A bill to be entitled

An act relating to health care; amending s. 400.471, F.S.; prohibiting the Agency for Health Care Administration from issuing an initial license to a home health agency for the purpose of opening a new home health agency under certain conditions until a specified date; prohibiting the agency from issuing a change-of-ownership license to a home health agency under certain conditions until a specified date; providing an exception; amending s. 400.474, F.S.; authorizing the agency to revoke a home health agency license if the applicant or any controlling interest has been sanctioned for acts specified under s. 400.471(10), F.S.; amending s. 400.9905, F.S.; specifying that certain licensure requirements do not apply to certain pediatric cardiological or perinatological clinical facilities; providing that part X of ch. 400, F.S., the Health Care Clinic Act, does not apply to entities owned by a corporation that has a specified amount of annual sales of health care services under certain circumstances; amending s. 408.815, F.S.; revising the grounds upon which the agency may deny or revoke an application for an initial license, a change-of-ownership license, or a licensure renewal for certain health care entities listed in s. 408.802, F.S.; amending s. 408.910, F.S.; revising the list of employers who are eligible to enroll in the Florida Health Choices Program; revising the membership of the board of directors of the

Florida Health Choices, Inc.; requiring the President of the Senate and the Speaker of the House of Representatives to initially appoint members to the board of directors for staggered terms; requiring that the members of the board appoint new members to the board of directors after a specified date, subject to Senate confirmation; deleting a provision that prohibits board members from serving for more than a certain number of consecutive years; amending s. 409.907, F.S.; extending the number of years that Medicaid providers must retain Medicaid recipient records; adding additional requirements to the Medicaid provider agreement; revising applicability of screening requirements; revising conditions under which the agency is authorized to deny a Medicaid provider application; amending s. 409.912, F.S.; revising requirements for Medicaid prepaid, fixed-sum, and managed care contracts; revising requirements for Medicaid durable medical equipment providers; repealing s. 409.9122(13), F.S., relating to the enrollee assignment process of Medicaid managed prepaid health plans for those Medicaid managed prepaid health plans operating in Miami-Dade County; amending s. 409.913, F.S.; removing a required element from the joint Medicaid fraud and abuse report submitted by the agency and the Medicaid Fraud Control Unit of the Department of Legal Affairs; extending the number of years that Medicaid providers must retain Medicaid recipient records; authorizing the Medicaid

program integrity staff to immediately suspend or terminate a Medicaid provider for engaging in specified conduct; removing a requirement for the agency to hold suspended Medicaid payments in a separate account; authorizing the agency to deny payment or require repayment to Medicaid providers convicted of certain crimes; authorizing the agency to terminate a Medicaid provider if the provider fails to reimburse a fine determined by a final order; authorizing the agency to withhold Medicaid reimbursement to a Medicaid provider that fails to pay a fine determined by a final order, fails to enter into a repayment plan, or fails to comply with a repayment plan or settlement agreement; requiring the biennial review of Medicaid fraud and abuse by the Office of Program Policy Analysis and Government Accountability to include a report on the Medicaid Fraud Control Unit within the Department of Legal Affairs; amending s. 409.9203, F.S.; providing that certain state employees are ineligible from receiving a reward for reporting Medicaid fraud; amending s. 456.001, F.S.; defining the term "affiliate" or "affiliated person" as it relates to health professions and occupations; amending s. 456.041, F.S.; requiring the Department of Health to include administrative complaints and any conviction information relating to the practitioner's profile; providing a disclaimer; amending s. 456.0635, F.S.; revising the grounds under which the Department of

Health or corresponding board is required to refuse to admit a candidate to an examination and refuse to issue or renew a license, certificate, or registration of a health care practitioner; providing an exception; amending s. 456.072, F.S.; clarifying a ground under which disciplinary actions may be taken; amending s. 456.073, F.S.; revising applicability of investigations and administrative complaints to include Medicaid fraud; amending s. 456.074, F.S.; authorizing the Department of Health to issue an emergency order suspending the license of any person licensed under ch. 456, F.S., who engages in specified criminal conduct; amending s. 499.01, F.S.; exempting certain persons from requirements for medical device manufacturer permits; providing an effective date.

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

Section 1. Subsection (11) of section 400.471, Florida Statutes, is amended to read:

400.471 Application for license; fee.—

(11)(a) The agency may not issue an initial license to a home health agency under part II of chapter 408 or this part for the purpose of opening a new home health agency until July 1, 2012 ~~2010~~, in any county that has at least one actively licensed home health agency and a population of persons 65 years of age or older, as indicated in the most recent population estimates published by the Executive Office of the Governor, of fewer than 1,200 per home health agency. In such counties, for any

application received by the agency prior to July 1, 2009, which has been deemed by the agency to be complete except for proof of accreditation, the agency may issue an initial ownership license only if the applicant has applied for accreditation before May 1, 2009, from an accrediting organization that is recognized by the agency.

(b) Effective October 1, 2009, the agency may not issue a change of ownership license to a home health agency under part II of chapter 408 or this part until July 1, 2012 ~~2010~~, in any county that has at least one actively licensed home health agency and a population of persons 65 years of age or older, as indicated in the most recent population estimates published by the Executive Office of the Governor, of fewer than 1,200 per home health agency. In such counties, for any application received by the agency before ~~prior to~~ October 1, 2009, which has been deemed by the agency to be complete except for proof of accreditation, the agency may issue a change of ownership license only if the applicant has applied for accreditation before August 1, 2009, from an accrediting organization that is recognized by the agency. This paragraph does not apply to an application for a change in ownership from an existing home health agency that is accredited, has been licensed by the state at least 5 years, and is in good standing with the agency.

Section 2. Subsection (8) is added to section 400.474, Florida Statutes, to read:

400.474 Administrative penalties.—

(8) The agency may revoke the license of a home health agency that is not eligible for licensure renewal under s. 400.471(10).

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

400.9905 Definitions.—

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

(l) Orthotic, ~~or~~ prosthetic, pediatric cardiological, or perinatological clinical facilities that are a publicly traded corporation or that are wholly owned, directly or indirectly, by a publicly traded corporation. As used in this paragraph, a publicly traded corporation is a corporation that issues securities traded on an exchange registered with the United States Securities and Exchange Commission as a national securities exchange.

(m) Entities that are owned by a corporation that has $250 million or more in total annual sales of health care services provided by licensed health care practitioners if one or more of the owners of the entity is a health care practitioner who is licensed in this state, is responsible for supervising the business activities of the entity, and is legally responsible for the entity's compliance with state law for purposes of this section.

Section 4. Subsections (1) and (4) of section 408.815, Florida Statutes, are amended, and subsection (5) is added to that section, to read:

408.815 License or application denial; revocation.—

(1) In addition to the grounds provided in authorizing statutes, grounds that may be used by the agency for denying and revoking a license or change of ownership application include any of the following actions by a controlling interest:

(a) False representation of a material fact in the license application or omission of any material fact from the application.

(b) An intentional or negligent act materially affecting the health or safety of a client of the provider.

(c) A violation of this part, authorizing statutes, or applicable rules.

(d) A demonstrated pattern of deficient performance.

(e) The applicant, licensee, or controlling interest has been or is currently excluded, suspended, or terminated from participation in the state Medicaid program, the Medicaid program of any other state, or the Medicare program.

(f) The applicant, licensee, or controlling interest is or was an administrator or controlling interest in a facility or entity during the period an event that caused or contributed to the facility or entity being excluded, suspended, or terminated from participation in the state Medicaid program, the Medicaid program of any other state, or the Medicare program.

