor and all records pertaining to prescription drugs subject to this subparagraph shall be subject to inspection by the agency or entity. All records relating to prescription drugs of a manufacturer under this subparagraph shall be subject to audit by the manufacturer of those drugs, without identifying individual patient information.

====== D I R E C T O R Y C L A U S E A M E N D M E N T ======
And the directory clause is amended as follows:

Delete line 5

and insert:

Section 1. Subsections (17), (19), (20), and (43), and paragraph (a) of subsection (54) of

================ T I T L E A M E N D M E N T ================
And the title is amended as follows:

Delete lines 267 - 268

and insert:

"distribution," "drug," "establishment," "prescription drug," and "wholesale distribution"; amending s. 499.01, F.S.;

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LEGISLATIVE ACTION

Senate . House

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The Committee on Health Regulation (Jones) recommended the following:

Senate Amendment to Amendment (416374) (with directory and title amendments)

Between lines 150 and 151

insert:

(t) *Health care clinic establishment permit.*—Effective January 1, 2009, a health care clinic establishment permit is required for the purchase of a prescription drug by a place of business at one general physical location that provides health care or veterinary services, which is owned and operated by a business entity that has been issued a federal employer tax identification number. For the purpose of this paragraph, the

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term "qualifying practitioner" means a licensed health care practitioner defined in s. 456.001, or a veterinarian licensed under chapter 474, who is authorized under the appropriate practice act to prescribe and administer a prescription drug.

1. An establishment must provide, as part of the application required under s. 499.012, designation of a qualifying practitioner who will be responsible for complying with all legal and regulatory requirements related to the purchase, recordkeeping, storage, and handling of the prescription drugs. In addition, the designated qualifying practitioner shall be the practitioner whose name, establishment address, and license number is used on all distribution documents for prescription drugs purchased or returned by the health care clinic establishment. Upon initial appointment of a qualifying practitioner, the qualifying practitioner and the health care clinic establishment shall notify the department on a form furnished by the department within 10 days after such employment. In addition, the qualifying practitioner and health care clinic establishment shall notify the department within 10 days after any subsequent change.

2. The health care clinic establishment must employ a qualifying practitioner at each establishment.

3. In addition to the remedies and penalties provided in this part, a violation of this chapter by the health care clinic establishment or qualifying practitioner constitutes grounds for discipline of the qualifying practitioner by the appropriate regulatory board.

4. The purchase of prescription drugs by the health care clinic establishment is prohibited during any period of time

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when the establishment does not comply with this paragraph.

5. A health care clinic establishment permit is not a pharmacy permit or otherwise subject to chapter 465. A health care clinic establishment that meets the criteria of a modified Class II institutional pharmacy under s. 465.019 is not eligible to be permitted under this paragraph.

6. This paragraph does not apply to the purchase of a prescription drug by a licensed practitioner under his or her license. A professional corporation or limited liability company composed of dentists and operating as authorized in s. 466.0285 may pay for prescription drugs obtained by a practitioner licensed under chapter 466, and the licensed practitioner is deemed the purchaser and owner of the prescription drugs.

====== D I R E C T O R Y C L A U S E A M E N D M E N T ======
And the directory clause is amended as follows:

Delete line 57

and insert:

Section 2. Paragraphs (c), (e), and (t) of subsection (2) of

================ T I T L E A M E N D M E N T ================
And the title is amended as follows:

Delete line 274

and insert:

intracompany sale or transfer of prescription drugs; authorizing certain business entities to pay for prescription drugs obtained by practitioners licensed under ch. 466, F.S.;

585952

LEGISLATIVE ACTION

Senate . House

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The Committee on Health Regulation (Diaz de la Portilla) recommended the following:

Senate Amendment to Amendment (416374) (with directory and title amendments)

Between lines 256 and 257

insert:

(4) A restricted prescription drug distributor permitholder that is under common ownership, directly or indirectly, with an entity licensed under chapter 395, may repackage prescription drugs, from a centralized location or otherwise, for transfer or distribution to or among entities that are also under common ownership, directly or indirectly, with an entity licensed under chapter 395.

