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]

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[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]

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[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-

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[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.