(4) In addition to the grounds provided in authorizing statutes, the agency shall deny an application for an initial ~~a~~ license or a change-of-ownership license ~~renewal~~ if the applicant or a person having a controlling interest in the ~~an~~ applicant ~~has been~~:

(a) Has been convicted of, or entered ~~enters~~ a plea of

guilty or nolo contendere to, regardless of adjudication, a felony under chapter 409, chapter 817, chapter 893, or a similar felony offense committed in another state or jurisdiction ~~21 U.S.C. ss. 801-970, or 42 U.S.C. ss. 1395-1396~~, unless the sentence and any subsequent period of probation for such conviction ~~convictions~~ or plea ended more than 15 years before ~~prior to~~ the date of the application;

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

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

(d) ~~(c)~~ Has been terminated for cause, pursuant to the appeals procedures established by the state, ~~or Federal Government, from the federal Medicare program or~~ from any other state Medicaid 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 before ~~prior to~~ the date of the application; or~~.~~

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

(5) In addition to the grounds provided in authorizing

statutes, the agency shall deny an application for licensure renewal if the applicant or a person having a controlling interest in the applicant:

(a) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under chapter 409, chapter 817, chapter 893, or a similar felony offense committed in another state or jurisdiction since July 1, 2009;

(b) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970, or 42 U.S.C. ss. 1395-1396 since July 1, 2009;

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

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

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

Section 5. Paragraph (a) of subsection (4) and subsection (11) of section 408.910, Florida Statutes, are amended to read:

408.910 Florida Health Choices Program.—

(4) ELIGIBILITY AND PARTICIPATION.—Participation in the

program is voluntary and shall be available to employers, individuals, vendors, and health insurance agents as specified in this subsection.

(a) Employers eligible to enroll in the program include:

1. Employers that have 1 to 50 employees.

2. Fiscally constrained counties described in s. 218.67.

3. Municipalities having populations of fewer than 50,000 residents.

4. School districts in fiscally constrained counties.

5. State universities and community colleges.

(11) CORPORATION.—There is created the Florida Health Choices, Inc., which shall be registered, incorporated, organized, and operated in compliance with part III of chapter 112 and chapters 119, 286, and 617. The purpose of the corporation is to administer the program created in this section and to conduct such other business as may further the administration of the program.

(a)1. The corporation shall be governed by a five-member ~~15-member~~ board of directors consisting of:

~~1. Three ex officio, nonvoting members to include:~~

~~a. The Secretary of Health Care Administration or a designee with expertise in health care services.~~

~~b. The Secretary of Management Services or a designee with expertise in state employee benefits.~~

~~c. The commissioner of the Office of Insurance Regulation or a designee with expertise in insurance regulation.~~

a.~~2.~~ One member ~~Four members~~ appointed by and serving at the pleasure of the Governor.

b.~~3.~~ Two ~~Four~~ members appointed by and serving at the

pleasure of the President of the Senate.

c.~~4.~~ Two ~~Four~~ members appointed by and serving at the pleasure of the Speaker of the House of Representatives.

2.~~5.~~ Board members may not include insurers, health insurance agents or brokers, health care providers, health maintenance organizations, prepaid service providers, or any other entity, affiliate or subsidiary of eligible vendors.

(b)1. Members shall be appointed for terms of up to 4 ~~3~~ years. In order to establish staggered terms, for the initial appointments the President of the Senate and the Speaker of the House of Representatives shall each appoint one member to a 2-year term and one member to a 4-year term. Any member is eligible for reappointment. A vacancy on the board shall be filled for the unexpired portion of the term in the same manner as the original appointment.

2. Beginning July 1, 2011, the members of the board of directors shall appoint new members to the board of directors, subject to confirmation by the Senate.

(c) The board shall select a chief executive officer for the corporation who shall be responsible for the selection of such other staff as may be authorized by the corporation's operating budget as adopted by the board.

(d) Board members are entitled to receive, from funds of the corporation, reimbursement for per diem and travel expenses as provided by s. 112.061. No other compensation is authorized.

(e) There is no liability on the part of, and no cause of action shall arise against, any member of the board or its employees or agents for any action taken by them in the performance of their powers and duties under this section.

(f) The board shall develop and adopt bylaws and other corporate procedures as necessary for the operation of the corporation and carrying out the purposes of this section. The bylaws shall:

1. Specify procedures for selection of officers and qualifications for reappointment~~, provided that no board member shall serve more than 9 consecutive years~~.

2. Require an annual membership meeting that provides an opportunity for input and interaction with individual participants in the program.

3. Specify policies and procedures regarding conflicts of interest, including the provisions of part III of chapter 112, which prohibit a member from participating in any decision that would inure to the benefit of the member or the organization that employs the member. The policies and procedures shall also require public disclosure of the interest that prevents the member from participating in a decision on a particular matter.

(g) The corporation may exercise all powers granted to it under chapter 617 necessary to carry out the purposes of this section, including, but not limited to, the power to receive and accept grants, loans, or advances of funds from any public or private agency and to receive and accept from any source contributions of money, property, labor, or any other thing of value to be held, used, and applied for the purposes of this section.

(h) The corporation may establish technical advisory panels consisting of interested parties, including consumers, health care providers, individuals with expertise in insurance regulation, and insurers.

(i) The corporation shall:

1. Determine eligibility of employers, vendors, individuals, and agents in accordance with subsection (4).

2. Establish procedures necessary for the operation of the program, including, but not limited to, procedures for application, enrollment, risk assessment, risk adjustment, plan administration, performance monitoring, and consumer education.

3. Arrange for collection of contributions from participating employers and individuals.

4. Arrange for payment of premiums and other appropriate disbursements based on the selections of products and services by the individual participants.

5. Establish criteria for disenrollment of participating individuals based on failure to pay the individual’s share of any contribution required to maintain enrollment in selected products.

6. Establish criteria for exclusion of vendors pursuant to paragraph (4)(d).

7. Develop and implement a plan for promoting public awareness of and participation in the program.

8. Secure staff and consultant services necessary to the operation of the program.

9. Establish policies and procedures regarding participation in the program for individuals, vendors, health insurance agents, and employers.

10. Develop a plan, in coordination with the Department of Revenue, to establish tax credits or refunds for employers that participate in the program. The corporation shall submit the plan to the Governor, the President of the Senate, and the

Speaker of the House of Representatives by January 1, 2009.

Section 6. Paragraph (c) of subsection (3) of section 409.907, Florida Statutes, is amended, paragraph (k) is added to that subsection, and subsection (8), paragraph (b) of subsection (9), and subsection (10) of that section are amended, to read:

409.907 Medicaid provider agreements.—The agency may make payments for medical assistance and related services rendered to Medicaid recipients only to an individual or entity who has a provider agreement in effect with the agency, who is performing services or supplying goods in accordance with federal, state, and local law, and who agrees that no person shall, on the grounds of handicap, race, color, or national origin, or for any other reason, be subjected to discrimination under any program or activity for which the provider receives payment from the agency.

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

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

(k) Report any change of any principal of the provider, including any officer, director, agent, managing employee, or affiliated person, or any partner or shareholder who has an ownership interest equal to 5 percent or more in the provider. The provider must report changes to the agency no later than 30 days after the change occurs. Reporting changes in controlling interests to the agency pursuant to s. 408.810(3) shall serve as compliance with this paragraph for hospitals licensed under

chapter 395 and nursing homes licensed under chapter 400.