585952

====== D I R E C T O R Y C L A U S E A M E N D M E N T ======

And the directory clause is amended as follows:

Delete lines 58 - 59

and insert:

section 499.01, Florida Statutes, are amended, and subsections (3) and (4) are added to that section, to read:

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

And the title is amended as follows:

Delete line 337

and insert:

relating to controlled substances; authorizing a restricted prescription drug distributor permitholder to repackage prescription drugs for a specific purpose; providing an

SENATOR JACK LATVALA
16th District

Tallahassee, Florida 32399-1100

COMMITTEES:
Transportation, *Chair*
Budget - Subcommittee on General Government Appropriations
Budget - Subcommittee on Transportation, Tourism, and Economic Development Appropriations
Environmental Preservation and Conservation
Governmental Oversight and Accountability
Health Regulation
Reapportionment

December 7, 2011

The Honorable Senator Renee Garcia, Chair
Senate Committee on Health Regulation
530 Knott Building
404 South Monroe Street
Tallahassee, FL 32399-1100

Dear Chairman Garcia:

I respectfully request consideration of Senate Bill 1006, a bill relating to Prescription Wholesale Regulations, by the Senate Committee on Health Regulation as soon as possible. The purpose of this bill is to enhance the effectiveness of permitting processes and criteria for out-of-state prescription drug wholesale distributors who sell their products in the state of Florida.

I would appreciate the opportunity to present this legislation at your earliest convenience. If you have any questions regarding this legislation, please contact me. Thank you for your consideration.

Sincerely,

Jack Latvala
State Senator
District 16

cc: Sandra Stovall, Staff Director

ENTERED
rec'd 12-21-11

REPLY TO:
❒ 12425 28th Street North, Suite 102, St. Petersburg, Florida 33716 (727) 556-6500
❒ 405 Senate Office Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5075

Senate's Website: *www.flsenate.gov*

MIKE HARIDOPOLOS
President of the Senate

MICHAEL S. "MIKE" BENNETT
President Pro Tempore

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 Health Regulation Committee

BILL: SB 1594

INTRODUCER: Senators Garcia and Flores

SUBJECT: Surgical First Assistants

DATE: February 8, 2012 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Davlantes	Stovall	HR	**Pre-meeting**
2.			BC	
3.				
4.				
5.				
6.				

I. Summary:

The bill provides for licensure, renewal of licensure, practice standards, and grounds for disciplinary action for certified surgical first assistants. Certified surgical first assistants may only practice under the direct supervision of an appropriately trained physician, who maintains liability for all supervised acts; within their scope of certification; and in certain medical facilities. It is not required that physicians or health care facilities contract with certified surgical first assistants. Licensure as a certified surgical first assistant is not required as a condition of employment for registered nurses, advanced registered nurse practitioners, registered nurse first assistants, or physician assistants. The Department of Health (the department) is given rulemaking authority to administer provisions relating to certified surgical first assistants.

The bill also requires that if a health insurance policy, health care services plan, or other contract provides for payment for surgical first assisting benefits or services, the policy, plan, or contract shall be construed as providing for payment to a physician assistant, a certified surgical first assistant, or their employers if reimbursement for an assisting physician would be covered and a physician assistant or certified surgical first assistant who performs such services is used as a substitute. Insurers are not required to directly reimburse certified surgical first assistants if the assistants will be paid for a surgical procedure by the health care facility at which the procedure is performed.

This bill creates one designated section of law and amends s. 627.419, F.S.

II. Present Situation:

Role of Surgical First Assistants

Surgical assistants provide aid in exposure, hemostasis, closure, and other intraoperative technical functions under the direct supervision of surgeons to help carry out safe operations with optimal results for patients. In addition to intraoperative duties, surgical assistants also perform preoperative and postoperative duties to better facilitate proper patient care.[1] Surgical first assistants provide primary assistance to the primary surgeon, must be listed on the operative record as first assistants, and cannot be involved in any other role during the procedure.[2]

The primary professional organizations for surgical assistants are the Association of Surgical Technology (AST) and the National Surgical Assistant Association (NSAA). The AST was established in 1969 by members of the American College of Surgeons, the American Hospital Association, and the Association of Perioperative Registered Nurses to ensure that surgical technologists and surgical assistants have the knowledge and skills to administer patient care of the highest quality.[3] The NSAA was formed by surgical assistants in 1983 and was the nation's first organization to provide standards for competency, professionalism, and scope of practice in the field.[4]

Duties within the scope of practice of a surgical assistant include positioning the patient; providing visualization of the operative site, including appropriate placement of retractors, suctioning and sponging, and manipulation of suture materials; assisting with hemostasis; participating in volume replacement or autotransfusion techniques, as appropriate; assisting with wound closure, including administration of sutures and subcutaneous injection of local anesthetics; selecting and applying wound dressings; and providing assistance in securing drainage systems to tissue.[5] Surgical assistants must be familiar with operating room procedures and able to anticipate the needs of the surgeon.[6]

Surgical First Assistants in Statute

Registered nurses licensed under ch. 464, F.S., may serve as surgical first assistants if they are certified in perioperative nursing through a year-long training program fulfilling certain conditions. Such nurses may be reimbursed by insurance companies for their first assistant services at a rate not less than 80 percent of what a physician would be paid for the same services.[7]