(8)(a) Each provider, or each principal of the provider if the provider is a corporation, partnership, association, or other entity, seeking to participate in the Medicaid program must submit a complete set of his or her fingerprints to the agency for the purpose of conducting a criminal history record check. Principals of the provider include any officer, director, billing agent, managing employee, or affiliated person, or any partner or shareholder who has an ownership interest equal to 5 percent or more in the provider. However, for hospitals licensed under chapter 395 and nursing homes licensed under chapter 400, principals of the provider are those who meet the definition of a controlling interest in s. 408.803(7). A director of a not-for-profit corporation or organization is not a principal for purposes of a background investigation as required by this section if the director: serves solely in a voluntary capacity for the corporation or organization, does not regularly take part in the day-to-day operational decisions of the corporation or organization, receives no remuneration from the not-for-profit corporation or organization for his or her service on the board of directors, has no financial interest in the not-for-profit corporation or organization, and has no family members with a financial interest in the not-for-profit corporation or organization~~; and if the director submits an affidavit, under penalty of perjury, to this effect to the agency and the not-for-profit corporation or organization submits an affidavit, under penalty of perjury, to this effect to the agency as part of the corporation's or organization's Medicaid provider agreement application~~. Notwithstanding the above, the agency may

require a background check for any person reasonably suspected by the agency to have been convicted of a crime. This subsection does ~~shall~~ not apply to:

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

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

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

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

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

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

(b) Background screening shall be conducted in accordance with chapter 435 and s. 408.809. ~~The agency shall submit the fingerprints to the Department of Law Enforcement. The department shall conduct a state criminal background investigation and forward the fingerprints to the Federal Bureau of Investigation for a national criminal history record check.~~ The cost of the state and national criminal record check shall be borne by the provider.

~~(c) The agency may permit a provider to participate in the Medicaid program pending the results of the criminal record check. However, such permission is fully revocable if the record~~

~~check reveals any crime-related history as provided in subsection (10).~~

(c)~~(d)~~ Proof of compliance with the requirements of level 2 screening under s. 435.04 conducted within 12 months prior to the date that the Medicaid provider application is submitted to the agency shall fulfill the requirements of this subsection. ~~Proof of compliance with the requirements of level 1 screening under s. 435.03 conducted within 12 months prior to the date that the Medicaid provider application is submitted to the agency shall meet the requirement that the Department of Law Enforcement conduct a state criminal history record check.~~

(9) Upon receipt of a completed, signed, and dated application, and completion of any necessary background investigation and criminal history record check, the agency must either:

(b) Deny the application if the agency finds that it is in the best interest of the Medicaid program to do so. The agency may consider any ~~the factors listed in subsection (10), as well as any other~~ factor that could affect the effective and efficient administration of the program, including, but not limited to, the applicant's demonstrated ability to provide services, conduct business, and operate a financially viable concern; the current availability of medical care, services, or supplies to recipients, taking into account geographic location and reasonable travel time; the number of providers of the same type already enrolled in the same geographic area; and the credentials, experience, success, and patient outcomes of the provider for the services that it is making application to provide in the Medicaid program. The agency shall deny the

application if the agency finds that a provider; any officer, director, agent, managing employee, or affiliated person; or any principal, partner, or shareholder having an ownership interest equal to 5 percent or greater in the provider if the provider is a corporation, partnership, or other business entity, has failed to pay all outstanding fines or overpayments assessed by final order of the agency or final order of the Centers for Medicare and Medicaid Services, not subject to further appeal, unless the provider agrees to a repayment plan that includes withholding Medicaid reimbursement until the amount due is paid in full.

(10) The agency shall deny the application if ~~may consider whether~~ the provider, or any officer, director, agent, managing employee, or affiliated person, or any principal, partner, or shareholder having an ownership interest equal to 5 percent or greater in the provider if the provider is a corporation, partnership, or other business entity, has committed an offense listed in s. 409.913(13), and may deny the application if one of these persons has:

(a) Made a false representation or omission of any material fact in making the application, including the submission of an application that conceals the controlling or ownership interest of any officer, director, agent, managing employee, affiliated person, or principal, partner, or shareholder who may not be eligible to participate;

(b) Been or is currently excluded, suspended, terminated from, or has involuntarily withdrawn from participation in, Florida's Medicaid program or any other state's Medicaid program, or from participation in any other governmental or private health care or health insurance program;

~~(c) Been 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;~~

~~(d) Been convicted under federal or state law of a criminal offense related to the neglect or abuse of a patient in connection with the delivery of any health care goods or services;~~

(c) ~~(e)~~ Been convicted under federal or state law of a criminal offense relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance;

(d) ~~(f)~~ Been convicted of any criminal offense relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct;

(e) ~~(g)~~ Been convicted under federal or state law of a crime punishable by imprisonment of a year or more which involves moral turpitude;

(f) ~~(h)~~ Been convicted in connection with the interference or obstruction of any investigation into any criminal offense listed in this subsection;

(g) ~~(i)~~ Been found to have violated federal or state laws~~,~~ ~~rules, or regulations~~ governing Florida's Medicaid program or any other state's Medicaid program, the Medicare program, or any other publicly funded federal or state health care or health insurance program, and been sanctioned accordingly;

(h) ~~(j)~~ Been previously found by a licensing, certifying, or

professional standards board or agency to have violated the standards or conditions relating to licensure or certification or the quality of services provided; or

(i) ~~(k)~~ Failed to pay any fine or overpayment properly assessed under the Medicaid program in which no appeal is pending or after resolution of the proceeding by stipulation or agreement, unless the agency has issued a specific letter of forgiveness or has approved a repayment schedule to which the provider agrees to adhere.

If the agency determines a provider did not participate or acquiesce in an offense specified in s. 409.913(13), the agency is not required to deny the provider application.

Section 7. Subsections (10), (32), and (48) of section 409.912, Florida Statutes, are amended to read:

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

including competitive bidding pursuant to s. 287.057, designed to facilitate the cost-effective purchase of a case-managed continuum of care. The agency shall also require providers to minimize the exposure of recipients to the need for acute inpatient, custodial, and other institutional care and the inappropriate or unnecessary use of high-cost services. The agency shall contract with a vendor to monitor and evaluate the clinical practice patterns of providers in order to identify trends that are outside the normal practice patterns of a provider’s professional peers or the national guidelines of a provider’s professional association. The vendor must be able to provide information and counseling to a provider whose practice patterns are outside the norms, in consultation with the agency, to improve patient care and reduce inappropriate utilization. The agency may mandate prior authorization, drug therapy management, or disease management participation for certain populations of Medicaid beneficiaries, certain drug classes, or particular drugs to prevent fraud, abuse, overuse, and possible dangerous drug interactions. The Pharmaceutical and Therapeutics Committee shall make recommendations to the agency on drugs for which prior authorization is required. The agency shall inform the Pharmaceutical and Therapeutics Committee of its decisions regarding drugs subject to prior authorization. The agency is authorized to limit the entities it contracts with or enrolls as Medicaid providers by developing a provider network through provider credentialing. The agency may competitively bid single-source-provider contracts if procurement of goods or services results in demonstrated cost savings to the state without limiting access to care. The agency may limit its network based

on the assessment of beneficiary access to care, provider availability, provider quality standards, time and distance standards for access to care, the cultural competence of the provider network, demographic characteristics of Medicaid beneficiaries, practice and provider-to-beneficiary standards, appointment wait times, beneficiary use of services, provider turnover, provider profiling, provider licensure history, previous program integrity investigations and findings, peer review, provider Medicaid policy and billing compliance records, clinical and medical record audits, and other factors. Providers shall not be entitled to enrollment in the Medicaid provider network. The agency shall determine instances in which allowing Medicaid beneficiaries to purchase durable medical equipment and other goods is less expensive to the Medicaid program than long-term rental of the equipment or goods. The agency may establish rules to facilitate purchases in lieu of long-term rentals in order to protect against fraud and abuse in the Medicaid program as defined in s. 409.913. The agency may seek federal waivers necessary to administer these policies.

(10) The agency shall not contract on a prepaid or fixed-sum basis for Medicaid services with an entity which knows or reasonably should know that any <u>principal,</u> officer, director, agent, managing employee, or owner of stock or beneficial interest in excess of 5 percent common or preferred stock, or the entity itself, has been found guilty of, regardless of adjudication, or entered a plea of nolo contendere, or guilty, to:

(a) <u>An offense listed in s. 408.809, s. 409.913(13), or s. 435.04</u> ~~Fraud~~;

(b) Violation of federal or state antitrust statutes, including those proscribing price fixing between competitors and the allocation of customers among competitors;

(c) Commission of a felony involving embezzlement, theft, forgery, income tax evasion, bribery, falsification or destruction of records, making false statements, receiving stolen property, making false claims, or obstruction of justice; or

(d) Any crime in any jurisdiction which directly relates to the provision of health services on a prepaid or fixed-sum basis.

(32) Each managed care plan that is under contract with the agency to provide health care services to Medicaid recipients shall annually conduct a background check with the Florida Department of Law Enforcement of all persons with ownership interest of 5 percent or more or executive management responsibility for the managed care plan and shall submit to the agency information concerning any such person who has been found guilty of, regardless of adjudication, or has entered a plea of nolo contendere or guilty to, any of the offenses listed in s. 408.809, s. 409.913(13), or s. 435.04 ~~s. 435.03~~.

(48)(a) A provider is not entitled to enrollment in the Medicaid provider network. The agency may implement a Medicaid fee-for-service provider network controls, including, but not limited to, competitive procurement and provider credentialing. If a credentialing process is used, the agency may limit its provider network based upon the following considerations: beneficiary access to care, provider availability, provider quality standards and quality assurance processes, cultural

competency, demographic characteristics of beneficiaries, practice standards, service wait times, provider turnover, provider licensure and accreditation history, program integrity history, peer review, Medicaid policy and billing compliance records, clinical and medical record audit findings, and such other areas that are considered necessary by the agency to ensure the integrity of the program.

(b) The agency shall limit its network of durable medical equipment and medical supply providers. For dates of service after January 1, 2009, the agency shall limit payment for durable medical equipment and supplies to providers that meet all the requirements of this paragraph.

1. Providers must be accredited by a Centers for Medicare and Medicaid Services deemed accreditation organization for suppliers of durable medical equipment, prosthetics, orthotics, and supplies. The provider must maintain accreditation and is subject to unannounced reviews by the accrediting organization.

2. Providers must provide the services or supplies directly to the Medicaid recipient or caregiver at the provider location or recipient’s residence or send the supplies directly to the recipient’s residence with receipt of mailed delivery. Subcontracting or consignment of the service or supply to a third party is prohibited.

3. Notwithstanding subparagraph 2., a durable medical equipment provider may store nebulizers at a physician’s office for the purpose of having the physician’s staff issue the equipment if it meets all of the following conditions:

a. The physician must document the medical necessity and need to prevent further deterioration of the patient’s

respiratory status by the timely delivery of the nebulizer in the physician's office.

b. The durable medical equipment provider must have written documentation of the competency and training by a Florida-licensed registered respiratory therapist of any durable medical equipment staff who participate in the training of physician office staff for the use of nebulizers, including cleaning, warranty, and special needs of patients.

c. The physician's office must have documented the training and competency of any staff member who initiates the delivery of nebulizers to patients. The durable medical equipment provider must maintain copies of all physician office training.

d. The physician's office must maintain inventory records of stored nebulizers, including documentation of the durable medical equipment provider source.

e. A physician contracted with a Medicaid durable medical equipment provider may not have a financial relationship with that provider or receive any financial gain from the delivery of nebulizers to patients.

4. Providers must have a physical business location and a functional landline business phone. The location must be within the state or not more than 50 miles from the Florida state line. The agency may make exceptions for providers of durable medical equipment or supplies not otherwise available from other enrolled providers located within the state.

5. Physical business locations must be clearly identified as a business that furnishes durable medical equipment or medical supplies by signage that can be read from 20 feet away. The location must be readily accessible to the public during

normal, posted business hours and must operate no less than 5 hours per day and no less than 5 days per week, with the exception of scheduled and posted holidays. The location may not be located within or at the same numbered street address as another enrolled Medicaid durable medical equipment or medical supply provider or as an enrolled Medicaid pharmacy that is also enrolled as a durable medical equipment provider. A licensed orthotist or prosthetist that provides only orthotic or prosthetic devices as a Medicaid durable medical equipment provider is exempt from the provisions in this paragraph.

6. Providers must maintain a stock of durable medical equipment and medical supplies on site that is readily available to meet the needs of the durable medical equipment business location's customers.

7. Providers must provide a surety bond of $50,000 for each provider location, up to a maximum of 5 bonds statewide or an aggregate bond of $250,000 statewide, as identified by Federal Employer Identification Number. Providers who post a statewide or an aggregate bond must identify all of their locations in any Medicaid durable medical equipment and medical supply provider enrollment application or bond renewal. Each provider location's surety bond must be renewed annually and the provider must submit proof of renewal even if the original bond is a continuous bond. A licensed orthotist or prosthetist that provides only orthotic or prosthetic devices as a Medicaid durable medical equipment provider is exempt from the provisions in this paragraph.

8. Providers must obtain a level 2 background screening, in accordance with chapter 435 and s. 408.809 ~~as provided under s.~~

~~435.04~~, for each provider employee in direct contact with or providing direct services to recipients of durable medical equipment and medical supplies in their homes. This requirement includes, but is not limited to, repair and service technicians, fitters, and delivery staff. The provider shall pay for the cost of the background screening.

9. The following providers are exempt from the requirements of subparagraphs 1. and 7.:

a. Durable medical equipment providers owned and operated by a government entity.

b. Durable medical equipment providers that are operating within a pharmacy that is currently enrolled as a Medicaid pharmacy provider.

c. Active, Medicaid-enrolled orthopedic physician groups, primarily owned by physicians, which provide only orthotic and prosthetic devices.

Section 8. Subsection (13) of section 409.9122, Florida Statutes, is repealed.