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[1] Association of Surgical Technologists, *Job Description: Surgical Assistant*, available at: http://www.ast.org/professionals/documents/2011_%20Surgical%20Assistant_Job_Description_4.5.pdf (last visited on January 26, 2012).
[2] American Board of Surgical Assistants, *Definitions*, available at: http://www.absa.net/definitions.php (last visited on February 7, 2012).
[3] AST, *About Us*, available at : http://www.ast.org/aboutus/about_ast.aspx (last visited on January 25, 2012).
[4] NSAA, *Welcome*, available at: http://www.nsaa.net/index.php (last visited on January 25, 2012).
[5] *Supra* fn. 1.
[6] NSAA, *Scope of Practice*, available at: http://www.nsaa.net/scope_of_practice.php (last visited on January 26, 2012).
[7] Sections 464.027 and 409.906(21), F.S.

Physician assistants may also be reimbursed by insurance companies for surgical first assistant services if they act as substitutes for physicians who would have performed the same services.[8]

National Certification of Surgical First Assistants

AST: Certified Surgical First Assistant
An applicant for the Certified Surgical First Assistant (CSFA) designation must fulfill one of the following:

- Be a graduate of a surgical assistant program accredited by the Commission on Accreditation of Allied Health Education Programs (CAAHEP);
- Hold current certification as a Certified Surgical Technologist from the AST, have participated in at least 350 cases within the last 4 years, and have completed at least 2 full years of surgical first assistant experience; or
- Hold current surgical assistant certification from the NSAA or the American Board of Surgical Assistants (ABSA), have completed 50 hours of AST-approved continuing education within the last 2 years, show proof of operative case experience, and have at least an associate's degree.

Eligible applicants may register to take the CSFA exam offered by the National Board of Surgical Technology and Surgical Assisting (NBSTSA).[9] The NBSTSA was previously known as the Liaison Council on Certification for the Surgical Technologist (LCCST). After passage of the exam and payment of $290 in fees, an applicant may be certified.[10]

CSFA certification must be renewed every 4 years either by retaking and passing the initial certification examination or completing 75 hours of continuing education approved by the AST. Recertification by examination costs $499.[11] Recertification by continuing education costs $6 per credit hour for AST members and $400 for non-members.[12]

More than 2,100 people currently hold CSFA certification.[13]

NSAA: Certified Surgical Assistant
Applicants for the Certified Surgical Assistant (CSA) designation must be graduates of approved surgical assistant training programs (there is one in Florida) or provide documentation of 2,250 hours of assisting experience along with several letters of reference from supervising surgeons. Applicants must also pass a multiple-choice examination offered by the NSAA which covers subjects such as anatomy, medical terminology, technical surgical skills, sterile technique, and anesthesia, and pay $400 in fees. Discounts apply for recent graduates and military personnel, and certification by endorsement is available to nurses, physician assistants, and other practitioners under certain conditions.

[8] Section 627.419(6), F.S.
[9] Edu-Search, *Surgical Technology Certification*, available at: http://www.surgicaltechnologists.net/education/certification (last visited on February 6, 2012).
[10] NBSTSA, *CSFA Examination*, available at: http://nbstsa.org/examinations-csfa.html (last visited on February 6, 2012).
[11] NBSTSA, *Renewal Options*, available at: http://nbstsa.org/renewal/index.html (last visited on February 6, 2012).
[12] AST, *Certification*, available at: http://www.ast.org/membership/certification.aspx (last visited on February 6, 2012).
[13] Telephone conversation with NBSTSA staff.

CSAs must be recertified every 2 years by completing 50 hours of approved continuing education or retaking and passing the initial certification exam. Recertification fees for NSAA non-members are $700 if via continuing education and $900 if via reexamination. Fees for NSAA members are $100 if via continuing education. Member fee for recertification via reexamination is not specified.[14,15]

NSAA membership dues are $300 annually and may be discounted for dual members of the NSAA and the American College of Surgeons.[16] 1,374 people currently hold CSA certification nationally.[17]

ABSA: Surgical Assistant-Certified
To be eligible to for ABSA certification, an applicant must hold at least an associate's degree with a "C" grade or higher in specified college-level courses, have completed an ABSA- or CAAHEP-approved surgical assistant training program, and have passed the ABSA Surgical Assistant-Certified (SA-C) examination. The examination consists of both multiple-choice and practical components and is offered four times per year in Miami, Chicago, New Jersey, and Houston. Payment of a $710 fee is also required.