Section 9. Section 409.913, Florida Statutes, is amended to read:

409.913 Oversight of the integrity of the Medicaid program.—The agency shall operate a program to oversee the activities of Florida Medicaid recipients, and providers and their representatives, to ensure that fraudulent and abusive behavior and neglect of recipients occur to the minimum extent possible, and to recover overpayments and impose sanctions as appropriate. Beginning January 1, 2003, and each year thereafter, the agency and the Medicaid Fraud Control Unit of the Department of Legal Affairs shall submit a joint report to

the Legislature documenting the effectiveness of the state's efforts to control Medicaid fraud and abuse and to recover Medicaid overpayments during the previous fiscal year. The report must describe the number of cases opened and investigated each year; the sources of the cases opened; the disposition of the cases closed each year; the amount of overpayments alleged in preliminary and final audit letters; the number and amount of fines or penalties imposed; any reductions in overpayment amounts negotiated in settlement agreements or by other means; the amount of final agency determinations of overpayments; the amount deducted from federal claiming as a result of overpayments; the amount of overpayments recovered each year; the amount of cost of investigation recovered each year; the average length of time to collect from the time the case was opened until the overpayment is paid in full; the amount determined as uncollectible and the portion of the uncollectible amount subsequently reclaimed from the Federal Government; the number of providers, by type, that are terminated from participation in the Medicaid program as a result of fraud and abuse; and all costs associated with discovering and prosecuting cases of Medicaid overpayments and making recoveries in such cases. The report must also document actions taken to prevent overpayments and the number of providers prevented from enrolling in or reenrolling in the Medicaid program as a result of documented Medicaid fraud and abuse and must include policy recommendations necessary to prevent or recover overpayments and changes necessary to prevent and detect Medicaid fraud. All policy recommendations in the report must include a detailed fiscal analysis, including, but not limited to, implementation

costs, estimated savings to the Medicaid program, and the return on investment. The agency must submit the policy recommendations and fiscal analyses in the report to the appropriate estimating conference, pursuant to s. 216.137, by February 15 of each year. The agency and the Medicaid Fraud Control Unit of the Department of Legal Affairs each must include detailed unit-specific performance standards, benchmarks, and metrics in the report~~, including projected cost savings to the state Medicaid program during the following fiscal year~~.

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

(a) "Abuse" means:

1. Provider practices that are inconsistent with generally accepted business or medical practices and that result in an unnecessary cost to the Medicaid program or in reimbursement for goods or services that are not medically necessary or that fail to meet professionally recognized standards for health care.

2. Recipient practices that result in unnecessary cost to the Medicaid program.

(b) "Complaint" means an allegation that fraud, abuse, or an overpayment has occurred.

(c) "Fraud" means an intentional deception or misrepresentation made by a person with the knowledge that the deception results in unauthorized benefit to herself or himself or another person. The term includes any act that constitutes fraud under applicable federal or state law.

(d) "Medical necessity" or "medically necessary" means any goods or services necessary to palliate the effects of a terminal condition, or to prevent, diagnose, correct, cure, alleviate, or preclude deterioration of a condition that

threatens life, causes pain or suffering, or results in illness or infirmity, which goods or services are provided in accordance with generally accepted standards of medical practice. For purposes of determining Medicaid reimbursement, the agency is the final arbiter of medical necessity. Determinations of medical necessity must be made by a licensed physician employed by or under contract with the agency and must be based upon information available at the time the goods or services are provided.

(e) "Overpayment" includes any amount that is not authorized to be paid by the Medicaid program whether paid as a result of inaccurate or improper cost reporting, improper claiming, unacceptable practices, fraud, abuse, or mistake.

(f) "Person" means any natural person, corporation, partnership, association, clinic, group, or other entity, whether or not such person is enrolled in the Medicaid program or is a provider of health care.

(2) The agency shall conduct, or cause to be conducted by contract or otherwise, reviews, investigations, analyses, audits, or any combination thereof, to determine possible fraud, abuse, overpayment, or recipient neglect in the Medicaid program and shall report the findings of any overpayments in audit reports as appropriate. At least 5 percent of all audits shall be conducted on a random basis. As part of its ongoing fraud detection activities, the agency shall identify and monitor, by contract or otherwise, patterns of overutilization of Medicaid services based on state averages. The agency shall track Medicaid provider prescription and billing patterns and evaluate them against Medicaid medical necessity criteria and coverage

and limitation guidelines adopted by rule. Medical necessity determination requires that service be consistent with symptoms or confirmed diagnosis of illness or injury under treatment and not in excess of the patient's needs. The agency shall conduct reviews of provider exceptions to peer group norms and shall, using statistical methodologies, provider profiling, and analysis of billing patterns, detect and investigate abnormal or unusual increases in billing or payment of claims for Medicaid services and medically unnecessary provision of services.

(3) The agency may conduct, or may contract for, prepayment review of provider claims to ensure cost-effective purchasing; to ensure that billing by a provider to the agency is in accordance with applicable provisions of all Medicaid rules, regulations, handbooks, and policies and in accordance with federal, state, and local law; and to ensure that appropriate care is rendered to Medicaid recipients. Such prepayment reviews may be conducted as determined appropriate by the agency, without any suspicion or allegation of fraud, abuse, or neglect, and may last for up to 1 year. Unless the agency has reliable evidence of fraud, misrepresentation, abuse, or neglect, claims shall be adjudicated for denial or payment within 90 days after receipt of complete documentation by the agency for review. If there is reliable evidence of fraud, misrepresentation, abuse, or neglect, claims shall be adjudicated for denial of payment within 180 days after receipt of complete documentation by the agency for review.

(4) Any suspected criminal violation identified by the agency must be referred to the Medicaid Fraud Control Unit of the Office of the Attorney General for investigation. The agency

and the Attorney General shall enter into a memorandum of understanding, which must include, but need not be limited to, a protocol for regularly sharing information and coordinating casework. The protocol must establish a procedure for the referral by the agency of cases involving suspected Medicaid fraud to the Medicaid Fraud Control Unit for investigation, and the return to the agency of those cases where investigation determines that administrative action by the agency is appropriate. Offices of the Medicaid program integrity program and the Medicaid Fraud Control Unit of the Department of Legal Affairs, shall, to the extent possible, be collocated. The agency and the Department of Legal Affairs shall periodically conduct joint training and other joint activities designed to increase communication and coordination in recovering overpayments.

(5) A Medicaid provider is subject to having goods and services that are paid for by the Medicaid program reviewed by an appropriate peer-review organization designated by the agency. The written findings of the applicable peer-review organization are admissible in any court or administrative proceeding as evidence of medical necessity or the lack thereof.

(6) Any notice required to be given to a provider under this section is presumed to be sufficient notice if sent to the address last shown on the provider enrollment file. It is the responsibility of the provider to furnish and keep the agency informed of the provider’s current address. United States Postal Service proof of mailing or certified or registered mailing of such notice to the provider at the address shown on the provider enrollment file constitutes sufficient proof of notice. Any

notice required to be given to the agency by this section must be sent to the agency at an address designated by rule.

(7) When presenting a claim for payment under the Medicaid program, a provider has an affirmative duty to supervise the provision of, and be responsible for, goods and services claimed to have been provided, to supervise and be responsible for preparation and submission of the claim, and to present a claim that is true and accurate and that is for goods and services that:

(a) Have actually been furnished to the recipient by the provider prior to submitting the claim.

(b) Are Medicaid-covered goods or services that are medically necessary.

(c) Are of a quality comparable to those furnished to the general public by the provider's peers.

(d) Have not been billed in whole or in part to a recipient or a recipient's responsible party, except for such copayments, coinsurance, or deductibles as are authorized by the agency.

(e) Are provided in accord with applicable provisions of all Medicaid rules, regulations, handbooks, and policies and in accordance with federal, state, and local law.

(f) Are documented by records made at the time the goods or services were provided, demonstrating the medical necessity for the goods or services rendered. Medicaid goods or services are excessive or not medically necessary unless both the medical basis and the specific need for them are fully and properly documented in the recipient's medical record.

The agency shall deny payment or require repayment for goods or

services that are not presented as required in this subsection.