SA-C certification must be renewed biennially by retaking and passing the initial certification exam or by completing certain professional development activities. Such activities include reading professional journals, presenting at a hospital seminar, publishing clinical research, and attending medical conferences. Each person must also document participation as a surgical first assistant in either 400 surgical cases or 1,500 procedure hours and hold current certification in cardiopulmonary resuscitation (CPR), advanced cardiac life support (ACLS), or pediatric advanced life support (PALS). Recertification via examination costs $180, while recertification via professional development costs $100.[18]

1,473 people currently hold active SA-C certification.[19]

III. Effect of Proposed Changes:

Section 1 creates an undesignated section of law. It provides various definitions, provides qualifications for supervising physicians of certified surgical first assistants, and states that supervising physicians may be liable for any acts or omission of certified surgical first assistants acting under the physician's supervision and control. A certified surgical first assistant may only perform duties within his or her scope of certification, delegated by a physician under direct supervision, and in certain medical facilities. Physicians or health care facilities are not required to contract with certified surgical first assistants, and the Board of Medicine (the board) may not limit the employment arrangement of a certified surgical first assistant.

[14] NSAA, *FAQs*, available at: http://nsaa.net/faq.php (last visited on January 26, 2012).
[15] NSAA, *Certification*, available at: http://www.nsaa.net/certification.php (last visited on January 26, 2012).
[16] NSAA, *Membership*, available at: http://www.nsaa.net/membership.php (last visited on January 26, 2012).
[17] Telephone conversation with NSAA staff.
[18] ABSA, *Candidate Information Booklet and Certification Examination Review Guide 2011-2012*, available at: http://www.absa.net/pdf/ABSA_Guide_2011-2012.pdf (last visited on February 7, 2012).
[19] ABSA, *History and Statistics*, available at: http://www.absa.net/statistics.php (last visited on February 7, 2012).

To be licensed as a certified surgical first assistant in Florida, an applicant must:

- Be at least 18 years old;
- Hold and maintain certification from the LCCST, the NSAA, or the ABSA;
- Complete an application form which includes a sworn statement of any prior felony convictions and any previous revocation or denial of licensure or certification; and
- Remit an application fee not to exceed $750 as set by the board.

Licensure by reciprocity may also be granted to surgical first assistants who are licensed in good standing by other states and by their certifying agency, who have paid the appropriate fees, and who have complied with all other licensure requirements of the board.

Licenses must be renewed biennially. Each renewal application must include a renewal fee not to exceed $1000 as set by the board, a sworn statement of no felony convictions in the previous 2 years, and proof of either completion of 40 hours of continuing education approved by certain national organizations or current certification from the LCCST, NSAA, or ABSA. Licenses in inactive or delinquent status may only be reactivated as provided in s. 456.036, F.S.

Certified surgical first assistant licensure does not authorize the licensee to engage in the practice of medicine or nursing and is not required for registered nurses, advanced registered nurse practitioners, registered nurse first assistants, or physician assistants as a condition of employment.

The bill provides certain penalties for certified surgical first assistants who violate or whose supervising physician violates provisions of ch. 456 or 458, F.S. Discipline may also be imposed on certified surgical first assistants if they or their supervising physicians are being investigated for a violation of these acts. Persons who are not licensed as certified surgical first assistants by the department but hold themselves to be so commit third-degree felonies. The board may deny, suspend, or revoke a certified surgical first assistant license if it determines that the licensee has violated provisions of ch. 456 or 458, F.S.

The bill also gives the department rulemaking authority to administer the provisions of this section and provides for the appropriation of fees collected under this section.

Section 2 amends s. 627.419, F.S., to require that if a health insurance policy, health care services plan, or other contract provides for payment for surgical first assisting benefits or services, the policy, plan, or contract shall be construed as providing for payment to a physician assistant or a certified surgical first assistant or their employers in addition to a registered nurse first assistant or his or her employer (only nurses are currently mentioned in this section). This provision applies only if reimbursement for an assisting physician, licensed under ch. 458 or 459, F.S., would be covered and a physician assistant, registered nurse first assistant, or certified surgical first assistant who performs such services is used as a substitute. Insurers are not required to directly reimburse certified surgical first assistants if the assistants will be paid for a surgical procedure by the health care facility at which the procedure is performed. The term "certified surgical first assistant" is also defined.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of the bill have no impact on public records or open meetings issues under the requirements of Article I, Section 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

People wishing to practice as surgical first assistants in Florida would be required to pay to the department up to $750 in application fees, up to $1,000 in license renewal fees, and several hundred dollars in other fees required to maintain national certification.

B. Private Sector Impact:

Anyone other than nurses, advanced registered nurse practitioners, or physician assistants who wishes to practice as a surgical first assistant in Florida must be licensed by the department.

C. Government Sector Impact:

The department will experience a recurring increase in workload relating to processing of applications for licensure and renewal of licensure for surgical first assistants. This will be offset by a corresponding increase in application and renewal fees. The department will also experience a non-recurring increase in workload related to rulemaking and updating the practitioner licensure database, both of which may be absorbed with current resources.

VI. Technical Deficiencies:

The bill creates an undesignated section of law and refers frequently to "the department" without specifying to which department it refers. Presumably this means the Department of Health.

The bill frequently refers to physicians and healthcare facilities in general terms. To be most clear, the bill should refer to practitioners and facilities according to the chapter of the Florida Statutes under which they are licensed.

Lines 71-73 and 74-76 are redundant. One of these sections could be eliminated to increase clarity. These lines also provide conflicting definitions for the scope of practice of certified surgical first assistants.

It is unclear why surgical first assistants must be referred to as both licensed and certified. It might be simpler to refer to them as "licensed surgical first assistants" and include national certification as part of the licensure process. Furthermore, calling such surgical first assistants "licensed" rather than "certified" in statute would help differentiate the state designation of certification from the CSFA designation offered by the AST.

VII. Related Issues:

It is unclear if the bill is requiring that all surgical first assistants other than a registered nurse, advanced registered nurse practitioner, a registered nurse first assistant or a physician assistant, practicing in the state be licensed as such. If the bill does require all surgical first assistants to be licensed, this would have major ramifications on surgical practice and the education of health care professionals. Currently, a wide variety of practitioners, both licensed and unlicensed, may serve in this role, including physicians, medical students, medical residents, physician assistant students, nursing students, and dental hygienists, dental hygienist students, podiatrists, podiatrist students, and surgical technologists. Requiring all these practitioners to be certified as surgical first assistants before letting them participate in surgery would be redundant as training programs for such practitioners already incorporate appropriate surgery skills, and surgical assisting is already in the scope of practice for the licensees.

This bill does not provide exemptions from licensure as certified surgical first assistants for people who are currently practicing as surgical first assistants. First assistants who have been practicing for decades may be forced to retake certification examinations, re-enroll in training programs, pay hundreds of dollars in fees, and fulfill other requirements necessary for national certification. Furthermore, a currently practicing first assistant who has been convicted of or entered a plea of guilty or nolo contendere to certain federal and state felonies would be denied licensure under ch. 456.0635, F.S., barring such a person from employment in what was formerly his or her career.

The definition of "direct supervision" in the bill requires certified surgical first assistants to be supervised by a physician under certain conditions. However, other practitioners, such as dentists and podiatrists, also perform surgery, and the bill currently does not permit them to supervise certified surgical first assistants. If all certified surgical first assistants are required to be licensed, as is provided in this bill, and such licensed practitioners may only practice under physicians, dentists and podiatrists may experience difficulty in finding employees to assist with their surgical procedures.

Language concerning liability of supervising physicians could be worded more strongly. Lines 63-69 and lines 158-161 state that such physicians *may* be liable for the acts and omissions of certified surgical first assistants they supervise, but this language does not *require* that physicians hold such liability. This lack of clear liability could lead to possible litigation.

Lines 77-79 state that a certified surgical first assistant may only perform his or her duties in a medical clinic, hospital, ambulatory surgical center, or similar medical institution. It is unclear if office surgery facilities are included in this definition; surgeries performed in physician offices constitute a large proportion of procedures performed in this state.

The language in lines 80-89 is vague and confusing, and the intention of this language is unclear.

Lines 96-97 require that licensed certified surgical first assistants hold and maintain certification from one of three recognized certifying agencies. However, some of these agencies offer a variety of certifications, and it might be helpful to designate exactly which certifications are required for licensure in Florida.

The bill makes no provision that applicants for licensure as certified surgical first assistants meet general licensure requirements for health care practitioners in ch. 456, F.S.

Lines 120-125 state that the board can impose certain penalties on CSFAs if they violate certain laws OR if their supervising physicians violate certain laws. It is unclear why certified surgical first assistants are held responsible for the actions of their supervisors.

Lines 133-140 specify conditions for the licensure by reciprocity for surgical first assistants licensed in other states. It is unclear if such applicants for licensure by reciprocity have to be licensed in good standing both by their state and by one of the three national certifying organizations. Furthermore, one of the provisions for licensure by reciprocity is "compliance with all other requirements of the board" (line 140). It is unclear why there is no similar provision concerning general licensure of certified surgical first assistants. Also, no entity is given the authority to designate the amount for "appropriate licensure fees" in line 139.

The bill provides in lines 141-143 that licenses on inactive or delinquent status may only be reactivated as provided in s. 456.036, F.S.; however, the bill makes no provisions as to how licenses become inactive or delinquent in the first place.

The bill provides a maximum application fee of $750 for surgical first assistant certification and a maximum renewal fee of $1000. These fees are significantly higher than the maximum fees set for licensure of other healthcare professionals. For example, the maximum fee for initial licensure or renewal of a physician is $500, and physicians have a much higher earning potential than surgical first assistants.[20] Furthermore, surgical first assistants must maintain certification from one of three national organizations mentioned in the bill to be eligible for licensure in Florida; initial certification fees from these organizations $290-700, and renewals range from $100-900. The substantial fees required to become a certified surgical first assistant in Florida may discourage many current and future practitioners from working in the state.