(8) The agency shall not reimburse any person or entity for any prescription for medications, medical supplies, or medical services if the prescription was written by a physician or other prescribing practitioner who is not enrolled in the Medicaid program. This section does not apply:

(a) In instances involving bona fide emergency medical conditions as determined by the agency;

(b) To a provider of medical services to a patient in a hospital emergency department, hospital inpatient or outpatient setting, or nursing home;

(c) To bona fide pro bono services by preapproved non-Medicaid providers as determined by the agency;

(d) To prescribing physicians who are board-certified specialists treating Medicaid recipients referred for treatment by a treating physician who is enrolled in the Medicaid program;

(e) To prescriptions written for dually eligible Medicare beneficiaries by an authorized Medicare provider who is not enrolled in the Medicaid program;

(f) To other physicians who are not enrolled in the Medicaid program but who provide a medically necessary service or prescription not otherwise reasonably available from a Medicaid-enrolled physician; or

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

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

(10) Payments for the services of billing agents or persons participating in the preparation of a Medicaid claim shall not be based on amounts for which they bill nor based on the amount a provider receives from the Medicaid program.

(11) The agency shall deny payment or require repayment for inappropriate, medically unnecessary, or excessive goods or services from the person furnishing them, the person under whose supervision they were furnished, or the person causing them to be furnished.

(12) The complaint and all information obtained pursuant to an investigation of a Medicaid provider, or the authorized representative or agent of a provider, relating to an allegation of fraud, abuse, or neglect are confidential and exempt from the provisions of s. 119.07(1):

(a) Until the agency takes final agency action with respect to the provider and requires repayment of any overpayment, or imposes an administrative sanction;

(b) Until the Attorney General refers the case for criminal prosecution;

(c) Until 10 days after the complaint is determined without merit; or

(d) At all times if the complaint or information is

otherwise protected by law.

(13) The agency shall immediately terminate participation of a Medicaid provider in the Medicaid program and may seek civil remedies or impose other administrative sanctions against a Medicaid provider, if the provider or any principal, officer, director, agent, managing employee, or affiliated person of the provider, or any partner or shareholder having an ownership interest in the provider equal to 5 percent or greater, has been:

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

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

(c) Found by a court of competent jurisdiction to have neglected or physically abused a patient in connection with the delivery of health care goods or services.

If the agency determines a provider did not participate or acquiesce in an offense specified in paragraph (a), paragraph (b), or paragraph (c), termination will not be imposed. If the agency effects a termination under this subsection, the agency shall issue an immediate termination ~~final~~ order as provided in subsection (16) ~~pursuant to s. 120.569(2)(n)~~.

(14) If the provider has been suspended or terminated from participation in the Medicaid program or the Medicare program by the Federal Government or any state, the agency must immediately

suspend or terminate, as appropriate, the provider's participation in this state's Medicaid program for a period no less than that imposed by the Federal Government or any other state, and may not enroll such provider in this state's Medicaid program while such foreign suspension or termination remains in effect. The agency shall also immediately suspend or terminate, as appropriate, a provider's participation in this state's Medicaid program if the provider participated or acquiesced in any action for which any principal, officer, director, agent, managing employee, or affiliated person of the provider, or any partner or shareholder having an ownership interest in the provider equal to 5 percent or greater, was suspended or terminated from participating in the Medicaid program or the Medicare program by the Federal Government or any state. This sanction is in addition to all other remedies provided by law. If the agency suspends or terminates a provider's participation in the state's Medicaid program under this subsection, the agency shall issue an immediate suspension or immediate termination order as provided in subsection (16).

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

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

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

Government;

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

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

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

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

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

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

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

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

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

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

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

(n) The provider fails to demonstrate that it had available during a specific audit or review period sufficient quantities

of goods, or sufficient time in the case of services, to support the provider's billings to the Medicaid program;

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

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

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

A provider is subject to sanctions for violations of this subsection as the result of actions or inactions of the provider, or actions or inactions of any principal, officer, director, agent, managing employee, or affiliated person of the provider, or any partner or shareholder having an ownership interest in the provider equal to 5 percent or greater, in which the provider participated or acquiesced. If the agency immediately suspends or immediately terminates a provider under this subsection, the agency shall issue an immediate suspension or immediate termination order as provided in subsection (16).

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

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

(b) Termination for a specific period of time of from more

than 1 year to 20 years. Termination shall preclude participation in the Medicaid program, which includes any action that results in a claim for payment to the Medicaid program as a result of furnishing, supervising a person who is furnishing, or causing a person to furnish goods or services.

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

(d) Immediate suspension, if the agency has received information of patient abuse or neglect, ~~or of~~ any act prohibited by s. 409.920, or any conduct listed in subsection (13) or subsection (14). Upon suspension, the agency must issue

an immediate suspension ~~final~~ order, which shall state that the agency has reasonable cause to believe that the provider, person, or entity named is engaging in or has engaged in patient abuse or neglect, any act prohibited by s. 409.920, or any conduct listed in subsection (13) or subsection (14). The order shall provide notice of administrative hearing rights under ss. 120.569 and 120.57 and is effective immediately upon notice to the provider, person, or entity ~~under s. 120.569(2)(n)~~.

(e) Immediate termination, if the agency has received information of a conviction based on patient abuse or neglect, any act prohibited by s. 409.920, or any conduct listed in subsection (13) or subsection (14). Upon termination, the agency must issue an immediate termination order, which shall state that the agency has reasonable cause to believe that the provider, person, or entity named has been convicted of patient abuse or neglect, any act prohibited by s. 409.920, or any conduct listed in subsection (13) or subsection (14). The termination order shall provide notice of administrative hearing rights under ss. 120.569 and 120.57 and is effective immediately upon notice to the provider, person, or entity.

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

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

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

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

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

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

The Secretary of Health Care Administration may make a determination that imposition of a sanction or disincentive is not in the best interest of the Medicaid program, in which case a sanction or disincentive shall not be imposed.

(17) In determining the appropriate administrative sanction to be applied, or the duration of any suspension or termination, the agency shall consider:

(a) The seriousness and extent of the violation or violations.

(b) Any prior history of violations by the provider relating to the delivery of health care programs which resulted in either a criminal conviction or in administrative sanction or penalty.

(c) Evidence of continued violation within the provider's management control of Medicaid statutes, rules, regulations, or policies after written notification to the provider of improper practice or instance of violation.

(d) The effect, if any, on the quality of medical care provided to Medicaid recipients as a result of the acts of the provider.

(e) Any action by a licensing agency respecting the

provider in any state in which the provider operates or has operated.

(f) The apparent impact on access by recipients to Medicaid services if the provider is suspended or terminated, in the best judgment of the agency.

The agency shall document the basis for all sanctioning actions and recommendations.

(18) The agency may take action to sanction, suspend, or terminate a particular provider working for a group provider, and may suspend or terminate Medicaid participation at a specific location, rather than or in addition to taking action against an entire group.

(19) The agency shall establish a process for conducting followup reviews of a sampling of providers who have a history of overpayment under the Medicaid program. This process must consider the magnitude of previous fraud or abuse and the potential effect of continued fraud or abuse on Medicaid costs.

(20) In making a determination of overpayment to a provider, the agency must use accepted and valid auditing, accounting, analytical, statistical, or peer-review methods, or combinations thereof. Appropriate statistical methods may include, but are not limited to, sampling and extension to the population, parametric and nonparametric statistics, tests of hypotheses, and other generally accepted statistical methods. Appropriate analytical methods may include, but are not limited to, reviews to determine variances between the quantities of products that a provider had on hand and available to be purveyed to Medicaid recipients during the review period and the

quantities of the same products paid for by the Medicaid program for the same period, taking into appropriate consideration sales of the same products to non-Medicaid customers during the same period. In meeting its burden of proof in any administrative or court proceeding, the agency may introduce the results of such statistical methods as evidence of overpayment.