The bill makes no reference to osteopathic physicians or ch. 459, F.S., the Osteopathic Medical Practice Act, in provisions concerning disciplinary action taken against certified surgical first assistants. It is unclear if osteopathic physicians are not permitted to supervise certified surgical first assistants under this bill or if no disciplinary action is associated with their misconduct or

[20] Sections 458.311 and 458.319, F.S.

the misconduct of certified surgical first assistants they supervise. Furthermore, the bill makes no provision to involve the Board of Osteopathic Medicine in any administrative procedures relating to certified surgical first assistants.

The bill identifies the LCCST as a certifying entity for certified surgical first assistants. However, this organization no longer exists; it has been replaced by the NBSTSA.

The bill mentions the LCCST, the NSAA, the ABSA, the American Medical Association (AMA), the AmeriScan Osteopathic Association (AOA), and the Accreditation Council on Continuing Medical Education (ACCME) as authorized providers of continuing education for surgical first assistant licensure renewal. The LCCST no longer exists and has been replaced by the NBSTSA, which does not provide continuing education; rather, the AST provides and approves continuing education credits to be used towards maintenance of CSFA certification. The AMA, AOA, and ACCME are physician organizations.

VIII. 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.

156390

LEGISLATIVE ACTION

Senate . House

. . . . . .

The Committee on Health Regulation (Garcia) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause and insert:

Section 1. Section 458.3478, Florida Statutes, is created to read:

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

(a) "Direct supervision" requires the physical presence of a supervising surgeon on the premises so that the surgeon is immediately available as needed. For purposes of this section, a surgeon is liable for any tasks performed under his or her supervision.

156390

(b) "Licensed surgical first assistant" means a surgical first assistant who meets the qualifications for licensure under this section.

(c) "Surgeon" means a physician licensed under this chapter or ch. 459, a podiatrist licensed under ch. 461, or a dentist licensed under ch. 466, who has completed appropriate training in surgery and is listed as the primary surgeon in the operative record.

(d) "Surgical first assistant" means a person who is listed in the operative record as the first assistant. Surgical first assistants perform duties delegated by a surgeon under his or her direct supervision which aid the surgeon in safely performing pre-operative, intra-operative, and post-operative tasks. Such duties may include, but are not limited to, positioning the patient, placing retractors, assisting with wound closure, and applying wound dressings.

(2) PERFORMANCE OF SURGICAL FIRST ASSISTANTS.

(a) Only licensed surgical first assistants shall practice as surgical first assistants in this state, except that other licensed health care practitioners and students may practice as surgical first assistants if they have been appropriately trained and any delegated duties fall within their scope of practice. Persons who were employed as surgical first assistants as of July 1, 2012, shall be exempt from the provisions of this section.

(b) The board may not limit by rule the employment arrangement of a licensed surgical first assistant.

(3) SURGICAL FIRST ASSISTANT LICENSURE.—

(a) Any person desiring to be licensed as a surgical first

156390

assistant who is not currently licensed in another state shall apply to the department on forms furnished by the department. The department shall license each applicant who the board certifies:

1. Is at least 18 years of age.

2. Currently holds one of the following certifications:

a. Certified Surgical First Assistant from the National Board of Surgical Technologists and Surgical Assistants.

b. Certified Surgical Assistant from the National Surgical Assistant Association.

c. Surgical Assistant-Certified from the American Board of Surgical Assistants.

3. Has completed the application form and remitted an application fee not to exceed $150 as set by the board. An application for licensure must include a statement of any previous revocation or denial of licensure or certification.

4. Meets any other criteria set by law or the board.

(b) A licensed surgical first assistant's licensure does not authorize him or her to practice medicine or professional nursing.

(4) RENEWAL OF LICENSURE.—

(a) Surgical first assistant licensure must be must be renewed biennially.

(b) The department shall renew a license upon receipt of a renewal application, a fee not to exceed $150 set by the board, and either proof of completion of at least 40 hours of continuing education approved by the board or proof of current certification from a certifying organization in subsection (3)(a)2.

156390

(5) GROUNDS FOR DISCIPLINARY ACTION.—

(a) The board may impose any of the penalties authorized under ss. 456.072, 458.331, 459.015, 461.013, or 466.028 upon a licensed surgical first assistant if he or she violates the provisions of chs. 456, 458, 459, 461, or 466. The licensed surgical first assistant may only be cited for violations of and issued penalties relating to the practice act of his or her supervising surgeon or surgeons. The board may transfer management of any violation of chs. 459, 461, or 466 to the Board of Osteopathic Medicine, Board of Podiatric Medicine, and Board of Dentistry, respectively.