(21) When making a determination that an overpayment has occurred, the agency shall prepare and issue an audit report to the provider showing the calculation of overpayments.

(22) The audit report, supported by agency work papers, showing an overpayment to a provider constitutes evidence of the overpayment. A provider may not present or elicit testimony, either on direct examination or cross-examination in any court or administrative proceeding, regarding the purchase or acquisition by any means of drugs, goods, or supplies; sales or divestment by any means of drugs, goods, or supplies; or inventory of drugs, goods, or supplies, unless such acquisition, sales, divestment, or inventory is documented by written invoices, written inventory records, or other competent written documentary evidence maintained in the normal course of the provider's business. Notwithstanding the applicable rules of discovery, all documentation that will be offered as evidence at an administrative hearing on a Medicaid overpayment must be exchanged by all parties at least 14 days before the administrative hearing or must be excluded from consideration.

(23)(a) In an audit or investigation of a violation committed by a provider which is conducted pursuant to this section, the agency is entitled to recover all investigative, legal, and expert witness costs if the agency's findings were

not contested by the provider or, if contested, the agency ultimately prevailed.

(b) The agency has the burden of documenting the costs, which include salaries and employee benefits and out-of-pocket expenses. The amount of costs that may be recovered must be reasonable in relation to the seriousness of the violation and must be set taking into consideration the financial resources, earning ability, and needs of the provider, who has the burden of demonstrating such factors.

(c) The provider may pay the costs over a period to be determined by the agency if the agency determines that an extreme hardship would result to the provider from immediate full payment. Any default in payment of costs may be collected by any means authorized by law.

(24) If the agency imposes an administrative sanction pursuant to subsection (13), subsection (14), or subsection (15), except paragraphs (15)(e) and (o), upon any provider or any principal, officer, director, agent, managing employee, or affiliated person of the provider who is regulated by another state entity, the agency shall notify that other entity of the imposition of the sanction within 5 business days. Such notification must include the provider’s or person’s name and license number and the specific reasons for sanction.

(25)(a) The agency shall withhold Medicaid payments, in whole or in part, to a provider upon receipt of reliable evidence that the circumstances giving rise to the need for a withholding of payments involve fraud, willful misrepresentation, or abuse under the Medicaid program, or a crime committed while rendering goods or services to Medicaid

recipients. If the provider is not paid within 14 days after the agency receives evidence ~~it is determined~~ that fraud, willful misrepresentation, abuse, or a crime did not occur, interest shall accrue at a rate of 10 percent a year ~~the payments withheld must be paid to the provider within 14 days after such determination with interest at the rate of 10 percent a year. Any money withheld in accordance with this paragraph shall be placed in a suspended account, readily accessible to the agency, so that any payment ultimately due the provider shall be made within 14 days~~.

(b) The agency shall deny payment, or require repayment, if the goods or services were furnished, supervised, or caused to be furnished by a person who has been convicted of a crime under subsection (13) or who has been suspended or terminated from the Medicaid program or Medicare program by the Federal Government or any state.

(c) Overpayments owed to the agency bear interest at the rate of 10 percent per year from the date of determination of the overpayment by the agency, and payment arrangements for overpayments and fines must be made within 35 days after the date of the final order ~~at the conclusion of legal proceedings. A provider who does not enter into or adhere to an agreed-upon repayment schedule may be terminated by the agency for nonpayment or partial payment~~.

(d) The agency, upon entry of a final agency order, a judgment or order of a court of competent jurisdiction, or a stipulation or settlement, may collect the moneys owed by all means allowable by law, including, but not limited to, notifying any fiscal intermediary of Medicare benefits that the state has

a superior right of payment. Upon receipt of such written notification, the Medicare fiscal intermediary shall remit to the state the sum claimed.

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

(26) The agency may impose administrative sanctions against a Medicaid recipient, or the agency may seek any other remedy provided by law, including, but not limited to, the remedies provided in s. 812.035, if the agency finds that a recipient has engaged in solicitation in violation of s. 409.920 or that the recipient has otherwise abused the Medicaid program.

(27) When the Agency for Health Care Administration has made a probable cause determination and alleged that an overpayment to a Medicaid provider has occurred, the agency, after notice to the provider, shall:

(a) Withhold, and continue to withhold during the pendency of an administrative hearing pursuant to chapter 120, any medical assistance reimbursement payments until such time as the overpayment is recovered, unless within 30 days after receiving notice thereof the provider:

1. Makes repayment in full; or

2. Establishes a repayment plan that is satisfactory to the Agency for Health Care Administration.

(b) Withhold, and continue to withhold during the pendency of an administrative hearing pursuant to chapter 120, medical assistance reimbursement payments if the terms of a repayment plan are not adhered to by the provider.

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

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

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

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

(32) Duly authorized agents and employees of the agency shall have the power to inspect, during normal business hours,

the records of any pharmacy, wholesale establishment, or manufacturer, or any other place in which drugs and medical supplies are manufactured, packed, packaged, made, stored, sold, or kept for sale, for the purpose of verifying the amount of drugs and medical supplies ordered, delivered, or purchased by a provider. The agency shall provide at least 2 business days' prior notice of any such inspection. The notice must identify the provider whose records will be inspected, and the inspection shall include only records specifically related to that provider.

(33) In accordance with federal law, Medicaid recipients convicted of a crime pursuant to 42 U.S.C. s. 1320a-7b may be limited, restricted, or suspended from Medicaid eligibility for a period not to exceed 1 year, as determined by the agency head or designee.

(34) To deter fraud and abuse in the Medicaid program, the agency may limit the number of Schedule II and Schedule III refill prescription claims submitted from a pharmacy provider. The agency shall limit the allowable amount of reimbursement of prescription refill claims for Schedule II and Schedule III pharmaceuticals if the agency or the Medicaid Fraud Control Unit determines that the specific prescription refill was not requested by the Medicaid recipient or authorized representative for whom the refill claim is submitted or was not prescribed by the recipient's medical provider or physician. Any such refill request must be consistent with the original prescription.

(35) The Office of Program Policy Analysis and Government Accountability shall provide a report to the President of the Senate and the Speaker of the House of Representatives on a

biennial basis, beginning January 31, 2006, on the agency's and the Medicaid Fraud Control Unit's efforts to prevent, detect, and deter, as well as recover funds lost to, fraud and abuse in the Medicaid program.

(36) At least three times a year, the agency shall provide to each Medicaid recipient or his or her representative an explanation of benefits in the form of a letter that is mailed to the most recent address of the recipient on the record with the Department of Children and Family Services. The explanation of benefits must include the patient's name, the name of the health care provider and the address of the location where the service was provided, a description of all services billed to Medicaid in terminology that should be understood by a reasonable person, and information on how to report inappropriate or incorrect billing to the agency or other law enforcement entities for review or investigation. At least once a year, the letter also must include information on how to report criminal Medicaid fraud, the Medicaid Fraud Control Unit's toll-free hotline number, and information about the rewards available under s. 409.9203. The explanation of benefits may not be mailed for Medicaid independent laboratory services as described in s. 409.905(7) or for Medicaid certified match services as described in ss. 409.9071 and 1011.70.

(37) The agency shall post on its website a current list of each Medicaid provider, including any principal, officer, director, agent, managing employee, or affiliated person of the provider, or any partner or shareholder having an ownership interest in the provider equal to 5 percent or greater, who has been terminated for cause from the Medicaid program or

sanctioned under this section. The list must be searchable by a variety of search parameters and provide for the creation of formatted lists that may be printed or imported into other applications, including spreadsheets. The agency shall update the list at least monthly.

(38) In order to improve the detection of health care fraud, use technology to prevent and detect fraud, and maximize the electronic exchange of health care fraud information, the agency shall:

(a) Compile, maintain, and publish on its website a detailed list of all state and federal databases that contain health care fraud information and update the list at least biannually;

(b) Develop a strategic plan to connect all databases that contain health care fraud information to facilitate the electronic exchange of health information between the agency, the Department of Health, the Department of Law Enforcement, and the Attorney General's Office. The plan must include recommended standard data formats, fraud identification strategies, and specifications for the technical interface between state and federal health care fraud databases;

(c) Monitor innovations in health information technology, specifically as it pertains to Medicaid fraud prevention and detection; and

(d) Periodically publish policy briefs that highlight available new technology to prevent or detect health care fraud and projects implemented by other states, the private sector, or the Federal Government which use technology to prevent or detect health care fraud.

Section 10. Subsection (5) is added to section 409.9203, Florida Statutes, to read:

409.9203 Rewards for reporting Medicaid fraud.—

(5) An employee of the Agency for Health Care Administration, the Department of Legal Affairs, the Department of Health, or the Department of Law Enforcement whose job responsibilities include the prevention, detection, and prosecution of Medicaid fraud is not eligible to receive a reward under this section.

Section 11. Subsection (8) is added to section 456.001, Florida Statutes, to read:

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

(8) "Affiliate" or "affiliated person" means any person who directly or indirectly manages, controls, or oversees the operation of a corporation or other business entity, regardless of whether such person is a partner, shareholder, owner, officer, director, or agent of the entity.

Section 12. Paragraph (c) of subsection (1) and subsections (2) and (3) of section 456.041, Florida Statutes, are amended to read:

456.041 Practitioner profile; creation.—

(1)

(c) Within 30 calendar days after receiving an update of information required for the practitioner's profile, the department shall update the practitioner's profile in accordance with the requirements of subsection (8) ~~(7)~~.

(2) Beginning July 1, 2010, on the profile published under subsection (1), the department shall include ~~indicate if~~ the information provided under s. 456.039(1)(a)7. or s.

456.0391(1)(a)7. and indicate if the information is or is not corroborated by a criminal history records check conducted according to this subsection. The department must include in each practitioner's profile the following statement: "The criminal history information, if any exists, may be incomplete. Federal criminal history information is not available to the public." ~~The department, or the board having regulatory authority over the practitioner acting on behalf of the department, shall investigate any information received by the department or the board.~~

(3) Beginning July 1, 2010, the department shall include in each practitioner's profile any open administrative complaint filed with the department against the practitioner in which probable cause has been found. ~~The Department of Health shall include in each practitioner's practitioner profile that criminal information that directly relates to the practitioner's ability to competently practice his or her profession. The department must include in each practitioner's practitioner profile the following statement: "The criminal history information, if any exists, may be incomplete; federal criminal history information is not available to the public."~~ The department shall provide in each practitioner profile, for every final disciplinary action taken against the practitioner, an easy-to-read narrative description that explains the administrative complaint filed against the practitioner and the final disciplinary action imposed on the practitioner. The department shall include a hyperlink to each final order listed in its website report of dispositions of recent disciplinary actions taken against practitioners.

Section 13. Section 456.0635, Florida Statutes, is amended to read:

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

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

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

(a) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under chapter 409, chapter 817, chapter 893, or a similar felony offense committed in another state or jurisdiction ~~21 U.S.C. ss. 801-970, or 42 U.S.C. ss. 1395-1396~~, unless the sentence and any subsequent period of probation for such conviction or plea ~~pleas~~ ended: ~~more than 15 years prior to the date of the application;~~

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

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

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

4. For felonies in which the defendant entered a plea of guilty or nolo contendere in an agreement with the court to

enter a pretrial intervention or drug diversion program, the department shall not approve or deny the application for a license, certificate, or registration until the final resolution of the case.

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

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

(d) ~~(c)~~ Has been terminated for cause, pursuant to the appeals procedures established by the state ~~or Federal Government~~, from any other state Medicaid program ~~or the federal Medicare program~~, unless the 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 before ~~prior to~~ the date of the application; or~~.~~

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

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

2009.

(3) Each board within the jurisdiction of the department, or the department if there is no board, shall refuse to renew a license, certificate, or registration of any applicant if the candidate or applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant:

(a) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under: chapter 409, chapter 817, chapter 893, or a similar felony offense committed in another state or jurisdiction since July 1, 2009.

(b) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970, or 42 U.S.C. ss. 1395-1396 since July 1, 2009.

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

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

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

(f) For felonies in which the defendant entered a plea of

guilty or nolo contendere in an agreement with the court to enter a pretrial intervention or drug diversion program, the department shall not approve or deny the application for a renewal of a license, certificate, or registration until the final resolution of the case.

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

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

(6) The department shall adopt rules to administer the provisions of this section related to denial of licensure renewal.

Section 14. Paragraph (kk) of subsection (1) of section 456.072, Florida Statutes, is amended to read:

456.072 Grounds for discipline; penalties; enforcement.—

(1) The following acts shall constitute grounds for which the disciplinary actions specified in subsection (2) may be taken:

(kk) Being terminated from the state Medicaid program pursuant to s. 409.913 or~~,~~ any other state Medicaid program~~,~~ or excluded from the federal Medicare program, unless eligibility to participate in the program from which the practitioner was terminated has been restored.

Section 15. Subsection (13) of section 456.073, Florida

Statutes, is amended to read:

456.073 Disciplinary proceedings.—Disciplinary proceedings for each board shall be within the jurisdiction of the department.

(13) Notwithstanding any provision of law to the contrary, an administrative complaint against a licensee shall be filed within 6 years after the time of the incident or occurrence giving rise to the complaint against the licensee. If such incident or occurrence involved fraud related to the Medicaid program, criminal actions, diversion of controlled substances, sexual misconduct, or impairment by the licensee, this subsection does not apply to bar initiation of an investigation or filing of an administrative complaint beyond the 6-year timeframe. In those cases covered by this subsection in which it can be shown that fraud, concealment, or intentional misrepresentation of fact prevented the discovery of the violation of law, the period of limitations is extended forward, but in no event to exceed 12 years after the time of the incident or occurrence.

Section 16. Subsection (1) of section 456.074, Florida Statutes, is amended to read:

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

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

contendere to, regardless of adjudication, to:

(a) A felony under chapter 409, chapter 812, chapter 817, or chapter 893, chapter 895, chapter 896, ~~or under~~ 21 U.S.C. ss. 801-970, or ~~under~~ 42 U.S.C. ss. 1395-1396; or

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

Section 17. Paragraph (q) of subsection (2) of section 499.01, Florida Statutes, is amended to read:

499.01 Permits.—

(2) The following permits are established:

(q) *Device manufacturer permit.*—A device manufacturer permit is required for any person that engages in the manufacture, repackaging, or assembly of medical devices for human use in this state, except that a permit is not required if:

1. The person does not manufacture, repackage, or assemble any medical devices or components for such devices, except those devices or components which are exempt from registration pursuant to s. 499.015(8); or

2. The person is engaged only in manufacturing, repackaging, or assembling a medical device pursuant to a practitioner's order for a specific patient.

a.~~1.~~ A manufacturer or repackager of medical devices in this state must comply with all appropriate state and federal good manufacturing practices and quality system rules.

b.~~2.~~ The department shall adopt rules related to storage, handling, and recordkeeping requirements for manufacturers of

medical devices for human use.

Section 18. This act shall take effect July 1, 2010.