(b) Any person who has not been licensed by the department as a licensed surgical first assistant and who in any way indicates or implies that he or she is a licensed surgical first assistant commits a felony of the third degree, punishable as provided in ss. 775.082, 775.083, or 775.084.

(6) RULES.—The board may adopt rules to administer this section. The Board of Osteopathic Medicine, Board of Podiatric Medicine, and Board of Dentistry may adopt rules relating to discipline of licensed surgical first assistants for violations of the appropriate practice acts.

(7) FEES.—The fees collected by the board under this section shall be used for the licensure and regulation of licensed surgical first assistants in accordance with this section.

Section 2. Subsection (6) of section 627.419, Florida Statutes, is amended to read:

627.419 Construction of policies.—

(6) Notwithstanding any other provision of law, when any

156390

health insurance policy, health care services plan, or other contract provides for payment for surgical first assisting benefits or services, the policy, plan, or contract is to be construed as providing for payment to a physician assistant, a licensed surgical first assistant, or a registered nurse first assistant or employers of a physician assistant, a licensed surgical first assistant, or registered nurse first assistant who performs such services that are within the scope of a physician assistant's, a licensed surgical first assistant's, or a registered nurse first assistant's professional license. The provisions of this subsection apply only if reimbursement for an assisting physician, licensed under chapter 458 or chapter 459, or an assisting podiatrist, licensed under chapter 461, would be covered and a physician assistant, licensed surgical first assistant, or a registered nurse first assistant who performs such services is used as a substitute.

Section 3. This act shall take effect July 1, 2012.

================ 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 surgical first assistants; creating s. 458.3478, F.S.; providing definitions; requiring that all surgical first assistants be licensed, with certain exceptions; providing an effective date; prohibiting the Board of Medicine from limiting employment of licensed surgical first assistants;

156390

specifying requirements for licensure and licensure renewal; providing grounds for disciplinary action; providing for transfer of management of certain violations to the appropriate practice board; providing rulemaking authority; specifying use of fees; amending s. 627.419, F.S.; allowing for payment of surgical assisting services under certain conditions; providing an effective date.

THE FLORIDA SENATE

SENATOR MIKE HARIDOPOLOS
President

February 6, 2012

The Honorable Rene Garcia
State Senator, District 40
330 Senate Office Building
404 S. Monroe Street
Tallahassee, FL 32399-1100

Dear Senator Garcia:

Pursuant to rule 2.27(5), I am hereby appointing Senator Mike Bennett to serve on the Senate Health Regulation Committee for February 9, 2012.

Sincerely,

Mike Haridopolos
President
MH/avh

cc: Secretary Debbie Brown
Senator Mike Bennett
Sandra Stovall, Staff Director
Senate Majority Office

CourtSmart Tag Report

Room: KN 412 **Case:** **Type:**
Caption: Senate Health Regulation **Judge:**

Started: 2/9/2012 1:25:02 PM
Ends: 2/9/2012 3:15:22 PM Length: 01:50:21

1:25:03 PM	Opening Remarks
1:25:03 PM	
1:25:14 PM	Roll Call
1:25:49 PM	Senator Garcia welcomes Senator Bennett
1:26:20 PM	Tab 1 SB 1316 by Senator Gaetz
1:26:32 PM	Senator Gaetz explains the bill (d-a amendment)
1:33:07 PM	Senator Thrasher explains parts of bill
1:41:30 PM	Senator Fasano w/comments and questions
1:41:59 PM	Senator Thrasher to answer
1:42:33 PM	Senator Fasano w/comments and questions
1:43:08 PM	Senator Gaetz to answer
1:43:46 PM	Senator Fasano w/questions
1:44:07 PM	Senator Garcia
1:44:13 PM	Senator Gaetz
1:44:44 PM	Senator Fasano
1:45:02 PM	Senator Sobel explains amendment
1:46:53 PM	Senator Diaz de la Portilla explains sub amendment
1:48:27 PM	Senator Garcia
1:48:34 PM	William Large, Florida Justice Reform Institute
1:49:08 PM	Jeff Scott, Florida Medical Association
1:50:34 PM	Debra Henley, Florida Justice Association
1:50:49 PM	Alexander Clem, FJA
1:50:50 PM	
1:57:07 PM	Senator Thrasher w/comments
1:59:02 PM	Senator Fasano
1:59:28 PM	Senator Gaetz w/comments
2:01:01 PM	Senator Diaz de la Portilla to close on amendment
2:13:10 PM	Senator Gaetz and Thrasher
2:15:27 PM	Senator Gaetz w/comments
2:17:36 PM	Senator Garcia to close on amendment
2:20:00 PM	Senator Diaz de la Portilla w/sub amendment
2:21:36 PM	Roll Call on amendment
2:24:38 PM	Jacklyn J. Burkett, Epilepsy Association of the Big Bend
2:24:48 PM	Velma Penermon Stevens, Sickle Cell Foundation of the Big Bend
2:25:00 PM	Dr. John Seay, NAMI Florida
2:25:05 PM	Neal Dunn, M.D., Florida Medical Association
2:25:13 PM	Anne Swerlick, Florida Legal Services
2:25:26 PM	Steven Grigas, Florida Bar, Health Law Executive Council
2:25:33 PM	Dana Brooks, Eubanks, Barrett, Fasig and Brooks
2:30:26 PM	William Large, Florida Justice Reform Institute
2:31:38 PM	Dr. Scott Hopes, Florida Optometric Association
2:31:46 PM	Dr. Ken Lawson, Florida Optometric Association
2:31:52 PM	Michael Garner, Florida Association of Health Plans
2:33:16 PM	Charles Slonim, M.D., Florida Society of Opthalmology & American Academy of Opthalomology
2:37:25 PM	Senator Fasano, with questioins
2:38:19 PM	Dr. Slonim
2:38:26 PM	Senator Fasano
2:38:33 PM	Dr. Slonim
2:38:41 PM	Senator Fasano
2:38:47 PM	Dr. Slonim
2:39:03 PM	Senator Fasano
2:39:22 PM	Dr. Slonim

2:39:27 PM Mark Delegal, Safety Net Hospital Alliance
2:39:49 PM Senator Sobel w/comments
2:41:37 PM Senator Fasano, w/comments
2:45:17 PM Senator Garcia, w/comments
2:46:28 PM Senator Gaetz w/closing remarks
2:49:15 PM Roll Call
2:49:48 PM Tab 2 SB 1506 by Senator Thrasher
2:50:04 PM Senator Thrasher
2:51:02 PM Senator Garcia
2:51:15 PM Dr. Ken Lawson, Florida Optometric Association
2:51:20 PM Dr. Scott Hopes, Florida Optometric Association
2:51:20 PM Dr. Neal Dunn, Florida Medical Association
2:51:26 PM William Large, Florida Justice Reform Institute
2:51:32 PM Ron Watson, Florida Dental Association
2:51:40 PM Teye Reeves, Florida Chamber of Commerce
2:51:53 PM Jim Gustafson
2:51:53 PM Stephen Cain, Florida Justice Association
2:51:54 PM Rebecca O'hara, Florida Medical Association
2:52:00 PM Charles Solnim, Florida Society of Ophthamology & American Adademy of Ophthamology
2:52:03 PM Mark Delegal, Safety Net Hospital Alliance
2:52:08 PM Jeff Scott, Florida Medical Association
2:52:09 PM Alexander Clem, Attorney, FJA
2:52:20 PM Roll Call
2:53:08 PM Tab 6, SB 282, Senator Wise
2:54:11 PM Senator Jones w/question
2:54:37 PM Phil Williams, AHCA to answer
2:55:14 PM Senator Garcia
2:55:21 PM Margaret Hooper, Florida Developmental Disabilities Council
2:55:54 PM Tab 3, SB 1516 Senator Negron
2:57:47 PM Senator Fasano, w/questions
2:58:01 PM Senator Negron
2:59:21 PM Carl Galloway, Maitland Academy & All Therapy
2:59:37 PM Lou Ogburn, Family Care Council Florida
2:59:47 PM Margaret Hooper, Florida Developmental Disabilities Council
3:00:26 PM Pamela Andrews, Child w/DD
3:05:03 PM Katie Porta, President, Quest, Inc.
3:05:52 PM Phillip Hall, Leon Advocacy and Resource Center
3:07:08 PM Senator Garcia
3:07:15 PM Senator Negron to close
3:08:34 PM Roll Call
3:09:13 PM Tab 5 SB 1808 by Senator Storms
3:10:06 PM Roll Call
3:10:20 PM Tab 7 SB 1474 by Senator Gibson
3:11:16 PM Roll Call
3:11:35 PM Tab 9 SB 1228 by Senator Montford
3:12:43 PM Senator Jones w/question
3:12:55 PM Senator Montford
3:13:08 PM Howard Adams, Florida Physical Therapy Assoc.
3:13:14 PM Natalie Hair, Florida PT & PTA Students
3:13:18 PM Bob Harris
3:13:23 PM Dr. Scott Harp, VP Florida Physical Therapy Assoc.
3:13:29 PM Roll Call
3:13:50 PM Tab 4 SB 1506 by Senator Sobel
3:14:33 PM Meeting Adjourned